




BMJ Open Patient experience, satisfaction and shared decision-making in colorectal cancer screening: protocol of the mixed-methods study CyDESA

Anna Selva ^{1,2}, Pilar López,¹ Teresa Puig,^{2,3} Francesc Macià,^{4,5} Clara Selva,⁶ Yolanda Álvarez-Pérez,⁷ Rebeca Terraza,⁸ Andrea Burón,^{4,5} Salvador Tarek Machlab,⁹ Carles Pericay,¹⁰ Ivan Solà ^{3,11}, Núria Torà,¹² Vanesa Rodríguez,¹³ Cristina Barrufet,⁴ Anna Aymar,³ Marisa Baré ¹⁴

To cite: Selva A, López P, Puig T, *et al.* Patient experience, satisfaction and shared decision-making in colorectal cancer screening: protocol of the mixed-methods study CyDESA. *BMJ Open* 2022;**12**:e057687. doi:10.1136/bmjopen-2021-057687

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-057687>).

Received 27 September 2021
Accepted 25 April 2022



© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Anna Selva; aselva@tauli.cat

ABSTRACT

Introduction Colorectal cancer (CRC) screening programmes can reduce incidence and mortality from this condition if adherence to them is high. As patient experience and satisfaction are key factors in determining adherence to screening programmes, they need to be measured. Furthermore, to promote highly patient-centred healthcare, the perception of patients regarding shared decision-making during CRC screening needs to be known. This study aims to assess the experience, satisfaction and participation in decision-making of participants in a CRC screening programme and of patients diagnosed with CRC through this programme in relation to the diagnostic and therapeutic processes of cancer.

Methods and analysis The CyDESA study is a mixed-methods study with a four phase sequential design. In phase 1, we will conduct a systematic review of patient-reported experience measures (PREMs) for patient experience or satisfaction with CRC screening. In case no located PREM can be applied, in phase 2, we will develop a new PREM. We will use the Delphi methodology to reach consensus among experts and patients and will conduct a pilot test of the developed PREM. Phase 3 is a multicentric cross-sectional study based on self-reported questionnaires that will be conducted at three Spanish hospitals (n=843). The objective is to find out about the experience, satisfaction and participation in decision-making of participants in the CRC screening programme who have had a positive screening test result according to their final screening diagnosis: false positives, colorectal polyps or CRC. Phase 4 is a qualitative phenomenological study based on individual interviews. It will explore the experiences of participants in the CRC screening programme and of those diagnosed with CRC.

Ethics and dissemination Ethics approval by the Ethics Committees of Corporació Sanitària Parc Taulí, Hospital de Sant Pau and Parc de Salut Mar. Findings will be published in peer-reviewed journals and presented at conferences.

Trial registration number NCT04610086.

INTRODUCTION

Colorectal cancer and colorectal cancer screening

Colorectal cancer (CRC) is one of the most frequently occurring cancers worldwide: it

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The combination of qualitative and quantitative methodologies enable obtaining a global and holistic vision of the studied phenomenon to be more representative of reality.
- ⇒ Selection bias due to non-responses might limit the validity of results.
- ⇒ Selection bias would be minimised by conducting reminder phone-calls to non-responders.
- ⇒ Findings may not be applicable in areas that use different colorectal cancer screening strategies than faecal immunochemical test every 2 years and successive colonoscopy.

is the second most common cancer among women and the third among men.¹ Its survival depends on tumour stage at diagnosis, which is around 56%–57% at 5 years.² That is why early detection of CRC using screening strategies can reduce the burden of this disease.^{3 4}

CRC screening programmes reduce the incidence and mortality from CRC as they detect the disease in its early stages,^{5–9} leading to a more effective treatment than if the disease is diagnosed when it is already symptomatic.⁵ There is a range of tests for CRC screening, including stool tests, particularly faecal immunochemical tests (FIT), the most commonly used in Europe,^{5 10 11} while colonoscopy is the most common procedure in North America.¹⁰

In Catalonia (Spain), the CRC screening programme is aimed at woman and men between 50 and 69 years of age and it is based on conducting a FIT every 2 years.^{12 13} People with a negative FIT result receive the result by postal letter. Only when the FIT is positive are people contacted by the hospital: it contacts them by telephone and asks them to attend

a consultation with the screening programme nurse who explains the meaning of having a positive FIT test and offers a colonoscopy with sedation.

Patient experience and satisfaction

Only when screening programmes have high participation do they achieve their expected efficacy and impact.⁵ Participation in screening programmes is related to patient experience and satisfaction with those programmes: satisfaction with past stool test screening strongly predicts participation in future screening rounds.^{14–16} Similarly, in breast cancer screening, women's satisfaction with the screening process is related to good adherence to the programme.^{17–20} In addition, it should be borne in mind that the health system offers screening programmes to asymptomatic populations that have not requested healthcare for this condition. For the foregoing reasons, it is important to measure and understand patient experience and satisfaction with CRC screening.

