Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 all 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

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Iran (Islamic Republic of)

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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
Isfehan

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 all
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

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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
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