Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the Effects of Motor Imagery and Transcranial Direct Current Stimulation (tDCS) Interventions Combined with Neuromuscular Training on Pain Intensity, Quadriceps Muscle Activity, Gait Pattern, and Range of Motion Using Machine Vision in Women with Knee Osteoarthritis

Protocol summary

Study aim

The aim of this study was to compare the effects of four weeks of motor imagery and transcranial direct current electrical stimulation combined with neuromuscular training on pain intensity and motor functions in women with knee osteoarthritis.

Design

This study is a randomized clinical trial with control and parallel groups, with blinding of the assessor, on 48 women with unilateral knee osteoarthritis. Randomization is performed in a block design and the unit of randomization is the individual. This study is conducted in the second phase of the clinical trial.

Settings and conduct

The study will be conducted in the laboratory and corrective exercise center of Razi University, Kermanshah. After initial assessments, participants will be randomly assigned to study groups. The evaluator will not be aware of group allocation and all interventions will be administered by the principal investigator.

Participants/Inclusion and exclusion criteria

Participants were women aged 40 to 65 years with unilateral knee osteoarthritis, chronic pain of at least three months and pain intensity of at least three out of ten, with a confirmed diagnosis Exclusion criteria included knee surgery or replacement within the past six months, neurological or inflammatory diseases, pregnancy or lactation, use of medications affecting the central nervous system, metal implants, or a history of seizures.

Intervention groups

Participants will be randomly assigned to three groups: The motor imagery plus neuromuscular training group, where motor imagery is performed before the training; The transcranial direct current electrical stimulation plus neuromuscular training group, where stimulation is applied before the training; The control group, which receives neuromuscular training only.

Main outcome variables

Pain intensity; quadriceps muscle activity; gait pattern; knee joint range of motion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251224068432N1**
Registration date: **2026-06-23, 1405/04/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-23, 1405/04/02**
Update count: **0**

Registration date

2026-06-23, 1405/04/02

Registrant information

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Name of organization / entity

The Razi University

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effects of Motor Imagery and Transcranial Direct Current Stimulation (tDCS) Interventions Combined with Neuromuscular Training on Pain Intensity, Quadriceps Muscle Activity, Gait Pattern, and Range of Motion Using Machine Vision in Women with Knee Osteoarthritis

Public title

The effect of motor imagery and transcranial direct current electrical stimulation combined with neuromuscular training on functional messages in knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with unilateral knee osteoarthritis: diagnosed by a specialist physician or physiotherapist, with chronic knee pain lasting at least 3 months and a pain intensity of ≥ 3 out of 10 on the Visual Analog Scale (VAS) .• Radiographic disease severity graded as ≤ II according to the Kellgren–Lawrence scale.• Age range: 40–65 years.• Sex: female.• A minimum score of 24 on the Mini-Mental State Examination (MMSE) to ensure adequate cognitive function .• Ability to participate in intervention sessions and assessment procedures.• Ability to understand and respond to questionnaires and therapeutic instructions.• No use of medications affecting the central nervous system, such as antidepressants or antiepileptic drugs, during the past 4 weeks.

Exclusion criteria:

* Age below 40 years or above 65 years.* History of knee surgery or knee joint replacement within the past 6 months.* Neurological, systemic, or inflammatory diseases affecting neuromuscular function, such as multiple sclerosis (MS), rheumatoid arthritis, or uncontrolled diabetes.* Pregnancy or breastfeeding.* Use of medications affecting the central nervous system within the past 4 weeks.* Participation in similar rehabilitation exercises within the past 3 months.* Presence of metal implants or electronic devices in the knee or head region.* History of seizures or epilepsy.* Severe psychiatric disorders (e.g., major depression, schizophrenia, bipolar disorder).* Physical or cognitive inability to properly perform motor imagery or neuromuscular exercises.* Participation in a similar study within the past 6 months.* Skin problems or wounds in the area of electrode placement for tDCS.

Age

From **40 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to study groups using block randomization. The unit of randomization in this study is the individual. To maintain a balanced number of participants in each study group and reduce the likelihood of group imbalance, block randomization with equal block sizes will be employed. The random sequence will be generated using Random Number Generator software based on a random number table. The randomization process will be conducted by an individual independent of the research team and assessors to prevent allocation bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

To prevent any potential bias in the results, the study assessor will be blinded, and the assessor will be different from the individual responsible for delivering the interventions. The intervention procedures, including motor imagery, transcranial direct current stimulation (tDCS), and neuromuscular exercises, as well as the assessment methods and participants' ethical and treatment rights, will be explained by the principal investigator.Random allocation will be performed using a random number table by an individual independent of the research team to prevent allocation bias. The randomization process will be carried out using Random Number Generator software, and each participant's allocation code will be placed in opaque, numbered envelopes. The envelopes will be opened only at the time of participant entry, after assessments, and by a person other than the assessor to maintain assessor blinding (the assessor will remain unaware of participants' group allocation and type of intervention).Preliminary screening will be conducted to confirm participants' ability to participate in the study, and each participant will then be assigned to one of the three study groups. In this study, participants will be randomly assigned to three intervention groups. All interventions will be conducted by the principal investigator.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Razi University

Street address
Razi University, Taq Bostan, Kermanshah

City
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Approval date
2026-06-06, 1405/03/16

Ethics committee reference number
IR.RAZI.REC.1405.017

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Knee joint pain severity based on visual analog scale (VAS) score

Timepoint
Measurement of knee joint pain intensity at two time points; once at the beginning of the study (pre-test and before the start of the intervention) and once after the end of 4 weeks of intervention and completion of 12 training sessions (post-test).

