

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 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

Name

Hossein Shahnazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3243

Email address

h_shahnazi@hlth.mui.ac.ir

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

Isfahan

Province

Isfahan

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 MacNew 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

Street address

Chamran Hospital, Third Mushtaq St., Bozorgmehr Bridge, Isfahan Province, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3260 0965

Email

h_shahnazi@hlth.mui.ac.ir

Web page address

https://www.google.com/url?sa=t&rct=j&q=&src=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwisgYjglaf9AhWG_bsiHUOLBQUQFnoECBMQAQ&url=http%3A%2F%2Fwww.paziresh24.com%2Fcenter%2F%25D8%25A8%25DB%258C%25D9%2585%25D8%25A7

%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=AOvVaw24RMA93N5UDz z9qstVlKoy

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

Street address

Hezarjarib Ave, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3200

Email

research@mui.ac.ir

Web page address

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjs_s7_k6f9AhVsiP0HHa_oA4sQFnoECBAQAQ&url=https%3A%2F%2Fmui.ac.ir%2F&usg=AOvVaw3_AmJxcvwCsO9WxLleEO2T

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

Health Promotion

Street address

Hezarjarib Ave, School of Health, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

h_shahnazi@hlth.mui.ac.ir

Web page address

<https://mui.ac.ir/en/school-hlth/Executive-board>

Person responsible for scientific 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

Health Promotion

Street address

Hezarjarib Ave, School of Health, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3200

Email

h_shahnazi@hlth.mui.ac.ir

Web page address

<https://mui.ac.ir/en/school-hlth/Executive-board>

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Atefeh Ghanavatpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

Hezarjarib Ave, School of Health, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

atefeghanavatpour1376@gmail.com

Web page address

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjs_s7_k6f9AhVsiP0HHa_oA4sQFnoECBAQAQ&url=https%3A%2F%2Fmui.ac.ir%2F&usg=AOvVaw3_AmjxcvWCsO9WxLleEO2T

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