

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effects of cognitive behavioral therapy and acceptance and commitment therapy on cognitive flexibility, executive function, anxiety, depression, and quality of life of patient and caregiver in patients with major depressive disorder after traumatic brain injury

Protocol summary

Study aim

Determining the effect of two cognitive-behavioral therapeutic approach and an acceptance and commitment-based therapy model on psychological flexibility, executive functions, depression, anxiety, quality of life associated with health related to patient and caregiver in patients with major depression after traumatic brain injury

Design

A clinical trial with a control group, sample size 60 people, with parallel groups of three groups of 20 people, single blind, randomized by random numbers table.

Settings and conduct

Trauma Research Center of Kashan University of Medical Sciences

Participants/Inclusion and exclusion criteria

Having MDD diagnosis after TBI means having P-TBI-MDD diagnosis

Intervention groups

Cognitive-behavioral group therapy (CBT): A treatment that will be done according to the 12-hour protocol that has been adapted from Bieling et al Acceptance and Commitment Therapy Model (ACT): An intervention that will be implemented according to the protocol of 12 sessions proposed by Robert D. Zettle Control group: No therapies will be received and members will discuss their problems in several sessions

Main outcome variables

Psychological flexibility; executive functions; Patient's anxiety and depression and quality of life; caregiver's anxiety and depression and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190115042371N1**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **retrospective**

Last update: **2019-02-19, 1397/11/30**

Update count: **0**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

Ali Faghihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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faghihi-a@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-27, 1397/07/05

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-09-27, 1397/07/05

Actual recruitment end date

2018-12-18, 1397/09/27

Trial completion date

2019-06-20, 1398/03/30

Scientific title

Comparison of the effects of cognitive behavioral therapy

and acceptance and commitment therapy on cognitive flexibility, executive function, anxiety, depression, and quality of life of patient and caregiver in patients with major depressive disorder after traumatic brain injury	
Public title	Comparison of the effects of cognitive behavioral therapy and acceptance and commitment therapy in major depressive disorder after traumatic brain injury
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Having MDD diagnosis after TBI means having a P-TBI-MDD diagnosis Duration of TBI between one and four years informed consent Ages 18 to 45 years Have at least 8 years of education Lack of alcohol, substance, or drugs abuse Not having dementia and delirium and mental disorders other than major depression Exclusion criteria: Dissuading from participating in research Abuse of alcohol, substance, or drugs after engaging in research Having a disease or problems affecting function and mental health after engaging in research Get absent in more than 2 sessions
Age	From 18 years old to 45 years old
Gender	Both
Phase	N/A
Groups that have been masked	Participant
Sample size	Target sample size: 60 Actual sample size reached: 60
Randomization (investigator's opinion)	Randomized
Randomization description	The list of patients suffering from brain injury was given to us through the medical records unit. Then all these people were coded. Subsequently, with the help of a random number table, sixty of these people are selected and then in the same way, they are divided into three groups (n=20).
Blinding (investigator's opinion)	Single blinded
Blinding description	Each group visits the hospital for treatment at different hours of the day, while the identity of the individuals in each group is hidden for other groups.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethical Committee of Kashan University of Medical Sciences
Street address	Ethics Committee of Kashan University of Medical Sciences, Ghotb Ravandi Boulevard, Kashan
City	Kashan
Province	Isfahan
Postal code	3713979671
Approval date	2018-06-25, 1397/04/04
Ethics committee reference number	IR.KAUMS.MEDNT.REC.1397.024
Health conditions studied	
1	
Description of health condition studied	Traumatic brain injury
ICD-10 code	S00-S09
ICD-10 code description	Injuries to the head
2	
Description of health condition studied	Major depressive disorder
ICD-10 code	F32
ICD-10 code description	Depressive episode
Primary outcomes	
1	
Description	Psychological flexibility
Timepoint	Before the intervention, in the middle of intervention, after intervention, three months after the intervention
Method of measurement	Acceptance and Action Questionnaire - II (AAQ-II)
2	
Description	Executive functions
Timepoint	Before the intervention, in the middle of intervention, after intervention, three months after the intervention
Method of measurement	

Wisconsin Card Sorting Test and Tower of London test

3

Description

Anxiety

Timepoint

Before the intervention, in the middle of intervention, after intervention, three months after the intervention

Method of measurement

Beck Anxiety Inventory, and Depression Anxiety and Stress Scales 21

4

Description

Depression

Timepoint

Before the intervention, in the middle of intervention, after intervention, three months after the intervention

Method of measurement

Beck Depression Inventory-II, and Depression Anxiety and Stress Scales 21

5

Description

Quality of Life

Timepoint

Before the intervention, in the middle of intervention, after intervention, three months after the intervention

Method of measurement

Quality of Life after Brain Injury

Secondary outcomes

1

Description

Problem solving

Timepoint

Before the intervention, in the middle of intervention, after intervention, three months after the intervention

Method of measurement

Wisconsin Card Sorting Test

2

Description

Planning

Timepoint

Before the intervention, in the middle of intervention, after intervention, three months after the intervention

Method of measurement

Tower of London test

3

Description

Caregiver anxiety

Timepoint

Before the intervention, after intervention, three months after the intervention

Method of measurement

Depression Anxiety and Stress Scales 21

4

Description

Caregiver depression

Timepoint

Before the intervention, after intervention, three months after the intervention

Method of measurement

Depression Anxiety and Stress Scales 21

5

Description

Caregiver quality of life

Timepoint

Before the intervention, after intervention, three months after the intervention

Method of measurement

Short Form Health Survey (SF-12)

Intervention groups

1

Description

Intervention group 1: Cognitive-behavioral group therapy (CBT). A treatment that will be done according to the 14-sessions protocol that has been adapted from Bieling et al

Category

Behavior

2

Description

Intervention group 2: Acceptance and Commitment Therapy model (ACT). An intervention that will be implemented according to the protocol of 12 sessions proposed by Robert D. Zettle

Category

Behavior

3

Description

Control group: No therapies will be received and members will discuss their problems in several sessions

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Trauma Research Center, Kashan University of Medical Sciences

Full name of responsible person

Dr. Esmaeil Fakharian

Street address

Shahid Beheshti Hospital, Kashan University of
Medical Sciences, Kashan, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamid Reza Banafshe

Street address

Ghotb Ravandi Boulevard, Kashan University of
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Web page address

<http://research.kaums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Ali Faghihi

Position

clinical psychology master student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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