

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Investigating the effect of clinical orientation teaching on anxiety, pain and satisfaction of patients candidating for endoscopy

#### Protocol summary

##### Study aim

Determining the effect of clinical familiarization training on anxiety, pain and satisfaction of endoscopic candidate patients

##### Design

Clinical trial with control group, with parallel, randomized, phase 3 groups on 60 patients.

Randomization is used for the drawing.

##### Settings and conduct

Intervention group: The intervention group receives in addition to routine ward training, clinical familiarization intervention with endoscopic procedure. Clinical familiarization is held in the form of a 30-40 minute tour. In the morning before the end of the procedure, after obtaining informed consent, they are transferred to the endoscopy unit and get acquainted with the endoscopy unit, equipment, equipment, medicines and observe how a patient performs endoscopy, then about how to perform endoscopy procedure. Post-procedure clinical care is also described. The researcher also answers patients' questions during this time.

##### Participants/Inclusion and exclusion criteria

Perform endoscopy No history of endoscopy

##### Intervention groups

Intervention group: The intervention group receives in addition to routine ward training, clinical familiarization intervention with endoscopic procedure. Clinical familiarization is held in the form of a 30-40 minute tour (12). In the morning before the end of the procedure, after obtaining informed consent, they are transferred to the endoscopy unit and get acquainted with the endoscopy unit, equipment, equipment, medicines and observe how a patient performs endoscopy, then about how to perform endoscopy procedure. Post-procedure clinical care is also described. The researcher also answers patients' questions during this time.

##### Main outcome variables

Anxiety, satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171002036498N4**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

##### Registration date

2021-03-17, 1399/12/27

##### Registrant information

##### Name

Ali Akbari

##### Name of organization / entity

Medical Sciences of Rafsanjan University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 5900

##### Email address

iccn@rums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Investigating the effect of clinical orientation teaching on anxiety, pain and satisfaction of patients candidating for endoscopy

**Public title**

Investigating the effect of clinical orientation teaching on anxiety, pain and satisfaction of patients candidating for endoscopy

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Prescribed endoscopy No history of endoscopy Non-emergency endoscopy No cognitive problems No physical disability Do not be deaf No visual impairment No history of mental illness Do not have severe pain due to other diseases (cancer, etc.) Ability to speak Persian

**Exclusion criteria:**

Uncooperative patient to continue The patient becomes ill or has a complication Use more sedatives than usual

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling method will be available. Samples are randomly assigned to the control and intervention groups based on age and sex variables. In this method, the first samples (20%) are randomly entered into the study and placed in each group. For the following examples, the sum of the indicators in the two groups is considered and the sample is assigned to the group that has a lesser sum.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan University of Medical

Sciences

**Street address**

NO.1, motahari Blvd.

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

771879755

**Approval date**

2019-07-17, 1398/04/26

**Ethics committee reference number**

IR.RUMS.REC.1398.073

**Health conditions studied****1****Description of health condition studied**

Gastrointestinal patients

**ICD-10 code**

K92.2

**ICD-10 code description**

Gastrointestinal hemorrhage, unspecified

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

Anxiety: The score that patients receive from the Spielberger situational questionnaire This numerical score is higher than 43.

**Timepoint**

Before and after the intervention

**Method of measurement**

Spielberger Anxiety Scale.

**2****Description**

satisfaction: The patient's feeling is about the performance of the treatment team, the condition of the disease and the diagnostic-therapeutic methods

**Timepoint**

Before and after the intervention

**Method of measurement**

Satisfaction Questionnaire

**Secondary outcomes****1****Description**

Unpleasant sensation and emotional experience

**Timepoint**

After the intervention

**Method of measurement**

Visual analogue scale

## Intervention groups

### 1

#### Description

Intervention group: The intervention group receives in addition to routine ward training, clinical familiarization intervention with endoscopic procedure. Clinical familiarization is held in the form of a 30-40 minute tour . In the morning before the end of the procedure, after obtaining informed consent, they are transferred to the endoscopy unit and get acquainted with the endoscopy unit, equipment, equipment, medicines and observe how a patient performs endoscopy, then about how to perform endoscopy procedure. Post-procedure clinical care is also described. The researcher also answers patients' questions during this time. After the endoscopy is performed, another patient is transferred to the endoscopy room. After receiving lidocaine spray and sedative injection, while lying on your left side, the doctor guides the endoscope tube through the mouth to the throat. After passing the endoscope tip through the throat, the researcher transfers the patient to the endoscopy room and the patient observes the endoscopy procedure closely. Observation includes the operation of equipment, monitors, methods of taking pictures of the gastrointestinal tract, sampling, etc. The patient returns to the waiting room before the endoscope is removed. Their questions will be answered during this period. It takes at least two hours for the patient to return to the endoscopy department for endoscopy, before the endoscopy the anxiety questionnaire is completed again. During this period, the patient has enough time to get answers to his questions based on the observations.

#### Category

N/A

### 2

#### Description

control group: Receive routine ward training, including nurse training.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ali Ebn-Abitaleb hospital

##### Full name of responsible person

Ali Akbari

##### Street address

No. 7, Benafshe Ave., West Shariati Blvd.

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7719717653

#### Phone

+98 34 3426 2818

#### Email

iccn87@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Ali Shamsizadeh

##### Street address

No. 7, Benafshe Ave., West Shariati Blvd.

##### City

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##### Province

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##### Postal code

7717917653

##### Phone

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##### Email

iccn87@gmail.com

#### Grant name

Ali Shamsizadeh

#### Grant code / Reference number

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

Yes

#### Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Ali Akbari

##### Position

instructor

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

### Contact

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Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Ali Akbari  
**Position**  
instructor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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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

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

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

### Analytic Code

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

### Data Dictionary

Not applicable