# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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
**Country**
Iran (Islamic Republic of)
**Phone**
+98 71 3627 3070
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ahmadij@sums.ac.ir


**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 ; decisided 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

mindfullness 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

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Profesor

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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*