Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effects of transcranial direct current stimulation (tDCS) plus exercise with exercise alone on pain, function and balance in individuals with patellofemoral pain

Protocol summary

Study aim
Comparison of the effects of transcranial direct current stimulation (tDCS) plus exercise with exercise alone on pain, function and balance in individuals with patellofemoral pain

Design
This study is a randomized controlled clinical trial with a parallel, double-blind, randomized block design with Block Randomization. The determined sample size is 12 persons in each group.

Settings and conduct
The study will be conducted at Shiraz school of Rehabilitation Sciences and the study population (n = 24) will be randomly divided into control and intervention groups. the intervention group will receive tDCS plus exercise for 4 weeks. This is a double-blinded study. The assessor, analyzer and the patients will be blinded to the participants' group.

Participants/Inclusion and exclusion criteria
Patients with patellofemoral pain complaining gradual anterior knee pain during last 3 months and age between 18 to 40 years old will be included. The patients with any previous knee trauma or other pathologies such as meniscus and ligament injuries or history of diseases that may be effected by tDCS such as epilepsy, brain tumor, brain implants will be excluded.

Intervention groups
In this study, one group will receive real tDCS with the protocol of Anode on CZ and Cathode on the middle of the forehead according to the 10-20 system, and the second group will receive sham tDCS with the same method. Then both groups will perform stretching exercises related to Hamstring, Gastrocnemius and Iliotibial band and strengthening exercises related to knee, hip and trunk.

Main outcome variables
Pain, function, balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131225015932N17**
Registration date: **2022-10-29, 1401/08/07**
Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**
Update count: **0**

Registration date
2022-10-29, 1401/08/07

Registrant information

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Alireza Motealleh
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-01, 1401/09/10

Expected recruitment end date
2023-05-20, 1402/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effects of transcranial direct current stimulation (tDCS) plus exercise with exercise alone on pain, function and balance in individuals with patellofemoral pain

Public title
Comparison of the effects of transcranial direct current stimulation (tDCS) plus exercise with exercise alone on pain, function and balance in individuals with patellofemoral pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women and men aged 18-40 years/old with unilateral patellofemoral pain Anterior knee pain provoked by at least 2 of the following activities: prolonged sitting, ascending or descending stairs, squatting, kneeling, jumping, running Pain on palpation of the medial and lateral patellar facets, and positive Clarke's sign Insidious onset of symptoms without a history of trauma and injury Average pain level of at least 3 out of 10 on VAS during the previous week in activities of daily living (ADL) Kujula scores 50-80 The presence of pain for at least 3 months

Exclusion criteria:
Other knee joint pathologies such as meniscus and ligament injuries, osteoarthritis and tendon impairments; Self-reported history of patellar subluxation or dislocations; plica syndrome and Osgood-Schlatter disease; trauma in hip; knee or ankle joint Previous knee surgery Radicular pain from other joints including lumbar spine, hip and sacroiliac joints Metabolic disorders such as Diabetes; neurological, and rheumatology diseases such as Stroke; MS; RA and balance disorders and peripheral Neuropathies Professional athletes who participates in a specific sport at least 2 h /day and 3 times a week regularly Pregnancy Heart diseases Consumption of alcohol and drugs that affect the central nervous system and balance such as Dextromethorphan and D_cycloserine Diseases that interfere with tDCS, such as history of epilepsy, history of brain surgery, brain tumor, brain implants Cognitive disorders due to the consumption of alcohol and drugs in the last six months Uncorrected vision and hearing impairment

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of patients into 2 intervention and control groups is done by the block randomization method. The allocation sequence is generated using the free web system at http://www.randomization.com. Opaque and sealed envelopes will be used to hide the allocation of patients to groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The physiotherapist who will measure the outcome measures and the physiotherapist who will analyze the outcome measures will be blinded to the patient’s allocation group

Placebo
Used

Assignment
Parallel

Other design features
In this study, according to previous related studies, the necessary sample size of 20 subjects (10 subjects in each group) will be considered, and considering 20% dropout and a 1:1 ratio (intervention: control), at least 12 subjects will be considered for each group. Allocation of participants to groups will be based on the block randomization method. One month after interventions both groups will be evaluated for follow-up.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Rehabilitation school of Shiraz University of Medical Sciences, Abivardi Ave., Chamran Boulevard

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shiraz

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Approval date
2022-09-16, 1401/06/25

Ethics committee reference number
IR.SUMS.REHAB.REC.1401.030

Health conditions studied

1

Description of health condition studied
Patellofemoral pain

ICD-10 code
M22.2

ICD-10 code description

Patellofemoral disorders

Primary outcomes

1

Description
Pain intensity
Timepoint
First,12th session and 1 month after interventions
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Function
Timepoint
First, 12th session, and 1 month after interventions
Method of measurement
Kujala questioner

2

Description
Function
Timepoint
First, 12th session, and 1 month after interventions
Method of measurement
Step down test

3

Description
Static balance
Timepoint
First,12th session and 1 month after interventions
Method of measurement
Single leg stance balance test

4

Description
Dynamic balance
Timepoint
First,12th session and 1 month after interventions
Method of measurement
Modified star excursion balance test

Intervention groups

1

Description
Intervention group: real tDCS plus knee, hip, and trunk strengthening exercises: In this group, the participants will receive 20 minutes of real tDCS for one month and 3 sessions per week, with the method of placing the anode on the CZ and the cathode on the middle of the forehead with a current of 2 mA and then they will do stretching exercises for quadriceps, hamstrings, iliotibial band, and calf muscles (3 repetitions, 30-second hold) and knee and hip and trunk strengthening exercises including quadriceps setting, terminal knee extension, straight leg raise, and hip abductor and external rotator, and Transversus abdominis and multifidus muscle training: Quadruped and prone with 10-second isometric contraction in the first and second week and 15 seconds in 3rd and 4th week, Sitting on the Swiss ball: with 20-second isometric contraction in the first and second week and 25 seconds in 3rd and 4th week, ventral bridge and lateral bridge with 30 seconds hold in the first and second week and 35 seconds hold in 3rd and 4th week. Each session almost will take time 60 minutes.
Category
Rehabilitation

2

Description
Control group: sham tDCS plus knee, hip, and trunk strengthening exercises: In this group, the participants will receive 20 minutes of sham tDCS for one month and 3 sessions per week, with the method of placing the anode on the CZ and the cathode on the middle of the forehead (but the current is only on for 10 seconds and then it is cut off). And then they will do stretching exercises for quadriceps, hamstring, iliotibial band, and calf muscles (3 repetitions, 30-second hold) and knee and hip and trunk strengthening exercises including quadriceps setting, terminal knee extension, straight leg raise, and hip abductor and external rotator, and Transversus abdominis and multifidus muscle training: Quadruped and prone with 10-second isometric contraction in the first and second week and 15 seconds in 3rd and 4th week, Sitting on the Swiss ball: with 20-second isometric contraction in the first and second week and 25 seconds in 3rd and 4th week, ventral bridge and lateral bridge with 30 seconds hold in the first and second week and 35 seconds hold in 3rd and 4th week. Each session almost will take time 60 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy clinic of Shiraz School of Rehabilitation
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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Mohtashamzade

Position

Master of science student in Physiotherapy

Latest degree

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Other areas of specialty/work

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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
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
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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available