Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of a community-based participatory intervention on colorectal cancer health literacy in Middle-Aged Population

Protocol summary

Study aim

Determining the impact of a community-based participatory intervention on colorectal cancer health literacy by determining: 1)health care dimension 2)disease prevention and 3) health promotion dimension of colorectal cancer health literacy in the middle-aged.

Design

This research will have a control group using a simple randomization method and a community-based study that examines 60 middle-aged people between the ages of 40 and 59.

Settings and conduct

This study will examine the people covered by a Health Service Center (located inMashhad). The research environment in this study will include Shahed Comprehensive Health Service Center, Ghadir Baba Ali Cultural Complex and mosque (5) and Isar Park.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent to conduct the study, living in the studied area for at least 5 years, reading and writing literacy, not suffering from colorectal cancer at the moment, age 40 to 59 years, not suffering from a known acute physical or mental illness. have a health record in health centers and the criteria for non-entry include: history of colorectal cancer in the person or first-degree relatives, occupation related to the field of health.

Intervention groups

Survey of the participants, Organizing group meetings with people, health center personnel to determine educational programs, Designing telephone counseling programs for each participant specifically, Holding five group training sessions as a workshop For 45 minutes in Cultural center, health center or neighborhood mosque, distribution of educational materials, telephone follow-up and referral of participants to perform screening tests to health centers. The control group will not receive any intervention.

Main outcome variables

Determining the impact of community-based intervention programs on people's health literacy about colorectal cancer and how to diagnose and prevent it.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230310057666N1**
Registration date: **2023-03-14, 1401/12/23**
Registration timing: **prospective**

Last update: **2023-03-14, 1401/12/23**
Update count: **0**

Registration date

2023-03-14, 1401/12/23

Registrant information

Name

Hesam Dolatabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3859 1511

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of a community-based participatory intervention on colorectal cancer health literacy in Middle-Aged Population

Public title
The effect of a community-based participatory intervention on colorectal cancer health literacy in Middle-Aged Population
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to study Living in the area under investigation for at least 5 years Literacy for reading and writing No current colorectal cancer Age 40 to 59 years Not suffering from known acute physical and mental illness Having health records in health centers
Exclusion criteria:
History of colorectal cancer in first degree relatives Having information and awareness of different methods related to colorectal cancer Health workers
Age
From **40 years** old to **59 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a simple and individual randomization method is used, at first we will have access to people by using the electronic file of people in the comprehensive middle-aged program of the health center, then according to the criteria of entry and non-entry, people will be called and after completing Questionnaires will be assigned to intervention and control groups by simple and individual randomization method using statistical software. The method of using Sequentially numbered, sealed, opaque envelopes (SNOSE) is also used for concealment. For this, a statistical consultant will be used so that the project implementers are not involved in this issue.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this case, the people participating in the study who are assigned to the intervention or control group are kept blind. Also, due to the use of a statistical consultant and information analyst, this person is kept blind from the way the study is conducted on people and the results of the questionnaires.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences
Street address
Faculty of Nursing and Midwifery, Doctora's Crossroad, Ibn Sina Street, Daneshgah street, Mashhad, Khorasan Razavi
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2023-03-04, 1401/12/13
Ethics committee reference number
IR.MUMS.NURSE.REC.1401.104

Health conditions studied

1

Description of health condition studied
Colorectal cancer health literacy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Colorectal cancer health literacy
Timepoint
before the start of the intervention, immediately after the intervention and one month after the intervention
Method of measurement
It will be controlled based on the European Health Literacy Questionnaire HLS-EU.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The components of the intervention program include; Survey of the participants - Organizing group meetings with the participation of ordinary people, health center personnel and health liaisons to determine educational and support programs - Designing individual and telephone counseling programs for each participant specifically - Holding five group training sessions as a workshop for 45 minutes in cultural center, health center or neighborhood mosque - preparation and distribution of educational materials and pamphlets - face-to-face follow-up through home visits by health liaisons and friendly meetings and asking about the condition and telephone follow-up and referral of participants to take the test Screening will be to health centers. The intervention has a triangulation mode and its three sides include; a) health centers b) mosques, cultural centers and c) members of the research team,

Category
Prevention

2

Description
Control group: They will not receive any intervention and only at the end of the study, in order to comply with the ethical standards, educational materials will be provided to them in the form of pamphlets.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahed Mashhad City Comprehensive Health Service Center

Full name of responsible person
Hamidreza zendehtalab

Street address
Razavi Khorasan Province, Mashhad, Payambar Azam Highway, Ansar 8, Ansar 8/1

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hesamdolat.hd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Majid Ghayour mobarhan

Street address
Khorasan Razavi, Mashhad, Daneshgah St., next to Hoizeh Cinema, University of Medical Sciences, 3rd Floor, Research and Technology Vice-Chancellor

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GhayourM@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Hamidreza zendetalab

Position
Assistant Professor of Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Ibn Sina St., Doktra crossroad, Daneshgah St., Mashhad, Razavi Khorasan

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Assistant Professor of Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

Latest degree
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Nursery

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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
Hesam Dolatabadi

Position
Postgraduate student

Latest degree
Master

Other areas of specialty/work
Nursery

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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
All data can be shared.

When the data will become available and for how long
The access time will be six months after the official publication of the results.

To whom data/document is available
The data will be available to researchers.

Under which criteria data/document could be used
In case of request to perform any action on the data, contact the following email. hesamdolat.hd@gmail.com

From where data/document is obtainable
In case of request to perform any action on the data, contact the following email. hesamdolat.hd@gmail.com

What processes are involved for a request to access data/document
The request will be answered after it is submitted to the Research Ethics Committee and the Research and Technology Committee of the Faculty of Nursing of Mashhad University of Medical Sciences.

Comments