

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 If the number of samples of each group is completed, that number will be withdrawn from the lottery container.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

Arezo Monfared

Street address

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

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a.monfared88@gmail.com

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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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

Arezo Monfared

Position

faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific 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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

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