Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 (β-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

Dear Sir/Madam, This is to inform you that participant recruitment for the study entitled “Comparison of the Effects of Closed Kinetic Chain Exercises Following Seven Consecutive Sessions of Non-Invasive Brain Stimulation (tDCS versus tPCS) on Pain, Balance, and Motor Function in Women with Knee Osteoarthritis” commenced on **April 21, 2025 (1 Ordibehesht 1404)** and was completed on **August 6, 2025 (15 Mordad 1404)**. A total of **54 participants** were recruited into the study. We kindly request that the actual recruitment start date and recruitment completion date be updated accordingly in the Iranian Registry of Clinical Trials (IRCT). Thank you for your cooperation.

Acronym

KKOAK

IRCT registration information

IRCT registration number: **IRCT20240911063011N1**
Registration date: **2025-03-18, 1403/12/28**
Registration timing: **prospective**

Last update: **2026-10-31, 1405/08/09**
Update count: **1**

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)
Phone
+98 990 972 5642
Email address
n.afrasiby9974@gmail.com

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
2025-04-21, 1404/02/01
Actual recruitment end date
2025-08-06, 1404/05/15
Trial completion date
2025-08-06, 1404/05/15

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. (Altamn et al., 1991) • Having II score ≤ 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>40kg/m2), 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
- Outcome assessor

Sample size
Target sample size: **45**
Actual sample size reached: **54**
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 (β-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 Inclinometer

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

Niloofar Afrasiaby

Street address

Kermanshah-Taqbestan Boulevard-Silk Garden of Razi University

City

Kermanshah

Province

Kermanshah

Postal code

۶۷۱۴۴۱۴۹۷۱

Phone

+98 905 762 2917

Email

n.afrasiaby9974@gmail.com

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

City

Kermanshah

Province

Kermanshah

Postal code

۶۷۱۴۴۱۴۹۷۱

Phone

+98 83 3427 7605

Email

gandomi777@gmail.com

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

Street address

Kermanshah - Taqbestan Blvd - Silk Garden - Razi University

City

Kermanshah

Province

Kermanshah

Postal code

۶۷۱۴۴۱۴۹۷۱

Phone

+98 83 3434 3515

Email

gandomi777@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Razi University of Kermanshah

Full name of responsible person

Niloofar Afrasiaby

Position

Master's student

Latest degree

Master

Other areas of specialty/work

Corrective movements

Street address
Kermanshah - Elahia, Resalat Square, 20 meters of Nahalestan St., Koi 16, No. 14

City
Kermanshah

Province
Kermanshah

Postal code
6719413331

Phone
+98 83 3724 3181

Email
n.afrasiaby9974@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
The University of razi Kermanshah

Full name of responsible person
Niloofar Afrasiaby

Position
Master's degree

Latest degree
Master

Other areas of specialty/work
Corrective movements

Street address
Kermanshah Elahiye Resalat 20th nahalestan Alely 16 Number 14

City
Kermanshah

Province
Kermanshah

Postal code
6719413331

Phone
+98 990 972 5642

Fax

Email
n.afrasiaby9974@gmail.com

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