Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The effect of the family-centered educational program on medication management and quality of life in elderly patients with ischemic heart disease

Protocol summary

Study aim
Determining the effect of family-based education program on drug management and quality of life in the elderly with ischemic heart disease

Design
This research is a randomized clinical trial with two groups of test and control.

Settings and conduct
The research population in this study will be all elderly people with ischemic heart disease who will be referred to the heart clinic of Kashan Beheshti Hospital in 1397. The control group will receive the usual training of the clinic and the intervention group will receive family-centered education.

Participants/Inclusion and exclusion criteria
Reading and writing literacy; age 60-75, absence of diagnosed psychological illness, heart disease diagnosis by the heart doctor, at least 6 months from the diagnosis of the disease, and Pain status and hemodynamic stability. Positive response to two or more questions is the HbL Drug Dangers Questionnaire, which is used to assess the problems associated with drug use in the elderly. Residence of the active member of the family at the place of residence of the patient or close to him, the possibility of making phone calls to the patient and the active member of the family; Exclusion criteria include: entering the acute phase of the disease, co-operating in other similar specialized studies, having even one absentee session in the classroom for the patient or active member of the family, the reluctance to continue Participation in the study or death of a patient or an active member of the family, failure to answer a telephone number is at least two.

Intervention groups
All elderly patients with ischemic heart disease eligible to participate in the study referring to the target center are randomly assigned to intervention and control groups.

Main outcome variables
Quality of Life, Pharmaceutical Management

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180513039646N1**
Registration date: **2018-09-23, 1397/07/01**
Registration timing: **retrospective**

Last update: **2018-09-23, 1397/07/01**
Update count: **0**

Registration date
2018-09-23, 1397/07/01

Registrant information

Name
Zahra Sadat Hejazi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-30, 1397/02/10

Expected recruitment end date
2018-06-10, 1397/03/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the family-centered educational program on medication management and quality of life in elderly patients with ischemic heart disease

Public title

The effect of the family-centered educational program on medication management and quality of life in elderly patients with ischemic heart disease.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Reading and writing literacy (for patient or family member) Age between 60 and 75 years The absence of diagnosed psychological illness Ischemic Heart Disease Detected by Heart Disease At least 6 months have passed since the diagnosis of the disease and has a sustained pain and hemodynamic status A positive response to two or more questions is the "HbL Drug Dangers Questionnaire" that is used to assess the problems associated with drug use in the elderly. Residence of an active member of the family at or near the patient's place of residence

Exclusion criteria:

Entry into the acute phase of the disease The company participated simultaneously in other similar specialized studies Having even a session absent in the classroom for a patient or family member Unwillingness (patient and active member of the family) to continue participating in the study or death of a sick person or an active member of the family Do not answer phone at least for two times

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is done in two steps, so that in the first step, random sampling is done using a random number table from the patient list to the sample size. In the second step, the samples are randomly allocated by blocking method in two groups of test and control (design of permutation blocks with two treatments). Given the letter "A" for the intervention group and the letter "B" for the control group, then all the permutation combinations that have six different combinations are written and for each permutation of one of the digits 1 to 6 (For example, a, b, b for digit 1, a, b, a, for digit 2, etc.). Then, from digits 1 through 6, a digit is selected randomly, and we continue to do this until the sample size reaches the quantification.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Initially, in both groups of patients with ischemic heart disease in research clinics with follow-up records, demographic and disease inventory, drug management tools and elite life quality of LEIPAD will be completed. In this study, the control group Only the clinic's usual education will be received and in the family-based training group, the training will be in the form of three sessions of training, 40-30 minutes, to the patient and the active member of the family. Clinical classroom sessions in groups of 3 to 6 (from each patient with an active member of the family at a meeting) will be agreed upon at the hour. It should be noted that at the end of this step, in order to comply with the ethics of the educational pamphlet, it will also be presented.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee on Ethics in the Research of Nursing Midwifery and Rehabilitation Faculty of Tehran Univer

Street address

Towhid Square, Dr Mirkhani Street (Eastern Nusrat), Faculty of Nursing, Tehran University of Medical Sciences

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Approval date

2018-02-10, 1396/11/21

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4476

Health conditions studied

1

Description of health condition studied

Ischemic Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischemic heart disease, unspecified

Primary outcomes

1

Description
Quality of Life: It is the individual's thoughts of his or her living conditions, according to the culture and value system in which they live, and the relation of these receipts to their goals, expectations, expectations, standards and priorities. Pharmaceutical Management: Includes patient-focused care that optimizes safe, effective, and effective drug treatment, and is provided through collaboration with patients and their care team.

Timepoint
These variables are measured at the beginning of the study and three months after the intervention.

Method of measurement
The quality of life in this study is a score that a person earns based on the LEIPAD Quality of Life Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in the intervention group, family-centered education will be provided to the patient and active member of the family in the form of three sessions of 40-30 minutes. Clinical classroom sessions in groups of 3 to 6 (from each patient with an active member of the family at a meeting) will be agreed upon at the hour, so that the first session includes the referencing and expression of the voluntary nature of the research, and Clarifying the researcher's expectations at different stages of the study, as well as identifying the expectations and expectations of the patients and their active members of the family, determining and agreeing on the length of the appointment or telephone appointment (the phone will be used only for essential reminders and conversations) and the purpose And the second session also includes the definition of ischemic heart disease, its types and the explanation of pathophysiology Xi concise and understandable for the patient, symptoms, risk, clinical protests. The third session includes an explanation of the various therapeutic and pharmaceutical approaches, the types of drugs in these diseases and important points during their use, the care and helpful strategies to improve the lifestyle of the elderly, such as diet, activity and stress control The way of self-care and the importance of maintaining mental, social and sexual performance. It should be noted that at the end of this step, in order to comply with the ethics of the educational pamphlet, it will also be presented.

Category
Lifestyle

2

Description
Control group: the control group will receive only the usual training of the clinic.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital of Kashan

Full name of responsible person
Zahra Sadat Hejazi

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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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

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

Zahra Sadat Hejazi

Position

Master of Science of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments

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