

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of self-care training based on Teach Back method on Health Anxiety in patients with coronary artery disease

Protocol summary

Study aim

Determining the effect of self-care training by feedback-based method on health anxiety in patients with coronary artery disorders

Design

A clinical trial with a control group with an investigation of the dependent variable of health anxiety and a double-blind and randomized through time block method on 50 patients.

Settings and conduct

Place of study: Heart department of Hazrat Rasool Hospital, Firdous city. Study population: hospitalized patients with coronary artery disorders. Type of blinding: No blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of coronary artery disease; Age:18 - 65 years; Having literacy at least reading and writing; independent in performing self-care activities; Willingness to cooperate in the study. Non-inclusion criteria: having a debilitating disease; having a history of mental disorders; Participation in other educational programs in this field

Intervention groups

Intervention group: in addition to the department's routine training, self-care training is also carried out in a feedback-oriented way in this group. Control group: only the department's routine training, such as pamphlets, etc., will be received by these patients.

Main outcome variables

health anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230523058264N1**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **retrospective**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

Registration date

2023-07-11, 1402/04/20

Registrant information

Name

Mansoor Barati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3273 1261

Email address

baratim.136563@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-27, 1401/05/05

Expected recruitment end date

2022-09-27, 1401/07/05

Actual recruitment start date

2022-08-16, 1401/05/25

Actual recruitment end date

2022-11-11, 1401/08/20

Trial completion date

empty

Scientific title

The effect of self-care training based on Teach Back method on Health Anxiety in patients with coronary artery disease

Public title

The effect of self-care training on the health anxiety of coronary artery patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
 Diagnosis of coronary artery disease Age of 18 - 65 years old Having literacy of at least reading and writing Independent in performing self-care activities Not being part of the health team (the patient himself and his family) Failure to participate in other educational programs in this field Willingness to cooperate in the study

Exclusion criteria:
 Having a debilitating disease Having a history of mental disorders

Age
 From **18 years** old to **65 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **50**
 Actual sample size reached: **50**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization of one-week time blocks, so that every week according to this sequence, patients will be placed in the intervention or control group to prevent information dissemination. Sampling will be done every week until Monday. For example: if this week is determined for the intervention group (by chance with the statistical software), all the patients will be considered in the intervention group. Sampling will be done from Saturday to Monday and no new sampling will be done until next Saturday. This group will be taught every other day.

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 Birjand University of Medical Sciences

Street address

Beheshti 7 Blvd

City

Ferdows

Province

South Khorasan

Postal code

9771885784

Approval date

2022-07-05, 1401/04/14

Ethics committee reference number

IR.BUMS.REC.1401.146

Health conditions studied

1

Description of health condition studied

CAD

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Health anxiety score in Salkofakis questionnaire

Timepoint

Before the intervention, two weeks after the intervention

Method of measurement

health anxiety questionnaire of Salkofakis 1 et al. (2002)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: feedback-based self-care training on coronary artery disease was given during one week and three sessions, which were held on a daily basis, and the health anxiety questionnaire was filled before and two weeks after the intervention. This training continues until the patient fully understands. The list is completed by the research assistant to ensure complete understanding).

Category

N/A

2

Description

Control group: The control group is only given routine training and the questionnaire is completed in two stages (first and two weeks later). Determination of intervention and control group is completely random based on spss software

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool hospital

Full name of responsible person

Mansoor Barati

Street address

Emam Reza Boulevard

City

Ferdous

Province

South Khorasan

Postal code

9771885784

Phone

+98 56 3162 7800

Email

Baratim.136563@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Ahmad Nasiri

Street address

Ghaffari street

City

Birjand

Province

South Khorasan

Postal code

9771885784

Phone

+98 56 3238 1426

Email

baratim.136563@gmail.com

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Mansoor Barati

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Beheshti 7 Boulevard

City

Ferdows

Province

South Khorasan

Postal code

9771885784

Phone

+98 56 3273 1261

Email

Baratim.136563@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mansoor Barati

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Beheshti 7 Boulevard

City

Ferdows

Province

South Khorasan

Postal code

9771885784

Phone

+98 56 3273 1261

Email

Baratim.136563@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mansoor Barati

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Ghaffari street

City

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data can be shared after anonymizing the patients

When the data will become available and for how long

Six months after paper publish

To whom data/document is available

Researchers working at the university

Under which criteria data/document could be used

When need to use content and data

From where data/document is obtainable

Postal address and email address and contact number

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

With any of the above methods, they can use the documents in less than a day

Comments