

A decision aid for helping people to decide about colorectal cancer screening

Submission date 10/12/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/12/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/07/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Regular colorectal cancer (CRC) screening is recommended for people older than 50 years old because they have a higher risk of developing this disease. However, a significant proportion of this population do not comply with this recommendation. The researchers have developed a web-based decision aid (DA) to help people to make an informed decision about undergoing CRC screening. It includes information about the disease, as well as two screening procedures: fecal occult blood test (FOBT) and colonoscopy (their characteristics, potential benefits and harms). The DA is available on the following link: <http://www.pydesalud.com/toma-de-decisiones-en-cancer-colorrectal/>. The aim of this study is to find out whether this DA can help people to make informed decisions about CRC screening.

Who can participate?

People between 50-69 years old who have no history of CRC or current symptoms, and who have never had been screened for CRC

What does the study involve?

Participants are randomly allocated to either individually review the DA accompanied by a researcher, or to not review the DA. The main outcome assessed is decisional conflict, that is, participants' uncertainty about undergoing CRC screening or not. The study also assesses their knowledge about CRC and the screening procedures, their intention to be screened, and the importance that they attributed to different characteristics of the screening procedures.

What are the possible benefits and risks of participating?

Regarding potential benefits, those allocated to the intervention group have access to evidence-based information about colorectal cancer screening. There are no risks of potential physical or psychological harm for participating in the trial.

Where is the study run from?

1. Primary care center of Santa Ursula (Tenerife)
2. Primary care center of Ofra (Tenerife)

When is the study starting and how long is it expected to run for?
January 2016 to March 2017

Who is funding the study?
Carlos III Health Institute (Spain)

Who is the main contact?
Amado Rivero-Santana

Contact information

Type(s)
Scientific

Contact name
Mr Amado Rivero-Santana

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI12/00509

Study information

Scientific Title
Effectiveness of a decision aid for promoting colorectal cancer screening in Spain: a randomized trial

Study objectives
Reviewing a decision aid about colorectal cancer screening will improve participants' decisional conflict about undergoing the procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Scientific and Ethics Committee of the Hospital Universitario Nuestra Señora de la Candelaria (Tenerife, Spain), January 2016, file number: 2013/21

Study design

Interventional randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet**Health condition(s) or problem(s) studied**

Colorectal cancer

Interventions

The study took place in two primary care centers: one located in an area where a public screening program was available, and other in which that program was not available at the moment of the study.

Participants were randomly allocated to the intervention (web-based decision aid) or usual care. Computerized randomization was carried out centrally by an independent researcher. Allocation was not blinded for patients and researchers.

The decision aid (DA) included information about colorectal cancer and two screening procedures: fecal occult blood test (FOBT) and colonoscopy (their characteristics, potential benefits and harms). It is available on the following link: <https://www.pydesalud.com/toma-de-decisiones-en-cancer-colorrectal/>

Each intervention participant reviewed the DA accompanied by a researcher in her/his primary care center. Outcome measures were assessed by questionnaires immediately after reviewing the DA.

Participants in the control group did not review the DA and just completed the questionnaires assessing the outcome measures.

Intervention Type

Other

Primary outcome measure

Decisional conflict, measured with the Decisional Conflict Scale (DCS) immediately after reviewing the DA in the intervention group, and at the baseline assessment in the control group

Secondary outcome measures

1. Knowledge of the disease and the screening procedures, assessed using 12 items questionnaire
 2. Intention to undergo screening (yes/no)
 3. Concordance between participants' values about the characteristics of the screening procedures (importance attributed in a 1-5 Likert scale) and their intention to be screened
- All assessments were performed immediately after reviewing the DA in the intervention group (except for knowledge, which was also measured before the application of the DA), and at the baseline assessment in the control group

Overall study start date

01/01/2016

Completion date

31/03/2017

Eligibility

Key inclusion criteria

1. Age 50-69
2. Having no CRC history or current symptoms
3. Having no family antecedents of CRC
4. Not been screened previously

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

126

Total final enrolment

107

Key exclusion criteria

Cognitive impairment that hinders understanding of the study aims, information provided in the DA, or filling out the questionnaires

Date of first enrolment

01/03/2016

Date of final enrolment

31/12/2016

Locations

Countries of recruitment

Spain

Study participating centre

Primary care center of Santa Ursula (Tenerife)

Spain

38390

Study participating centre

Primary care center of Ofra (Tenerife)

Spain

38320

Sponsor information

Organisation

Carlos III Health Institute (Spanish Ministry of Economy, Industry and Competitiveness)

Sponsor details

C/ Sinesio Delgado, 4 (entrada por Avda. Monforte de Lemos, 5)

Madrid

Spain

28029

Sponsor type

Government

Website

<http://www.isciii.es/ISCIII/es/general/index.shtml>

ROR

<https://ror.org/00ca2c886>

Funder(s)

Funder type

Government

Funder Name

Instituto de Salud Carlos III

Alternative Name(s)

SaludISCI, Instituto de Salud Carlos III, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Results and Publications

Publication and dissemination plan

An article reporting the study results is currently under review in the journal BMC Medical Informatics and Decision Making.

Intention to publish date

28/02/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Lilisbeth Perestelo-Pérez (lilisbeth.peresteloperez@sescs.es). The trialists will share all of the individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures and appendices). Other documents available: study protocol, statistical analysis plan, informed consent form, analytic code. The data will be available immediately following publication (no end date). The data will be available for researchers who provide a methodologically sound proposal to achieve aims in the approved proposal. Proposals should be directed to Dr Lilisbeth Perestelo-Perez (lilisbeth.peresteloperez@sescs.es). To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/01/2019	14/01/2019	Yes	No