

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effectiveness of educational intervention base on Preventive Health Model for performing colorectal cancer screening in 30-50 years old population referred to health center of Karoon city in 2018

Protocol summary

Study aim

The Effectiveness of educational intervention base on Preventive Health Model for performing colorectal cancer screening in 30-50 years old population referred to health center of Karoon city in 2018

Design

Clinical trial with one intervention group and one control group, parallel groups and randomized.

Settings and conduct

The present study is a randomized controlled trial on two groups of test and control in 2018. The research population consists of 30-50 year old men and women referring to comprehensive health care centers of Karoun County. The data collection tool is a three-part questionnaire. Educational intervention involves installing the app and distributing pamphlets. Two months after completing the pre-test and intervention questionnaire, two groups will be contacted and invited to complete the questionnaire. After completing the questionnaires by both groups, the data will be entered into the SPSS 23 software and the data will be analyzed .

Participants/Inclusion and exclusion criteria

age 30 to 50, Inclination to participate in research, Diploma and higher education ,The absence of a person or primary relatives with colorectal cancer ,No history of colorectal screening ,People without any clinical symptoms, Having informed consent. Non arrival: Not having Android mobile phone to install educational content Having physical limitation

Intervention groups

There will be no training and intervention for the control group. Educational content provided to the intervention group includes an app that is designed based on preventive health model, and an educational pamphlet on colorectal cancer, the importance of screening and a variety of colorectal cancer screening methods.

Main outcome variables

Perceived self-efficacy; Perceived sensitivity; Worries and fears; Screening efficiency; social support; Behavioral intention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180909040980N1**

Registration date: **2019-02-04, 1397/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-04, 1397/11/15**

Update count: **0**

Registration date

2019-02-04, 1397/11/15

Registrant information

Name

Fatemeh Fayazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3553 1822

Email address

fatemeh.fayazi200@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-16, 1397/06/25

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of educational intervention base on Preventive Health Model for performing colorectal cancer screening in 30-50 years old population referred to health center of Karoon city in 2018

Public title

The effectiveness of educational intervention for performing colorectal cancer screening

Purpose

Screening

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 30 to 50 years Inclination to participate in research Diploma and higher education The absence of a person or primary relatives with colorectal cancer No history of colorectal screening People without any clinical symptoms (asymptomatic) Having informed consent

Exclusion criteria:

Not having Android mobile phone to install educational content Having physical limitation

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **160****Randomization (investigator's opinion)**

Randomized

Randomization description

Samples were randomly selected from 2 centers by block sampling method and samples of both groups will be matched based on demographic variables such as age, education, and so on. Random assignment of selected individuals will be done by block random method using quad blocks. For two groups of intervention and comparison use two letters A and B. So the size of each block is twice the number of groups, that is, the number 4. By dividing the sample size by block size, the number of blocks is determined. Sample size is 160 people. Each group consists of 80 people, and the number of blocks in each group is 20 blocks, each of which specifies the assignment of 4 individuals. Finally, all letters A and B are separated, and each person who is not the researcher, by lot, will be suspended by each letter in a group. For example, A intervention group and B control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Committee of University of Medical Sciences of Jundishapur of Ahwaz

Street address

Ahwaz.Golestan.after Golestan Hospital, Jundishapur University of Ahwaz

City

Ahwaz

Province

Khouzestan

Postal code

15794- 61357

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.AJUMS.REC.1397.319

Health conditions studied**1****Description of health condition studied**

Colorectal cancer

ICD-10 code

C19

ICD-10 code description

Malignant neoplasm of rectosigmoid junction

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

Perceived self-efficacy

Timepoint

2 months after the beginning of the study

Method of measurement

Colorectal screening questionnaire

2**Description**

Perceived sensitivity

Timepoint

2 months after the beginning of the study

Method of measurement

Colorectal screening questionnaire

3

Description

Worries and fears

Timepoint

2 months after the beginning of the study

Method of measurement

Colorectal screening questionnaire

4

Description

Screening Effectiveness

Timepoint

2 months after the beginning of the study

Method of measurement

Colorectal screening questionnaire

5

Description

Social support

Timepoint

2 months after the beginning of the study

Method of measurement

Colorectal screening questionnaire

6

Description

Behavioral intention

Timepoint

2 months after the beginning of the study

Method of measurement

Colorectal screening questionnaire

Secondary outcomes

1

Description

Screening behavior

Timepoint

2 months after the beginning of the study

Method of measurement

Colorectal screening questionnaire

Intervention groups

1

Description

One group in the study will receive educational intervention. Educational content provided to the intervention group includes an app that is designed based on preventive health model, and an educational pamphlet about colorectal cancer, the importance of screening and a variety of colorectal cancer screening methods.

Category

N/A

2

Description

Control group: One group as a control group will enter the study, that will not receive any training and intervention.

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Health center of Karoon City

Full name of responsible person

Fatemeh Fayazi

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No9. Baharan 5 Ave, Padad Shahr, Ahvaz

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology Development of Jondishapour of Ahwaz

Street address

Jundishapur University of Medical Sciences and Health Services, Academic town, Golestan, Ahvaz

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research@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Fatemeh Fayazi
Position
Employee
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable