

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effectiveness of cognitive rehabilitation on executive functions and cravings in patients undergoing addiction treatment

Protocol summary

Study aim

Investigating the effect of cognitive rehabilitation on executive functions and cravings in patients undergoing addiction treatment

Design

The clinical trial has a control group, with a pre-test - post-test design. The trial phase on 30 patients undergoing addiction treatment, spss software is used for data analysis.

Settings and conduct

The present study will be conducted on people suffering from addiction who were kept in compulsory addiction treatment centers in Semnan city. 30 people will be randomly selected and will be placed in two groups of 15 people, intervention and control. Cognitive rehabilitation intervention will be done in 14 sessions in the form of exercises on the intervention group, then the data obtained from the pre-test and post-test stages. The test will be analyzed by spss software

Participants/Inclusion and exclusion criteria

Entry requirements: people undergoing addiction treatment
Non-entry conditions: People with mental disorders

Intervention groups

Cognitive rehabilitation intervention (in the form of exercises) will be done to strengthen the executive functions of people with substance disorders who have been treated. The control group is the people undergoing addiction treatment who will not receive cognitive rehabilitation

Main outcome variables

Executive functions: creates purposeful behavior in humans
Craving: Strong desire to use drugs

General information

Reason for update

Acronym

AEFS

IRCT registration information

IRCT registration number: **IRCT20230808059086N1**

Registration date: **2023-09-27, 1402/07/05**

Registration timing: **retrospective**

Last update: **2023-09-27, 1402/07/05**

Update count: **0**

Registration date

2023-09-27, 1402/07/05

Registrant information

Name

Mahnaz Zargarani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3335 1017

Email address

mzargarani47@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-02, 1402/06/11

Expected recruitment end date

2023-09-12, 1402/06/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive rehabilitation on executive functions and cravings in patients undergoing addiction treatment

Public title

Investigating the effect of cognitive rehabilitation on addiction treatment

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a history of drug use for at least one year or more
Passing more than a week of people's stay in the addiction treatment center
Age range of minimum 18 and maximum 55 years

Exclusion criteria:

Have mental disorders (psychosis, bipolar, acute depression). Suffer from certain physical diseases

Age

From **18 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random number tables (Morgan's table), 30 people were selected from the available population. The unit of randomization was individual. The number of 30 subjects were randomly assigned to two groups, then in the randomization stage of the experimental procedure, the subjects were placed in two control and intervention groups. The control and intervention groups were not known in advance, and after assigning people to two groups randomly, one group was selected as the intervention group and the other group as the control group. At this stage, concealment was done to prevent any predictions from the participants and the researcher.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This study has two experimental and control groups, which is done only on the experimental rehabilitation intervention group

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Islamic Azad University, semnan branch

Street address

Eynak negah noo, moalem Square, semnan

City

Semnan

Province

Semnan

Postal code

3514713198

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

IR.IAU.SEMNAN.REC.1402.034

Health conditions studied**1****Description of health condition studied**

Drug addiction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Executive functions: are a set of cognitive processes that are necessary for the cognitive control of behavior, which include basic processes such as response inhibition, cognitive flexibility, and response inhibition.

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (after 14 sessions of cognitive rehabilitation intervention)

Method of measurement

Wisconsin card sorting tool, N BACK application, go no go assignment

2**Description**

Craving: It is called a strong and uncontrollable desire in patients suffering from addiction to get the drug again

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (after 14 sessions of cognitive rehabilitation)

Method of measurement

Instant consumption craving questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: NEAT cognitive rehabilitation intervention will take place on this group (15 people).

The NEAT intervention will be presented to the study participants in the form of paper-based assignments. These tasks include finding the differences, finding lost objects, mazes, puzzles, vocabulary tables. The rehabilitation sessions are 14 sessions, which will be held during 7 weeks and 2 sessions each week with the aim of strengthening and improving the executive functions of the brain.

Category

Rehabilitation

2**Description**

Control group: There is no intervention on the control group

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Compulsory addiction treatment center semnan city

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mohammad Karim Sohrabi

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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

Islamic Azad University

Proportion provided by this source

5

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

Mahnaz Zargarani

Position

Collegian

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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