

# 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)

##### Phone

+98 86 4622 1536

##### Email address

hamid52us@yahoo.com

##### 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

**City**

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3881687954

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+98 86 4633 2211

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info@khomeinums.ac.ir

**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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Quds Blvd, Khomein, Iran

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3881858573

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**Web page address**

https://edu.khomeinums.ac.ir/

**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

**Name of organization / entity**  
The Khomein Faculty of Medical Sciences  
**Full name of responsible person**  
Hamid Momeni  
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Faculty member  
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Master  
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## Person responsible for updating data

### Contact

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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