

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### "The effectiveness of Prolonged Exposure Therapy for Post-Traumatic Stress Disorder (PTSD) in reducing symptoms and improving the quality of life of veterans and combatants of the Eight-Year Iran-Iraq War."

#### Protocol summary

##### Study aim

Determining the Effectiveness of Prolonged Exposure (PE) Therapy in Reducing Symptoms of Post-Traumatic Stress Disorder (PTSD) and Improving Quality of Life among Veterans of the Eight-Year Iran-Iraq War in Ardabil Province

##### Design

The study includes 3 individuals with post-traumatic stress disorder (PTSD) selected from the research population through purposive sampling.

##### Settings and conduct

With the introduction of the provincial deputy and research officer to the command of the military unit, the intervention site will be located in the Basirat building in the health section of the study unit.

##### Participants/Inclusion and exclusion criteria

Active-duty or retired military personnel with a history of war-related trauma. Having war-related Post-Traumatic Stress Disorder (PTSD) with a medical record and currently under pharmacological treatment. No history of receiving psychological treatments prior to entering the study. Ability to read and write. Patient's consent to participate in the study and signing the written informed consent form. Suffering from other major psychiatric disorders (excluding PTSD and comorbid symptoms of depression and anxiety), such as personality disorders, psychotic disorders, or substance and alcohol addiction. Having suicidal thoughts. Possessing non-therapeutic motivations (e.g., seeking secondary gains such as increasing disability benefits). Presence of severe medical conditions or physical injuries, such as spinal cord

##### Intervention groups

The treatment sessions are 12 sessions, weekly or twice a week, each session usually lasting 90 minutes, and the duration of treatment for each client will be 2 to 4 months. It will be conducted individually based on the PE

Prolonged Exposure Therapy (PE) protocol for PTSD developed by Foa et al.

##### Main outcome variables

Symptoms of Post-Traumatic Stress Disorder (PTSD).  
Quality of Life.

#### General information

##### Reason for update

##### Acronym

PET

##### IRCT registration information

IRCT registration number: **IRCT20250806066778N1**

Registration date: **2025-09-16, 1404/06/25**

Registration timing: **prospective**

Last update: **2025-09-16, 1404/06/25**

Update count: **0**

##### Registration date

2025-09-16, 1404/06/25

##### Registrant information

##### Name

Mohammad Amiri

##### Name of organization / entity

University of Tabriz

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 781 1797

##### Email address

amiri100370@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-09-22, 1404/06/31

**Expected recruitment end date**

2025-10-22, 1404/07/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

"The effectiveness of Prolonged Exposure Therapy for Post-Traumatic Stress Disorder (PTSD) in reducing symptoms and improving the quality of life of veterans and combatants of the Eight-Year Iran-Iraq War."

**Public title**

Evaluating the Effectiveness of Prolonged Exposure Therapy for Post-Traumatic Stress Disorder (PTSD) in Reducing Symptoms and Improving Quality of Life among Veterans of the Iran-Iraq War

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Active-duty or retired military personnel with a history of war-related trauma. Having war-related Post-Traumatic Stress Disorder (PTSD) with a medical record and currently under pharmacological treatment. No history of receiving psychological treatments prior to entering the study. Ability to read and write. Patient's consent to participate in the study and signing the written informed consent form.

**Exclusion criteria:**

Suffering from other major psychiatric disorders (excluding PTSD and comorbid symptoms of depression and anxiety), such as personality disorders, psychotic disorders, or substance and alcohol addiction. Having suicidal thoughts. Possessing non-therapeutic motivations (e.g., seeking secondary gains such as increasing disability benefits). Presence of severe medical conditions or physical injuries, such as spinal cord lesions, that would cause significant difficulties for the patient's attendance in therapy sessions.

**Age**

No age limit

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **5**

The intervention will be conducted individually, based on the Prolonged Exposure (PE) therapy protocol for Post-Traumatic Stress Disorder (PTSD) developed by Foa and colleagues, and will be administered by the researcher.

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Working Group of the Research Ethics Committee of the University of Tabriz

**Street address**

Tabriz, Oruj Square, University of Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166616471

**Approval date**

2025-07-22, 1404/04/31

**Ethics committee reference number**

IR.TABRIZU.REC.1404.078

**Health conditions studied****1****Description of health condition studied**

Post-Traumatic Stress Disorder - PTSD

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Percentage improvement (Scruggs and Mastropiri, 1998) in single-subject research designs is one of the quantitative indicators for measuring the effectiveness of interventions, which shows the amount of change in behavior or the dependent variable as a percentage compared to the baseline situation.

