

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the effectiveness of attention bias modification (ABM) with/without Trance cranial direct current stimulation (TDCS) on reduction of attention bias and severity of perceived pain in chronic low back pain patients.

Protocol summary

Study aim

comparison of effectiveness of attention bias modification (ABM) with/without trance cranial direct current stimulation (TDCS) on attention bias, reduction of severity of perceived pain, disability due to pain and depression in chronic low back pain patients.

Design

Participants randomly assign to experimental, control and placebo groups. The sample includes all of the low back pain patients between 20 and 50 years old who met the criteria for more than 3 months. Patients referring to Rofeideh hospital. The final sample size is 60.

Settings and conduct

Current study was conducted aiming at comparing attention bias modification with and without trance cranial direct current stimulation and its impact on reduction of pain and attention bias in patients with chronic low back pain at Rofideh Hospital. It is an experimental study with control and placebo group and two intervention groups. Blindness was achieved so that first the physician referred individuals to the examiner based on inclusion and exclusion criteria. The examiner performed required evaluations, and referred them to the therapist randomly. Following intervention, the subjects were referred to the second examiner in order to evaluate the outcomes. Thus, the physician, subjects, and outcome evaluators were kept blind in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: Age between 20 and 50 years. ability for writing and reading. low back pain more than 3 months. Exclusion criteria are: Substance and addictive disorder. psychiatric disorder (psychosis or bipolar disorder). migraine or recurrent headache. brain injury.

Intervention groups

One of the experimental groups receives attention bias modification task by computer through 5 sessions of 20

minutes and the other received the same combined with trance cranial direct current stimulation (tDCS). Control group fill questionnaires. Placebo group receive sham trance cranial direct current stimulation.

Main outcome variables

The primary outcomes are decrease in attention bias and severity of perceived pain. Secondary outcomes are the decrease of depression and disability due to pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171107037306N1**

Registration date: **2017-12-17, 1396/09/26**

Registration timing: **prospective**

Last update: **2017-12-17, 1396/09/26**

Update count: **0**

Registration date

2017-12-17, 1396/09/26

Registrant information

Name

yasaman shiasy

Name of organization / entity

The university of welfare and rehabilitation science.

Country

Iran (Islamic Republic of)

Phone

+98 88037571

Email address

ya.shiasy@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Some cost is paid by researcher and residual will be paid by Rofeideh hospital.

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of attention bias modification (ABM) with/without Trance cranial direct current stimulation (TDCS) on reduction of attention bias and severity of perceived pain in chronic low back pain patients.

Public title

Effectiveness of attention bias modification and Trance cranial direct current stimulation on reduction of pain and attention bias.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 20 and 50 years. ability for writing and reading. low back pain more than 3 months.

Exclusion criteria:

Substance and addictive disorder. Psychiatric disorder(psychosis or bipolar disorder). Migraine or recurrent headaches. Brain injury.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the subjects are randomly assigned into intervention, control, and placebo groups using random number table. Sealed non-transparent envelopes with random sequence were used to conceal random assignment. Following constructing random sequence by random table, 60 envelopes with aluminum wrappers (in order to obscure the envelopes) were prepared based on the research sample size, and each of random sequences was recorded on a card, and the cards were placed in the envelopes in order. External surface of the envelopes are numbered in the same order for preserving random

sequence. Based on the order by which the qualified subjects entered to the study, the envelopes were opened and the assigned group for the subject was specified.

Blinding (investigator's opinion)

Double blinded

Blinding description

First, the physician interviewed with the patients considering inclusion and exclusion criteria. Then, individuals qualified with inclusion criteria, who were content with participation in the research, were introduced to the interviewer and he conducted the primary evaluation. The subjects were then referred to the therapist and were randomly assigned into the intervention or placebo groups. After intervention, the subjects were introduced to the examiner author, and secondary evaluation was carried out. Second examiner was unaware of assignment of subjects in intervention groups. Thus, the subjects, outcome valuator (second examiner), and clinical care provider were kept blind toward the group assignments in this study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of university of Social Welfare and Rehabilitation Sciences

Street address

Koodakyar Ave, Daneshjo Blvd ,Evin, Tehran

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2017-08-01, 1396/05/10

Ethics committee reference number

IR.USWR.REC.1396.47

Health conditions studied**1****Description of health condition studied**

chronic low back pain

ICD-10 code

F45.4

ICD-10 code description

Pain disorders related to psychological factors.

