

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Clinical Trial Effect of Family_Center Empowerment Model on adherence to treatment plan patients undergoing coronary artery bypass

Protocol summary

Summary

Objectives: Our goal was to study the effect of Family-Center Empowerment Model in patients undergo coronary bypass graft surgery, as a family centered intervention, on their treatment regime adherence.

Design: The present study was a clinical trial, quasi-experimental, pre and post design with a comparison group was conducted with 102 patients and 102 active member patient's family from 2010 to 2011 in ICU open heart in Hospital of Tehran University of Medical Science

Setting and conduct: The present study was a clinical trial that fulfilled after blocking randomized sampling, each subject were randomly assigned to experimental or control group. Participants including major eligibility criteria: All patients undergoing emergency heart surgery is not received, mental illness - mental hearths are not known and possibility of direct telephone call home patients was enrolled. After discharge the patients were hospitalized again and failed to comply with treatment programs were excluded.

Intervention: For experimental group, family-center empowerment model implement with four dimensional that including: Perceived threat, self-efficacy, educational partnership and evaluation; and for control group do usual care. The research tools involves the questionnaires of demographic, adherence of therapeutic regime and empowerment dimensional information that related to patient and active member patient's family.

Main outcome measures: The dimensions of patient adherence to treatment plan before the intervention at all levels in both groups was identical ($0.05 < P$), after the intervention in terms of experience in all aspects were more significant ($0.000 > p$), the dimensions of adherence active member of the family health plan as well as pre -intervention levels in all groups was similar ($0.05 < p$) and after intervention in all aspects of were statistically significant ($0.000 > p$)

Variables: Main variables in the study included measuring levels of adherence of treatment plan and the empowering of subjects run the Family_Center

Empowerment Model.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104276314N1**

Registration date: **2011-06-13, 1390/03/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-13, 1390/03/23

Registrant information

Name

Soraya Nejati

Name of organization / entity

Tehran University Medical of Science

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Science

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-02-18, 1389/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical Trial Effect of Family_Center Empowerment Model on adherence to treatment plan patients undergoing coronary artery bypass

Public title
Family_Center Empowerment Model and treatment regime adherence

Purpose
Supportive

Inclusion/Exclusion criteria
inclusion: Patient or his family, read and write have; patient or family can understand and have the speech in Farsi; patient undergoing emergency heart surgery is not received; client for the first time for coronary bypass surgery are hospitalized; mental illness - mental health are not known; possibility of a direct telephone call home patients exist. exclusion: Patients with cardiac problems due to reasons other than the current, or need for hospitalization and intervention is Avrzhans so that the curriculum fails to comply; during the study or the patient's disease will progress to death; patient developed a new physical limitations that will prevent him from compliance Exercise program should be.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **102**

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

Ethics committee of Tehran university medical science

Street address

Sixth Floor, Central Building Education, Ghods Street, Keshavarz Blvd, Tehran

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

89/130/980/5

Health conditions studied

1

Description of health condition studied

Ischemic Heart disease

ICD-10 code

I20, I21,

ICD-10 code description

Ischemic Heart disease

Primary outcomes

1

Description

Adherence to treatment regimen

Timepoint

Before the intervention and 8 weeks after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Empowerment

Timepoint

Before and one month after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

In this study, for experimental group, Family_Center Empowerment Model on four dimensions of perceived threat, self-efficacy, educational participation and evaluation was performed. In the first step (understanding threats) about the disease, the need for treatment (transplant coronary artery surgery), prognosis, condition after the operation, care during surgery and after effects of treatment failure and a short program and fourth in the second session till about nutrition, drug activity, movement, stress, tobacco discussion were, stage II Problem solving or problem-solving method group took meetings solving method group in groups of four to six persons for patients was

held and the purpose of this phase increased levels efficacy of patients had stage III or participation in the training phase subjects discussed at meetings by the active member of his family had the education, stage IV or stage of the evaluation at this stage after finishing the intervention group and control group experienced adherence questionnaire Treatment plan and specific tools of empowerment was completed by subjects.

Category

Lifestyle

2

Description

Intervention control group only received routine section. Routine part of the intervention order, health and educational measures is no difference for all patients whether or control group experienced was done. In this study, the control group only received the care and the experimental group received the care and training classes on the steps of empowering family centered model was also used. In fact, in the present study, a researcher for the control group did not do any intervention and control groups experienced similar educational programs and health sector by health care providers are doing for them was used.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Soraya Nejati

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University Medical Science

Full name of responsible person

Soraya Nejati

Street address

Tehran University School of Nursing and Midwifery, East Nosrat St, Forsat St, Tohid Square, Tehran

City

Tehran

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, Tehran University Medical Science

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

Tehran University Medical Science

Full name of responsible person

Soraya Nejati

Position

Faculty of Nursing and Midwifery Tehran

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