

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Examining the Effectiveness of Emotion Efficacy Therapy on Emotional Memory, Emotion Regulation Strategies, Rumination, and Relapse Tendency in Individuals with Substance Use Disorder Under Methadone Maintenance Treatment

Protocol summary

Study aim

To determine the effectiveness of Emotion Efficacy Therapy on emotional memory, emotion regulation strategies, rumination, and relapse tendency in individuals with substance use disorder undergoing methadone maintenance treatment.

Design

Randomized controlled trial, parallel-group, single-blind (assessor-blinded), with a control group and 1:1 allocation ratio. The sample size is estimated at 30 participants (15 per group). Simple randomization will be used. Data analysis will be performed based on intention-to-treat (ITT) using multivariate analysis of covariance (MANCOVA)

Settings and conduct

the study will be conducted in methadone maintenance treatment clinics in Ahvaz, Iran. two time points (pre-test and post-test) by an assessor psychologist who is blinded to group allocation

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ability to read, write, and attend sessions; providing informed consent; absence of severe mental illnesses (schizophrenia spectrum, bipolar I, severe personality disorders) based on DSM-5 clinical interview; meeting DSM-5 diagnostic criteria for substance use disorder; age 25–45 years; not receiving any concurrent psychological treatment; being treated with methadone for at least the past 3 months. Exclusion criteria: Developing severe psychological disorders during intervention; more than 2 absences from sessions; unwillingness to continue treatment; relapse of substance use (positive morphine test).

Intervention groups

Intervention group: Emotion Efficacy Therapy (EET) delivered in 8 weekly 90-minute sessions (based on McKay & West, 2016 protocol). Control group: Structured

psychoeducation (8 sessions of 90 minutes including general education on relapse prevention, stress management, and craving coping) for ethical considerations

Main outcome variables

Emotional memory (EMT); emotion regulation strategies (ERQ); rumination relapse tendency (RPS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260530069576N1**

Registration date: **2026-06-01, 1405/03/11**

Registration timing: **retrospective**

Last update: **2026-06-01, 1405/03/11**

Update count: **0**

Registration date

2026-06-01, 1405/03/11

Registrant information

Name

Nassim Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-01, 1404/12/10

Expected recruitment end date

2026-04-30, 1405/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the Effectiveness of Emotion Efficacy Therapy on Emotional Memory, Emotion Regulation Strategies, Rumination, and Relapse Tendency in Individuals with Substance Use Disorder Under Methadone Maintenance Treatment

Public title

Examining the Effectiveness of Emotion Efficacy Therapy on Emotional Memory, Emotion Regulation Strategies, Rumination, and Relapse Tendency in Individuals with Substance Use Disorder Under Methadone Maintenance Treatment

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ability to read, write, and attend sessions Having informed consent to participate in the research and completing the informed consent form Not having severe mental illnesses including schizophrenia spectrum disorders, bipolar type I, and severe personality disorders (assessed via clinical interview) Meeting diagnostic criteria for substance use disorder Being aged 25 to 45 years Not receiving any psychological treatment Being treated with methadone

Exclusion criteria:**Age**

From **25 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **30**

15 people in the intervention group and 15 people in the control group

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple (lottery). The names of all eligible and volunteer participants are written on identical separate pieces of paper. A person external to the research, who has no role in patient enrollment or assessment, randomly draws the names from a container

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, a single-blind (assessor-blind) method is used. Participants and the therapist cannot be blinded to the type of intervention due to the nature of group psychotherapy and skills training, which makes it impossible to conceal the treatment type from these two groups. However, the assessor responsible for data collection (a clinical psychologist) is completely blinded to group allocation (intervention or control). The assessor has no role in the treatment process and is unaware of the type of intervention received by each participant prior to conducting the post-test. Additionally, the statistical data analyst is also blinded to group allocation, as data are provided using numeric codes without any mention of group names. Thus, bias in outcome measurement and data analysis is minimized.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

کمیته اخلاق در پژوهش دانشکده پزشکی دانشگاه علوم پزشکی کرمانشاه

Street address

Taq-e Bostan Boulevard, Kermanshah University of Medical Sciences, Faculty of Medicine, Second Floor, Ethics Committee

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2026-02-01, 1404/11/12

Ethics committee reference number

IR.KUMS.MED.REC.1404.268

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

Substance Use Disorder

ICD-10 code

F19.2

ICD-10 code description

Other psychoactive substance dependence

Primary outcomes

1

Description

Emotional Memory

Timepoint

Pre-test (before the intervention) and post-test
(immediately after completion of treatment sessions)

Method of measurement

Emotional Memory Task

2

Description

Emotion Regulation Strategies

Timepoint

Pre-test (before the intervention) and post-test
(immediately after completion of treatment sessions)

Method of measurement

Emotion Regulation Questionnaire

3

Description

Rumination

Timepoint

Pre-test (before the intervention) and post-test
(immediately after completion of treatment sessions)

Method of measurement

Ruminative Responses Scale

4

Description

Relapse Tendency

Timepoint

Pre-test (before the intervention) and post-test
(immediately after completion of treatment sessions)

Method of measurement

Relapse Prediction Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Behavior

2

Description

Control group:

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital

Full name of responsible person

Nassim Rezaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

KUM

Street address

Kermanshah - Shahid Beheshti Boulevard - Central
Building of Kermanshah University of Medical
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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Nassim Rezaei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

داده‌های فردی شرکت‌کنندگان به صورت غیرقابل شناسایی (بدون نام و با کد عددی) شامل: نمرات پیش‌آزمون و پس‌آزمون متغیرهای حافظه هیجانی (آزمون حافظه هیجانی)، راهبردهای تنظیم هیجان (پرسشنامه و گرایش به عود (پرسشنامه RRS) نشخوار فکری (مقیاس ERQ)، به همراه اطلاعات دموگرافیک (سن، جنسیت، وضعیت تأهل، RPS) تحصیلات، مدت مصرف، مدت درمان با متادون). فایل راهنمای متغیرها و پروتکل مطالعه نیز ارائه خواهد شد. عنوان و جزئی

When the data will become available and for how long

Starting six months after publication of the main results (after manuscript acceptance and print) and continuing for 5 years.

To whom data/document is available

Researchers affiliated with recognized academic or research institutions (universities, research centers, teaching hospitals). Requests from industry (private companies) will be considered on a case-by-case basis if the proposed use aligns with research ethics.

Under which criteria data/document could be used

Data may be used solely for legitimate and ethical research purposes such as meta-analysis, independent

replication, verification of results, or secondary analyses related to substance use disorder, emotion regulation, and emotion efficacy therapies. Commercial use or any attempt to re-identify participants is prohibited. Requests must include a scientific proposal and approval from the requester's institutional ethics committee.

From where data/document is obtainable

Nassim Rezaei (corresponding researcher / MSc student) via email: Nassim.rre@gmail.com Alternatively, the principal investigator, Dr. Nasrin Jaberghaderi, can be contacted at: n_jg2004@yahoo.com Postal address: Department of Clinical Psychology, Faculty of Medicine, Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard, Kermanshah, Iran.

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

Requester sends a written request including a scientific proposal, approval from their institutional ethics committee, and a clear description of the intended use to the above emails. The request will be reviewed by the principal investigator and researcher within 2 weeks. If approved, the requester must sign a data use agreement (committing to no re-identification and no commercial use). After receiving the signed agreement, a download link for the de-identified data (Excel or CSV format) along with a data dictionary will be provided within 1 week. The entire process typically takes less than 1 month.

Comments