

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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@gmle.com

Person responsible for updating data

Sorab.saadat1988@gmail.com

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

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