Although they are usually used interchangeably, patient experience and satisfaction have a slightly different meaning.^{21–22} Patient experience refers to how patients perceive the medical care received. However, patient satisfaction implies a subjective evaluation or rating of that experience,²¹ comparing it to with previous patient expectations.^{22–23} Patient experience and satisfaction are patient-reported measures frequently used as quality indicators of healthcare services, to establish hospital rankings, benchmark healthcare centre performance and to measure the effectiveness of interventions.^{21–24}

Shared decision-making

Healthcare is becoming increasingly more patient-centred, considering the patient's views and preferences and sharing with them the decisions related to their healthcare process. Shared decision-making is the process through which patients and healthcare professionals work together to make optimal decisions, along with the best scientific evidence available.^{25–26}

Shared decision-making is especially relevant in fields such as oncology, where it is common to find interventions in which the equilibrium between benefits and risks is very balanced and the best option depends on the patient's context and his/her values and preferences.²⁷ For example, some patients would prefer to live for a shorter period of time as carriers of a stoma while others prefer to suffer major adverse effects in exchange for small increases in survival.²⁸ Shared decision-making processes must be individualised, since patients' preferences are not homogeneous and depend on personal factors such as age or gender.²⁹

Published studies on patient satisfaction with CRC screening have focused mainly on some specific aspects of the whole screening process: the screening test used,³⁰ the conducting of a colonoscopy^{31–32} or the most initial part of the screening process (invitation to and conducting of a screening test).³³ However, to the best of our knowledge, there is no study that has assessed patient experience, satisfaction and participation in shared decision-making during the whole CRC screening process, focusing particularly on the processes that follow a positive screening test result and that take place in hospitals.

The primary objectives of this study are: (1) to find out about the experience, satisfaction and participation in decision-making of participants in a CRC screening programme who had a positive screening result and (2) to find out about the experience, satisfaction and participation in decision-making of patients diagnosed with CRC through the screening programme in relation to the cancer diagnostic and therapeutic processes.

As secondary objectives, we aim to: (1) identify and assess all available patient-reported experience measures (PREMs) for patient experience and satisfaction with CRC screening; (2) identify which factors are associated with and influence patient experience, satisfaction and participation in decision-making in relation to CRC screening and cancer diagnostic and therapeutic processes and (3) gain an in-depth knowledge of patients' experience, satisfaction and perceptions of shared decision-making in relation to CRC screening and the cancer diagnostic and therapeutic process.

METHODS

Overall study design and setting

This is a four phase, multicentric, mixed-methods study³⁴ where the results of each study phase will inform the data collection and analysis in proceeding phases (figure 1). The study is scheduled to be conducted between July 2020 and July 2023. Phase 1 consists of a systematic review of PREMs for patient experience or satisfaction with CRC screening. In case no identified PREM can be feasibly applied to our context, in phase 2, we will develop a new PREM to measure patient experience or satisfaction with CRC screening. Phase 3 is a multicentric cross-sectional study that will be conducted in three hospitals. Finally,

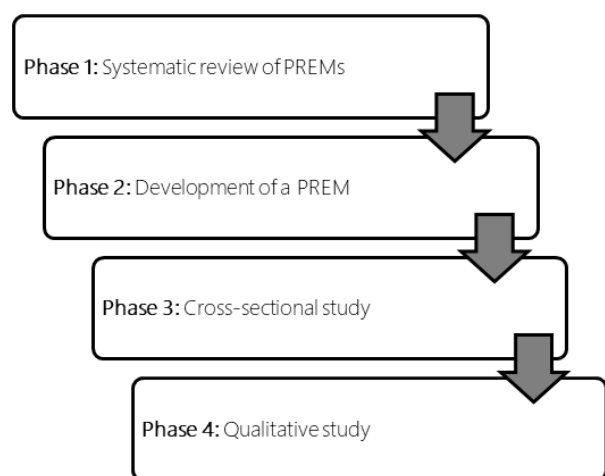


Figure 1 Study phases and design. PREM, patient-reported experience measure.

phase 4 will comprise a qualitative study based on individual interviews.

Phase 1: a systematic review of patient-reported experience measures (PREMs) for patient experience and satisfaction with colorectal cancer screening

Design

We will conduct a systematic review of existing PREMs to measure patient experience and satisfaction with colorectal cancer screening in order to: (1) identify and critically appraise the quality of the measurement properties of validated PREMs that are suitable for use in phase 3 of the study and (2) identify the domains and items explored by the PREMs identified. The protocol for this systematic review has been registered in PROSPERO (<https://www.crd.york.ac.uk/prospero/>; CRD42019118527). We will conduct this systematic review following the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) methodology^{35 36} and will report the results following the preferred reporting items for systematic review and meta-analysis statement.³⁷

Search methods

We will conduct an exhaustive search in MEDLINE (PubMed), EMBASE (Ovid), PsycINFO (Ovid) and CINAHL (EBSCOHost) without language or date restrictions. We will also search in BiblioPRO and check the references listed in included studies. We will keep the search updated while we conduct the review. The detailed search strategies are available in online supplemental annex I. We will use the software Procite® to manage search results and delete duplicates.

