

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Efficacy of Comprehensive Cardiac Rehabilitation on Health Promoting Lifestyle in People with Implantable Cardioverter Defibrillator

Protocol summary

Study aim

Determining the effect of comprehensive cardiac rehabilitation on the health promoting lifestyle of individuals with implantable cardioverter defibrillators

Design

Quasi-experimental, including control group, parallel, non-blinded, non-randomized of 70 participants

Settings and conduct

Selection of available samples from Shahid Faghihi Hospital and Al-Zahra Heart Hospital affiliated to Shiraz University of Medical Sciences and non-randomly assigned to two groups of control and intervention

Participants/Inclusion and exclusion criteria

Inclusion: Age 18- 60 years old; At least 3 months passed from the insertion of implantable cardioverter defibrillator; Hearing and vision and perception in communication; Exclusion: Neurological, cognitive and motor disorders, according to documents; Other than sinus rhythm or ventricular tachycardia in the pre-intervention analysis;

Intervention groups

Comprehensive cardiac rehabilitation program is conducted for 5 weeks, 2 sessions each week, for a period of 1.5 hours, including 45 minutes of physical activity and 45 minutes of educational intervention in the intervention group. No intervention is performed in control group.

Main outcome variables

Physical activity and nutrition dimensions from health promotion lifestyle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180617040122N1**

Registration date: **2018-07-09, 1397/04/18**

Registration timing: **retrospective**

Last update: **2018-07-09, 1397/04/18**

Update count: **0**

Registration date

2018-07-09, 1397/04/18

Registrant information

Name

Mahnaz Siahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-04-09, 1397/01/20

Trial completion date

empty

Scientific title

Efficacy of Comprehensive Cardiac Rehabilitation on Health Promoting Lifestyle in People with Implantable Cardioverter Defibrillator

Public title

The effect of cardiac rehabilitation in people with cardiac defibrillator

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-60 years old At least 3 months passed from insertion of implantable cardioverter defibrillator Hearing and vision and perception in communication

Exclusion criteria:

Neurological, cognitive and motor disorders, according to documents Other than sinus rhythm or ventricular tachycardia in the pre-intervention analysis

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

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Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

IR.IUMS.FMD.REC 1396.931168900

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

Individuals with implantable cardioverter defibrillator

ICD-10 code

I46.2

ICD-10 code description

Cardiac arrest due to underlying cardiac condition

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

Nutrition

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Health promoting lifestyle Questionnaire

2**Description**

Physical activity

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Health promoting lifestyle Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Comprehensive cardiac rehabilitation intervention was performed for 10 sessions in 5 weeks, 2 sessions per week, 1.5 hours per session. At the beginning of each session, the exercise intervention was performed for 45 minutes by the researcher under the supervision of a physiotherapist in the intervention group, which included 10 minutes of warm up, 8 minutes of bicycle, 8 minutes of running or walking, 8 minutes of aerobic training, and at the end, 10 minutes of cool down. Then, the educational intervention includes nutrition education and physical activity and reduction of cardiovascular risk factors was carried out by the researcher at the end of each session of physical training for 45 minutes.

Category

Other

2**Description**

Control group: No intervention was done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Faghihi hospital
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Sponsors / Funding sources

1

Sponsor

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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
Iran 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

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after unidentifying Individuals.

When the data will become available and for how long

Accessible 6 months after result publication

To whom data/document is available

Data will be available just for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

In order to cite in other researches

From where data/document is obtainable

m.siahi8361@gmail.com

What processes are involved for a request to access data/document

Send a request via email

Comments