ISRCTN11841256 https://doi.org/10.1186/ISRCTN11841256

Can new strategies promote attendance at colorectal cancer screening programs?

Submission date
15/03/2022

Recruitment status
No longer recruiting

Registration date
20/02/2023

Overall study status
Completed

Last Edited
17/07/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
In European countries, colorectal cancer (CRC, also known as bowel cancer) represents an important public health problem. Screening by a faecal occult blood test (FOBT, a test for the detection of blood in the faeces which is not visually apparent) has proven to be effective in reducing CRC mortality. Currently, population-based screening programmes using FOBT have been or are heading towards being implemented in many European countries. Faecal immunochemical test (FIT, another test for the detection of blood in the faeces which is not visually apparent) has been adopted by most Italian regions as the default screening test. Flexible sigmoidoscopy (FS, an exam used to evaluate the lower part of the large intestine (colon) using a thin, flexible tube (sigmoidoscope) is inserted into the rectum) screening offered to people 58 years old has shown to reduce CRC. Although, the attendance rate in CRC screening programmes still remains suboptimal in Italy. Numerous international agencies recommend, among the tests able to identify CRC and precancerous lesions, CT Colonography (CTC), or "virtual colonoscopy", with a five-year interval. Some trials have evaluated CTC as a screening test, with contradictory results. Recently a new approach based on "behavioural economics" (BE) concepts has been proposed with the aim to provide new insights into people's behaviours and suggest new tools to promote screening uptake. Thus, the idea to design screening invitation letters according to new behavioural concepts seems appealing.
The aim of the project is to evaluate the impact on CRC screening attendance of different strategies for inviting people.

Who can participate?
For this study, 84,600 people of both gender and aged 54-70 years, non-respondents to FIT-based screening, will be randomised into six groups.

What does the study involve?
A total of 79,600 people will be invited to get a FIT; subjects randomised in arms 1a, 1b and 1c will be invited by mail with three different types of experimental letters drafted according to BE principles, whereas 40,000 subjects will be invited with a standard invitation letter (arm 2). Lastly, 3,000 subjects and 2,000 subjects will be invited to undergo an FS or a CTC examination, respectively (arm 3 and arm 4). Our project will be carried out in the territories of the three Local Health Units of Tuscany. The attendance rate will be compared among the six groups, in order to

assess the efficacy of single strategies.
A qualitative phase will aim to develop the experimental invitation letter models containing messages drafted according to behavioural economics concepts of normative feedback and minority norm. This material will be evaluated through Interviews, in order to collect participants views on behavioural economics messages and to assess the comprehensibility and clarity of the texts. Interviews will be carried out with volunteers of both genders (selected from screening archives) non-respondents to CRC screening.
In this part of the project, the readability of the invitation letters will be also evaluated. In particular, possible reading comprehension difficulties met by subjects will be correlated with their personal information such as age, sex, etc. For this purpose, READ-IT (http://www.italianlp.it/demo/read-it/), the first readability assessment tool existing for the Italian language, will be exploited.
This study started from the pilot (involving ISPRO-Florence, CPO-Piedimont, ASL Roma 2-Lazio, Latina-Lazio) which aimed to increase participation in the FIT using strategies proposed by a new approach based on "behavioural economics". The pilot involved a sample composed of 12,600 people randomly selected and allocated to the different arms. 50% of the participants belonged to the control group and received the standard invitation letter. The remaining 50% was divided into 3 equal large treatment groups and they were sent different invitation letters.

What are the possible benefit and risks of participation?
Subjects who usually do not respond to the screening invitation may choose to undertake the test due to the invitation strategy. In this case, the patient will benefit from the prevention efficacy of screening. The screening methodologies implemented in the tests are all validated and suggested at a national level. However, risks related to endoscopic procedures are different from those related to FIT tests.

Where is the study run from?
Institute for cancer research, prevention, and clinical network in Florence, Italy, is the coordinating centre of the project. The other centers involved in the study are CPO Piemonte, ASL Roma 2, ASL Latina, Local Health Unit Toscana Nord Ovest, Local Health Unit Toscana Sud-Est, Local Health Unit Toscana Centro.

