

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effects of a support program based on psychosocial needs of families on care burdens of family caregivers of patients with ischemic heart disease hospitalized in Chamran heart ward of Isfahan University of Medical Sciences in 1394

Protocol summary

Summary

The aim of study was to analysis of the effects of a support program based on psychosocial needs of families on care burdens of family caregivers of patients with ischemic heart disease. Inclusion criteria included: caregiver is responsible for Patient Care and the age range between 18-65 years. Exclusion criteria: there is any problem so that families are not able to participate in the study; patients are dying or dead during the study. This study consisted of 64 patients with ischemic heart disease (32 people in experimental group and 32 people in control group) who were referred to inner heart wards of Chamran hospital Isfahan. Intervention consists of three 45 minute sessions in groups of 5-6 people to support family caregivers and controls in additional routine care hospitals, participated in 2 session with care in heart patients. The study was conducted in 1394. To assess the burden of caring for the caregivers of patients with ischemic heart disease three times before, immediately after and one month after the intervention, the results of two intervention and control groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041127331N1**

Registration date: **2016-05-04, 1395/02/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-04, 1395/02/15

Registrant information

Name

Fateme Shariatifar

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3825 0621

Email address

mgholami@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-12-28, 1394/10/07

Expected recruitment end date

2016-02-26, 1394/12/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of a support program based on psychosocial needs of families on care burdens of family caregivers of patients with ischemic heart disease hospitalized in Chamran heart ward of Isfahan University of Medical Sciences in 1394

Public title

The effect of nursing support on family caregiver burden for patients with ischemic heart disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria were: the patient's immediate family; able to speak and write in Persian; Family members not responsible for the care of someone else sick; the age range between 18-65 years. Exclusion criteria: there is any problem so that families are not able to participate in the study; patients are dying or dead during the study.

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: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Street Hezarjarib, School of Nursing and Midwifery
Isfahan University of Medical Sciences.

City

Isfahan

Postal code

81746-73461

Approval date

2015-10-13, 1394/07/21

Ethics committee reference number

IR.MUI.REC.1394.3.561

Health conditions studied

1

Description of health condition studied

Ischemic heart disease

ICD-10 code

I24

ICD-10 code description

Other acute ischaemic heart diseases

2

Description of health condition studied

Ischemic heart disease

ICD-10 code

I25

ICD-10 code description

Chronic ischaemic heart disease

3

Description of health condition studied

Ischemic heart disease

ICD-10 code

I23

ICD-10 code description

Certain current complications following acute myocardial infarction

4

Description of health condition studied

Ischemic heart disease

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

5

Description of health condition studied

Ischemic heart disease

ICD-10 code

I22

ICD-10 code description

Subsequent myocardial infarction

6

Description of health condition studied

Ischemic heart disease

ICD-10 code

I20

ICD-10 code description

Angina pectoris

Primary outcomes

1

Description

Family caregiver burden for patients with ischemic heart disease

Timepoint

before intervention, Immediately after the intervention, 1 month after intervention

Method of measurement

Caregiver Burden Interview

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group: Intervention consist supportive training sessions in three 45 minute sessions in three days for patients' family members. Training in groups of 5-6 persons on family caregivers was conducted in Chamran Hospital

Category

Other

2

Description

Control group: This group, along with routine care hospitals, two 45 minute session in relation to ischemic heart disease care received during the same period.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital, Isfahan University of Medical Sciences

Full name of responsible person

Fateme Shariatifar

Street address

Street Moshtagh 3, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mahin Moeini

Street address

St. Hezarjarib, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Esfahan

City

Isfahan

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

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

Fateme Shariatifar

Position

Master of Nursing

Other areas of specialty/work

Street address

St. Hezarjarib, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Esfahan

City

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 7533

Fax

+98 31 3669 9398

Email

fatemehshariatifar@gmail.com

Web page address

nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fateme Shariatifar

Position

Master of Nursing

Other areas of specialty/work

Street address

St. Hezarjarib, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Esfahan

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Phone

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Fax

+98 31 3669 9398

Email

fatemehshariatifar@gmail.com

Web page address

nm.mui.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Fateme Shariatifar

Position

Master of Nursing

Other areas of specialty/work**Street address**

Isfahan, street hezar jarib University of Medical Sciences, School of Nursing and Midwifery

City

Isfahan

Postal code

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Phone

+98 31 3792 7533

Fax

+98 31 3669 9398

Email

fatemehshariatifar@gmail.com

Web page address

nm.mui.ac.ir

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