Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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
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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 is 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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

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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
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