

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Effect of Theory-Based Education on promoting Colorectal Cancer Screening Behavior in People 69-50Years Old

Protocol summary

Study aim

The Effect of Theory-Based Education on promoting Colorectal Cancer Screening Behavior in People 69-50Years Old

Design

Randomized controlled trial with 2 parallel groups in 2 comprehensive urban health service centers, for 2 intervention and control groups by block randomization with a sample size of 80 people (40 people for each group)

Settings and conduct

This study is conducted in Aligoudarz, first the pre-test questionnaire is completed by the participants and after analyzing the information, the educational needs of the intervention group based on the health belief model are performed in person. 1 month and 3 months after the intervention, the questionnaires are completed again and the individual's information before and after the intervention is analyzed with SPSS software. Blinding is not done

Participants/Inclusion and exclusion criteria

Age 50 to 69 years Iranian nationality residence in Aligoudarz No history of colon cancer Literacy for reading and writing Physical ability Having mental health Having decision-making power Access to cyberspace

Intervention groups

In this interventional study, 80 people aged 50 to 69 years in two intervention and control groups are evaluated. Both groups receive routine training related to colon cancer, but in the intervention group, training is done in person based on the Health Belief Model and Needs Assessment. Awareness, health belief model constructs, behavior and behavioral intention will be compared in 2 groups before the intervention, 1 month and 3 months after the intervention.

Main outcome variables

awareness, sensitivity, severity, perceived benefits and barriers, practice guides, self-efficacy and behavioral intent and behavior regarding colorectal cancer

screening behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220216054041N1**

Registration date: **2022-07-19, 1401/04/28**

Registration timing: **retrospective**

Last update: **2022-07-19, 1401/04/28**

Update count: **0**

Registration date

2022-07-19, 1401/04/28

Registrant information

Name

Ferdous Ghyasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4332 2212

Email address

ghyasiferdos21@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Theory-Based Education on promoting Colorectal Cancer Screening Behavior in People 69-50Years Old

Public title

The Effect of Theory-Based Education on promoting Colorectal Cancer Screening Behavior in People 69-50Years Old

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 50 to 69 years Iranian nationality residence in Aligoudarz No history of colon cancer Literacy for reading and writing Physical ability Having mental health Having decision-making power Access to cyberspace

Exclusion criteria:

Reluctance to cooperate Distorted and incomplete questionnaire Failure to attend more than 20% of training classes Immigrating to another city

Age

From **50 years** old to **69 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Random Method will be used to assign eligible people to two groups. The size of the blocks is 4 and 6. Randomization will be done individually. In the Block Method, due to the use of different combinations in each block, it is not possible to predict the randomization sequence, so the concealment process will also be observed. For the guaranteed encryption process, the randomization files are generated in Excel and will remain close to the epidemiologist's colleague, then the Epidemiologist will be contacted to allocate the eligible people to two groups, the sick person, and to position each person in the groups, will be decided according to the randomization sequence. The online program available on the Sealed Envelope website will be used to generate the block randomization sequence.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, in addition to the constructs of the health belief model, behavioral intent and screening behavior are also investigated

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Shahid Shiroodi St,Alam al-Huda St

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2021-12-05, 1400/09/14

Ethics committee reference number

IR.ARAKMU.REC.1400.265

Health conditions studied

1

Description of health condition studied

Behavioral intention and behavior of colorectal cancer screening in people aged 50 to 69 years

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

awareness

Timepoint

Before intervention and 1 month after educational intervention

Method of measurement

questionnaire

2

Description

colorectal cancer screening behavior

Timepoint

Before intervention and 1 and 3 month after educational intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

sensitivity

Timepoint

Before intervention and 1 month after educational intervention

Method of measurement

questionnaire

2

Description

severity

Timepoint

Before intervention and 1 month after educational intervention

Method of measurement

questionnaire

3

Description

perceived benefits

Timepoint

Before intervention and 1 month after educational intervention

Method of measurement

questionnaire

4

Description

perceived barriers

Timepoint

Before intervention and 1 month after educational intervention

Method of measurement

questionnaire

5

Description

causes to action

Timepoint

Before intervention and 1 month after educational intervention

Method of measurement

questionnaire

6

Description

self-efficacy

Timepoint

Before intervention and 1 month after educational intervention

Method of measurement

questionnaire

7

Description

behavioral intent

Timepoint

Before intervention and 1 month after educational

intervention

Method of measurement

questionnaire

Intervention groups

1

Description

In the intervention group, the educational intervention was based on the model of health belief and needs assessment, which was done before the training and using valid books and educational booklets and the latest instructions issued by the Ministry of Health and appropriate to the level of literacy of learners and based on adult education. Health belief model structures will be prepared, developed and implemented.

Category

Behavior

2

Description

Control group: The control group will receive routine training from health centers.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers No3

Full name of responsible person

Dr.mahboobeh khorsandi

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Recruitment center

Name of recruitment center

Health centers No3

Full name of responsible person

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Sponsors / Funding sources

1

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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
Arak 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
Arak University of Medical Sciences
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Professor, School of Health, Arak University of Medical Sciences
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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

No - There is not a plan to make this available

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

No - There is not a plan to make this available