

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effect of Orem-based self-care program on sleep quality, daily living activity (ADL) and lower extremity edema in patients with coronary artery bypass graft surgery (CABG)

Protocol summary

Study aim

Determining the effect of Orem-based self-care program on sleep quality, daily activity of the lower extremity and the quality of life in patients with coronary artery bypass graft surgery

Design

Clinical trial, two groups

Settings and conduct

Patients were selected by Convenience Sampling from surgery ward in Kashani Hospital, in Shahr-e-Kasr, and randomly distributed in two groups. the intervention group received three training sessions based on the information obtained from the questionnaires and completed the letters after two months.

Participants/Inclusion and exclusion criteria

The willingness to participate in the study; Age between 75-55 years Only CABG surgery cases ; The surgical procedure is using the cardiopulmonary bypass method ; Residence in Chahar Mahal and Bakhtiari province ; Not having hearing and speaking problems Ability to understand conversation in Farsi ; The least patient or family member should be able to read and write; Not having a history of known mental illness; Patients who are in educational support according to the OREM requirement form; Non-participation of CABG patients in educational programs

Intervention groups

Sampling will be carried out in an easy and accessible way. Patients will gradually be included in the study and then assigned to the control and intervention groups by random allocation method using the software of the subjects. For the intervention group, three training sessions are conducted based on the required assessment form and the routine care group is received.

Main outcome variables

quality of sleep; edema; activity of daily living

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190328043127N1**

Registration date: **2019-07-28, 1398/05/06**

Registration timing: **retrospective**

Last update: **2019-07-28, 1398/05/06**

Update count: **0**

Registration date

2019-07-28, 1398/05/06

Registrant information

Name

Zahra Moosaviean

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 38 3333 5648

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-02, 1397/07/10

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

2018-10-03, 1397/07/11

Actual recruitment end date

2019-02-05, 1397/11/16

Trial completion date

2019-02-09, 1397/11/20

Scientific title

The effect of Orem-based self-care program on sleep quality, daily living activity (ADL) and lower extremity edema in patients with coronary artery bypass graft surgery (CABG)

Public title

The effect of Orem-based self-care program on sleep quality, daily living activity (ADL) and lower extremity edema in patients with coronary artery bypass graft surgery (CABG)

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 55-75 years old Surgery using cardiopulmonary bypass method Residence in Chahar Mahal and Bakhtiari province No hearing problem and ability to speak Speech conversation in Farsi at least patient or one Have family members reading and writing Not having a history of known mental illness People who are in the educational support level according to the ORM requirement No CABG patient participation in educational programs only CABG surgery

Exclusion criteria:

Unusual stressful event, such as returning to the operating room death Absence of patient's willingness to continue cooperation Not doing educated self-care activities

Age

From **55 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Actual sample size reached: **73**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients assigned by random allocation method and using the software of the subjects in the two groups of control and intervention.

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

Shahrekord Univ Ethics Committee university of Medical Sciences

Street address

Shahrekord University of Medical Sciences .Kashani street, Shahrekord , Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

88961-46311

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.SKUMS.REC.1397.179

Health conditions studied

1

Description of health condition studied

Patients with open heart surgery

ICD-10 code

I51.6

ICD-10 code description

Cardiovascular disease, unspecified

2

Description of health condition studied

cardiovascular diseases

ICD-10 code

I51.6

ICD-10 code description

Cardiovascular disease

Primary outcomes

1

Description

quality of sleep

Timepoint

Before the intervention, immediately after the intervention, two months after the end of the intervention

Method of measurement

questionnaire

2

Description

activity daily of the life

Timepoint

Before the intervention, immediately after the intervention, two months after the end of the intervention

Method of measurement

questionnaire

3

Description

lower limb edema

Timepoint

Before the intervention, immediately after the intervention, two months after the end of the intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

sleep

Timepoint

2month follow up

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: In the intervention group based on the needs assessment form, the educational needs of the patient will be extracted and then three training sessions will be conducted

Category

Rehabilitation

2

Description

Control group: Receive no specific intervention and only routine intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Zahra Moosavian

Street address

Parastar Street, Ayatollah Kashani Hospital, Shahrekord, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Fatemeh Aliakbari

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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

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

Fatemeh Aliakbari

Position

استادیار

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Individual data from the study included demographic data and Pittsburgh Sleep Quality Questionnaire and Bartlett's Letters Questionnaire.

When the data will become available and for how long

The documentation will be published after analysis and gathering in the form of a research paper in scientific sources that will accept this documentation.

To whom data/document is available

All participants in the study, colleagues from the treatment team including physicians, nurses, paramedics and policy makers in treatment and education can benefit from this documentation.

Under which criteria data/document could be used

this document can be used as a baseline protocol for development of educational program for CABG patients based on orem self care model.

From where data/document is obtainable

Contact the following email address to receive the documentation: zahra.moosaviean237@gmail.com

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

The researcher Committed to respond promptly as soon as your request is submitted through the same address.

Comments