

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)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Hamed Ekhtiari

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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

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
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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