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 from18 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)

Phone

+98 21 4446 3174

Email address

fatemeh.ardestani78@yahoo.com

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

Questionnaire of adherence to treatment regimen

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., Keshavarz Blvd., Tehran

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 0000

Email
Imamhospital@tums.ac.ir

2

Recruitment center

Name of recruitment center
Shariati hospital

Full name of responsible person
Shahrzad Ghiyasvandian

Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy, Tehran

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8822 1444

Email
Shariatihosp@tums.ac.ir

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

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 8899 2970

Email
vcr@sina.tums.ac.ir

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
Street address
No. 28, Unit 1, Asgari Alley, 16 meters first North, Baath Blvd., Central Janat Abad
City
Tehran
Province
Tehran
Postal code
1474854411
Phone
+98 21 4446 3174
Email
fatemeh.ardestani78@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahrzad Ghiyasvandian
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Tawheed Square, Nusrat East St., Tehran
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4517
Email
shghiyas@tums.ac.ir

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
Nursery
Street address
No. 28, Unit 1, Asgari Alley, 16 meters first North, Baath Blvd., Central Janat Abad
City
Tehran
Province
Tehran
Postal code
1474854411
Phone
+98 21 4446 3174
Email
fatemeh.ardestani78@yahoo.com

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