

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the Effectiveness of LORETA Z Score Neurofeedback with Cognitive Rehabilitation on Decreasing of Craving in Opioid Addicts

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Craving reduction in Opioids Users

Design

In this research, 20 eligible opioids addicts were chosen purposefully that refer to clinics and MMT centers. Then, patients were randomly divided into two neurofeedback and cognitive rehabilitation intervention. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

20, one hour sessions for every body in neurofeedback group and 15 sessions(each session: 20 minute) for everybody in cognitive rehabilitation group will be done in MMT center. Pre and post tests of intervention groups will be compare with pre and post tests of control groups.

Participants/Inclusion and exclusion criteria

a) Inclusion Criteria: - Written consent to participate in this study - The patients must use opioids alone b) Exclusion Criteria: 1.Alcoholic and other substance use patients 2.Addicts that are treated by other drugs such as buprenorphine, opium tincture, tranquilizers 3.Psychotic, bipolar, antisocial, personality disorders and borderline patients. 4.Multi drug abusers.

Intervention groups

Opioids users are intervention groups that will be divided to neurofeedback therapy and cognitive rehabilitation groups, and will be compare with intervention group, that are compatible-in number and sex.

Main outcome variables

Craving reduction and outcome improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170924036386N1**

Registration date: **2018-01-08, 1396/10/18**

Last update: **2018-04-24, 1397/02/04**

Update count: **1**

Registration date

2018-01-08, 1396/10/18

Registrant information

Name

Alireza Faridi

Name of organization / entity

Zanjan university of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 33448430

Email address

dr.a.faridi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of LORETA Z Score Neurofeedback with Cognitive Rehabilitation on Decreasing of Craving in Opioid Addicts

Public title

Effect of neurofeedback and cognitive rehabilitation in treatment of opium and heroin addicts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Opium and heroin addicts Age range: 18-70 Males Drug use: Methadone

Exclusion criteria:

Age > 70 y/o Females Methadone > 100 mg/d Non opioides addicts

Age

From **18 years** old to **70 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Table of random numbers

Blinding (investigator's opinion)

Not blinded

Blinding description

No blinding

Placebo

Not used

Assignment

Parallel

Other design features

Using Neruoguide and Dot Probe software for clinical interventions

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University Of Medical Science

Street address

Zanjan- Bulvar Azadi

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.ZUMS.REC.1396.97

Health conditions studied

1

Description of health condition studied

Opioids Addiction

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

Craving

Timepoint

Begin-mid- end of study

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Addiction Severity Index

Timepoint

At the beginning and end of the study

Method of measurement

Questionnaire

2

Description

Recovery assessment scale

Timepoint

At the beginning and end of the study

Method of measurement

Questionnaire

3

Description

LDQ

Timepoint

At the beginning and end of the study

Method of measurement

Questionnaire

4

Description

Stroop Task

Timepoint

At the beginning and end of the study

Method of measurement

Questionnaire

5

Description

Quality of Life

Timepoint

At the beginning and end of the study

Method of measurement

Questionnaire

6

Description

Anxiety

Timepoint

At the beginning, middle and end of the study

Method of measurement

Questionnaire

7

Description

Depression

Timepoint

At the beginning, middle and end of the study

Method of measurement

Questionnaire

8

Description

Response inhibition

Timepoint

At the beginning and end of the study

Method of measurement

Questionnaire

9

Description

Attention bias

Timepoint

At the beginning and end of the study

Method of measurement

Questionnaire

Intervention groups

1

Description

Cognitive rehabilitation by Dot Probe software. 15 sessions(each session: 20 minute) for everybody in cognitive rehabilitation group will be done in MMT center. Pre and post tests of intervention groups will be compare with pre and post tests of control groups.

Category

Rehabilitation

2

Description

loreta Neurofeedback therapy.20 sessions and one hour for each session for every body in neurofeedback group

will be done in MMT center. Pre and post tests of intervention groups will be compare with pre and post tests of control groups.

Category

Other

3

Description

Control group:20 members. All pre and post tests of intervention groups will be done for this group for comparing.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

MMT clinics in city

Full name of responsible person

Physician

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Sponsors / Funding sources

1

Sponsor

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Grant name
Grant code / Reference number
A-11-187-13
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Alireza Faridi
Position
Dr- executer
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