

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

comparing the effectiveness of mindfulness-based relapse prevention group therapy with treatment as usual on shame, perfectionism and self-criticism among people with opioids use disorder

Protocol summary

Study aim

Determining the effectiveness of mindfulness-based relapse prevention group therapy on shame, perfectionism and self-criticism among people with opioids use disorder and comparing it with usual treatments

Design

This is a randomized clinical, controlled, parallel groups trial. 30 participants will randomly assigned to study groups using a random sequence generation of quadrilateral block.

Settings and conduct

Iranian National Center for Addiction Studies. After going to this center and studying patients files, patients who meet criteria for the study, will be enrolled to the study after completing written informed consent.

Participants/Inclusion and exclusion criteria

inclusion criteria: age: 20 to 45 years old education: at least 8 grades opioids use disorder based on DSM-5 criteria informed consent for participating in research maintenance therapy with methadone or buprenorphine more than 1 week and less than 24 weeks exclusion criteria: having psychotic symptoms organic brain disorder having suicide thoughts based on interview meeting criteria for personality disorder

Intervention groups

Experiment group will receive mindfulness-based relapse prevention group therapy within 8 sessions and usual treatments like methadone therapy, buprenorphine, or family therapy. control group will receive just usual treatments.

Main outcome variables

shame, perfectionism, self-criticism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170702034844N5**
Registration date: **2020-04-28, 1399/02/09**
Registration timing: **retrospective**

Last update: **2020-04-28, 1399/02/09**

Update count: **0**

Registration date

2020-04-28, 1399/02/09

Registrant information

Name

Alireza Noroozi

Name of organization / entity

Iranian National Center for Addiction Studies (INCAS)

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 1144

Email address

noroozi_a@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the effectiveness of mindfulness-based relapse prevention group therapy with treatment as usual on shame, perfectionism and self-criticism among people with opioids use disorder

Public title

effectiveness of mindfulness-based relapse prevention group therapy among people with opioids use disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

age: 20 to 45 years old education: at least 8 grades opioids use disorder based on DSM-5 criteria informed consent for participating in research maintenance therapy with methadone or buprenorphine more than 1 week and less than 24 weeks

Exclusion criteria:

having psychotic symptoms organic brain disorder having suicide thoughts based on interview meeting criteria for personality disorder

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

randomization: using a random sequence generation, a quadrilateral block is used with a random number table. allocation: by a third-party supervisor who is a physician at the National Center for Addictive Studies and coordinating the placement of each patient in each treatment group.

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 shahid beheshti university

Street address

faculty of cognitive sciences and brain, shahid

beheshti university, daneshjoo blvd, Evin.

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2019-07-20, 1398/04/29

Ethics committee reference number

IR.SBU.REC.1399.008

Health conditions studied**1****Description of health condition studied**

Opioids dependence

ICD-10 code

F11.2

ICD-10 code description

Opioid dependence

Primary outcomes**1****Description**

Shame score other ad shamer scale

Timepoint

Before starting the treatment, after treatment, and 1 month after treatment.

Method of measurement

Using other as shamer scale

2**Description**

scores in positive and negative perfectionism questionnaire

Timepoint

Before starting the treatment, after treatment, and 1 month after treatment.

Method of measurement

Using positive and negative perfectionism questionnaire.

3**Description**

scores in self-criticism questionnaire

Timepoint

Before starting the treatment, after treatment, and 1 month after treatment.

Method of measurement

Using self criticism questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group contains patients with opioid use disorder that after meeting entrance criteria will enter the group. At first, patients will fill the questionnaires of shame, positive and negative perfectionism, self-criticism, and addiction severity index. Then they receive the mindfulness based relapse prevention intervention within 8 sessions. This program is combined of mindfulness skills and cognitive behavioral therapy. This group will also receive usual treatments like methadone or buprenorphine therapy or single psychotherapies. At the end of the intervention and 1 month after that, questionnaires will be repeated.

Category

Behavior

2

Description

Control group: This group contains patients with opioid use disorder that after meeting entrance criteria will enter the group. At first, patients will fill the questionnaires of shame, positive and negative perfectionism, self-criticism, and addiction severity index. This group will receive usual treatments like methadone or buprenorphine therapy or single psychotherapies. At the end of the intervention of intervention group and after 1 month later, control group will fill the questionnaires again.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian National Center for Addiction Studies

Full name of responsible person

Alireza Norouzi

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No. 486, South Karegar Ave, Qazvin Square

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1336616357

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Email

incas@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian National Center for Addiction Studies

Full name of responsible person

Dr. Alireza Noroozi

Street address

No 486, next to Farabi hospital, Qazvin sq, south kargar ave.

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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

Iranian National Center for Addiction Studies

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Alireza Noroozi

Position

psychiatrist

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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No 486, South kargar St, Qazvin Sq, Next to Farabi Hospital

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Dr. Alireza Noroozi
Position
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Participants data file: The participants data without identifying information will be available after completion of the study. Clinical study report: The clinical study report will be available after completion of the study.

When the data will become available and for how long

From August 2020

To whom data/document is available

Researchers of psychiatric disorders clinical studies.

Under which criteria data/document could be used

Using study data for systematic reviews and meta-analysis studies is permitted.

From where data/document is obtainable

Dr. Alireza Noroozi, Psychiatric clinic, Iranian National Center for Addiction Studies, No 486, south karegar St, Tehran, Iran. Email: a_r_noroozi@yahoo.com

What processes are involved for a request to access data/document

The data request need to clearly define data needs. The study contact person will provide available data within 1 week after receiving the request.

Comments