

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of educational - supportive intervention based on Orem model, on self care in patient with myocardial infarction.

Protocol summary

Summary

Objective: Determining the effect of an educational-supportive intervention based on Orem model on self-care of patients with heart attack (myocardial infarction)
Method: Randomized clinical trial with intervention and control groups
Population: Patients with heart attack and history of hospitalization in 22 Bahman hospital
Inclusion criteria: 1) approved heart attack 2) at least one hospitalization for heart attack 3) up to three months passed from the last heart attack caused hospitalization 4) having no verbal and auditory problems and no mental, physical and psychological disabilities 5) willingness to participate in study
Exclusion criteria: 1) more than 3 months passed from the last heart attack caused hospitalization 2) no willingness to participate in study 3) unexpected events
Sample: 63 patients in each group
Intervention: The intervention groups consisted of three 21-members groups which will be educated with a face to face and group discussion method (universal, developmental and health derived requisites in three domains of awareness, motivation and proficiency). Each group will receive two 45-minutes educational sessions in one week. The follow up period will be 45 days, in which every 15 days the researcher contacts with samples and plan a visit in specified days of a week.
Study outcomes: If this intervention has positive effects on these patients, their ability will improved and it will be possible to participate them in different parts of their own self-care and they can reach to an appropriate level of self-care with taking responsibilities.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202219096N1**
Registration date: **2012-03-14, 1390/12/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-14, 1390/12/24

Registrant information

Name

Narjes Rahmati Sharghi

Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Vice Chansellor for Research, Gonabad University of Medical Sciences

Expected recruitment start date

2012-03-05, 1390/12/15

Expected recruitment end date

2012-05-04, 1391/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational - supportive intervention based on Orem model, on self care in patient with myocardial infarction.

Public title

The effect of on Orem model, on self care in patient with myocardial infarction.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Approved heart attack; At least one hospitalization for heart attack; Up to three months passed from the last heart attack caused hospitalization; Having no verbal and auditory problems and no mental, physical and psychological disabilities; Willingness to participate in study. Exclusion criteria: More than 3 months passed from the last heart attack caused hospitalization; No willingness to participate in study; Unexpected events.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 126

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethic Committe of Gonabad University of Medical Sciences

Street address

Asian Road, Gonabad University of Medical Sciences ,
Gonabad

City

Gonabad

Postal code

9691793718

Approval date

2012-02-25, 1390/12/06

Ethics committee reference number

90/4/8 /I س

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I23

ICD-10 code description

Certain current complications following acute myocardial infarction

Primary outcomes

1

Description

Educational - supportive System

Timepoint

Before and After Intervention

Method of measurement

Questionnaire based on OREM Model

Secondary outcomes

1

Description

Self care

Timepoint

Before and After Intervention

Method of measurement

Questionnaire based on OREM Model

Intervention groups

1

Description

Intervention group: The intervention group will be educated with a face to face and focus group discussion and will be supported, consulted and advised in universal, developmental and health derived requisites in three domains of awareness, motivation and proficiency. Samples will be divided into three 21-members groups and each group will receive two 45-minutes educational sessions in one week. The educational environment will be the same for all groups and be held in university or hospital (up to the patients mind). After finishing educational sessions, patients will be followed for 45 days and each 15 days the researcher will contact them by telephone calls and if needed patients receive individual education and consultation. Then the level of self-care in both control and intervention groups will be assessed.

Category

Rehabilitation

2

Description

control group: Without intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahman 22 Hospital

Full name of responsible person

Street address

City

Gnabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Ekrami Ali

Street address

Asian Road, Gonabad University of Medical Sciences ,

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City

Gonabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

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Full name of responsible person

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Position

master student nursing

Other areas of specialty/work

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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