Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of The Effects of Single-Site and Concurrent Transcranial Direct Current Stimulation (M1, DLPFC) on Pain Intensity, Balance, Motor Function and Quadriceps Muscle Strength in Female Students with Patellofemoral Pain Syndrome

Protocol summary

Study aim

The aim of this study is to compare the effects of transcranial direct current stimulation over the primary motor cortex (M1) alone with simultaneous stimulation of the primary motor cortex (M1) and dorsolateral prefrontal cortex (DLPFC) on pain intensity, balance, motor function, and quadriceps muscle strength in female students with patellofemoral pain syndrome.

Design

This is a randomized, double-blind, parallel-group, controlled clinical trial involving 42 female students with patellofemoral pain syndrome. Participants will be allocated by an independent researcher using simple randomization with a Random Allocation Software into three groups of 14 participants each.

Settings and conduct

This study will be conducted at the Faculty of Sport Sciences, Razi University, Kermanshah. After written informed consent, participants will be randomly allocated to three groups of 14. Group 1 will receive M1 stimulation, Group 2 simultaneous M1 and DLPFC stimulation, and the Control Group sham stimulation. Stimulation will be delivered at 2 mA for 20 minutes over six sessions. The Control Group will receive sham stimulation under similar conditions.

Participants/Inclusion and exclusion criteria

Participants in this study will be female students aged 18–35 years with patellofemoral pain syndrome and a minimum anterior knee pain intensity of 3. Individuals with a history of knee injury or surgery, other knee pathologies, patellar dislocation, pregnancy, psychiatric disorders, use of nonsteroidal anti-inflammatory drugs (NSAIDs) within the past week, or treatment for knee pain within the past 6 months will be excluded from the study.

Intervention groups

Experimental Group 1 (M1 stimulation), Experimental Group 2 (M1 + DLPFC stimulation), and Control Group (sham stimulation)

Main outcome variables

Pain intensity; Balance; Forward Step-Down Test score; Physical function; Quadriceps muscle strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260629070006N1**
Registration date: **2026-08-25, 1405/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-25, 1405/06/03**
Update count: **0**

Registration date

2026-08-25, 1405/06/03

Registrant information

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Name of organization / entity
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Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01
Expected recruitment end date
2026-11-22, 1405/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of The Effects of Single-Site and Concurrent Transcranial Direct Current Stimulation (M1, DLPFC) on Pain Intensity, Balance, Motor Function and Quadriceps Muscle Strength in Female Students with Patellofemoral Pain Syndrome

Public title
The effects of transcranial electrical brain stimulation on pain, balance, and motor function in female students with anterior knee pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Sex: Female Age range: 18–35 years The presence of knee valgus, as assessed by the Forward Step-Down Test Unilateral knee pain A minimum pain score of 3 on the Visual Analog Scale (VAS) Anterior knee pain elicited during at least three of the following: prolonged sitting, stair ascent or descent, squatting, palpation of the patellar facets, bilateral squat, or a positive Clarke's test
Exclusion criteria:
History of knee injury or surgery involving the ligaments, menisci, or other knee structures. Participants with knee pathologies such as knee osteoarthritis, patellar tendinopathy, meniscal lesions, osteochondral lesions, or ligament injuries. Traumatic or recurrent patellar dislocation Use of nonsteroidal anti-inflammatory drugs (NSAIDs) within the past week Pregnancy Psychiatric disorders Previous treatment within the past 6 months
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants were randomly allocated using simple randomization to three groups of 14 participants each: Experimental Group 1 (receiving transcranial direct current stimulation [tDCS] over the primary motor cortex), Experimental Group 2 (receiving simultaneous tDCS over the primary motor cortex and dorsolateral prefrontal cortex), and the sham group (receiving sham stimulation without an actual therapeutic effect). The random allocation sequence was generated using the Random Allocation Software by an independent individual who was not involved in the study. For allocation concealment, a random code was assigned to each allocation, and the codes generated from the randomization sequence were placed separately in opaque, sealed envelopes. After each eligible participant entered the study, the envelopes were made available to the participant, who randomly selected one envelope. After opening the envelope, the code inside was matched with the randomization list, and the participant’s assigned group was determined. Thus, the participant’s selection of an envelope resulted in random allocation to one of the three groups, and group assignment could not be predicted or observed before the envelope was selected. The unit of randomization was the individual participant, and no block, stratified, or cluster randomization was used.
Blinding (investigator's opinion)
Double blinded
Blinding description
Outcome assessors and participants were blinded to the type of intervention administered. Prior to the commencement of the study, to ensure allocation concealment, the codes generated from the random allocation sequence by an independent individual who was not involved in the study, using the Random Allocation Software, were placed separately in opaque, sealed envelopes. After each eligible participant entered the study, the participant randomly selected one of the envelopes. After opening the envelope, the code inside was matched with the randomization list, and the participant’s assigned group was determined. Thus, group allocation could not be observed or predicted by the participant or the outcome assessor before the envelope was selected and opened. The interventions across the study groups were similar in terms of administration procedure, number and duration of sessions, and conditions of stimulation, with the only difference being the stimulation site in the active intervention groups. In the sham group, sham stimulation was administered using the same procedure. Therefore, participants were unaware of the type of intervention they received and their group allocation. Since participants were also unaware of the type of intervention administered to the other groups, they could not determine which group they had been assigned to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Razi University, Kermanshah

Street address
Faculty of Sport Sciences, Razi University Campus, Baghe Abrisham, Kermanshah, Iran

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Province
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Approval date
2026-07-01, 1405/04/10

Ethics committee reference number
IR.RAZI.REC.1405.041

Health conditions studied

1

Description of health condition studied
Patellofemoral Pain Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain intensity

Timepoint
Before the intervention (pre-intervention) and after completion of the intervention (post-intervention)

Method of measurement
Pain intensity will be measured using the Visual Analog Scale (VAS).

