

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Investigating the effect of using a mobile application on preparation and anxiety before colonoscopy

Protocol summary

Study aim

Investigating the effect of using a mobile app on preparation and anxiety before colonoscopy

Design

The study will be conducted as a clinical trial with a control group, with parallel groups, one side blind, with the participation of 80 colonoscopy candidate patients. Randomization will be done using white and black colored cards

Settings and conduct

Candidate colonoscopy patients referred to Ayatollah Taleghani Medical Training Center in Tehran, if eligible, will be included in the study and will be randomly assigned to intervention and control groups using colored cards. This study will be performed in a blind way. Researcher A teaches the patients and the questionnaires are completed by Researcher B, who will be 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 have a smartphone and the ability to use it and who have no medical history of suffering from cognitive diseases and depression and taking neuropsychiatric drugs will be included in the study.

Intervention groups

In the intervention group, training will be given using the mobile app prepared about colonoscopy (reasons, how to perform, how to prepare and consume laxatives, ensuring readiness) and in the regular group, training will be done with a bowel preparation pamphlet.

Main outcome variables

Bowl Preparation, Colonoscopy anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210131050189N6**

Registration date: **2023-11-01, 1402/08/10**

Registration timing: **prospective**

Last update: **2023-11-01, 1402/08/10**

Update count: **0**

Registration date

2023-11-01, 1402/08/10

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

2023-11-02, 1402/08/11

Expected recruitment end date

2024-01-31, 1402/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using a mobile application on preparation and anxiety before colonoscopy

Public title

Use of mobile application on preparation and anxiety

before colonoscopy

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
be a colonoscopy candidate Having a smart phone
Exclusion criteria:
Inability to use a smartphone Having a medical history of suffering from cognitive diseases and depression or taking neuroleptics

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Before starting the research, 40 white color cards and 40 black cards will be prepared. All the cards will be placed in an envelope, then the cards will be taken out randomly and numbered from 1 to 80 in order of exit. Each card will then be placed in a sealed envelope and its number will be written on the envelope. As each patient enters the study, a special envelope from number 1 to 80 will be opened for him. If the card is white, the participant will be assigned to the intervention group, and if the card is black, the participant will be assigned to the control group.

Blinding (investigator's opinion)
Single blinded

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

Placebo
Not used

Assignment
Other

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
Tehran
Postal code
1985717443
Approval date
2023-10-09, 1402/07/17
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1402.109

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 neoplasm of colon 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
ICD-10 code description
Crohn's disease [regional enteritis]

Primary outcomes

1

Description
Bowl Preparation
Timepoint
an colonoscopy
Method of measurement
The Boston Bowel Preparation Scale (BBPS)

2

Description
Colonoscopy Anxiety
Timepoint

After Colonoscopy
Method of measurement
Colonoscopy anxiety tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: On the day of going to the clinic and making an appointment for colonoscopy, the mobile application is provided, and after installation, training was given and followed up with it. The program contains information related to the causes of colonoscopy, preparation for colonoscopy, evaluation of the patient's readiness, and evaluation of the patient's medications and underlying diseases.

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

Street address

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Raziyeh Ghafouri

Position

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Latest degree

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