Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the effectiveness of Cognitive-Behavioral Therapy and usual care on depression and dysfunctional attitudes in patients with cardiovascular diseases after coronary artery bypass graft surgery: a randomized clinical trial

Protocol summary

Study aim

The main objective of the study was to determine the effectiveness of cognitive-behavioral therapy on depressive symptoms and dysfunctional attitudes in patients after CABG surgery

Design

The study used a randomized clinical trial design comparing a Cognitive Behavioral Therapy based on problem solving model with usual care group (control group). Participants were selected based on available sampling and randomly allocated to groups using random numbers table.

Settings and conduct

This study is a randomized clinical trial in which two-group pretest–posttest design will be used. Instruments used for data gathering in this study is Beck Depression Inventory and Dysfunctional Attitude Scale (DAS). Location of study: Shadeed Modarres Hospital. Number of patients in the intervention group: 22. Number of patients in the control group: 22.

Participants/Inclusion and exclusion criteria

Inclusion criteria: meeting DSM-5 diagnostic criteria for depression associated with another medical condition; Under 70 years old; Education: At least diploma; Fluent in Persian language; Score of the Beck Depression Inventory: more than 10; Score of the Dysfunctional Attitude Scale (DAS): more than 26. Non-inclusion criteria: Taking psychiatric drugs during the last 6 months; Taking current psychiatric drugs; Patients with psychiatric disorder who need urgent treatment; Participate in other treatments, simultaneously.

Intervention groups

Treatment group: Cognitive Behavioral Therapy based on problem solving model. Patients in intervention group received Cognitive Behavioral Therapy individually through six 1-hour sessions. The content of the sessions were problem-solving skills, pleasurable activity scheduling and homework during the period of 35-date. Control group: control group only received two usual educational sessions.

Main outcome variables

Depression; Dysfunctional Attitudes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170808035568N2**
Registration date: **2019-03-05, 1397/12/14**
Registration timing: **retrospective**

Last update: **2019-03-05, 1397/12/14**
Update count: **0**

Registration date

2019-03-05, 1397/12/14

Registrant information

Name
Nima Hajitabar Firouzjaei
Name of organization / entity
Shahid Beheshti University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 21 6670 5780
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-09-27, 1397/07/05
Expected recruitment end date
2018-12-01, 1397/09/10
Actual recruitment start date
2018-09-11, 1397/06/20
Actual recruitment end date
2018-11-06, 1397/08/15
Trial completion date
2018-11-06, 1397/08/15

Scientific title
Comparative study of the effectiveness of Cognitive-Behavioral Therapy and usual care on depression and dysfunctional attitudes in patients with cardiovascular diseases after coronary artery bypass graft surgery: a randomized clinical trial

Public title
Effectiveness of Cognitive-Behavioral Therapy on Depression and Dysfunctional attitudes in patients with Cardiovascular diseases
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having DSM-5 diagnostic criteria for depression associated with another medical condition Under 70 years old Education: At least diploma Fluent in Persian language Score of the Beck Depression Inventory: more than 10 Score of the Dysfunctional Attitude Scale (DAS): more than 26
Exclusion criteria:
Taking psychiatric drugs during the last 6 months. Taking current psychiatric drugs Patients with psychiatric disorder who need urgent treatment Participate in other treatments, simultaneously
Age
From **25 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **65**
Actual sample size reached: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Sample selection were performed based on available sampling and participants were randomly allocated to groups using 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 Shahid Beheshti University of Medical Science
Street address
Medical College, Shahid Beheshti University of Medical Sciences, Arabi street, Daneshjoo bouleward, Evin
City
Tehran
Province
Tehran
Postal code
89
Approval date
2015-06-28, 1394/04/07
Ethics committee reference number
IR.SBMU.MSP.REC.1394.47

Health conditions studied

1

Description of health condition studied
Cardiovascular Disease
ICD-10 code
I20-I25
ICD-10 code description
Ischemic heart diseases

Primary outcomes

1

Description
Depression score
Timepoint
Pre-intervention, During the intervention and Post-intervention
Method of measurement
Beck Depression Inventory

Secondary outcomes

1

Description
Dysfunctional Attitudes
Timepoint
Pre-intervention, During the intervention and Post-intervention
Method of measurement
Dysfunctional Attitudes Scale-26

Intervention groups

1

Description
Intervention group: Cognitive-Behavioral Therapy program based on problem-solving model. Number of sessions: 8 individual 90 minute sessions, three days a week. Study protocol: Problem solving model, adapted from Robert L. Leahy.

Category
Treatment - Other

2

Description
Control group: participants in the usual care group received two educational sessions on cardiovascular disease. Educational sessions included the following topics:1) Medical education about heart disease and CABG surgery. 2) General education about health care after heart Bypass surgery. 3) Having a good Diet Program. 4) Having a daily walking program. The mentioned educations has been under the supervision of cardiologist.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Modarres Hospital

Full name of responsible person
Dr. Mohammad Masoud Majidi Tehrani

Street address
Saadat Abad Street - Yadegare Imam Highway

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Fax
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Email
modarres@sbmu.ac.ir

Web page address
https://modarres.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Seyed Ali Ziaei

Street address
Medical College, Shahid Beheshti University of Medical Sciences, Arabi street, Daneshjoo bouleward, Evin

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Nima Hajitabar Firouzjaei

Position
MSc

Latest degree
Master

Other areas of specialty/work
Psychology

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Next to Ayatollah Taleghani hospital, Shahid Arabi street, Yaman street, Shahid Chamran highway

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
MSc
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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Web page address
https://www.sbmu.ac.ir/

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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable