

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Transcranial Direct Current Stimulation and Pharmacotherapy on Pain Management in Patients with Chronic Pain

Protocol summary

Study aim

The present study aimed to investigate the effectiveness of transcranial direct current stimulation and pharmacotherapy on pain management in patients with chronic pain

Design

After sampling, the participants were assigned randomly via casting lots in three groups of experimental pharmacotherapy, tDCS, and control groups.

Settings and conduct

The present study followed a clinical trial design, with both the experimental and control groups and a pre-test, post-test, and follow up.

Participants/Inclusion and exclusion criteria

The statistical population consists of patients with chronic pain admitted to Pardis Multidisciplinary Pain Clinic, located in Tehran. The inclusion criteria were suffering from chronic pain, being female, the age range of 35 to 60 years, holding at least a school completion certificate, and being interested in participation in the intervention treatment. The exclusion criteria were suffering from severe psychological diseases in terms of diagnostic and statistical psychological disorder guidance (5th edition), which was diagnosed on the basis of the clinical interview.

Intervention groups

Pharmacotherapy Transcranial Direct Current Stimulation (tDCS)

Main outcome variables

Pain Management

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211026052879N1**

Registration date: **2021-11-18, 1400/08/27**

Registration timing: **retrospective**

Last update: **2021-11-18, 1400/08/27**

Update count: **0**

Registration date

2021-11-18, 1400/08/27

Registrant information

Name

Atefeh Lotfi Jabali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7650 5891

Email address

atlotfi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

2011-06-22, 1390/04/01

Actual recruitment end date

2020-08-22, 1399/06/01

Trial completion date

2020-12-21, 1399/10/01

Scientific title

Effectiveness of Transcranial Direct Current Stimulation and Pharmacotherapy on Pain Management in Patients with Chronic Pain

Public title

tDCS and Pharmacotherapy on Pain Management in Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Suffering from chronic pain Being female Age range of 35 to 60 years Holding at least a school completion certificate being interested in participation in the intervention treatment

Exclusion criteria:
Suffering from severe psychological diseases in terms of diagnostic and statistical psychological disorder guidance

Age
From **35 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were divided into experimental and control groups based on a table of random numbers, so that odd numbers were considered for the experimental group and even numbers were considered for the control group. As a result, participants were assigned to experimental and control groups according to the type of random number they received.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Islamic Azad University, Roudehen, Iran.

Street address

Islamic Azad University, Roudehen, Iran.

City

Tehran

Province

Tehran

Postal code

3973188981

Approval date

2020-05-26, 1399/03/06

Ethics committee reference number

1134820005987911399162344200

Health conditions studied

1

Description of health condition studied

Chronic Pain

ICD-10 code

G89.29

ICD-10 code description

Other chronic pain

Primary outcomes

1

Description

Pain management

Timepoint

Post-test

Method of measurement

The McGill Pain Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pharmacotherapy: Pharmacotherapy involved taking 600 mg of gabapentin twice a day (300 mg in the morning and 300 mg at night) for three weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Transcranial Direct Current Stimulation: tDCS involved increasing the delta waves (0.5-3 Hz) to raise endorphins and, therefore, alleviate pain and promote a sense of peacefulness. All the participants in the tDCS group received 20 minutes of delta wave at a 2μA current for 10 weeks straight (one month). Anode and cathode electrodes were placed on the frontal C3 and FP2 regions, respectively. Every 20-minute session started upon connecting the ear clips and automatically ended after a certain time elapsed. At the end of the 10th week, the participants were no longer allowed to continue treatment or receive any type of tDCS.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Pardis Pain Clinic (Tehran)
Full name of responsible person
Atefeh Lotfi Jabali
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellor for Research, Roudehen Branch,
Islamic Azad University
Full name of responsible person
Malek Mirhashemi
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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

Vice-Chancellor for Research, Roudehen Branch, Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University
Full name of responsible person
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Position
PhD student
Latest degree
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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

Ethical considerations and privacy of participants

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