

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of nutritional consulting program on nutritional behavior and relationship with re-hospitalization among patients with Myocardial Infarction

Protocol summary

Summary

Myocardial infarction is the cause of numerous heart diseases, which can bring patients back to treatment centers even long after the hospital discharge. Due to reduced severity of disease signs and symptoms and the passage of time, patients' adherence to self-care behaviors is diminished in most cases, which will result in worsening symptoms and signs and even increased risk of re-hospitalization. Methodology: This study was a randomized clinical trial conducted on 120 patients with myocardial infarction who were randomly divided into two 60-member intervention and control groups. Inclusion Criteria: definitive diagnosis of myocardial infarction by a cardiologist for the first time; hospitalization in cardiac wards or intensive care units; stability of the patient's hemodynamic status; not receiving nutritional consultation by another person. Exclusion criteria: suffering from untreated heart failure; uncontrolled arrhythmias; severe and persistent chest pain or discontinuation of cooperation; suffering from an underlying; if interacted to the consultation plan, it will exit from study; death during the study. Instruments: The MEDFICTS questionnaire was filled out before and two months after the intervention. The intervention group was invited to participate in 3 nutritional counseling sessions. Two months after counseling sessions, weekly telephone follow-ups will be done. The control group will receive only routine care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502035987N17**

Registration date: **2015-07-01, 1394/04/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-01, 1394/04/10

Registrant information

Name

Shahrzad Ghiasvandian

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-04-19, 1394/01/30

Expected recruitment end date

2015-07-21, 1394/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of nutritional consulting program on nutritional behavior and relationship with re-hospitalization among patients with Myocardial Infarction

Public title

Effects of nutritional consulting program on nutritional

behavior and relationship with rehospitalization among patients with Myocardial Infarction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion / Exclusion: Inclusion Criteria: definitive diagnosis of myocardial infarction by a cardiologist for the first time; hospitalization in cardiac wards or intensive care units; stability of the patient's hemodynamic status; not receiving nutritional consultation by another person. Exclusion criteria: suffering from untreated heart failure; uncontrolled arrhythmias; severe and persistent chest pain or discontinuation of cooperation; suffering from an underlying; if interacted to the consultation plan, it will exit from study; death during the study.

Age

From **36 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Based on simple randomly, according to odd and even numbers, individuals were selected to the control and intervention group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran, Amir Abad, Keshavarz Blvd.

City

Tehran

Postal code

1419733171

Approval date

2015-02-10, 1393/11/21

Ethics committee reference number

9111196003122574

Health conditions studied

1

Description of health condition studied

Myocardial Infraction

ICD-10 code

I219

ICD-10 code description

Diseases of the circulatory system

Primary outcomes

1

Description

Nutritional behavior

Timepoint

Two months

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Re-hospitalization

Timepoint

two months

Method of measurement

Self-reported

Intervention groups

1

Description

Intervention group: This study is a randomized clinical trial investigating 120 patients with myocardial infarction. Using the research tools, the researcher measured subjects' nutritional behavior and hospital readmission before and two months after nutritional counselling. In this study, the nutritional counseling program included three 90-minute sessions during one week. Moreover, if necessary, patients' questions will be answered after individual counseling sessions in person and through telephone follow-ups.

Category

Prevention

2

Description

Control group: These patients will receive routine care including giving an explanation of the prescription and make a recommendation to see the doctor at the appointed time for the next visit. Data will be collected using the self-report method and a questionnaire.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeyni Hospital

Full name of responsible person

Roghaye Eghbali

Street address

Tehran, Tohid Square.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masood Younesian

Street address

The central building of Tehran University of Medical Sciences, Qods Street, Keshavarz Street, Tehran, Iran

City

Tehran

Grant name

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Grant code / Reference number

000

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

Yes

Title of funding source

Vice chancellor for research, Tehran 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**

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Roghaye Eghbali

Position

Student of Nursing in Master of Science

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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