

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Close Kinetic Chain Exercises Following Seven Consecutive Sessions of Non-Invasive Brain Stimulation (tDCS vs. tPCS) on Pain, Balance, Movement Function of Women Affected by Knee Osteoarthritis.

Protocol summary

Study aim

Determining the effects of closed motor chain exercises following 7 consecutive sessions of non-invasive brain stimulation (tDCS versus tPCS) on pain, balance and motor performance of women with knee osteoarthritis in Kermanshah.

Design

Based on G.Power software version 3.1 with error level (α) of 0.05 for statistical tests of two domains, statistical power ($\beta-1$) of 0.80 and effect size reported by studies for effectiveness. Exercise therapy and education have been reported from 0.3 to 0.6 for pain and function

Settings and conduct

The participants underwent one of the transcranial stimulations of tDCS, tPCS or sham for 7 consecutive days and after finishing the stimulations, for one month, during 12 sessions (3 sessions per week), under strengthening exercises.

Participants/Inclusion and exclusion criteria

Entry criteria Age 40 to 70 years, not using intra-articular injections in the last 3 months. chronic knee pain most days, Reduction of joint space Entry ban criteria Uncontrolled diabetes. excessive obesity Physiotherapy or knee surgery (within the last 12 months). Lower limb arthroplasty. Intra-articular steroid injections (within the last 6 months). Systemic arthritic disease. Additional orthopedic injuries: joint dysplasia Neuromuscular diseases (MS and Parkinson's) Fracture and surgery in the lower limb.

Intervention groups

Group 1: 12 sessions of closed motor chain exercises followed by seven consecutive sessions of itDCS stimulation Group 2: 12 sessions of closed motor chain exercises followed by seven consecutive sessions of itPCS stimulation Group 3: 12 sessions of closed motor chain exercises followed by seven consecutive sessions of sham stimulation

Main outcome variables

Pain intensity and perceived fatigue Physical performance indicators Knee instability sense of depth Static balance and postural oscillations Strength and electrical activity of quadriceps muscles

General information

Reason for update

Acronym

KKOAK

IRCT registration information

IRCT registration number: **IRCT20240911063011N1**

Registration date: **2025-03-18, 1403/12/28**

Registration timing: **registered_while_recruiting**

Last update: **2025-03-18, 1403/12/28**

Update count: **0**

Registration date

2025-03-18, 1403/12/28

Registrant information

Name

Niloofar Afrasiaby

Name of organization / entity

The University of razi Kermanshah

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-05-21, 1404/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Close Kinetic Chain Exercises Following Seven Consecutive Sessions of Non-Invasive Brain Stimulation (tDCS vs. tPCS) on Pain, Balance, Movement Function of Women Affected by Knee Osteoarthritis.

Public title

The Effect of Close Kinetic Chain Exercises Following Seven Consecutive Sessions of Non-Invasive Brain Stimulation (tDCS vs. tPCS) on Pain, Balance, Movement Function of Women Affected by Knee Osteoarthritis in Kermanshah Province.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

- Having the clinical criteria of knee osteoarthritis of the American College of Rheumatology. (Altam et al., 1991)
- Having II score $\leq$ in the Kellgren and Lawrence criteria.
- Not using intra-articular injections during the last 3 months.
- Chronic knee pain most days, for at least 3 months, pain score of at least 4 on the visual analogue pain scale.
- Reduction of joint space or osteophyte in radiography.

Exclusion criteria:

- Uncontrolled diabetes.
- Body mass index greater than or equal to ($BMI > 40 \text{ kg/m}^2$), patients with extreme obesity.
- Physiotherapy or knee surgery (within the last 12 months).
- Lower limb arthroplasty.
- Intra-articular steroid injections (during the last 6 months).
- Systemic arthritic disease.
- Additional orthopedic injuries in the lower limb (such as joint dysplasia).
- Neuromuscular disorders that interfere with daily functioning such as (stroke, uncontrolled muscle stiffness, tumor,...) patients who are unable to walk without assistive devices.
- Patients who have undergone other exercise or nutritional treatments in the last three months.
- Neuromuscular diseases (such as MS and Parkinson's) that interfere with the training program.
- Fracture and surgery in the lower limb.
- Use of any other therapeutic intervention during the period that the subjects are in the study.

