Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Comparison effect of Group Discussion and Video-Learning on Stress, anxiety,depression and self-efficacy in patients undergoing Pacemaker and Implantable- Cardioverter Defibrillator

Protocol summary

Study aim
Comparison of the effect of training by video and group discussion on the stress, anxiety and self-efficacy of pacemaker patients and cardiac implantation defibrillator referred to Shahid Beheshti Hospital in Kashan 2017

Design
Randomised, Uncorrupted, Factorial, controlled clinical trial.

Settings and conduct
Training for Patients with Pacemaker and Implantable Cardioverter Defibrillator, Kashan University of Medical Sciences Hospital, as group and video training sessions

Participants/Inclusion and exclusion criteria
Patients with pacemakers and implantable cardioverter defibrillator

Intervention groups
Learning in the form of group discussion

Main outcome variables
Assessment of stress score; Anxiety scoring; Depression score assessment; Self-efficacy scoring

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180120038453N1**
Registration date: **2018-03-06, 1396/12/15**
Registration timing: **retrospective**

Last update: **2018-03-06, 1396/12/15**
Update count: **0**

Registration date
2018-03-06, 1396/12/15

Registrant information

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Allahyar Golabchi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-11, 1396/06/20

Expected recruitment end date
2017-11-22, 1396/09/01

Actual recruitment start date
2017-09-11, 1396/06/20

Actual recruitment end date
2017-11-22, 1396/09/01

Trial completion date
empty

Scientific title
The Comparison effect of Group Discussion and Video-Learning on Stress, anxiety,depression and self-efficacy in patients undergoing Pacemaker and Implantable-Cardioverter Defibrillator

Public title
The effect of training on stress, anxiety,depression and self-efficacy in patients with pacemakers and cardiopulmonary defibrillator

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
All patients who are first implanted with pacemakers or cardiac defibrillators. They tended to participate in the

study. Were in the age group of 18-75 years old. No psychiatric illness. The patient himself or his relatives were not members of the health team.

Exclusion criteria:

The patient died during the study. During the study, you should not cooperate with the researcher An unfortunate event that adds to anxiety and reduces self-efficacy.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Actual sample size reached: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

After the device was fitted, the informed consent form was given to qualified patients willing to participate in the study, and after completing the pre-test written permission and ensuring the confidentiality of the information, a demographic information questionnaire for the patients was completed.After completing initial information and rejection of psychiatric diseases, if the patient was at the age group and the patient or first-degree relatives were not part of the medical staff, they were divided into three groups based on the age group and date of the device, and according to the necessity Group discussion sessions were held for the video, the beginning of training with the group was discussed.

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 Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences

City

Kashan

Province

Isfehan

Postal code

8741135911

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1396.24

Health conditions studied

1

Description of health condition studied

Patients with pacemakers or cardiac implantation defibrillators

ICD-10 code

Z95.0

ICD-10 code description

Presence of cardiac pacemaker

Primary outcomes

1

Description

Stress score in the questionnaire DASS21

Timepoint

At the beginning of the study (before the training) and three weeks after the training

Method of measurement

Stress questionnaire DASS21

2

Description

Anxiety score in the questionnaire DASS21

Timepoint

At the beginning of the study (before the training) and three weeks after the training

Method of measurement

Anxiety questionnaire DASS21

3

Description

Depression score in the questionnaire DASS21

Timepoint

At the beginning of the study (before the training) and three weeks after the training

Method of measurement

Depression questionnaire DASS21

4

Description

Self-efficacy scores in self-efficacy questionnaire for patients with pacemakers

Timepoint

At the beginning of the study (before the training) and three weeks after the training

Method of measurement

Self-efficacy questionnaire for patients with pacemakers

5

Description
Self-efficacy score in patients self-efficacy questionnaire has Cardiac implantable cardioverter defibrillator
Timepoint
At the beginning of the study (before the training) and three weeks after the training
Method of measurement
Self-efficacy questionnaire for patients with implantable cardioverter defibrillator

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Learning by group discussion method : After calling patients and forming groups of 10-6, structured training was started during a 2-hour session at the conference hall of Shahid Beheshti Hospital with the participation of researchers after the completion of the initial questionnaires.
Category
Behavior

2

Description
Intervention group 2: Video tutorial: After filming the content provided by the researchers in the group discussion group and reviewing and editing, a compact disc prepared from each session is reviewed by three qualified individuals (an educational expert and two cardiologists) in the minimum possible time (7-10 days). And confirmed and presented to the video tutoring group in person after completion of the initial questionnaires. The approximate duration of the video was about an hour and fifteen minutes.
Category
Behavior

3

Description
Control group: Routine tutorial: This group did not receive any educational intervention except for a manual and explanations provided by the department to all patients (even two educational groups).
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Medical Sciences Hospital
Full name of responsible person
Sareh Sokout Arani
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Allahyar Golabchi

Position
Assistant Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable