Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of group compassion focused therapy in opiate addicts under methadone maintenance treatment with a two-month follow-up

Protocol summary

Study aim
Determining the effectiveness of group compassion focused therapy in opiate addicts under methadone maintenance treatment

Design
The statistical population consisted of all opium addicts who referred to Iran Psychiatric Hospital in Tehran in 1398. From the selection of subjects according to the entry criteria, the subjects are assigned to experimental and control groups. Each group consists of 15 samples. Of course, considering the issue of dropping the subjects, the number of subjects is initially more than 15 people. All participants completed demographic questionnaires and the quality of life questionnaire and Beck Depression Inventory and the four-system anxiety scale at the beginning of the sessions and again at the end of the treatment session and again two months after the end of the sessions.

Settings and conduct
Iran Psychiatric Hospital

Participants/Inclusion and exclusion criteria
Entry Criteria: primary diagnosis of opiate dependence according to DSM5 criteria, being male, having 20 to 50 years of age, having a minimum level of education, a history of consuming medication, a minimum methadone treatment time of one day and a maximum of 6 months. Severe psychiatric and personality disorders

Intervention groups
group compassion focused therapy

Main outcome variables
Quality of Life - Anxiety - Depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141108019855N8**
Registration date: **2019-04-25, 1398/02/05**
Registration timing: **retrospective**

Last update: **2019-04-25, 1398/02/05**
Update count: **0**

Registration date
2019-04-25, 1398/02/05

Registrant information

Name
Samira Masumian

Name of organization / entity
Tehran Psychiatry Institue

Country
Iran (Islamic Republic of)

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+98 21 3349 6990

Email address
samira.masumian@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of group compassion focused therapy in opiate addicts under methadone maintenance treatment with a two-month follow-up

Public title
group compassion focused therapy in opiate addicts

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Primary and primary diagnosis of opioid dependence according to DSM5 criteria when entering methadone treatment Age 20 to 50
Exclusion criteria:
Age
From **20 years** old to **50 years** old
Gender
Male

Phase
1-2
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Through the lottery, Through the lottery so that the names of the patients are written in a sheet and selected by draw.
Blinding (investigator's opinion)
Single blinded
Blinding description
The main therapist and the assessing person from the groups are not known
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Next to Milad Tower- Hemat Highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2018-04-21, 1397/02/01
Ethics committee reference number
IR.IUMS.REC.1397.1075

Health conditions studied

1

Description of health condition studied
opioids use disorder
ICD-10 code
F11
ICD-10 code description
Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description
Anxiety
Timepoint
Before and after and 2 months after treatment
Method of measurement
Anxiety Quad System Scale

2

Description
Quality of Life
Timepoint
Before and after and 2 months after treatment
Method of measurement
World Health Organization Quality of Life Questionnaire

3

Description
Depression
Timepoint
Before and after and 2 months after treatment
Method of measurement
Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: group compassion focused therapy: The program is based on Gilbert's Guide in eight 90-minute sessions on a weekly basis:1) First session; explanation of the rules and familiarity with the work of the group; explaining and introducing the group to the logic of compassion-based therapy and the goals of treatment;2) second session; explaining the concept of self-compassion and its two bipolar components3) Session 3: Learning to distance and watch wisely, break the identity of the thoughts, change self-criticism to self-correction4) Fourth session; teaching attention, thinking, behavior and feeling comfortable5) Fifth Session; Wandering Minds, Transparent Images, Locations and

Incarnate Color Enhancements, Creating a Safe Place6) Sixth session; the mind of consciousness, attention and sensibility, consciousness and action mind, mindfulness and consciousness7) Seventh session; focusing on self-compassion toward others, expanding compassion towards oneself using memory, creating an amiable ideal8) Session eighth; overview of previous sessions, lessons and exercises, treatment termination

Category

Treatment - Other

2

Description

Control group: The control group receives their usual drug therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Hospital

Full name of responsible person

Samira Masumian

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Mansouri alley- Avenue praying- Street Sattarkhan

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Kazam Malakoti

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

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adminsite@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

30

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

Iran University of Medical Sciences

Full name of responsible person

Samira Masumian

Position

Clinical Psychologist

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Results should be published in the article
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The effectiveness of group compassion focused therapy in opiate addicts under methadone maintenance treatment with a two-month follow-up
When the data will become available and for how long
Year 1387
To whom data/document is available
Specialists and therapists
Under which criteria data/document could be used
For psychotherapy
From where data/document is obtainable
Researcher of the project
What processes are involved for a request to access data/document
By email researcher
Comments