Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Nov 2026

Evaluation of the effect of Johnson model care program on behavioral systems of patients undergoing coronary artery bypass graft surgery (CABG)

Protocol summary

Study aim
The effect of implementing a care program based on Johnson's model on the behavioral system of patients undergoing coronary artery bypass surgery

Design
A clinical trial with a control group, with parallel groups, randomized on 144 patients.

Settings and conduct
This is a clinical trial. 144 patients after CABG, are randomly divided into 2 intervention and control groups. At first, pretest will be completed for both groups, then an intervention program will be done for the intervention group. 2 weeks later post test will be completed for both groups and analyzed and compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18-75 years old, aware of time and people, able to communicate, have a telephone line, have a companion, and undergo open heart surgery. exclusion criteria: patient’s unwillingness to cooperate

Intervention groups
Intervention group: Interventions during 4 training sessions with a duration of 30 min-1 h for each patient based on Johnson's behavioral model are carried out in eight subsystems: Restorative, Ingestive, eliminative, protective, dependency, achievement, Affiliative, and sexual. The patient's companion also participates in these meetings. Specialized care related to the behavioral subsystem is performed with the aim of increasing efficiency in a positive direction for the patient and based on the subsystem involved, According to nursing standards, a related educational pamphlet is provided to the patient. After 4 sessions, up to 2 weeks, the patient will be followed up through phone call. Control group: In the control group, the data collection method will be similar to the test method (in the hospital and two weeks later), but they will only receive usual care.

Main outcome variables
Behavioral systems, Behavior of patients in the sub-systems of storage-absorption-disposal-protection-dependency-achievement-belonging and familiarity-sex

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220831055838N1**
Registration date: **2022-12-05, 1401/09/14**
Registration timing: **prospective**

Last update: **2022-12-05, 1401/09/14**
Update count: **0**

Registration date
2022-12-05, 1401/09/14

Registrant information

Name
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Johnson model care program on behavioral systems of patients undergoing coronary artery bypass graft surgery (CABG)

Public title

The effect of Johnson care program on the behavior of patients after open heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being aware of time and people Having the ability to communicate Under open heart surgery The presence of a companion who is aware of the patient's condition Having a phone line

Exclusion criteria:

The patient's unwillingness to cooperate

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the permutation block randomization method. Blocking is usually used in order to balance the number of samples allocated to each of the studied groups. This feature helps the researchers to have the same number of samples assigned to each of the studied groups in cases where intermediate analyzes are needed during the sampling process. In this two-group clinical trial, block sizes of 4, 6, and 8 have been considered (in this method, the number of people assigned to each group in the blocks is equal). The randomization tool is also used from random sequence generation software (Random allocation software), which in addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method. For concealment, we use Concealment Allocation, which refers to the method used to perform a random sequence on the participants in the study, in such a way that the allocated group is not known before the allocation of the individual. By using opaque, sealed, numbered sequentially envelopes, in this method, each random sequence created is recorded on a card, and the cards are placed inside the envelopes in order They are placed. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

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 Ahvaz Jundishapur University of Medical Sciences

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Esfand St, Farvardin St,Golestan Blvd, Ahvaz

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Approval date

2022-08-20, 1401/05/29

Ethics committee reference number

IR.AJUMS.REC.1401.201

Health conditions studied

1

Description of health condition studied

Coronary artery bypass surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Behavioral systems of patients undergoing coronary artery bypass surgery

Timepoint

Before surgery and 14 days after surgery

Method of measurement

Behavioral assessment tool

Secondary outcomes

1

Description
Subsystem of affiliation
Timepoint
before surgery and 14 days after the intervention
Method of measurement
Behavioral assessment tool

2

Description
protection subsystem
Timepoint
before surgery and 14 days after the intervention
Method of measurement
Behavioral assessment tool

3

Description
Acheivement Subsystem
Timepoint
before surgery and 14 days after the intervention
Method of measurement
Behavioral assessment tool

4

Description
Ingestive subsystem
Timepoint
before surgery and 14 days after the intervention
Method of measurement
Behavioral assessment tool

5

Description
eliminative subsystem
Timepoint
before surgery and 14 days after the intervention
Method of measurement
Behavioral assessment tool

6

Description
Restorative subsystem
Timepoint
before surgery and 14 days after the intervention
Method of measurement
Behavioral assessment tool

7

Description
Sexual subsystem
Timepoint
before surgery and 14 days after the intervention
Method of measurement
Behavioral assessment tool

8

Description
dependency subsystem
Timepoint
before surgery and 14 days after the intervention
Method of measurement
Behavioral assessment tool

Intervention groups

1

Description
Intervention group: :the patients' status in each of the 8 behavioral subsystems based on the degree of patient's imbalance and priority is assessed and nursing care based on standard nursing interventions in patients after coronary artery bypass surgery are designed and implemented. For each patient, an average of 4 training sessions by the researcher is performed. At the beginning of the first session, a demographic questionnaire will be completed and informed consent will be obtained from the patient, and then a questionnaire will be used to evaluate the patient's subsystems. Patient care begins after identifying the affected subsystems (reducing efficacy with a negative effect on the activity of the individual behavioral system). In this session, which lasts from about 30 minutes to 1 hour, depending on the patient's tolerance, the researcher will prioritize the specialized care-related behavior of the subsystems with the aim of increasing the effectiveness of the patient and based on the subsystem involved with the educational pamphlet associated with it To the patient. In each patient shift, the patient is monitored by the researcher and his colleagues, and according to the patient's need, appropriate action is taken in accordance with the Standard Nursing Interventions with the purposes of stimulation, development and support for the patient. Then, during the next sessions, the patient's condition will be monitored and gradually the priority will be taken care of and controlled by all of its subsystems. After 4 sessions up to two weeks, the patient will be followed up through phone call and her recovery process is evaluated, and again the patient's subsystems assessment questionnaire is completed and the status of the balance of the subsystems was determined. intervention in every subsystem is as follows: Restorative subsystem:1- The ability to breathe comfortably: -2- The ability to sleep properly - 3- The ability to control and manage fatigue - 4- The ability to calm oneself in the face of stressful factors: teaching relaxation techniques, encouraging the patient to express his feelings and if he is upset Ask for help. Ingestive subsystem:1- The ability to consume enough liquids and food 2- Appetite 3- Weight control: 4- The ability to tolerate food 5- The ability to obtain information related to the recommended diet 6- The ability to obtain information related to prescribed drugs - The ability to obtain information

related to activity and recommended exercises. 8- The amount of drugs used to control pain. eliminative subsystem1-Frequency of defecation-2-Urine output 3- Ability to express feelings verbally and non-verbally. protective subsystem: 1- The ability to prevent bedsores 2- The ability to prevent and deal with possible bleeding 3- The ability to protect oneself from falling down due to dizziness and postural hypotension 4- The ability to control mental emotions. dependency subsystem: 1- The ability to do things inside or outside the home without help 2- The extent of getting help from others to perform tasks and self-care 3- Feeling the need to do religious and spiritual activities 4- Relying on the medical or nursing profession for emotional support. achievement sub system: 1- Adherence to the treatment regimen. 2- The patient is taught how to check blood sugar and blood pressure, feedback is taken from him, and if there is a problem, it is resolved. 3- The ability to play spiritual roles. Affiliative sub-system: In this subsystem, the patient's emotional relationship with family members and the ability to participate in society (resuming a job, etc.) and the ability to use skills in relation to others are questioned. sexual subsystem: Educate the patient about resuming sexual intercourse approximately 2-4 weeks after surgery when the wound has healed and pain has subsided.

Category

Behavior

2

Description

Control group: The control group will receive only routine ward interventions. The routine interventions of the department mean therapeutic and educational measures that will be performed without any difference for all hospitalized patients, whether in the experimental or control group, and the researcher will not perform any intervention for the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Shahram Molvinejad

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2

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Sponsors / Funding sources

1

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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

Ahvaz 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
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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
Yes - There is 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
Data may be available by request submitted to the corresponding author.
When the data will become available and for how long
Data can be shared immediately after the article is published.
To whom data/document is available
It will be available for researchers working in academic and scientific institutions
Under which criteria data/document could be used
For related research
From where data/document is obtainable

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

It is possible to receive the abstract by referring to the email address and using the thesis by referring to the central library of Ahvaz University of Medical Sciences

Comments