Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Name
Hadi Ghazanfari
Name of organization / entity
Iran univercity of medical of iran
Country
Iran (Islamic Republic of)
Phone
+98 21 6655 1616
Email address
ghzanfari.h@tak.iums.ac.ir

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.
City
Tehran
Province
Tehran
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
Street address
Baradaran Ave., Shahid Ayatollah Sadr highway, Sadr Psychiatric Hospital
City
Tehran
Province
Tehran
Postal code
14665-354
Phone
+98 21 2254 9750
Fax
+98 21 2254 9750
Email
ghazanfari.hadi67@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seid kazam malakouti

Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
14665-354
Phone
+98 21 8867 3423
Fax
+98 21 8867 3323
Email
ghazanfari.hadi67@gmail.com

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 general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hadi ghaznafari
Position
Ph D student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Tehran; Shahid Hemmat Highway, Next to the Milad Tower, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
14665-354
Phone
+98 21 6655 1616
Fax
+98 21 6655 1616
Email
ghazanfari.hadi67@gmail.com

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
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
14665-354
Phone
+98 21 2254 9750
Fax
+98 21 6655 1616
Email
ghazanfari.hadi67@gmail.com
Web page address
http://iums.ac.ir/

Person responsible for updating data

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
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
123456789
Phone
+98 21 8676 3452
Email
Ghazanafari.hadi67@gmail.com
Web page address
http://iums.ac.ir/

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