Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Isfehan

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
Street address
Kashan, km 5 Ravand road - Ravandi boulevard - Shahid Beheshti Hospital
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Isfehan
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87159/81151
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beheshtihospital@kaums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Mahtab Hadavand
Street address
Kashan, km 5 Ravand road, Ravandi boulevard, Shahid Beheshti Hospital
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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 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