

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative study the effect of active and sham transcranial direct current stimulation (tDCS) on disability, anxiety and kinesiophobia in athletes with chronic shoulder injury

Protocol summary

Study aim

Determining the effect of active and sham transcranial direct current stimulation and comparing them on disability, anxiety, and kinesiophobia in athletes with a history of chronic shoulder injury

Design

A parallel-group, double-blind, randomized controlled clinical trial of 36 patients. Permuted block randomization method is used for randomization.

Settings and conduct

This study will be conducted with the voluntary participation of athletes with a history of chronic shoulder injury who have a fear of movement. In the intervention group, the treatment protocol includes the use of real tDCS (direct current transcranial stimulation) on the DLPFC area of the head, and in the control group, fake tDCS (sham). The patients will be treated in 10 sessions. The first 5 sessions will be consecutive and the next 5 sessions will be one day apart. Disability, anxiety, and kinesiophobia will be assessed before and after the intervention and one month after the end of the study (follow-up). Patients and the evaluator are blinded to the grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range between 18 and 35 years; having a score of 37 in the Tampa questionnaire; Not receiving psychological treatment in the past year.
Exclusion criteria: Having prosthesis in skull; having cardiac pacemaker; acute shoulder injury.

Intervention groups

In the intervention group, a direct stimulation current will be used by a pair of electrodes (cathode and anode). A current of 2 mA is applied to the left DLPFC for 20 minutes. In the control (sham) group, the current is first applied for 2 minutes, then the device is turned off.

Main outcome variables

Kinesiophobia; disability; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221023056277N1**

Registration date: **2022-11-14, 1401/08/23**

Registration timing: **prospective**

Last update: **2022-11-14, 1401/08/23**

Update count: **0**

Registration date

2022-11-14, 1401/08/23

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study the effect of active and sham transcranial direct current stimulation (tDCS) on disability, anxiety and kinesiophobia in athletes with chronic shoulder injury

Public title

The effect of transcranial direct current stimulation (tDCS) on anxiety and kinesiophobia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range between 18 and 35 years old Willingness to participate in research Patients with shoulder joint injury with fear of movement who perform overhead exercises At least 6 months have passed since the history of musculoskeletal injury Having the severity of the injury to the extent that the athlete has been away from sports and training for at least two months Having a score of 37 in the Tampa questionnaire Not receiving psychological treatment in the past year

Exclusion criteria:

Acute shoulder injury Having a prosthesis in the skull Having a cardiac pacemaker

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the method of Stratified Permuted Block Randomization with 6 blocks of 6, assignment to two groups is done. In this method, A represents the intervention group and B represents the sham group. In this way, the order of interventions A and B in the form of blocks from number 1 to 6 is determined by the methodological consultant of the project and given to the executive supervisor of the project, and the researcher obtains assignments from the executive supervisor to assign each eligible person.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to reduce the bias in the study, the main researcher will perform all the treatment sessions, and the evaluation sessions before and after the intervention will be done by the research assistant who is a physiotherapist and is blinded to the grouping. The participants in each group will remain unaware of the treatment of the other group, and the evaluator will not be aware of the grouping of people. Therefore, this study is a double-blind study (patients and evaluator).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd., Semnan

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3519899951

Approval date

2022-10-15, 1401/07/23

Ethics committee reference number

IR.SEMUMS.REC.1401.158

Health conditions studied

1

Description of health condition studied

Chronic shoulder injury

ICD-10 code

M75.9

ICD-10 code description

Shoulder lesion, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

Before the study, after 2 weeks Intervention, and one month after the end of the study.

Method of measurement

Competitive State Anxiety Inventory-2 (CSAI-2)

Secondary outcomes

1

Description

Disability

Timepoint

Before the study, after 2 weeks Intervention, and one month after the end of the study.

Method of measurement

Disability of Arm, Shoulder and Hand (DASH) questionnaire

2**Description**

Kinesiophobia

Timepoint

Before the study, after 2 weeks Intervention, and one month after the end of the study.

Method of measurement

Tampa Scale for Kinesiophobia (TSK) questionnaire

Intervention groups**1****Description**

Intervention group: To use the tDCS tool in the intervention group, a direct stimulation current will be used by a pair of electrodes (cathode and anode). A current of 2 mA was applied to the left DLPFC for a maximum of 20 min. The cathode electrode will be used in the right DLPFC. The anode active electrode is placed on the left prefrontal area, corresponding to the F3 point on the international EEG scale of 20-10, and the cathode passive electrode is placed on the right prefrontal area, corresponding to the F4 point on the international scale of -10. 20 EEG is placed. In the intervention group, current electric current is applied

Category

Rehabilitation

2**Description**

Control group: In the sham group, the current is first applied for 2 minutes, then the device is turned off.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neuromuscular Rehabilitation Research Center,
Semnan University of Medical Sciences

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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

Semnan 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**

Semnan University of Medical Sciences

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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