Primary outcomes

1

Description

severity of perceived pain

Timepoint

Before intervention,one week after intervention,one month after intervention

Method of measurement

Visual analog scale- questionnaire of severity of chronic pain questinnaire.

2

Description

attention bais

Timepoint

Before intervention,one week after intervention,one month after intervention

Method of measurement

Dot probe test

Secondary outcomes

1

Description

Depression

Timepoint

Before intervention,one week after intervention,one month after intervention

Method of measurement

DASS questionnaire

2

Description

Disability due to pain

Timepoint

Before intervention,one week after intervention,one month after intervention

Method of measurement

Roland & Moris disability questionnaire

Intervention groups

1

Description

The second experimental group receive the attention bias modification task combined with trance cranial direct current stimulation through 5 sessions of 20 minutes.

Category

Rehabilitation

2

Description

placebo group receive sham Trance cranial direct current stimulation.(TDCS)

Category

Placebo

3

Description

One of the experimental groups receives attention bias modification task by computer through 5 sessions of 20 minutes .

Category

Rehabilitation

4

Description

control group answer the questionnaire and dont receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh Rehabilitation Hospital

Full name of responsible person

Shima Shakiba

Street address

Nematy Ave, West Soleimany Ave, Gheitareh,Tehran

City

Tehran

Province

Tehran

Postal code

1935973476

Phone

+98 21 2220 5326

Fax

+98 21 2223 2741

Email

rofeideh.hospital@uswr.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rofeideh Rehabilitation Hospital

Full name of responsible person

Shima Shakiba

Street address

Nematy Ave, West Soleimany Ave, Gheitareh,

City

Tehran

Province

Tehran

Postal code

1935973476

Phone
+98 21 2220 5326

Fax
+98 21 2223 2741

Email
shimashakibash.psy@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Rofeideh Rehabilitation Hospital

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
Rofeideh Rehabilitation Hospital

Full name of responsible person
Shima Shakiba

Position
Supervisor of psychology ward in Rofeideh Hospital.

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Nematy Ave, Soleimany Ave, Gheitaerh

City
Tehran

Province
Tehran

Postal code
1935973476

Phone
+98 21 2223 3017

Fax

Email
shimashakibash.psy@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Yasaman Shiasy

Position

Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
Koodakyar Ave, Daneshjo Blv, Evin, Tehan

City
Tehran

Province
Tehran

Postal code
1993696691

Phone
+98 21 8803 7571

Fax

Email
syasaman@rocketmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Yasaman Shiasy

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
Koodakyar Ave, Daneshjo Blv, Evin, Tehran

City
Tehran

Province
Tehran

Postal code
1993696691

Phone
+98 21 8803 7571

Fax

Email
syasaman@rocketmail.com

Web page address

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

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

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

Title and more details about the data/document

Protocol of interventions including sessions' description, the way of intervention, and system and software setting as well as number of the sessions will be published.

When the data will become available and for how long

Complete details of the protocol can be accessible after paper publication.

To whom data/document is available

All researcher working in academic and scientific institutes would be able to access the protocol.

Under which criteria data/document could be used

All researchers who will study the similar search or, need to this protocol for completing history can use the protocol.

From where data/document is obtainable

To receive the protocol send an email to this address: Syasaman@rocketmail.com(yasaman shiasy)

What processes are involved for a request to access data/document

To receive the protocol, first applicant send a curriculum vitae by email and explain aim of study. The items will check and then applicant will receive the answer in a week.

Comments