Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Nurse-Peer-Led Support Intervention on Quality of Life in Patients with an Implantable Cardioverter Defibrillator in Seyyed al Shohada university hospital Urmia in 2017-2018

Protocol summary

Study aim

The aim of this study was to determine the effect of applying nurse-peer-led support intervention on quality of life in patients with an implantable cardioverter defibrillator in Seyyed-Al-Shohada Hospital in Urmia.

Design

A clinical trial with a pre-post-test control group, randomized

Settings and conduct

From all participants was taken a pre-test with the MacNew quality of life questionnaire. Then participants were randomly divided into two groups intervention and control. In the intervention group, 6 people who had the highest quality of life scores and eligible peers were selected and 4 sessions 60 minutes about implantation defibrillator and its complications, self-care, and compatibility with the device were trained by the face-to-face method. The rest of the intervention group was divided into 6 groups of 9, and then each of their peers randomly entered one of the groups. The duration of nurse-peer-led support intervention sessions for each group was 4 sessions of 45 minutes. The venue for the sessions was in the specialty and subspecialty centers of the heart of Seyed-Al-shohada in Urmia.

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study: 1) All patients with an Implantable Cardioverter Defibrillator 2) At least 3 months have passed since the insertion of Implantable Cardioverter Defibrillator. exclusion criteria for the study: 1) Unwillingness to continue to participate in this study by the patient

Intervention groups

In the intervention group, a nurse-peer-led support intervention was implemented for five months from the beginning of February to the end of July and quality of life rate in patients with an implantable cardioverter defibrillator in the two groups before and after the appalling of nurse-peer-led support intervention were analyzed.

Main outcome variables

Quality of life and its dimensions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180808040742N1**
Registration date: **2018-08-28, 1397/06/06**
Registration timing: **retrospective**

Last update: **2018-08-28, 1397/06/06**
Update count: **0**

Registration date

2018-08-28, 1397/06/06

Registrant information

Name

Yaser Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3336 7978

Email address

y.moradi@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

2017-11-11, 1396/08/20

Actual recruitment end date

2018-02-04, 1396/11/15

Trial completion date

empty

Scientific title

The Effect of Nurse-Peer-Led Support Intervention on Quality of Life in Patients with an Implantable Cardioverter Defibrillator in Seyyed al Shohada university hospital Urmia in 2017-2018

Public title

The Nurse-Peer-Led Support Intervention and Quality of Life in Patients with an Implantable Cardioverter Defibrillator

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with an Implantable Cardioverter Defibrillator At least 3 months have passed since the insertion of Implantable Cardioverter Defibrillator.

Exclusion criteria:

Unwillingness to continue to participate in this study by the patient The absence of more than two sessions of classes formed by nurses and peer

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study was done based on a random number table.

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 Urmia University of Medical Sciences

Street address

Vice-chancellor for research of Urmia University of Medical Sciences, Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-10-12, 1396/07/20

Ethics committee reference number

IR.UMSU.rec.1396.349

Health conditions studied

1

Description of health condition studied

patients with an implantable cardioverter defibrillator

ICD-10 code

Z95.0

ICD-10 code description

Presence of electronic cardiac devices

Primary outcomes

1

Description

Quality of Life Score in the McNew Questionnaire

Timepoint

Before the intervention and 15 days after the intervention

Method of measurement

MacNew quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 6 people who had the highest quality of life scores in the pre-test and eligible peers were selected and 4 sessions 60 minutes about implantation defibrillator and its complications, self-care, and compatibility with the device were trained by the face-to-face method. The rest of the intervention group was divided into 6 groups of 9, and then each of their peers randomly entered one of the groups. The duration of nurse-peer-led support intervention sessions for each group was 4 sessions of 45 minutes.

Category

Lifestyle

2

Description
Control group: The control group received routine care.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyyed-Al-Shohada Hospital in Urmia
Full name of responsible person
Sohrab Saadat
Street address
Seyyed-Al-Shohada Hospital, 17 shahrivar Blvd.
City
Urmia
Province
West Azarbaijan
Postal code
5712546325
Phone
+98 44 3237 5910
Email
Sorab.saadat1988@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Sohrab Saadat
Street address
No. 20, Mehrab Ave.
City
Urmia
Province
West Azarbaijan
Postal code
5714256365
Phone
+98 44 3238 3923
Email
Sorab.saadat1988@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia University of Medical Sciences
Proportion provided by this source
10
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
Oroumia University of Medical Sciences
Full name of responsible person
Sohrab Saadat
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Seyyed-Al-Shohada Hospital, 17 Shaahrivar Blvd.
City
Urmia
Province
West Azarbaijan
Postal code
5711452563
Phone
+98 443275910
Email
Sorab.saadat1988@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Alireza Rahmani
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Sero Road, Pardis Nazlou
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3275 4918
Email
Alirezarahmani2005@gmile.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Sohrab saadat

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 20, Mehrab Ave.

City
Urmia

Province
West Azarbaijan

Postal code
5711452536

Phone
+98 44 3238 3923

Email
Sorab.saadat1988@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Not applicable

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