Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Moderating Effects of Trauma Severity and Comorbid Major Depression on the Efficacy of Transdiagnostic Cognitive-Behavioral Therapy for Clinical Symptoms and Emotional Indicators in Veterans with Posttraumatic Stress Disorder: A Randomized Controlled Trial

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of transdiagnostic cognitive-behavioral therapy (TD-CBT) on the clinical symptoms and emotional indices of veterans with post-traumatic stress disorder (PTSD), while examining the moderating roles of trauma severity and comorbid major depressive disorder (MDD).

Design

A controlled clinical trial, with parallel groups, unblinded and randomized.

Settings and conduct

The study will be conducted at Isar Psychiatric Hospital in Ardabil without a placebo, and blinding will be done on the participants and the person who will assess the outcomes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: a diagnosis of PTSD established by a psychiatrist using the Structured Clinical Interview for DSM-5 (SCID-5); a score greater than 33 on the PTSD Checklist for DSM-5 (PCL-5); and stable psychotropic medication use during the preceding three months. Exclusion criteria: the presence of active psychosis, substance use, or concurrent participation in another form of psychotherapy.

Intervention groups

Transdiagnostic cognitive-behavioral therapy (CBT) is recognized as a transdiagnostic intervention that targets dimensional constructs and shared processes underlying emotional disorders. In this study, male veterans with post-traumatic stress disorder (PTSD) will be randomly assigned to either an intervention group or a control group. The intervention group will then receive transdiagnostic cognitive-behavioral therapy in 8–10 sessions, each lasting 90 minutes, delivered twice weekly under the supervision of a trained therapist, whereas the control group will receive no intervention. Following the intervention, both groups will undergo post-treatment assessments as well as 3-month and 6-month follow-up evaluations.

Main outcome variables

Trauma severity; major depression; emotion regulation; experiential avoidance and emotional reactivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250301064887N3**
Registration date: **2026-08-10, 1405/05/19**
Registration timing: **prospective**

Last update: **2026-08-10, 1405/05/19**
Update count: **0**

Registration date

2026-08-10, 1405/05/19

Registrant information

Name

Soran Khataie

Name of organization / entity

The University of Kurdistan

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01
Expected recruitment end date
2027-06-21, 1406/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Moderating Effects of Trauma Severity and Comorbid Major Depression on the Efficacy of Transdiagnostic Cognitive-Behavioral Therapy for Clinical Symptoms and Emotional Indicators in Veterans with Posttraumatic Stress Disorder: A Randomized Controlled Trial

Public title
The Effect of Transdiagnostic Cognitive-Behavioral Therapy on Improving Posttraumatic Stress Disorder in Veterans
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A diagnosis of PTSD established by a psychiatrist based on the Structured Clinical Interview for DSM-5 (SCID-5) A score greater than 33 on the Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) Stable psychotropic medication use during the previous three months Provision of written informed consent to participate in the treatment sessions
Exclusion criteria:
Current psychotic disorder or substance use disorder Concurrent participation in another form of psychotherapy
Age
From **40 years** old to **60 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be performed using the online Sealed Envelope randomization service. Given the total sample size of 60 participants and the presence of two study arms (intervention and control), block sizes will be selected as multiples of two (i.e., blocks of 2 and 4). Based on the generated randomization sequence and the predefined allocation codes, participants will be assigned to either the intervention group (A) or the control group (B).
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will employ a double-blind design, in which both the participants and the outcome assessors will be blinded to study group allocation. Participants will not be informed of their assigned treatment group and will receive only general information regarding the overall objectives of the study. Likewise, the outcome assessors will remain blinded to group allocation throughout the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of University of Mohaghegh Ardabili
Street address
University of Mohaghegh Ardabili, the end of University Street
City
Ardabil
Province
Ardabil
Postal code
1313156199
Approval date
2026-07-01, 1405/04/10
Ethics committee reference number
IR.UMA.REC.1405.025

Health conditions studied

1

Description of health condition studied
Post-Traumatic Stress Disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
Post-traumatic stress disorder score
Timepoint
Measuring the post-traumatic stress disorder before the intervention, after the intervention, three and six months

after the end of the intervention

Method of measurement

Post-traumatic stress disorder scale

2

Description

Major depression score

Timepoint

Measurement of major depression before the intervention, after the intervention, three and six months after the end of the intervention

Method of measurement

Beck depression inventory

3

Description

Trauma severity score

Timepoint

Measurement of trauma severity before intervention, after intervention, three and six months after the end of intervention

Method of measurement

Harvard trauma questionnaire

Secondary outcomes

1

Description

Emotion regulation score

Timepoint

Measurement of emotion regulation before the intervention, after the intervention, three and six months after the end of the intervention

Method of measurement

Difficulties in emotion regulation scale

2

Description

Experiential avoidance score

Timepoint

Measurement of experiential avoidance before the intervention, after the intervention, three and six months after the end of the intervention

Method of measurement

Acceptance and action questionnaire

3

Description

Emotional reactivity score

Timepoint

Measurement of emotional reactivity before the intervention, after the intervention, three and six months after the end of the intervention

Method of measurement

Emotional reactivity scale

Intervention groups

1

Description

Intervention group: transdiagnostic cognitive-behavioral therapy. For this group, the transdiagnostic cognitive-behavioral therapy of Barlow et al. (2017) will be used. This intervention will include 10 individual treatment sessions, each of which will last 90 minutes. Specifically, the goal of this protocol is reducing the intensity and frequency of negative emotions. Unified protocol is designed to accomplish this goal through emotion-focused education, awareness techniques, cognitive strategies, problem-solving and an array of behavioral strategies, including a full-range of exposure and activation techniques.

Category

Treatment - Other

2

Description

Control group: The group awaiting transdiagnostic cognitive-behavioral therapy. After the intervention group sessions are completed, transdiagnostic cognitive-behavioral therapy will be implemented as in intervention group number one.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isar psychiatric specialty hospital, Ardabil

Full name of responsible person

Mohammad Narimani

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Isar Psychiatric Specialty Hospital, Ataei Street, Next to Shorabil Recreational Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Mohaghegh Ardabili

Full name of responsible person

Mohtasham Mohebbi

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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
The University of Mohaghegh Ardabili

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
The University of Kurdistan

Full name of responsible person
Sanaz Eyni

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In general, personal information about participants' data is not shared. Rather, some of the information related to the main outcome of the study, namely the results of the participants' statistical data, is published.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

In general, researchers working in academic and scientific institutions, students, and professors are allowed to apply, and others are also allowed to apply, provided that ethical considerations are observed.

Under which criteria data/document could be used

In general, scientific research documentation is provided to university employees, professors, and students for the exchange of scientific information, but personal data is not provided to others due to compliance with professional ethics in research and non-abuse.

From where data/document is obtainable

Applicants must contact the researcher via email to receive documents and data. Researcher's details and email address" First and last name: Sanaz Eyni Email address: s.eyni@uok.ac.ir

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

First, the applicant must send an email to the researcher, and depending on the applicant's circumstances, a scientific commitment letter is obtained from the applicant to comply with professional ethics and avoid abuse, and then the research documentation and data are provided to the applicant.

Comments