When is the study starting and how long is it expected to run for?
January 2017 to December 2024.

Who is funding the study?
The pilot phase was part of a European Project funded by the European Commission [SRSS/S2018/066]. The full trial is funded by the Tuscany Region [DD 975 16/01/2020]

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
16875

Study information

Scientific Title
New strategies for promoting attendance at colorectal cancer screening programs

Acronym
BEST CC

Study objectives
Changing colorectal cancer screening offers should increase participation in previous non-responders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 19/01/2021, Comitato etico regionale per la sperimentazione clinica della Regione Toscana - sezione area vasta centro (Nuovo Ingresso Careggi - Largo Brambilla 3, Firenze, Italy; +39055794111; segrcesf@unifi.it), ref: 16875_spe
2. Pilot study approval 11/07/2017, Comitato etico regionale per la sperimentazione clinica della Regione Toscana - sezione area vasta centro (Nuovo Ingresso Careggi - Largo Brambilla 3, Firenze, Italy; +39055794111; segrcesf@unifi.it), ref: CEAVC Em. 2019-380 – Studio OSS_10546

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Attendance to colorectal screening programmes in previous non-responders

Interventions
In the screening programs participating in this study, men and women aged 50-69/70 years are invited by mail to get a FIT kit at pharmacies or at Local Health Units. The screening test is an immunochemical latex agglutination test with a cut-off set at 20 µg haemoglobin/gr faeces.

The study is composed of two phases:

1. The pilot (limited to the behavioral economics invitation) conducted in Turin, Florence, Rome, and Latina.
The sample was composed of 12,600 people randomly selected and allocated to the different arms. 50% of the participants belonged to the control group and received the standard invitation letter. The remaining 50% was divided into 3 equal large treatment groups and they were sent different invitation letters.

2. The full trial will be conducted in three Local Health Units of Tuscany.
The sample is composed of 84,600 randomized subjects aged 54-70 years previously invited to CRC screening for at least two consecutive rounds and who never did a FIT. The sample will be randomised into four groups according to the four following strategies:
Arm 1: screening by a fecal immunochemical test (FIT) with three different types of invitation letters (arms 1a/1b/1c) drafted according to behavioral economics principles (39,600 subjects aged 54-70 years)
Arm 2: screening by FIT with a standard invitation letter (40,000 subjects 54-70 years)
Arm 3: screening by flexible sigmoidoscopy (FS) (3,000 subjects aged 58-60 years)
Arm 4: screening by virtual colonoscopy (CTC) (2,000 subjects aged 58-60 years)
Subjects enrolled in arm 3 or arm 4 will be asked to sign a consent form
Randomization performed using a specific procedure designed within the STATA system.

Intervention Type
Behavioural

Primary outcome(s)
Attendance rate will be measured as the proportion of people who will return a stool sample within 6 months of the mailing of the reminder invitation letter. In arms 3 and 4 attendance in screening will be measured as the proportion of people who will undergo screening tests within 6 months of the mailing of the reminder invitation letter.

Key secondary outcome(s))
Readability of the invitation letters evaluated using READ-IT (http://www.italianlp.it/demo/read-it/) during the study

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Subjects of both genders aged 54-70 years living in the areas of the screening programs participating in the study, who have not attended CRC screening for at least two consecutive rounds.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
54 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
Never had a FIT test within the screening program.

Date of first enrolment
01/07/2020

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Italy

Study participating centre
Istituto per lo Studio la Prevenzione e la Rete Oncologica
Via Cosimo il Vecchio 2, 50139 Firenze
Florence
Italy
50139

Study participating centre

Il Centro di Riferimento per l'Epidemiologia e la Prevenzione Oncologica in Piemonte (CPO Piemonte)
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Study participating centre
ASL Roma 2
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Study participating centre
Istituto di Linguistica Computazionale A. Zampolli
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Sponsor information

Organisation
Istituto per lo Studio e la Prevenzione Oncologica

ROR
https://ror.org/007wes890

Funder(s)

Funder type
Government

Funder Name
Regione Toscana

Alternative Name(s)
Region of Tuscany, Tuscany Region

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Funder Name
European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available due to privacy restrictions.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/07/2023	17/07/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes