Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The efficacy of cognitive-behavioral therapy for internet addiction with and without cognitive training on improving the cognitive functions of patients

Protocol summary

Study aim
Investigating the efficacy of CBT-IA treatment with and without cognitive training in improving cognitive functions in individuals with IGD

Design
The clinical trial have a control group, with parallel groups, double-blind, randomized, on 40 patients. Individuals will be divided into two groups using restricted randomization method with random allocation rule.

Settings and conduct
Once IGD is detected based on the IGDS-SF9 score and a clinical interview, individuals are asked to visit the medical centers of the University of Social Welfare and Rehabilitation Sciences in Tehran. Participants sign an informed consent form. All individuals will undergo pre and post-treatment evaluations.

Participants/Inclusion and exclusion criteria
Entry conditions: Age over 18, suffering from IGD disorder. Non-entry conditions: suffering from these disorders : organic brain disorders, psychotic disorders, obsessive-compulsive disorder, bipolar disorder, substance abuse and gambling disorder.

Intervention groups
Cognitive Behavioral Therapy for internet addiction : It consists of 12 weekly sessions. The initial focus is on behavioral techniques targeting specific behaviors and situations. In the second stage, the focus is more on cognitive assumptions and distortions, and its techniques include evaluating the type of cognitive distortions, problem solving skills, and teaching coping strategies. The final stage involves addressing underlying problems and comorbid disorders, if present. Additionally, cognitive training involves sessions of computerized behavioral interventions to improve cognitive functions related to addiction stimuli.

Main outcome variables
Reducing the severity of symptoms, maladaptive cognitions, cravings and attention bias and increasing inhibitory control in people with IGD

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180208038667N1**
Registration date: **2024-08-25, 1403/06/04**
Registration timing: **prospective**

Last update: **2024-08-25, 1403/06/04**
Update count: **0**

Registration date
2024-08-25, 1403/06/04

Registrant information

Name
Fahime Maleki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7708 2415

Email address
fa.maleki@uswr.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-06, 1403/07/15

Expected recruitment end date
2025-04-04, 1404/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The efficacy of cognitive-behavioral therapy for internet addiction with and without cognitive training on improving the cognitive functions of patients

Public title
Investigating the effect of cognitive behavioral therapy with and without cognitive training on patients with internet gaming disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being over 18 years old Suffering from internet gaming disorder
Exclusion criteria:
Suffering from an organic brain disorder Suffering from psychotic disorders Suffering from obsessive compulsive disorder Suffering from bipolar disorder Suffering from substance abuse disorder Suffering from Gambling disorder
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the classification of sample individuals into two treatment and control groups will be done using Restricted randomization method through random allocation rule in the following way: after selecting 40 sample , 20 balls will be assigned to the control group and 20 balls to the treatment group, these balls will be placed in a lottery box and then randomly, without replacement, balls will be removed from the box and the sequence will be recorded.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, all participants in the two treatment and control groups, the therapist who is responsible for pre-, during-, and post-treatment evaluations, and the data analyst are kept blind to the differences between the two treatment groups in terms of the type of interventions and which group each individual is assigned to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committee of University of Social Welfare and Rehabilitation Sciences
Street address
No. 19, West19th Ave., Tohid Blvd., Ghanat kosar
City
Tehran
Province
Tehran
Postal code
1653667638
Approval date
2021-08-25, 1400/06/03
Ethics committee reference number
IR.USWR.REC.1400.137

Health conditions studied

1

Description of health condition studied
Gaming disorder
ICD-10 code
6C51
ICD-10 code description
Gaming disorder

Primary outcomes

1

Description
Reducing the total score in the short form of the Internet Gaming Disorder Scale to a score lower than 36
Timepoint
Before the start of therapeutic interventions and after the end of therapeutic interventions
Method of measurement
Internet Gaming Disorder Scale Short-Form

2

Description
Reducing the score of maladaptive cognitions in the maladaptive gaming-related cognitions scale
Timepoint
Before starting therapeutic interventions and after the end of therapeutic interventions
Method of measurement

Maladaptive Gaming-Related Cognitions Scale

3

Description
Reduction in the score of craving for internet gaming scale
Timepoint
Before the start of therapeutic interventions and after the end of therapeutic interventions
Method of measurement
Craving for Internet Gaming Scale

