

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of therapeutic engagement model and routine cardiac rehabilitation on the sense of coherence and medication adherence of patients undergoing coronary artery bypass graft surgery: a randomised clinical study

Protocol summary

Study aim

Determination of the efficacy of therapeutic engagement model and cardiac rehabilitation on adherence to treatment and sense of coherence of patients after coronary artery bypass graft surgery

Design

This study is a clinical trial. 72 patients undergoing coronary artery bypass graft surgery will assign in two groups, intervention and control by random block method.

Settings and conduct

This study will be carried out in Farshchian Cardiovascular Hospital, affiliated to the Hamadan University of Medical Sciences in Hamadan.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients after coronary artery bypass grafting; desire to participate in the study. Exclusion Criteria: Heart Failure class III and IV; Positive exercise test; Severe musculoskeletal problems.

Intervention groups

Intervention group: Patients will receive a continuous care program for four months alongside a cardiac rehab program. control group: patients will receive cardiac rehabilitation according to the routine program rehabilitation center. Patients will participate 3 sessions a week for one hour during one month in a supervised rehab program.

Main outcome variables

Sense of coherence; Adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012439N4**

Registration date: **2019-07-09, 1398/04/18**

Registration timing: **prospective**

Last update: **2019-07-09, 1398/04/18**

Update count: **0**

Registration date

2019-07-09, 1398/04/18

Registrant information

Name

Fatemeh Pakrad

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 3131 4041

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of therapeutic engagement model and routine cardiac rehabilitation on the sense of

coherence and medication adherence of patients undergoing coronary artery bypass graft surgery: a randomised clinical study

Public title

the effect of therapeutic engagement model and routine cardiac rehabilitation on the sense of coherence and medication adherence of patients undergoing coronary artery bypass graft surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients after coronary artery bypass graft surgery
patient's willingness to participate in educational programs based on a therapeutic engagement model

Exclusion criteria:

Heart Failure class III and IV Severe musculoskeletal problems Positive exercise test

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

First of all, from patients with coronary artery bypass graft surgery and having inclusion criteria, a sample is selected according to the convenience sampling method and based on balance block randomization method will be placed in cardiac rehabilitation group with education based on therapeutic engagement model and the cardiac rehabilitation group. For this purpose, four sheets of paper are provided by the researcher, writing on two sheets "1" for "first" and on two "2" for second". The paper sheets will be pooled, placed in a container, and randomly will be drawn one at a time for each patient without replacement until all four sheets are drawn. Then, the four paper sheets will be placed back into the container and this action will be repeated until the sample size is reached.

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

Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Blvd, Pajouhesh Sq

City

Hamadan

Province

Hamadan

Postal code

6517838698

Approval date

2019-07-06, 1398/04/15

Ethics committee reference number

IR.UMSHA.REC.1398.307

Health conditions studied

1

Description of health condition studied

Patients undergoing coronary artery bypass graft surgery

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Adherence to treatment score

Timepoint

Before, one month and three months after the intervention

Method of measurement

Adherence to treatment questionnaire

Secondary outcomes

1

Description

Sense of Coherence score

Timepoint

Before, one month and three months after the intervention

Method of measurement

Sense of Coherence questionnaire

Intervention groups

1

Description

Intervention group: In the first intervention group, the

intervention will be as follows: Upon introduction of the study and statement of the purposes, the patients will provide informed consents and complete the demographics form, adherence to treatment and sense of coherence questionnaires. Then, the therapeutic engagement model will be presented to the participants along with cardiac rehabilitation program for four months. At the end, one month and three months after intervention, adherence to treatment and sense of coherence questionnaires will be completed.

Category

Rehabilitation

2

Description

Control group: In this group, patients will receive cardiac rehabilitation according to the routine program rehabilitation center. Patients will participate 3 sessions a week for one hour during one month in a supervised rehab program.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Cardiac Center

Full name of responsible person

Fatemeh Pakrad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Pakrad

Position

Employee

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Khodayar Oshvandi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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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

I must provide all information for the sponsoring institution.

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