

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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****Name of organization / entity**

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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

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Hesam Dolatabadi

Position

Postgraduate student

Latest degree

Master

Other areas of specialty/work

Nursery

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Fax**Email**

dolatabadihm992@mums.ac.ir

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