

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effect of cognitive-behavioral therapy and treatment based on acceptance and commitment on family functioning, care burden, quality of life, experiential avoidance, anxiety, depression and stress in informal caregiver patients with traumatic brain injury.

Protocol summary

Study aim

Comparison of the Effect of Cognitive-Behavioral Therapy and Acceptance and Commitment-Based Therapy on Family Emotional and Behavioral Factors and unofficial Caregivers of Patients with Brain Injury

Design

The clinical trial has two groups of intervention and one control group, with parallel groups, randomized

Settings and conduct

Sixty people who are caring for an individual who are diagnosed with brain damage will be selected on a non-target based sampling basis. Demographic information is collected through interviews and questionnaires and then they will be controlled. The random allocation of individuals in the intervention and control groups will be done in random blocks and then will be aggregated. Then in an intervention group, an ACT group and a CBT group will be treated. After the end, follow up courses that will be completed 2 months and 4 months after the treatment will be completed, so that the questionnaires will be administered to both groups,

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Having a family member with a diagnosis of traumatic brain damage 2- Have minimum cycle education 3- Care for at least 3 consecutive months 4. Conscientiousness 5. Not having a history of physical illness and severe mental illness before engaging in research. 6- Individuals aged 25-50 years Exclusion criteria: 1. More than two absentee sessions in the treatment of CBT 2. More than one absentee session in ACT treatment 3. Acute or chronic mental or physical illness after engaging in research 4. Need for medication or other therapies

Intervention groups

An intervention group is undergoing cognitive-behavioral therapy, and the other intervention group receiving

treatment based on acceptance and commitment

Main outcome variables

Changes in healthcare policy and management; treatment costs; quality of diagnosis and treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190704044100N1**

Registration date: **2020-09-03, 1399/06/13**

Registration timing: **retrospective**

Last update: **2020-09-03, 1399/06/13**

Update count: **0**

Registration date

2020-09-03, 1399/06/13

Registrant information

Name

mahtab hadavand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 8432 3338

Email address

mahtab.hadavand@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-11-22, 1398/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of cognitive-behavioral therapy and treatment based on acceptance and commitment on family functioning, care burden, quality of life, experiential avoidance, anxiety, depression and stress in informal caregiver patients with traumatic brain injury.

Public title
Comparison of the Effect of Cognitive-Behavioral Therapy and Acceptance and Commitment-Based Therapy on Caregivers of Patients with Brain Injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having a family member with a diagnosis of traumatic brain damage Have minimum cycle education Care for at least 3 consecutive months Informed consent Not having a history of physical illness (cancer, MS) and severe psychosis (types of psychotic disorders) before engaging in research People aged 25-50 years
Exclusion criteria:
More than two absentee sessions in the treatment of CBT
More than one absentee session in ACT treatment Acute or chronic mental or physical illness after engaging in research Need for medication or other therapies

Age
From **25 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of individuals in intervention and control groups is done in random blocks . The randomization unit will be done individually by the table of random numbers.

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 kashan University of Medical Sciences

Street address

Kashan, Roubandi Boulevard, Kashan University of Medical Sciences and Health Services

City

kashan

Province

Isfahan

Postal code

8715973474

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.076

Health conditions studied

1

Description of health condition studied

Traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Depression score, anxiety and stress in the DASS21 questionnaire

Timepoint

Measurement of depression, anxiety, stress at the beginning of the study, end of study, 2 months after the end of the study, 4 months after the end of the study

Method of measurement

DASS21 questionnaire

Secondary outcomes

1

Description

The score that a person earns in quality of life questionnaires(SF-36).

Timepoint

Before the intervention, the end of the intervention, 2 months after the intervention, 4 months after the intervention

Method of measurement

SF-36

Intervention groups**1****Description**

Intervention group: cognitive behavioral therapy

Category

Treatment - Other

2**Description**

Intervention group: Acceptance and commitment therapy

Category

Treatment - Other

3**Description**

Control group

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Dr. Ismail Fakharian

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Mahtab Hadavand

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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

Mahtab Hadavand

Position

Master of Science in Clinical Psychology

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences
Full name of responsible person
Mahtab Hadavand
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Other areas of specialty/work
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Person responsible for updating data

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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

The whole data can be shared after unidentifiable
people.

When the data will become available and for how long

Data will be available approximately 4-6 months after
data interruptions.

To whom data/document is available

Data will only be available to researchers working in
academic and academic institutions.

Under which criteria data/document could be used

At the request of the applicant is in line with the
objectives of the study, it promotes the development of
prevention and treatment, promotes research in the field
of study.

From where data/document is obtainable

09037671285 mahtab.hadavand@yahoo.com

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

About 4-6 months after the data interruption is available.
The applicant is only required to send a request to the
contact number and email. After examining the
application, it will be emailed about one to two weeks if
the request is in line with the intended purpose.

Comments