

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the Effect of Reinforced Education on the Satisfaction of the Patients Undergoing Colonoscopy

Protocol summary

Study aim

Evaluation of the Effect of Reinforced Education on the Satisfaction of the Patients Undergoing Colonoscopy

Design

The study was a clinical trial with a control group, with parallel groups, Single blind with the participation of 84 colonoscopy candidates. Randomization was done using white and black colored cards

Settings and conduct

Candidate colonoscopy patients referred to Ayatollah Taleghani Medical Training Center in Tehran, if eligible, were included in the study and were randomly assigned to intervention and control groups using colored cards. This study was conducted in a Single blind manner. The researcher A taught the patients and the questionnaires were completed by researcher B, who was unaware of the allocation of groups. Also, the data analyst did not know the type of intervention.

Participants/Inclusion and exclusion criteria

Candidates for colonoscopy who had access to virtual space and educational videos and had no movement, hearing and vision disorders and had no medical history of suffering from cognitive diseases and depression and taking neuropsychiatric drugs participated in the study.

Intervention groups

In the intervention group, Reinforced Education was given using media along with pamphlets. In this way, the day before the colonoscopy, the patients were contacted and educational files about bowel preparation, including clips, software, and Instagram pages, were sent to them through Whats App, and their questions were answered. The usual education in control group was using a education pamphlet sheet.

Main outcome variables

Satisfaction, anxiety and bowl preparation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210131050189N5**

Registration date: **2023-04-06, 1402/01/17**

Registration timing: **retrospective**

Last update: **2023-04-06, 1402/01/17**

Update count: **0**

Registration date

2023-04-06, 1402/01/17

Registrant information

Name

Raziyeh Ghafouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3335 4520

Email address

ghafouri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

2022-05-22, 1401/03/01

Actual recruitment end date

2022-08-21, 1401/05/30

Trial completion date

2022-09-21, 1401/06/30

Scientific title

Evaluation of the Effect of Reinforced Education on the Satisfaction of the Patients Undergoing Colonoscopy

Public title

Evaluation of the effect of reinforced education on colonoscopy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

be a colonoscopy candidate access to cyberspace and educational videos

Exclusion criteria:

Having movement disability, hearing and vision disorders
Having a medical history of suffering from cognitive diseases and depression Taking neuroleptics

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Before the intervention, 40 white cards and 40 black cards were prepared. All the cards were placed in an envelope, then the cards were taken out randomly and numbered from 1 to 80 in order of removal. Then each card was placed in a sealed envelope and its number was written on the envelope. As each patient entered the study, a special envelope from number 1 to 80 was opened for him. If the card was white, the participant was assigned to the intervention group, and if the card was black, the participant was assigned to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The training was given by Researcher A and the results were evaluated by Researcher B, who was unaware of the allocation of groups. Also, the data analyst will not know the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahid Beheshti University of Medical Sciences

Street address

Shahid Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

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Postal code

1985717443

Approval date

2022-02-27, 1400/12/08

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.1082

Health conditions studied

1

Description of health condition studied

Suspected neoplasm of colon who were candidates for colonoscopy

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

2

Description of health condition studied

Suspected Irritable bowel syndrome who were candidates for colonoscopy

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

3

Description of health condition studied

Crohn's disease

ICD-10 code

K50.1

ICD-10 code description

Crohn's disease of large intestine

Primary outcomes

1

Description

Patient satisfaction

Timepoint

48 hours after colonoscopy

Method of measurement

researcher made tool for satisfaction

2

Description

health anxiety

Timepoint

before and after education

Method of measurement

health anxiety inventory

3

Description

bowel preparation

Timepoint

an colonoscopy

Method of measurement

The Boston Bowel Preparation Scale (BBPS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: On the day of going to the clinic, pamphlets were given to the participants regarding the use of laxatives for bowel preparation. In the reinforced education, on the day before the colonoscopy, the time to use laxatives and adherence to a fiber-free diet were emphasized in a phone call, and reminder messages were sent to them. Also, through Instagram and WhatsApp, educational files about bowel preparation, including clips and software, were sent to them and their questions were answered.

Category

Early detection

2

Description

Control group: On the day of going to the clinic, pamphlets were given to the participants regarding the use of laxatives for bowel preparation,

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

(Ayatollah) Taleghani Educational Hospital

Full name of responsible person

Raziyeh Ghafouri

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Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zergi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Raziyeh Ghafouri

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

SBMU School of Nursing & Midwifery, Vali-Asr Avenue,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

By email to the corresponding author

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

More research

From where data/document is obtainable

By email to the corresponding author

What processes are involved for a request to access data/document

By email to the corresponding author

Comments