

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 2026

Comparing the effectiveness of Acceptance-Based Behavioral Therapy and pharmacotherapy in Posttraumatic stress disorder (PTSD)

Protocol summary

Study aim

The purpose of this study was to compare the effectiveness of Acceptance-Based Behavioral Therapy and pharmacotherapy in Post-traumatic stress disorder (PTSD).

Design

The present study is a randomized clinical trial conducted from August 4 to December 27, 2017 in Sadr and Baqiyatallah Hospital in Tehran, Iran. The statistical population of the study consisted of war-related PTSD patients who referred to the hospitals in Baqiyatallah and Sadr Hospitals in Tehran. The research sample was selected on the basis of previous research and using the formula for estimating the sample size of 41 people. In order to calculate the sample size, the test power 80% and the significance level 95% was considered. After the psychiatric interview, based on psychiatric diagnostic criteria (DSM-5) by a psychiatrist and a structured clinical interview with SCID-I and II, the subjects were randomly by random numbers assigned to two experimental groups (ABBT with pharmacotherapy) and a control group (pharmacotherapy).

Settings and conduct

After coordination with Sadr and Baqiyatallah Hospital in Tehran, Iran medical sessions start. , ABBT was performed in 12 individual sessions for 45 minutes, based on the guidelines for the development of the Roemer and Orsillo Psychological Disorders Protocol, which was coordinated by the present study authors for PTSD. ABBT's setting agenda is: session1: Implementation of pre- test included Assessment of the severity of the symptoms of PTSD, experiential avoidance, quality of life, and valuable life. Introducing Acceptance-Based Behavioral Therapy, assessment of One's Relationship with Internal Experiences, Challenging the control of negative thoughts and emotions (control as the problem: creative hopelessness) and the Destructive Effects of Experiential Avoidance, Introductory Breathing Exercise, Introduction to self-

monitoring. session 2-4: Introducing Mindfulness and Cognitive defuse, To teach mindfulness exercises included: Body scan practice, The Three Minute Breathing Space and Mindfulness practice in everyday life. session 5-7: Introducing Values and Values-Driven Behavior, Assessment of Values, Goals, Actions, and Barriers, Increasing Engagement in Valued Activities. session 8-10: Introducing Acceptance and Enhancing Commitment, Cultivating Acceptance through Mindfulness skills and metaphors. session 11-12: Maintaining and Enhancing Mindfulness, Acceptance, and Commitment, implementation of post- test included Assessment of severity of the symptoms of PTSD, experiential avoidance, quality of life, and valuable life.

Participants/Inclusion and exclusion criteria

Samples were Patients referring to Sadr and Baqiyatallah Hospital. This study inclusion criteria were: the diagnosis of PTSD type of war, the lack of psychological treatment for at least one month before entering the study, having a minimum age of 18 and a maximum of 60 years, and the ability to read and write. Exclusion criteria were: having psychotic symptoms and substance abuse, having suicidal thoughts and having severe personality disorders.

Intervention groups

The intervention and control group of PTSD patients is referred to the Sadr and Baqiyatallah Hospital. on average, they were in the Iran-Iraq war for three years. All subjects received medication at least 3 months ag. Pharmacotherapy (experimental and control group) was supervised by the psychiatrist for both groups. Each group received 50 to 200 mg of sertraline or fluoxetine 20 to 80 mg per day. The intervention group received ABBT and Pharmacotherapy at the same time. The control group received only Pharmacotherapy .

Main outcome variables

the severity of the symptoms of PTSD, experiential avoidance, quality of life, and valuable life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170409033333N2**

Registration date: **2018-01-24, 1396/11/04**

Registration timing: **retrospective**

Last update: **2018-01-24, 1396/11/04**

Update count: **0**

Registration date

2018-01-24, 1396/11/04

Registrant information

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Hadi Ghazanfari

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-04, 1396/05/13

Expected recruitment end date

2017-12-27, 1396/10/06

Actual recruitment start date

2017-08-04, 1396/05/13

Actual recruitment end date

2017-12-27, 1396/10/06

Trial completion date

empty

Scientific title

Comparing the effectiveness of Acceptance-Based Behavioral Therapy and pharmacotherapy in Posttraumatic stress disorder (PTSD)

Public title

Comparing the effectiveness of Acceptance-Based Behavioral Therapy and pharmacotherapy in Posttraumatic stress disorder (PTSD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

the diagnosis of PTSD type of war the lack of psychological treatment for at least one month before entering the study having a minimum age of 18 and a maximum of 60 years and the ability to read and write

Exclusion criteria:

having psychotic symptoms and substance abuse having suicidal thoughts having severe personality disorders

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **41**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

by random numbers table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran.

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Province

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Postal code

14665-354

Approval date

2017-08-02, 1396/05/11

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9221521201

Health conditions studied

1

Description of health condition studied

Post traumatic stress disorder (PTSD)

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description

the severity of the symptoms of PTSD

Timepoint

pretest and posttest

Method of measurement

questionnaire (Davidson Trauma Scale (DTS))

2

Description

experiential avoidance

Timepoint

pretest and post test

Method of measurement

questionnaire (Action and acceptance questionnaire (AAQ))

3

Description

quality of life

Timepoint

pretest and post test

Method of measurement

questionnaire(Quality of life questionnaire (SF-36))

4

Description

Valued living questionnaire

Timepoint

pretest and post test

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: experimental group received ABBT in 12 individual sessions for 45 minutes, based on the guidelines for the development of the Roemer and Orsillo Psychological Disorders Protocol, which was coordinated by the present study authors for PTSD. : session1: Implementation of pre- test included Assessment of the severity of the symptoms of PTSD, experiential avoidance, quality of life, and valuable life. Introducing Acceptance-Based Behavioral Therapy, assessment of One's Relationship with Internal Experiences, Challenging the control of negative thoughts and emotions (control as the problem: creative hopelessness) and the Destructive Effects of Experiential Avoidance, Introductory Breathing Exercise, Introduction to self-monitoring. session 2-4: Introducing Mindfulness and

Cognitive defuse, To teach mindfulness exercises included: Body scan practice, The Three Minute Breathing Space and Mindfulness practice in everyday life. session 5-7: Introducing Values and Values-Driven Behavior, Assessment of Values, Goals, Actions, and Barriers, Increasing Engagement in Valued Activities. session 8-10: Introducing Acceptance and Enhancing Commitment, Cultivating Acceptance through Mindfulness skills and metaphors. session 11-12: Maintaining and Enhancing Mindfulness, Acceptance, and Commitment, implementation of post- test included Assessment of severity of the symptoms of PTSD, experiential avoidance, quality of life, and valuable life.

Category

Behavior

2

Description

Control group: The control group received only pharmacotherapy at the same time as the experimental group. Pharmacotherapy was supervised by the psychiatrist for both groups. Each group received 50 to 200 mg of sertraline or fluoxetine 20 to 80 mg per day. All subjects received medication at least 3 months ago.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadr Psychiatric Hospital

Full name of responsible person

Hadi ghazanfari

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Sponsors / Funding sources

1

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Name of organization / entity

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Full name of responsible person

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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

Iran University of Medical Sciences

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 scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Hadi ghazanfari

Position

PhD student

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

Research article

When the data will become available and for how long

2018

To whom data/document is available

free

Under which criteria data/document could be used

For use in evidence-based treatments

From where data/document is obtainable

email: ghazanfari.hadi67@gmail.com

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

Hadi ghazanfari

Comments