Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effectiveness of Positive Psychotherapy on Bio psychological Markers of Chronic Coronary Heart Patients.

Protocol summary

Summary

Objectives, assessing of effectiveness of positive psychotherapy based on optimism on bio psychological markers of chronic coronary heart Patients. Biological markers are fasting blood sugar, serum lipids and, inflammatory makers including: hs- CRP, IL-6, Fibrinogen, Irizin. Psychobehavioral markers are depression, anxiety, optimism, hope, satisfaction with life, positive affects, happiness, physical activity, diet and drug adherence. (2) Design, This research is a quasi-experimental study, consisting of randomized experimental and control groups with pre-test, post-test and follow-up test diagram. 3) Setting and conduct, Sixty patients with chronic coronary heart diseases, registered in the cardiac research center, Isfahan University of Medical Sciences, are selected based on inclusion criteria and randomly assigned to intervention or attentional control group. At first, the two groups are initially checked for demographic data, history of cardiovascular risk factors, echocardiography, cardiac stress test, blood pressure and body mass index. Then, they undergo psychological evaluations (depression, anxiety, optimism, hope, life satisfaction, positive affect, happiness, diet and drug adherence through questionnaires) and biological assessments (fasting blood sugar, serum lipids and inflammatory markers such as hs- CRP, IL-6, Fibrinogen, Irizin, and walking test to check the physical activity status). The experimental group will then receive group positive psychotherapy and the control group will receive training on medical issues. Finally, after the intervention and a two month follow-up, two groups are assessed for bio-psychological evaluations similar to pre test. (4) Participants (including major eligibility criteria), inclusion criteria are as the following; patients with Coronary Heart diseases (stable angina, unstable angina and myocardial infarction); a minimum 70 percent blocked in one of the coronary arteries based on angiography; passage of at least six months from the acute or inflammatory phase of the disease; age between 35 to 60 years; above elementary education level; Patient consent to participation in research. Exclusion criteria are: history of Inflammatory and autoimmune diseases, current serious psychiatric disorders; taking immunologic or psychiatric drugs; unwilling to participate or continue the research. (5) Intervention, the experimental group will receive eight weekly sessions of group positive psychotherapy based on optimism; the control group will receive 8 weekly sessions of training on medical issues without referring to optimism. (6) Main outcome measures (variables), Primary outcomes are fasting blood sugar, serum lipids, inflammatory markers (including: hs- CRP, IL-6, Fibrinogen, Irizin), depression, anxiety, optimism, hope, life satisfaction, positive affect, happiness, physical activity, diet and drug adherence

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070328769N1**
Registration date: **2017-02-19, 1395/12/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-02-19, 1395/12/01

Registrant information

Name

Narges Mohammadi

Name of organization / entity

Payam Noor University, PHD Center

Country

Iran (Islamic Republic of)

Phone

+98 314461872

Email address

m_psrc@mui.ac.ir

Recruitment status
Recruitment complete
Funding source
Research grant of supervisor

Expected recruitment start date
2016-07-22, 1395/05/01
Expected recruitment end date
2016-12-21, 1395/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Positive Psychotherapy on Bio psychological Markers of Chronic Coronary Heart Patients.

Public title
The Effectiveness of Positive Psychotherapy on Bio psychological Markers of Chronic Coronary Heart Patients
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria are as the following; patients with Coronary Heart diseases (stable angina, unstable angina and myocardial infarction); a minimum 70 percent blocked in one of the coronary arteries based on angiography; passage of at least six months from the acute or inflammatory phase of the disease; age between 35 to 60 years; above elementary education level; Patient consent to participation in research. Exclusion criteria are: history of Inflammatory and autoimmune diseases, current serious psychiatric disorders; taking immunologic or psychiatric drugs; unwilling to participate or continue the research.
Age
From **35 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Isfahan medical sciensis
Street address
Vice chancellor for research,Isfahan University of Medical Sciences , Hezar Jerib, Isfahan, Iran
City
Isfahan
Postal code
8174673461
Approval date
2017-02-13, 1395/11/25
Ethics committee reference number
IR.MUI.REC.1395.4.075

