Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 backContraindications 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

1.Change in the names of the participant recruitment centers due to the lack of cooperation from the previously designated centers in posting recruitment advertisements. 2. Change in the person responsible for responding to scientific inquiries about the study, from the student researcher to the study supervisor. 3. Revision of the publication plan due to the lack of a final decision regarding the publication of information related to the study protocol and dataset

Acronym

IRCT registration information

IRCT registration number: **IRCT20250408065257N1**
Registration date: **2025-05-12, 1404/02/22**
Registration timing: **prospective**

Last update: **2026-11-20, 1405/08/29**
Update count: **1**

Registration date

2025-05-12, 1404/02/22

Registrant information

Name

Samira Karimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3939

Email address

karimpour-s@razi.tums.ac.ir

Recruitment status

Recruitment complete

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
IR.TUMS.FNM.REC.1404.046

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
School of Rehabilitation of Tehran University of Medical Sciences

Full name of responsible person
Mohammad Reza Hadian

Street address
School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1148965111

Phone
+98 21 7753 3939

Email
hadianrs@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ramin Kordi

Street address
6th Floor, Deputy of Research and Technology Central Administration Building of Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
141765383761

Phone
+98 21 8163 3698

Email
vcr@tums.ac.ir

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
Ph.D student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1148965111

Phone
+98 21 7753 3939

Fax

Email
karimpour-s@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Reza Hadian

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1148965111

Phone
+98 21 7753 3939

Fax

Email
hadianrs@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Samira Karimpour
Position
Ph.D student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1148965111
Phone
+98 21 7753 3939
Fax
Email
karimpour-s@razi.tums.ac.ir

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
There is no further information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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