

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Comparison of the effect of two educational methods of multimedia (educational film) and peer education on the anxiety of patients with trans esophageal echo cardiography candidates

Protocol summary

Study aim

1-The comparison of the effects of two methods of multimedia education and peer education on the anxiety of patients with TEE candidates 2- Determine the anxiety level of the patients before and after education in the multimedia group, peer group and control group.

Design

This study is a randomized, controlled clinical trial. Sampling is done in a purpose-based manner. Patients who are candidates for TEE are selected as research samples if they have criteria for entry into the study

Settings and conduct

Patients with TEE candidates are selected as the sample. Sample size is 45 individuals (15 persons per group). The random allocation of the weekly block is done. The training is done before the TEE. To investigate the anxiety of patients, the Spielberger questionnaire is filled out immediately before the training and the second one is completed one hour before the TEE is performed. Control group: Includes patients who use routine training at the TEE clinic. To collect data in this group, the questionnaire was filled once a day, one day before the TEE and the second one is filled one hour before the TEE is performed at the TEE clinic.

Participants/Inclusion and exclusion criteria

Entrance criteria: At least 18 years of age, TEE for the first time in non-emergency situations, patient's willingness to participate in the curriculum, having at least reading and writing skills, no cognitive impairment, vision or hearing, speaking and understanding of Persian, lack of addiction and education Medical or related, lack of medical diagnosis of anxiety and depression, no sedation 3 hours before the TEE. Exit criteria: Having experience of other invasive diagnostic methods, dissatisfaction with continuing the collaboration with the researcher, illness and death

Intervention groups

Multimedia group, peer group

Main outcome variables

anxiety

General information

Reason for update

Acronym

دو روش آموزشی مولتی مدیا (فیلم آموزشی) و آموزش توسط همتا بر میزان اضطراب

IRCT registration information

IRCT registration number: **IRCT20141026019677N6**

Registration date: **2018-07-22, 1397/04/31**

Registration timing: **retrospective**

Last update: **2018-07-22, 1397/04/31**

Update count: **0**

Registration date

2018-07-22, 1397/04/31

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-15, 1397/02/25

Expected recruitment end date

2018-07-16, 1397/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of two educational methods of multimedia (educational film) and peer education on the anxiety of patients with trans esophageal echo cardiography candidates

Public title
Comparison of the effect of two educational methods of multimedia (educational film) and peer education on the anxiety of patients with trans esophageal echo cardiography candidates

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
having at least 18 years of age Performing TEE for the first time in a non-emergency The patient's willingness to participate in the educational program Have at least reading and writing skills (elementary education) The absence of any cognitive, visual or auditory (disorder Disturbing communication and lack of attention and understanding of training) Based on the evidence in the previous medical record and self-declaration Being able to speak and understand Persian language No addiction Not having medical education or related Unmet medical diagnosis of anxiety and depression (based on medical records) Do not use sedative medicine 3 hours before TEE
Exclusion criteria:
Having experience of other invasive diagnostic methods (such as angiography) before taking trans esophageal echo cardiography Dissatisfaction to continue with the researcher Getting sick Death of the patient

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Block random assignment is done. Block random assignment means that the person belonging to the target group is unpredictable. In this study, due to the nature of the research (due to the interval of at least two weeks between the time of admission of patients and performing TEE), to prevent the interference of

intervention and control groups, their allocation to the groups is selected randomly and weekly blocks. ; So that by using the cards on which the names of each of the groups are written separately is chosen randomly, which of the control, multimedia and peer groups are sampled each week, this method continues so much To reach the required sample size

Blinding (investigator's opinion)

Double blinded

Blinding description

Vote Preventing Injury and Infecting Information Starting sampling per week is subject to the TEE of all units under study last week. If not even one of the units is discharged, sampling will not be done until the TEE is completed. In order to prevent bogus, according to the activity of three different physicians in the TEE unit, all three physicians are sampled every three days of each week. The statistical analyst also does not know the allocation of people to any of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

We will have three groups in this research Which is a group; education by multimedia (educational video), a peer education group and a third group of control group Which will receive routine training.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Vice-Chancellor for Research, Mazandaran University of Medical Sciences, Teacher Field,Sari

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Qaemshahr

Province

Mazandaran

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4816715793

Approval date

2018-05-01, 1397/02/11

Ethics committee reference number

IR.MAZUMS.REC.1397.003

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes**1****Description**

anxiety

Timepoint

Immediately before training, one hour before performing TEE

Method of measurement

Spielberger Anxiety Inventory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: peer group, peer education training session for peer group patients one day before TEE, delivered by lecture and question and answer method, held at Fatemeh Zahra Hospital, Sari. To select the peer for training, before starting the study and sampling, referring to the Echo Mary Clinic, among the patients who referred to the TEE and selected according to the criteria for the peer, is selected based on the review of the text.

Category

Other

2**Description**

Intervention group: A multimedia group for educating multimedia group patients, educational researcher (CD) for 7 minutes and 12 seconds with introductory content and necessity of TEE diagnostic method, its procedure, possible complications and care before and after. It will be shown one day before performing the TEE at the training hall of Fatemeh Zahra (S) Sari Hospital, as a group presentation.

Category

Other

3**Description**

Control group (control): Includes patients who use the current routine training (educational brochure) at the TEE clinic.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mazandaran Heart Center Hospital

Full name of responsible person

Zahra Ranjbar Katie Late

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Sari 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Zahra Ranjbar Katie Late

Position

Master of critical Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

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