Secondary outcomes

1

Description
Static balance

Timepoint
Before the intervention (pre-intervention) and after completion of the intervention (post-intervention)

Method of measurement
Static balance will be assessed using the TECNOBODY Prokin 252 balance system (Italy), located at the Exercise Physiology Laboratory, Faculty of Sport Sciences, Razi University.

2

Description
Dynamic balance

Timepoint
Before the intervention (pre-intervention) and after completion of the intervention (post-intervention)

Method of measurement
Dynamic balance will be assessed using the Y-Balance Test (YBT).

3

Description
Forward Step-Down Test score

Timepoint
Before the intervention (pre-intervention) and after completion of the intervention (post-intervention)

Method of measurement
The Forward Step-Down Test score will be assessed using the Forward Step-Down Test. During the test, participants will stand on a 20-cm step with their arms crossed over their chest. They will then be instructed to step forward toward the floor while maintaining balance on the weight-bearing limb. After the heel of the non-weight-bearing foot makes initial contact with the floor, they will return to the starting position.

4

Description
Motor function

Timepoint
Before the intervention (pre-intervention) and after completion of the intervention (post-intervention)

Method of measurement
Motor function will be assessed using the Anterior Knee Pain Scale (AKPS), also known as the Kujala Questionnaire. This questionnaire evaluates patients' self-reported symptoms and functional limitations related to patellofemoral pain syndrome. It consists of 13 items assessing knee function during daily activities.

5

Description
Quadriceps muscle strength

Timepoint
Before the intervention (pre-intervention) and after completion of the intervention (post-intervention)

Method of measurement
Quadriceps muscle strength will be assessed using a hand-held dynamometer.

Intervention groups

1

Description
Intervention group: Transcranial Direct Current Stimulation Over the Primary Motor Cortex Participants in this group received transcranial direct current stimulation (tDCS) targeting the primary motor cortex.

The intervention was administered using a Nerostim2 device manufactured by Medina Teb Gostar, Tehran, Iran, at a current intensity of 2 mA for 20 minutes per session. A total of 6 sessions were conducted, with 3 sessions per week over a period of 2 weeks. The international 10–20 brain mapping system and a dedicated electroencephalography cap were used to determine the precise electrode placement. Sponge electrodes soaked in saline solution were placed over the pre-marked areas. In participants with predominant symptoms in the right knee, the 4 × 5 cm anode was placed over the C3 location, whereas in participants with predominant symptoms in the left knee, the anode was placed over the C4 location. The 4 × 9 cm cathode was placed over the upper region of the contralateral orbit.

Category

Treatment - Devices

2

Description

Intervention group: Simultaneous Transcranial Direct Current Stimulation Over the Primary Motor Cortex and Dorsolateral Prefrontal Cortex Participants in this group received transcranial direct current stimulation (tDCS) targeting the primary motor cortex and dorsolateral prefrontal cortex simultaneously. The intervention was administered using a Nerostim2 device manufactured by Medina Teb Gostar, Tehran, Iran, at a current intensity of 2 mA for 20 minutes per session. The intervention consisted of a total of 6 sessions, with 3 sessions per week over a period of 2 weeks. The international 10–20 brain mapping system and a dedicated electroencephalography cap were used to determine the electrode placement. Sponge electrodes soaked in saline solution were placed over the marked areas. In this group, two 4 × 5 cm anodes were placed at the F3 and Cz locations. Two 4 × 9 cm cathodes were placed at AF8 and between AFz and FPz, respectively.

Category

Treatment - Devices

3

Description

Control group: Sham Transcranial Direct Current Stimulation Participants in the control group received sham transcranial direct current stimulation (sham tDCS). The intervention was administered using a Nerostim2 device manufactured by Medina Teb Gostar, Tehran, Iran. To maintain conditions comparable to those of the intervention groups, participants underwent a total of 6 stimulation sessions, with 3 sessions per week over a period of 2 weeks. Each session lasted 20 minutes.The international 10–20 brain mapping system and a dedicated electroencephalography cap were used to determine the electrode placement. Sponge electrodes soaked in saline solution were placed over the designated areas. In the control group, the electrode placement procedure and session conditions were similar to those of the intervention groups. However, in the sham stimulation condition, the electrical current was gradually increased over a period of 30 seconds to mimic the sensation associated with anodal stimulation, after which the current was discontinued and returned to the initial state. Thus, no effective electrical stimulation was delivered to the target areas.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Sport Sciences, Razi University, Kermanshah

Full name of responsible person

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Sponsors / Funding sources

1

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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, 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

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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 the confidentiality and privacy of participants' information and due to restrictions on sharing individual-level data, the raw and individual participant data will not be made publicly available. The overall study results will be reported in an aggregated form, without any possibility of identifying individual participants.
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

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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