

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6693 0711

##### Email address

nejatiso@sina.tums.ac.ir

##### 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 Avrzhrans 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

##### City

Tehran

## 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

##### Street address

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+98 21 6692 7171

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nedasanaie@ymail.com

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

### Contact

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Tehran

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Web page address

## 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*