

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Examining the effect of nursing care based on Roy adaptation model on quality of life and fatigue among patients undergoing coronary artery bypass graft

Protocol summary

Study aim

Determination of the effect of nursing care based on Roy adaptation model on quality of life and fatigue among patients undergoing coronary artery bypass graft in Kashani hospital of Shahre-kord

Design

This clinical trial has two groups, The groups are parallel, randomized and sample size in each group is 33.

Settings and conduct

As mentioned study population are people with coronary artery bypass graft that selected by simple sampling. The place of intervention is Kashani hospitals of Shahrekord. Sample size in each group is 33. The intervention group received a nursing care program based on the Roy adaptation model in 4 individual sessions and 2 general sessions and the control group receives routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years old; lack of mental disorders and mental retardation; patients undergoing coronary artery bypass surgery that have been transferred to the heart surgery ward; willingness to cooperate in the study; no problem communicating. Non-inclusion criterion: unwilling to participate in the study; inability to implement the training program.

Intervention groups

The study consists of two groups. The intervention group receives a nursing care program based on the Roy adaptation model and the control group receives routine care.

Main outcome variables

Improve quality of life; improve fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181024041449N2**

Registration date: **2018-12-06, 1397/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-06, 1397/09/15**

Update count: **0**

Registration date

2018-12-06, 1397/09/15

Registrant information

Name

ali hassanpourdehkordi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3334 6720

Email address

alihassanpourdehkordi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-29, 1397/07/07

Expected recruitment end date

2019-09-29, 1398/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the effect of nursing care based on Roy adaptation model on quality of life and fatigue among

patients undergoing coronary artery bypass graft

Public title

Examining the effect of Roy adaptation model on patients undergoing coronary artery bypass graft

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years old
Lack of mental disorders and mental retardation
Patients undergoing coronary artery bypass surgery that have been transferred to the heart surgery ward
Willingness to cooperate in the study
No communicating problem

Exclusion criteria:

Unwilling to participate in the study
Inability to implement the training program

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: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation; the study participants are divided into two intervention and control groups using a random number table, which is extracted from random statistical software.

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 Shahrkord University Of Medical Sciences

Street address

Shahrkord University of Medical Sciences, Rahmatie, Shahrkord Town.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2018-09-29, 1397/07/07

Ethics committee reference number

IR.SKUMS.REC.1397.156

Health conditions studied

1

Description of health condition studied

Coronary artery bypass graft

ICD-10 code

T82.9

ICD-10 code description

Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description

Quality of Life

Timepoint

At the beginning of the study and 2 month after the intervention

Method of measurement

Ferans and Pavers questionnaire

2

Description

Fatigue

Timepoint

At the beginning of the study and 2 month after the intervention

Method of measurement

Fatigue Severity Scale (FSS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for the intervention group, a nursing care program based on the Roy model is implemented. At first, incompatible behaviors of patients are identified using a researcher-made form of patient assessment based on Roy pattern. In the next stage, based on incompatible behaviors, 6 educational sessions will be conducted, 2 general education sessions and 4 individual training sessions and direct intervention of 30 to 45 minutes will be done by the researcher for each patient.

Category

Treatment - Other

2

Description

Control group: the control group receive treatment and routine care through visiting by his doctor's at office.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Ali Hassanpour Dehkordi

Street address

Ayatollah Kashani hospital, Parastar ave.

City

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Chahar-Mahal-va-Bakhtiari

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8816758915

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+98 38 3226 4826

Email

Kashani@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Kamal Solati

Street address

Shahrekord University Of Medical Sciences, Rahmatie, Shahrkord.

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kamal_solati@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Ali Hassanpour Dehkordi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Ali Hassanpour Dehkordi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mojtaba Esmailian

Position

employe

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable