

Invitation strategies for colorectal (CRC) screening programmes - The impact of an advance notification letter

Submission date 28/01/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/02/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/12/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

An advance notification letter conveying information on colorectal cancer (CRC) risk and the intervention offered in the screening programme, may increase the likelihood of a positive response to the subsequent screening invitation, as the subject will have progressed in his degree of readiness for change. In addition, it has been shown that, in particular for less educated subjects, general practitioners (GP) advice may have a strong influence on the decision to be screened. The study aims to assess the impact on the response rate to the invitation for CRC screening, in the context of population based programs, of an advance notification letter mailed to subjects eligible for invitation. The additional cost per person examined and the additional workload for the subjects GPs will be assessed.

Who can participate?

All subjects (male and female) aged 50 to 69 targeted for CRC screening in 8 population based programmes in Italy.

What does the study involve?

During the enrolment period all subjects targeted for invitation in these screening programs were randomly allocated to three groups:

A: standard personal invitation letter, signed by the GP, to undergo CRC screening

B: advance notification letter, mailed one month before the standard invitation letter (same as in A), conveying information on CRC risk, on the screening program and on the expected benefits and potential harms of screening

C: as in B, with the addition, in the advance notification letter, of the offer of a personal encounter with the subjects GP, to discuss pros and cons of screening. The response rate across the different groups will be assessed at 6 months following the invitation letter.

What are the possible benefits and risks of participating?

People allocated to the intervention groups will have the opportunity to get additional information on the proposed screening, which may be helpful to orient their decision-making process, favoring an informed decision about participation. Available evidence suggests that no

harm can be expected when people receive additional information. Subjects allocated to the control group (A) will follow the standard procedures offered to the general population in the study areas in a routine basis. They are not expected therefore to incur any additional risk.

Where is the study run from?

The study, coordinated by the centre of Verona, will be conducted in each trial centre by the local Screening Organization Unit; the data analysis will be performed by the CPO in Turin.

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

October 2010 to October 2012.

Who is funding the study?

Italian Ministry of Health; funding administration: ASR Abruzzo

Who is the main contact?

Dr Carlo Senore

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Impact of an advance notification letter on participation in CRC screening. Is it different when using sigmoidoscopy or fecal occult blood test (FIT) screening?

Study objectives

According to the trans-theoretical model of behavioural change, the adoption of preventive behaviours represents the final step of a multi-phase decision process. In this process the subject passes through a growing degree of readiness for change before actually engaging in the proposed behaviour. An advance notification letter conveying information on colorectal

cancer risk, available preventive test, screening programme, may increase the likelihood of a positive response to the subsequent invitation letter offering the appointment for the screening test, as the subject will have progressed in his degree of readiness for change.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not required as the study involves just mailing of additional information to people who would be invited for CRC screening in the context of ongoing regional screening programmes

Study design

Randomised clinical trial

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Colorectal cancer screening

Interventions

1. Standard invitation letter
2. Advance notification letter (mailed 1 month before the personal invitation letter conveying information on CRC risk, screening programme and screening test
3. Advance notification letter (mailed 1 month before the personal invitation letter conveying information on CRC risk, screening programme and screening test, signed by the subject's GP, offering the option of personal encounter with the GP.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Participation rate at 6 months from the invitation letter by study group and screening strategy (FIT and FS)

Key secondary outcome(s)

1. Participation rate at 6 months from the invitation stratified by previous screening history (FIT programmes only)
2. Costs of the different options
3. GP's workload and proportion of subjects who accept the offer of a personal encounter

Completion date

01/10/2012

Eligibility

Key inclusion criteria

All subjects (male and female) aged 50 to 69 targeted for CRC screening in 8 population based programmes in Italy, using immunochemical fecal occult blood test (FIT) in 5 cases (biennial screening offered to subjects aged 50 to 69), or sigmoidoscopy (FS) in 3 cases (FS offered once in the lifetime to all subjects aged 58-60)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. People with personal or family (>1 first degree relative with CRC) of CRC
2. Inflammatory bowel disease
3. Inability to give an informed consent
4. Severe life-threatening disease

Date of first enrolment

01/10/2010

Date of final enrolment

01/10/2012

Locations

Countries of recruitment

Italy

Study participating centre

Via S Francesco da Paola 31

Turin

Italy

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Sponsor information

Organisation

ASR Abruzzo (Italy)

ROR

<https://ror.org/05v16nd64>

Funder(s)**Funder type**

Government

Funder Name

Italian Ministry of Health (Italy) - Funding coordinated by the Abruzzo Regional Health Authority

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2015		Yes	No