

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the effectiveness of pharmacotherapy with venlafaxine versus Acceptance and Commitment Therapy (ACT) enriched with Compassion Focus Therapy (CFT) on depression, stress, and anxiety in addict patients undergoing Methadone Maintenance Therapy (MMT)

Protocol summary

Study aim

Comparison of the effectiveness of pharmacotherapy with venlafaxine versus Acceptance and Commitment Therapy (ACT) enriched with Compassion Focus Therapy (CFT) on depression, stress, and anxiety in addict patients undergoing Methadone Maintenance Therapy (MMT)

Design

This study is a quasi-experimental study with pre-test and post-test design. First, 60 addicts under methadone maintenance treatment will be selected by available sampling method and then randomly divided into three groups.

Settings and conduct

In addicts undergoing maintenance treatment with methadone referred to addiction treatment clinics in Yazd in 1398 will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria include the following: • Age range 20-45 years • Methadone has been used for at least 6 months. Exclusion criteria include the following: • Severe mental disorder such as psychosis • Existence of instant psychosis due to the use of psychotropic substances • Having chronic physical illnesses that affect mood and emotions • Simultaneous use of NA and similar classes • Use of opiates and morphine • Lack of regular participation in training classes • Not doing homework • Failure to complete the questionnaire in pre-test and post-test

Intervention groups

In the present study, patients will be divided into three groups. The first group: treatment based on acceptance and commitment + treatment based on compassion The second group: treatment based on acceptance and commitment + treatment based on compassion + treatment with venlafaxine Group 3: Treatment with

venlafaxine

Main outcome variables

Stress; Anxiety; Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N3**

Registration date: **2021-04-21, 1400/02/01**

Registration timing: **prospective**

Last update: **2021-04-21, 1400/02/01**

Update count: **0**

Registration date

2021-04-21, 1400/02/01

Registrant information

Name

Mohsen Zabihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3865

Email address

mzabihi100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of pharmacotherapy with venlafaxine versus Acceptance and Commitment Therapy (ACT) enriched with Compassion Focus Therapy (CFT) on depression, stress, and anxiety in addict patients undergoing Methadone Maintenance Therapy (MMT)

Public title

Evaluation of the effects of venlafaxine and Acceptance and Commitment Therapy (ACT) enriched with Compassion Focus Therapy (CFT) on depression, stress, and anxiety

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Duration of methadon use for at least the 6 months The age range of 20_45 years

Exclusion criteria:

Existence of severe mental disorder such as psychosis
Existence of instant psychosis due to psychotropic consumption. Simultaneous use of NA and similar classes. Having chronic physical illnesses that affect mood and emotions. Use of opiates and morphine
Not doing homework at home
Failure to complete the questionnaire in pre-test and post-test

Age

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

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the samples in each group, the subjects are divided into three groups A, B and C using the RAN() function of Excel software, and according to the type of intervention, drug use and participation in mental training classes. It is a treatment, there is no possibility of blindness, there is no intervener and the subjects, and only the statistical analyst does not know what kind of intervention was done by each 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**

thics committee of 'Shahid Sadoughi University of Medical Sciences

Street address

Alem sq.

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2020-11-10, 1399/08/20

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.170

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

in addict patients undergoing Methadone Maintenance Therapy

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

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

Depression, stress, and anxiety

Timepoint

Before and after treatment

Method of measurement

DASS-21

Secondary outcomes**1****Description**

Depression, stress, and anxiety

Timepoint

Before and after treatment

Method of measurement

DASS-21 questionnaire

Intervention groups

1

Description

Intervention group: Acceptance and commitment therapy plus Compassion Focus Therapy

Category

Other

2

Description

Intervention group: Acceptance and commitment therapy plus Compassion Focus Therapy plus treatment with venlafaxine

Category

Treatment - Drugs

3

Description

Intervention group: Venlafaxine

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction treatment clinics

Full name of responsible person

Dr. Mohsen Zabihi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd University of Medical Sciences

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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohsen Zabihi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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