

Can new strategies promote attendance at colorectal cancer screening programs?

Submission date 15/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/02/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/07/2023	Condition category Other	<input type="checkbox"/> 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Screening

Participant information sheet

Not applicable for arms 1 and 2. An informed consent for flexible sigmoidoscopy and virtual colonoscopy has been approved by the ethical committee (not available in web format, please use contact details to request participant consent form)

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 measure

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.

Secondary outcome measures

Readability of the invitation letters evaluated using READ-IT (<http://www.italianlp.it/demo/read-it/>) during the study

Overall study start date

01/01/2017

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

Age group

Adult

Lower age limit

54 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

Full trial 84,600; Pilot 12,600

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)

Via Santena 7, 10126 Torino

Turin

Italy

10126

Study participating centre

ASL Roma 2

via M. Brighenti 23, Roma

Rome

Italy

00159

Study participating centre

ASL Latina

Via P.L. Nervi cc LatinaFiori, Latina

Latina

Italy

04100

Study participating centre

Local Health Unit Toscana Nord Ovest

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Italy

56121

Study participating centre
Local Health Unit Toscana Sud East
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Study participating centre
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50100

Study participating centre
Istituto di Linguistica Computazionale A. Zampolli
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Sponsor information

Organisation
Istituto per lo Studio e la Prevenzione Oncologica

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Sponsor type
Research organisation

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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, Ευρωπαϊκή Επιτροπή, Европейская комиссия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságrol, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

The results of the project will be disseminated and replicated by other screening programs of the Tuscany region and in Italy. Outcomes of the project will be relevant especially for those CRC screening programmes with very low attendance, like in some areas of Tuscan territory or in the South of Italy. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

20/12/2024

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