

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Developing a Family-centered Health Program and Comparing its Effectiveness with Cardiac Rehabilitation Program on Biological and Psychological Components in Individuals with Coronary Heart Disease

Protocol summary

Study aim

Developing a Family-centered Health Program and Comparing its Effectiveness with Cardiac Rehabilitation Program on Biological and Psychological Components in Individuals with Coronary Heart Disease

Design

Clinical trial with one control and two intervention groups, with parallel groups, designed for 120 patients, without blindness, randomized.

Settings and conduct

This study is performed at ward 7, CCU (K), CCU (G) and the Rehabilitation center at Rajaie Cardiovascular, Medical and Research Center Hospital on patients with coronary heart disease. Blindness will not do in this study.

Participants/Inclusion and exclusion criteria

The criteria for admitting the subjects in this study include: - Diagnosis of coronary heart disease - Education level of junior high school or above - 40 to 65 years of age - No history of hospitalization in psychiatric hospitals - Being married - Willingness to participate in the study
The exclusion criteria for the experimental group include: - Reluctance to continue attending the intervention sessions - Patients with acute myocardial infarction or acute coronary syndrome - History of Coronary Artery Bypass Grafting - History of inflammatory diseases such as collagen vascular disease, vascular necrosis, and chronic infectious diseases

Intervention groups

First in the intervention group 1: drug treatments and family-centered health program and in intervention group 2: drug treatments and cardiac rehabilitation program.

Main outcome variables

Biological components (blood pressure and body mass index) and psychological (quality of life related to health, attitude and adherence to self-care behavior)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210307050608N1**

Registration date: **2022-03-14, 1400/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-14, 1400/12/23**

Update count: **0**

Registration date

2022-03-14, 1400/12/23

Registrant information

Name

Negin Dorri

Name of organization / entity

University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 2254 0944

Email address

negin.dorri@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-05-21, 1401/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Developing a Family-centered Health Program and Comparing its Effectiveness with Cardiac Rehabilitation Program on Biological and Psychological Components in Individuals with Coronary Heart Disease

Public title

Developing a Family-centered Health Program and Comparing its Effectiveness with Cardiac Rehabilitation Program on Biological and Psychological Components in Individuals with Coronary Heart Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The criteria for admitting the subjects in this study include:- Diagnosis of coronary heart disease patients. - Education level of junior high school or above - 40 to 65 years of age - No history of hospitalization in psychiatric hospitals - History of Percutaneous Coronary Intervention - Being married - Willingness to participate in the study

Exclusion criteria:

The exclusion criteria for the experimental group include Reluctance to continue attending the intervention sessions - Patients with acute myocardial infarction or acute coronary syndrome - History of Coronary Artery Bypass Grafting (CABG) - History of inflammatory diseases such as collagen vascular disease, avascular necrosis, and chronic infectious diseases - Primary Percutaneous Coronary Intervention

Age

From **40 years** old to **65 years** old

Gender

Male

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, individuals are randomly divided into two groups of intervention and one control group using random number table. In this method, the first selected number (randomly) set in the first intervention group and the next numbers assign to the second intervention and control groups respectively. Intervention group 1 receive drug treatments 8 sessions of Family-centered Health Program, intervention group 2 receive drug treatments and 8 sessions of Cardiac Rehabilitation Program and the third group as the control, only receive drug treatments.

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

Faculty of Psychology and Educational Sciences

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No. 3. Doulatshahi Ave., Rastvan Ave., Darrus.,
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Province

Tehran

Postal code

1944965711

Approval date

2021-09-25, 1400/07/03

Ethics committee reference number

IR.UT.PSYEDU.REC.1400.050

Health conditions studied

1

Description of health condition studied

Coronary Heart Disease

ICD-10 code

I25.11

ICD-10 code description

Atherosclerotic heart disease of native coronary artery with angina pectoris

Primary outcomes

1

Description

The effectiveness of Family-centered health program
Blood Pressure

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

In this study, patients with coronary heart disease (CHD) will be identified by cardiologists.

2

Description

The effectiveness of Family-centered health program in
Body Mass Index

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

BMI is weight in kilograms divided by height in meters squared. Weight will be measured using a digital scale with 100 gram accuracy, and height will be measured accurately using a non-stretching tape measure with 0.5 accuracy.

3

Description

The effectiveness of Family-centered health program in Awareness, attitudes, and adherence to self-care behaviors

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

In this study, self-care will be determined based on the subject's score on the Health Behavior Scale (Conn et al., 1991).

4

Description

The effectiveness of Family-centered health program model in Health-related quality of life

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

In this study, health-related quality of life will be determined based on the subject's score in the Health-Related Quality of Life Scale.

5

Description

The effectiveness of Family-centered health program model on depression, Anxiety and Stress

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

In this study, depression, Anxiety and Stress level will be determined based on t The Depression, Anxiety and Stress Scale - 21 Items.

Secondary outcomes

1

Description

Heart Rate

Timepoint

Before an intervention, immediately after the intervention, 3 months after the end of intervention

Method of measurement

In this study, heart rate will be determined by heart rate monitor device.

Intervention groups

1

Description

Intervention group: Drug treatments and 8 sessions of Family-centered Health Program receive 2 to 2.5 hours and one a week.

Category

Diagnosis

2

Description

Intervention group: Drug treatments and 8 sessions of Cardiac Rehabilitation Program receive 2 to 2.5 hours and one a week.

Category

Diagnosis

3

Description

Control group: They only receive drug treatment.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular, Medical & Research Center

Full name of responsible person

Negin Dorri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 No
Title of funding source
 Faculty of Psychology and Educational Sciences
Proportion provided by this source
 100
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 Yes - There is a plan to make this available
Study Protocol
 Yes - There is a plan to make this available
Statistical Analysis Plan
 Yes - There is a plan to make this available
Informed Consent Form
 Yes - There is a plan to make this available
Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All related data to participants are shared after hiding patient's name.

When the data will become available and for how long

The period of access to the present research data will be available 6 months after publication of the research results in the form of research articles.

To whom data/document is available

The present study data will be available only to researchers working in the academic and scientific institutions.

Under which criteria data/document could be used

The output of statistical analysis will be available

From where data/document is obtainable

Applicants can apply for documentation and data via email at negin.dorri@ut.ac.ir

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

After completion of the research and publication of the extracted articles, it will be available for a maximum 6 months later.

Comments