Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Mansoore 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
Mansoore Barati

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Emam Reza Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Dr. ahmad Nasiri

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Ghaffari street

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Birjand

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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
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
Mansoore Barati

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Latest degree
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Person responsible for updating data

Contact

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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