

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

"The effect of cardiac rehabilitation based on multimedia on self-efficacy, illness perception and cardiac biomarkers in patients undergoing per cutaneous coronary intervention referring to hospitals affiliated to Shiraz University of Medical Sciences

Protocol summary

Study aim

The effect of cardiac rehabilitation based on multimedia on self-efficacy, illness perception and cardiac biomarkers in patients undergoing per cutaneous coronary intervention

Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct

After the approval of the Ethics Committee's approval and permission from the relevant authorities, they are referred to Alzahra Heart Hospital and affiliated to Shiraz Medical Sciences and selected in accordance with the rehabilitation ward of patients with inclusion criteria. After explaining, completing the questionnaire and taking blood samples from both groups, the educational content CD will be delivered to the patients in the intervention group, telephone follow up. Patients, principal analysts, and researchers are not aware of the intervention or control group, and the unknown questionnaire is completed to allow blindness.

Participants/Inclusion and exclusion criteria

Inclusion: Patients undergoing per cutaneous coronary intervention; willingness to participate in research; access to computers, the ability to use a CD; enjoy normal hearing, vision, and mental power; access to telephones. Exclusion: Aortic stenosis less than 1 cm; Uncontrolled ventricular or atrial arrhythmia; grade 3 blockade without pacemaker; Uncompensated heart failure; Severe orthopedic problems preventing activity; Chronic mental illness

Intervention groups

After blood sampling, patients in intervention group will be given a CD, illness perception, self-efficacy, how to perform cardiac rehabilitation training, and phono followup and consult if needed. control group: only

routine rehabilitation is done.

Main outcome variables

The effect of cardiac rehabilitation based on multimedia on self-efficacy, illness perception and cardiac biomarkers in patients undergoing per cutaneous coronary intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190405043164N1**

Registration date: **2020-04-06, 1399/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

Sara Fadaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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sarafadaei56@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-10, 1398/10/20
Expected recruitment end date
 2020-07-22, 1399/05/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 "The effect of cardiac rehabilitation based on multimedia on self-efficacy, illness perception and cardiac biomarkers in patients undergoing per cutaneous coronary intervention referring to hospitals affiliated to Shiraz University of Medical Sciences

Public title
 "The effect of multimedia rehabilitation education on self-efficacy, perception of heart disease and biomarkers in patients undergoing coronary intervention."

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with coronary artery intervention Willingness to participate in the research Access the computer and have the ability to use a CD on a computer for multimedia use Have normal hearing, vision and mental power to communicate with the researcher or patient's diagnosis No doctor's diagnosis of mental illness and acute cognitive impairment Access to the phone after discharge
Exclusion criteria:
 Uncontrolled hypertension, resting systole greater than 180 mm Hg or diastole greater than 110 mm Hg Clear aortic stenosis smaller than 1cm detected. Uncontrolled ventricular or atrial arrhythmia and grade 3 block with no pacemaker diagnosed. unrecovered heart failure that has been diagnosed. metabolic diseases such as acute thyroiditis, hypokalaemia, hyperkalemia, uncontrolled diabetes, and fever or acute systemic disease that have been diagnosed. Severe orthopedic problems and severe musculoskeletal problems that impede activity. Diagnosed chronic mental illness or cognitive impairment

Age
 No age limit

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **70**

Randomization (investigator's opinion)
 Randomized

Randomization description

Patients are divided into two groups of 35 according to the regular allocation technique. First, by simple randomization, the first patient referred from the sealed envelope removes the control or intervention word in the target group, and this is done by hiding the patient. The patient will be placed in the opposite group in each follow-up group. Other subsequent clients are also included in the intervention and control groups as one. The randomization unit is the patient and the construction is in random order.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are blinded by the following methods: Patients referring to the intervention and control groups will be randomly assigned to the intervention and control groups based on the systematic random allocation technique; They don't have patients. The blinding of the study evaluator was done as follows: Principal Investigator آوری Data collectors and people preparing the paper are not aware of patients in the control and intervention groups. The study information and telephone fallout are only available to the intervention group. The consultation is based on the needs of patients in the intervention group and the control group does not have information about the content of the study and telephone phonoop and consultation. Obviously, after one month and evaluation of the patients in the control group, training is provided to the control group according to their needs and study information.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

University of Medical Sciences,Zand ave,Shiraz

City

Shiraz

Province

Fars

Postal code

۱۴۳۳۶ - ۷۱۳۴۸

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.SUMS.REC.1398.685

Health conditions studied

1

Description of health condition studied

coronary artery disease rehabilitation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Inflammatory Factors with Neutrophil; Eosinophil and platelet Checkpoint

Timepoint

30days

Method of measurement

CBC quantifier

2

Description

Self-efficacy score on Sullivan questionnaire

Timepoint

30days

Method of measurement

Sullivan questionnaire

3

Description

illness perception score in B-IPQ questionnaire

Timepoint

30days

Method of measurement

B-IPQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who received multimedia illness perception and self-efficacy during 10-sessions (each on 20 min) in addition to routine rehabilitation training, after one month by blood sampling, changes in inflammatory factors, and by the ((B-IPQ)Questionnaire and Sullivan's self-efficacy Questionnaire changes in their illness perceptions and self-efficacy exams

Category

Rehabilitation

2

Description

Control group: Patients who receive only routine

rehabilitation training and practice.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra heart hospital

Full name of responsible person

Rosta.Hojatollah

Street address

Sibooye Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ghasemi.Yones

Street address

Headquarters of Shiraz University of Medical Sciences, Zand Street, opposite Palestine Street, Shiraz

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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

Shiraz University of Medical 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**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Rakhshan.Mahnaz

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Fadaei.Sara

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MS student

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Fax**Email**

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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

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of course 6 months after the article is published

To whom data/document is available

Employed in academic and scientific institutions

Under which criteria data/document could be used

The data will be accessible for similar scientific research and with respect to the rights of early researchers

From where data/document is obtainable

Email address, or website, and phone numbers

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

Contact Fred Mosul by email sarafadaei56@yahoo.com

Comments