# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Investigation the effect of care program on Betty Neuman system model on anxiety level and stressors in patient undergoing coronary artery bypass graft surgery

## Protocol summary


**Study aim**

Care plan Based on Betty Neuman Systematic Model, on Level of Stressor and Anxiety in Patients Undergoing Coronary Artery Bypass surgery.

**Design**

This research is a blind study clinical trial in two-groups , and in three-steps, which runs in two intervention and control groups. Research samples will be provided by admitted patients waiting for coronary artery bypass surgery. To run this research the control and the intervention group will be selected by referring to Shahid Chamran Hospital and studying the list of candidates for coronary artery bypass graft surgery of the following day. Sampling perform in an easy and accessible condition and it will be continue until the right sample volume obtained. Then the people who have the criteria for entering the research will be choose accidentally . Each group contains 32 persons.

**Settings and conduct**

To run this research the control and the intervention group will be selected by referring to Shahid Chamran Hospital and studying the list of candidates for coronary artery bypass graft surgery of the following day.

**Participants/Inclusion and exclusion criteria**

Full individual consciousness, Patients undergoing coronary artery bypass surgery,Have no known psychiatric disorders,30-70 years,Patients who have no open heart surgery experience .

**Intervention groups**

Intervention group: A care program based on the Betty-Neuman system model will be conducted in consecutive sessions of 45-60 minutes Before and after surgery in the three level of prevention. Control group: This group will be recived routine of hospital

**Main outcome variables**

Providing the best strategy and using a care program based on Betty Neuman systematic model in Isfahan hospitals to modify stressor and anxiety in patients undergoing coronary artery bypass graft surgery.


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180116038397N1**
Registration date: **2018-03-19, 1396/12/28**
Registration timing: **prospective**

Last update: **2018-10-27, 1397/08/05**
Update count: **1**

**Registration date**

2018-03-19, 1396/12/28

**Registrant information**


**Name**

Elham Akhlaghi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 3668 0048

**Email address**

makhlaghi@nm.mui.ac.ir


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-03-20, 1396/12/29

**Expected recruitment end date**

2018-05-04, 1397/02/14

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation the effect of care program on Betty Neuman system model on anxiety level and stressors in patient undergoing coronary artery bypass graft surgery

**Public title**

Investigation the effect of care program on Betty Neuman system model on anxiety level and stressors in patient undergoing coronary artery bypass graft surgery

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Complete awareness of the individual, awareness of the time and place, and the person who has the ability to communicate (question and answer) in a desirable manner. Patients undergo coronary artery bypass surgery. Age of 30-70 years. Guest to participate in the study

**Exclusion criteria:**

Patients with a history of open heart surgery People with known psychiatric disorder

**Age**

From **30 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants are unaware of the allocation of study groups. They conclude that all participants received intervention

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezarjereeb Street, Isfahan, Iran.

**City**

Isfahan

**Province**

Isfehan

**Postal code**

81746-73461

**Approval date**

2018-02-18, 1396/11/29

**Ethics committee reference number**

IR.MUI.REC.1396.3.838

## Health conditions studied

### 1

**Description of health condition studied**

Coronary Artery Bypass Graft

**ICD-10 code**

I25.7

**ICD-10 code description**

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

## Primary outcomes

### 1

**Description**

anxiety level and stressors

**Timepoint**

preintervention, Immediately after intervention, Before discharge

**Method of measurement**

Spielberger questionnaire-(RCSSS)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Control group: This group will be recieved routine of hospital

**Category**

Other

### 2

**Description**

Intervention group: A care program based on the Betty-Neuman system model will be conducted in one or two consecutive sessions of 45-60 minutes prior to the operation in the first and second level prevention by a

researcher on the patient bedside at Shahid Chamran Hospital in Isfahan. In the third stage, prevention of Benson relaxation is performed in the intervention group

**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Chamran Heart Hospital

**Full name of responsible person**
Elham Akhlaghi

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Chamran Hospital

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Research Department

**Street address**
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makhlaghi@nm.mui.ac.ir

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Esfahan University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Elham Akhlaghi

**Position**
medical-surgical nursing Student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available