Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

The effect of transcranial direct current stimulation(TDCS) with postural training on balance, static and dynamic standing postural stability in the patients with chronic low back pain(CLBP)

Protocol summary

Summary

The aim of present study was to evaluate the effect of transcranial direct current stimulation (TDCS) with postural training on balance, static and dynamic standing postural stability in the patients with chronic low back pain (CLBP). This study is a clinical trial design. Participants randomly will be divided into three groups. People of the first group to received TDCS over the primary motor cortex area with postural training in twenty minutes during two weeks; people of second group to received postural training with TDCS in the form of placebo in twenty minutes per session during two weeks (set up TDCS device electrodes on primary motor cortex area and contralateral supraorbital area and then electrical stimulation was turned off after thirty seconds) and people of third group to received just postural training without electrical stimulation. Stabilization exercise will be performed on Byodex Balance System (BBS) in each session about 20 minutes for 3 sessions per week during 2 weeks. Volunteer patients with chronic low back pain (CLBP) who are between ages of 18 to 40 years and they have chronic back pain for at least 3 months (12 weeks) by medical diagnosis and physiotherapy, and as well as peoples who will be entered into study to signed the informed consent form. The exclusion criteria are include the patients with other chronic pain syndromes, spinal cord surgery in the last 6 months, neurological diseases, rheumatology and psychiatric diseases, pregnancy or getting pregnant during the study, use of pacemakers or any other instrument in the body, previous treatments with transcranial direct current stimulation (TDCS), specific pathologies in the spinal cord (fracture, neoplasm, deformity, Schuermann's disease, infection, radiculopathy, vertebral fractures or spondylolisthesis), use of medication and drug or alcohol abuse, participation in athletic activities and not athlete, vestibular disorders, use of drugs that affecting on balance and history of migraine. All participants will be requested to stand on each static and dynamic surfaces of Byodex Balance System for 30 seconds in before and after transcranial direct current stimulation. Accordingly, the anterior/posterior, medial/lateral and overall stability indexes will be measured in before and after TDCS. Also the individuals balance level after intervention will be measured with the Berg Balance Scale. On the other hand, people of study will be re-evaluated after one month. The participants of each group and assessors to blinded the experimental conditions and interventions in each group and the study is double blind side.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070934969N1**
Registration date: **2017-08-30, 1396/06/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-30, 1396/06/08

Registrant information

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Name of organization / entity

Neuromuscular Rehabilitation Research Center

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Recruitment status
Recruitment complete
Funding source
Deputy of Research and Technology of Semnan University of Medical Sciences

Expected recruitment start date
2017-07-23, 1396/05/01
Expected recruitment end date
2017-09-23, 1396/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of transcranial direct current stimulation(TDCS) with postural training on balance, static and dynamic standing postural stability in the patients with chronic low back pain(CLBP)

Public title
The effect of transcranial direct current stimulation(TDCS) with postural training on balance, static and dynamic standing postural stability in the patients with chronic low back pain(CLBP)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Volunteer patients with chronic low back pain (CLBP) who are between ages of 18 to 40 years and they have chronic back pain for at least 3 months (12 weeks) by medical diagnosis and physiotherapy, and as well as peoples who will be entered into study to signed the informed consent form. The exclusion criteria are include the patients with other chronic pain syndromes, spinal cord surgery in the last 6 months, neurological diseases, rheumatology and psychiatric diseases, pregnancy or getting pregnant during the study, use of pacemakers or any other instrument in the body, previous treatments with transcranial direct current stimulation (TDCS), specific pathologies in the spinal cord (fracture, neoplasm, deformity, Schuermann's disease, infection, radiculopathy, vertebral fractures or spondylolisthesis), use of medication and drug or alcohol abuse, participation in athletic activities and not athlete, vestibular disorders, use of drugs that affecting on balance and history of migraine
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
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 science
Street address
Semnan، University of Medical Sciences Semnan، 5 km road Damghan ،Faculty of Rehabilitation
City
semnan
Postal code
Approval date
2017-07-16, 1396/04/25
Ethics committee reference number
IR.SEMUMS.REC.1396.61

Health conditions studied

1

Description of health condition studied
Low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Static and dynamic stability indices
Timepoint
Before and after receiving after intervention
Method of measurement
Byodex Balance System

Secondary outcomes

1

Description

balance

Timepoint

Before and after receiving intervention

Method of measurement

Berg balance scale

Intervention groups

1

Description

Intervention group: All participants will be requested to stand on each static and dynamic surfaces of Byodex Balance System for 30 seconds in before and after transcranial direct current stimulation. In the intervention of TDCS, the anode and cathode electrodes respectively will be placed on primary motor cortex and contralateral supraorbital area and the stimulation will be applied with 2 milliamps intensity for 20 minutes. The postural training with TDCS intervention will be performed for 3 sessions per week for 2 weeks.

Category

Rehabilitation

2

Description

Control group: All participants will be requested to stand on static and dynamic surfaces of Byodex Balance System for 30-second in before and after postural training with sham-TDCS intervention. In sham-TDCS intervention, anode and cathode electrodes respectively will be placed on primary motor cortex and contralateral supraorbital area. Stimulations will be applied with 2 milliamps intensity for 30 seconds. Postural training with sham-TDCS intervention will be performed for 3 sessions per week for 2 weeks.

Category

Rehabilitation

3

Description

Control group: All participants will be requested to stand on static and dynamic surfaces of Byodex Balance System for 30-second in before and after just postural training. Postural training alone will be performed for 3 sessions per week for 2 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation research Center

Full name of responsible person

fatemeh ehsani

Street address

Ghods Blvd, Semnan

City

semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Semnan University of Medical Sciences

Full name of responsible person

dr.ali rashidipour

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research and Technology, Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty