Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Family-Centered Empowerment Model (FCEM) on self-care of the patient with prosthetic cardiac valve in armed forces hospitals.

Protocol summary

Summary

The project aims to investigate the impact of family-centered empowerment model on self-care of patients with prosthetic heart valve. Family-centered empowerment model designed to emphasis on the role of patients and family members to be effective. In this study, after that the proposal approved in the university, an assessment tool provided by the researcher. In this quasi-experimental study 40 patients were selected by available method and divided two groups(test group and control group). Intervention in test group has four steps: In first step, I am going to have meetings with the aim of perceived threat, by increasing the level of knowledge and understanding. In the second step, problem-solving is as a method of problem- solving group study will have done to increase self-efficacy, self-esteem and self-control in patients. In the third step, from the patients ask participate in training their family members. Each session an educational card will have sent for family training with participants. A week after the intervention patients self-care will have measured by above instrument. Then one and half months will have given time to the patient and family members to performance the model. Then self-care will have evaluated with the tool. In the control group, after doing pre- test, we will have done post-test after one and half month passed, Then The control group will have measured. In the end, both groups will have analyzed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015083120041N2**
Registration date: **2016-03-31, 1395/01/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-03-31, 1395/01/12

Registrant information

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Name of organization / entity
Military University of Medical Science (AJA)
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Recruitment status

Recruitment complete

Funding source

AJA University of Medical Sciences

Expected recruitment start date

2015-10-29, 1394/08/07

Expected recruitment end date

2016-01-05, 1394/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Family-Centered Empowerment Model (FCEM) on self-care of the patient with prosthetic cardiac valve in armed forces hospitals.

Public title

The effect of Family-Centered Empowerment Model (FCEM) on self-care of the patient with prosthetic heart valve in armed forces hospitals.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: having at least one artificial heart valve; embedded artificial heart valves for the first time; age between 18 -85 years old; 72 hours after cardiac surgery; ability to read and write by the patient or family member participating in patient care; access patient or family member participate for phone; patients have the ability to communicate and hard; lack of mental disorder and amnesia; the patient or family member participate not have been a doctor or nurse; lack of underlying incurable disease. Exclusion criteria: withdrew from further participation in the study or patient death; the unavailability of the patient after discharge.

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This is a quasi-experimental study. It has a control group. Patients were selected if available. Hospital chose base on doing heart valve surgery.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AJA University of Medical Sciences

Street address

AJA University of Medical Sciences, Etemadzadeh St., Fatemi St., Tehran. .

City

Tehran

Postal code

Approval date

2015-10-26, 1394/08/04

Ethics committee reference number

IR.AJAUMS.REC.1394.40

Health conditions studied

1

Description of health condition studied

Heart valve replacement

ICD-10 code

Z95.4

ICD-10 code description

Presence of heart -valve replacement

Primary outcomes

1

Description

Self-care

Timepoint

Before intervention and one and half months after intervention

Method of measurement

Questionnaire prepared by researcher

Secondary outcomes

empty

Intervention groups

1

Description

Test group:1) Pre test; 2) performance of four step: In first step, I am going to have meetings with the aim of perceived threat, by increasing the level of knowledge and understanding. In the second step, problem-solving is as a method of problem- solving group study will have done to increase self-efficacy, self-esteem and self-control in patients. In the third step, from the patients ask participate in training their family members. Each session an educational card will have sent for family training with participants.In the fourth step, a week after the intervention patients self-care will have measured by above instrument. Then one and half months will have given time to the patient and family members to performance the model. Then self-care will have evaluated with the tool.

Category

Lifestyle

2

Description

In the control group, after doing pre- test, we will have done post-test after one and half month passed, Then The control group will have measured. In the end, both groups will have analyzed and compared.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Jamaran Haspital

Full name of responsible person
Abedini Fahimh

Street address
Jamaran Haspital, Jamaran St., Bahonar St., Thran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
AJA University of Medical Sciences

Full name of responsible person
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AJA University of Medical Sciences, Etemadzadh St, Fatmi St, Tehran.

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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
AJA 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

Contact

Name of organization / entity
AJA University of Medical Sciences

Full name of responsible person
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Other areas of specialty/work

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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