

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Intervention Based on Patient Expectations on Coronary Surgery Outcomes

Protocol summary

Study aim

Effect of Intervention Based on Patient Expectations on Coronary Surgery Outcomes

Design

Clinical trial study on 86 patients who were scheduled for CABG randomly divided into control and intervention group

Settings and conduct

The study took place in the Cardiac surgery ward of Golestan hospital in Ahvaz, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria included Patient with Age over 18 years old and Fluency in Persian and no serious underlying and mental illness and Coronary artery surgery for the first time and Lack of emergency surgery and Satisfaction to participation in the study :Exclusion criteria member of treatment staff and family members is a medical staff

Intervention groups

In this study, participants randomly allocated to 2 groups of intervention and control, Patient Expectation Questionnaire 1 or 2 weeks before surgery completed by researcher in two control and intervention groups. In the intervention group, after analyzing the expectation, interventions will be performed to optimize the expectation, which include the expectation outcomes and individual control intervention. This is while no intervention is taken in control group, in intervention group in two session researcher give information about coronary surgery and benefit to patient and helped patients develop positive yet realistic expectation about surgery and outcomes, for individual control, patients are asked to state their expectation after surgery then explained what changes make to their health behaviors that will be help them recover faster. Before admission and 1-3 month after surgery in two groups completed Questionnaire include Pain Disability, Cardiac Anxiety, Patient Expectation and longest stay in hospital and readmission.

Main outcome variables

Patient Expectation: Pain Disability: Cardiac Anxiety: Length of stay, and readmission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210303050566N1**

Registration date: **2021-07-08, 1400/04/17**

Registration timing: **prospective**

Last update: **2021-07-08, 1400/04/17**

Update count: **0**

Registration date

2021-07-08, 1400/04/17

Registrant information

Name

Kobra Norouzi larki

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3221 7609

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intervention Based on Patient Expectations on Coronary Surgery Outcomes

Public title

intervention based on Patient Expectation under Coronary Surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years old Coronary artery surgery for the first time Fluency in Persian Elective surgery Satisfaction to participate in the study No serious underlying disease and mental illness (respiratory and renal failure and dialysis)

Exclusion criteria:

Member of treatment staff Family members is a medical staff

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **86****Randomization (investigator's opinion)**

Randomized

Randomization description

Sampling will initially be according to available sampling. This means that patients who meet the inclusion criteria will be included in the study. Patients are then divided into two groups of control and intervention based on random allocation of four blocks. For this purpose, four blocks are selected, so that the intervention group will have the letter A and the control group will have the letter B; The six possible states are written on separate cards and each card will be assigned a number from one to six, then the numbers will be written on paper and removed randomly. Until the expected number of samples is completed. In this study, the online randomization service ([http // www.sealedenvelope.com / simple-randomiser / v1 / lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)) will be used to block block randomization. Concealment of random allocation will be done using packets in the package. In this way, one of the letters is placed inside each envelope in the specified order, after which the envelope lid will be closed and will be given to the researcher.

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**

Institutional research ethics committee of Nursing, Midwifery & Rehabilitation school

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School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat street. Tohid sq.

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Approval date

2021-02-20, 1399/12/02

Ethics committee reference number

IR.TUMS.FNM.REC.1399.217

Health conditions studied**1****Description of health condition studied**

Dementia/ Alzheimer

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes**1****Description**

Patients Expectation

Timepoint

Before intervention, 1 and 3 months after coronary surgery

Method of measurement

Patient expectation questionnaire

2**Description**

Cardiac Anxiety

Timepoint

Before intervention, 1 and 3 months after coronary surgery

Method of measurement

Cardiac Anxiety Questionnaire

Secondary outcomes

1

Description

Pain Disability

Timepoint

Before intervention, 1 and 3 months after coronary surgery

Method of measurement

The Pain Disability Questionnaire

2

Description

Length of Hospital Stay

Timepoint

After Discharge from hospital

Method of measurement

Based on day

3

Description

Readmission

Timepoint

until 3 month after surgery

Method of measurement

Noted number of readmission during 3 month after surgery

Intervention groups

1

Description

Intervention group: Between one to week before surgery with patient in this research were contacted using telephone interview questionnaires Patient expectations will be completed by the researcher. Expectation questionnaire The patient will be analyzed and the necessary points to perform the intervention (intervention will be determined based on expectation and optimization of these expectation .After determining the points for intervention, before hospital admission at least two sessions will be held with patients. It is noteworthy that to perform interventions was coordinated with a cardiologist and a psychiatrist Ahvaz Golestan Hospital then will be scheduled. In the expectations_based intervention outcomes The researcher provides information about surgery and benefits of surgery (The purpose is give information only is not patient education). The aims of these information to cultivate realistic expectation of treatment and will not be very optimistic . then asked each patient to state their individual expectation of treatment as well as their activity plan after surgery. An example of this activity plan could be this which of the following activities can be used during the recovery process enjoy. And even asked about these activities have illustration and imagination. For positive impact on expectations individual control , to patient about possible symptoms after surgery they have information given. For example , gag reflexes due to the respiratory tract. Researcher and patient share ideas and they will develop programs for adapt to these symptoms.

Also talk to patient about what change in health behaviors to help them accelerate recovery . Thus, the expectations of patient individual control are also will be strengthened . After discharge from hospital also during phone call to patient or through WhatsApp the content of specific intervention will be reminded .

Category

N/A

2

Description

Control group: The control group will receive only ordinary ward intervention, which includes explanations of nurse and doctors about heart surgery and care after discharge of hospital.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Kobra Norouzilarki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Kobra Norouzilarki

Position

MS Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

