

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparing the effectiveness of cognitive-behavioral therapy and transcranial direct current stimulation(tDCS) in reducing symptoms and improving the executive functions of students with Internet addiction

Protocol summary

Study aim

Determining the effectiveness of cognitive-behavioral therapy specific to Internet addiction and transcranial direct current stimulation (tDCS) in reducing symptoms and improving executive functions of students with Internet addiction.

Design

The clinical trial will have a control group, a sham group in parallel, randomized, on 40 people. For randomization, the computer program will be used.

Settings and conduct

Students who are addicted to the Internet and who refer to Shahid Beheshti Hospital in Zanjan during the study will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups. This study will be conducted in a double-blind manner.

Participants/Inclusion and exclusion criteria

The inclusion criteria: informed consent and voluntarily participating; age at least 18 and at maximum 38 years old; diagnosed case for internet addiction. The exclusion criteria: depression, schizophrenia, other psychotic disorders, obsessive-compulsive disorder, bipolar disorder, anxiety disorders, etc.; receiving psychiatric drugs; receiving psychological treatments.

Intervention groups

Intervention group 1: cognitive behavioral therapy will be performed based on the treatment protocol, cognitive-behavioral therapy specific to Internet addiction, recognizing dysfunctional feelings and actions, social and behavioral defects, motivation, and creating behaviors replaces Intervention group 2:tDCS, this device is a brand name Activadose, which is manufactured in Canada. Intervention group 3: sham for tdcS, same as group 2 but without brain stimulation Intervention group 4: while no intervention is performed on the research community.

Main outcome variables

Internet addiction; Executive functions; Cognitive abilities ; Excitement regulation ; Impulsiveness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221214056816N2**

Registration date: **2023-10-25, 1402/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-25, 1402/08/03**

Update count: **0**

Registration date

2023-10-25, 1402/08/03

Registrant information

Name

zakaria eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of cognitive-behavioral therapy and transcranial direct current stimulation(tDCS) in reducing symptoms and improving the executive functions of students with Internet addiction

Public title

Investigating cognitive-behavioral therapy and direct current brain stimulation (tDCS) in Internet addiction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent and voluntary participation in internet addiction treatment sessions Being at least 18 and at most 38 years old Being a student Being diagnosed with internet addiction

Exclusion criteria:

Having other psychiatric disorders such as depression, schizophrenia, other psychotic disorders, obsessive disorders, bipolar disorder, anxiety disorders, etc. Receiving psychiatric drugs Receiving psychological treatments

Age

From **18 years** old to **38 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The initial samples will be available as sampling, and then according to the screening tools, those who have been diagnosed with Internet addiction will be selected through simple randomization using computer programs from the table of random numbers to be assigned to sham and treatment groups. became. In this method, all members of the community have an equal chance to be elected. To use the table of random numbers, the researcher first defines the framework of his statistical society; and gives them a code or machine gun number respectively so that the samples can be selected.

Blinding (investigator's opinion)

Not 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 Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, SHahrak town, Mahdavi Blvd.,

City

zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.ZUMS.REC.1401.390

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

Internet addiction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Young's Internet Addiction Questionnaire score

Timepoint

Pre-test, before the intervention - post-test, 1 week after the intervention - follow-up, 3 months after the intervention

Method of measurement

Young Internet Addiction Questionnaire

2**Description**

Nejati Cognitive Abilities Questionnaire score

Timepoint

Pre-test, before the intervention - post-test, 1 week after the intervention - follow-up, 3 months after the intervention

Method of measurement

Nejati Cognitive Abilities Questionnaire

3**Description**

Gertz and Roemer's Emotion Regulation Difficulty Questionnaire score

Timepoint
Pre-test, before the intervention - post-test, 1 week after the intervention - follow-up, 3 months after the intervention

Method of measurement
Roemer's Emotion Regulation Difficulty Questionnaire

4

Description
Bart's Impulsivity Questionnaire score

Timepoint
Pre-test, before the intervention - post-test, 1 week after the intervention - follow-up, 3 months after the intervention

Method of measurement
Barrett's Impulsivity Test

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: cognitive-behavioral therapy specific to Internet addiction, deals with recognizing dysfunctional feelings and actions, social and behavioral defects, motivation, and creating alternative behaviors, which includes twelve weekly sessions and a six-month follow-up.

Category
Treatment - Other

2

Description
The second intervention group: transcranial direct current stimulation by the Actiodose device made in Canada, which is a non-invasive, painless and tolerable brain stimulation technique that is able to change the activation of the cerebral cortex and a weak direct current through surface electrodes on the scalp. It applies this weak and direct current through the connection of two electrodes, anode and cathode, at different points on the surface of the skull, leading to an increase and decrease in the stimulation of the underlying neurons. This treatment will be 12 sessions of 20 minutes.

Category
Treatment - Devices

3

Description
Sham group: Electrodes will be placed on their skulls, but no brain stimulation will take place. This treatment will be 12 sessions of 20 minutes by tDCS actiodose device made in Canada.

Category
Placebo

4

Description
Control group: No treatment is performed and only evaluations are performed

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Specialized Medical Training Center

Full name of responsible person
Zakaria Eskandari, Zanzan University of Medical Sciences, Zanzan University

Street address
Shahid Beheshti Specialized and Subspecialized Medical Training Center, Above Arg Square ,Zanzan

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beheshti @zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanzan University of Medical Sciences

Full name of responsible person
Dr. Samad Nedri

Street address
Zanzan University of Medical Sciences, Dr. Youssef Soubouti Blvd., Zanzan

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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

Zanjan 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

Addiction studies department, Beheshti Hospital,

Zanjan University of Medical Science, Znan

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Fax**Email**

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Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Mehdi khani

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Contact**Name of organization / entity**

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Full name of responsible person

Mehdi khani

Position

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Master

Other areas of specialty/work

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Sharing plan**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Zakaria Eskandari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

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