

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Implementation and evaluation of an intervention program based on social marketing theory on participation in colorectal cancer screening

Protocol summary

Study aim

Determining the effect of colorectal cancer screening program based on social marketing theory on participation in colorectal cancer screening and individuals' health beliefs

Design

A clinical trial with control group, parallel group randomized trial, a single blinded

Settings and conduct

Setting: Comprehensive Health Centers of Yasouj University of Medical Sciences, Data collector and statistician are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Persons over 50 years old age (persons at average risk): Willingness to participate in the study ; Residence in Yasuj city Exclusion criteria include: Self-report of a positive history of colorectal cancer or polyps; Participation in previous training programs related to colorectal cancer screening; Persons over 70 years old age

Intervention groups

. Intervention group: The intervention program includes a set of communicational, executive proceedings, educational and informational programs and Transfer effective messages, is carried out for one month. Three months and 6 months after the intervention, the level of participation in fecal immunochemistry is assessed and compared with the control group. Also, before the interventions and 3 months and 6 months after the interventions, the mean score of health beliefs about colorectal cancer screening is determined and compared between the two groups. Control group: In this group, any of the interventions of the intervention group is presented. If participation in this group recourse for a Fecal Immunochemistry test, the test will be done for them.

Main outcome variables

Colorectal Cancer Screening Health Beliefs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131117015426N8**

Registration date: **2021-12-17, 1400/09/26**

Registration timing: **prospective**

Last update: **2021-12-17, 1400/09/26**

Update count: **0**

Registration date

2021-12-17, 1400/09/26

Registrant information

Name

Maryam Hazrati

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 3949

Email address

hazratim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-06-04, 1401/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Implementation and evaluation of an intervention program based on social marketing theory on participation in colorectal cancer screening

Public title

The effect of interventions on participation in colorectal cancer screening

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

Persons over 50 years old age (persons at average risk)
Willingness to participate in the study
Residence in Yasuj city

Exclusion criteria:

Self-report of a positive history of colorectal cancer or polyps
Participation in previous training programs related to colorectal cancer screening
Persons over 70 years old age

Age

From **50 years** old to **70 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

Firstly, 200 samples with having inclusion criteria will be selected using a table of random numbers. Then, a random allocation software will be used to create 50 blocks with a block size of four. In order to create a list of block randomization, refer to following website is done: <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. Then, based on this generated list (BABA, ABBA, BAAB, BABA, AABB, ...), the subjects will be allocated into the intervention (B) or control (A) groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to perform blinding, assistant researcher who collects data before and after the intervention, as well as statistician who analyzes the data, are blinded to the groups and the assignment of individuals in the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shiraz University of Medical Sciences

Street address

Vice chancellor for research affairs, seven floor, Shiraz University of Medical Science, beside Helal Ahmar, Zand Ave, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Approval date

2021-04-05, 1400/01/16

Ethics committee reference number

IR.SUMS.REC.1400.003

Health conditions studied

1

Description of health condition studied

Colon Cancer

ICD-10 code

C18.9

ICD-10 code description

Malignant neoplasm of colon, unspecified

2

Description of health condition studied

Rectom Cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes

1

Description

Colorectal Cancer Screening

Timepoint

Before, 3 and 6 months after the intervention

Method of measurement

Participation rate in Fecal Immunochemistry Test

2

Description

Health Beliefs

Timepoint

3 and 6 months after the intervention

Method of measurement

Champion's Health Belief Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, an intervention program is designed focusing on the components of the social Marketing Mix or 4P (product, price, place, promotion). This intervention program includes a set of communication, executive proceedings, educational and informational programs and Transfer effective messages through the preferred communication channels mentioned by the participants to reduce or eliminate barriers and create facilitators to perform the desired behavior, which is participation in fecal immunochemistry, is carried out for one month. To evaluate the effectiveness of the intervention program, three months and 6 months after the intervention, the level of participation in fecal immunochemistry is assessed and compared with the control group. Also, before the interventions and 3 months and 6 months after the interventions, refer to the experimental and control groups again and the champion questionnaire is completed and the mean score of health beliefs about colorectal cancer screening is determined and compared between the two groups.

Category

Prevention

2

Description

Control group: In this group, any of the interventions of the intervention group is presented. If participation in this group recourse for a Fecal Immunochemistry test, the test will be done for them. At the end of the research, in order to comply with ethical issues, all the designed training materials will be provided to the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers affiliated to Yasuj University of Medical Sciences

Full name of responsible person

Maryam Hazrati

Street address

Nursing and Midwifery College, Namazee Sq, Zand Ave, Shiraz

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7193613119

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Email

hazratishirazy@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaieanzadeh

Street address

Vice chancellor for research affairs of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

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71348-14336

Phone

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Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Hazrati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

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Associate professor

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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

Primary outcomes would be shared.

When the data will become available and for how long

Starting 6 months after publication article

To whom data/document is available

People and researchers working in academic institutions

Under which criteria data/document could be used

Data are provided for information only.

From where data/document is obtainable

Data is available via email hazratishirazy@gmail.com

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

Data is available via email hazratishirazy@gmail.com

Comments