Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Development and Validation of an Artificial Intelligence-Assisted Cognitive Therapy Package for Enhancing Prefrontal Cortex Functions and Evaluating Its Effectiveness on Executive Functions and Academic Self-Regulation in Adolescents with Internet Addiction

Protocol summary

Study aim

Assess a supervised AI-supported cognitive therapy package targeting prefrontal cortex functions for effects on cognitive control, flexibility, impulsivity, reward processing, moral intelligence, and academic self-regulation in male adolescents scoring ≥50 on Young's Internet Addiction Test; assess at baseline, post-intervention, and two-month follow-up.

Design

Open-label, two-arm parallel randomized controlled trial; 50 participants, 25/group. Individual allocation is 1:1 using variable block sizes of 4 and 6. Sealed Envelope generates the sequence; sequentially numbered, opaque, sealed envelopes conceal allocation. Phase: not applicable.

Settings and conduct

The study involves male students at Shahid Asadi Shahed Upper Secondary School, Azarshahr. The researcher delivers 12 weekly 90-min online group sessions via Shad; parents/guardians receive a 30–45-min orientation. Controls receive usual school services. Participants and researcher are not blinded.

Participants/Inclusion and exclusion criteria

Fifty male students aged 15–18 at Shahid Asadi Shahed Upper Secondary School, Azarshahr, with an Internet Addiction Test score ≥50, adolescent assent, and parent/guardian consent. Severe psychiatric disorder or medication likely to affect outcomes, if identified before allocation, excludes participation.

Intervention groups

Intervention: Twelve weekly 90-minute group cognitive therapy sessions targeting prefrontal cortex functions, with supervised AI support; plus a 30–45-minute parent/guardian orientation. Control: Usual school educational and counseling services plus a waitlist; the package is offered after two-month follow-up.

Main outcome variables

Impulsivity; Reward Responsiveness; Cognitive Control; Cognitive Flexibility; Moral Intelligence; Academic Self-Regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200111046085N1**
Registration date: **2026-11-05, 1405/08/14**
Registration timing: **prospective**

Last update: **2026-11-05, 1405/08/14**
Update count: **0**

Registration date

2026-11-05, 1405/08/14

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-07, 1405/08/16

Expected recruitment end date
2027-01-09, 1405/10/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Development and Validation of an Artificial Intelligence-Assisted Cognitive Therapy Package for Enhancing Prefrontal Cortex Functions and Evaluating Its Effectiveness on Executive Functions and Academic Self-Regulation in Adolescents with Internet Addiction

Public title
Comparison of the Effectiveness of a Cognitive Therapy Package Targeting Prefrontal Cortex Functions Versus a Control Group on Executive Functions and Academic Self-Regulation in Adolescents with Internet Addiction
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Enrollment in Shahid Asadi Shahed Upper Secondary School in Azarshahr. Age between 15 and 18 years. Male sex. A score of 50 or higher on Young's Internet Addiction Test (IAT), used as the operational screening and study-entry criterion. Provision of written informed assent by the adolescent to participate in the study. Provision of written informed consent by the parent or legal guardian.
Exclusion criteria:
A severe psychiatric disorder at the time of screening, based on treatment records or a psychiatrist's diagnosis. Current use of psychiatric medication that, in the judgment of the relevant specialist and the researcher, is likely to substantially affect the study outcomes.
Age
From **15 years** old to **18 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **1**
Each participant contributes one study unit. Outcome data are collected from the same participant at three time points: baseline (pre-intervention), post-intervention, and two-month follow-up. These repeated measurements do not constitute separate samples.
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to the study groups using block randomization with variable block sizes. The unit of randomization will be the individual participant. After screening, verification of eligibility criteria, obtaining written informed consent from a parent or legal guardian and informed assent from the adolescent, and completion of baseline assessments, eligible participants will be allocated in a 1:1 ratio to the intervention and control groups. The target sample size is 50 participants, with 25 participants in each group. The random allocation sequence will be generated using the online Sealed Envelope tool, with variable block sizes of 4 and 6 participants. Before allocation begins, the generated sequence will be checked to ensure that the final list contains 50 allocations, with exactly 25 assignments to each group. If necessary, a new sequence will be generated using the same settings and a new random seed and will be checked again. The final random seed, output file, and date of sequence generation will be documented and retained. Stratified randomization will not be used. To ensure allocation concealment, the complete allocation sequence and assignment order will be held by a person independent of participant screening and enrollment. Preferably, each allocation will be placed in an opaque, sealed, sequentially numbered envelope. The envelope for each participant will be opened only after final eligibility has been confirmed, informed consent and assent have been obtained, and baseline assessments have been completed. This procedure is intended to prevent knowledge of the anticipated group assignment from influencing participant selection and enrollment.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This clinical trial represents the quantitative effectiveness-evaluation phase of a multistage study aimed at developing, validating, and evaluating a cognitive therapy package. Following package development and content validation by experts, the effectiveness of the finalized intervention will be assessed in a two-arm parallel-group randomized controlled trial. Outcomes will be assessed at three time points: baseline, post-intervention, and two-month follow-up. The intervention comprises 12 weekly group sessions, each lasting 90 minutes, preceded by a separate 30–45-minute orientation session for a parent or legal guardian. Artificial intelligence will be used solely as a supervised support tool for predefined exercises and homework tasks. It will not replace the therapist or function as an independent clinical decision-maker. The control group will continue to receive usual educational, behavioral, and counseling services at school, and the cognitive therapy package will be offered to the control group after completion of follow-up, in accordance with the study protocol.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Urmia University

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Approval date
2026-09-08, 1405/06/17

Ethics committee reference number
IR.URMIA.REC.1405.013

Health conditions studied

1

Description of health condition studied
Internet Addiction (Problematic Internet Use, defined as a score of 50 or higher on Young's Internet Addiction Test [IAT])

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Change in Total Impulsivity Score. The effect of the intervention on adolescents' impulsivity will be evaluated by examining changes in the total impulsivity score from baseline to post-intervention and follow-up. Higher scores indicate greater impulsivity.

Timepoint
1. Baseline, before the intervention begins; 2. immediately after completion of the twelve-session intervention; 3. two months after completion of the intervention.

Method of measurement
Using the total score of the Barratt Impulsiveness Scale, Eleventh Version, a thirty-item instrument. The total score ranges from 30 to 120, with higher scores indicating greater impulsivity.

2

Description
Change in Reward Responsiveness Score, as the operational measure of reward processing. The intervention effect will be evaluated by examining changes in reward responsiveness across the three assessment time points. Higher scores indicate greater responsiveness to rewarding stimuli.

Timepoint
1. Baseline, before the intervention begins; 2. immediately after completion of the twelve-session intervention; 3. two months after completion of the intervention.

Method of measurement
Using the score of the five-item Reward Responsiveness subscale of the Behavioral Inhibition System and Behavioral Activation System Scales. The subscale score ranges from 5 to 20, with higher scores indicating greater responsiveness to rewarding stimuli.

3

Description
Change in Total Cognitive Control Score. The effect of the intervention on adolescents' cognitive control will be evaluated by examining changes in the total effortful control score, used as the operational measure of cognitive control, from baseline to post-intervention and follow-up. Higher scores indicate greater effortful control and cognitive control.

Timepoint
1. Baseline, before the intervention begins; 2. immediately after completion of the twelve-session intervention; 3. two months after completion of the intervention.

Method of measurement
Using the total score of the Effortful Control Scale derived from the revised Early Adolescent Temperament Questionnaire. The scale contains twenty items, with a total score range of 20 to 100. Higher scores indicate greater effortful control.

4

Description
Change in Total Cognitive Flexibility Score. The effect of the intervention on adolescents' cognitive flexibility will be evaluated by examining changes in the total cognitive flexibility score from baseline to post-intervention and follow-up. Higher scores indicate greater cognitive flexibility.

Timepoint
1. Baseline, before the intervention begins; 2. immediately after completion of the twelve-session intervention; 3. two months after completion of the intervention.

Method of measurement
Using the total score of the Cognitive Flexibility Inventory developed by Dennis and Vander Wal. The instrument contains twenty items rated on a seven-point response scale, with a total score range of 20 to 140. Higher scores indicate greater cognitive flexibility.

