Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
City
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Markazi
Postal code
3848176593
Phone
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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
Street address
University complex of the Great prophet, Basij square, Sardasht
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Postal code
3819693345
Phone
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Email
golmehrsherafati@gmail.com
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