

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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 be 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

hcv@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