

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effectiveness of self-care interventions based on sleep health, healthy diet and physical activity on quality of sleep in post CABG patients

Protocol summary

Study aim

Determining the effect of self-care interventions based on sleep hygiene, healthy nutrition and physical activity on sleep quality of patients after coronary artery bypass graft surgery.

Design

The experimental study was 160 people randomly divided into intervention and control groups. Then they were invited to participate in a question and answer session. Then, the written consent forms were completed by samples in both groups, and the personal information form and Pittsburgh sleep quality questionnaire were completed. Finally, the intervention group entered the intervention phase.

Settings and conduct

Samples were patients discharged after coronary artery bypass graft surgery in Seyyed Alshohada Hospital of Urmia in 1396. The intervention group attended a healthy sleep and nutrition education course for three months and appropriate physical activities that was held in the conference hall of the hospital and participated monthly in counseling sessions held by the researcher. The control group spent their normal lives during this period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least reading and writing literacy; Willingness to participation; People aged 20-60 years; Do not take hypnotic drugs; Absence of debilitating diseases; Exclusion criteria: Dissatisfaction to continue participation; Absence three or more sessions.

Intervention groups

Intervention group: They trained for self-care for sleep hygiene, healthy nutrition, and physical activity, by interventions including presenting films and education in sessions. Control group: These people had their normal life during this period.

Main outcome variables

Sleep quality in patients after coronary artery bypass surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180515039677N1**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **retrospective**

Last update: **2018-06-30, 1397/04/09**

Update count: **0**

Registration date

2018-06-30, 1397/04/09

Registrant information

Name

Fahimeh Safarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-01-20, 1396/10/30

Trial completion date
empty

Scientific title
The effectiveness of self-care interventions based on sleep health, healthy diet and physical activity on quality of sleep in post CABG patients

Public title
The effectiveness of self-care interventions on quality of sleep in post CABG patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Have at least reading and writing skills, to fill in the questionnaire or answer questions Willingness to participate; People aged 20-60 years; Do not use hypnotic drugs; Failure to develop other debilitating diseases, such as diabetes, hypertension, MS, stroke
Exclusion criteria:
 Unwillingness to continue participation any reason and at any stage of the research three or more sessions absence

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **80**
 Actual sample size reached: **73**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method in this research was convenience based on inclusion criteria considering the number of samples,. At first, the file numbers of individuals were placed on cards of the same form and placed inside the pot. Then the cards were pulled out one by one to make up the number of research samples. Then samples were divided into two intervention and control groups by simple random allocation method.

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 Urmia University of Medical Sciences

Street address

West Azarbaijan, Urmia, Resalat Blvd, Jihad Street, Emergency Coyote, Research & Technology Dept.

City

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Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.UMSU.REC.1396.234

Health conditions studied

1

Description of health condition studied

cardiovascular diseases

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Sleep quality score in Pittsburgh questionnaire after postoperative coronary artery bypass graft surgery

Timepoint

Measurement of sleep quality based on the Pittsburgh questionnaire, at the beginning of the intervention and 3 months after the implementation of self-care interventions including sleep health, healthy eating and physical activity.

Method of measurement

Pittsburgh questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, self-care education classes were held at Sayyid al-Shohada Hospital twice a week for 6 sessions each week (including 2 sessions on sleep hygiene, 2 sessions on

healthy eating and 2 physical exercise sessions). Monthly counseling session was arranged by the researcher to solve self-care problems and respond to the questions of the subjects under study. During these sessions, checklist of diet, exercise, and sleep hygiene that was completed by research samples in the intervention group during the week was reviewed by the researcher and given feedback to the samples. Finally, the Pittsburgh questionnaire was completed again.

Category

Lifestyle

2**Description**

Control group: At the first session, the written consent form was signed by the control group and a personal profile and Pittsburgh sleep quality questionnaire were completed. They were checked by the researcher, once a month, blood pressure and pulse. Last session, again, the sleep quality questionnaire was completed by him.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Urmia Seyyed Al- Shohada Hospital

Full name of responsible person

Fahimeh Safarzadeh

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Seyed Shahada Hospital, Sefid Shahrivar St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Iraj

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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

Oroumia 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**

Tabriz University of Medical Sciences

Full name of responsible person

Fahimeh Safarzadeh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position
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Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to confidentiality of personal data data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Effect of Self-care Interventions on Sleep Hygiene,
Healthy Nutrition and Physical Activity on Sleep Quality
of Patients after Coronary Artery Disease

When the data will become available and for how long

Start the access period 6 months after printing the
results

To whom data/document is available

All people working in academic and scientific institutions
and those working in medical sciences

Under which criteria data/document could be used

For clinical use to improve dormancy of heart patients

From where data/document is obtainable

Email address

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

Six months after printing results, you can visit my e-mail

Comments