

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of an educational intervention based on PRECEDE model in improving sleep quality of patients after coronary artery bypass surgery

Protocol summary

Summary

This study is an open uncontrolled trial type. The aim of this study is to determine the effectiveness of an educational intervention based on PRECEDE model in improving sleep quality of patients after coronary artery bypass surgery. First, 100 patients referral to cardiac rehabilitation clinic of Tehran Heart Center having inclusion criteria will be selected and randomly assigned into intervention and control group (50 patients in each group). Selection criteria in the present study is: the patient's agreement to participate, patients of two genders between 40-80 years of age, only CABG treatment (not combined with valve replacement surgery), current complaint of poor SQ (score > 5 of SQ scale), no history of chronic insomnia for at least one year before surgery, body mass index (BMI) ≤ 35 kg/m², no indication of receiving treatments for depression and anxiety and no history of a major and serious comorbidity except for the risk factors of atherosclerosis such as diabetic. During the study period, patients who receive sleeping medications were excluded from the study. Then, pre-test to measure PRECEDE model items (including predisposing, enabling and reinforcing factors regarding sleep) for both groups will be done. After performing pre-test and analyzing the data, educational intervention will be designed according to the pre-test results. Then, educational intervention will be performed for the intervention group. It is considered that the two groups received the provided usual interventions by cardiac rehabilitation clinic. Finally, the two groups are followed 1 month after the intervention and the effect of intervention in sleep quality of patients in the two groups will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305047132N5**

Registration date: **2013-12-21, 1392/09/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-21, 1392/09/30

Registrant information

Name

Tahereh Dehdari

Name of organization / entity

Iran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 2188779118263

Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences and Health Services

Expected recruitment start date

2013-04-06, 1392/01/17

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an educational intervention based on PRECEDE model in improving sleep quality of patients after coronary artery bypass surgery

Public title

Design and evaluation of educational intervention based on PRECEDE model in improving sleep quality of patients after coronary artery bypass surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The patient's agreement to participate, patients of two genders between 40-80 years of age, only CABG treatment (not combined with valve replacement surgery), current complaint of poor SQ (score > 5 of SQ scale), no history of chronic insomnia for at least one year before surgery, body mass index (BMI) ≤ 35 kg/m², no indication of receiving treatments for depression and anxiety and no history of a major and serious comorbidity except for the risk factors of atherosclerosis such as diabetic. exclusion criteria: patients who receive sleeping medications during the study.

Age

From **35 years** old to **80 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran University of Medical Sciences and Health Services

Street address

Hashid Hemmat Highway, Iran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2013-12-11, 1392/09/20

Ethics committee reference number

23597

Health conditions studied**1****Description of health condition studied**

Sleep disorders

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes**1****Description**

Improving sleep quality

Timepoint

One month after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Performing educational intervention .The educational intervention content and educational planning will be designed based on pre-test results.

Category

Behavior

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

Cardiac Rehabilitation Clinic of Tehran Heart Center

Full name of responsible person

Dr. Saeid sadeghian

Street address

Tehran

City

Tehran

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

Vice chancellor for research of Iran University of Medical Sciences and Health Services

Full name of responsible person

Dr. Abbas Motevalian

Street address

Shahid Hemmat Highway, Iran University of Medical Sciences

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Iran University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Iran University of Medical Sciences and Health Services

Full name of responsible person

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Position

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Fax**Email****Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty