

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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