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
Khouzestan
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
daftarriasat@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
Khouzestan

Postal code
۶۱۷۷۷۷۴۶۹۰

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
Khouzestan

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
Khouzestan

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 جزیی

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