ISRCTN84448636 https://doi.org/10.1186/ISRCTN84448636

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

Submission date
28/01/2013

Recruitment status
No longer recruiting

Registration date
19/02/2013

Overall study status
Completed

Last Edited
16/12/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
carlo.senore@cpo.it

Contact information

Type(s)
Scientific

Contact name
Dr Carlo Senore

Contact details
Via S Francesco da Paola 31
Turin
Italy
10123
+39 011 6333890
carlo.senore@cpo.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
'Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/10/2010

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 subjecst aged 58-60)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2500 people in each group in each centre, i.e. 60,000 subjects

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
10123

Sponsor information

Organisation
ASR Abruzzo (Italy)

Sponsor details
via Attilio Monti, 9
Pescara
Italy
65127
+ 39 085450871
direzionegenerale@asrabruzzo.it

Sponsor type
Government

Website
http://www.asrabruzzo.it/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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