

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Mindfulness-based cognitive therapy on reduction of psychological symptoms, craving beliefs and increase self-efficacy in opioid abusers

Protocol summary

Summary

The Efficacy of mindfulness-based cognitive therapy on reduction of psychological symptoms, craving beliefs and increase self-efficacy in opioid abusers 1) Objectives: the main aim of this study is the effectiveness of mindfulness-based cognitive therapy on reduction of psychological symptoms, craving beliefs and increase of self-efficacy in opioid abusers. 2) Design: the present study is a pilot design with intervention groups (examination group) and the control group. 3) Setting and conduct : First, all individuals willing to participate in this study are evaluated by a structured clinical interview (DSM-5) for axis I and II disorders. then , 40 opiate addicted (opium, heroin, tramadol and Similar substances) were randomly selected and will be replaced in experimental group (n = 20) and control group (n = 20). 4) Participants : the statistical population of this study was all people that refer to drug abuse center at shiraz university of medical sciences. Inclusion major criteria is included Being male , substance abuse and independency to Stimulants , having a minimum secondary education. also, exclusion major criteria is having mental retardation and psychotic disorders. 5) Intervention : intervention sessions for the experimental group are 8 sessions, each week a session (90 minutes), mindfulness-based cognitive therapy applied for the experimental group. 6) Main outcome measure (variables) : psychological symptoms, craving beliefs and increase self-efficacy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081325160N7**

Registration date: **2017-09-25, 1396/07/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-25, 1396/07/03

Registrant information

Name

Jamshid Ahmadi

Name of organization / entity

Shiraz University of Medical Sciences

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Phone

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Mindfulness-based cognitive therapy on reduction of psychological symptoms, craving beliefs and increase self-efficacy in opioid abusers

Public title

The Efficacy of mindfulness-based cognitive therapy on reduction of psychological symptoms, craving beliefs and

increase self-efficacy in opioid abusers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion major eligibility criteria to study: Being male and having age between 20 to 45 years ; having a minimum secondary education ; substance abuse and independency to Stimulants ; having diagnostic criteria for the use of opioids to the initial diagnosis of a psychiatrist and the diagnosis of clinical psychologist based on the results of a structured clinical interview for axial disturbances (DSM-5) ; dependence on at least one opiate substance (opium, heroin, tramadol and Similar substances) based on clinical interviews ; passed at least one year of drug ; lack of participation in psychotherapy groups including NA in the last 6 months ; complete consent for participation in research. Exclusion major eligibility criteria of study: Having mental retardation ; psychotic disorders ; organic brain disorder ; having serious thoughts on suicide based on psychiatrist interviews ;having complete criteria for personality disorder in axis II based on the results of structured interviews of the disordered axis two ; employment in psychology or counseling ; receiving another psychological intervention at the same time or having a kinship or friendship with each member of the intervention group ; decided to leave the group.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Ethics committee of Shiraz University of Medical Science

Street address

Shiraz University of Medical Sciences, Zand Blvd

City

Shiraz

Postal code

7194634786

Approval date

2017-06-11, 1396/03/21

Ethics committee reference number

IR.SUMS.REC.1396.58

Health conditions studied

1

Description of health condition studied

opioid abusers

ICD-10 code

F 11

ICD-10 code description

This block contains a wide variety of disorders that differ in severity and clinical form but that are all attributable to the use of one or more psychoactive substances, which may or may not have been medically prescribed.

The third character of the code

Primary outcomes

1

Description

psychological symptoms

Timepoint

weekly to 2 months

Method of measurement

Clinical Interview for Focal I Disorders in DSM-IV-Clinical Version (SCID-I / CV)

Secondary outcomes

1

Description

craving beliefs

Timepoint

weekly to 2 months

Method of measurement

Addiction Severity Index (ASI) - Brief Symptom Inventory (BSI)

Intervention groups

1

Description

experimental group: The present study is a pilot design with two experimental group (mindfulness-based cognitive therapy) and the control group. in this study, the pilot project is pretest - posttest by using random assignment. Intervention is only on experimental group. The intervention is included the protocol of Cognitive therapy according to protocol of application of

mindfulness in intervention of addiction and Addictive behaviours (rebbecaeei, Williams, joli s. craft, 2012).
The intervention sessions for the experimental group are 8 sessions, each week a session (90 minutes), is applied cognitive-based cognitive therapy approach for the test group.

Category

Behavior

2

Description

in this study, control group does not receive no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebne Sina Hospital

Full name of responsible person

Jamshid Ahmadi M.D

Street address

Ebne Sina Hospital, Hafeziye street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Vice Chancellery for Research Affairs, Shiraz University of Medical Sciences, Zand Blvd

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice chancellor for research, Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

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Position

Profesor

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Person responsible for updating data

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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