Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of education based on continuous care model on quality of life, quality of sleep and fatigue in patients undergoing coronary artery bypass surgery.

Protocol summary

Study aim
The impact of education based on continuous care model on quality of life, sleep quality and fatigue in patients undergoing coronary artery bypass surgery

Design
The clinical trial has two intervention and control groups, with parallel groups, unblinded study, non-random assignment to test and control groups, no study phase, sample size 140 patients

Settings and conduct
The current study is a before and after trial that will be conducted in the rehabilitation clinic of the Rehabilitation Research Center on 140 patients undergoing coronary artery bypass surgery in the Cardiology Research Institute.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- People who have had at least 2 months of coronary artery bypass grafting (CABG) and have been admitted to Chamran Hospital and have a hospital record 2- Consent to participate in the study 3- Having reading and writing literacy 4- Internet access 5- The ability to use virtual space to participate in web meetings and to use programs such as Skyroom 6- Resident of Isfahan Not inclusion criteria: 1- Prohibition of physical activity as determined by the physician 2- Having a special diet recommended by the physician 3- Having other disabilities such as blindness, deafness and mental retardation 4- Suffering from neurological, cerebro-vascular, psychiatric, urinary-genital disorders, being treated with psychiatric drugs (due to non-cardiac diseases) based on the patient's record

Intervention groups
Intervention group: The duration of the continuous care model is 12 weeks, which is done during a familiarization phase and 6 sensitization sessions in a period of four weeks and two control and evaluation stages by questionnaire. Control group: Only familiarization phase will be held to this group

Main outcome variables
Quality of life, quality of sleep and fatigue in patients undergoing coronary artery transplantation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230219057454N1**
Registration date: **2023-03-02, 1401/12/11**
Registration timing: **prospective**

Last update: **2023-03-02, 1401/12/11**
Update count: **0**

Registration date
2023-03-02, 1401/12/11

Registrant information

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Hossein Shahnazi

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of education based on continuous care model on quality of life, quality of sleep and fatigue in patients undergoing coronary artery bypass surgery.

Public title

Investigating the effect of training on quality of life, quality of sleep and fatigue in cardiac patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

People who have had at least 2 months of coronary artery bypass grafting (CABG) and have been admitted to Chamran Hospital and have a hospital record Consent to participate in the study Having reading and writing literacy Internet access The ability to use virtual space to participate in web meetings and to use programs such as Skyroom Resident of Isfahan

Exclusion criteria:

Prohibition of physical activity as determined by the physician Having a special diet recommended by the physician Having other disabilities such as blindness, deafness and mental retardation Suffering from neurological, cerebro-vascular, psychiatric, urinary-genital disorders, being treated with psychiatric drugs (due to non-cardiac diseases) based on the patient's record

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Ave, Isfahan University of Medical Sciences, Isfahan

City

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Isfehan

Postal code

81746-73461

Approval date

2023-02-27, 1401/12/08

Ethics committee reference number

IR.MUI.RESEARCH.REC.1401.371

Health conditions studied

1

Description of health condition studied

Quality of life, quality of sleep and fatigue

ICD-10 code

ICD-10 code description

Acute myocardial infarction, unspecified

Primary outcomes

1

Description

Fatigue score in Chalder's Fatigue Questionnaire

Timepoint

Completing the fatigue questionnaire form before the intervention (familiarization phase) and at the end of the first month and the end of the second month after the intervention (evaluation phase)

Method of measurement

Chalder fatigue questionnaire

2

Description

Sleep quality score in the Pittsburgh Sleep Quality Questionnaire

Timepoint

Completing the sleep quality questionnaire form before the intervention (familiarization phase) and at the end of the first month and the end of the second month after the intervention (evaluation phase)

Method of measurement

Pittsburgh sleep quality questionnaire

3

Description

Quality of life score in the MǻcNew quality of life questionnaire

Timepoint

Completing the quality of life questionnaire form before the intervention (familiarization phase) and at the end of the first month and the end of the second month after the intervention (evaluation phase)

Method of measurement

MacNew Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Description of the intervention in the intervention group: The stages of this model are: familiarization, sensitization, control and evaluation. The duration of the implementation of the continuous care model is 12 weeks, which includes a familiarization phase and 6 sensitization sessions in a period of four weeks and two control phases, and the evaluation is done by a questionnaire. The connected and coherent stages of the continuous care model are: Familiarization stage: The actions of this stage include introducing the trainer to the patient and family, clarifying the trainer's expectations in the study stages, specifying the patient's and his family's expectations and expectations, completing ethical consideration forms, Completing the questionnaire forms after selecting and accepting the patient and family through the press line, determining and agreeing on the time of training sessions, by phone and mentioning the goals and how to communicate, this step is done for both intervention and control groups. Sensitization stage: The actions of this stage include examining the situation and explaining the skill training needs of the patient and the family, explaining about the disease and the existing and possible resulting complications, examining the basic needs regarding the quality of life, sleep quality, fatigue and justifying the need to pay attention to it, explaining The problems are caused by the complications of the disease and addressing the desired questions and answers with an emphasis on the risk factors. Familiarization and sensitization stages will be held in the first 4 weeks of the implementation of the model in 6 sessions of 30 to 45 minutes according to the level of tolerance and acceptance of the patients. At this stage, the quality of life, sleep quality and fatigue questionnaires are completed by the patients of the intervention group .Control phase: The actions of this phase include direct and indirect evaluation of acquired skills, checking the stability of health behaviors, checking new needs with regard to new problems and re-sensitizing regarding problem solving, strengthening health behaviors and justifying the beneficial effects of actions with regard to improving the index. tangible things, controlling the studied variables, exchanging opinions about the success and failure of the measures taken, explaining the proposed solution with the help of the patient and family. In this stage, follow-up care consultations will be carried out frequently for two months with phone calls according to the care needs of the intervention group. Evaluation stage: The actions of this stage include the evaluation of the desired variables using questionnaires. Finally, this stage ends with completing the questionnaire at the end of the first month and the end of the second month after the intervention.

Category

Lifestyle

2

Description

Control group: : Familiarization stage: The first step in the continuous care model is familiarization, the purpose of which is mutual recognition (patient, family and teacher) and explanation of the model stages. The actions of this stage include introducing the trainer to the patient and the family, clarifying the trainer's expectations during the study stages, specifying the expectations and expectations of the patient and his family, completing the ethical consideration forms, completing the questionnaire forms after selecting and accepting the patient and the family through the press line. Determining and agreeing on the time of the training sessions, on the phone, and mentioning the goals and how the communication is possible which this process is done in the control stage.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Heart and Vascular Hospital

Full name of responsible person

Atefeh Ghanavatpour

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%25D8%25B1%25D8%25B3%25D8%25AA%25D8%25A7%25D9%2586-%25D9%2581%25D9%2588%25D9%2582-%25D8%25AA%25D8%25AE%25D8%25B5%25D8%25B5%25DB%258C-%25D9%2582%25D9%2584%25D8%25A8-%25D8%25B4%25D9%2587%25DB%258C%25D8%25AF-%25D8%25AF%25DA%25A9%25D8%25AA%25D8%25B1-%25DA%2586%25D9%2585%25D8%25B1%25D8%25A7%25D9%2586%2F&usg=AOvVaw24RMA93N5UDzz9qstVlKoy

Sponsors / Funding sources

1

Sponsor

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Hossein Shahnazi

Position
Associate professor

Latest degree
Ph.D.

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
In this plan, there is no need to publish information
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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available