

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 902 390 8569

##### Email address

nassim.rre@gmail.com

##### 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

**Street address**

Sepidar

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6111111111

**Phone**

+98 21 1111 1111

**Email**

nassim.rre@gmail.com

## 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  
Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3835 8943

**Email**

daftarriyat@kums.ac.ir

**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**  
Psychology

**Street address**  
Sepidar

**City**  
Ahvaz

**Province**  
Khuzestan

**Postal code**  
۶۱۷۷۷۴۶۹۰

**Phone**  
+98 21 0000 0000

**Email**  
Re.nasim@yahoo.com

## Person responsible for scientific 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**  
Psychology

**Street address**  
Sepidar-mehrgan4

**City**  
Ahvaz

**Province**  
Khuzestan

**Postal code**  
6177111111

**Phone**  
00980000000000

**Email**  
nassim.rre@gmail.com

## Person responsible for updating data

### 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

Psychology

### Street address

Sepidar

### City

Ahvaz

### Province

Khuzestan

### Postal code

6111111111

### Phone

00980000000000

### Email

nassim.rre@gmail.com

## 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**