

# Testing the effectiveness of a new screening system for colorectal cancer screening: a community trial

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<b>Registration date</b> 19/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/11/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Colorectal cancer incidence is the third, globally, after lung and breast cancer; unfortunately, there is rising incidence, especially among young age groups in Saudi Arabia in the last 18 years due to changes in diet that mimic western countries. On the other hand, there is a great gap in the screening service that matches the current context in Saudi Arabia; this is reflected by the lack of a well-structured screening service that encourages participation and adherence. Low awareness about the importance of screening, fear of cancer, and the absence of a clear vision on how to implement and provide the service are the main obstacles for a successful screening program. This study aims to test the effectiveness of a new system for colorectal cancer screening composed of an integrated network of professionals. This system is expected to facilitate participation by providing psychological support, health education and testing at the health facility level and outreach using community mobilization, health education campaigns, and media.

### Who can participate?

Individuals of both genders, aged 40 and over, who are at risk of colorectal cancer attending the selected hospitals (King Fahad and King Khalid Hospitals in Tabuk) in addition to 18 public health centers

### What does the study involve?

Participating facilities are randomly allocated to either the intervention or the control group. The control group receive routine care. The intervention is an integrated system composed of a psychologist, an endoscopy physician, a family physician, and audiovisuals in the waiting area; in addition to text messages of information, education and communication (IEC) delivered to the participants at the hospital center, outreach, and education campaigns in order to mobilize the individuals going for screening. Trained health staff provide counseling and education; likewise, well-designed IEC materials and videos are displayed on the waiting area screen, as well as social media and short text messages. Participants attend two counseling and educational sessions: an

initial session with a psychologist to educate participants on the importance of the screening and to discuss the screening methods; illiterate participants are given pictorial IEC messages. Experts in IEC prepare and pilot all materials.

What are the possible benefits and risks of participating?

Participants receive a free integrated screening service (counseling, education, and testing for colorectal cancer). No harms or risks are expected.

Where is the study run from?

University of Tabuk (Saudi Arabia)

When is the study starting and how long is it expected to run for?

June 2019 to September 2022

Who is funding the study?

1. Ministry of Education (Saudi Arabia)
2. University of Tabuk (Saudi Arabia)
3. Ain Alhayt Medical Center, Tabuk (Saudi Arabia)

Who is the main contact?

Dr Fakhralddin Elfakki

f-elfakki@ut.edu.sa

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Fakhralddin Elfakki

**Contact details**

Tabuk University

Doba Street

PO Box 741

Tabuk

Saudi Arabia

71491

+966 (0)535817539

f-elfakki@ut.edu.sa

## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

Nil known

## Study information

## **Scientific Title**

Effectiveness of a new integrated colorectal cancer screening system in Saudi Arabia: a randomized clustered trial

## **Study objectives**

Hypothesis 2: H0: There is no difference in the detection rate between the intervention groups that use ICRCSS and the control group that use routine care.

Hypothesis 1: H0: The application of an ICRCSS at the public hospital centers has no effect on supporting, educating, and mobilizing people with average risk participating colorectal cancer screening.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 24/09/2019, University of Tabuk Ethics Research Committee (Doba Street, PO Box 741, Tabuk, 71491, Saudi Arabia; +966509363929; irb-tabuk@moh.gov.sa), ref: TU-077/019/012

## **Study design**

Clustered double-blinded randomized trial

## **Primary study design**

Interventional

## **Study type(s)**

Screening

## **Health condition(s) or problem(s) studied**

Colorectal cancer

## **Interventions**

Randomization:

Participants will be randomly allocated to either the intervention or the control group. The study will cover the big two public hospitals (King Fahad and Ain Alhayat Hospitals) and all health centers in Tabuk city (18 health centers). Cluster-based randomization will be generated and each trial arm is composed of 10 clusters selected from a list of 18 health centers and two big hospitals. Random number generator software is used from: <https://www.random.org/>. The randomization will be held centrally by the research team and selected health centers will be identified prior to the starting date of the trial. Selected centers will be maintained throughout the trial and no change is allowed. Contacts will be held with the selected health centers authorities to obtain permission. Half of the facilities will be the intervention sites and the other half will be the control sites with no intervention.

Intervention:

The intervention is an integrated system composed of a psychologist, an endoscopy physician, a family physician, and audiovisuals in the waiting area; in addition to text messages of information, education and communication (IEC) delivered to the participants at the hospital center, outreach, and education campaigns in order to mobilize the individuals going for screening; there are 18 public primary health care centers in the Tabuk city that will be used for both intervention and control groups. Eligible people from the Saudi Public Pension Agency

(PPA) in the Tabuk will be mobilized to participate in the study. Trained health staff will provide counseling and education; likewise, well-designed IEC materials and videos to be visualized on the waiting area screen, as well as social media and short text messages. Participants are planned to attend two counseling and educational sessions: an initial session with a psychologist to educate participants on the importance of the screening and to discuss the screening methods; illiterate participants will be given pictorial IEC messages. Experts in IEC will prepare and pilot all materials.

#### Comparators:

The comparators will be individuals with risk of colorectal cancer of both genders attending the selected hospital center at (King Fahad or Ain Alhayat private hospital plus 9 public health centers in Tabuk) receiving routine care.

#### Intervention Type

Mixed

#### Primary outcome(s)

The effectiveness of an Integrated Colo-rectal Cancer Screening System (ICRCSS) as measured by the percentage of individuals with average risk of CRC who:

1. Underwent CRC screening
  2. Enrolled for follow-up after screening
  3. Screened positive for signs of a precancerous CRC condition
- compared with individuals receiving routine care at 3 years after the start of the program.

#### Key secondary outcome(s)

The effectiveness of an Integrated Colo-rectal Cancer Screening System (ICRCSS) as measured by the percentage of individuals with a high risk of CRC who:

1. Underwent CRC screening
  2. Enrolled for follow-up after screening
  3. Screened positive for signs of a precancerous CRC condition
- compared with individuals receiving routine care at 3 years after the start of the program.

#### Completion date

01/09/2022

## Eligibility

#### Key inclusion criteria

1. Individuals of both genders at risk of colorectal cancer attending the selected hospitals (King Fahad Hospital and Ain Alhayat Medical Center in Tabuk) in addition to 18 public health centers
2. Aged 40 years and above
3. Saudi citizens and non-Saudis who are eligible to receive free public health services. Those who are not eligible to use the free public health service will be excluded
4. The participants will be interviewed at the start to collect baseline data about their risk of colorectal cancer

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Those who are not eligible to use the free public health service in the Kingdom of Saudi Arabia
2. Patients who are already diagnosed or under follow-up with colorectal cancer care

**Date of first enrolment**

01/09/2019

**Date of final enrolment**

01/12/2019

**Locations****Countries of recruitment**

Saudi Arabia

**Study participating centre****University of Tabuk**

Doba Street

PO Box 741

Tabuk

Saudi Arabia

71491

**Sponsor information****Organisation**

University of Tabuk

**ROR**

<https://ror.org/04yej8x59>

**Funder(s)**

**Funder type**

Government

**Funder Name**

Ministry of Education Saudi Arabia

**Funder Name**

University of Tabuk

**Funder Name**

Ain Alhayt Medical Center, Tabuk

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analyzed during the current study will be available upon request from Fakhralddin Abbas Elfakki (abbasfakhraddin@gmail.com). The data will be available after three months of the start of the trial.

**IPD sharing plan summary**

Available on request