

Using nudges to increase participation in the colorectal cancer prevention program in the Valencian region

Submission date 22/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/06/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/06/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Colorectal cancer (CRC) is a significant health issue. Preventing it is the most effective way to reduce its occurrence and death rates. This can be done by promoting healthy habits like not smoking, maintaining a healthy weight, exercising daily, and participating in cancer screening programs. The European Union recommends CRC screening to detect cancer early and reduce deaths. In the Valencian region of Spain, a CRC screening program started in 2005 and covers everyone by 2016. The program targets men and women aged 50-69 who show no symptoms. It uses a fecal occult blood test (FOBT) for screening and a colonoscopy if the FOBT is positive. The study aims to improve participation in this screening program, especially among men aged 60-69 who participate the least.

Who can participate?

Men aged 60-69 years who have been invited to the CRC screening program but have never participated.

What does the study involve?

Participants will be part of a randomized control trial with three different invitation strategies:

1. Control group: Invited in the usual way.
2. Intervention 1 (I1): Invited with a modified letter that includes behavioral change messages.
3. Intervention 2 (I2): Same as I1, plus an SMS with a link to accept the invitation.
4. Intervention 3 (I3): Invited with the modified letter and an SMS notification. They will receive the FOBT kit directly with the invitation.

What are the possible benefits and risks of participating?

Benefits include early detection of colorectal cancer, which can lead to better treatment outcomes. There are minimal risks involved, mainly related to the discomfort of the screening tests.

Where is the study run from?

Fundación para el fomento de la investigación sanitaria y biomédica de la Comunitat Valenciana (FISABIO) (Spain)

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

The study is expected to start soon and will run for a specified period to gather enough data on the effectiveness of the different invitation strategies.

Who is funding the study?

Conselleria de Educación, Cultura, Universidades y Empleo (Generalitat Valenciana) (Spain)

Spanish Ministry of Science and Innovation

European Commission

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

EU4H-2022-JA-IBA-02

Study information

Scientific Title

Promote healthy lifestyles for cancer prevention in underserved populations through targeted nudges

Acronym

NCCRCV

Study objectives

The more intense the nudge in the CRCSP-VR invitation process the more participation of men over 60 years of age will be, thus reducing inequalities in participation in this vulnerable group.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/09/2024, COMITÉ ÉTICO DE INVESTIGACIÓN DE LA FUNDACIÓN PARA EL FOMENTO DE LA INVESTIGACIÓN SANITARIA Y BIOMÉDICA DE LA COMUNIDAD VALENCIANA (FISABIO), CEI de Salud Pública (CEI-SP) - Comité Ético Externo del Biobanco IBSP-CV y Red Valenciana de Biobancos (Avda. Cataluña, 21, Valencia, E-46020, Spain; +34 961 926 359; cei_sp@fisabio.es), ref: CEI-SP 20240927/10/E

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Increase the participation of men 60-69 years in the Valencian region who have not participated in the colon cancer prevention program

Interventions

The control group will be invited in the usual way of the CRCSP-VR (current screening invitation process)

Intervention 1 (I1): they will be invited to participate with a modified invitation letter (enhancing participation using behavioural change messages) (nudge 1); the participation acceptance process will be the same as in the current screening invitation process (by a pre-paid card).

Intervention 2 (I2): they will receive the modified letter from the I1 (nudge 1); the pre-paid card and an SMS that will have a link for participation acceptance (nudge 2). By clicking the link they will be able to accept the invitation to participate in the screening program and to receive the FOBT at their home.

Intervention 3 (I3): They will receive the invitation to participate through the invitation letter modified in I1 (nudge 1) and also an SMS notifying them that they have received the invitation letter at home along with the kit (nudge 2). Instead of receiving the pre-paid card or the SMS to accept participation, they will directly receive the FOBT in the invitation letter (nudge 3).

These interventions would introduce an increasing intensity of the nudge: absent (control), present (nudge 1), intense (nudge 1 + 2) and very intense (nudge 1 + 2 + 3).

Allocation

Sequence generation: Before the start of the intervention, a list of individuals who meet the inclusion and exclusion criteria will be obtained from the CRCSP-VR (Colorectal Cancer Screening Programme of the Valencian region) Information System until the sample size is reached. A database will be developed to allow the randomization of study subjects through automatic random numbers computer generation.

Allocation concealment mechanism: The allocation of the subject will be assigned randomly in each of the four groups (control, intervention 1, intervention 2, and intervention 3).

Implementation: The generation of random numbers for randomisation, as well as the allocation of individuals to each group, will be carried out by the authorised researchers (statistical personnel). Recruitment will be conducted by the CRCSP-VR staff (public health managers, who are also part of the research team) according to the criteria defined in the study protocol.

Blinding (masking)

The only ones blinded in the study will be the study participants. Both researchers and public health managers will know who is allocated to each of the intervention groups. Nevertheless, only public health managers will have access to the personal data of study subjects. The researcher will treat the data in a pseudo-anonymised way.

Intervention Type

Behavioural

Primary outcome measure

Participation in CRCSP-VR (no/yes). (Yes: a person is considered a participant when they perform the screening FOBT, which means that they have collected the stool sample and delivered it to their Primary Health Center). This measure will be gathered prospectively 6 months after inviting the study population in this trial through data extraction from the CRCSP-VR Information System.

Secondary outcome measures

Delay in participation: time elapsed from the date of invitation to delivery of the FOBT in the CAP. It will be analyzed both continuously and categorically (<1m / 1-2m / 3-4m / 5-6m / > 6m).

Overall study start date

27/09/2024

Completion date

15/06/2025

Eligibility

Key inclusion criteria

Men 60-69 years who have been invited to participate in the colorectal cancer screening programme one or several times and never attended.

Participant type(s)

Population

Age group

Adult

Lower age limit

60 Years

Upper age limit

69 Years

Sex

Male

Target number of participants

6000

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

15/11/2024

Date of final enrolment

15/05/2025

Locations

Countries of recruitment

Spain

Study participating centre

Fundación para el fomento de la investigación sanitaria y biomédica de la Comunitat Valenciana (FISABIO)

Avda. Cataluña, 21

Valencia

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Sponsor information

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Funder(s)

Funder type

Government

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**Funder Name**

Conselleria de Educación, Cultura, Universidades y Empleo (Generalitat Valenciana)

Funder Name

Ministerio de Ciencia e Innovación

Alternative Name(s)

CienciaGob, Ministerio de Ciencia e Innovación de España, Ministry of Science and Innovation, Spanish Ministry of Science and Innovation, Ministry of Science and Innovation of Spain, Spain, Ministry for Science and Innovation, Ministeri de Ciència i Innovació, MCIN, MICINN

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

01/07/2026

Individual participant data (IPD) sharing plan

The datasets of the study contain confidential data of the participants, and cannot be made available.

IPD sharing plan summary

Not expected to be made available