

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of applying the support group based on Roy's Model on the adaptation of patients with implantable cardioverter-defibrillators

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of applying the support group based on Roy's Model on the adaptation of patients with implantable cardioverter-defibrillators.

Design

In this clinical trial study, patients are assigned to the intervention and control groups using randomization blocks of 4 according to the gender (male and female) and left ventricular ejection fraction (lower and higher 35%). The number of the patients in each of groups will be 30 persons.

Settings and conduct

The study will be conducted in Farshchian Heart Hospital of Hamadan. Patients randomly assigned to the intervention and control groups. In the intervention group, patients participate in support group. For all patients at least two support groups will be held. Before and one and a half months after the intervention, adaptation of patients will be assessed by nursing assessment and recognition form. In the control group patients will receive only routine care.

Participants/Inclusion and exclusion criteria

Patients with implantable cardioverter-defibrillator are selected as study samples. The inclusion criteria are age of 60 years and lower, able to hearing and speaking, lack of diagnosed mental disease, implanting cardioverter-defibrillator for at least six months. Patients with failure to complete the nursing assessment and recognition form were excluded from the study.

Intervention groups

In the experimental group, patients participate in support group. In this groups, educational topics and psychological counseling are presented. In the control group patients will receive only routine care.

Main outcome variables

The primary variables include the number of adjusted behaviors related to the health of patients, which are assessed by assessment and recognition form of the Roy

nursing model before and one and a half months after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180826040874N1**

Registration date: **2020-03-13, 1398/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-13, 1398/12/23**

Update count: **0**

Registration date

2020-03-13, 1398/12/23

Registrant information

Name

Mohammadreza Razavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3827 1145

Email address

m.razavi@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-19, 1398/11/30

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of applying the support group based on Roy's Model on the adaptation of patients with implantable cardioverter-defibrillators

Public title

The effectiveness of the support group based on Roy's Model on the adaptation of patients with implantable cardioverter-defibrillators

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

maximum age of 60 years Hearing and speaking ability
lack of diagnosed mental disease Patients with cardiac
defibrillator implantation for at least six months

Exclusion criteria:

Failure to complete the nursing assessment and
recognition

Age

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)

Randomized

Randomization description

Individuals referred to therapeutic center and with inclusion criteria to the study will selected by convenience sampling method and were randomly divided into intervention and control groups. In this study, individuals were divided into two groups using randomization blocks of 4 method. In this method, A represents the individual receiving the intervention and B represents the individual in the control group. Then codes will indicate as Code 1: AABB, code 2: ABAB, code 3: ABBA, code 4: BAAB, code 5: BBAA and code 6: BABA. After that, the starting point is randomly selected using the random number table. Given the sequence of table numbers, each number that is assigned will be determined a code. For example, if the first three numbers of the random number table are 2, 1 and 6, the order of assigning the first 12 patients in groups of the study will be ABABAABBBABA, respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamadan University of Medical
Sciences

Street address

Shahid Fahmideh Ave, Pajohesh Squ., Hamadan city

City

Hamadan

Province

Hamadan

Postal code

6517765178

Approval date

2020-02-09, 1398/11/20

Ethics committee reference number

IR.UMSHA.REC.1398.999

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

Cardiovascular disease

ICD-10 code

Z95.810

ICD-10 code description

Presence of automatic (implantable) cardiac defibrillator

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

Adaptation of patients

Timepoint

before and 1.5 months after intervention.

Method of measurement

Adaptation is measured using assessment and
recognition form of Roy nursing model.

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

In this study, secondary outcome is level of social
adaptation.

Timepoint

Level of social adaptation is measured at before and 1.5
months after intervention.

Method of measurement

Level of social adaptation is measured using Bell
adaptation questionnaire.

Intervention groups

1

Description

Intervention group: patients participate in support group. Selecting the educational topics and content of each support group as well as the patients' health status are identified based on the assessment and recognition form of Roy nursing model. Support group members will include patients with better health status, patients with poor health status, and a family member who is responsible for caring them, as well as a psychologist and researcher. the duration of each session will vary depending on the patients' educational needs. For all patients, two support groups is held at least in one month. The content of these groups included discussions about their past, present and future of illness, actions required after receiving shock, questions and answers to device and illness, suggestions for daily living activities, lifestyle changes and doing sports activities, providing information about phantom shock, driving, marrying, and supporting family members. One and a half months after participating in the support group, patients are reassessed by the assessment and recognition form of Roy nursing model.

Category

Behavior

2

Description

Control group: In the control group patients will receive only routine care that includes an educational pamphlet provided by the health center.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Hamadan Unoversity of Medical Sciences

Street address

Shahid Fahmideh Aven, Pajohesh Squ., Hamadan city

City

Hamadan

Province

Hamadan

Postal code

6517839131

Phone

+98 81 3838 1740

Email

hcvc@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Vice chancellor for research & technology, Hamadan University of medical Sciences

Street address

Shahid Fahmideh Ave., Pajohesh Squ., Hamadan City

City

Hamadan

Province

Hamadan

Postal code

6517765178

Phone

+98 81 3838 0717

Email

Fanavari@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mohammadreza Razavi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Fahmideh Ave., Pajohesh Squ., Hamadan City

City

Hamadan

Province

Hamadan

Postal code

6517765178

Phone
+98 81 3827 1145
Email
mrerazavi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohammadreza Razavi
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Shahid Fahmideh Ave., Pajohesh Squ., Hamadan City
City
Hamadan
Province
Hamadan
Postal code
6517765178
Phone
+98 81 3827 1145
Email
mrerazavi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohammadreza Razavi
Position

PhD student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Shahid Fahmideh Ave., Pajohesh Squ., Hamadan city
City
Hamadan
Province
Hamadan
Postal code
6517765178
Phone
+98 81 3827 1145
Email
mrerazavi@yahoo.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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available