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

Submission date
15/04/2019

Recruitment status
No longer recruiting

Registration date
19/04/2019

Overall study status
Completed

Last Edited
19/11/2019

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/06/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
440

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
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Sponsor information

Organisation
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Sponsor type
University/education

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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

Publication and dissemination plan
A systematic review plus three to four publications on the trial outcomes and experience will be published in a high impact journal in order to share knowledge with others who are concerned with the development of screening programs all over the globe.

Intention to publish date
01/09/2023

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