Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of education based on the family-centered empowerment model on anticoagulant adherence of patients with prosthetic heart valve.

Protocol summary

Summary

This study will be conducted to investigate the effect of education based on family-centered empowerment model on adherence to anticoagulant regimen treatmentin patients with prosthetic heart valve. This clinical trial study will be conductedon 60 patients and 30 family members (in intervention groups) in open-heart surgery of Imam Reza (AS) Hospital of Mashhad. Patients were selected using available sampling method and they were randomly divided into intervention and control groups. For intervention group, family-centered empowerment modelwill be conducted with four steps (to improve knowledge, self-efficacy, self-esteem, and evaluation) through individual instruction, group discussions, and question and answer. The control group received only one training session on the day of their discharge from the hospital. After 1.5 months,adherence to anticoagulant regiment treatmentin both groups (intervention and control) will be investigated and the data will be analyzed using SPSS 16 software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100624395N1**
Registration date: **2015-12-30, 1394/10/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-30, 1394/10/09

Registrant information

Name

Maryam Mohammadpour Ostad

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences (90%) and the Research Center for Evidence-based care (10%)

Expected recruitment start date

2015-08-21, 1394/05/30

Expected recruitment end date

2015-12-30, 1394/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on the family-centered empowerment model on anticoagulant adherence of patients with prosthetic heart valve.

Public title

The effect of education based on the family-centered empowerment model on anticoagulant adherence of patients with prosthetic heart valve.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in the study ; The age range of 65- 18 years; living in Mashhad;

Artificial valve replacement surgery;The first shift valve replacement surgery; Failure to develop an advanced chronic disease (stroke, kidney failure) and lack cognitive and mental disorders (Alzheimer's, depression); Loss of speech and hearing problems; Having read and write; The patient has no health personnel; A family member (spouse, child, sister, etc.) that further cooperation in the field of health -care and the patient is Family members living with the patient; Lack of family members to valve disease Inclusion criteria 10,11 and 12 will be considered for patients in the intervention group. Inclusion criteria of active member of the family: willingness to participate in research; having read and write; lack of drug addiction; without the risk of heart valve disease; Is not of Health care worker Exclusion criteria: unwillingness of research or a member of his family to cooperate at every stage of research; hospitalization for any reason at any stage of research; changes in the anticoagulant medication; The incidence of postoperative complications requiring surgery, physical or mental problems that lead to disability at any stage of the research.

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: **60**

Randomization (investigator's opinion)
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
Mashhad University of Medical Sciences

Street address
Deputy of Research and Technology, Mashhad University of Science, next to the Hovyzeh cinema, Daneshgah street, Mashhad

City
Mashhad

Postal code

Approval date
2015-09-26, 1394/07/04

Ethics committee reference number
IR.MUMS.REC.1394.414

Health conditions studied

1

Description of health condition studied
Valvular heart disease

ICD-10 code
I39

ICD-10 code description
Endocarditis and Heart valve Disorders in Diseases Classified Elsewhere

Primary outcomes

1

Description
Adherence to anticoagulant treatment regimen

Timepoint
one and half month after intervention

Method of measurement
Questionnaire of Adherence to anticoagulant treatment regimen

Secondary outcomes

1

Description
bleeding

Timepoint
Three months after intervention

Method of measurement
Landfield questionnaire

Intervention groups

1

Description
The education will be implemented based on the family-centered empowerment model steps as follows: 1- the first step is to increase the participants' perceived threat (severity and susceptibility). The perceived severity means to understand the risk of the absence of proper caring behavior and the perceived susceptibility means to comprehend how a person is at risk for the diseases resulting from lack of proper caring behavior. Thus, by Two 45-60 minute sessions by Individual Training, group discussions and question and answer that will lead to complications and problems, we will try to improve the perceived threat (severity and perceived susceptibility). 2- the second step is problem solving. Problem solving will be conducted via group discussions in a manner that promotes the participants' self-esteem. The goal of this step is understanding the problems providing their solutions. The problem-solving sessions will hold in one

45-60minute small group discussions under supervision of the researcher in discharging day. In these sessions, some objective examples of their problems with the caring behaviors will be presented. Then, the researcher conducts the group-discussion and let them to modify their wrong caring behaviors. At this stage, the caregivers get practically familiar with their problems and their solving process. This issue will enhance their self-efficacy. 3- the third step is participation in the training. In this step, the patient transfer the discussed topics in the previous meetings by the pamphlets and a booklet to active member of the family. 4- the fourth step is evaluation. It includes two stages, process evaluation and final evaluation. The final evaluation will be performed 1.5 months after discharge.

Category

Prevention

2

Description

In the control group will be provided to patients and family members one training session 60-45 minutes in discharge day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza(AS) Hospltal

Full name of responsible person

Maryam Mohammadpour ostad

Street address

Imam Reza(AS) Hospltal, Doctora intersection, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Tafaghodi

Street address

Mashhad University of Medical Sciences Research and Technology

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Mohammadpour Ostad

Position

MSc Student in Nursing

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