

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Designing a Neuro Cognitive Rehabilitation Package for Drug Addicted Patients (NECOREDA) and Studying its Efficiency: Randomized Clinical Trial

Protocol summary

Summary

Present study is aimed to design and study the efficacy of a developed package for neurocognitive rehabilitation of addicted people particularly opioid and stimulants dependents as a supplementary therapeutic service. This investigation is going to be conducted as a randomized controlled single blind trial with 120 patients at a residential treatment center who meet our inclusion criteria (age 20-40, ability to read and speak in Farsi, meet DSV-IV-TR criteria for opiate dependence, to give written informed consent). Our exclusion criteria are suffering from serious chronic mental disease, demonstration of withdrawal symptoms at the end of first 2-weeks admission, or a history of a suicide attempt during last month. Participants will be randomly classified into two groups; intervention (n=60) or control group (n=60). Participants in the intervention group are scheduled for 32 one-hour group sessions four times a week and those in control group receive painting session as a placebo beside their standard treatment. To assess the efficacy of implementing of the developed package, assessments will be conducted at baseline, midterm, at the end of study and follow-up period (1, 3 and 6 month). These assessments are both related to cognitive functions such as memory and attention and treatment outcomes such as the results of urine tests and treatment commitment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090123849N1**
Registration date: **2015-11-27, 1394/09/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-27, 1394/09/06

Registrant information

Name

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Name of organization / entity

Institute for Cognitive Science Studies

Country

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Recruitment status

Recruitment complete

Funding source

Cognitive Science and Technologies Council (CSTS)

Expected recruitment start date

2015-10-25, 1394/08/03

Expected recruitment end date

2016-01-25, 1394/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing a Neuro Cognitive Rehabilitation Package for Drug Addicted Patients (NECOREDA) and Studying its Efficiency: Randomized Clinical Trial

Public title

Neurocognitive Rehabilitation Program for Disease of Addiction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20 -40 years old; ability to read and speak in Farsi; meet DSM-IV-TR criteria for opiate dependence; have voluntary and informed consent.
Exclusion criteria: suffer from serious chronic mental disease; history of suicide during last month; demonstrate withdrawal symptoms at the end of first two weeks of admission.

Age

From **20 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

Street address

kodakyar Ave., daneshjo Blvd.,Evin

City

Tehran

Postal code

Approval date

2014-09-16, 1393/06/25

Ethics committee reference number

USWR.REC.1393.161

Health conditions studied

1

Description of health condition studied

Opiate Dependence

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

Improvement of cognitive performance

Timepoint

Baseline, Midterm, Final, follow- up(1,3,6 month)

Method of measurement

Cognitive Assessment Battery

Secondary outcomes

1

Description

Change in adiction treatment outcomes

Timepoint

At the end of intervention and follow- up (1,3,6 month)

Method of measurement

Subjective reports, Urine tests

Intervention groups

1

Description

Intervention: Intervention group receive neurocognitive rehabilitation with developed package during 2 months. Cognitive rehabilitation sessions are 32 one-hour group sessions that hold 4 times a week.

Category

Rehabilitation

2

Description

Control : Control group receive placebo intervention that is painting during 2 months. Painting sessions are 32 one-hour group sessions that hold 4 times a week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian National Center for Addiction Studies

Full name of responsible person

Tara Rezapour

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cognitive Science and Technologies Council (CSTS)

Full name of responsible person

Dr.Majid Nili (Research Group)

Street address

No 35, Presidency Building, Alvand St, Argentina Sq

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Cognitive Science and Technologies Council (CSTS)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Translational Neuroscience Program, Institute for Cognitive Science Studies, Tehran, Iran

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Position

PhD Student

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty