

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of peer support on quality of life and self care in patients with cardiac implanted electronic device

Protocol summary

Study aim

Investigating the impact of peer support on quality of life and self-care in patients with intracardiac implantable electrical Device

Design

semi-experimental study of the pretest-posttest type with two groups, intervention, and control. Due to the open environment and the risk of information leakage between the two groups random allocation may not be feasible. The sample size for each group is 30 individuals.

Settings and conduct

Catheterization laboratory and Heart Department of Imam Khomeini hospital. peer support under the supervision of the research team for one month and at least twice a week.

Participants/Inclusion and exclusion criteria

Entry criteria: People between 18 and 60 years old, people for whom implantable device is installed inside the heart for the first time, People who speak Persian, People who have access to mobile phones, Non-entry criteria: Having underlying conditions, such as kidney failure and strokes, People with known and treated cognitive disorders, Having the history of replacing the generator, Participation in the previous similar plan

Intervention groups

Control group: Patients who met the inclusion criteria, are asked to complete the study tools after obtaining informed consent and again, one month and two months later, they complete the tool. Intervention group: After obtaining informed consent from the patients, peer support intervention is done for them under the supervision of the research team; In this way, the peers call the patients at least twice a week for a month and exchange information and solve the patients' problems, and the researcher calls the peers at least twice a week and inquiries about the condition of the patients and answers their questions. At the end of the first month and then the second month after the intervention, the study tool is completed again by the patients

Main outcome variables

Quality of life, self care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190913044760N3**

Registration date: **2024-02-04, 1402/11/15**

Registration timing: **prospective**

Last update: **2024-02-04, 1402/11/15**

Update count: **0**

Registration date

2024-02-04, 1402/11/15

Registrant information

Name

Zahra Abbbasi Dolatabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4401

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zahra_abasi2000@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of peer support on quality of life and self care in patients with cardiac implanted electronic device

Public title

Effect of peer support on quality of life and self care in patients with cardiac implanted electronic device

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

People between 18 and 60 years old
People for whom implantable equipment is installed inside the heart for the first time
People who speak Persian
People who have access to mobile phones

Exclusion criteria:

Underlying diseases include kidney failure and strokes
People with known and treated cognitive disorders
Having a history of replacing the generator
Participation in the previous similar plan

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

Paying attention to the fact that the number of samples is limited according to the entry criteria and since it is not possible to conduct a study in a multi-centered manner due to the time limit available to the researcher, until the required sample size is reached, sampling can continue. To prevent leakage of information between the control and intervention groups, sampling will be done in the control group first, and after reaching the required sample size, sampling will be done in the intervention group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Imam Khomeini Hospital of Tehran university of medical sciences

Street address

Imam Khomeini Hospital Complex, Dr. Gharib Street, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2023-08-29, 1402/06/07

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.209

Health conditions studied**1****Description of health condition studied**

Pacemakers

ICD-10 code

Z95.0

ICD-10 code description

Presence of cardiac pacemaker

Primary outcomes**1****Description**

Quality of life

Timepoint

Before the intervention and 1 and 2 months after the intervention

Method of measurement

Questionnaire for assessment of Quality of life and Related events of patients with electronic cardiac implantable devices

Secondary outcomes**1****Description**

Self care

Timepoint

Before the intervention and 1 and 2 months after the intervention

Method of measurement

Miller self care questionnaire

Intervention groups

1

Description

Control group:In the Catheterization laboratory and Heart Department of Imam Khomeini hospital, as a control, patients are asked to complete the study tools after obtaining informed consent. The above process will continue until reaching the determined sample size.

Category

Other

2

Description

Intervention group:In the Catheterization laboratory and Heart Department of Imam Khomeini hospital after obtaining informed consent from the patients, the study instrument is completed by them. Then peer support intervention is done for them under the supervision of the research team; In this way, the peers call the patients at least twice a week for a month and exchange information and solve the patients' problems, and the researcher calls the peers at least twice a week and inquires about the condition of the patients and answers their questions. At the end of the first month and then the second month after the intervention, the study tool is completed again by the patients.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Hanieh Kordi Kalaki

Street address

Dr. gharib Street, Keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Akbari Sari

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6th floor,Vice Chancellor of Research and

Technology,Central Organization of the University,
corner of Quds St, Keshavarz Blvd.

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Web page address

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

Hanieh Kordi kalaki

Position

Master student of medical surgical nursing

Latest degree

Bachelor

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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All unidentifiable data can be provided if required

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

All researchers working in academic and scientific institutions who send requests

Under which criteria data/document could be used

The data can be used in accordance with copyright law and for conducting further research in this field.

From where data/document is obtainable

Send an email to Ms. Hanieh Kordi Kalaki at Hanieh.kordi@gmail.com

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

After reviewing the request and the conditions of the applicant, if approved, the data will be sent within one month.

Comments