

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of post-discharge education on the quality of life and anxiety of patients after coronary angiography

Protocol summary

Study aim

The effect of post-discharge education on the quality of life and anxiety of patients after coronary angiography

Design

Clinical trial with a control group, with parallel groups, Single blinded, randomized on 90 patients. Sealed Envelope software will be used for randomization.

Settings and conduct

This study will be conducted on cardiac patients who are candidates for coronary angiography in Amir al-Momenin Hospital in Arak. First, the level of anxiety and quality of life of the patient is measured using valid questionnaires. In the intervention group, the necessary training is given to the patient in the form of a podcast, but in the control group, no training is given. The training will continue for 40 days. After that, their anxiety and quality of life will be measured again. Then, the level of anxiety and the quality of life of the two groups are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Be literate, Be able to use the WhatsApp social network: Exclusion criteria: Unwillingness to participate in the study, Patients with mental disorder and depression, Bereavement experience in the last 6 months, Having a history of angiography

Intervention groups

Intervention group includes patients with heart disease who have undergone angiography, who receive the necessary training for post-angiography care, such as care of the catheter insertion area, how to open the dressing, and how to receive medications. At first, two questionnaires are used to check the quality of life of heart patients and Spiel Berger's anxiety, which are completed by the patients before and after the study. Finally, the changes of two main variables will be examined. Control group includes patients with heart disease who have undergone angiography, who do not receive any intervention and only fill out questionnaires.

Main outcome variables

Quality of life and anxiety level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051142N7**

Registration date: **2023-01-14, 1401/10/24**

Registration timing: **prospective**

Last update: **2023-01-14, 1401/10/24**

Update count: **0**

Registration date

2023-01-14, 1401/10/24

Registrant information

Name

Aida Arjloo

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3402 0115

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golmehrsherafati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of post-discharge education on the quality of life and anxiety of patients after coronary angiography

Public title
The effect of post-discharge education on the quality of life and anxiety of patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Be literate Be able to use the WhatsApp social network
Exclusion criteria:
Unwillingness to participate in the study Patients with mental disorder and depression Bereavement experience in the last 6 months Having a history of angiography

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are assigned to groups in the order of arrival and based on the randomization sequence that will be generated in advance. This sequence is unpredictable and does not have a specific pattern, and its arrangement is completely random. To assign the samples to two groups, the block randomization method will be used with a block size of 4, so that by using the random number generation software in the block method, the randomization sequence will be produced according to the required sample size for the two groups. First, all the states where two letters A and B can be arranged together in a block of 2 are created, and a block is randomly selected by placing it between the blocks, and from the arrangement pattern in that block for patient allocation is used then this block will be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer will not know how the samples are placed in the intervention and control groups. Other people in the study will be aware of this placement.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak university of medical sciences
Street address
Arak university of medical sciences, Basij Sq., Sardasht region
City
Arak
Province
Markazi
Postal code
3848176593

Approval date
2022-11-14, 1401/08/23

Ethics committee reference number
IR.ARAKMU.REC.1401.220

Health conditions studied

1

Description of health condition studied
The level of anxiety and quality of life

ICD-10 code
F06.4

ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
The level of anxiety

Timepoint
Before the intervention and 40 days after the start of the first intervention, the level of anxiety of each patient is measured.

Method of measurement
At the beginning and end of the study, the demographic questionnaire, the Spielberger questionnaire is completed by the patients of both groups, and based on this, the level of anxiety is determined.

Secondary outcomes

1

Description

Review of quality of life

Timepoint

Before the intervention and 40 days after the start of the first intervention, the quality of life of each patient is checked.

Method of measurement

At the beginning and end of the study, the demographic questionnaire and the standard questionnaire of the quality of life of heart patients are completed by the patients of both groups, and based on this, the level of the quality of life of the patients is determined.

Intervention groups

1

Description

The intervention group includes patients with heart disease who have undergone angiography, who received the necessary training for post-angiography care that has been approved by a cardiologist, such as care of the catheter entry area, how to open the dressing, how to receive drugs (For example, they receive GTN spray during sudden chest pain) and having a healthy lifestyle. Our training starts from the first day and continues in three sessions, each for 20 minutes. Communication with the teaching nurse will continue on the WhatsApp network during discharge. In addition, it is possible for the patient to call the nurse at any hour of the day.

Category

Other

2

Description

The control group consisted of patients with heart disease who underwent angiography, who did not receive any intervention and only fill relevant questionnaires.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir al-Mu'menin hospital of Arak city

Full name of responsible person

Alireza Ali Saidi

Street address

Gerdoo St., Tandorosti Blvd., Arak city Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

DR Alireza Kamali

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University complex of the Great prophet, Basij square, Sardasht

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Grant name

Arak University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

80

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

Arak University of Medical Sciences

Full name of responsible person

Alireza Ali Saidi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Education

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only the part of the data related to the original outcome will be able to be shared.

When the data will become available and for how long

Since the spring of 2023

To whom data/document is available

Researchers and students in this field

Under which criteria data/document could be used

In situations where it is necessary to know the information required by heart patients after angiography, so that the treatment is completed correctly and the patient does not get worried and anxious knowing this information.

From where data/document is obtainable

Vice chancellor for education and research, Arak university of medical sciences. E-mail of the Vice-Chancellor: sajadimahbobeh@yahoo.com

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

These documents will be available on the website of Arak university of medical sciences.

Comments