

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating the effectiveness of Unified transdiagnostic treatment on emotion regulation, distress tolerance, experiential avoidance, persistence on treatment in methadone maintenance

Protocol summary

Study aim

Determining the effectiveness of integrated transdiagnostic treatment on emotional regulation, emotional disturbance, distress tolerance, experiential avoidance and persistence in treatment in patients undergoing maintenance treatment with methadone

Design

A clinical trial with a control group, with an experimental group, randomized on 40 patients

Settings and conduct

This clinical intervention is performed in a psychiatric hospital in Iran.

Participants/Inclusion and exclusion criteria

- Being under maintenance treatment with methadone - Suffering from emotional problems based on questionnaires and interviews - Consent to participate in the research - Patients who take psychiatric drugs must be confirmed by the relevant psychiatrist that it is possible to keep the amount and type of drug constant during the research and that there are no risks for the patient. - Not having a personality disorder based on the interview - Absence of concurrent drug use based on urine test - Absence of acute psychiatric problems, including bipolar disorder and psychosis based on the interview

Intervention groups

The research sample consists of 40 of these people who meet the criteria for entering the study and are selected by available sampling method; These people are randomly placed in two experimental and control groups. After the pre-test, the experimental group will be treated and the control group will receive the usual treatments of the clinic. At the end of the intervention, the post-test will be performed on both experimental and control groups.

Main outcome variables

emotion regulation, emotional disturbance, distress

tolerance, experiential avoidance, persistence on treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230627058600N1**

Registration date: **2023-07-09, 1402/04/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-09, 1402/04/18**

Update count: **0**

Registration date

2023-07-09, 1402/04/18

Registrant information

Name

Zahra Mokhtari

Name of organization / entity

Semnan Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 31 4542 2861

Email address

zahra.m1369@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Unified transdiagnostic treatment on emotion regulation:distress tolerance, :experiential avoidance :persistence on treatment in methadone maintenance

Public title

Investigating the effectiveness of Unified transdiagnostic treatment on emotion regulation:distress tolerance, :experiential avoidance :persistence

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being under maintenance treatment with methadone- Suffering from emotional problems based on questionnaires and interviews- Consent to participate in the research- Patients who take psychiatric drugs must be confirmed by the relevant psychiatrist that it is possible to keep the amount and type of drug constant during the research and that there are no risks for the patient.- Not having a personality disorder based on the interview- Absence of concurrent drug use based on urine test- Absence of acute psychiatric problems, including bipolar disorder and psychosis based on the interview

Exclusion criteria:

Receiving any type of psychotherapy or medication at the same time for the desired emotional problems- History of receiving integrated metadiagnostic treatment- Two consecutive positive morphine urine tests within two weeks- Absence of more than a week- The person's unwillingness to continue the treatment process- Changes in the amount and type of psychiatric drugs during the research due to the worsening of the patient's symptoms or the presence of risks such as suicide, which should increase or change the amount and type of drugs

AgeFrom **18 years** old to **68 years** old**Gender**

Male

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

These people are randomly placed in two experimental and control groups. After the pre-test, the experimental group will be treated and the control group will receive the usual treatments of the clinic. At the end of the intervention, the post-test will be performed on both experimental and control groups. In this research, the

tap or line method is used for randomization to determine the intervention and control groups. This method is very simple and the researcher's opinion will not be involved in it. «نماد «مورد تأیید انجمن»

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Semnan Azad University

Street address

At the end of Army Highway, Qamar Bani Hashem, Block 10, Unit 23

City

Tehran

Province

Tehran

Postal code

11698613361

Approval date

2023-07-02, 1402/04/11

Ethics committee reference number

IR.IAU.SEMNAN.REC.1402.004

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

Emotion regulation, emotional disturbance, distress tolerance, persistence on treatment, experiential avoidance

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Score DASS-21

Timepoint

The measurement of DASS-21 is done on two occasions including before the intervention and at the end of the intervention.

Method of measurement

DASS 21 question questionnaire

2

Description

Experiential avoidance score in BEAQ questionnaire

Timepoint

before the beginning of the intervention and at the end of the intervention
«نماد «مورد تأیید انجمن»

Method of measurement

Experiential avoidance questionnaire-short form

3

Description

DTS questionnaire score

Timepoint

Before the start of the intervention and the end of the intervention

Method of measurement

DTS Distress Tolerance Questionnaire

4

Description

DERS questionnaire score

Timepoint

Before the start of the intervention and the end of the intervention

Method of measurement

DERS emotion dysregulation questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The research sample consists of 40 of these people who meet the criteria for entering the study and are selected by available sampling method; These people are randomly placed in two experimental and control groups. After the pre-test, the experimental group will be treated and the control group will receive the usual treatments of the clinic.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان روانپزشکی ایران

Full name of responsible person

Zahra Mokhtari

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At the end of Army Highway, Qamar Bani Hashem, Block 10, Unit 23.

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1698613361

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Email

zahra.m1369@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan Islamic Azad University

Full name of responsible person

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Email

zahra.m7457@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan Islamic Azad University

Proportion provided by this source

1

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

Semnan Islamic Azad University

Full name of responsible person

Zahra Mokhtari

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not 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

Part of the data

When the data will become available and for how long

Year 1403

To whom data/document is available

The results of this research can be used by other researchers, service providers and psychological treatment specialists in various organizations and institutions, including addiction treatment centers and psychological clinics.

Under which criteria data/document could be used

Researchers and students

From where data/document is obtainable

Zahra Mokhtari zahra.m1369@yahoo.com

What processes are involved for a request to access data/document

two months

Comments