

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effectiveness of pharmacotherapy with sertraline 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

Evaluation of the effects of sertraline and 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 1400.

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 sertraline Group 3: Treatment with sertraline

Main outcome variables

Stress - Anxiety - Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N1**

Registration date: **2021-04-14, 1400/01/25**

Registration timing: **prospective**

Last update: **2021-04-14, 1400/01/25**

Update count: **0**

Registration date

2021-04-14, 1400/01/25

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

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of pharmacotherapy with sertraline 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 sertraline 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

ethics committee of *Shahid Sadoughi University of Medical Sciences

Street address

Alem sq.

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Yazd

Province

Yazd

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Approval date

2020-11-10, 1399/08/20

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.171

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 score

Timepoint

28 days after intervention

Method of measurement

Examination of the patient and based on a standard questionnaire

Secondary outcomes

1

Description

depression, stress, and anxiety

Timepoint

Before and after treatment

Method of measurement

DASS-21

Intervention groups

1

Description

Intervention group: Acceptance and Commitment Therapy + Compassionate therapy, group-based acceptance and commitment sessions will be held in 8 1-hour sessions, once a week. The training course will last for two months. At the end of each session, a task is given. In this section, the titles and general structure of the sessions are briefly mentioned. The general framework of acceptance and commitment therapy sessions is based on Hayes et al.'s (1999) and Tohi (2007) Therapeutic Guidelines. The description of the sessions is as follows: Session 1: Familiarity with group members and establishing therapeutic relationship, determining the rules governing the therapy sessions, clarifying the therapeutic relationship, introducing and measuring emotion, starting creative helplessness and presenting homework, Session 2: reviewing homework and receiving feedback from Previous session (done in each session), Continuation of creative helplessness, metaphor of the hole and presentation of the task of the third session, introduction of control as a problem, discussion of the inner world and its difference with the outer world, metaphor of the polygraph and presentation of the task, fourth session : Introducing acceptance and desire as an alternative to control, guest metaphor and expression of pure and unclean feelings, Session 5: Familiarity with the hidden features of language that cause fusion, expression of fault, bus metaphor, Session 6: Introduction of its types, chess metaphor Introduction to the conceptualized past and future, Session 7: Moving towards a valuable life with a receptive and observant self, Identifying values and measuring the values of references, Session 8: Commitment to action and values despite obstacles, metaphor of seedlings, Evaluation of commitment to action, providing a permanent assignment, filling in a compassion-focused post-test: In this study, treatment-focused sessions Compassion will be held in 8 sessions of 120 minutes in a group and once a week. The treatment sessions were based on Gilbert's treatment plan (21). Description of compassion-focused therapy sessions: □ Session 1: Establishing a therapeutic relationship, familiarizing members with each other, explaining group rules, a brief explanation of CFT, a brief explanation of emotions, Training and implementation of mindfulness breathing exercises and homework □ Session 2: Review of the previous session's practice, introduction of three emotional regulation systems and how they interact with each other, familiarity with negative and threatening emotions from CFT perspective, the nature of compassion and homework □ Session Third: Reviewing the practice of the previous session, getting acquainted with the characteristics of people with compassion (kindness, empathy, tolerating distress, not judging), cultivating and understanding that others have flaws and problems, cultivating a sense of human commonality in the face of self-destructive feelings and shame, presentation Homework □ Session 4: Review of the previous session's practice, self-

compassion training (wisdom, strength, kindness, not judging yourself and responsibility), how to illustrate about self-compassion, self-compassion growth training and homework, session 5: Review the previous session practice, practice compassion skills (compassionate behavior, compassionate mental image, compassionate feeling) and empathy training, session Sixth: Reviewing the practice of the previous session, cultivating compassion for others, teaching forgiveness, focusing oneself compassionately on others □ Session 7: Training to accept problems and face different challenges and changes ahead, homework Reviewing the practice of the previous session, Identify thoughts that hinder the cultivation of compassion and work on them, learn to write compassionate letters, session eight: for yourself and others, do compassion color exercises, compassion sound and image, homework, review and practice the skills presented in the sessions Prior and summary concepts reviewed

Category

Other

2

Description

Intervention group: Intervention group: Acceptance and commitment therapy + Compassion Focus Therapy + treatment with Sertraline

Category

Treatment - Drugs

3

Description

Intervention group: Sertraline

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

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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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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