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 size
Target 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
Isfehan
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mohammad Nurbakhsh
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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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Postal code
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Email
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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
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 updating data

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M.A.student

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Other areas of specialty/work
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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