

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Study of the effect of family-centered self-care program on medication and dietary regimen adherence in patients with acute coronary syndrome discharged from hospital

Protocol summary

Study aim

Determination of the effect of family-centered self-care program on medication and dietary regimen adherence in patients with acute coronary syndrome discharged from hospital

Design

This study is a two-group and three-stage clinical trial. The researcher assessed the adherence to the dietary and pharmaceutical diet in both groups before and immediately before and 1.5 months after the intervention.

Settings and conduct

Sampling will begin at the hospital and CCU and intervention at home and with the family and patient care will be done. The person who will summarize the statistics will not know about the placement of samples in the intervention and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have at least reading and writing skills in the patient and the main caregiver. The patient and his main caregiver will have an acquaintance in Persian. Patient's home is in Isfahan. Possibility to make phone calls and face-to-face visits with the patient and his caregiver. The sick person does not live alone. The absence of mental illness, mental retardation, blindness, deafness and severe malignancy in the patient and his primary caregiver. Exclusion criteria: Progression of illness during study or patient death. Unwillingness to continue participating in the study.

Intervention groups

In this research, the standard home visits (starting, before, visit, ending, post-visit) steps will be followed. At the visiting stage, an educational and support intervention will be held during 5 to 7 sessions of 45 to 60 minutes with each test group and within 7 weeks (one week each week). Control group members receive only routine nursing care (Pharmacotherapy and control of

vital signs and the implementation of physician orders).

Main outcome variables

medication and dietary regimen adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180306038970N1**

Registration date: **2018-09-08, 1397/06/17**

Registration timing: **retrospective**

Last update: **2018-09-08, 1397/06/17**

Update count: **0**

Registration date

2018-09-08, 1397/06/17

Registrant information

Name

Maryam Montazami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4522 3097

Email address

maryam.montazami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of family-centered self-care program on medication and dietary regimen adherence in patients with acute coronary syndrome discharged from hospital

Public title

The effect of family-centered self-care program in patients with acute coronary syndrome

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having at least reading and writing skills in the patient and the main caregiver The patient and his main caregiver will have an acquaintance in Persian. Patient's home is in Isfahan. Possibility to make phone calls and face-to-face visits with the patient and his caregiver The sick person does not live alone.

Exclusion criteria:

The presence of mental illness, mental retardation, blindness, deafness and severe malignancy in the patient and his primary caregiver

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **72****Randomization (investigator's opinion)**

Randomized

Randomization description

Sampling patients easily, Then, the randomization was divided into two groups: intervention and control simply based on random numbers

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**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar jarib Ave

City

Esfahan

Province

Isfahan

Postal code

73461-81746

Approval date

2018-03-05, 1396/12/14

Ethics committee reference number

396869

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

Acute coronary syndrome

ICD-10 code

I25.9

ICD-10 code description

NOS I25.9

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

Mean score of medication adherence in Morisky questionnaire

Timepoint

Measurement of Medium medication Adherence before, Immediately and 1.5 months after the intervention

Method of measurement

Morisky questionnaire

2**Description**

The mean of dietary adherence score in Neda Sanaei's dietary adherence questionnaire

Timepoint

Measurement of Medium dietary Adherence before, Immediately and 1.5 months after the intervention

Method of measurement

Neda Sanaei's Adherence to Dietary Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Implementation of family-centered self-care program in intervention group through 5 to 7 meeting sessions at the patient's home based on the

pattern of visiting the patient home

Category

Lifestyle

2

Description

Control group: Complete relevant questionnaires and provide training for these patients after completing the study

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran hospital

Full name of responsible person

Maryam Montazami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology of Isfahan
University of Medical Sciences

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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

Esfahan University of Medical Sciences

Proportion provided by this source

60

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

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Montazami

Position

Master of Community health nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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City
Shahin shahr
Province

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available