# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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)

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**Recruitment status**

**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

**Street address**

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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University of Mohaghegh Ardabili, University Street

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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 scientific inquiries

**Contact**

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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**