

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Comparison of the Effectiveness of Happiness training with Cognitive- Behavioral Therapy(CBT) on Depression, Happiness, Optimism, General health and C-reactive protein(CRP) in coronary patients

Protocol summary

Study aim

Comparison of the effectiveness of happiness training and cognitive behavioral therapy on depression, happiness, optimism, general health and C-reactive protein (CRP) in coronary patients

Design

study design was experimental with pre-test, post-test, and follow-up measurements comparing with attention control group. From patients referring to Isfahan Cardiac Rehabilitation Center 75 participants were randomly selected and assigned randomly to the happiness training and cognitive-behavioral therapy groups or attention control condition using concealed cards.

Settings and conduct

Psychological disorders, especially depression are known as the important factors in increasing the mortality of coronary patients. This study compared the effectiveness of happiness training and cognitive-behavioral therapy on psychological variables and CRP of these patients. This study was performed on cardiac patients referred to the Isfahan Cardiovascular Research Center. Measurements were performed at pre-test, post-test and follow-up. Interventions were performed based on Lyubomirsky Happiness training program, cognitive-behavioral therapy and routine medical education, during 8 sessions (90 minutes, 8 weeks). Participants were blind to grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Documented diagnosis of coronary artery disease 2- Agreement for participation in study
Exclusion criteria: 1-Receive anti-inflammatory drugs or any other psychological intervention or treatment

Intervention groups

intervention groups consisted of two experimental and one control groups. Each group included 25 coronary patients. Experimental group 1 received happiness training, experimental groups 2 received cognitive

behavioral therapy, and attention control group received usual medical education in 8 sessions (90 minutes for 8 weeks).

Main outcome variables

Depression; CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180428039458N1**

Registration date: **2018-11-14, 1397/08/23**

Registration timing: **retrospective**

Last update: **2018-11-14, 1397/08/23**

Update count: **0**

Registration date

2018-11-14, 1397/08/23

Registrant information

Name

Maryam Baghooli Kermani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3235 6684

Email address

6maryam5@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

2018-04-03, 1397/01/14

Actual recruitment end date

2018-05-05, 1397/02/15

Trial completion date

2018-08-23, 1397/06/01

Scientific title

The Comparison of the Effectiveness of Happiness training with Cognitive- Behavioral Therapy(CBT) on Depression, Happiness, Optimism, General health and C-reactive protein(CRP) in coronary patients

Public title

The Comparison of the Effectiveness of Happiness training with Cognitive- Behavioral Therapy(CBT) in Coronary Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Documented diagnosis of coronary artery disease
Agreement to participate in study

Exclusion criteria:

Receive anti-inflammatory drugs
Receive any other psychological intervention or treatment

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **75**

More than 1 sample in each individual

Number of samples in each individual: **3**

Measurements were performed at pre-test, post-test and follow-up stages.

Actual sample size reached: **75**

More than 1 sample in each individual

Actual sample size in each individual: **3**

Measurements were performed at pre-test, post-test and follow-up stages.

Randomization (investigator's opinion)

Randomized

Randomization description

Present study was a randomized pilot trial to compare the effectiveness of two interventions of happiness training and cognitive-behavioral therapy among patients with heart disease who were randomly selected from patients referring to the Rehabilitation Center of the Isfahan Cardiovascular Research Institute. Participants were then randomized to the experimental or control condition using concealed cards with group assignment listed that were only accessed by study staff following completion of baseline assessments.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants were blinded about the grouping and assignments

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National research Ethics Committee of Islamic Azad University -branch Isfahan (Khorasgan)

Street address

University Blvd, Arghavanieh, The East Jey St., Isfahan

City

Isfahan

Province

Isfahan

Postal code

81551-39998

Approval date

2018-09-12, 1397/06/21

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.075

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

Coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

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

C-reactive protein (CRP)

Timepoint

Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the intervention).

Method of measurement

hs-CRP Kit

Secondary outcomes

1

Description

Depression

Timepoint

Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the intervention).

Method of measurement

Beck Depression Inventory

2

Description

Happiness

Timepoint

Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the post-test)

Method of measurement

Oxford Happiness Scale

3

Description

optimism

Timepoint

Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the post-test)

Method of measurement

Life Orientation Test(LOT)

4

Description

general health

Timepoint

Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the post-test)

Method of measurement

Goldberg General Health Questionnaire(GHQ)

Intervention groups

1

Description

The first intervention group: received Lyubomirsky happiness training program (2008) for 8 sessions of 90 minutes (once a week).

Category

Behavior

2

Description

The second intervention groups: received cognitive-behavioral therapy (CBT) for 8 sessions of 90 minutes (once a week).

Category

Behavior

3

Description

Attention control group: received routine medical education for cardiac patients for 8 sessions of 90 minutes (once a week).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Cardiovascular Research Center

Full name of responsible person

Masoumeh Sadeghi

Street address

Shahid Rahmani Alley, next to Shahid Chamran Heart Center, after the Shahrestan bridge, the third Moshtaq Ave

City

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Nurbakhsh

Street address

2nd Kilometer of Mobarakeh Road-Boroujen -

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Email

info@iauboroujen.ac.ir

Web page address

<http://www.iauboroujen.ac.ir>

Grant name

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

Yes

Title of funding source
Islamic Azad University

Proportion provided by this source
1

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

2

Sponsor

Name of organization / entity
Isfahan Cardiovascular Research Center

Full name of responsible person
Masoumeh Sadeghi

Street address
Shahid Rahmani Alley, next to Shahid Chamran, Heart Center, after the SHahrestan bridge, Third Moshtagh Ave

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Title of funding source
Isfahan Cardiovascular Research Center

Proportion provided by this source
1

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

Islamic Azad University

Full name of responsible person
Maryam Baghooli Kermani

Position
M.A.student

Latest degree
Master

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Gholam Reza Nikrahan

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Maryam Baghooli Kermani

Position
M.A.student

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

The total potential data can be shared after being "unidentifiable"

When the data will become available and for how long

Start the access period 6 months after publishing of the results

To whom data/document is available

It will be accessible for everyone

Under which criteria data/document could be used

There will be no specific condition

From where data/document is obtainable

Maryam Baghooli Kermani

What processes are involved for a request to access data/document

There will not be any specific process, we will be responsive after receiving an email

Comments