

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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 Institute

Country

Iran (Islamic Republic of)

Phone

+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

۱۴۳۹۶۱۴۵۳۵

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

Street address

Mansouri alley- Avenue praying- Street Sattarkhan

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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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adminsitem@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

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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