Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison study of effectiveness of Matrix model,repetitive Transcranial Magnetic Stimulation and cognitive rehabilitation on decreasing of craving and assessment of dopamine receptors expression in peripheral blood lymphocytes of stimulant substance user.

Protocol summary

Study aim
Effectiveness of effective therapies for reducing craving in stimulant-dependent consumers

Design
The clinical trial group was divided into 3 intervention groups, each of which consisted of 10 subjects, simple randomized, two groups, pre-test and post-test

Settings and conduct
24, 45 minute sessions for every body in Matrix group and 15 sessions(each session: 40 minute) for everybody in cognitive rehabilitation group will be done in MMT center. 10 session of Repetitive Transcranial Magnetic Stimulation for every body in Iranian national center for addiction study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Written consent to participate in this study; The patients must use stimulant alone. Exclusion Criteria: Alcoholic and other substance use patients; Psychotic, bipolar, antisocial, personality disorders and borderline patients; Multidrug abusers; Methadone users

Intervention groups
1. Matrix treatment (Intervention group) 2. Treatment with magnetic stimulation (Intervention group) 3. Treatment with Cognitive Rehab (Intervention group)

Main outcome variables
Change the status of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171004036553N2**
Registration date: **2018-04-13, 1397/01/24**
Registration timing: **registered_while_recruiting**
Last update: **2018-04-13, 1397/01/24**
Update count: **0**

Registration date
2018-04-13, 1397/01/24

Registrant information

Name
Sahar Esmaili

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2018-05-22, 1397/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison study of effectiveness of Matrix model,repetitive Transcranial Magnetic Stimulation and cognitive rehabilitation on decreasing of craving and assessment of dopamine receptors expression in peripheral blood lymphocytes of stimulant substance user.

Public title
Comparison study of effectiveness treatments on decreasing of craving of stimulant substance user.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Sex: Male Diagnosis of Substance use of the subjects Having Satisfication of doing project
Exclusion criteria:
Using Methadon and the other drugs Patients treated with alternative therapies other than methadone. Patients with severe psychiatric disorders such as psychosis, bipolar depression.
Age
From **20 years** old to **55 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Table of random numbers
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Using Dot Probe and Working memorey training software for clinical interventions

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Central Branch of Zanjan University of Medical Sciences, Beginning of the Islamic Republic Blvd., Azadi Square, Zanjan
City
Zanjan
Province
Zanjan
Postal code
4515613191
Approval date
2017-08-08, 1396/05/17
Ethics committee reference number
ZUMS.REC.1396.96

Health conditions studied

1

Description of health condition studied
Stimulant Addiction
ICD-10 code
F15
ICD-10 code description
Other stimulant related disorders

Primary outcomes

1

Description
Crayving
Timepoint
Before the intervention after the end of the therapeutic interventions and 3 months later
Method of measurement
Questionnaires and cognitive tests

2

Description
Gene expression of dopamine receptors
Timepoint
Before the intervention after the end of the treatment interventions
Method of measurement
The real time pcr method

Secondary outcomes

1

Description
Anxiety Score
Timepoint
Before and after the intervention
Method of measurement
Anxiety Questionnaire

2

Description
Depression Score
Timepoint
Before and after the intervention
Method of measurement
Depression Questionnaire

3

Description
General Welbeing Score
Timepoint

Before and after the intervention

Method of measurement

General Welbeing Questionnaire

4

Description

Score of Crayving Assessment

Timepoint

Before and after the intervention

Method of measurement

Craving Assessment Questionnaire

5

Description

Screening Score and Addiction Severity Score

Timepoint

Before and after the intervention

Method of measurement

Screening and Measuring the Severity of Addiction

6

Description

Work Memory Score and Attention Detection

Timepoint

Before and after the intervention

Method of measurement

Work Memory and Detection Attention

Intervention groups

1

Description

"Intervention group 1: Outpatient psychotherapy method". In this intervention, the outpatient treatment method is used using a booklet therapy and cognitive behavioral assignments. The total number of sessions is 24 sessions per week and three times a week.

Category

Treatment - Other

2

Description

The "intervention group 2: cognitive rehabilitation" in this intervention uses cognitive programs to strengthen the two cognitive components of memory and attention.

Category

Rehabilitation

3

Description

"Intervention Group 3: By Brain Magnetic Stimulation" In this method, magnetic pulses are applied to the brain by magnetic resonance imaging (RTMS), causing activity of the neurons in the brain.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction treatment clinics

Full name of responsible person

Sahar Esmaeili

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mahnaz Varghaei

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Web page address

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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

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

Sahar Esmaeili

Position

Resident

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available