

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Synergistic Effects of transcranial Direct Current Stimulation, transcranial Alternative Current Stimulation and Neuromuscular Electrical Stimulation Combined with Exercise Therapy on Clinical Outcomes and Electroencephalographic Activity in Women with Patellofemoral Pain Syndrome

Protocol summary

Study aim

Investigation and Comparison of the Synergistic Effects of tDCS, tACS, and NMES Combined with Exercise Therapy on Clinical Outcomes and EEG Activity in Women with Patellofemoral Pain Syndrome

Design

A three-arm parallel, double-blind, randomized clinical trial conducted on 42 patients. Randomization was performed using the RAND function in Microsoft Excel

Settings and conduct

42 eligible women with patellofemoral pain syndrome will be randomly assigned to one of three intervention groups. Initial assessments will be conducted at the physiotherapy laboratory of the School of Rehabilitation. Subsequently, participants will undergo 12 treatment sessions, held three times per week over a continuous period of four weeks, at the physiotherapy clinic of the same school. Post-treatment assessments will be carried out after the completion of the intervention sessions and in one month followup. Both the participants and the physiotherapist responsible for pre- and post-treatment evaluations will be blinded to the group assignments.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women aged between 18 and 35 years, A history of unilateral or bilateral pain around or behind the patella, Tenderness to palpation over the medial or lateral facet of the patella, Non-traumatic onset of symptoms Exclusion Criteria: History of knee injuries such as meniscal, tendon, or ligament damage, History of partial or complete patellar dislocation, Any musculoskeletal condition affecting other joints in the lower limbs or the back Contraindications for the use of neuromodulation techniques

Intervention groups

Group 1: NMES+Exe Group 2: tDCS+Exe Group 3: tACS+Exe

Main outcome variables

Pain intensity, Functional activity level, Functional performance, Dynamic balance, Mean relative and absolute power of the delta, theta, alpha1 and alpha2 frequency bands

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250408065257N1**

Registration date: **2025-05-12, 1404/02/22**

Registration timing: **prospective**

Last update: **2025-05-12, 1404/02/22**

Update count: **0**

Registration date

2025-05-12, 1404/02/22

Registrant information

Name

Samira Karimpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Synergistic Effects of transcranial Direct Current Stimulation, transcranial Alternative Current Stimulation and Neuromuscular Electrical Stimulation Combined with Exercise Therapy on Clinical Outcomes and Electroencephalographic Activity in Women with Patellofemoral Pain Syndrome

Public title

Effects of Central and Peripheral Stimulation Combined with Exercise in Women with Patellofemoral Pain Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women Aged Between 18 and 35 Years History of Unilateral or Bilateral Pain Around or Behind the Patella, Exacerbated by at Least Two of the Following Activities: Squatting, Going Up or Down Stairs, or Prolonged Sitting with Knees Bent Tenderness to Palpation Over the Medial or Lateral Facets of the Patella Pain During Isometric Contraction of the Quadriceps Against Resistance Applied Above the Patella, and Pain During Resisted Knee Extension at Various Degrees of Flexion Non-traumatic Onset of Symptoms Patellofemoral Joint Pain for at Least the Past 3 Months Minimum Literacy Level Equivalent to Completion of Middle School

Exclusion criteria:

History of Knee Injuries such as Meniscal, Tendon, or Ligament Damage History of Patellar Subluxation or Dislocation Any Condition Affecting Other Joints Involving the Lower Limbs or the Back History of Fractures in the Spine or Lower Limbs History of Surgery or Arthroscopy in any of the Lower Limb Joints History of Head Trauma, Neurological Disorders, or Mental Health Issues Contraindications for Neuromodulation such as Pregnancy, Presence of Metal Implants, Epilepsy, History of Skull Fracture, or Cardiac Pacemaker

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

All Eligible Patients will be Randomly Assigned Using Block Randomization with Blocks of Size 6, Equally Distributed into Three Groups (with an Allocation Ratio of 1:1:1): NMES+EX, tDCS+EX, and tACS+EX. The Group Allocation for Each Participant will be Concealed Using Sealed Envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blinded. Both participants and the outcome assessor will be blinded to the group allocation. All assessments will be performed by a physiotherapist who is independent of the research team and will only work with participant codes. In the tDCS and tACS groups, 20-minute brain stimulation is delivered prior to the exercise in a seated and relaxed position, using a constant intensity of 2 mA. Electrode placement is identical in both groups. The device interface and settings are indistinguishable, and the display screen is masked to prevent revealing the type of current. Participants are informed that the study involves different types of brain stimulation without specifying which type. In the NMES group, electrical stimulation is applied simultaneously with strengthening exercises, which makes complete blinding of participants in this group not feasible. However, the assessor remains blinded throughout and is not involved in any part of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Central Building of Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2025-04-24, 1404/02/04

Ethics committee reference number

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 on Visual Analogue Scale

Timepoint

Pain intensity will be measured at the beginning of the study (before the start of the intervention), after completing 12 intervention sessions, and one month after the end of the intervention.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Functional Activity Level

Timepoint

Functional Activity Level will be measured at the beginning of the study (before the start of the intervention), after completing 12 intervention sessions, and one month after the end of the intervention

Method of measurement

Kujala Questionnaire

2

Description

Dynamic Balance

Timepoint

Dynamic Balance will be measured at the beginning of the study (before the start of the intervention), after completing 12 intervention sessions, and one month after the end of the intervention

Method of measurement

Y-balance test

3

Description

Functional Performance

Timepoint

Functional Performance will be measured at the beginning of the study (before the start of the intervention), after completing 12 intervention sessions, and one month after the end of the intervention

Method of measurement

Step-Down test

4

Description

Mean relative power of the EEG frequency bands

Timepoint

Mean relative power of the EEG frequency bands will be measured at the beginning of the study (before the start of the intervention), after completing 12 intervention sessions, and one month after the end of the intervention

Method of measurement

Recording with an EEG device and measurement using sLORETA software

5

Description

Mean absolute power of the EEG frequency bands

Timepoint

Mean absolute power of the EEG frequency bands will be measured at the beginning of the study (before the start of the intervention), after completing 12 intervention sessions, and one month after the end of the intervention

Method of measurement

Recording with an EEG device and measurement using sLORETA software

Intervention groups

1

Description

Intervention group: NMES and Exercise Therapy

Category

Rehabilitation

2

Description

Intervention group: tDCS and Exercise Therapy

Category

Rehabilitation

3

Description

Intervention group: tACS and Exercise Therapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Seyede Zahra Emami Razavi

Street address

Dr.Gharib st., End of Keshavarz Blvd.

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2

Recruitment center

Name of recruitment center
Children's Medical Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Samira Karimpour
Position
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Latest degree
Master
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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

It has been decided that the study protocol will be published as an article.

When the data will become available and for how long

The start of the article protocol's access period depends on the journal review process and is not predictable.

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

1. Permitted Analyses: Only analyses that align with the original aims of the study or that have been approved by the principal investigator and ethics committee are allowed. Secondary analyses must be related to public health or scientific research and must not attempt to re-identify individuals. 2. Permitted Use of Documents: Documents such as study protocols, informed consent forms, and anonymized data sheets may be used solely for scientific research, academic review, or regulatory purposes. Use for commercial purposes is strictly prohibited. 3. Governance Mechanisms: A data use agreement must be signed before any data is shared. All data sharing will comply with applicable ethical and legal guidelines, including data protection and confidentiality standards. Any publication resulting from the use of shared data must acknowledge the original study and its investigators

From where data/document is obtainable

Individuals interested in receiving more information can contact the person responsible for the scientific correspondence of the study via email at karimpour-s@razi.tums.ac.ir.

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

After receiving and reviewing the applicant's request email, and in consultation with the supervising professors, the requested data will be sent as soon as possible.

Comments