# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 2026

## The effect of implementing continuous care model on self-care management of the elderly with pacemakers

### Protocol summary

**Study aim**
Determining the effect of continuous care on self-care of the elderly with pacemakers

**Design**
Clinical trial with control and test groups, randomized quasi-experimental, sample size in each group of 40 people, heads or tails randomization method

**Settings and conduct**
He referred to the heart clinic of Imam Khomeini Hospital and among the eligible individuals were placed in the experimental and control groups using a simple random method. Telephone intervention in the experimental group will be performed by the researcher for 12 weeks (at least once a week). In addition, in each telephone conversation session, the content of the conversation will be recorded in the set form. It should be noted that during the intervention, the control group will not be subject to any intervention by the researcher. At the end of the intervention, both groups will again answer the same questionnaires that they answered at the beginning of the study as a pre-test, as a post-test and then will be collected.

**Participants/Inclusion and exclusion criteria**
Age 60 to 74 years (young elderly) - Has a permanent pacemaker - Access to the phone with caller ID at home Lack of speech and hearing problems Lack of advanced cardiovascular disease and other vital organs - No history of receiving follow-up care using the phone Death - Reluctance to continue cooperation - Disconnection of telephone communication for two weeks in the first month and for 3 weeks in the second and third month of intervention

**Intervention groups**
The experimental group includes the elderly with heart failure with pacemaker for whom telephone counseling intervention will be performed for 12 weeks and also the control group includes the elderly with heart failure with pacemaker who during the intervention of the control group under no intervention. Will not be placed by the researcher.

**Main outcome variables**
Self-care management

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20201103049253N1**
Registration date: **2021-02-07, 1399/11/19**
Registration timing: **retrospective**

Last update: **2021-02-07, 1399/11/19**
Update count: **0**

**Registration date**
2021-02-07, 1399/11/19

**Registrant information**

**Name**
Mohammad Amini

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 5573 0315

**Email address**
mohammadaminitaha@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-04-21, 1398/02/01

**Expected recruitment end date**
2019-07-23, 1398/05/01

**Actual recruitment start date**
2019-04-21, 1398/02/01

**Actual recruitment end date**

2019-07-23, 1398/05/01

**Trial completion date**

2019-08-23, 1398/06/01

**Scientific title**

The effect of implementing continuous care model on self-care management of the elderly with pacemakers

**Public title**

Investigating the effect of caring for the elderly with pacemakers

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age 60 to 74 years (young elderly) Has a permanent pacemaker At least 24 hours have elapsed since the pacemaker was installed Access to a caller ID phone at home No known mental disorders Be literate

**Exclusion criteria:**

Reluctance to continue cooperation Telephone disconnection for two weeks in the first month and for 3 weeks in the second and third months of the intervention Becoming serious or causing any serious disruption affecting the research process

**Age**

From **30 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

Actual sample size reached: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization that the samples will be randomly placed in the control and test groups using the heads or tails method.

**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**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Dr. Mirkhani Ave., (Eastern Nusrat)., Tohid square

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Approval date**

2019-04-21, 1398/02/01

**Ethics committee reference number**

IR.TUMS.FNM.REC.1398.007

## Health conditions studied

### 1

**Description of health condition studied**

Heart failure, pacemaker

**ICD-10 code**

Z95.0

**ICD-10 code description**

Presence of cardiac pacemaker

## Primary outcomes

### 1

**Description**

Self-care

**Timepoint**

At the beginning of the study and then for 12 weeks and at least once a week

**Method of measurement**

Primary questionnaire and self-care questionnaire for the elderly with pacemakers

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: 40 elderly people with heart failure who have pacemakers. In this group, after filling in the initial questionnaire, the needs of the pacemaker will be assessed in relation to their educational needs and the items they feel the need to learn. Then, the telephone intervention in the experimental group will be performed by the researcher for 12 weeks. will be.; The content of the conversations will include: advice and training necessary to care for the pacemaker and control the infection, how to use the correct medication, appropriate activities for the elderly with pacemakers, and finally to provide a suggested solution and answer possible questions that come with it. The elderly will be involved. The content of the conversation will be recorded in the set form. Finally, the information of the two groups will

be collected in the form of a post-test questionnaire.

**Category**

Rehabilitation

**2**

**Description**

Control group: 40 elderly people with heart failure who have a pacemaker. During the intervention, the control group will not be subject to any intervention by the researcher and only their information will be collected by demographic questionnaire and researcher-made questionnaire related to self-care of patients with pacemakers in the form of pretest and post-test.

**Category**

Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Mohammad Amini

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**Email**

fnm@tums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mehrnaz Granmayeh

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran University 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Amini

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable