Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The evaluation of the priming effect of transcranial direct current stimulation over primary motor cortex and primary somatosensory cortex on the effect of exercise training on pain, function, balance , kinesiophobia and quality of life in patients with knee osteoarthritis-a randomized controlled trial

Protocol summary

Study aim
The evaluation of the priming effect of transcranial direct current stimulation over primary motor cortex and primary somatosensory cortex on the effect of exercise training on pain, function, balance ,kinesiophobia and quality of life in patients with knee osteoarthritis-a randomized controlled trial

Design
control group (exercise therapy with sham tDCS), exercise therapy group with anodal tDCS and exercise therapy group with cathodal tDCS The randomization list was prepared with the Random Allocation software The sample size is total of 45 people

Settings and conduct
The research is in the field of medical services and is conducted in the form of a double-blind clinical trial in Shiraz Faculty of Rehabilitation Sciences

Participants/Inclusion and exclusion criteria
inclusion criteria: People aged 50 to 70 , Diagnosis of osteoarthritis in one or both knees by an orthopedic specialist for these patients. Grade two or three of diseases , minimum pain intensity of four out of ten in VAS. exclusion criteria :Traumatic knee injuries, Acute joint inflammation, Rheumatology diseases, History of surgery in one or both knees, History of head surgery, brain tumor or metal implant in the head , History of lower limb surgery in the last six months, Inability to walk without an assistive device, Receiving treatment or rehabilitation services for knee osteoarthritis in the last three months, Taking drugs that affect the central nervous system in the last six months, Drug or alcohol abuse

Intervention groups
The control group receives exercise therapy along with sham tDCS. For the two intervention groups, in addition to therapeutic exercises, the tDCS device will be used in two different ways, anodal in the M1 region and cathodal in the S1 region.

Main outcome variables
Pain, Function, Balance, Kinesiophobia and Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131225015932N18**
Registration date: **2023-02-10, 1401/11/21**
Registration timing: **prospective**

Last update: **2023-02-10, 1401/11/21**
Update count: **0**

Registration date
2023-02-10, 1401/11/21

Registrant information

Name
Alireza Motealleh

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15
Expected recruitment end date
2023-10-07, 1402/07/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of the priming effect of transcranial direct current stimulation over primary motor cortex and primary somatosensory cortex on the effect of exercise training on pain, function, balance , kinesiophobia and quality of life in patients with knee osteoarthritis-a randomized controlled trial

Public title
The evaluation of the priming effect of transcranial direct current stimulation over primary motor cortex and primary somatosensory cortex on the effect of exercise training on pain, function, balance, kinesiophobia and quality of life in patients with knee osteoarthritis-a randomized controlled trial
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of osteoarthritis in one or both knees by an orthopedic specialist for these patients (having at least three of the six criteria of the American College of Rheumatology, including age over 50 years, morning stiffness less than half an hour, tenderness in bone margins, crepitus in active joint movements, bone enlargement and no palpable increase in temperature People aged 50 to 70 who are willing and eager to enter the study and can cooperate in various stages of evaluation, treatment and follow-up Grade two or three of diseases in the knee osteoarthritis classification system (Kllgren and Lawrence system classification) according to a radiograph that was taken at most one year ago minimum pain intensity of four out of ten (while walking in the last week) in Visual analogue scale of pain.
Exclusion criteria:
Traumatic knee injuries Acute joint inflammation Rheumatology diseases such as Rheumatoid arthritis, lupus erythematosus and Fibromyalgia, Neurological diseases that affect the function of the lower limbs, such as stroke, Parkinson's disease, MS, peripheral neuropathy and a history of seizures or their occurrence, severe headaches after the first session of receiving the electrical current, mental and cognitive problems (Mini-Mental Status Exam score ≤ 23),Cardiovascular problems such as high blood pressure or heart attack History of surgery (such as joint replacement or tibial osteotomy) in one or both knees, history of head surgery, Brain tumor or metal implant in the head, history of lower limb surgery in the last six months Inability to walk without an assistive device, receiving treatment or rehabilitation services for knee osteoarthritis in the last three months Taking drugs that affect the central nervous system such as dextromethorphan and D-cycloserine in the last six months Drug or alcohol abuse Being hospitalized for the past year due to mental illnesses
Age
From **50 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization list was prepared with the Random Allocation software, based on the permuted block randomization method in which the block size was 3 and the number of blocks was 15.
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher who assigns the volunteers to different groups based on the random list is different from the researcher who performs the treatment and another researcher will also analyze the data.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences Building, Zand Street,shiraz.
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2023-01-30, 1401/11/10
Ethics committee reference number
IR.SUMS.REHAB.REC.1401.047

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
Pain
Timepoint
Before treatment, third week of treatment, fourth week of treatment and one month after treatment
Method of measurement
Visual analogue scale

2

Description
Balance
Timepoint
Before treatment, third week of treatment, fourth week of treatment and one month after treatment
Method of measurement
Modified star excursion balance test

3

Description
Quality of life
Timepoint
Before treatment, third week of treatment, fourth week of treatment and one month after treatment
Method of measurement
SF36 questionnaire

4

Description
Kinesiophobia
Timepoint
Before treatment, third week of treatment, fourth week of treatment and one month after treatment
Method of measurement
Tampa scale

5

Description
Function
Timepoint
Before treatment, third week of treatment, fourth week of treatment and one month after treatment
Method of measurement
WOMAC

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Exercise therapy and placebo tDCS
Category
Placebo

2

Description
Intervention group: Exercise therapy and anodal tDCS on M1
Category
Treatment - Devices

3

Description
Intervention group: Exercise therapy and cathodal tDCS on S1
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy Clinic, Faculty of Rehabilitation Sciences, Shiraz University of Medical Sciences
Full name of responsible person
Alireza Motealleh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Mohammadhashem Hashempour

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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Amin Rastgar sangari
Position
Physiotherapy Master's student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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

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

Data Dictionary

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