

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of Orlando's theory-based nursing care on the level of postural anxiety in patients undergoing Coronary Artery Bypass Graft

Protocol summary

Study aim

The effect of nursing care based on Orlando's theory on the situational anxiety level of patients undergoing Coronary Artery Bypass Surgery

Design

Clinical trial, intervention group and control group, randomized and blinded

Settings and conduct

First, patients who candidates for coronary artery bypass surgery in the heart surgery department of Fatemeh Zahra select by available sampling method with considering the entry criteria. Then, they divide into two intervention and control groups by random allocation method. Interventions will perform individually based on the survey was made the Orlando's model. Samples will be blinded and each participant will be examined in a private room.

Participants/Inclusion and exclusion criteria

Entry criteria: 1-Coronary Artery Bypass Graft candidate for the first time 2-Willingness to participate in the study 3-Hospitalization at least one day before surgery 4-Having the ability to listen, understand and answer the questions Non-entry criteria: 1-Have the history of mental problems such as suffering from anxiety disorders(listed in the patient's file)

Intervention groups

Participants will receive nursing care based on Orlando's theory individually and also routine nursing care in the intervention group but in the control group, participants will receive only routine nursing care.

Main outcome variables

Postural anxiety

General information

Reason for update

Acronym

Effect of Orlando's theory on the level of postural anxiety in patients undergoing Coronary Artery Bypass Graft

IRCT registration information

IRCT registration number: **IRCT20230528058319N1**

Registration date: **2023-06-29, 1402/04/08**

Registration timing: **prospective**

Last update: **2023-06-29, 1402/04/08**

Update count: **0**

Registration date

2023-06-29, 1402/04/08

Registrant information

Name

Mobarakeh Abbasi Firoozjah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 992 319 4667

Email address

abbasimobarakeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Orlando's theory-based nursing care on the level of postural anxiety in patients undergoing Coronary Artery Bypass Graft

Public title

Effect of Orlando's theory-based nursing care on the level of postural anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Coronary Artery Bypass Graft candidate for the first time
Willingness to participate in the study
Hospitalization at least one day before surgery
Having the ability to listen, understand and answer the questions

Exclusion criteria:

Having a history of mental problems such as suffering from anxiety disorders (listed in the patient's file)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

First, the samples will select with the available sampling method by considering the entry criteria. Then, patients will divide into two groups A and B by random allocation method using the website <https://graphpad.com/quickcalcs/index.fm>. Participants A are in intervention group and participants B are in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants do not know which group they are in because the study is individual. Each participant will examine in a separate place.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganj Afrooz Ave

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2022-12-12, 1401/09/21

Ethics committee reference number

IR.MUBABOL.REC.1401.134

Health conditions studied

1

Description of health condition studied

Postural anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

2

Description of health condition studied

Coronary Artery Bypass Graft

ICD-10 code

T82.2

ICD-10 code description

Mechanical complication of coronary artery bypass graft and biological heart valve graft

Primary outcomes

1

Description

Postural anxiety

Timepoint

Before the intervention: before the surgery in the evening. After the intervention: before starting the surgery on the morning of the operation day.

Method of measurement

Spielberger postural(state) anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the survey based on the Orlando model will be given to the intervention group. Also, the non-verbal and verbal behavior of the patient will be observed and the factors that cause postural anxiety can be identified (patient behavior examination). After these factors express by the nurse and confirm by the patient (nurse reaction). Then, nursing interventions will perform based on the result of the verbal and non-

verbal behavior individually and face to face (nurse performance). For the intervention group, the individual training program will be conducted in a private room in the hospital. Also, the intervention group will receive routine nursing care. The intervention is in the form of education and counseling.

Category

Behavior

2

Description

Control group: Participants in the control group receive only routine nursing care. Routine care includes monitoring vital signs, coordinating with physicians and following physician orders.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital

Full name of responsible person

Mobarakeh Abbasi Firoozjah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mahdi Rajabnia

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mobarakeh Abbasi Firoozjah

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Associate professor

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Ph.D.

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Person responsible for updating data

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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