Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Direct Transcranial Electrical Stimulation (TDCS) and Internet-Delivered Acceptance and Commitment Therapy (IACT) on Pain Indicators of Patients with Chronic Pain : Randomized Controlled Trial

Protocol summary

Study aim

Comparing the effectiveness of two therapeutic methods: "transcranial electrical stimulation (tDCS)" and "web-based acceptance and commitment therapy (iACT)" in improving psychological outcomes and pain severity in patients with chronic pain

Design

This study is a phase 3, single-blind, parallel-design, randomized controlled trial of 60 patients with chronic pain. The samples were selected by convenience sampling and then randomly assigned to two treatment groups and a control group. The randomization sequence was generated using the Random Allocation software using a block-based method to maintain a balance in the number of subjects in the groups.

Settings and conduct

This study is a clinical trial with three groups(tDCS, iACT and control) conducted on 51 patients. After the pretest, the tDCS group will receive eight daily brain stimulation sessions, the iACT group will receive eight web-based training sessions, and the control group will receive routine treatment. Assessments will be conducted in three phases: pretest, posttest, and follow-up .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 20 to 60 years with chronic diffuse musculoskeletal pain, no history of substance abuse, psychiatric/neurological disorders, or recent psychological treatment, with minimal literacy and informed consent. Exclusion criteria: organic damage or mental retardation, history of stroke or brain surgery, inability to cooperate with questionnaires, or absence of more than two treatment sessions.

Intervention groups

tDCS group: Received 8 sessions of 20-minute brain stimulation on 8 consecutive days.iACT group: Received 8 sessions of web-based training (Skyroom) focusing on pain management and mindfulness.Control group: Received routine medical care without research interventions.

Main outcome variables

Change in pain intensity and Change in pain acceptance score

General information

Reason for update

Acronym

درمان مبتنی بر پذیرش TDCS : درمان تحریک الکتریکی فراجمجمه ای و تعهد IACT:

IRCT registration information

IRCT registration number: **IRCT20251209068264N1**
Registration date: **2026-06-08, 1405/03/18**
Registration timing: **prospective**

Last update: **2026-06-08, 1405/03/18**
Update count: **0**

Registration date

2026-06-08, 1405/03/18

Registrant information

Name

Shahrzad Khoushghamat Aziz

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-06-16, 1405/03/26
Expected recruitment end date
2026-07-17, 1405/04/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Direct Transcranial Electrical Stimulation (TDCS) and Internet-Delivered Acceptance and Commitment Therapy (IACT) on Pain Indicators of Patients with Chronic Pain : Randomized Controlled Trial

Public title
“Comparing the Efficacy of Transcranial Direct Current Stimulation (TDCS) and Internet-Based Acceptance and Commitment Therapy (IACT) on Chronic Pain Reduction”
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of Chronic Pain with Diffuse Musculoskeletal Pain, based on Interview and Clinical Examinations by a Neurologist, Rheumatologist, Physical Medicine Specialist, or Psychiatrist Patient Age between 20-60 Years No History of Psychological Treatment within 6 Months prior to the Study Absence of Major Neurological Disorders and Major Psychiatric Disorders No Substance Dependence or Abuse. Full Consent to Participate in the Research Project. Minimum Literacy (Reading and Writing).
Exclusion criteria:
Mental Retardation Or Severe Organic Impairment Lack Of Consent To Complete The Questionnaires Or Any Incident Preventing The Completion Of The Questionnaires Absence From More Than Two Treatment Sessions History Of Surgery Or Stroke
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
“The Sampling was performed using Convenience Sampling, and the Random Allocation Sequence was Generated by the Random Allocation Software Using the Block Randomization Method. Furthermore, the unit of Randomization is Individual.”
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the interventions (web-based psychological intervention and electrical stimulation), blinding of participants is not possible. However, to reduce bias, the study will be conducted in an “assessor-blind” manner. The person responsible for collecting data, completing questionnaires, and assessing study outcomes is completely unaware of the group allocation (whether each individual is in the intervention or control group). The study’s statistical analyst will also remain unaware of the identity of the groups (labeled as Groups A, B, and C) until the end of data analysis to prevent bias in the analysis of the results. The principal investigator is also aware of the groups to monitor the implementation of the protocols, but the assessment of outcomes is directly performed by the blinded assessor.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Vice President for Research and Technology، Building No. 4 ، Isfahan University of Medical Sciences and Health Services ، Hezar Jerib Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2025-09-28, 1404/07/06
Ethics committee reference number
IR.MUI.MED.REC.1404.252

Health conditions studied

1

Description of health condition studied
Chronic Pain
ICD-10 code
MG30
ICD-10 code description
دردی که به طور مداوم یا مکرر در طول زمان (معمولاً بیش از ۳ ماه) تجربه می‌شود و تأثیر قابل توجهی بر زندگی روزمره فرد، عملکرد

اجتماعی و سلامت روان او بگذارد

Primary outcomes

1

Description

Pain acceptance: Pain acceptance indicates the degree to which a patient is willing to experience pain without excessive avoidance while continuing daily activities despite the pain. This variable includes various dimensions of psychological adjustment to chronic pain. The change in the pain acceptance score before and after the intervention will indicate the effect of the treatment on the acceptance of the pain experience and the patient's psychological functioning. A higher score usually indicates greater pain acceptance.

Timepoint

Measurement of Pain Acceptance at the Beginning of the Study (before the Intervention), after the Intervention, and Three Months after the Intervention (Follow-up)

Method of measurement

The Chronic Pain Acceptance Questionnaire (CPAQ)

2

Description

Pain intensity: It reflects the subjective experience of pain in patients with chronic pain. This variable is assessed using a numerical rating scale from 0 (no pain) to 10 (worst possible pain). Patients are asked to rate their average daily pain over the past week. A decrease in the score indicates an improvement in the patient's pain status.

Timepoint

Measurement of Pain Intensity at the Beginning of the Study (before the Intervention), after the Intervention, and Three Months after the Intervention (Follow-up)

Method of measurement

Pain Intensity Scale (PIS)

Secondary outcomes

1

Description

Pain catastrophizing: Pain catastrophizing refers to a person's negative and exaggerated cognitive pattern about pain; in such a way that the patient experiences pain as more threatening, unbearable, and severe than it actually is. This variable usually includes components such as rumination, magnification, and helplessness. A decrease in the score of this questionnaire after intervention indicates a decrease in negative thoughts related to pain. This variable is considered one of the important cognitive-emotional outcomes in chronic pain.

Timepoint

Measurement of Pain Catastrophizing at the Beginning of the Study (before the Intervention), after the Intervention, and Three Months after the Intervention (Follow-up)

Method of measurement

Pain Catastrophizing Scale (PCS)

2

Description

Patient health includes anxiety, depression, and somatization. Anxiety: Anxiety is a dimension of mental health that may increase in patients with chronic pain due to persistent pain, functional limitations, and concerns about the future. This variable is measured through the anxiety subscale in the patient health questionnaire. A decrease in anxiety score after intervention indicates an improvement in the patient's emotional state and a decrease in psychological stress. Depression: Depression indicates a decrease in mood, hopelessness, apathy, and decreased enjoyment of life, which are common in patients with chronic pain. This variable is assessed through the depression subscale in the patient health questionnaire. Changes in this score before and after the intervention indicate the extent to which the treatment has been able to affect the emotional and mood aspects of the patients. A decrease in the depression score is a sign of improved mental health. Somatization: Somatization is the tendency of an individual to experience and express psychological distress in the form of physical symptoms. In chronic pain patients, this phenomenon can lead to increased pain perception and frequent referrals to medical services. This variable is measured by the somatization subscale in the Patient Health Questionnaire. A decrease in its score after the intervention can indicate a decrease in the patient's focus on physical symptoms and improved emotional regulation.

Timepoint

Measurement of Patient Health at the Beginning of the Study (before the Intervention), after the Intervention, and Three Months after the Intervention (Follow-up)

Method of measurement

Patient Health Questionnaire (PHQ)

3

Description

Satisfaction with life: One of the important indicators of quality of life is subjective and shows the degree to which a person's overall assessment of their circumstances and life is higher. This variable reflects more the cognitive-value aspect of quality of life. The change in this score after intervention can indicate to what extent the treatment has affected the person's overall outlook on life and their satisfaction with their current circumstances. A higher score usually indicates greater satisfaction with life.

Timepoint

Measurement of Satisfaction With Life at the Beginning of the Study (before the Intervention), after the Intervention, and Three Months after the Intervention (Follow-up)

Method of measurement

Satisfaction With Life Scale (SWLS)

Intervention groups

1

Description

Intervention Group 1: Direct Transcranial Electrical Stimulation Treatment; 2 Electrodes with a Positive and a Negative Pole through a Sponge Pad Moistened with a Conductive Solution are Placed on the Head. The Positive Electrode (Anode) is Placed on the Primary Motor Cortex (M1) and the Negative Electrode (Cathode) is Placed on the Contralateral Supraorbital Area (DLPFC). A Weak Current of 2 mA is Applied to the Head for 20 Minutes. This Treatment will be Performed for 8 Sessions (one Session per Day) for each Individual.

Category

Treatment - Devices

2

Description

Intervention Group 2 : Web-based Acceptance and Commitment Therapy ; This Therapy will be Carried out in 8 One-Hour Sessions (Two Sessions per Week) in the Skyroom Platform According to the Acceptance and Commitment Psychological Therapy Protocol. Session content: First session - Introduction and basic concepts of treatment (basic rules, introductions, reason for attendance, overview of treatment and main goals, review of basic concepts, homework) Second session - Options for learning to live despite pain (mindfulness, review of homework, relationships between mood and pain and function, conclusion of the session) Third session - Learning to live with chronic pain (mindfulness, review of homework, acceptance of chronic pain, values, mindfulness, today's treatment results) Session Four - Values and Actions (Mindfulness, Review of Homework, Discussion of Values, Obstacles to Values, Goals and Action, Conclusion) Session Five - Action (Mindfulness, Review of Homework, Planning and Action, Mindfulness and Self-Observation, Committed Action, Conclusions of the Session) Session Six - Commitment (Mindfulness Practice, Review of Homework and Previous Practice Materials, Willingness, Commitment to Actions and Values Despite Obstacles, Conclusions of the Session) Session Seven - Review and Practice (Mindfulness Practice, Review of Previous Practice Materials, Homework) Session Eight - Maintaining Treatment Gains for the Rest of Your Life (Mindfulness, Commitment, Preventing Relapse and Retreat, Saying Goodbye to the Therapist, Assignments)

Category

Treatment - Other

3

Description

Control Group : This Group did not Receive any of the Treatments in the first and second Groups and Simply continued their Routine Treatments.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Dr Shila haghighat

Street address
Isfahan, Soffeh Blvd. - Al-Zahra Educational and Medical Center

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3822 0000

Email
Shila_haghighat@med.mui.ac.ir

Web page address
https://alzahra.mui.ac.ir/fa

2

Recruitment center

Name of recruitment center
Khorshid medical educational research complex

Full name of responsible person
Dr Razieh maghroori

Street address
Isfahan, Ostandari Street - Khorshid Educational, Medical and Research Complex

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Phone
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Web page address
https://nour.mui.ac.ir/fa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr Gholamreza asgari

Street address
Vice-Department of Research and Technology ، Building No. 4 ، Isfahan University of Medical Sciences and Health Services ، Hezar Jerib Street ، Isfahan

City

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Province
Isfehan

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Web page address
https://research.mui.ac.ir/fa/moaven/moarefi

Grant name
گرنت هیئت علمی

Grant code / Reference number
1234

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Shahrzad khoushghamat aziz

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Unit 3 ،No. 2 ،Seventh Alley ،Nemati St ،Dolat St. (Martyr Kolahduz) ،Qolhak

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Province
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Email
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Amrollah ebrahimi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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Position
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Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Postal code
1939734654

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Email
sh_khoushghamat@resident.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The raw data for this study consists of information collected from participants after they completed the treatment process. This data is shareable after removing directly identifiable information (such as name and contact information). The final dataset will include the following variables: Demographic information: age, gender, education level, marital status. Primary outcome variables: pain intensity at different time points (pre-intervention, post-intervention, and follow-up). Secondary outcome variables: scores on the Pain Acceptance Questionnaire (CPAQ), Pain Catastrophizing Questionnaire (PCS), Patient Health Questionnaire (PHQ for anxiety, depression, somatization), and Satisfaction with Life [SWLS Questionnaire] at the same time points. Treatment group information: tDCS or iACT group allocation. Relevant clinical information: duration of chronic pain, history of previous treatments. The purpose of sharing these data is to enable peer review of the results by other researchers, replication of similar studies, and secondary analyses to discover new associations. The final decision to share all or parts of the data (such as only the primary outcome) will be made after further review, with full respect for ethical principles and individual privacy.

When the data will become available and for how long

The data from this study will be made available after the statistical analysis process is completed and the results of the study are formally published in a reputable scientific journal or presented at relevant congresses. The start date of data access will be six (6) months after the date of publication of the first scientific article based on the results of this clinical trial. The data access period will continue for five (5) years after the said start date. This period of time will allow researchers sufficient time to request access, review the data, and conduct secondary analyses.

To whom data/document is available

Data and documentation from this study will be made available only to qualified researchers, particularly those working in academic institutions, research centers, or scientific centers. Applicants must provide a clear research objective, a valid research design, and a commitment to ethical principles, confidentiality, and anonymity of participants. Access for non-academic/industrial individuals or institutions is also possible only if their request is scientifically and ethically justified and accompanied by the consent of the study director/principal investigator. Public and open access to raw participant data will not be provided.

Under which criteria data/document could be used

The data and documentation from this study may be used for non-commercial research and scientific purposes only. These purposes include: Confirming and reviewing the results of the current study: Using the data to validate published findings and ensure their accuracy. Conducting secondary analyses: Examining the data to discover new patterns, relationships, or findings that are not directly related to the original research questions but that contribute to scientific knowledge about chronic pain, the effectiveness of treatments, or related factors. Development of new analytical methods: Use of data to test and validate new algorithms or statistical methods. Education and learning: Use of data in educational settings (such as workshops or specialized courses) to train students and researchers in clinical data analysis. Restrictions on use: No commercial use: Any direct or indirect commercial use of the data, such as for the development of products or services, is prohibited. No redistribution of raw data: Raw data (even after de-identification) should not be published in whole or in part in public data repositories or other publications without express permission from the research team. Privacy: The researcher undertakes to make reasonable efforts to prevent re-identification of individuals, even if the data are presented in a non-identifiable form. Attribution: In any report, article, or presentation using these data, the original source of the study (the IRCT clinical trial with the study ID) and the research team must be fully cited. Submission of secondary analysis results: The results of secondary analyses that lead to significant scientific findings must be submitted to the study's scientific team for initial review. Requirements for submitting an access request: Applicants must submit the following with their application: 1- Completed access request form: A form that includes full contact information, institutional affiliation, and details of the research proposal. 2- Submit a research proposal: A proposal that clearly describes the research objectives, research questions, intended methodology (including the type of statistical analyses), and how the data will be used. The proposal should demonstrate a direct connection to the study data. 3- Submit a scientific resume 4- Non-Disclosure and Ethical Use Agreement (NDA): Sign a non-disclosure agreement in which the applicant agrees to the terms of use, maintaining data confidentiality, not republishing raw data, and using it solely for research purposes.

From where data/document is obtainable

Visit the official website of the Iranian Clinical Trial Registration System (IRCT): Website: www.irct.ir In this system, you can find details about registered studies, including this study. Contact the study data coordinator: Name of the coordinator: Shahrzad Khoushghamat Aziz Position: Study Project Manager Email: shahrzad.kht20@yahoo.com or sh_khoushghamat@resident.mui.ac.ir Telephone: 22000184_021 or 09129341123 Response hours: Saturday to Wednesday, 8 am to 4 pm Important notes for applicants: Initial referral: First follow up on your request via the IRCT website and then via email. Also, when calling or sending an email, be sure to mention the relevant study ID (IRCT ID). And provide your full information, institutional affiliation, and a brief summary of your research proposal so that your request can be properly referred. Please note that reviewing requests

and coordinating data sharing may take time. After submitting your request, be patient and follow up again by email or phone if you do not receive a response within a reasonable period of time (e.g., two business weeks).

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

The approximate duration of this process varies depending on the complexity of the request and the workload of the review team, usually between 2 and 6 weeks. Process of reviewing and granting access to data/documents: Submission of initial request: The applicant, by referring to the introduced resources (IRCT website, data coordinator email, or postal address), completes the access request form and submits it together with the research proposal, curriculum vitae (CV), and other required documents (such as research ethics approval if necessary). Duration: Immediately after submission by the applicant. Registration and initial review of the application: The submitted documents are initially reviewed for completeness and compliance with the required formats. If any documents are incomplete, the applicant will be notified and given the opportunity to complete the documents. Duration: 1 to 3 working days. Technical and scientific review of the proposal: In this stage, the research objectives, methodology, direct connection of the research to existing data, and the suitability of the application with data sharing policies are evaluated. Duration: 1 to 2 working weeks. Review of Non-Disclosure Agreement (NDA): This agreement is required by the applicant. Duration: 1-2 business days Final decision: Duration: 1-3 business days. Notification of result to the applicant: The applicant will be informed of the result of the review (approval or rejection of the application) along with the necessary explanations (in case of rejection). Duration: 1-2 business days. Preparation and submission of data/documentation: If the application is approved, the desired data and documentation will be prepared. This step may include processes to de-identify the data. Duration: 1-2 business weeks (depending on the volume and complexity of the preparation). Completion of the process: After receiving the data, the applicant must send an acknowledgement of receipt to the study team.

Comments