Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
۱۴۳۳۶ - 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

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4258

Fax

+98 71 3647 4258

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

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3235 7282

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
Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71 3647 4258
Email
hazratishirazy@gmail.com

Person responsible for scientific 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
Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71 3647 4258
Email
hazratishirazy@gmail.com

Person responsible for updating data

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
Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71 3647 4258
Email
hazratishirazy@gmail.com

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