5

Description
Change in Total Moral Intelligence Score. The effect of the intervention on adolescents' moral intelligence will be evaluated by examining changes in the total moral intelligence score from baseline to post-intervention and follow-up. Higher scores indicate higher moral intelligence.

Timepoint

1. Baseline, before the intervention begins; 2. immediately after completion of the twelve-session intervention; 3. two months after completion of the intervention.

Method of measurement

Using the total score of the Moral Intelligence Adolescents Scale, a seventy-one-item instrument rated on a five-point response scale. The total score ranges from 71 to 355, with higher scores indicating higher moral intelligence.

6

Description

Change in Total Academic Self-Regulation Score. The effect of the intervention on adolescents' academic self-regulation will be evaluated by examining changes in the total academic self-regulation score from baseline to post-intervention and follow-up. Higher scores indicate higher academic self-regulation.

Timepoint

1. Baseline, before the intervention begins; 2. immediately after completion of the twelve-session intervention; 3. two months after completion of the intervention.

Method of measurement

Using the total score of the fourteen-item Academic Self-Regulation Questionnaire developed by Bouffard and colleagues. The instrument assesses cognitive and metacognitive strategies. The total score ranges from 14 to 70, with higher scores indicating higher academic self-regulation.

Secondary outcomes

1

Description

Frequency and Types of Adverse Events During the Study: Participant safety will be assessed by recording the number and types of adverse events experienced or reported during the study, regardless of whether a causal relationship with the intervention is established. Events of interest include increased psychological distress, worsening conflict between the adolescent and a parent or guardian, unintended disclosure of private information, receipt of inappropriate or misleading content from the artificial intelligence system, and technical or safety incidents that interfere with the safe delivery of the intervention. The timing, type, severity or observable consequences of each event, actions taken, and outcome of any human referral will be documented. This outcome will be reported descriptively.

Timepoint

Monitoring throughout the intervention sessions, with each adverse event recorded when observed or reported during the participant's involvement in the study.

Method of measurement

Using a researcher-developed Adverse Event Monitoring and Reporting Form documenting the timing and type of each event, its severity or observable consequences, initial actions taken, decisions regarding temporary interruption or continuation of the intervention, and the outcome of any human referral.

Intervention groups

1

Description

Intervention group: Intervention Group: Artificial Intelligence-Assisted Cognitive Therapy Targeting Prefrontal Cortex Functions Participants in this group will receive the developed and validated cognitive therapy package assisted by artificial intelligence in 12 group sessions. The intervention is designed to enhance cognitive and executive processes and improve academic self-regulation. Artificial intelligence will be used only as a supervised support tool for pre-approved activities and exercises and will not replace the therapist.

Category

Behavior

2

Description

Control group: Control Group: Usual School Educational Activities Participants in this group will not receive the study cognitive therapy package during the intervention period and will continue their usual school educational activities. After completion of the study and data collection, the educational materials or cognitive therapy package may also be made available to them, subject to their interest and coordination with school authorities.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Hossein Asadi Shahed Upper Secondary School

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
PhD Dissertation Research Allowance

Grant code / Reference number
34044

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

Title of funding source
Urmia University

Proportion provided by this source
3

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

2

Sponsor

Name of organization / entity
Iran National Science Foundation (INSF)

Full name of responsible person
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Grant name
First Comprehensive Call for Humanities, Social Sciences, and the Arts / Social Harms + Social Harms / Addiction + Social Harms / Violence and Aggression + Psychosocial Issues / Globalization and Globalization Processes + Psychosocial Issues / Media + Psychosocial Issues / Ethics + Psychosocial Issues / Identity + Cognitive Topics / Cognitive Processes + Emerging Technologies and Psychology / Cyberspace + Emerging Technologies and Psychology / Psychological Tools

Grant code / Reference number
40508820

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

Title of funding source
Iran National Science Foundation (INSF)

Proportion provided by this source
97

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
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Latest degree
Master

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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
Controlled Access to De-identified Individual Participant Data and Supporting Study Documents The study data and documentation may be shared upon an approved request. The materials may include the de-identified individual participant dataset, covering the study variables and assessment time points; the study protocol; the statistical analysis plan; blank informed consent and adolescent assent forms; the final clinical study report; the data dictionary; and analysis code or syntax, where available. Direct personal identifiers will not be shared. Before any data are transferred, indirect identifiers and the risk of re-identification will be assessed. Sensitive free-text information, private communications, and other information that could reasonably identify participants will be excluded or appropriately protected. Materials will be provided through controlled access rather than unrestricted public release.

