

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

##### Email address

hajitabarnima@gmail.com

##### 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 boulevard, 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1998734383

##### Phone

+98 21 2207 4087

##### Fax

+98 21 2207 4101

##### 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 boulevard, Evin

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23871

##### Email

info@sbmu.ac.ir

##### Web page address

<https://www.sbmu.ac.ir/>

##### 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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23871

##### Email

info@sbmu.ac.ir

**Web page address**

<https://www.sbm.ac.ir/>

**Person responsible for scientific 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

**Street address**

Medical College, Shahid Beheshti University of  
Medical Sciences, Arabi street, Daneshjoo boulevard,  
Evin

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 23871

**Email**

[info@sbmu.ac.ir](mailto:info@sbmu.ac.ir)

**Web page address**

<https://www.sbm.ac.ir/>

**Person responsible for updating data****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

**Street address**

Medical College, Shahid Beheshti University of  
Medical Sciences, Arabi street, Daneshjoo boulevard,  
Evin

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 23871

**Email**

[info@sbmu.ac.ir](mailto:info@sbmu.ac.ir)

**Web page address**

<https://www.sbm.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