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
Email address
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
Pacemekers

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

City
Tehran

Province
Tehran

Postal code

Phone
+98 21 6119 0000

Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Ali Akbari Sari

Street address
6th floor,Vice Chancellor of Research and Technology,Central Organization of the University, corner of Quds St, Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 8163 3685

Email
vcr@sina.tums.ac.ir

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

Street address
Gholhak St

City
Tehran

Province
Tehran

Postal code
1939646436

Phone
+98 21 2264 1793

Email
Hanieh.kordi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zahra Abbasi Dolatabadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health in Emergency and Disaster
Street address
Mirkhani Blvd
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 4329 6105
Email
zahra_abasi2000@yahoo.com

Person responsible for updating data

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
Street address
Gholhak St
City
Tehran
Province
Tehran
Postal code
1939646436
Phone
+98 21 2264 1793
Email
Hanieh.kordi@gmail.com

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@gmai.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