

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of comprehensive family-centered empowerment program on Adherence to Treatment and recovery process in patients after coronary angioplasty

Protocol summary

Study aim

Determining the effect of implementing family-centered empowerment program on the recovery process and treatment compliance of patients after coronary angioplasty.

Design

The clinical trial with control group, with parallel groups, without blinding. The samples will be allocated in two intervention and control groups by random block allocation method with 4 blocks of equal size and a combination of letters A for the intervention group and B for the control group. The sample size will be 84 people based on the estimate of the statistical consultant and taking into account the possibility of dropping out.

Settings and conduct

Location: Selected hospitals of Tehran University of Medical Sciences During 8 sessions, there will be 5 training sessions and 3 follow-up sessions and 1 session every week. Group meetings will be held in groups of 4 to 7 people for 20-30 minutes. Completing the questionnaires again immediately after the intervention and also 4 weeks after the completion of the interventions Providing training booklets to both groups.

Participants/Inclusion and exclusion criteria

The study inclusion criteria include: Adults from 18 to 60 years old Diagnosis of coronary artery disease by a specialist doctor Presence of patients on the waiting list for coronary angioplasty The cooperation of one family member with the patient Having minimum reading and writing literacy for the patient and active family member Non-entry criteria: The existence of diagnosed psychological problems Participate in similar empowerment program

Intervention groups

In this 8-week study, the control group will receive the usual care, while the intervention group will also receive the comprehensive heart empowerment program in

addition to the usual care. booklet will be available to the control group in order to comply with ethical considerations.

Main outcome variables

Adherence to Treatment Recovery process

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220929056055N1**

Registration date: **2023-04-24, 1402/02/04**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-08, 1402/10/18**

Update count: **1**

Registration date

2023-04-24, 1402/02/04

Registrant information

Name

fatemeh ardestani mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-11, 1401/12/20

Expected recruitment end date

2023-06-12, 1402/03/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of comprehensive family-centered empowerment program on Adherence to Treatment and recovery process in patients after coronary angioplasty

Public title

The effect of comprehensive family-centered empowerment program on Adherence to Treatment and recovery process in patients after coronary angioplasty

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Adults from 18 to 60 years old
Diagnosis of coronary artery disease by a specialist doctor
Presence of patients on the waiting list for coronary angioplasty
The cooperation of one family member with the patient
Having minimum reading and writing literacy for the patient and active family member

Exclusion criteria:

Psychological problems has been diagnosed
Failure to participate in a similar empowerment program

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected through continuous sampling and will be divided into two intervention and control groups. The sample members will be allocated in two intervention and control groups by random block allocation method with 4 blocks of equal size and a combination of letters A for the intervention group and B for the control group. Then, the cards containing the blocks are placed inside the standard envelope, and based on the eligible inpatient samples, an envelope will be selected by the researcher by random sampling method, and finally, the method of random allocation of research samples will be determined.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics Committee in Research Faculty of Nursing and Midwifery and Rehabilitation Faculty of Tehran U

Street address

Room 604, 6th floor, Tehran University of Medical Sciences office building, Intersection of Qods st., Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1474854411

Approval date

2022-09-28, 1401/07/06

Ethics committee reference number

IR.TUMS.FNM.REC.1401.076

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

Coronary Artery Disease

ICD-10 code

I70-I79

ICD-10 code description

کد ذیل مربوط به بیماری های شریانی است

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

The rate of patient recovery with the recovery process questionnaire

Timepoint

Before and after the intervention and 4 weeks after the end of the intervention

Method of measurement

Questionnaire of recovery process

Secondary outcomes**1****Description**

The degree of compliance with the treatment plan in the questionnaire of adherence to treatment regimen

Timepoint

Before and after the intervention and 4 weeks after the end of the intervention

Method of measurement

Intervention groups

1

Description

Intervention group: 8 family-centered intervention sessions will be conducted in the form of 5 group training sessions and 3 follow-up sessions and 1 session every week. Group meetings will be held in groups of 4 to 7 people for 20-30 minutes. During these sessions, he will provide training on the nature of the disease, factors affecting the aggravation or improvement of symptoms, methods of preventing heart diseases by modifying lifestyle, physical activity, proper nutrition, stress control methods, follow-up of drug therapy and adherence to the treatment plan. became. Then, the researcher will encourage the members of the intervention group to have a group discussion and exchange their experiences related to the disease and the complications they experienced and lifestyle. Also, the training booklet will be given to the sample members to read it and ask the researcher any questions that come to their mind. The family members attend the meetings and in these meetings under the supervision of the researcher, they will discuss their problems and how to solve them, which will finally end in adopting a solution and try to strengthen the patients' ability in this field. In the step of educational participation, the family members are asked to transfer the learned information to the patient in the presence of the researcher along with the educational card. The last meeting will be held with the presence of an active member of the family to review the received training and fix the problems and summarize the meetings and evaluate the model. Evaluation is done in two ways: Formative and Summative evaluation. Formative evaluation will be in the form of questions and answers during each session will be from the topics of the previous sessions, and the Summative evaluation will be for the completion of the questionnaires immediately after the intervention and the re-completion of the questionnaires will be done 4 weeks after the completion of the interventions. In order to comply with ethical considerations, the training booklet was also provided to the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Shahrzad Ghiyasvandian

Street address

Imam Khomeini hospital Complex, Dr. Gharib St.,
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2

Recruitment center

Name of recruitment center

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Full name of responsible person

Shahrzad Ghiyasvandian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr akbar Fotouhi

Street address

6th floor of Research and Technology Vice-Chancellor,
Central Organization of the University, Corner of Qods
st., Keshavarz Blvd., Tehran

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Web page address

<http://vcr.tums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Ardestani Mohammadi

Position

Master student

Latest degree

Bachelor

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**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Ardestani Mohammadi

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**Undecided - It is not yet known if there will be 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**Undecided - It is not yet known if there will be 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