**Timepoint**

Effect size in single-subject research designs is a quantitative indicator used to measure the extent to which an intervention has an effect on the dependent treatment (the behavior or outcome under study) and its strength or change.

**Method of measurement**

In the present study, the 17-item version of the

Posttraumatic Stress Symptoms Scale (interview form) developed by Foa, Riggs, Danko, and Rothiam (1993) will be used.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In this study, the World Health Organization's 26-item short form of the Quality of Life Questionnaire (WHO-QOL-BREF) was used. The 17-item version of the Posttraumatic Stress Disorder Scale (interview form) developed by Foa, Riggs, Danko, and Rothiam (1993) will be used. An information session, and obtaining written consent and answers to possible questions from participants, 12 treatment sessions, which are weekly or twice a week, with each session usually lasting 90 minutes. No medication will be used in the treatment. The psychotherapy process is based on 4 important components of long-term exposure, namely psychoeducation, visual exposure, real exposure, and emotional processing, based on the treatment protocol presented by Foa et al.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

military unit

##### Full name of responsible person

Mohammad Amiri

##### Street address

Daneshgah Street, Daneshgah Square, Ardabil  
University of Medical Sciences, Central Headquarters

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5615871897

##### Phone

+98 914 451 1797

##### Email

amiri100370@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of Tabriz

##### Full name of responsible person

Professor Abbas Bakhshipour

#### Street address

Tabriz, 29 Bahman Boulevard, University

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166616471

#### Phone

+98 41 3334 0081

#### Email

bakhshipour@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

I have no financial resources

#### Proportion provided by this source

1

#### 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

Ardabil University of Medical Sciences

##### Full name of responsible person

Mohammad Amiri

##### Position

Head of the Student Counseling and Mental Health  
Department at Ardabil University of Medical Science

##### Latest degree

Master

##### Other areas of specialty/work

Psychology

##### Street address

Daneshgah Street, Daneshgah Square, Ardabil  
University of Medical Sciences Headquarters

##### City

Ardabil

##### Province

Ardabil

##### Postal code

8599156189

##### Phone

+98 45 3353 4722

##### Email

amiri100370@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University of Tabriz

**Full name of responsible person**

Professor Abbas Bakhshipour

**Position**

Full Professor, University of Tabriz

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Tabriz, 29 Bahman Boulevard, University of Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166616471

**Phone**

+98 41 3334 0081

**Fax**

+98 41 3334 0081

**Email**

bakhshipour@gmail.com

**Web page address****Email**

amiri100370@gmail.com

**Web page address**

<https://www.heyvagroup.com/blog/84808/%D8%B3%D8%A7%DB%8C%D8%AA-%D8%AF%D8%A7%D9%86%D8%B4%DA%AF%D8%A7%D9%87-%D8%AA%D8%A8%D8%B1%DB%8C%D8%B2.html>

## 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**

Stress is one of the factors threatening mental health and was one of the consequences of the eight-year Sacred Defense war in Iran. As research has shown, even more than forty years after the end of the war, many veterans or combatants (disabled war veterans) still suffer from post-traumatic stress disorder (PTSD). The most common symptoms among them are increased arousal and reactivity. Therefore, paying attention to this issue is still necessary and there is more work to be done.

**When the data will become available and for how long**

The preliminary studies for this project started in 2023 and, God willing, will be available by mid-2026.

**To whom data/document is available**

Respected university professors and those who want to provide services to the warriors and veterans of the eight years of sacred defense

**Under which criteria data/document could be used**

If the intended goals are to help improve the quality of life of veterans and fighters of the eight years of sacred defense.

**From where data/document is obtainable**

Website of the Vice Chancellor for Research and Research Technology of Ardabil University of Medical Sciences

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

By visiting the website of the Vice President for Research and Research Technology of Ardabil University of Medical Sciences

**Comments**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Mohammad Amiri

**Position**

Head of the Student Counseling and Mental Health Department at Ardabil University of Medical Science

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

Daneshgah Street, Daneshgah Square, Ardabil University of Medical Sciences Headquarters

**City**

Ardabil

**Province**

Ardabil

**Postal code**

8599156189

**Phone**

+98 45 3353 4722

**Fax**

+98 45 3353 4773