

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

A comparative study of the impact of nursing care based on the specific situational model and OREM`s Self Care Model on the quality of life of heart attack patients

Protocol summary

Study aim

Determining the effectiveness of nursing care based on the specific situational model and OREM`s Self Care Model on the quality of life of heart attack patients

Design

Clinical trial with control group, with two parallel groups, double blind, randomized, phase 3 on 75 patients. A table of random numbers was used for randomization.

Settings and conduct

After obtaining the permits, the researcher went to the special cardiac care unit of Imam Khomeini Hospital in Khomein and selected 75 patients with MI eligible to enter randomly 25 patients in each group. Then, measuring the quality of life of the patients in 3 groups based on the SF-36 questionnaire before the intervention is done. In study group 1, the implementation of nursing care for 2 months is started based on the pattern of specific situation. In study group 2, the implementation of nursing care for 2 months starts based on Orem's nursing care model. The patients of the control group are under the usual care of the department. Two months after the discharge of the patients, the questionnaire will be completed again by all three groups. At the end of the comparison of the average score of the quality of life in 3 groups, the conclusion is announced. This is a double-blind study in such a way that the patients are unaware of the type of intervention in other groups and the research data is provided to the data analyst in raw form

Participants/Inclusion and exclusion criteria

Conditions for entering the study: having a heart attack according to the physician's diagnosis; not sufferer from cancer; no mental disorders. Conditions of not entering the study: history of hospitalization in cardiac care unit.

Intervention groups

Nursing intervention group based on specific situation model. Nursing intervention group based on Orem's nursing care model. Control group with routine nursing

care

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231224060510N1**

Registration date: **2024-01-15, 1402/10/25**

Registration timing: **prospective**

Last update: **2024-01-15, 1402/10/25**

Update count: **0**

Registration date

2024-01-15, 1402/10/25

Registrant information

Name

Hamid Momeni

Name of organization / entity

Khomein Faculty of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the impact of nursing care based on the specific situational model and OREM`s Self Care Model on the quality of life of heart attack patients

Public title
A comparative study of the impact of nursing care based on the specific situational model and OREM`s Self Care Model on the quality of life of heart attack patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having a heart attack according to the physician's diagnosis and entered in the patient's file Not sufferer from cancer No mental disorders Consent to participate in the research by filling out Informed consent form A resident of Khomein city

Exclusion criteria:
History of hospitalization in cardiac care unit

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: 75

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done based on the table of random numbers. In this way, in the beginning, all the research units were numbered, then the RandBetween function was used by Excel software, and between the numbers 1 and 75 random numbers were obtained, and then the first 25 random numbers in the first study group, the second 25 random numbers. In the second study group and 25 random numbers in the third are placed in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The research units are unaware of the type of intervention in other groups. The data analyst also has access to the raw data.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Khomein Faculty of Medical Sciences

Street address

Khomein Faculty of Medical Sciences, Quds Blvd.

City

Khomein

Province

Markazi

Postal code

3881743364

Approval date

2023-12-12, 1402/09/21

Ethics committee reference number

IR.KHOMEIN.REC.1402.025

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21.9

ICD-10 code description

Myocardial infarction

Primary outcomes

1

Description

Quality of Life

Timepoint

Quality of life is measured at the beginning of the intervention and 2 months after the intervention

Method of measurement

Quality of life questionnaire SF-36

Secondary outcomes

empty

Intervention groups

1

Description

Nursing care for 2 months based on the specific situational model. In this group, after completing the quality of life questionnaire, first a preliminary meeting is held and educational materials are presented and a notebook containing the information needed by the

patient is given to him in simple language. There is also a table in this notebook where weekly information such as blood pressure, weight and edema are recorded. At the end of 2 months, the quality of life questionnaire is completed again.

Category

Rehabilitation

2**Description**

Nursing care for 2 months based on Orem's nursing care model. In this group, after completing the quality of life questionnaire, 3 sessions will be held in the cardiac special care unit. 24 hours after admission, 72 hours after admission and before discharge from the ward. In the first session, introduction and communication with the patient is done and a special educational pamphlet is presented to them. In the second session, training is given on the disease, symptoms and treatment, and in the third session, summary and discharge training is given. The condition of the patient is followed up every week for 2 months and the necessary training is given. After 2 months, the quality of life questionnaire will be completed again.

Category

Rehabilitation

3**Description**

The patients of the control group are under the usual care of the department. Actions include daily visits, giving prescribed medicines based on the physician's order, vital signs control, cardiac rhythm control, regular education about drugs, diet, exercise, follow-up of tests and referrals.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Hamid Momeni

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Moddares Square, Khomein, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

The Khomein Faculty of Medical Sciences

Full name of responsible person

Maryam Chegeni

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Grant name

Vice President of Research and Technology of Khomein Faculty of Medical Sciences

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The Khomein Faculty 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**

The Khomein Faculty of Medical Sciences

Full name of responsible person

Hamid Momeni

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Research results

When the data will become available and for how long

The end of the research

To whom data/document is available

- Researchers working in academic institutions -
Employees in the nursing profession

Under which criteria data/document could be used

All actions that are not contrary to ethics in research can be done

From where data/document is obtainable

The request should be sent to hamid52us@yahoo.com.

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

The request should be sent to hamid52us@yahoo.com.

Comments