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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Email address
katinorouzi@gmail.com

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 meddical staff

Age
From **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) 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

Street address
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 tow 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
nmcrc@tums.ac.ir
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
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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