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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	[_] Prospectively registered [_] Protocol
Registration date 05/06/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/06/2025	**Condition category** Cancer	[_] Individual participant data [X] 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?
Dr Inigo Iturbe-Ormaetxe, iturbe@ua.es
Dr Ana Molina Barceló, ana.molina@fisabio.es

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Ana Molina Barceló

Contact details
Avda. Cataluña, 21
Valencia
Spain
E-46020
+34 961925831
ana.molina@fisabio.es

Type(s)
Public

Contact name
Dr Inigo Iturbe Ormaeche

ORCID ID
https://orcid.org/0000-0002-2385-2471

Contact details
Universidad de Alicante
San Vicente del Raspeig
Spain
E-03690
+34 965 90 36 14
iturbe@ua.es

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))

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).

Completion date
15/06/2025

Eligibility

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

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
60 years

Upper age limit
69 years

Sex
Male

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
Spain
E-46020

Sponsor information

Organisation
Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana

ROR
https://ror.org/0116vew40

Funder(s)

Funder type
Government

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

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes