# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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)

**Phone**

+98 21 6655 1658

**Email address**

arezoomandan.r@iums.ac.ir

**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
**Age**
From **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
**Province**
Tehran
**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
**Street address**
Zand St., in front of Phelestine St., the central building of Shiraz University of Medical Sciences
**City**
Shiraz
**Province**
Fars
**Postal code**
۷۱۳۴۸۱۴۳۳۶
**Phone**
+98 71 3212 2713
**Fax**
+98 71 3230 8200
**Email**
Arezoomandan@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Dr. Abbas Motavlian
**Street address**
اتوبان همت، جنب برج میلاد، دانشگاه علوم پزشکی ایران
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Phone**
+98 21 86701
**Email**
Adminsite@iums.ac.ir
**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

**Street address**
Mansouri St, Faculty of Behavioral Sciences and Mental Health
**City**
Tehran
**Province**
Tehran
**Postal code**
1445613111
**Phone**
+98 21 6655 1655
**Email**
Arezoomandan@yahoo.com

## Person responsible for scientific 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
**Street address**
خیابان منصوری، دانشکده علوم رفتاری و سلامت روان
**City**
Tehran
**Province**
Tehran
**Postal code**
1445613111
**Phone**
+98 21 6655 1555
**Email**
Arezoomandan@yahoo.com

## Person responsible for updating data

**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
**Street address**
Mansouri St., Faculty of Behavioral Sciences and Mental Health
**City**
Tehran
**Province**
Tehran
**Postal code**
1445613111
**Phone**
+98 21 6655 1555
**Email**
arezoomandan.r@ums.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**
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**