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

Submission date	Recruitment status	[_] Prospectively registered
10/12/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/12/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2019	Cancer	

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
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Additional identifiers

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
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 aplication of the DA), and at the baseline assessment in the control group

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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)

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

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