Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of continues care program on self efficacy and outcomes in patients with Implantable Cardioverter Defibrillator

Protocol summary

Study aim
Investigate of effectiveness of follow up care program on self efficacy and short term outcomes in patients with an Implantable Cardioverter Defibrillator.

Design
Randomized, blinded, shame controlled clinical trial, with a blinded, Parallel group design of 154 patients

Settings and conduct
Implanting Cardioverter Defibrillator is the popular treatment of patients suffering from cardiac arrhythmia. The research is performed in the electrophysiology sector of Shaheed Rajaie's Cardiovascular Medical and Research Center and after the approval of the ethical committee. Patients that need Implantable Cardioverter Defibrillator (ICD) were identified and after gaining their written satisfaction, sampling is performed. After they discharge, the researcher trains them face to face but the patients are not aware of their group. The researcher is not the part of the staff and the staff does not participate in the intervention.

Participants/Inclusion and exclusion criteria
Patients 20 to 80 years old who being able to read, write, and speak Persian, and have received Implantable Cardioverter Defibrillator can participate in the study; they are excluded from study if they have a Commorbidity that prevent their discharge from the hospital, or suffering from cognitive disorders.

Intervention groups
Patients in the control group are discharged after receiving routine care, including a booklet recognizing the device and its care; patients in the intervention group receive a follow-up care program in addition to routine care, including two 1.5 hour training sessions and An instruction book featuring other patients' experiences and weekly follow ups for up to 12 weeks..

Main outcome variables
Self-efficacy Expectations and Out come Expectations score; Anxiety score; Referral out of plan to Medical center; Number of received shock.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100725004443N24**
Registration date: **2018-12-29, 1397/10/08**
Registration timing: **prospective**

Last update: **2018-12-29, 1397/10/08**
Update count: **0**

Registration date
2018-12-29, 1397/10/08

Registrant information

Name
Masoumeh Zakerimoghadam
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source
Research deputy of Shaheed Rajaei's Cardiovascular Medical and Rresearch Center

Expected recruitment start date
2018-12-31, 1397/10/10

Expected recruitment end date
2019-01-30, 1397/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effectiveness of continues care program on self efficacy and outcomes in patients with Implantable Cardioverter Defibrillator

Public title
Effectiveness of continues care program on self efficacy and outcomes in patients with cardiac shocker

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being 20 to 80 years old Being ability to read, write, and speak in Persian Accessing phone call Implanting Cardioverter Defibrillator for the first time

Exclusion criteria:
Suffering from Cognitive Disorders Suffering from Commorbidity results in hospitalization Participation in other intervention program

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **154**

Randomization (investigator's opinion)
Randomized

Randomization description
Assignment of patients in two groups of test and control was done by Block Balanced Randomization (BBR) method. The Randomization Sequence was generated with using the free web site at http://www.randomization.com.

Blinding (investigator's opinion)
Single blinded

Blinding description
When discharging the patient, the researcher trains on the research and its method. However, he does not make the patient aware of his group and the researcher is not the member of the staff and the hospital staff does not participate in the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic commitee of Shaheed Rajaie's Cardiovascular Medical and Rresearch Center

Street address
Shaheed Rajaie's Cardiovascular Medical and Rresearch Center, Niayesh Blvd., Vali-Asr Ave.

City
Tehran

Province
Tehran

Postal code
199691-1151

Approval date
2017-01-23, 1395/11/04

Ethics committee reference number
RHC.AC.IR.REC.1395.31

Health conditions studied

1

Description of health condition studied
The patient with an Implantable Cardioverter Defibrillator

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Self-efficacy

Timepoint
Before the intervention, immediately after ending the intervention

Method of measurement
Self-efficacy questionnaire

Secondary outcomes

1

Description
Anxiety

Timepoint
Before the intervention, immediately after ending the intervention

Method of measurement
Speil-berger State-Trait Anxiety Inventory

2

Description
Number of received shocks

Timepoint
Immediately after ending the intervention

Method of measurement
patient report

3

Description
Referrals outside of the plan to Medical centers
Timepoint
Immediately after ending the intervention
Method of measurement
patient report

Intervention groups

1

Description
Control group:This patients do not receive any intervention from the researcher and are discharged after receiving regular care at the facility.
Category
Other

2

Description
Intervention group: The intervention includes two training sessions for 1.5 hours by the researcher and one month later, they go to the health-care center. In these sessions, the researcher trains the patients about the ability to take care of oneself after received shock, the way to register the shocks, the performance of the Device, their feeling when evacuating the energy and the required changes in lifestyle, the warning and follow-up and their relationship with the family members is explained. The researcher tells about the ways of reducing stress such as praying, relaxation, listening to music and distraction of mind and describes the solution based on the patient's will. After the second session,a training book is given to the patients including two parts. The first part explains the performance and equipment and the second part is about the experience of patients with Implantable Cardioverter Defibrillator. Finally, the patient's phone number is taken and the patient is followed from 8 am to 8 pm for 10 to 20 minutes based on the patient's need, verbal encouragement, responsiveness of the patient's questions, their current concerns, behavioral techniques to be consistent with the living conditions with heart shocker and relaxation in the book. In addition to phone follow-up, the participants in the intervention can access the researcher from morning to night and ask their questions.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shaheed Rajaie's Cardiovascular Medical and Research Center
Full name of responsible person
Zakerimoqhadam Masoumeh
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Shaheed Rajaie's Cardiovascular Medical and Research Center, Niayesh Blvd., Vali-asr Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shaheed Rajaie's Cardiovascular Medical and Research Center
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
Tehran University of Medical Sciences

Full name of responsible person
Zakerimoghadam Masoumeh

Position
Assistant professor and Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Full name of responsible person
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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