

# 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

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

##### Phone

+98 21 2303 1100

##### Email

taleghani@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Afshin Zergi

#### Street address

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

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#### Phone

+98 21 2243 9770

#### Email

Intl\_office@sbmu.ac.ir

#### 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, Cross of Vali-Asr Avenue and Hashemi Rafsanjani (Neiaiesh) Highway, Tehran.

##### City

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##### Province

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##### Postal code

1996835119

##### Phone

+98 21 8820 2520

##### Email

raziehghafouri@gmail.com

## Person responsible for scientific 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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## 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**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

SBMU School of Nursing & Midwifery, Vali-Asr Avenue,