Eligibility criteria and study selection

We will include studies on the development or validation of questionnaires measuring patient experience or satisfaction with: colorectal cancer screening (irrespective of the screening test used), colonoscopy (irrespective of it being performed in the context of a screening programme) and the screening result notification process. We will also consider studies (irrespective of their design) that assessed patient experience or satisfaction with colorectal screening as an outcome in order to obtain information on the questionnaire used and try to locate its validation study. Two authors will independently assess the results of the search for eligibility and will then make a final decision based on the full text of references deemed eligible.

Data extraction and methodological assessment

We will develop and pilot-test a case report form on Google Forms to extract data from included studies. Two authors will independently extract data on the general characteristics of the study (country, year and language), population, characteristics of the questionnaire (including domains and items assessed), evidence for its validity, information on instrument's psychometric properties and information on interpretability and feasibility. Two

authors will assess the methodological quality of studies using the COSMIN Risk of Bias checklist³⁸ and will rate the result of each measurement property against the updated criteria for good measurement properties based on Terwee *et al*³⁹ and Prinsen *et al*.⁴⁰ Disagreements will be solved by consensus.

Data synthesis and analysis

We will use descriptive statistics to synthesise findings and try to quantitatively pool the results of measurement properties of questionnaires reported by different studies. We will use SPSS V.25.0 (SPSS, Chicago, IL, USA) to perform the statistical analysis. We will report findings as a narrative synthesis of the characteristics and measurement properties from each instrument.

Phase 2: development of a patient-reported experience measure (PREM) questionnaire

We will develop a PREM based on the findings obtained in phase 1, following a multistep process if we cannot identify any validated PREM that can be feasibly applied in our context.

First, we will identify the different domains assessed in the questionnaires included in the systematic review and will collect all the items and questions used in each domain. We will discuss each of these domains within all the research team and will decide which would be the key domains for our PREM. Two authors will independently read all the questions identified for each domain and classify them into three categories: adequate, adequate with changes or not adequate for measuring experience or satisfaction with colorectal cancer screening. Disagreements will be solved by consensus. We will also identify if there are any uncovered domains for which new questions need to be developed.

Then, two authors will develop an initial version of the PREM that will be written in Catalan and Spanish. This version will be discussed with experts in cancer screening and patients using a Delphi consensus survey on Google Forms.^{41–43} A convenience sample of two to three patients will be invited to participate in the Delphi survey. Patients will be offered to participate during the nurse visit in which the final diagnosis of the screening programme is communicated. The objective of this Delphi consensus survey will be to identify the most and least relevant items, assess their content validity by asking about their relevance, comprehensiveness and comprehensibility and to establish the best order of items. We will conduct the necessary Delphi rounds until a consensus is reached.

Finally, we will pilot-test the final version of the questionnaire with a sample of 20 participants in the colorectal cancer screening programme with a positive screening result using the Survey Monkey® software. After its completion, we will conduct a phone interview with respondents to assess the acceptability of the PREM, the time needed to complete it, its relevance, comprehensibility and comprehensiveness (content validity). We will modify the PREM according to the input received and

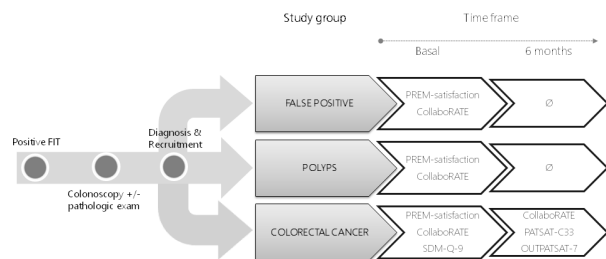


Figure 2 Study scheme. FIT, faecal immunochemical test; OUTPATSAT-7, satisfaction with outpatient cancer care; PATSAT-C33, satisfaction with cancer care—core questionnaire; PREM, patient-reported experience measure; SDM-Q-9, 9-item Shared Decision-Making Questionnaire.

will circulate the final version of the PREM among whole the research team for its approval. We plan to assess other measurement properties of the developed PREM (construct validity, internal consistency and test–retest reliability) in specific validation study.

Phase 3: multicentre cross-sectional study

Design

Multicentre cross-sectional study based on surveys, with three study groups according to the final diagnosis of screening: (1) false positive group: patients with a positive FIT and without risky lesions found through colonoscopy (includes colonoscopy with no lesion or with no risky lesions); (2) polyps group: patients with colorectal polyps (either adenomas or serrated polyps of any size, grade of dysplasia and any number thereof, including *carcinoma in situ*) and (3) colorectal cancer group: patients with colorectal cancer that at least infiltrates the submucosa (pT1 according the TNM classification⁴⁴). **Figure 2** describes the study scheme.

This study will be conducted in three hospitals in Catalonia (Spain) that take part in the region's organised colorectal cancer screening programme: Parc Taulí Hospital Universitari (Sabadell), Hospital del Mar (Barcelona) and Hospital de la Santa Creu i Sant Pau (Barcelona). These three hospitals are in urban areas and provide care to similar populations.

Population

We will include women and men between the ages of 50 and 69 (target population of the colorectal cancer screening programme) that have a positive FIT in the colorectal cancer screening programme for whom a colonoscopy is indicated. Such population has the experience of participating in the whole screening process. We will exclude people for whom a colonoscopy is not indicated for medical reasons or because they refuse it; that do not understand Spanish or Catalan; with an impaired cognitive status that precludes them from understanding or answering the questionnaires on their own or with the help of a caregiver; or that have undertaken part of the diagnostic process in another hospital, for example, in a private centre.

Selection and recruitment

Patients will be selected for their inclusion once the colonoscopy findings and the pathology examination are available and communicated to them. According to these findings, patients will be classified into one of the three study groups: false positives; polyps or colorectal cancer.

Patients will be recruited during the nurse visit in which the final screening programme diagnosis and the recommended surveillance is communicated to patients. The screening programme nurse will explain the study objectives and obtain the informed consent. Patients with no lesions that do not require a face-to-face nurse visit will be recruited by phone and the informed consent will be sent along with the questionnaires. Patients will be recruited consecutively until sample size is reached.

Sample size

The sample size calculation is based on the proportion of patients in whom shared decision-making is achieved, according to the CollaboRATE top score (proportion of patients with the maximum score). We conducted a separate sample size calculation for each diagnostic group (false positives, polyps and colorectal cancer) to ensure a representative estimation of the proportion of patients in each group that finally are diagnosed as a consequence of their participation in the screening programme. According to the number of patients expected to be diagnosed in 1 year for each study group (760 false positives, 1650 polyps and 120 CRC) in the three hospitals, to detect at least a proportion of 50% of patients who achieve shared decision-making (maximum uncertainty scenario), and accepting an alpha risk of 0.05, a precision of 0.05% and 30% of follow-up losses, it will be necessary to include 831 patients (321 false positives, 411 with polyps and 99 with colorectal cancer).

Outcomes and data acquisition

The main outcomes will be satisfaction with the colorectal cancer screening programme and with the cancer diagnostic and therapeutic process and participation in shared decision-making. Data will be obtained using self-reported questionnaires administered online or on paper depending on the participant's preference. We will use the software Survey Monkey® (<https://www.surveymonkey.com/>) for online surveys. Paper questionnaires will be sent by post and will contain a postage paid envelope for their return. If no response is received after 3 weeks, we will make a reminder phone call. We will use the following questionnaires: (1) the PREM for measuring patient experience and satisfaction with colorectal cancer screening identified in phase 1 or developed in phase 2 (PREM-satisfaction); (2) the CollaboRATE questionnaire^{45–47} and the 9-item Shared Decision-Making Questionnaire (SDM-Q-9),^{48 49} two validated questionnaires for measuring participation in share-decision making and (3) the Satisfaction with cancer care core questionnaire (EORTC PATSAT-C33) and the Satisfaction with outpatient cancer care (EORTC OUT-PATSAT7)^{50 51} for measuring patient

satisfaction with care delivery, two questionnaires based on the validated questionnaire IN-PATSAT32^{52 53} that are currently undergoing a large-scale cross-cultural psychometric assessment. Questionnaire rating is available in online supplemental annex II.

For false positive and polyps groups, we will administer the PREM-satisfaction and CollaboRATE questionnaires after participants have received the screening result. For patients diagnosed with colorectal cancer, we will administer questionnaires at two different stages: (1) after the medical visit where the patient is informed of their cancer diagnosis: PREM-satisfaction, CollaboRATE and SDM-Q-9; (2) at 6 months of inclusion in the study: CollaboRATE, SDM-Q-9 and PATSAT-C33 and OUT-PATSAT7. Figure 2 describes the time that the questionnaires are administered to each study group.

We will collect information on sociodemographic variables (eg, age, sex and occupation), clinical variables (eg, symptoms, other health conditions, familiar history of colorectal cancer, characteristics of the colonoscopy, tumour stage and treatment in the colorectal cancer group) and variables related to the care process (eg, hospital centre and dates of FIT analysis, colonoscopy, pathology report and first treatment). A full list of study variables is available in online supplemental annex III. Information on these variables will be obtained from hospital medical records and from the screening programme software.

Data analysis plan

We will conduct a descriptive analysis using natural frequencies and proportions for categorical variables and using mean or median and SD or IQRs for quantitative outcomes. Basal characteristics of participants in each study group will be compared using the χ^2 test or Fisher's exact test for categorical variables and Student's t-test or Mann-Whitney U test for continuous variables. Sample size was calculated for the main outcome participants who reached shared decision-making. We will compare the proportion of participants with the top score in the CollaboRATE questionnaire according to the different study groups, sex, age (categorised) and hospital centre, using cross tabs and the χ^2 Test, the Fisher Exact Test or Monte Carlo Exact Test if appropriate. A two-sided alpha level of 0.05 will be considered statistically significant. We will conduct a multivariate analysis by logistic regression in which the dependent variable will be the proportion of participants with the maximum score in CollaboRATE and will consider as covariables those that were statistically significant in the bivariate analysis at a p value of <0.10 and those that were not will be if deemed clinically relevant. Analysis will be conducted with SPSS V.25.0 (SPSS, Chicago, IL, USA). The analysis for other outcomes is described in online supplemental annex IV. Open-ended questions on questionnaires will be analysed thematically in order to obtain categories with the support of the programme Atlas.ti.

Phase 4: qualitative study

Design

Qualitative, exploratory-descriptive study following the phenomenological approach based on individual interviews. Its objective is to find out about: (1) the experience of participants in the colorectal cancer screening programme who had a positive screening result, and (2) the experience of people diagnosed with colorectal cancer in the screening programme in relation to the cancer diagnostic and therapeutic processes. This study will be registered on Open Science Framework registries (osf.io) and will be conducted from the etic perspective (from outside).⁵⁴

Population and setting

This study will take place in one of the participating centres, Hospital Parc Taulí, starting after the previous study phases are concluded. As centres in which the CRC screening programme is conducted have similar characteristics and the target population of the programme is the same in all them, by conducting a purposeful sampling of participants in one centre, we can get a representative profile of the people who participate in the screening programme. We will recruit a theoretical purposive sample of participants in order to achieve the maximum discursive variability.^{54–56} The sample will include representation of three groups of informants according to the final diagnosis of the screening programme as previously described. Each group will comprise a category of informants and will include different profiles based on gender, age, recommended surveillance and treatment of colorectal cancer. Table 1 summarises the groups of informants, their profiles and the estimated number of participants. Inclusion and exclusion criteria and recruitment of participants will be the same as described in phase 3.

Data acquisition

We will conduct individual interviews as this is the most appropriate method of data acquisition when asking about personal experiences and to guarantee that participants are comfortable.^{54 57} Interviews will be conducted online (with the Zoom software) or face-to-face according to participants' preference.

We plan to conduct 44 individual interviews according to a pragmatic decision around sampling. We estimated that such number of participants could provide a rich corpus of data catching the breadth of our research question and the experiential diversity from the participants.⁵⁸ Individual interviews will be semistructured, based on an interview guide (online supplemental annex V), audio-taped and transcribed verbatim.⁵⁹ They will be conducted by three researchers with experience in qualitative research who are not related to the colorectal cancer screening programme and will last approximately 40 min.

Data analysis plan

We will conduct a reflexive thematic analysis.⁶⁰ This strategy entails starting with the data to arrive at concepts:

Table 1 Description of the theoretical sample

Groups of informants	Description	Surveillance/treatment	Profiles	Number of participants
False positive	Colonoscopy without lesions or with benign lesions	Return to screening programme after 10 years	Women 50–59 years	2
			Women 60–69 years	2
			Men 50–59 years	2
			Men 60–69 years	2
Polyps	Polyps that do not require surveillance	Return to screening programme after 10 years	Women 50–59 years	2
			Women 60–69 years	2
			Men 50–59 years	2
			Men 60–69 years	2
	Polyps that require standard surveillance	Colonoscopy after 3 years	Women 50–59 years	2
			Women 60–69 years	2
			Men 50–59 years	2
			Men 60–69 years	2
	Polyps that require intensive surveillance	Colonoscopy after 1 year	Women 50–59 years	2
			Women 60–69 years	2
			Men 50–59 years	2
			Men 60–69 years	2
Colorectal cancer	Diagnosis of colorectal cancer	Endoscopic resection	Women	2
			Men	2
		Surgery (without radio/chemotherapy)	Women	2
			Men	2
		Radio/chemotherapy±surgery	Women	2
			Men	2

by reading and analysing the transcripts of interviews, we will elaborate a tentative list of codes. Data will be segmented by group of informants. We will use the software Atlas.ti for the analysis.

To guarantee quality of data, it will be contrasted with informants. Information will be triangulated by comparing the different groups of informants. Three experienced analysts will participate in this part.

Patient and public involvement statement

Patients will be involved in conducting the research, specifically in the development of a PREM for measuring patient satisfaction with CRC screening (study phase 2). Patients will be invited to participate together with experts in cancer screening in a Delphi survey to identify the most and least relevant items of the first version of the PREM, assess their content validity and establish the best order of items.

Ethics and dissemination

This study will be conducted in accordance with the Helsinki Declaration.⁶¹ It has been approved by the

research ethics committees of Corporació Sanitària Parc Taulí, Hospital de la Santa Creu i Sant Pau and Parc de Salut Mar. All personal data will be anonymised, assigning a study code to each participant. Questionnaires used in phase 3 will be identified by the study code and will not include any identifiable data. Participants in phases 3 and 4 will be required to read the participant information sheet and sign the informed consent form. This study involves human participants and was approved by Ethics Committee for Research of the Parc Taulí Hospital, Sabadell; Ethics Committee for Research of Sant Pau Hospital, Barcelona; Ethics Committee for Research of Hospital del Mar, Barcelona (Reference number: 2019/502). Participants gave informed consent to participate in the study before taking part.

Interviews to persons with CRC cancer will be conducted by a psychologist with wide experience in conducting individual interviews (CS). Also, we will avoid mentioning the word ‘cancer’ or ‘tumour’ in the questionnaires and interviews, and will refer to the health problem as ‘your intestinal health problem’. We do not expect any adverse

event for participating in this study, just the time required to answer the questionnaires (phase 3) and attend the interviews (phase 4).

The dissemination plan includes publication in peer-reviewed journals, presentations at conferences, dissemination of plain language summaries through institutional webpages, an executive summary of study findings for participants and social media posts.

DISCUSSION

This study will provide an insight into areas for improvement in the CRC screening programme and in cancer diagnostic and therapeutic processes, focusing on patients' views and experiences. By using a mixed approach, combining quantitative and qualitative methods, we will quantify the phenomenon of interest and identify the associated factors and also delve into the phenomenon based on the experience of those affected, obtaining a global understanding of the phenomenon.

If results confirm that the study hypotheses, satisfaction and perception of shared decision-making of patients differ according to the final screening diagnostic, it will be possible to design different strategies (eg, in the communication of screening results or in the management of waiting times) adapted to the diagnostic group of participants in order to minimise inconveniences.

Author affiliations

¹Clinical Epidemiology and Cancer Screening, Consorci Corporació Sanitària Parc Taulí, Sabadell, Catalunya, Spain

²Department of Paediatrics, Obstetrics, Gynaecology and Preventive Medicine, Autonomous University of Barcelona, Barcelona, Catalunya, Spain

³Clinical Epidemiology and Healthcare Services, Institut d'Investigació Biomèdica Sant Pau IIB Sant Pau, Barcelona, Catalunya, Spain

⁴Epidemiology and Evaluation Department, Hospital del Mar Institute for Medical Research, Barcelona, Catalunya, Spain

⁵Health Services Research on Chronic Patients Network, REDISSEC, Madrid, Spain

⁶Psychology and Educational Sciences Studies, UOC, Barcelona, Catalunya, Spain

⁷Servicio de Evaluación del Servicio Canario de la Salud, Fundación Canaria Instituto de Investigación Sanitaria de Canarias (FIISC), Santa Cruz de Tenerife, Santa Cruz de Tenerife, Spain

⁸Departament de Salut, Barcelona, Catalunya, Spain

⁹Gastroenterology Department, Consorci Corporació Sanitària Parc Taulí, Sabadell, Catalunya, Spain

¹⁰Medical Oncology Department, Consorci Corporació Sanitària Parc Taulí, Sabadell, Catalunya, Spain

¹¹CIBERESP, CIBER, Madrid, Comunidad de Madrid, Spain

¹²Cancer Screening Programs, Althaia Foundation of Manresa, Manresa, Catalunya, Spain

¹³TecnoCampus Superior School of Health Science, Pompeu Fabra University, Mataró, Catalunya, Spain

¹⁴Epidemiology and Cancer Screening, Consorcio Corporación Sanitaria Parc Taulí, Sabadell, Spain

Twitter Anna Selva AnnaSelva @cribratgetauli

Acknowledgements To Christina McGown for reviewing the English language edition.

Contributors AS conceptualised and designed the study, in collaboration with NT, VR, RT, PL, CS, MB and IS. STM and CP provided clinical expertise. NT provided statistical advice. RT, CS, AB and YA-P provided expertise in qualitative methodology. IS provided expertise in systematic review methodology and is responsible of the design and conduction of search strategies. AS, PLL, TP, AA, FM,

AB, CB are responsible for the organisation of the fieldwork in each centre. AS, TP and FM were responsible for obtaining the Ethics Committee approval. AS wrote the manuscript and STM, TP, AB, CB, CS, RT, YA-P, NT and IV critically reviewed it and made significant contributions to its improvement. All authors approved the final manuscript.

Funding This work was supported by Instituto de Salud Carlos Tercero, grant number (PI18/00460); Fondo Europeo de Desarrollo Regional (FEDER), "Una manera de hacer Europa".

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Anna Selva <http://orcid.org/0000-0002-2754-3158>

Ivan Solà <http://orcid.org/0000-0003-0078-3706>

Marisa Baré <http://orcid.org/0000-0001-8085-2833>

REFERENCES

- 1 IARC. Globocan 2012: estimated cancer incidence, mortality and prevalence worldwide in 2012. Available: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx [Accessed 1 Aug 2018].
- 2 De Angelis R, Sant M, Coleman MP, *et al*. Cancer survival in Europe 1999–2007 by country and age: results of EUROCARE--5—a population-based study. *Lancet Oncol* 2014;15:23–34 <http://linkinghub.elsevier.com/retrieve/pii/S1470204513705461>
- 3 edCubiella JF, Castillejo MM MJ. *Diagnóstico Y prevención del cáncer colorectal. Guía de práctica clínica*. Madrid: Asociación Española de Gastroenterología y Sociedad Española de Medicina de Familia y comunitaria, 2018.
- 4 Issa IA, Noureddine M. Colorectal cancer screening: an updated review of the available options. *World J Gastroenterol* 2017;23:5086–96 <https://pubmed.ncbi.nlm.nih.gov/28811705/>
- 5 Comission ESegnan N, Patnick J von KL, eds. *European guidelines for quality assurance in colorectal cancer screening and diagnosis*. 1st ed. Luxembourg, 2010.
- 6 Hewitson P, Glasziou P, Irwig L, *et al*. Screening for colorectal cancer using the faecal occult blood test, Hemoccult. *Cochrane Database Syst Rev* 2007;2007:CD001216 <https://pubmed.ncbi.nlm.nih.gov/17253456/>
- 7 Shaukat A, Mongin SJ, Geisser MS, *et al*. Long-Term mortality after screening for colorectal cancer. *N Engl J Med* 2013;369:1106–14 <https://pubmed.ncbi.nlm.nih.gov/24047060/>
- 8 Fitzpatrick-Lewis D, Ali MU, Warren R, *et al*. Screening for colorectal cancer: a systematic review and meta-analysis. *Clin Colorectal Cancer* 2016;15:298–313 <https://pubmed.ncbi.nlm.nih.gov/27133893/>
- 9 Ventura L, Mantellini P, Grazzini G, *et al*. The impact of immunochemical faecal occult blood testing on colorectal cancer incidence. *Dig Liver Dis* 2014;46:82–6 <https://pubmed.ncbi.nlm.nih.gov/24011791/>
- 10 Navarro M, Nicolas A, Ferrandez A, *et al*. Colorectal cancer population screening programs worldwide in 2016: an update. *World*

- J Gastroenterol* 2017;23:3632–42 <https://pubmed.ncbi.nlm.nih.gov/28611516/>
- 11 Schreuders EH, Ruco A, Rabeneck L, *et al.* Colorectal cancer screening: a global overview of existing programmes. *Gut* 2015;64:1637–49 <https://pubmed.ncbi.nlm.nih.gov/26041752/>
 - 12 Ministerio de Sanidad y Política Social. *Estrategia en cancer del.* Madrid: Sistema Nacional de Salud, 2010.
 - 13 d'Oncologia PD. Pla Contra El C ncer a Catalunya 2015–2020 2015.
 - 14 Osborne JM, Wilson C, Duncan A, *et al.* Patterns of participation over four rounds of annual fecal immunochemical test-based screening for colorectal cancer: what predicts rescreening? *BMC Public Health* 2017;18:81 <https://pubmed.ncbi.nlm.nih.gov/28764667/>
 - 15 Duncan A, Turnbull D, Wilson C, *et al.* Behavioural and demographic predictors of adherence to three consecutive faecal occult blood test screening opportunities: a population study. *BMC Public Health* 2014;14:238.
 - 16 Duncan A, Turnbull D, Gregory T, *et al.* Using the Transtheoretical model of behaviour change to describe readiness to rescreen for colorectal cancer with faecal occult blood testing. *Health Promot J Austr* 2012;23:122–8 <https://pubmed.ncbi.nlm.nih.gov/23088473/>
 - 17 Soler-Michel P, Courtial I, Bremond A. [Reattendance of women for breast cancer screening programs. A review]. *Rev Epidemiol Sante Publique* 2005;53:549–67 <https://pubmed.ncbi.nlm.nih.gov/16434928/>
 - 18 Almog R, Hagoel L, Tamir A. Quality Control in a National Program for the Early Detection of Breast Cancer. Women's Satisfaction With the Mammography Process. *Women's Heal Issues* 2008;18:110–7 <https://pubmed.ncbi.nlm.nih.gov/18319148/>
 - 19 Tang TS, Patterson SK, Roubidoux MA, *et al.* Women's mammography experience and its impact on screening adherence. *Psychooncology* 2009;18:727–34 <https://pubmed.ncbi.nlm.nih.gov/19035468/>
 - 20 Peipins LA, Shapiro JA, Bobo JK, *et al.* Impact of women's experiences during mammography on adherence to rescreening (United States). *Cancer Causes Control* 2006;17:439–47 <https://pubmed.ncbi.nlm.nih.gov/16596296/>
 - 21 Beattie M, Murphy DJ, Atherton I, *et al.* Instruments to measure patient experience of healthcare quality in hospitals: a systematic review. *Syst Rev* 2015;4:97 <https://pubmed.ncbi.nlm.nih.gov/26202326/>
 - 22 Klose K, Kreimeier S, Tangermann U, *et al.* Patient- and person-reports on healthcare: preferences, outcomes, experiences, and satisfaction – an essay. *Health Econ Rev* 2016;6:1–11.
 - 23 Crow R, Gage H, Hampson S. The measurement of satisfaction with healthcare: Implications for practice from a systematic review of the literature [Internet]. Vol. 6, Health Technology Assessment. *Health Technol Assess* 2002 <https://pubmed.ncbi.nlm.nih.gov/12925269/>
 - 24 Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open* 2013;3. doi:10.1136/bmjopen-2012-001570. [Epub ahead of print: 03 Jan 2013] <https://pubmed.ncbi.nlm.nih.gov/23293244/>
 - 25 Elwyn G, Frosch D, Thomson R, *et al.* Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361–7 <https://pubmed.ncbi.nlm.nih.gov/22618581/>
 - 26 Olthuis G, Leget C, Grypdonck M. Shared decision making needs a care perspective. *BMJ* 2012;345:e7419.
 - 27 Zafar SY, Malin JL, Grambow SC, *et al.* Chemotherapy use and patient treatment preferences in advanced colorectal cancer: a prospective cohort study. *Cancer* 2013;119:854–62 <http://www.ncbi.nlm.nih.gov/pubmed/22972673>
 - 28 Currie A, Askari A, Nachiappan S, *et al.* A systematic review of patient preference elicitation methods in the treatment of colorectal cancer. *Colorectal Dis* 2015;17:17–25 <http://doi.wiley.com/doi/10.1111/cod.12444>
