

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effectiveness of Cognitive Behavioral Therapy on symptoms of depression, dysfunctional attitudes and level of social support in patients with cardiovascular disease

Protocol summary

Summary

The main objective of the study was to determine the effectiveness of cognitive-behavioral therapy on depressive symptoms, dysfunctional attitudes and social support in cardiovascular patients. Present research is basic-applied and is experimental methodologically; Plan: Pretest and Post-test with control group. After the preliminary screening of 167 patients who has been referred to Hospital, 24 people of eligible patients for this study were selected. In the end: 21 people of the patients were selected. 10 sample for treatment group and 11 sample for control group. Inclusion criteria are: sufficient knowledge of the Persian language, meeting the diagnostic criteria for depression due to other medical condition according to DSM-5, age: under 70 years, the minimum official education: diploma, a minimum score of 10 on the Beck Depression Inventory, a minimum score of 26 on the Dysfunctional Attitudes Scale-26. Exclusion criteria are: already receiving psychotherapy for mental health problems, taking psychiatric drugs during the last 6 months, the presence of severe depressive symptoms (indicated by a score above 40 on the items of the Beck Depression Inventory-II; BDI-II). Intervention: Problem Solving Therapy (PST) on based Robert Leahy protocol. Time: 50 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080835568N1**
Registration date: **2017-08-13, 1396/05/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-13, 1396/05/22

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

Investigator

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Cognitive Behavioral Therapy on symptoms of depression, dysfunctional attitudes and level of social support in patients with cardiovascular disease

Public title

Cognitive-Behavioral Therapy for Cardiovascular Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: sufficient knowledge of the Persian language, meeting the diagnostic criteria for depression due to other medical condition according to DSM-5, age: under 70 years, the minimum official education: diploma, a minimum score of 10 on the Beck Depression Inventory, a minimum score of 26 on the Dysfunctional Attitudes Scale-26. Exclusion criteria are: already receiving psychotherapy for mental health problems, taking psychiatric drugs during the last 6 months, the presence of severe depressive symptoms (indicated by a score above 40 on the items of the Beck Depression Inventory-II; BDI-II).

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: **21**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Science

Street address

Teharan - Evin - Student boulevard- Arabi street- Medical College, Shahid Beheshti University of Medical Science.

City

Tehran

Postal code

89

Approval date

2015-05-05, 1394/02/15

Ethics committee reference number

ir.sbm.u.msp.rec.1394.47

Health conditions studied

1

Description of health condition studied

Cardiovascular Disease

ICD-10 code

I20-I25 ,

ICD-10 code description

Ischaemic heart diseases , Other forms of heart disease

Primary outcomes

1

Description

Depression

Timepoint

Pre-intervention, During the intervention and Post-intervention.

Method of measurement

BDI-II

Secondary outcomes

1

Description

Dysfunctional Attitudes

Timepoint

Pre-intervention, During the intervention and Post-intervention.

Method of measurement

Dysfunctional Attitudes Scale-26

2

Description

Social Support

Timepoint

Pre-intervention, During the intervention and Post-intervention.

Method of measurement

Multidimensional Scale of Perceived Social Support Scale

Intervention groups

1

Description

The study used a randomized controlled design comparing a Problem Solving Therapy with usual care group (control group). The study protocol has been approved by the Medical Ethics Committee of the Medicine Faculty of Shahid Beheshti University of Medical Science. All patients in the treatment group receive basic information on the use of the program.

Category

Treatment - Other

2

Description

Participants in the usual care condition received two

educational sessions on cardiovascular disease and a depression brochure. 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

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Nima Hajitabar Firouzjaei

Street address

Teharan - Evin - Student boulevard- Arabi street-
Medical College, Shahid Beheshti University of
Medical Science.

City

Tehran

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 Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Nima Hajitabar Firouzjaei

Position

MSc, Clinical Psychology

Other areas of specialty/work

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Position

MSc, Clinical Psychology

Other areas of specialty/work

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty