Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 effictiveness 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 rondom 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 compeleting 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 maitenance therapy with methadone or buprenorphine more than 1 week and less than 24 weeks exclusion criteria: having psychotic syptoms organic brain disorder having suicide thoughts based on interiew meeting critera for personality disorder

Intervention groups
Experiment group will recieve mindfulness- based relapse prevention group therapy within 8 sessions and usual teatments like methadone therapy, bupronorphine, or family therapy. contol group will recieve 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)

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+98 21 5542 1144

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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 maitenance therapy with methadone or buprenorphine more than 1 week and less than 24 weeks
Exclusion criteria:
having psychotic syptoms organic brain disorder having suicide thoughts based on interiew meeting critera 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 fo 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 commitee 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 questionarre
Timepoint
Before starting the treatment, after treatment, and 1 month after treatment.
Method of measurement
Using positive and negative perfectionism questionarre.

3

Description
scores in self-criticism questionarre
Timepoint
Before starting the treatment, after treatment, and 1 month after treatment.
Method of measurement
Using self criticism questionarre.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group contains patients with opioid use disorder that aftermeeting interance critera will enter the group. At first, patients will fill the qustionarres of shame, positive and negative perfectionism, self- criticism, and addiction severity index.Then they reieve the mindfulness based relapse prevention intervention whithin 8 sessions. This programe is combined of mindfulness skills and cognitive behavioral therapy. This group will also recieve usual treatments like methadone or bupronorphine therapy or single psychotherapies. At the end of the intervention and 1 month after that, questionarres will be reapeted.

Category

Behavior

2

Description

Control group: This group contains patients with opioid use disorder that aftermeeting interance critera will enter the group. At first, patients will fill the qustionarres of shame, positive and negative perfectionism, self-criticism, and addiction severity index.This group will recieve usual treatments like methadone or bupronorphine therapy or single psychotherapies.At the end of the intervention of intervention group and after 1 month later, control group will fill the questionarres 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

Street address

No. 486, South Karegar Ave, Qazvin Square

City

Tehran

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Tehran

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1336616357

Phone

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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

Street address

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

City

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Province

Tehran

Postal code

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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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Position
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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 copmletion 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