Health conditions studied

1

Description of health condition studied
chronic coronary heart disease
ICD-10 code
I20.0, I21
ICD-10 code description
Unstable angina Angina: crescendo de novo effort worsening effort Intermediate coronary syndrome Preinfarction syndrome , Acute myocardial infarction Incl.: myocardial infarction specified as acute or with a sta

Primary outcomes

1

Description
optimism
Timepoint
preintervention, postintervention and two month after intervention
Method of measurement
Life orientation questionnaire

Secondary outcomes

1

Description
Happiness
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
Oxford Happiness questionnaire

2

Description
Depression
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
Hospital Anxiety and depression Scale

3

Description
Anxiety
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
Hospital Anxiety and depression Scale

4

Description
positive affect
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
Positive and negative affect

5

Description
Hope
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
Life Hope Questionnaire

6

Description
Satisfaction With Life
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
Dinner Satisfaction With Life Scale

7

Description
physical activities
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
Six- Minute Walking Test

8

Description
Drug Adherence
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
Drug Adherence Questionnaire

9

Description
Food regime adherence
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
Food Frequency Questionnaire

10

Description
inflammation marker, hs- CRP
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
blood test

11

Description
inflammation marker, Fibrinogen
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
blood test

12

Description
inflammation marker ,interleukin-6
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
blood test

13

Description
inflammation marker, Irizin
Timepoint
preintervention, postintervention and one month after intervention
Method of measurement
blood test

Intervention groups

1

Description
Eight weekly sessions of group positive psychotherapy based on optimism for 2 hours a week (psychology

intervention)

Category

Other

2

Description

Eight weekly sessions of group education about the disease without reference to psychological topics

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular Research Center in Isfahan

Full name of responsible person

dr Masoumeh Sadeghi

Street address

Cardiovascular Research Center, Complex Medical Research Centers Hazrat S T, Khoram St, Islamic Republic Sq, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Payam Noor University

Full name of responsible person

Dr Alireza Aghayousefi

Street address

Vice chancellor for research, Centeral Organization of Payam Noor University, Nakhl Av, First of Naft city, Artesh Blvd, Mini City, Thehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Payam Noor University

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Masoumeh Sadeghi

Street address

Cardiovascular Research Center, Complex Medical Research centers Hazrat S T, Khoram St, Islamic Republic Sq, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

95112

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Proportion provided by this source

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

Isfahan University of Medical sciences

Full name of responsible person

Narges Mohammadi

Position

Employee

Other areas of specialty/work

Street address

No 7, Shahidan Malek Mohammad Alley, Lalleh Alley, Kaveh Av, Isfahan, Iran

City

Isfahan

Postal code

8148983671

Phone

+98 31 3446 1872

Fax

Email

nargesmohammadi53@yahoo.com, m_psrc@mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Payam Noor University
Full name of responsible person
Dr Alireza Aghayousefi
Position
PHD in Psychology
Other areas of specialty/work
Street address
Payam Noor University,PHD Center, Safaa Alley, Shahnaz Alley, Haj Mahmoud Noori St, North Dibaji Av, Farmaniyeh Blvd, Tehran, Iran
City
Tehran
Postal code
1953633511
Phone
+98 21228308578
Fax
+98 21 2280 8494
Email
arayeh1100@gmail.com
Web page address
www.phd.pnu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical sciences
Full name of responsible person
Narges Mohammadi
Position
PHD candideat in Psychology/Employee
Other areas of specialty/work
Street address
No 7, Shahidan Malek Mohammad Alley, Lalleh Alley, Kaveh Av, Isfahan, Iran
City
Isfahan
Postal code
8148983671
Phone
+98 31 3446 1872
Fax
Email
nargesmohammadi53@yahoo.com, m_psrc@mui.ac.ir
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