

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of cognitive behavioral therapy in reducing internet addiction, sleep quality, and mental health among students of Islamic Azad University of Ahvaz Branch.

Protocol summary

Study aim

Determining the effectiveness of cognitive behavioral therapy in reducing internet addiction, sleep quality, and mental health

Design

This study is designed as a randomized clinical trial with two parallel groups (15 participants). The experimental group will receive a structured CBT intervention, the control group will receive no intervention. Participant allocation will be done by block randomization (block size 4) and through sealed envelopes.

Settings and conduct

This study is a clinical trial conducted on students of Ahvaz Azad University. The samples are randomly divided into two intervention groups (receiving CBT) and control, and data are collected with standard questionnaires. The outcome assessor is blinded to the grouping of the samples to avoid bias.

Participants/Inclusion and exclusion criteria

Entry requirements: Be Iranian and resident of Ahvaz city, be a student, have a smartphone, have at least one year of creating an account on social networks such as Instagram, etc., age 18 to 25 years. Exclusion criteria: Be under psychiatric treatment due to mental health problems, be addicted to drugs, psychotropic drugs, alcohol, or abuse medication.

Intervention groups

Intervention group (experiment): This group will receive a cognitive-behavioral therapy (CBT) intervention protocol specifically designed to reduce Internet addiction. The intervention will consist of structured sessions (e.g., 8 to 10 weekly 90-minute sessions) that cover topics such as time management, identifying cognitive distortions, improving communication skills, and emotion regulation. Control group: This group will not receive any active intervention during the study period.

Main outcome variables

Internet addiction, sleep quality, mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250611066182N1**

Registration date: **2025-09-05, 1404/06/14**

Registration timing: **prospective**

Last update: **2025-09-05, 1404/06/14**

Update count: **0**

Registration date

2025-09-05, 1404/06/14

Registrant information

Name

Nahid Saeedinasb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4352 1611

Email address

nahid.saeedinasb@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-21, 1404/06/30

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of cognitive behavioral therapy in reducing internet addiction, sleep quality, and mental health among students of Islamic Azad University of Ahvaz Branch.

Public title
Cognitive behavioral therapy in reducing internet addiction, sleep quality, and mental health

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Be Iranian and a resident of Ahvaz city
Be a student
Have a smartphone
Have at least one year of creating an account on social networks such as Instagram, etc.
Be between 18 and 25 years of age.
Exclusion criteria:
Addiction to narcotics, psychotropic substances, alcohol, or medication abuse
Are under psychiatric treatment due to mental health problems

Age
From **18 years** old to **25 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
This study used a block randomization method with a block size of 4. The sequence of group allocation (experimental/control) was generated using Excel software and protected in sealed envelopes. After screening and obtaining consent, participants were assigned to groups based on the order of arrival and opening of the envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, due to the non-blinded nature of the intervention (cognitive-behavioral therapy), only the Outcome Assessor and Data Analyst will be blinded. After random assignment of participants to the experimental and control groups, the assessor, who is responsible for collecting post-test and follow-up data, will not be aware of the purpose of the study and the type of group assignment of the participants. The data will be provided to him/her in coded form (without group identifiers). Also, the data analyst will perform statistical analysis without knowing the grouping of the samples to avoid any bias.

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University of Ahvaz
Street address
Islamic Azad University, Ahvaz Branch, Farhang Shahr, Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
3733361349

Approval date
2025-06-07, 1404/03/17

Ethics committee reference number
IR.IAU.AHVAZ.REC.1404.165

Health conditions studied

1

Description of health condition studied
Internet addiction

ICD-10 code
F51.9

ICD-10 code description
Sleep disorder not due to a substance or known physiological condition, unspecified

Primary outcomes

1

Description
Internet addiction

Timepoint
Pretest (before the intervention), posttest (immediately after the intervention), and follow-up (at least 2 months after the intervention).

Method of measurement
Young's Internet Addiction Questionnaire

Secondary outcomes

1

Description
Sleep quality

Timepoint

Pre-test (before the intervention), post-test (immediately after the completion of the 8-week intervention), and follow-up (2 months after the completion of the intervention).

Method of measurement

Pittsburgh Standardized Sleep Quality Questionnaire

2

Description

Mental health

Timepoint

Pre-test (before the intervention), post-test (immediately after the completion of the 8-week intervention), and follow-up (2 months after the completion of the intervention).

Method of measurement

Standardized General Health Questionnaire

Intervention groups

1

Description

Intervention group: 15 eligible students will receive a structured cognitive-behavioral therapy (CBT) protocol. The intervention will consist of 8 90-minute sessions (one session per week) with educational content and practical exercises to manage internet addiction, improve sleep quality, and improve mental health.

Category

N/A

2

Description

Control group: Fifteen eligible students who do not receive any active intervention and will only be assessed at pre-test, post-test, and follow-up will be included. In order to comply with ethical considerations, if the intervention is effective, similar training will be provided to this group after the study is completed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Ahvaz Branch

Full name of responsible person

Narges Heydarianfar

Street address

Islamic Azad University, Ahvaz Branch, Farhang Shahr, Golestan Highway

City

Ahvaz

Province

Khuzestan

Postal code

3733361349

Phone

+98 61 3334 8421

Email

info@iauahvaz.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Pejman Taghipour Birgani

Street address

Islamic Azad University, Ahvaz Branch, Farhang Shahr, Golestan Highway

City

Ahvaz

Province

Khuzestan

Postal code

3733361349

Phone

+98 61 3334 8421

Email

info@iauahvaz.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Narges Heydarianfar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Islamic Azad University, Ahvaz Branch, Farhang
Shahr, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

3733361349

Phone

+98 61 3334 8421

Email

info@iauahvaz.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Narges Heydarianfar

Position

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Latest degree

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Phone

+98 61 3334 8421

Email

info@iauahvaz.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nahid Saeedinasb

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

No. 17, Second North Alley, West Mehdi Street, Chevli
Street

City

Izeh

Province

Khouzestan

Postal code

3733361349

Phone

+98 61 4352 1611

Fax

Email

info@iauahvaz.ac.ir

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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable