Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Unified Transdiagnostic Interventions on Experiential Avoidance, Emotion Regulation, and Treatment Sustainability in Individuals Undergoing Substance Abuse Treatment

Protocol summary

Study aim
Determining the Effectiveness of Unified Transdiagnostic Interventions on Experiential Avoidance, Emotion Regulation, and Treatment Sustainability in Individuals Undergoing Substance Abuse Treatment

Design
A randomized, controlled, parallel-group clinical trial will be conducted on 30 individuals undergoing substance abuse treatment. Participants will be randomly assigned to either the intervention group or the control group using a simple randomization method.

Settings and conduct
This study is being conducted at the Sina Substance Abuse Treatment Center in Semnan, involving individuals undergoing treatment for substance abuse who, following an initial assessment, are randomly assigned to either an intervention group or a control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18–60 years, diagnosis of substance use disorder, at least one month of maintenance treatment, and informed consent. Exclusion criteria: severe psychiatric or cognitive disorders, need for hospitalization or urgent psychiatric services, and concurrent use of substances or medications affecting cognitive and emotional states.

Intervention groups
In this study, the intervention group undergoes an integrated transdiagnostic intervention delivered in eight weekly, 90-minute sessions. The session content encompasses increasing awareness of emotional experiences, identifying maladaptive emotional and behavioral patterns, teaching emotion regulation skills, fostering acceptance of and exposure to emotions, and reducing experiential avoidance. The control group does not receive the specialized intervention and continues to receive their usual therapeutic services throughout the study.

Main outcome variables
Experiential avoidance, emotion regulation, and treatment durability.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260920071126N1**
Registration date: **2026-09-24, 1405/07/02**
Registration timing: **prospective**

Last update: **2026-09-24, 1405/07/02**
Update count: **0**
Registration date
2026-09-24, 1405/07/02

Registrant information
Name
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-10-22, 1405/07/30
Expected recruitment end date
2026-12-21, 1405/09/30
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Unified Transdiagnostic Interventions on Experiential Avoidance, Emotion Regulation, and Treatment Sustainability in Individuals Undergoing Substance Abuse Treatment

Public title

The Effect of Unified Transdiagnostic Interventions on Experiential Avoidance, Emotion Regulation, and Treatment Sustainability in Individuals Undergoing Substance Abuse Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Visiting and receiving treatment services at substance abuse treatment centers in the city of Semnan. Ages 18 to 60 Diagnosis of substance use disorder based on medical records At least one month of history receiving maintenance therapy Stability of physical and mental condition at the time of enrollment in the study Informed consent and willingness to participate in research Ability to comprehend material and complete research instruments Possessing the readiness and ability to attend intervention sessions regularly

Exclusion criteria:

Suffering from severe psychiatric disorders such as psychosis or severe bipolar disorder Presence of cognitive impairment or intellectual disability affecting the understanding and implementation of the intervention Urgent need for hospitalization or specialized psychiatric services Concomitant use of substances or medications that significantly affect an individual's cognitive and emotional state.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, eligible individuals will be randomly assigned to either the intervention or control group following initial assessments. A simple randomization method will be employed for this purpose. First, each participant will be assigned a unique identification number. These numbers will then be entered into the Random Allocation Software (RAS) to randomly assign participants to the intervention or control group. To maintain the independence of the allocation process and minimize the risk of bias, randomization will be performed by an individual independent of the intervention implementation team. This approach ensures that every participant has an equal chance of being assigned to either group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Semnan Branch

Street address

Islamic Azad University, University Town, Semnan

City

Semnan

Province

Semnan

Postal code

3513137111

Approval date

2026-08-31, 1405/06/09

Ethics committee reference number

IR.IAU.SEMNAN.REC.1405.075

Health conditions studied

1

Description of health condition studied

Opioid abuse

ICD-10 code

F11.1

ICD-10 code description

Opioid abuse

Primary outcomes

1

Description

Experiential avoidance

Timepoint

Before the start of the intervention and after the completion of the 8 intervention sessions

Method of measurement

Gámez et al.'s (2014) Brief Experiential Avoidance Questionnaire

2

Description
Emotion regulation
Timepoint
Before the start of the intervention and after the completion of the 8 intervention sessions
Method of measurement
Gross and John (2003) Emotion Regulation Questionnaire

3

Description
Treatment retention
Timepoint
From the start of maintenance treatment until treatment discontinuation by the participant
Method of measurement
The number of days of treatment retention, from initiation to discontinuation.

Secondary outcomes

1

Description
Substance craving
Timepoint
Before the start of the intervention and after the completion of the 8 intervention sessions
Method of measurement
Somoza et al.'s (1995) Substance Craving Questionnaire

2

Description
Substance cessation self-efficacy
Timepoint
Before the start of the intervention and after the completion of the 8 intervention sessions
Method of measurement
Bramson's Addiction Cessation Self-Efficacy Questionnaire (1999)

3

Description
Quality of life
Timepoint
Before the start of the intervention and after the completion of the 8 intervention sessions
Method of measurement
World Health Organization Quality of Life Questionnaire

Intervention groups

1

Description
Intervention group: The intervention group undergoes an integrated transdiagnostic intervention consisting of eight weekly, 90-minute sessions. This intervention is designed to reduce experiential avoidance, improve emotion regulation, and enhance treatment durability. The sessions focus on increasing individuals' awareness of their emotional experiences, thoughts, and behavioral patterns, as well as identifying maladaptive emotion regulation strategies. Subsequently, using transdiagnostic techniques, participants are taught skills related to acceptance and emotional exposure, the reduction of experiential avoidance, emotion regulation, and the modification of maladaptive patterns. In the final sessions, the acquired skills are reviewed, with an emphasis on consolidating and applying them in daily life and situations relevant to the treatment process.
Category
Treatment - Other

2

Description
Control group: Participants in this group will not receive any intervention from the researcher during the study and will simply benefit from the center's standard treatment services. No additional therapeutic or educational sessions will be conducted for this group, and their routine treatment process will continue unchanged.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Substance Abuse Treatment Center
Full name of responsible person
Majid Mazinani
Street address
No. 59, 11th East St., Modarres Blvd., Motahari Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Islamic Azad University, Semnan Branch

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
Islamic Azad University, Semnan Branch

Full name of responsible person
Fatemeh Shahjouei

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be available for sharing after the removal of participants' identifying information and confirmation that the data are fully anonymized.

When the data will become available and for how long

The data can be made available one week after the results are published.

To whom data/document is available

The data and documentation from this study will be accessible exclusively to researchers and specialists in fields related to substance abuse, psychology, behavioral sciences, and the treatment of substance use disorders who are affiliated with academic institutions, research centers, and reputable scientific organizations.

Under which criteria data/document could be used

The data and documentation may be used for study or research purposes, provided the source is cited.

From where data/document is obtainable

If the data is required, please contact fateme.shahjuiee@iau.ir via email.

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

Upon receipt and review of the request by the principal investigator, the data—accompanied by an undertaking not to publish the data without the principal investigator's name—will be sent to the requester within a maximum of one week.

Comments