Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Age
From **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 interventionنماد «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
Street address
At the end of Army Highway, Qamar Bani Hashem, Block 10, Unit 23.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan Islamic Azad University
Full name of responsible person
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Street address
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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
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

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Full name of responsible person
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Latest degree
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Other areas of specialty/work
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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