

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effectiveness of emotion regulation therapy on craving and emotion dysregulation in patients with substance use disorders.

Protocol summary

Summary

Objectives: the study aims to evaluate effectiveness of emotion regulation therapy on craving and emotion dysregulation in patients with substance use disorders. Design: this is a controlled clinical trial with pretest and post- test stages. Setting and conduct: Using convenient sampling, 30 patients admitted to the Noor hospital of Isfahan were assigned in Methadone therapy or experimental group (Methadone therapy and emotion regulation therapy) randomly. Difficulties in emotion regulation scale, marital adjustment questionnaire and craving beliefs questionnaire will administer in pre and post treatment in both groups. Major Inclusion and Exclusion criteria: inclusion criteria: having a diagnosis of substance use disorder diagnosis criteria psychiatrist; not receiving psychological treatment for at least a month before the study; having at least 18 years and a maximum of 60 years; having at least third-level education in guided school and agreement to participate in research according to informed consent. Exclusion criteria: having psychotic symptoms; having full criteria for psychiatric disorders in axis I; having serious suicidal thoughts; having symptoms of borderline personality disorder and antisocial personality disorder. Intervention: the experimental group will receive eight weekly treatments. Main outcome measures: difficulties in emotion regulation, marital adjustment and craving beliefs.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201505157227N2**

Registration date: **2015-07-31, 1394/05/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-31, 1394/05/09

Registrant information

Name

Fatemeh Zargar

Name of organization / entity

Tehran Psychiatric Institute, Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of emotion regulation therapy on craving and emotion dysregulation in patients with substance use disorders.

Public title

A randomized clinical trial of effect of emotion regulation therapy on craving and emotion dysregulation in patients

with substance use disorders.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: having a diagnosis of substance use disorder diagnosis criteria psychiatrist; not receiving psychological treatment for at least a month before the study; at least 18 years and a maximum of 60 years; at least third-level education in guided school; patients agreed to participate in research According to informed consent. Exclusion criteria: having psychotic symptoms; having full criteria for psychiatric axis I disorders; thoughts of suicide are serious about the possibility of drug and makes it impossible to maintain it; having symptoms of borderline personality disorder and antisocial personality disorder.

Age
From **18 years** old to **60 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

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
Azad University, Khorasgan branch

Street address
Isfahan

City
Isfahan

Postal code

Approval date
2013-09-23, 1392/07/01

Ethics committee reference number
2382/701/92/3

Health conditions studied

1

Description of health condition studied
Mental and behavioural disorders due to use of opioids

ICD-10 code
F-11

ICD-10 code description
Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description
Marital adjustment

Timepoint
pre-test and 2 months after starting intervention

Method of measurement
Spanier marital adjustment

2

Description
Craving

Timepoint
pre-test and 2 months after starting intervention

Method of measurement
Craving beliefs questionnaire

3

Description
Emotion dysregulation

Timepoint
pre-test and 2 months after starting intervention

Method of measurement
difficulties in emotion regulation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Methadone therapy combined to emotion regulation therapy

Category
Behavior

2

Description
Control group: Methadone therapy

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor hospital

Full name of responsible person

Nasim Bagheri

Street address

Noor hospital, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

investigator

Full name of responsible person

Nasim Bagheri

Street address

700, Hossein Abad, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

investigator

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

Kashan university in medical sciences

Full name of responsible person

Fatemeh Zargar

Position

Ph.D. in clinical psychology, assistant profesor

Other areas of specialty/work

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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