When the data will become available and for how long
Access will begin 12 months after completion of the study or after publication of the primary study results, whichever occurs later, and will remain available for five years. Access will be granted on a request-by-request basis, subject to eligibility review, applicable ethical approvals, and the conditions described in this data-sharing plan. No unrestricted public download will be provided.

To whom data/document is available
Qualified researchers affiliated with recognized universities or research institutions, as well as competent ethics committees, regulatory authorities, or other legally authorized bodies acting within their official responsibilities, may submit a request. Applicants must demonstrate an appropriate institutional affiliation, professional competence, and a legitimate research, ethical oversight, or regulatory purpose. Access is not automatic and is subject to review and approval.

Under which criteria data/document could be used

Data and documents may be used for legitimate scientific research, verification of reported findings, evidence synthesis, meta-analysis, and other secondary analyses consistent with the approved purpose and applicable ethical requirements. Each request must specify the research question, intended analyses, requested variables or documents, institutional affiliation, and data protection arrangements. Ethics committee approval or other authorization must be provided where required. Approved recipients must sign a data-use or data-sharing agreement, use the materials only for the approved purpose, protect them through appropriate security measures, refrain from attempting to identify or contact participants, and not transfer the materials to unauthorized third parties. Only the data and documents necessary and proportionate to the approved request will be released. Any sharing of individual participant data involving minors will additionally require confirmation that the proposed sharing is consistent with the applicable ethics approval and informed consent arrangements.

From where data/document is obtainable

Requests should be addressed to Mahdi Chitsaz, PhD Candidate, Faculty of Literature and Humanities, University of Urmia, Urmia, West Azerbaijan Province, Iran. Email: mahdi.chitsaz77@gmail.com Postal Address: University of Urmia, Nazlu Campus, 11th Km, Sero Road, Urmia, West Azerbaijan Province, Iran. Applicants should provide details of the requested dataset or documents, their institutional affiliation, contact information, and a brief description of the intended purpose of use. Requests will be reviewed by the dissertation supervisors and the doctoral candidate in accordance with applicable institutional and ethical requirements.

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

The applicant must submit a written request specifying the required data or documents, the research question, the planned analyses, the intended purpose, the applicant's institutional affiliation, and the relevant ethics approval or authorization, where applicable. The supervisors will assess the applicant's qualifications, the legitimacy of the scientific or official purpose, the appropriateness of the scope of the request, potential confidentiality risks, and the request's consistency with the study protocol, informed consent arrangements, ethics approvals, and relevant institutional requirements. A preliminary decision will normally be communicated to the applicant within 30 working days of receipt of a complete request. Additional time may be required if consultation with the relevant ethics committee or responsible institution is necessary. If the request is approved, the recipient must sign the applicable data-use or data-sharing agreement. The approved data or documents will normally be transferred securely within 15 working days after all required documentation and agreements have been completed. A request may be declined, restricted to a subset of the requested materials, or delayed until the relevant issues are resolved if the proposed access poses a risk to confidentiality or conflicts with applicable ethical, legal, or institutional requirements. The applicant will be informed of the decision and, where appropriate, the reasons for any restrictions.

Comments

This plan is based on controlled access and does not constitute a commitment to unrestricted public disclosure of information. The Principal Investigator is willing to review reasonable and well-justified requests from qualified applicants seeking access to the study data and documentation, in accordance with the conditions described above. No direct personal identifiers or information that could reasonably lead to the identification of participants will be disclosed. Protecting the privacy of adolescent participants is a priority. Individual participant data will be shared only if such sharing is permitted by the ethics approval, informed consent arrangements, and relevant institutional requirements. If additional ethical approval or amendments to the approved informed consent arrangements are required, the necessary authorization must be obtained before the data are provided. The scope of data sharing will be determined based on the approved request, the principle of data minimization, confidentiality safeguards, and applicable ethical and legal requirements.