

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. 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 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

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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

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Fax

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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

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

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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

Contact

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Full name of responsible person

nooshin dayani

Position

student

Latest degree

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Other areas of specialty/work

mathematic

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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