

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Study of the effects of a Multimedia education intervention on anxiety before colonoscopy procedures.

#### Protocol summary

##### Study aim

reduction of the anxiety of patient before colonoscopy by multimedia intervention

##### Design

Patients based on the date referring to the clinic divided into two groups assigned randomly by using the website [www.randomize.com](http://www.randomize.com). Overall, 36 patients divided into two control and intervention groups (n=18). Control group received an educational booklet about colonoscopy, whereas patients in the intervention group watched a video clip about colonoscopy procedures in addition to the educational booklet. The booklet contents compiled from [uptodate.com](http://uptodate.com) website and edited by a gastroenterologist. Content validity of the booklet is approved by the opinion of five experts. Video clip is prepared according to the booklet contents. The rate of anxiety and knowledge of patients before intervention (at the time of the physical examination) and before colonoscopy will be compared. Also, the rate of tranquilizer administration during colonoscopy in both groups will be compared.

##### Settings and conduct

All patients complete Spielberger knowledge and anxiety questionnaire and will receive an educational booklet. Patients in the intervention group will watch an educational video clip. On the day of colonoscopy in endoscopy section of Qaem hospital, patients will complete Spielberger knowledge and anxiety questionnaire.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 30-70, reading literacy, candidate for the colonoscopy because four reasons include: of rectology, abdominal pain, changes in bowel habit, iron deficiency anemia. Exclusion criteria: history of colonoscopy. if the interval between visit and colonoscopy is more than 10 days

##### Intervention groups

Intervention group receive colonoscopy educational booklet and watch a video clip about colonoscopy.

Control group receive colonoscopy educational booklet.

##### Main outcome variables

anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180904040943N1**

Registration date: **2018-10-26, 1397/08/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-26, 1397/08/04**

Update count: **0**

##### Registration date

2018-10-26, 1397/08/04

##### Registrant information

##### Name

Nooshin Dayani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3727 3735

##### Email address

dayanin1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-20, 1397/07/28

##### Expected recruitment end date

2019-02-09, 1397/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Study of the effects of a Multimedia education intervention on anxiety before colonoscopy procedures.

**Public title**  
the effects of a education intervention on anxiety before colonoscopy procedures.

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
female able to read age between 30-70 One of the four factors to be candidate for colonoscopy: rectology, pain stomach, Changes in bowel habits, iron anemia  
**Exclusion criteria:**  
history of colonoscopy

**Age**  
From **30 years** old to **70 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **36**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
random sampling, individual, tools:randomization website

**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**

Ethic committee of mashhad university of medical sciences

**Street address**

mashhad university of medical science, ghorishi building, daneshgah st. masshad

**City**

mashhad

**Province**

Razavi Khorasan  
**Postal code**  
951-91735  
**Approval date**  
2018-07-18, 1397/04/27  
**Ethics committee reference number**  
IR.MUMS.MEDICAL.REC.1397.025

## Health conditions studied

1

### Description of health condition studied

Digestive problems

**ICD-10 code**

D01

**ICD-10 code description**

Carcinoma in situ of other and unspecified digestive organs

## Primary outcomes

1

### Description

Change rate in spielberger anxiety scale in patients candidate for colonoscopy

**Timepoint**

Amount of anxiety in patients was evaluated before the intervention. After that, a booklet is given to both intervention and control group. In addition to the booklet, patients in the intervention group watched an educational film at the office. After the intervention, amount of anxiety in both groups was evaluated on the colonoscopy day.

**Method of measurement**

spielberger anxiety questionnaire

## Secondary outcomes

1

### Description

knowledge's patient about colonoscopy

**Timepoint**

visit time in clinic (before intervention), after intervention in colonoscopy day in andoscopy ward

**Method of measurement**

Researcher made Questionnaire

2

### Description

The amount of tranquilizer administration during colonoscopy.

**Timepoint**

during colonoscopy

**Method of measurement**

milliliter

### 3

#### Description

Duration of Culmonoscopy

#### Timepoint

during colonoscopy

#### Method of measurement

minute

## Intervention groups

### 1

#### Description

Patients in the intervention group received a colonoscopy educational booklet and watched a video clip about colonoscopy procedures.

#### Category

Other

### 2

#### Description

Patients in the control group only received colonoscopy educational booklet.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

qhaem hospital mashhad university of medical science

##### Full name of responsible person

nooshin dayani

##### Street address

informatic group, medical faculty, mashhad university of medical science, park square, mashhad

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

##### Phone

+98 51 3845 4344

##### Email

dayanin1@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

mashhad university of medical science

##### Full name of responsible person

dr. tafaghodi

##### Street address

mashhad university of medical science, ghorishi building, daneshgah st. masshad

##### City

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##### Postal code

ghorshi bulging, da

##### Phone

+98 51 3841 2081

##### Fax

+98 51 3843 0249

##### Email

vcresearch@mums.ac.ir

##### Web page address

<http://v-research.mums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

mashhad university of medical science

#### 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

Mashhad University of Medical Sciences

##### Full name of responsible person

nooshin dayani

##### Position

student

##### Latest degree

Bachelor

##### Other areas of specialty/work

mathematics science

##### Street address

Department of Medical Informatics, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad

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##### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Hasibian

**Position**

educational academic staff

**Latest degree**

Master

**Other areas of specialty/work**

Computer Engineering (Artificial Intelligence)

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## Person responsible for updating data

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**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

nooshin dayani

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

mathematic

**Street address**

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**Fax****Email**

dayanin1@mums.ac.ir

## 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