

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effectiveness of mindfulness based group therapy with usual in the individual reduction of risk factors for relapse in opioid addicted

Protocol summary

Summary

The aim of this quasi-experimental study is Comparison of the effectiveness of mindfulness based group therapy with usual in the individual reduction of risk factors for relapse in opioid addicted. The patients who have the opium abuse according to the psychiatric interventions are accepted based on the entry measures. Under study population are the patients who are dependent on the opium substances, provided in the Iranian National Center for Addiction Study to treatment with methadone with the accessible sampling method of 30 people who are the volunteer of the medical services and the entry measurements in a random way and 15 people in each group are studied as the treatment and control group. Each individual intervention is in 8 sessions one a week. The primary evaluation before the treatment is the pre-test and the entry measurements in two groups. The intervention group is based on mindfulness based group therapy in 8 treatment sessions. After interventions, the final evaluation and post-test and the treatment process are fully considered. The control group similar to the intervention group participates in the primary or pre-test evaluations and the final or post-test evaluations. This group would not receive the any other psychotherapy intervention or pharmaceutical treatment than the normal treatment in INCAS center. The evaluation occurs via alcohol and craving, alcohol and drug use consequences, mindfulness, acceptance, meditation practice, difficulties in emotion regulation scale, addiction severity index, depression, anxiety and stress scale questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031612826N1**

Registration date: **2013-06-28, 1392/04/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-28, 1392/04/07

Registrant information

Name

Saeed Imani

Name of organization / entity

Tehran University of Medical Sciences-Tehran
Psychiatric Institute

Country

Iran (Islamic Republic of)

Phone

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Email address

psychology2008@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-06-10, 1392/03/20

Expected recruitment end date

2013-07-21, 1392/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of mindfulness based

group therapy with usual in the individual reduction of risk factors for relapse in opioid addicted

Public title

Effectiveness of mindfulness based group therapy reduction of risk factors for relapse in opioid addicted

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having age between 15 to 40 years old; at least one study tips; having a history of opioid abuse and patients agreed to participate in research on informed consent. Exclusion criteria: psychotic symptoms; organic brain disorder; have serious thoughts about suicide, which may be impossible to participate in research.

Age

From **18 years** old to **40 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

Tehran University of Medical Sciences and Health Services

Street address

Keshavarz Blvd, Qods St, University of Central- Floor - Sixth

City

tehran

Postal code

Approval date

2012-12-30, 1391/10/10

Ethics committee reference number

130/2083/91/ص

Health conditions studied

1

Description of health condition studied

Opioid Dependence

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

Improvement in a situation of opiates, retention in treatment and ratio negative drug test for methamphetamine, morphine and benzodiazepines

Timepoint

Before treatment and after treatment

Method of measurement

The evaluation occurs via eligibility screening, alcohol and craving, alcohol and drug use consequences, mindfulness, acceptance, meditation practice, difficulties in emotion regulation scale, addiction severity index, depression, anxiety and stress scale questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Mindfulness based group therapy; receive 8 sessions (in addition to the primary and final evaluations). Mindfulness based group therapy sessions were held once per week, each session lasting 2 hours. Mindfulness based group therapy were performed based on Bowen, Chawala and Marlatt treatment Manual. Mindfulness based group therapy is provided by a doctoral student in clinical psychology.

Category

Prevention

2

Description

Control group did not receive treatment for eight weeks except treatment as usual INCAS and were evaluated only 2 times.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian National Center for Addiction Studies
Full name of responsible person
Dr. Ali Reza Nowrozi
Street address
City
Tehran

Email
psychology2008@gmail.com;
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Web page address

Person responsible for scientific inquiries

Contact

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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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Rahim Nia
Street address
St Ghods, Keshavarz blv.
City
Tehran
Grant name
123700
Grant code / Reference number
30121
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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Name of organization / entity
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Psychiatric Institute
Full name of responsible person
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PhD candidate in Clinical Psychology
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Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty