

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The efficacy of cognitive-behavioral therapy based on Rumination on depression, anxiety and hostility in patients undergoing cardiac rehabilitation

Protocol summary

Study aim

Determining The efficacy of cognitive-behavioral therapy based on Rumination on depression, anxiety and hostility in patients undergoing cardiac rehabilitation

Design

The clinical trial is divided into two groups: rehabilitation intervention and psychotherapy and one control group. The assignment in the groups is randomly and number of sample is 48 patients.

Settings and conduct

First, After obtaining permission from related authorities, referring to the heart centers (Sadr heart center). After obtaining the informed consent the PHQ-9 questionnaires, BAI anxiety inventory and The Aggression Questionnaire- AQ will be delivered to patients. Then, 48 patients will be selected according to the entry and exit criteria.

Participants/Inclusion and exclusion criteria

inclusion criteria: Open heart surgery following coronary heart disease, ability to participate in a rehabilitation program and doing homework with a cardiologist's diagnosis and rehabilitation, a mild to moderate score in the questionnaires, having reading and writing skills, lack of severe mental disorder, exclusion criteria: Having cognitive disorders such as Alzheimer's and dementia, Having thyroid problems.

Intervention groups

INT1: Cognitive behavioral therapy based on rumination
INT2: rehabilitation CONTROL

Main outcome variables

Depression, Anxiety, Hostility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042100N1**

Registration date: **2019-03-27, 1398/01/07**

Registration timing: **retrospective**

Last update: **2019-03-27, 1398/01/07**

Update count: **0**

Registration date

2019-03-27, 1398/01/07

Registrant information

Name

Mahdi Fatemizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6636 7569

Email address

m4567458@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-15, 1397/04/24

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2018-07-23, 1397/05/01

Actual recruitment end date

2018-10-23, 1397/08/01

Trial completion date

2018-12-21, 1397/09/30

Scientific title

The efficacy of cognitive-behavioral therapy based on Rumination on depression, anxiety and hostility in patients undergoing cardiac rehabilitation

Public title

The efficacy of cognitive-behavioral therapy based on Rumination on depression, anxiety and hostility in cardiac patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Open heart surgery following coronary heart disease
Ability to participate in the rehabilitation program and doing assignments with a diagnosis of cardiologist and rehabilitation specialist
A mild or moderate score in the questionnaire (5 upwards at PHQ-9, 8 up on BAI, and 40 up at BPAQ)
Have reading and writing skills
No other physical illness that limits attendance at meetings
No change in psychiatric medications from one month before intervention
No history of receiving psychotherapy before intervention
Age 40 to 70 years

Exclusion criteria:

Having cognitive disorders such as Alzheimer's and dementia
having severe mental disorder (Personality disorders, Psychotic disorders and Dissociatives disorders)
Thyroid Problems

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

After having the entry criteria, one number was assigned to each person, and the numbers were assigned to three groups of intervention, rehabilitation and control according to the 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 of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Eraby street, Student Blvd, Velenjk, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.SBMU.MSP.REC.1397.587

Health conditions studied**1****Description of health condition studied**

cardiovascular

ICD-10 code

I51.6

ICD-10 code description

Cardiovascular disease, unspecified

2**Description of health condition studied**

depression

ICD-10 code

F32

ICD-10 code description

In typical mild, moderate, or severe depressive episodes, the patient suffers from lowering of mood, reduction of energy, and decrease in activity.

3**Description of health condition studied**

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstance

4**Description of health condition studied**

hostility

ICD-10 code

R45.5

ICD-10 code description

signs and symptoms constituting part of a mental disorder

Primary outcomes**1****Description**

Depression
Timepoint
Pre-test, Post-test, after 2 month
Method of measurement
Beck depression questionnaire

2

Description
Anxiety
Timepoint
Pre-test, Post-test, after 2 month
Method of measurement
Beck Anxiety questionnaire

3

Description
Hostility
Timepoint
Pre-test, Post-test, after 2 month
Method of measurement
The Aggression Questionnaire- AQ

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will receive 12 sessions of cognitive-behavioral behavioral therapy based on Rumination for one session per week. The protocol has been devised to treat depression and And focuses on changing the rumination of patients.
Category
Treatment - Other

2

Description
Intervention group: The rehabilitation group will receive 40 sessions of rehabilitation program weekly in 3 sessions
Category
Rehabilitation

3

Description
Control group: The control group will be selected from the waiting list and will not receive any intervention
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialized Clinic Heart of Sadr
Full name of responsible person
Arash Ghanavati
Street address
Specialized Clinic Heart of Sadr, firuze street, Vali Asr Square, Tehran
City
Tehran
Province
Tehran
Postal code
1593714317
Phone
+98 21 8603 4831
Email
rasoul.2828@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
private organization
Full name of responsible person
Mahdi fatemizadeh
Street address
number 121, valiasr town, bojnourd, north khorasan
City
bojnourd
Province
North Khorasan
Postal code
9417896483
Phone
+98 58 3225 4183
Email
rasoul.2828@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
private organization
Proportion provided by this source
50

Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasoul mohammadian

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

10th Alley, Resalat street

City

Shahindezh

Province

West Azarbaijan

Postal code

5981944451

Phone

+98 44 4632 1250

Email

rasoul.2828@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasoul Mohammadian

Position

student

Latest degree

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Province

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Postal code

5981944451

Phone

+98 44 4632 1250

Email

Rasoul.2828@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

rasoul mohammadian

Position

master of science student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

10th alley, resalat street, shahindezh

City

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Province

West Azarbaijan

Postal code

5981944451

Phone

+98 44 4632 1250

Email

rasoul.2828@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

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