Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of the effectiveness of Unified transdiagnostic group therapy (UP) and cognitive-behavioral group therapy (CBT) on reducing comorbid sleep problems, emotional disturbances, drug cravings and relapse prevention in Men with opioid use disorder living in Therapeutic Community (TC)

Protocol summary

Study aim
Comparison of the effectiveness of integrated transdiagnostic group therapy (UP) with cognitive-behavioral group therapy (CBT) on reducing sleep problems associated with drug dependence disorder in male patients treated in Therapeutic Community (TC) Comparison of the effectiveness of integrated transdiagnostic group therapy (UP) with cognitive-behavioral group therapy (CBT) on reducing emotional distress associated with drug dependence disorder in male patients treated in Therapeutic Community (TC) Comparison of the effectiveness of integrated transdiagnostic group therapy (UP) with cognitive-behavioral group therapy (CBT) on reducing craving in men with substance use disorder treated in Therapeutic Community (TC) Comparison of the effectiveness of integrated transdiagnostic group therapy (UP) with cognitive-behavioral group therapy (CBT) in preventing relapse in men with substance use disorder treated in Therapeutic Community (TC)

Design
tow arm parallel group (with control group) randomized trial

Settings and conduct
Using a convenient sampling method and based on entry and exit criteria, 45 people were selected .in Arshia Alborz TC .protocol training

Participants/Inclusion and exclusion criteria
No psychiatric disorder or specific medical disorders (such as head trauma, seizures, etc.) Age between 18 and 65 years Literacy at least up to the first year of high school Recording the amount and type of sleeping medication used Being under treatment for at least three months Willingness to participate in the study Starting treatment within the last month Assessment of substance use history and type or types of substance used

Intervention groups
Three groups of 15 people, including the UP group, the CBT group, and the usual treatment group in the centers

Main outcome variables
Reducing sleep problems, emotional disturbance, substance cravings, and preventing relapse

General information

Reason for update

Acronym
GCBT-GUP

IRCT registration information
IRCT registration number: **IRCT20251027067788N1**
Registration date: **2026-02-13, 1404/11/24**
Registration timing: **retrospective**

Last update: **2026-02-13, 1404/11/24**
Update count: **0**

Registration date
2026-02-13, 1404/11/24

Registrant information

Name
Tabassom Saeid par var

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-12-06, 1404/09/15
Expected recruitment end date
2026-01-05, 1404/10/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effectiveness of Unified transdiagnostic group therapy (UP) and cognitive-behavioral group therapy (CBT) on reducing comorbid sleep problems, emotional disturbances, drug cravings and relapse prevention in Men with opioid use disorder living in Therapeutic Community (TC)

Public title
The effectiveness of group therapy on opioid users undergoing treatment in Therapeutic Community
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Men with features of opioid use disorder in a Therapeutic Community Do not have a psychiatric disorder Have no history of specific medical disorders (such as head trauma, seizures, etc.) Literacy at least up to the first year of high school Recording the amount and type of sleeping medication used and being under treatment for at least three months in addiction treatment centers Willingness to participate in the study (informed consent) Treatment started within the last month Assessing substance use history and type(s) of substance used
Exclusion criteria:
Simultaneous use of multiple addictive substances Comorbidity with severe psychiatric disorders such as bipolar disorder, psychotic disorders, and other disorders that may overshadow the therapeutic relationship No motivation for treatment Mental retardation/disability Having a history of previous psychological interventions, especially CBT Diagnosis of a comorbid condition such as schizophrenia or bipolar disorder, or other conditions specifically other than impulsivity and sleep problems Changing the dosage of sleep medications
Age
From **18 years** old to **65 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization. Individual. Random number table.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
no

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی ایران
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No.131 Setani Ave . first square of Tehran pars /Tehran. Iran. t
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Postal code
1651699614
Approval date
2025-07-15, 1404/04/24
Ethics committee reference number
IR.IUMS.REC.1404.424

Health conditions studied

1

Description of health condition studied
Addiction
ICD-10 code
F11.2
ICD-10 code description
Opioid dependence, in remission

Primary outcomes

1

Description
Comorbid sleep problems are the scores that subjects obtain on the Morin Insomnia Severity Index (ISI) (1993). Emotional disturbance is the score that the subject receives on the Depression, Anxiety, Stress Scale (DASS, Lavibond & Lavibond, cited in Anthony et al., 1998). Craving is the score that participants obtain on the Drug Craving Questionnaire (DDQ) developed by Franken et al. (2002). Relapse prevention is actually the result that the

subject obtains on the Morphine Trial (TLC), such that a positive result indicates relapse and re-use, and a negative result indicates relapse prevention.

Timepoint

The beginning of the study, the end of the study (about two months), and the two-month follow-up after treatment.

Method of measurement

Drug Craving Questionnaire (DDQ). Morphine Test (TLC). Morin Insomnia Severity Index (ISI). Depression, Anxiety, Stress Scale (DASS). Unified Transdiagnostic Group Therapy (UP). Cognitive Behavioral Group Therapy (CBT). Psychiatric Symptom Checklist - Short Form (SCL-25). Structured Clinical Interview (SCID).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Unified transdiagnostic group therapy. This type of therapy identifies and targets factors that are common to multiple mental disorders. The 12-session protocol of Barlow et al. (2020; 2011) will be used. This protocol consists of 12 60-minute sessions.

Category

Behavior

2

Description

Intervention group 2: Cognitive-Behavioral Therapy (CBT) is a psychotherapy approach that uses a combination of cognitive and behavioral therapy methods in a group setting. The goal of this approach is to help individuals identify and change unhealthy thought and behavioral patterns and develop coping skills. This program consists of 12 sessions, each session lasting 60 minutes.

Category

Behavior

3

Description

Control group: Control group: Control group with normal and conventional treatments at the TC center.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arshia (Therapeutic Community)Comprehensive Addiction Treatment Center

Full name of responsible person

Dr. Ali Rafeeie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabassom Saeid par var

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?

No

Title of funding source

-

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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