

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effectiveness of cognitive rehabilitation intervention on the improvement of cognitive deficits (working memory and selective attention) and quantitative electroencephalogram (QEEG) indices in men with heroin and methamphetamine use disorders

Protocol summary

Study aim

RehaCom package cognitive rehabilitation training can be effective in finding an effective treatment model to improve executive functions in substance abusers. The main purpose of this study is Evaluation of the effectiveness of cognitive rehabilitation intervention on the improvement of cognitive deficits (working memory and selective attention) and quantitative electroencephalogram (QEEG) indices in men with heroin and methamphetamine use disorders

Design

12 intervention sessions and duration of intervention sessions 6 weeks and 2 sessions per week with an interval of 3 days (each session = 60 minutes) are held individually for methamphetamine and heroin group participants.

Settings and conduct

Substance Abuse Clinic of Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Men with a minimum age of 20 years and a maximum of 50 year - Having at least secondary education (cycle) - Having diagnostic criteria for dependence on opiates (heroin) and stimulants (methamphetamine)
Exclusion criteria: - Having any psychiatric disorder except for drug-related disorders, - Traumatic brain injuries (medium to severe) along with neurologic deficits or suffering from acute and unstable medical conditions - having serious suicidal thoughts - Receiving another medical or psychological intervention at the same time

Intervention groups

After initial and pre-test evaluation (completion of attention and memory tests and EEG recording), 12 sessions of RehaCom cognitive rehabilitation intervention are performed for both methamphetamine and heroin

groups. Patients will be re-evaluated (follow up) two months after the end of the intervention.

Main outcome variables

cognitive deficits (working memory and selective attention) and quantitative electroencephalogram (QEEG) indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161026030510N4**

Registration date: **2022-01-07, 1400/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-07, 1400/10/17**

Update count: **0**

Registration date

2022-01-07, 1400/10/17

Registrant information

Name

Reza Arezoomandan

Name of organization / entity

Addiction Department, School of Behavioral Sciences and Mental Health (Institute of Tehran Psychiatr

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-29, 1400/08/07

Expected recruitment end date

2021-12-28, 1400/10/07

Actual recruitment start date

2021-11-01, 1400/08/10

Actual recruitment end date

2022-01-30, 1400/11/10

Trial completion date

2022-07-20, 1401/04/29

Scientific title

Evaluation of the effectiveness of cognitive rehabilitation intervention on the improvement of cognitive deficits (working memory and selective attention) and quantitative electroencephalogram (QEEG) indices in men with heroin and methamphetamine use disorders

Public title

Evaluation of the effectiveness of cognitive rehabilitation intervention on the improvement of cognitive deficits (working memory and selective attention) and quantitative electroencephalogram (QEEG) indices in men with heroin and methamphetamine use disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

-Men with a minimum age of 20 years and a maximum of 50 year- Having at least secondary education (cycle) - Having diagnostic criteria for dependence on opiates (heroin) and stimulants (methamphetamine - Have lower than average scores on attention and memory tests based on initial assessment using RehaCom cognitive software screening modules - No participating in psychotherapy groups including NA in the last 6 months - Complete the informed consent form

Exclusion criteria:

- Having any psychiatric disorder except for drug-related disorders - Traumatic brain injuries (medium to severe) along with neurologic deficits or suffering from acute and unstable medical conditions - having serious suicidal thoughts - Receiving another medical or psychological intervention at the same time

AgeFrom **20 years** old to **50 years** old**Gender**

Male

Phase

1-2

Groups that have been masked*No information***Sample size**Target sample size: **40**Actual sample size reached: **40****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway; Next to Milad Tower

City

Tehran

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Postal code

14665-354

Approval date

2021-10-27, 1400/08/05

Ethics committee reference number

IR.IUMS.REC.1400.688

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

Men with Heroin Disorder - Men with Methamphetamine Disorder

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

Selective Attention

Timepoint

Before and after the intervention

Method of measurement

Stroop test

2**Description**

Quantitative Electroencephalogram (QEEG) Indices

Timepoint

Before and after the intervention

Method of measurement

QEEG 3840 -Neuroguide software

3

Description

working memory

Timepoint

Before and after the intervention

Method of measurement

Wechsler Memory Scale-Third Edition (WMS-III)

Secondary outcomes

empty

Intervention groups

1

Description

Methamphetamine (n=20) group is assessed by structured clinical interview (DSM-5) for Axis I and II disorders. They are then assessed (pre-test) through attention tests (Stroop test) and memory (Wechsler memory test). After the initial assessment (completion of attention and memory tests and EEG recording), 12 sessions of RehaCom cognitive rehabilitation intervention are performed. Also, patients will be re-evaluated ((post-test) two months after the end of the interventions (follow up).

Category

Rehabilitation

2

Description

The heroin group (n = 20) is assessed by structured clinical interview (DSM-5) for Axis I and II disorders. They are then assessed (pre-test) through attention tests (Stroop test) and memory (Wechsler memory test). After the initial assessment (completion of attention and memory tests and EEG recording), 12 sessions of RehaCom cognitive rehabilitation intervention are performed. Also, patients will be re-evaluated ((post-test) two months after the end of the interventions (follow up).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Substance Abuse Clinic of Shiraz University of Medical Sciences

Full name of responsible person

Reza arezoomandan

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Zand St., in front of Phelestine St., the central building of Shiraz University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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اتوبان همت، جنب برج میلاد، دانشگاه علوم پزشکی ایران

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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

Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Dr. Reza Arezoomandan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Clinical and cognitive outcomes of patients after the
intervention

When the data will become available and for how long

2022

To whom data/document is available

Researchers

Under which criteria data/document could be used

Researchers from all scientific centers

From where data/document is obtainable

Email

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

Email - 4 Weeks

Comments