4

Description
Improved performance in the Stroop task
Timepoint
Before the start of therapeutic interventions and after the end of therapeutic interventions
Method of measurement
Stroop task

5

Description
Improved performance in the GO\NOGO task
Timepoint
Before the start of therapeutic interventions and after the end of therapeutic interventions
Method of measurement
GO/NOGO task

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will undergo combined cognitive behavioral therapy for Internet addiction (CBT-IA) and cognitive training. CBT-IA treatment introduced by Young et al. (2011) includes elements of traditional Cognitive Behavioral Therapy (CBT) and internet-related interventions to address internet addiction. This treatment is conducted over 12 weekly sessions, consisting of three phases: 1) behavioral modification 2) cognitive restructuring 3) harm reduction. In addition, cognitive training such as GO/NOGO and approach/avoidance adapted for internet gaming disorder are provided in the first and second phase, where individuals are instructed and given therapeutic tasks to practice this computer-based tasks as part of the therapeutic assignments in addition to CBT-IA therapeutic tasks during the intervals between sessions.
Category
Treatment - Other

2

Description
Control group: This group will undergo Cognitive-Behavioral Therapy for Internet Addiction (CBT-IA) . CBT-IA, introduced by Young et al. (2011), encompasses classic Cognitive Behavioral Therapy (CBT) elements and internet-related interventions for treating internet addiction. This treatment consists of 12 weekly sessions and includes three phases: 1) Behavioral modification 2) Cognitive restructuring 3) Harm reduction.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
University of Social welfare and rehabilitation science
Full name of responsible person
Fahime Maleki
Street address
No. 19, West19th Ave., Tohid Blvd., Ghanat kosar
City
Tehran
Province
Tehran
Postal code
1653667638
Phone
+98 21 7726 5298
Email
fa.maleki@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cognitive Sciences and Technologies Council
Full name of responsible person
Majid Nili Ahmadabadi
Street address
No. 3, third floor, Ostad Daryabandari Street (Armaghan Gharbi), above Niayesh Intersection, Vali Asr Street.
City
Tehran
Province
Tehran
Postal code
۱۹۶۷۸۷۵۳۱۹
Phone
+98 21 2266 0770
Email
fa.maleki@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Cognitive Sciences and Technologies Council
Proportion provided by this source
50
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
University of social welfare and rehabilitation sciences
Full name of responsible person
Ghonche Raheb
Street address
Research Center for Substance Abuse and Dependency, third floor, Farabi Building, University of Rehabilitation Sciences and Social Health., Koodakiar Ave., Daneshju Boulevard., Evin
City
Tehran
Province
Tehran
Postal code
1985713871
Phone
+98 21 7173 2853
Email
sadrc@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation sciences
Proportion provided by this source
50
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
University of social welfare and rehabilitation sciences
Full name of responsible person
Fahime Maleki
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
No. 19, West 19th Ave., Tohid Blvd., Ghanat kosar
City
Tehran
Province
Tehran
Postal code
1653667638
Phone
+98 21 7780 1524
Email
fa.maleki@uswr.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Fahime Maleki
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
No. 19, West19th Ave., Tohid Blvd., Ghanat kosar
City
Tehran
Province
Tehran
Postal code
1653667638
Phone
+98 21 7780 1624
Email
fa.maleki@uswr.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Fahime Maleki
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address

No. 19, West 19 th Ave., Tohid Blvd., Ghanat Kosar

City

Tehran

Province

Tehran

Postal code

1653667638

Phone

+98 21 7780 1524

Email

fa.maleki@uswr.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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data is presented in the form of individuals' scores in pre- and post-treatment assessments in both groups in a way that individuals' identities are unidentifiable, and it is provided in an Excel file.

When the data will become available and for how long

Access period begins 6 months after the publication of results and lasts for one year.

To whom data/document is available

Information is available for professionals, researchers, and therapists in the fields of psychology, psychiatry and cognitive sciences.

Under which criteria data/document could be used

Researchers in the field of internet gaming addiction under the following conditions: Keeping the data confidential and not disclosing it; Not using the data for writing scientific research articles or participating in scientific conferences

From where data/document is obtainable

Fahime Maleki Email address: fa.maleki@uswr.ac.ir

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

Requests received via email are reviewed by the research team, and if approved, the data will be sent within 1 to 2 weeks

Comments