Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Survey the effect of education with film on anxiety level of patients undergoing coronary angiography in educational therapeutic center of heshmat

Protocol summary

Study aim
Determining the effect of education with film on anxiety level of patients undergoing coronary angiography in educational therapeutic center of heshmat in Rasht

Design
Randomized clinical trial with control group, community-based, single blind, randomized

Settings and conduct
Samples will be drawn by lottery and will be randomly assigned to the studied groups. After reviewing the eligible patients, they will be satisfied. A draw box in which 2 are three paper with numbers 1(test) and 2(control) in it is provided to the patient to randomly remove a number. That number represents the group in which it is placed. If the number of samples of each group is completed, that number will be withdrawn from the lottery container. This will continue to the required number of samples for two groups. The sample size of each group is 64 patients. For the test group, the questionnaire is completed first day before the angiography, Then the educational film is provided to the patient and after all the patient's questions will be answered. However, in the control group the day before the angiography, the questionnaire was completed by the patient and the patient receives only routine hospitalized training. Then, the morning of the angiography, the anxiety questionnaire is again completed by the patients. one of the patients knew the type of training in the other group, and each group was checked in a week to not interact.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient satisfaction, 25-75 years, no history of angiography, the ability to communicate verbally and understand Persian language, Lack of blindness and deafness Exclusion criteria: Detection of anxiety and depression in medical records, Cancellation of angiography during study

Intervention groups
The test group receives training through film.

Main outcome variables
anxiety control

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180303038934N2**
Registration date: **2018-10-18, 1397/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-18, 1397/07/26**
Update count: **0**

Registration date
2018-10-18, 1397/07/26

Registrant information

Name
Arezoo Monfared

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3355 5058

Email address
a.monfared@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-07, 1397/07/15

Expected recruitment end date
2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of education with film on anxiety level of patients undergoing coronary angiography in educational therapeutic center of heshmat

Public title

The effect of education with film on anxiety level of patients undergoing coronary angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient satisfaction 25-75 years no history of angiography The ability to communicate verbally and understand Persian language Lack of blindness and deafness

Exclusion criteria:

Detection of anxiety and depression in medical records Patient dissatisfaction Cancellation of angiography during study

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be drawn by lottery and will be randomly assigned to the studied groups. After reviewing the eligible patients, they will be satisfied. A draw box in which 2 are three paper with numbers 1(test) and 2(control) in it is provided to the patient to randomly remove a number. That number represents the group in which it is placed. If the number of samples of each group is completed, that number will be withdrawn from the lottery container. This will continue to the required number of samples for two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

All actions, including the completion of questionnaires and the use of educational film, are done by a researcher and the study is single blind, and the patients in 2 groups are not informed of any of the differences in education.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

In Front of the 17 Shahrivar Hospital .,Seiadati Ave., Namjo Ave., Rasht City

City

Rasht

Province

Guilan

Postal code

39841-41469

Approval date

2017-02-11, 1395/11/23

Ethics committee reference number

IR.GUMS.REC:1395.333

Health conditions studied

1

Description of health condition studied

Coronary Angiography

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

2

Description of health condition studied

anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes

1

Description

the spielberger's Anxiety Inventory contains 20 questions for State anxiety and 20 questions for Trait anxiety. The final score is in the range of 80-20 and the higher score indicates more anxiety.

Timepoint

The anxiety questionnaire is completed twice. Before training and after training to the patient

Method of measurement

spielberger's Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the test group, the day before the angiography is completed, the questionnaires are completed and then the educational film will be provided to the patient and after the end of the film all the patient's questions will be answered. Then, the morning of the angiography, the anxiety questionnaire is again completed by the patient.

Category
Behavior

2

Description
Control group: In the control group the day before the angiography, the questionnaire was completed by the patient and the patient receives only routine hospitalized training. Then, the morning of the angiography, the anxiety questionnaire is again completed by the patient.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Heshmat Educational and Therapeutic Center of Rasht

Full name of responsible person
Arezoo Monfared

Street address
Rasht, 15 Khordad Ave. Heshmat Educational and Therapeutic Center of Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Dr Shadman Nemati

Street address
In Front of 17 Shahrivar Hospital., Siadati Ave., Namjo Ave., Rasht

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Phone
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Email
nemati@gums.ac.ir

Web page address
http://www.gums.ac.ir/research/303/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C.aspx

Grant name

Grant code / Reference number

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

Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Arezoo Monfared

Position
faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
خیابان دانشجو، بزرگراه شهید بهشتی، رشت

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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
Not applicable

Title and more details about the data/document
Based on the goals in the design, the amount of anxiety is reported before and after the training and some of the individual information listed in the Variables section

When the data will become available and for how long
Starting from the second half of 2019

To whom data/document is available
Researchers, Guilan University of Medical Sciences, samples of study, University and Hospital Researchers

Under which criteria data/document could be used
Data after analysis, is available to others through publication in scientific journals

From where data/document is obtainable
Arezoo monfared Email : a.monfared88@gmail.com Address: Student Ave., Shahid Beheshti Blu., Rasht, Iran Postal code: 41635- 1873 Tel: +98 13 3355 5056 Tel: +98 9113479959

What processes are involved for a request to access data/document
Usually, information will be available through the publication of the paper. But if the person asks for more and more information, can submit application by email and phone and in person. Then information will be provided according to the size and type of data that will be considered.

Comments