

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

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 committee of Shaheed Rajaie's Cardiovascular Medical and Rresearch Center

Street address

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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shaheed Rajaie's Cardiovascular Medical and Research Center

Full name of responsible person

Maleki Majid

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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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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zakerimoghadam Masoumeh

Position

Assistant professor, Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

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Shaheed Rajaie's Cardiovascular Medical and
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Full name of responsible person

Haghjoo Majid

Position

Professor, Scientific Faculty member

Latest degree

Subspecialist

Other areas of specialty/work

Internal Heart Adult

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Fax

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