Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effects of addition of transcranial direct current stimulation to therapeutic exercise on pain, functional disability and grip strength in patients with tennis elbow

Protocol summary

Study aim
The aim of this study is to investigate the effects of adding transcranial direct current stimulation (tDCS) to exercise training in patients with tennis elbow

Design
This study is a participant-, assessor-, and data analyst-blind, parallel group randomized clinical trial. 40 patients will be randomly assigned to one of two groups of the study with Block Randomization method.

Settings and conduct
Therapeutic groups are treated for four weeks, three times a week. Outcome measures will be assessed pre- and post-interventions, and 4 weeks post-intervention in both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: unilateral lateral elbow pain for 6 weeks to 1 year, average pain intensity of 3 or more on visual analog scale during the last week, age between 30 to 55, a score of 33 or more on patient-rated tennis elbow evaluation questionnaire Exclusion criteria: history of local trauma, surgery, physiotherapy treatment or corticosteroid injection in the lateral epicondyle within the last 3 month, cervical radiculopathy, systemic diseases, history of stroke, intracranial surgery, migraine, brain cancer, mental or neurological disorder, taking drugs that alter neuronal activity, any metal implants, pregnancy or breastfeeding, balance disorder or dizziness, active infection, scalp or skin condition, seizure, history of epilepsy, adverse effects to previous tDCS or other brain stimulation techniques, Covid-19 infection during the study or during one month before the start of the study, carpal tunnel syndrome, fibromyalgia

Intervention groups
Intervention group: 12 sessions of therapeutic exercise plus anodal tDCS over 4 weeks. Control group: 12 sessions of therapeutic exercise plus sham tDCS over 4 weeks.

Main outcome variables
pain intensity, functional disability, grip strength, dexterity, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140408017177N2**
Registration date: **2023-01-01, 1401/10/11**
Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**
Update count: **0**

Registration date
2023-01-01, 1401/10/11

Registrant information

Name
Iman Rezaei

Name of organization / entity
School of Rehabilitation

Country
Iran (Islamic Republic of)

Phone
+98 71 1627 1551

Email address
irezaei@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-25, 1401/11/05

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of addition of transcranial direct current stimulation to therapeutic exercise on pain, functional disability and grip strength in patients with tennis elbow

Public title
The effects of addition of transcranial direct current stimulation to exercise in patients with lateral elbow pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
unilateral lateral elbow pain for 6 weeks to 1 year average pain intensity of 3 or more on visual analog scale during the last week age between 30 to 55 years a score of 33 or more on the patient-rated tennis elbow evaluation questionnaire pain over the lateral humeral epicondyle provoked by at least two of the following four tests:1) palpation of the external epicondyle, 2) Resisted wrist extension (Thomsen/Cozen's test), 3) Resistance extension of fingers (Maudsley test), 4) Passive stretching of the extensor muscle group (Mills test)
Exclusion criteria:
history of local trauma, surgery, physiotherapy treatment or corticosteroid injection in the lateral epicondyle within the last 3 month cervical radiculopathy systemic diseases such as diabetes and rheumatological disorders heart problems history of stroke intracranial surgery, migraine, brain cancer, mental or neurological disorder taking drugs that alter neuronal activity any metal implants, including intracranial electrodes, surgical clips, cochlear implants or pacemakers, or other implanted electronic devices pregnancy or breastfeeding balance disorder or dizziness active infection or scalp or skin condition (e.g., psoriasis or eczema) a head injury that resulted in a loss of consciousness that required further investigation (e.g., a brain scan) seizure epilepsy or a history of epilepsy adverse effects to previous transcranial direct current stimulation or other brain stimulation techniques Covid-19 infection during the study or during one month before the start of the study carpal tunnel syndrome fibromyalgia
Age
From **30 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized
Randomization description
The samples will be randomly assigned to one of the two study groups by block randomization method using random allocation software in 10 blocks of 4. Allocation concealment will be done by using sequentially numbered, opaque sealed envelopes.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, treating therapist is not blind to the stimulation condition. Outcome assessor differs from the treating therapist and is blinded to group allocation. There will be two groups of participants in this study and both groups will receive the same exercises but different stimulation conditions. First group will receive active transcranial direct current stimulation and second group will receive sham transcranial direct current stimulation. They will be aware that they could receive either sham or active stimulation but they will be blinded to stimulation condition they receive during treatment sessions. The data analyst who is different from the treating therapist will be blinded to group allocation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Science
Street address
Shiraz University of Medical Sciences, Zand street, Shiraz, Fars, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2022-10-19, 1401/07/27
Ethics committee reference number
IR.SUMS.REHAB.REC.1401.045

Health conditions studied

1

Description of health condition studied
Tennis elbow

ICD-10 code
M77.1
ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
Pain
Timepoint
pre-intervention, post-intervention, 4 weeks post-intervention
Method of measurement
Visual analog scale

2

Description
Functional disability
Timepoint
pre-intervention, post-intervention, 4 weeks post-intervention
Method of measurement
Patient-rated tennis elbow evaluation

3

Description
grip strength
Timepoint
pre-intervention, post-intervention, 4 weeks post-intervention
Method of measurement
manual dynamometer

Secondary outcomes

1

Description
Finger & hand dexterity
Timepoint
pre-intervention, post-intervention, 4 weeks post-intervention
Method of measurement
Perdue pegboard

2

Description
Quality of life
Timepoint
pre-intervention, post-intervention, 4 weeks post-intervention
Method of measurement
12-Item Short Form Survey

Intervention groups

1

Description
active transcranial direct current stimulation group: 1) progressive eccentric exercises of the wrist extensors / 3 sets of 10 repetitions. 2) Extensor carpi radialis brevis muscle stretch/ 6 repetitions / 3 times before and 3 times after eccentric exercises with 30 seconds of rest between each repetition / 30 to 45 seconds each time. 3) Anodal transcranial direct current stimulation with an intensity of 2 mA for 20 minutes
Category
Rehabilitation

2

Description
sham transcranial direct current stimulation group: 1) progressive eccentric exercises of the wrist extensors / 3 sets of 10 repetitions. 2) Extensor carpi radialis brevis muscle stretch/ 6 repetitions / 3 times before and 3 times after eccentric exercises with 30 seconds of rest between each repetition / 30 to 45 seconds each time. 3) sham transcranial direct current stimulation with an intensity of 2 mA for 30 seconds
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation school, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Iman Rezaei
Street address
no. 32, Abiverdi 1 Avenue, Chamran Blvd, Shiraz, Fars, Iran
City
Shiraz
Province
Fars
Postal code
7194733669
Phone
+98 71 3627 1551
Email
irezaei@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mahtab Memarpour
Street address

Shiraz University Of Medical Sciences Building, Zand Street, Shiraz

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3235 7282

Email
memarpour@sums.ac.ir

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
Iman Rezaei

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
School or Rehabilitation, Sheikh Abivardi 1 street, Chamran Blvd

City
Shiraz

Province
Fars

Postal code
7194733669

Phone
+98 71 3627 1551

Email
irezaei@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Iman Rezaei

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
School of Rehabilitation, Abiverdi1, Chamran Blvd.

City
Shiraz

Province
Fars

Postal code
7194733669

Phone
+98 71 3627 1551

Email
irezaei@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Neda Zarei

Position
Master of science student of Physiotherapy

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
School of Rehabilitation, Abiverdi1, Chamran Blvd.

City
Shiraz

Province
Fars

Postal code
7194733669

Phone
+98 71 3627 1551

Email
zareineda@sums.ac.ir

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