

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of continue care model on self-concept and adherence to therapy in patients undergoing coronary artery bypass grafting in Seyed-al-Shohada educational hospital of Urmia during 2018-2019

Protocol summary

Study aim

The effect of continue care model on self-concept and adherence to therapy in patients undergoing coronary artery bypass grafting in Seyed-al-Shohada teaching hospital of Urmia

Design

This project is implemented in two groups of testing and control. Samples are assigned to groups in the form of blocked strain. Each group will consist of thirty samples and a total of sixty samples. The study will be in the form of a clinical trial.

Settings and conduct

The present study is designed to evaluate the effects of ongoing care and self-concept on compliance with the treatment of patients undergoing coronary artery bypass grafting. The sample size will be 60 patients who will be randomly divided into two groups receiving intervention and control. This study is in the center Educational treatment will be done in Seyed-ul-Shohada, Urmia.

Participants/Inclusion and exclusion criteria

Patients in this study will be included as research samples that have the following features: 1. Do not undergo any other surgery during the bypass surgery 2. No psychiatric illness over the past 6 months, according to the patient 3. Not having speech, audible and perceptual problems 4- Age 30 to 70 years Non-arrival conditions 1-Patient's dissatisfaction 2. Unavailability of the patient

Intervention groups

Continuance care is done in 4 steps for the intervention group. One-time follow-up is done 1-2 times by telephone or presence. After 8-12 weeks, the questionnaire is re-completed for both groups. The control group uses routine training and routine treatment of the treatment center.

Main outcome variables

Continuance care; self-concept; Adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181105041560N2**

Registration date: **2019-06-30, 1398/04/09**

Registration timing: **retrospective**

Last update: **2019-06-30, 1398/04/09**

Update count: **0**

Registration date

2019-06-30, 1398/04/09

Registrant information

Name

Yusef Haghighi moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3275 4961

Email address

hagigym@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-20, 1398/01/31

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of continue care model on self-concept and adherence to therapy in patients undergoing coronary artery bypass grafting in Seyed-al-Shohada educational hospital of Urmia during 2018-2019

Public title

The Effect of Continuous Care Modeling on Self-Concept and Adherence to Treatment in Patients with Coronary-Related Transplantation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

During the bypass surgery, they will not undergo any other surgery Not having psychiatric illness over the past 6 months, according to the patient Not having spoken, audible and perceptual problems Age of 30 to 70 years

Exclusion criteria:

Unavailability of the patient Dissatisfaction of patient

Age

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

Patients will be selected based on inclusion criteria and then classified into two groups receiving intervention and control group, using the random block method in quadruple blocks based on the obtained list. To generate random sequences in this clinical trial, <http://www.graphpad.com/quickcalcs/index.cfm> will be used.

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

Ethic committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Jahad Ave.,
Urmia, I.R. Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.UMSU.REC.1397.352

Health conditions studied

1

Description of health condition studied

Investigating the effect of continuous care on self-concept and adherence to treatment of patients undergoing coronary artery bypass grafting

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

Continuance care

Timepoint

At the beginning of the study and 3 months after the start of the study

Method of measurement

Continuance care questionnaire

2

Description

Self-concept

Timepoint

At the beginning of the study and 3 months after the start of the study

Method of measurement

Beck's Self Concept Test

3

Description

Adherence to treatment

Timepoint

At the beginning of the study and 3 months after the start of the study

Method of measurement

Treatment adherence questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Continuance care, which is considered as a native model of Iran, will be conducted by telephone within 8 to 12 weeks after surgery. Continuance care has 4 stages including awareness, sensitization, control and evaluation. Transparency of stages will take 30-40 minutes, before discharge consultation will take 30-40 minutes, and consultation after discharge at home by phone will take 20-30 minutes. After the completion of the study, the adherence to treatment will be measured again.

Category

Treatment - Drugs

2

Description

Control group: In the control group, there is no surplus intervention except routine care, and the nursing and doctor's recommendations will be based on the routine of surgery ward and after the completion of the practice, adherence to the treatment will be checked again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed-al-Shohada educational hospital of Urmia

Full name of responsible person

Yusef.Hagigy Mogadam

Street address

Jahad Avenue, Urmia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Yusef.Hagigy Mogadam

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Yusef.Hagigy mogadam

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Behnam.Askary

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After completing sampling and analyzing data, the study is published as a paper

When the data will become available and for how long

5 months

To whom data/document is available

29/5000 Researchers and nursing students

Under which criteria data/document could be used

In order to use and publish the results of the study through the legal procedures approved by the Urmia University of Medical Sciences

From where data/document is obtainable

Urmia University of Medical Sciences

What processes are involved for a request to access data/document

Request from the responsible author

Comments