Method of measurement
The visual pain scale consists of a 10-centimeter line, one end of which indicates "no pain" and the other end indicates "the most severe pain imaginable," and the intensity of the pain is determined by the individual on this scale.

Secondary outcomes

1

Description
Quadriceps electrical activity based on the amplitude of the signal recorded from the quadriceps muscles during functional activities including walking, climbing stairs, and sitting and standing.

Timepoint
Measurement of the electrical activity of the quadriceps muscle in two stages: before the start of the intervention (pre-test) and after the completion of the four-week intervention period and 12 training sessions (post-test).

Method of measurement
The Nuraxon wireless surface electromyography device uses disposable surface electrodes and records the electrical signal of the quadriceps muscles during functional activities.

2

Description
Knee joint range of motion based on knee joint flexion and extension angles during the sit-to-stand test, measured through video image analysis.

Timepoint
Measurement of knee joint range of motion in two stages: before the intervention (pre-test) and after the completion of the four-week intervention period and 12 training sessions (post-test).

Method of measurement
Digital filming of the sit-to-stand test and image analysis using an image processing method based on an algorithm to detect key body points in order to extract the angle of knee joint flexion and extension.

3

Description
Gait pattern based on lower limb kinematic parameters including knee joint motion angles while walking on a treadmill.

Timepoint
Gait pattern measurement in two stages: before the intervention (pre-test) and after the completion of the four-week intervention period and 12 training sessions (post-test).

Method of measurement
Digital video recording of the subject's walking on a treadmill and analysis of kinematic parameters using Kinovia motion analysis software.

4

Description
Physical performance score of patients with knee osteoarthritis based on the Osteoarthritis Index questionnaire from Western Ontario and McMaster Universities.

Timepoint
Before the start of the intervention (pre-test) and after the completion of the four-week intervention period (post-test).

Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index Questionnaire.

5

Description
The level of fear of movement and physical activity related to knee pain based on the score of the

agoraphobia questionnaire.

Timepoint

Before the start of the intervention (pre-test) and after the completion of the four-week intervention period (post-test).

Method of measurement

Tampa Agoraphobia Questionnaire.

6

Description

The degree of perceived instability of the knee joint based on the score of the Knee Instability Questionnaire.

Timepoint

Before the start of the intervention (pre-test) and after the completion of the four-week intervention period (post-test).

Method of measurement

Knee joint instability questionnaire.

Intervention groups

1

Description

Intervention group:Participants in this group will participate in a neuromuscular training program for 4 weeks (12 sessions, 3 sessions per week). Each session consists of 60 minutes of neuromuscular training aimed at improving motor control, balance, proprioception, muscle coordination, and knee joint stability. In addition, a guided motor imagery intervention will be performed before the exercises begin. In this section, participants imagine the functional movements and exercises in question without actually performing them, but only mentally and from a first-person perspective. Motor imagery sessions will be performed before the neuromuscular training in each session and will continue throughout the 4-week period.

Category

Rehabilitation

2

Description

Intervention group:Participants in this group will participate in a neuromuscular training program for 4 weeks (12 sessions, 3 sessions per week). In addition to the training, they will receive 20 minutes of transcranial direct current stimulation (tDCS) per session. Stimulation will be performed using a NeuroStim 2 device manufactured by Medina Teb Gostar Company, Tehran. The anode electrode will be placed on the primary motor cortex (M1) opposite the affected leg at the C3/C4 position based on the international 20-10 system, and the cathode electrode will be placed on the contralateral supraocular region. The current intensity will be 2 mA, and the stimulation will be applied for 20 minutes. After the stimulation ends, participants will perform neuromuscular training for 60 minutes.

Category

Rehabilitation

3

Description

Control group: Participants in this group will receive only the neuromuscular training program for 4 weeks (12 sessions, 3 sessions per week). Each session will consist of 60 minutes of neuromuscular training aimed at improving motor control, balance, proprioception, muscle coordination, and knee joint stability. This group will not receive any additional interventions, including motor imagery or transcranial direct current stimulation (tDCS).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Sport Sciences, Razi University

Full name of responsible person

Farzaneh Gandami

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Kermanshah, Taq Bostan, Daneshgah St., Razi University, Faculty of Sport Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Farzaneh Gandomi
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Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
To protect participant confidentiality and comply with research ethical considerations, there is no plan to share individual participant data (IPD). Access to the raw data will be restricted to the principal investigators and will be used solely for the purposes of the present study.
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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document

Study protocol, statistical analysis plan, informed consent form, and final study report. These documents include the study methodology, interventions, statistical analysis procedures, ethical considerations, and final study results and do not contain identifiable participant information.

When the data will become available and for how long

The documents will be available from the time of publication of the study results and for at least 5 years thereafter.

To whom data/document is available

Researchers, faculty members, graduate students, and other applicants with legitimate scientific and research purposes.

Under which criteria data/document could be used

The documents may be used solely for scientific, educational, and research purposes. Commercial use or any use inconsistent with research ethics is prohibited. Applicants must provide a written description of the intended use.

From where data/document is obtainable

Applicants may submit their requests through correspondence with the principal investigator or the Faculty of Sport Sciences, Razi University.

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

Requests will be reviewed by the principal investigator. If approved, the requested documents will be provided within a maximum of 30 working days.

Comments

Individual participant data and raw datasets will not be shared. Participant confidentiality will be protected in accordance with research ethics principles.