Age

From **40 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Statistical sample based on G.Power software version 3.1 with error level (α) of 0.05 for statistical tests of two domains, statistical power ($\beta-1$) of 0.80 and effect size reported by Studies for the effectiveness of exercise therapy and training have reported from 0.3 to 0.6 for pain and function[76], where 0.5 was considered as the effect size. Therefore, the number of selected samples for the statistical test of covariance, where the pre-tests are considered as covariance variables, was estimated to be 42 people, which was determined by considering the attrition of 45 people. Subjects were randomized by Random Allocation software into groups: 12 sessions of closed motor chain exercises followed by seven consecutive sessions of non-invasive brain stimulation (tDCS), 12 sessions of closed motor chain exercises followed by seven consecutive sessions of non-invasive brain stimulation (tDCS). tPCS) and 12 sessions of closed motor chain exercises will be assigned following seven sessions of consecutive non-invasive brain stimulation (sham).

Blinding (investigator's opinion)

Double blinded

Blinding description

The arrangements considered for this study are two-way blind. So that by applying non-invasive stimulations by a person not involved in the research, the evaluator will not have any knowledge about the type of electrical stimulation intervention assigned to the groups, and the subjects will not know about the differences applied in the type of stimulation of the groups. parallels will be unaware, so that they will receive the stimulation in the first 30 seconds and will be gradually cut off; Also, it will be possible to keep the person who will analyze the data about the groups and exercises assigned to them.

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 of Kermanshah

Street address

Kermanshah, Elahia, Resalat Square, 20 meters Nahalistan St., Koi 16, No. 14

City

Kermanshah

Province

Kermanshah

Postal code

6719413331

Approval date

2024-05-15, 1403/02/26

Ethics committee reference number

IR.RAZI.REC.1403.014

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 intensity

Timepoint

At baseline (before the intervention) and 30 days after the intervention

Method of measurement

visual analog scale

2

Description

degree of perceived fatigue

Timepoint

At baseline (before the intervention) and 30 days after the intervention

Method of measurement

Borg CR10 Index

3

Description

physical performance

Timepoint

At baseline (before the intervention) and 30 days after the intervention

Method of measurement

WOMAC questionnaire

4

Description

proprioception

Timepoint

At baseline (before the intervention) and 30 days after the intervention

Method of measurement

Bubble Inclinator

5

Description

balance

Timepoint

At baseline (before the intervention) and 30 days after the intervention

Method of measurement

PT-SCAN

6

Description

strength

Timepoint

At baseline (before the intervention) and 30 days after the intervention

Method of measurement

dynamometer

7

Description

electrical activity of the quadriceps muscles.

Timepoint

At baseline (before the intervention) and 30 days after the intervention

Method of measurement

Electromyography

8

Description

Knee instability

Timepoint

At baseline (before the intervention) and 30 days after the intervention

Method of measurement

Felson questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Non-invasive transcranial stimulation device (TPCS) with a current of 1.5 mA for 15 minutes+Closed kinetic chain exercises

Category

Rehabilitation

2

Description

Intervention group: non-invasive transcranial stimulation device (tdcs) with a current of 2 milliamps for to 20 minutes+Closed kinetic chain exercises

Category

Rehabilitation

3

Description

Control group: Closed kinetic chain exercises

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi University Sports Science Faculty Laboratory

Full name of responsible person

Nilloofar Afrasiaby

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Kermanshah-Taqbestan Boulevard-Silk Garden of Razi University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University of Kermanshah

Full name of responsible person

Keyvan Amini

Street address

Kermanshah - Taqbestan Blvd - Silk Garden - Razi University

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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 of Kermanshah

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 of Kermanshah

Full name of responsible person

Farzaneh Gandomi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Corrective movements

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nilloofar Afrasiaby

Position

Master's student

Latest degree

Master

Other areas of specialty/work

Corrective movements

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Position

Master's degree

Latest degree

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Other areas of specialty/work

Corrective movements

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Studying the effects of closed motor chain exercises following seven consecutive sessions of non-invasive brain stimulation (tDCS versus tPCS) on pain, balance and motor function of women with knee osteoarthritis in Kermanshah.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Masters and PhD students in corrective movements

Under which criteria data/document could be used

In order to be used in the field of rehabilitation and its promotion

From where data/document is obtainable

Razi University of Kermanshah - Faculty of Sports Sciences, Dr. Farzaneh Gandami

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

Maximum 3 months after application

Comments