

# 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

Ravanbakhsh Esmaeili

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

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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

##### City

Qaemshahr

##### Province

Mazandaran

##### Postal code

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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Mazandaran Heart Center Hospital, Artesh Blvd,

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

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**Full name of responsible person**

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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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Ph.D.

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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