

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Orem's self-care model application on self-care ability of patients with implantable cardioverter defibrillator

Protocol summary

Summary

This research is a quasi-experimental study. Each research group is containing 66 persons that have criterions of entering the study. These groups are divided to 2 groups of test and control by draw. Each group are trained for a month (control group without researcher intermediation and based on department routine and test group with researcher intermediation according to Orem's model). After one month from education, they fill self-care ability evaluation questionnaire. Study period for each group is two months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090710772N1**
Registration date: **2012-10-27, 1391/08/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-27, 1391/08/06

Registrant information

Name

Khodadad Keshmiri

Name of organization / entity

Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Orem's self-care model application on self-care ability of patients with implantable cardioverter defibrillator

Public title

The self-care model application on patients with implantable cardioverter defibrillator

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having the ability to understanding and speaking Persian; Having the tendency to cooperate and participate in the study; Having at least reading and writing ability; Implantable Cardioverter Defibrillator is placed to their body in the last two weeks; having at least four self-care necessities. Exclusion criteria: no willingness to continue participating in the study; not participating in more than one sessions; The patient death during the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 66

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences

City

Hamadan

Postal code

6517838698

Approval date

2012-08-18, 1391/05/28

Ethics committee reference number

1834\9\35\16\پ\پ

Health conditions studied

1

Description of health condition studied

Refractory arrhythmias or reversible

ICD-10 code

I47

ICD-10 code description

Ventricular tachycardia

Primary outcomes

1

Description

Self-care ability

Timepoint

Before the intervention, one month after intervention

Method of measurement

Self designed questionnaire to measure self-care

Secondary outcomes

empty

Intervention groups

1

Description

First meeting: Test group is divided to 3 groups of 8 persons and one group of 9 persons by their similar care requirements and self-care score. Self-care educating for test group according to Orem's model is done 20 to 30 minutes per each week. Second meeting: At the beginning of this meeting, the importance of controlling signs of infection in these patients will be discussed. At the end of this meeting, the check list of self-care in the case of controlling signs of infection will be given to them. They will request to participate in third meeting one week later. Third meeting: At the beginning of this meeting, the importance of avoiding doing hard exercises will be discussed and participants are encouragement to do allowed movements. At later meetings, related check list is given to participants. They will request to participate in fourth meeting one week later. Fourth meeting: In forth meeting, the importance of time of reporting shock to doctor will be discussed. At the end of this meeting, the self-care check list will be given to participants. At the end of education meetings, the participants are requested to do their learnt things for one month

Category

Behavior

2

Description

Control group: routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Rajai Cardiovascular Hospital

Full name of responsible person

Dr.Zahra Emkanjoo

Street address

Electrophysiology Center, Shaheed Rajai Hospital
Cardiology -

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr.Khodayar Oshvandi

Street address

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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
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty