Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

The effect of collaborative care on the quality of life of patients after coronary angioplasty

Protocol summary

Summary

The aim of this study was to evaluate the effect of collaborative care on the quality of life of patients after coronary angioplasty. The present study is a two-group two-stage of before and after clinical trial. In this study samples were selected randomly by simple sampling and divided into two groups of intervention (25 participants) and control (25 participants). Collaborative care model was executed in the intervention group for 3 months. The inclusion criteria were being aged more than 18 and less than 70 years, having appropriate clinical condition according to physician's diagnosis and not having any constraints for performing the interventions. Also if the patient of the intervention group was absent for more than 2 educational sessions, die or encounter any problem that would make them unable to continue the study, they were excluded. In the intervention group, collaborative treatment program was conducted in 5 sessions and for the control group, two sessions were conducted to discuss the importance of medication, diet and exercise. Data was gathered before and 3 months after the intervention using demographic characteristics and quality of life (SF-36) questionnaires.

General information

Acronym

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IRCT registration information

IRCT registration number: **IRCT2015120120912N4**
Registration date: **2016-03-03, 1394/12/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-03-03, 1394/12/13

Registrant information

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Mohsen Shahriari
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of collaborative care on the quality of life of patients after coronary angioplasty

Public title

The effect of cooperation of treatment team and the patient on the quality of life in patients after coronary angioplasty

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being aged more than 18 and less than 70 years; being conscious; having the ability to make

communication; being aware of their disease; being able to read and write; not having an acute cardiovascular disease, diabetes type 1 and 2, hormone disorders and renal and mental diseases; having appropriate clinical condition according to physician’s diagnosis and not having any constraints for performing the interventions. Exclusion criteria: being absent for more than 2 educational sessions for intervention group; die or encounter any problem that would make them unable to continue the study.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezarjrib Ave, Isfahan

City
Isfahan

Postal code

Approval date
2015-05-26, 1394/03/05

Ethics committee reference number
394174

Health conditions studied

1

Description of health condition studied
patients after coronary angioplasty

ICD-10 code
Z95.5

ICD-10 code description
Presence of coronary angioplasty implant and graft

Primary outcomes

1

Description
quality of life

Timepoint
Before the intervention and 3 month after intervention

Method of measurement
SF-36 questionnaire

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Intervention group: collaborative treatment program was conducted in 5 group sessions; in a way that 3 educational collaborative care sessions were conducted weekly and 2 collaborative care follow-up sessions were conducted every other week and each session was 45 to 60 minutes. At first, the educational content was prepared by the researcher nurse based on authentic texts and original sources and in a collaborative session in the presence of the expert physician and the participants, the educational content was represented and the collaborative program was finalized after each participant’s agreement. During the session speech, question and answer and groups and individual discussion were used. After conducting the collaborative program, follow-up was conducted by calling the participants and addressing their questions and problems, as it has been agreed on before. During the first session patients were introduced to their current disease and its threats and complications and appropriate diet and physical activity and the right method of drug consumption for patients with coronary artery disease was explained to them by an expert physician and a nurse through a speech. During the second session, the presented educational content was discussed between the physician and the nurse with participation of the patients and an agreement was reached about the appropriate diet and physical activities and the final program was executed by

patients' opinion. During the third session the presented educational program was discussed between the physician, the nurse and the patients and an agreement was reached about the right method of drug consumption and the final program was executed by patients' opinion. The collaborative care follow-up sessions were conducted for continuity of the care program and involvement of the patients. Sessions were conducted every other week and twice for each patient. After the collaborative follow-up sessions, patients were followed up for 12 weeks through phone calls and by addressing their questions and problems, as it has been agreed on before.

Category
Other

2

Description
Control group: two group sessions were conducted to discuss the importance of medication, diet and exercise. sessions were held weekly each lasting 60 minutes.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Shahid Chamran Hospital

Full name of responsible person
Mohsen Shahriari

Street address
Isfahan Shahid Chamran Hospital, Moshtagh Ave, Isfahan

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Isfahan University of Medical Sciences

Full name of responsible person
Mehdi Nemathbakhsh

Street address
Isfahan University of Medical Sciences, Hezarjrib Ave, Isfahan

City
Isfahan

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 of Isfahan University of Medical Sciences

Proportion provided by this source
100

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
Parastoo Rezapoor

Position
MSc

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Assistant professor, PhD

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00

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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