

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of family-centered education on self-care behaviors of patients after acute myocardial infarction

Protocol summary

Study aim

Determining the effect of family-centered education on self-care behaviors in patients after acute myocardial infarction

Design

The number of samples in this study is 70 based on the sample size formula. Patients are selected by sampling method and are placed in two groups of control and intervention according to the table of random numbers.

Settings and conduct

This study will be performed on patients with acute myocardial infarction admitted to CCU wards of hospitals affiliated to Shiraz University of Medical Sciences. For the intervention group, family-centered education will be implemented in three sessions. Data collection tools include demographic information form and a specialized questionnaire to assess the self-care ability in heart patients of Kerni and Felicher. The specialized questionnaire will be completed in three stages before the intervention, one and two months after the completion of the internship in both groups. At the end of the three training sessions, patients will be given a checklist of daily activities, and patients will be followed up by telephone every two weeks until the questionnaire is completed.

Participants/Inclusion and exclusion criteria

being over 18 years old; Diagnosis and confirmation of myocardial infarction by a specialist physician; having a minimum literacy for the patient and active family member; fluency in Persian in the patient and active family member; no known mental illness in the patient and active family member; patient desire And an active family member to participate in the study

Intervention groups

In the intervention group, the intervention is held in the form of self-care training to the patient with an active family member in 3 sessions of 45-60 minutes. In the control group, no intervention will take place and they will receive only the usual care of the ward.

Main outcome variables

Self-care behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211116053078N1**

Registration date: **2021-11-23, 1400/09/02**

Registration timing: **prospective**

Last update: **2021-11-23, 1400/09/02**

Update count: **0**

Registration date

2021-11-23, 1400/09/02

Registrant information

Name

Elham Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

e_taheri@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered education on self-care behaviors of patients after acute myocardial infarction

Public title

The effect of family and patient education on care behaviors in patients with myocardial infarction

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Active family member (according to the patient, a family member who is the main caregiver of the patient and spends the most time with her) Having an age range above 18 years Diagnosis and confirmation of myocardial infarction based on Ck mb-troponin I enzyme tests, ECG changes, clinical signs by a specialist doctor Having the minimum literacy to read and write in the patient and active family member Fluency in Persian language in the patient and active family member Lack of known mental illness in the patient and active family member The desire of the patient and active family member to participate in the study

Exclusion criteria:

Not wanting to continue participating in the study Non-Iranian nationality Living alone or in a nursing home

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

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

Samples will be selected by available sampling from among patients with acute myocardial infarction admitted to the CCU wards of selected hospitals who are eligible for admission and after selection by random allocation using a random number table will be divided into control and intervention groups. The letters a and b will be considered as code, so that the letter a will be assigned to one of the groups and the letter b to the other group. Samples will be selected from the same number of selected centers.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is a blind sur. The help of a researcher who is unaware of the intervention and control group will be used to collect questionnaires and evaluate the data.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz, Namazi Square "Namazi Hospital" Fatemeh School of Nursing and Midwifery

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2021-09-06, 1400/06/15

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1400.023

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

Acute myocardial infarction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Self-care behaviors

Timepoint

Before the intervention, one month and two months after the intervention

Method of measurement

Self-care behaviors questionnaire in heart patients from Carney and Fleischer

Secondary outcomes

empty

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

Intervention group: Teaching self-care behaviors in three sessions to patients with acute myocardial infarction with

an active family member.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital, Saadi Hospital, Al-Zahra Heart Hospital

Full name of responsible person

Elham Taheri

Street address

Shiraz, Namazi Square "Namazi Hospital" Fatemeh School of Nursing and Midwifery

City

Shiraz

Province

Fars

Postal code

71936-13119

Phone

+98 71 3647 4254

Email

elhamtaheri32@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Kamyar Zomordian

Street address

Shiraz, Namazi Square "Namazi Hospital" Fatemeh School of Nursing and Midwifery

City

Shiraz

Province

Fars

Postal code

71936-13119

Phone

+98 71 3647 4254

Email

nurs-midwif@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Shiraz University of Medical Sciences

Full name of responsible person

Elham Taheri

Position

Master student in adult intensive care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Phone

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Fax

Email

e_taheri@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

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Person responsible for updating data

Contact

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Province

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Fax**Email**

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participants' personal data can be shared after being
unidentified and information about the main outcome.

When the data will become available and for how long

A few 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

Use the results of other research

From where data/document is obtainable

Taheri Elham elhamtaheri32@yahoo.com

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

Request via email address

Comments