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

Street address

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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 5565

Fax

+98 21 6690 4252

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 5565

Email

fnm-researchdeputy@tums.ac.ir

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 5565

Email

fnm@tums.ac.ir

Person responsible for scientific 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

Street address

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

City

Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 5565
Email
mohammadaminitaha@gmail.com

Person responsible for updating data

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
Street address
Dr. Mirkhani Ave., (Eastern Nusrat)., Tohid square
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 5565
Email
Mohammadaminitaha@gmail.com

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