

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

investigation effect of self-management program on medication adherence and self-efficacy in patients with mechanical heart valve

Protocol summary

Summary

The purpose of this study is investigation effect of self-management program on medication adherence and self-efficacy in patients with mechanical heart valve. It's a quasi-experimental study. Subjects of study will be mechanical heart valve patients hospitalized in MCCU and SCCU. In this study, 88 eligible patients with convenience sampling method (available) will be selected randomly (draw) and will be enrolled the study in both intervention and control groups. After completing demographic information, drug adherence and self-efficacy questionnaires, INR test will be controlled in both groups. control group will be received regular cares but intervention group will be participate in self-management program. this program contain two workshops, Then intervention group will be followed with telephone contacts at afternoons every week for 8 weeks. after 8 weeks drug adherence and self-efficacy questionnaires will be completed with both groups and INR test will be controlled.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406154443N13**

Registration date: **2015-06-07, 1394/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-07, 1394/03/17

Registrant information

Name

Masoumeh Zakerimoghdam

Name of organization / entity

Tehran University of Medical Sciences

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of Medical Scinces

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigation effect of self-management program on medication adherence and self-efficacy in patients with mechanical heart valve

Public title

self-management program in patients with mechanical heart valve

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The use of warfarin as an anticoagulant; The patient or the patient's immediate family members are not members of the treatment team; having 18-60 years old; Doesn't be under another study; having heart valve replacement surgery in recent year for the first time; Doesn't have chronic disease;

Doesn't have mental disorder. Exclusion criteria: During the study, patients had a complications of drug abuse; Wouldn't like to continue; Wouldn't like to continue intervention followed with telephone contacts.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **88**

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

research deputy Tehran university of medical science

Street address

Ghods street, Keshavarz boulevard

City

Tehran

Postal code

Approval date

2014-08-23, 1393/06/01

Ethics committee reference number

130/1225/93/3

Health conditions studied

1

Description of health condition studied

mechanical heart valve patients

ICD-10 code

z95.2

ICD-10 code description

Presence of prosthetic heart valve

Primary outcomes

1

Description

drug adherence

Timepoint

before and 8 weeks after intervention

Method of measurement

drug adherence questionnaire and INR test

2

Description

self-efficacy

Timepoint

before and 8 weeks after intervention

Method of measurement

self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In control group just will receive regular care, without any intervention

Category

Prevention

2

Description

The intervention group, in addition to usual care, will participate in self-management program .Self-management program contains of 3 parts: medical management, role management, and emotional management, and 5 core skills of problem solving, decision making, resource utilization, the formation of the therapeutic relationship between the patient and the caregiver. workshop for 2 days and each day will be held for 4 hours and minimum of 5 and a maximum of 15 patients with mechanical heart valve will be attended in the workshop. Then the patients will be given an educational booklet. Then intervention group will be followed by telephone contacts at afternoons every week in 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Masoumeh Zakeri Moghadam

Street address

Eastern Nosrat street, Tohid square

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of
Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghadam

Street address

Eastern Nosrat street, Tohid square

City

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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

Vice chancellor for research of Tehran 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

Nursing- Midwifery Faculty of Tehran University of
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Full name of responsible person

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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