

# 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 &amp; 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 of 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