Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ʾShahid 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
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3820 3419
Email
mzabihi100@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mohsen Mirzaie
Street address
Bahonar sq.
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3726 3733
Email
dvc.research@ssu.ac.ir
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
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8915173149
Phone
+98 35 3820 3419
Email
mzabihi100@gmail.com

Person responsible for scientific 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
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8915173149
Phone
+98 35 3820 3419
Email
mzabihi100@gmail.com

Person responsible for updating data

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
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8915173149
Phone
+98 35 3820 3419
Email
mzabihi100@gmail.com

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