

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The Effect of Neuroscience-Informed Psychoeducation (NIPE) on Self-Efficacy of People with Substance Use Disorder

#### Protocol summary

##### Study aim

Examining the effect of neuroscience-informed psychoeducation (NIPE) on self-efficacy of people with substance use disorder

##### Design

Two arms parallel group randomized trial with three months follow-up

##### Settings and conduct

The study sample will be taken from outpatient treatment centers. Eligible participants will be divided into intervention or control groups and the intervention group will receive four 120-minute training sessions.

##### Participants/Inclusion and exclusion criteria

- Ages 18 to 65 years
- Male
- Detection of substance use disorders (opiates, methamphetamine, cannabis or alcohol) based on DSM-5 criteria
- Receiving standard treatment based on Ministry of Health protocols (more than two weeks and less than 24 weeks after treatment)
- Failure to understand intervention protocol or assessments
- Referral to legal centers
- Psychiatric disorders that are severe (such as severe depression, bipolar disorder, psychosis and suicide history)

##### Intervention groups

Neuroscience-informed psychoeducation (NIPE) Protocol (NIPE): Includes ten main areas (including: attention, memory, decision making and control, mobility and speech, brain-body communication, arousal and sleep, pleasant feeling, unpleasant feeling, social cognition and awareness and Insight), will be performed in four 120-minute sessions in intervention group. The control group receive only standard treatment and after one month of pre-test, which is equivalent to four weekly sessions of the experimental group, they are re-evaluated. The ten areas are taught in four sessions in the following order:

- Session One: Attention and Memory
- Second session: unpleasant sensation, brain-body communication, arousal and sleep
- Third session: decision making and control, mobility and speech
- Fourth session: awareness, insights, social skills, pleasant feeling

#### Main outcome variables

Self-efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121020011172N3**

Registration date: **2020-04-26, 1399/02/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-26, 1399/02/07**

Update count: **0**

##### Registration date

2020-04-26, 1399/02/07

##### Registrant information

##### Name

Hamed Ekhtiari

##### Name of organization / entity

The center of molecular and cellular imaging

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2640 3626

##### Email address

h\_ekhtiari@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-07, 1399/01/19

##### Expected recruitment end date

2020-09-20, 1399/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The Effect of Neuroscience-Informed Psychoeducation (NIPE) on Self-Efficacy of People with Substance Use Disorder

**Public title**  
The Effect of Neuroscience-Informed Psychoeducation in People with Addiction

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Ages 18 to 65 years Male Detection of substance use disorders (opiates, methamphetamine and cannabis or alcohol) based on DSM-5 Receiving standard treatment based on Ministry of Health protocols (more than two weeks and less than 24 weeks after treatment) Desire and informed consent to enter the project  
**Exclusion criteria:**  
• Failure to understand intervention protocol or assessments • Concurrent participation in research projects providing pharmacological or psychological interventions • Referral to legal centers • Psychiatric disorders that are severe (such as severe depression, bipolar disorder, psychosis and suicide history )

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **240**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization will be a randomized block design with 6 blocks, the sequence of randomization will be determined through sealed envelope.com site and based on this, the researcher considers eligible subjects for two study groups.

**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 Tehran University of Medical Sciences

**Street address**

Ghods Ave, Keshavarz Blvd, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2020-01-04, 1398/10/14

**Ethics committee reference number**

IR.TUMS.VCR.REC.1398.771

## Health conditions studied

### 1

**Description of health condition studied**

Substance Use Disorder

**ICD-10 code**

F11

**ICD-10 code description**

Opioid related disorders

### 2

**Description of health condition studied**

Alcohol Use Disorder

**ICD-10 code**

F10

**ICD-10 code description**

Alcohol related disorders

## Primary outcomes

### 1

**Description**

Self-efficacy measured by Situational Confidence Questionnaire (SCQ)

**Timepoint**

Before and after the intervention

**Method of measurement**

Self-efficacy measured by Situational Confidence Questionnaire (SCQ)

## Secondary outcomes

### 1

**Description**

Cognitive problems in response to self-reported cognitive difficulties questionnaire

### **Timepoint**

Before and after the intervention

### **Method of measurement**

Cognitive problems in response to self-reported cognitive difficulties questionnaire

## **2**

### **Description**

The mood status in response to the Positive and Negative Affect Schedule (PANAS)

### **Timepoint**

Before and after the intervention

### **Method of measurement**

The mood status in response to the Positive and Negative Affect Schedule (PANAS)

## **3**

### **Description**

Passion and satisfaction: Subjective response measured on a visual analogue scale

### **Timepoint**

Before and after the intervention

### **Method of measurement**

Passion and satisfaction: Subjective response measured on a visual analogue scale

## **4**

### **Description**

Life satisfaction in response to The Satisfaction With Life Scale (SWLS)

### **Timepoint**

Before and after the intervention

### **Method of measurement**

Life satisfaction in response to The Satisfaction With Life Scale (SWLS)

## **Intervention groups**

## **1**

### **Description**

Intervention group: Neuroscience-informed psychoeducation (NIPE) Protocol (NIPE): Includes ten main areas (including: attention, memory, decision making and control, mobility and speech, brain-body communication, arousal and sleep, pleasant feeling, unpleasant feeling, social cognition and awareness and Insight), will be performed in four 120-minute sessions in intervention group. T. The ten areas are taught in four sessions in the following order: • Session One: Attention and Memory • Second session: unpleasant sensation, brain-body communication, arousal and sleep • Third session: decision making and control, mobility and speech • Fourth session: awareness, insights, social skills, pleasant feeling

### **Category**

Other

## **2**

### **Description**

Control group: The control group receive only standard treatment and after one month of pre-test, which is equivalent to four weekly sessions of the experimental group, they are re-evaluated.

### **Category**

N/A

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Iranian National Center for Addiction Studies (INCAS)

#### **Full name of responsible person**

Nastaran Malmir

#### **Street address**

Iranian National Center for Addiction Studies (INCAS), Farabi Hospital, Qazvin Square, Tehran, Iran

#### **City**

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#### **Province**

Tehran

#### **Postal code**

1635713366

#### **Phone**

+98 21 5542 1155

#### **Email**

incas@tums.ac.ir

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

#### **Name of organization / entity**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Dr Hamed Ekhtiari

#### **Street address**

Tehran University of Medical Sciences, Central department, the crossing of Qods Street and Keshavarz Blvd., Tehran

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#### **Province**

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#### **Phone**

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#### **Email**

tums\_edu@tums.ac.ir

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

Tehran 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**  
Iranian National Center for Addiction Studies (INCAS)  
**Full name of responsible person**  
Nastaran Malmir  
**Position**  
Student  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Psychology  
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Iranian National Center for Addiction Studies (INCAS),  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Laureate Institute for Brain Research  
**Full name of responsible person**  
Dr Hamed Ekhtiari  
**Position**  
Associate Investigator-Laureate Institute for Brain  
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**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iranian National Center for Addiction Studies (INCAS)  
**Full name of responsible person**  
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**Other areas of specialty/work**  
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**Street address**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to

make this available