

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effectiveness of Trauma-Focused Cognitive-Behavioral Therapy on PTSD Symptoms in Women Victims of Iraq War

Protocol summary

Study aim

Effectiveness of Trauma-Focused Cognitive-Behavioral Therapy on PTSD Symptoms in Women Victims of Iraq War

Design

The research has two groups of control and experimental, in parallel and one-way blind (study participants) and simple randomization by computer random code algorithm.

Settings and conduct

The study will be conducted in the Iraqi province of Sulaymaniyah, and the participants in this study will be employed by the Jian Institute for Human Rights. This research will be pre-test-post-test. The research will be conducted with informed written consent, confidentiality of data, freedom to discontinue treatment, non-conflict of interest in clinical research and other important ethical points of research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: PTSD diagnosis based on DSM-5 criteria; Having symptoms of depression; Having at least a high school education; The age range is between 18 and 50 years and no psychotherapy has been received in the last six months. Exclusion criteria: pathological compatibility with other psychiatric disorders; Having psychotic symptoms; intellectual disability; Existence of personality disorders.

Intervention groups

The control group will not receive any intervention; But the experimental group will receive 12 90-minute weekly intervention sessions that are pre-prepared as a protocol.

Main outcome variables

The effect of trauma-focused cognitive-behavioral therapy on symptoms of anxiety, depression, emotion regulation strategies in Sinhala women victims of the Iraq war; Fear, helplessness and panic and quality of life of Shengali women victims of the Iraq war.

General information

Reason for update

Due to the termination of the disease before the registration of the trial, the exact number of samples is corrected; Also, the groups are assigned by a random computer code algorithm, which is incorrectly expressed in the form of a sealed envelope, and is corrected in this update. Also, the date of illness and the end of the trial have been corrected and stated.

Acronym

PTSD

IRCT registration information

IRCT registration number: **IRCT20200216046517N1**

Registration date: **2020-07-27, 1399/05/06**

Registration timing: **retrospective**

Last update: **2020-08-08, 1399/05/18**

Update count: **1**

Registration date

2020-07-27, 1399/05/06

Registrant information

Name

Reza Didehban

Name of organization / entity

The University of Kurdistan

Country

Iran (Islamic Republic of)

Phone

+98 25 3887 1052

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reza.didehbann@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2019-11-21, 1398/08/30
Actual recruitment start date
 2019-10-22, 1398/07/30
Actual recruitment end date
 2019-11-21, 1398/08/30
Trial completion date
 2020-03-10, 1398/12/20

Scientific title
 Effectiveness of Trauma-Focused Cognitive-Behavioral Therapy on PTSD Symptoms in Women Victims of Iraq War

Public title
 Effectiveness of Trauma-Focused Cognitive-Behavioral Therapy on PTSD Symptoms

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 War Trauma Not receiving psychotherapy for the past six months Depression Diagnosis of PTSD based on DSM-5 criteria Having at least a high school education Age range between 18 and 50 years
Exclusion criteria:
 Pathological association with other psychiatric disorders Psychotic symptoms intellectual disability Personality disorders

Age
 From **18 years** old to **50 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **60**
 Actual sample size reached: **48**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization: In this study, to randomly assign participants to two groups of 30, the Random function in MATLAB software was used to generate random numbers between 0 and 1; If the random numbers generated were less than 0.5, the person was placed in the experimental group and if it is more than 0.5, the person was placed in the control group. It should be noted that after the completion of the study, an intervention was made for the control group to observe research ethics.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 One-way blinding: In this study, only participants (subjects) in both experimental and control groups are kept blind and have no information that there are two groups of control and experimental and do not have the type and form of intervention; Also, at each stage of pre-test, post-test and intervention (for the experimental group), they will not be given any additional information

about the research. For example, those in the experimental group who have been intervened do not know that they have been intervened and that the class or workshop they are in is the same as the intervention; The control group, like the experimental group, does not know that there is an intervention and completing the questionnaire in the pre-test and post-test is just to collect some information.

Placebo
 Not used
Assignment
 Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Kurdistan (UOK)

Street address

University of Kurdistan, Pasdaran St, Sanandaj, Kurdistan

City

Sanandaj

Province

Kurdistan

Postal code

۶۶۱۷۷-۱۵۱۷۵

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.UOK.REC.1399.017

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

Timepoint

Before the intervention - after the intervention - one month after the intervention (follow-up)

Method of measurement

Structured Clinical Interview for DSM-5 (SCID-5) - PTSD Checklist-5 - War-Related Trauma - Life Events Checklist

- The Patient Health Questionnaire - Difficulties in Emotion Regulation Scale (DERS) - WHOQOL-BREF - The Depression, Anxiety, and Stress Scales with 21 items

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Shengali women victims of the Iraq war. The method of conducting the research will be that initially the pre-test will be performed by research assistants on all members of both groups; Then TF-CBT intervention (including 12 sessions of 90 minutes per week) is performed on one group (experimental group) and therapeutic intervention is not performed on the control group. At the end of the intervention sessions, the research tools in the post-test phase are immediately implemented again for the members of both groups and their scores are compared with their previous scores according to the dependent variables of the research.

Category

Treatment - Other

2

Description

Control group: Shengali women victims of the Iraq war. The method of conducting the research will be that initially the pre-test will be performed by research assistants on all members of both groups; Since no intervention is performed on the control group, after the intervention on the experimental group, post-test is performed on both groups simultaneously. Research tools in the post-test stage are immediately implemented for members of both groups and their scores are compared with their previous scores in terms of research-dependent variables.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Jian Institute for Human Rights

Full name of responsible person

Ako Mohammad

Street address

Jian Institute; next to the industrial town, Shores, Chamchamal, Soleimaniyeh, Iraq

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Chamchamal

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Kurdistan

Full name of responsible person

Mahdi Zemestani

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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 Kurdistan

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

Mahdi Zemestani

Position

Associate professor

Latest degree

Ph.D.

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

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

Title and more details about the data/document

All research data

When the data will become available and for how long

Simultaneously with the release

To whom data/document is available

All researchers and enthusiasts

Under which criteria data/document could be used

Only with the permission of researchers

From where data/document is obtainable

The person responsible for the general response of the trial The person responsible for the scientific accountability of the study The person responsible for updating the information

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

Send request via email

Comments