Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of cognitive behavioral therapy (CBT) programs with cathodal DLPFC transcranial direct current stimulation on fear in patient with non-specific chronic low back pain with high fear

Protocol summary

Study aim

The effect of cognitive behavioral therapy(CBT) programs with cathodal DLPFC transcranial direct current stimulation on fear in patient with non-specific chronic low back pain with high fear

Design

In this research, 45 eligible patients with non-specific chronic low back pain referring to neuromuscular research of Semnan university of medical sciences will be chose purposefully and a code will be considered to each one of them. Then, patients will be randomly divided into 3 intervention, sham and control groups. All participants and assessor will be blind to group allocation.

Settings and conduct

Neuromuscular Rehabilitation Research Center Semnan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

45 patients with non-specific chronic low back pain referring to Neuromuscular Rehabilitation Research Center Semnan University of Medical Sciences. Inclusion criteria: Age between 18-45; Having periodic low back pain for 12 weeks; Visual analog scale less than 3; Pain anxiety symptoms scale more than 30. Exclusion criteria: Any symptoms of spinal cord involvement; Cauda equina syndrome symptoms; Sciatica symptoms; Root canal involvement symptoms; History of spinal surgery; Fracture in spinal column; Impairment of learning; Pregnancy.

Intervention groups

Intervention group: Receive 20 minutes cognitive behavioral therapy with cathodal transcranial direct current stimulation (tDCS). Sham intervention group: Receive 20 minutes cognitive behavioral therapy with 30 seconds cathodal tDCS. Control group: Receive only 20 minutes cognitive behavioral therapy. All groups received intervention for 8 sessions during 4 weeks.

Main outcome variables

Fear of pain, fear of movement, disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150302021294N6**
Registration date: **2018-02-07, 1396/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-07, 1396/11/18**
Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name
Fatemeh Ehsani
Name of organization / entity
Semnan 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

2017-12-22, 1396/10/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of cognitive behavioral therapy (CBT) programs with cathodal DLPFC transcranial direct current stimulation on fear in patient with non-specific chronic low back pain with high fear

Public title
The effect of cognitive behavioral therapy (CBT) programs with cathodal DLPFC transcranial direct current stimulation on fear in patient with non-specific chronic low back pain with high fear
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-45 Having periodic low back pain for 12 weeks Visual analog scale less than 3 Pain anxiety symptoms scale more than 30
Exclusion criteria:
Any symptoms of spinal cord involvement Cauda equina syndrome symptoms Sciatica symptoms Root canal involvement symptoms History of spinal surgery Fracture in spinal column Impairment of learning Pregnancy
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 3). Using Excel software to generate random number tables.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in each group and assessors are blind to the experimental conditions and interventions (intervention group, sham group and control group).
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 Sciences
Street address
Neuromuscular Rehabilitation research Center, Qods Blvd, Mashahir Aven.
City
Semnan
Province
Semnan
Postal code
3513138111
Approval date
2017-12-12, 1396/09/21
Ethics committee reference number
IR.SEMUMS.REC.1396.162

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
Score of fear in Pain Anxiety Symptoms Scale
Timepoint
Before interventions, immediately after intervention and 2 weeks after intervention
Method of measurement
Pain Anxiety Symptoms Scale to measure fear of pain

2

Description
Score of fear of movement in Tampa Scale for Kinesiophobia
Timepoint
Before intervention, immediately after intervention and 2 weeks later after intervention
Method of measurement
Tampa Scale for Kinesiophobia to measure fear of movement

3

Description
Disability
Timepoint

Before intervention, immediately after intervention and 2 weeks later after intervention

Method of measurement

Roland Morris questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Cognitive behavioral therapy with 20 minutes cathodal transcranial direct current stimulation on left DLPFC for 4 weeks, 2 sessions in each week

Category

Rehabilitation

2

Description

Intervention group 2: Cognitive behavioral therapy with 30 seconds cathodal transcranial direct current stimulation on left DLPFC for 4 weeks, 2 sessions in each week

Category

Placebo

3

Description

Control group: Cognitive behavioral therapy without transcranial direct current stimulation for 4 weeks, 2 sessions in each week

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Fatemeh Ehsani

Street address

Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammadreza Asgari

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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

Full name of responsible person

Fatemeh Ehsani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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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