# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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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+98 24 3315 6444
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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, Zanjan University of Medical Sciences, Zanjan University

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Shahid Beheshti Specialized and Subspecialized Medical Training Center, Above Arg Square ,Zanjan

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Samad Nedri

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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

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Zanjan University of Medical Sciences
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Student
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## Person responsible for updating data

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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**
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