

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Investigating the effect of using mobile app of colon cancer on early detection of colorectal cancer

Protocol summary

Study aim

Determining the effect of using colon cancer mobile application on early detection of colorectal cancer

Design

The study will be conducted as a clinical trial with a control group, with parallel groups, one-sided blind with the participation of 200 volunteers. Randomization will be done using the Study Randomizer software. [Software Application]. (2017) Available at: <https://www.studyrandomizer.com>

Settings and conduct

This study will be conducted in the patients of Taleghani hospital in Tehran. Clients are divided into two groups according to the inclusion criteria using colored cards. The intervention group will be provided with the necessary training on colon cancer prevention and diagnosis with software, and the control group will be taught face-to-face and pamphlets. Then, two groups will be evaluated in terms of early detection of colorectal cancer symptoms. This study will be performed in single blind. In this way, researcher A will do the evaluation and the emergence of disease symptoms will be done by researcher B, who will be unaware of the allocation of groups. Also, the data analyst will not know about the grouping of the participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having a smart phone and the ability to read and write Exclusion criteria: not wanting to install the app on your mobile phone

Intervention groups

The intervention group includes people who receive the training intervention to improve self-care ability in preventing and contracting colon cancer using the colon cancer mobile app, and the control group includes people who receive training to improve self-care ability in prevention. and get colon cancer through face-to-face education and pamphlets.

Main outcome variables

Early detection of colorectal cancer symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210131050189N9**

Registration date: **2024-02-13, 1402/11/24**

Registration timing: **prospective**

Last update: **2024-02-13, 1402/11/24**

Update count: **0**

Registration date

2024-02-13, 1402/11/24

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

2024-02-19, 1402/11/30

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using mobile app of colon cancer on early detection of colorectal cancer

Public title

Evaluation of colon cancer mobile application on early detection of colorectal cancer

Purpose

Screening

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a smart phone Ability to read and write

Exclusion criteria:

Reluctance to use mobile application

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done with using study randomizer software. Study Randomizer [Software Application]. (2017) Available at: <https://www.studyrandomizer.com> After registering in the software, first the study details including the number of study groups, the number of participants are registered in the software. In the next step, a code will be assigned to each participant in the order of entering the research along with random assignment to the intervention and control group by the software. In the software, the sequence of allocation of participants is recorded. In the present study, the time of entry of each participant using this software will be used to allocate to the intervention or control group and the process will continue until the end of sampling.

Blinding (investigator's opinion)

Single blinded

Blinding description

Colorectal cancer self-care training in two groups of control (usual training) and intervention (training with software) is done by researcher A, and the evaluation of the incidence of colorectal cancer symptoms is checked by researcher B. 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

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**

colorectal cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

2**Description of health condition studied**

colorectal cancer

ICD-10 code

C19

ICD-10 code description

Malignant neoplasm of rectosigmoid junction

3**Description of health condition studied**

colorectal cancer

ICD-10 code

D01.1

ICD-10 code description

Carcinoma in situ of rectosigmoid junction

Primary outcomes**1****Description**

Early detection of colorectal cancer symptoms

Timepoint

One month after using the program

Method of measurement

Occurrence of symptoms of abdominal pain during defecation, chronic bleeding from the anus, feeling of

mass in the anus, having a history of inflammatory bowel diseases, having a history of polyps and colon cancer in first degree relatives

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, using the colon cancer software prepared, they are taught about the colon, colon cancer, stages of cancer, its early symptoms, risk factors, and ways to reduce the risk of infection and screening. They are promoted in identifying early symptoms and taking care of themselves in the prevention of colorectal cancer. Also, there are two self-assessment programs in the software that users can use to assess their risk of developing colorectal cancer and give feedback based on each person's condition.

Category

Early detection

2

Description

In the control group, about colorectal cancer, the stages of colorectal cancer, its early symptoms, risk factors and ways to reduce the risk and screening are taught face-to-face and using pamphlets.

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 Zergj

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
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Other areas of specialty/work
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Person responsible for updating data

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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

The data of the current research can be shared after de-identifying the participants.

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

Academic researchers can use the results of the current research for retrospective research, provided they have the approval of the National Ethics Committee of Iran in the research and mention the source of the research.

From where data/document is obtainable

By email to the corresponding author
raziehghafouri@gmail.com

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

By email to the corresponding author
raziehghafouri@gmail.com

Comments