Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Investigating the effect of family-centered education on adherence to medication regimen in patients with cardiomyopathy

Protocol summary

Study aim

Determining the effect of family-oriented education on adherence to drug regimen in patients with cardiomyopathy

Design

Clinical trial with a randomized control group, intervention on 80 patients including 40 people in the control group and 40 people in the intervention group. Randomization using the block method

Settings and conduct

Sampling at the Rajaee heart center in Tehran, explanation of study objectives and obtaining consent, in the intervention group, the patient must attend the meetings together with a permanent member. Due to the inability to tolerate multiple visits, the training will be conducted in 2 half-hour sessions in groups of 4-6 people using a combination of training methods. In the last session, the patient's contact number will be obtained for evaluation after the intervention. According to the opinion of the relevant doctor, after 4 weeks, the electronic form of the questionnaire will be sent to the patient to be completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria Doctor's confirmation for the patient in terms of having cardiomyopathy Having a minimum of 18 and a maximum of 65 years Residence in Tehran or the possibility of staying in Tehran for at least one week if you are a passenger. Having literacy for both the patient and the family member Access to a smartphone and the ability to work with a smartphone (for patients or active caregivers) Residence of an active family member in the patient's place of residence or close to him The possibility of making a phone call with the patient or an active family member Non-entry criteria: Patients who do not have sufficient physical and mental capacity to participate in the study or who have a severe and critical illness

Intervention groups

Intervention group: including 40 people, in which the level of adherence to the medication regimen will be measured by Morisky medication adherence questionnaire (MMAS-8) once before providing family-oriented education and once after providing education. Control group: includes 40 people who will complete MMAS-8 by these people without providing family-oriented education and only by providing regular and routine education.

Main outcome variables

The degree of adherence with the medication regimen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230216057433N1**
Registration date: **2023-04-10, 1402/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-10, 1402/01/21**
Update count: **0**

Registration date

2023-04-10, 1402/01/21

Registrant information

Name

Fatemeh Kheirkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-04-09, 1402/01/20
Expected recruitment end date
2023-08-11, 1402/05/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of family-centered education on adherence to medication regimen in patients with cardiomyopathy

Public title
The effect of family-centered education on adherence to medication regimen in patients with cardiomyopathy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
• Doctor's confirmation for the patient in terms of having cardiomyopathy• with symptoms classified as class II or higher heart failure, with a left ventricular ejection fraction of 45% or less • Absence of diagnosed psychological illness, • Having a minimum of 18 and a maximum of 65 years to enter the study for both the patient and the family member • Residence in Tehran or the possibility of staying in Tehran for at least one week if you are a traveler, in order to be able to attend training sessions • Failure to simultaneously participate in other similar researches, • Being literate in reading and writing for both the patient and the family member • Access to a smartphone and the ability to work with a smartphone (for the patient or an active caregiver) to follow up • Residence of an active family member in the patient's place of residence or close to him • The possibility of making a phone call with the patient or an active family member
Exclusion criteria:
Patients who do not have sufficient physical and mental capacity to participate in the study or who have a severe and critical illness.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Available sampling in the form of block random allocation. Considering that in this study we have two groups including an intervention group and a control group, the size of the blocks will be twice the number of groups, i.e. 4, and the number of blocks obtained will be 6 blocks (AABB, ABAB, ABBA, BBAA BABA, BAAB). First, one of the numbers of the blocks is randomly selected by the statistical software, and then the samples will be assigned to the corresponding group based on the order of placement in each block. In the block, patients will enter one of the intervention and control groups (intervention = A, control = B). This work will continue until the number of samples is completed.
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 Iran University of Medical Sciences
Street address
No 8, East 9th Ave, Salehi St, Laleh Blvd, Tehransar
City
Tehran
Province
Tehran
Postal code
1387977338
Approval date
2023-02-22, 1401/12/03
Ethics committee reference number
IR.IUMS.REC.1401.955

Health conditions studied

1

Description of health condition studied
Cardiomyopathy
ICD-10 code
I42.9
ICD-10 code description
Cardiomyopathy, unspecified

2

Description of health condition studied
Adherence to medication regimen
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Family-centered education
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The degree of adherence with the medication regimen
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
The way to measure the variable in this study is Morisky's 8-question medication adherence questionnaire, which includes 6 yes/no questions and one question with a likert scale from never to always.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, the patient must attend the meetings together with a fixed member designated by the patient.Due to the physical condition of the patients and the inability to tolerate multiple visits, according to the doctor's opinion, the trainings are held in 2 half-hour sessions in groups of 4-6 people using a combination of educational methods in the form of showing a voiced video containing text and images and providing an educational pamphlet. And a short speech will be made. The educational content in the first session includes: Familiarity with cardiomyopathy, how to control vital signs, the importance of following the medication regimen and accurate medication use, and in the second session: Familiarity with important medications in cardiomyopathy and how to take care and precautions in using the patient's medications, drug side effects and their management.In the last session, the contact number of the patient and the active member will be obtained to coordinate for the evaluation after the intervention. Due to the fact that it is difficult for the participants to visit in person after the intervention due to their illness or age, and in addition, the time of the next visit for the visit is not the same for all patients, in order to maintain the consistency of the examination time after 4 weeks of the intervention. According to the opinion of the relevant FLO), first, the electronic form of the questionnaire will be sent to the contact number or email address of the patient or active family member and will be reminded to complete the questionnaire during a phone call. After receiving the completed form of the questionnaires, the collected data will be entered into the SPSS software It will be 16.The data will be analyzed with appropriate statistical tests. Control group: The training in the control group will be with the routine training of the hospital. This group will complete the questionnaire twice, once before and once after 4 weeks of receiving the routine training of the hospital.
Category
Lifestyle

2

Description
Control group: The control group consists of 40 people in the study, who entered this group by random allocation method of block type, and completed the Morisky medication adherence questionnaire by them, twice, without providing family-centerd education and only with providing routine and usual training will be done during the period of 4 weeks.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Cardiovascular Research and Treatment Center
Full name of responsible person
Fatemeh Kheirkhah
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Masoomeh Kheirkhah
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Phone
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Email
info@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Fatemeh kheirkhah
Position
Senior nursing student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data related to the disease and medication compliance before and after the intervention will be shared.
When the data will become available and for how long
Access starts 3 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There is no limitation in performing statistical analysis on the data of this study. Researchers can use the data as a reference in their studies, mainly in the description of existing conditions.

From where data/document is obtainable

Applicants can contact the following email address to receive the data. fn.kheirkhah@gmail.com

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

Honorable applicants must send along with their application, the purpose of the data request, the title of their research work and the code of research ethics for which they need the data of the present study. After checking the title and confirming the code of ethics, the data will be sent to the applicant's email address as soon as possible.

Comments