 - 29 Damm K, Vogel A, Prenzler A. Preferences of colorectal cancer patients for treatment and decision-making: a systematic literature review. *Eur J Cancer Care* 2014;23:762–72 <http://www.ncbi.nlm.nih.gov/pubmed/24840999>
 - 30 Kirkøen B, Berstad P, Botteri E, *et al.* Acceptability of two colorectal cancer screening tests: pain as a key determinant in sigmoidoscopy. *Endoscopy* 2017;49:1075–86 <http://www.thieme-connect.de/DOI/DOI>
 - 31 Sipe BW, Fischer M, Baluyut AR, *et al.* A low-residue diet improved patient satisfaction with split-dose oral sulfate solution without impairing colonic preparation. *Gastrointest Endosc* 2013;77:932–6 <https://pubmed.ncbi.nlm.nih.gov/23531424/>
 - 32 Ghanouni A, Plumb A, Hewitson P, *et al.* Patients' experience of colonoscopy in the English bowel cancer screening programme. *Endoscopy* 2016;48:232–40 <https://pubmed.ncbi.nlm.nih.gov/26841268/>
 - 33 Burón A, Posso M, Sivilla J, *et al.* Analysis of participant satisfaction in the Barcelona colorectal cancer screening programme: positive evaluation of the community pharmacy. *Gastroenterol Hepatol* 2017;40:265–75 <https://pubmed.ncbi.nlm.nih.gov/27292268/>
 - 34 Fetter MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. *Health Serv Res* 2013;48:2134–56 <https://pubmed.ncbi.nlm.nih.gov/24279835/>
 - 35 Prinsen CAC, Mokkink LB, Bouter LM, *et al.* COSMIN guideline for systematic reviews of patient-reported outcome measures. *Qual Life Res* 2018;27:1147–57 <http://www.ncbi.nlm.nih.gov/pubmed/29435801>
 - 36 Mokkink LB, Prinsen CAC, Patrick DL. COSMIN methodology for systematic reviews of Patient-Reported outcome measures (PROMs). *Qual Life Res* 2018 https://www.cosmin.nl/wp-content/uploads/COSMIN-syst-review-for-PROMs-manual_version-1_feb-2018.pdf
 - 37 Moher D, Shamseer L, Clarke M, *et al.* Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4:1 <http://www.ncbi.nlm.nih.gov/pubmed/25554246>
 - 38 Mokkink LB, de Vet HCW, Prinsen CAC, *et al.* COSMIN risk of bias checklist for systematic reviews of patient-reported outcome measures. *Qual Life Res* 2018;27:1171–9 <http://www.ncbi.nlm.nih.gov/pubmed/29260445>
 - 39 Terwee CB, Bot SDM, de Boer MR, *et al.* Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol* 2007;60:34–42 <https://pubmed.ncbi.nlm.nih.gov/17161752/>
 - 40 Prinsen CAC, Vohra S, Rose MR, *et al.* How to select outcome measurement instruments for outcomes included in a "Core Outcome Set" – a practical guideline. *Trials* 2016;17:449 <https://pubmed.ncbi.nlm.nih.gov/27618914/>
 - 41 Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. *J Adv Nurs* 2000;32:1008–15 <https://pubmed.ncbi.nlm.nih.gov/11095242/>
 - 42 Geist MR. Using the Delphi method to engage stakeholders: a comparison of two studies. *Eval Program Plann* 2010;33:147–54 <https://pubmed.ncbi.nlm.nih.gov/19581002/>
 - 43 McPherson S, Reese C, Wendler MC. Methodology update: Delphi studies. *Nurs Res* 2018;67:404–10 <https://pubmed.ncbi.nlm.nih.gov/30052591/>
 - 44 Brierley JD, ed. *Tnm classification of malignant tumours*. 8th ed. Wiley, 2021. <https://www.wiley.com/en-ad/TNM+Classification+of+Malignant+Tumours%2C+8th+Edition-p-9781119263579>
 - 45 Forcino RC, Bustamante N, Thompson R, *et al.* Developing and pilot testing a Spanish translation of collaborate for use in the United States. *PLoS One* 2016;11:e0168538 <https://pubmed.ncbi.nlm.nih.gov/28002422/>
 - 46 Elwyn G, Barr PJ, Grande SW, *et al.* Developing collaborate: a fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns* 2013;93:102–7 <https://pubmed.ncbi.nlm.nih.gov/23768763/>
 - 47 Barr PJ, Thompson R, Walsh T, *et al.* The psychometric properties of collaborate: a fast and frugal patient-reported measure of the shared decision-making process. *J Med Internet Res* 2014;16:e2 <https://pubmed.ncbi.nlm.nih.gov/24389354/>
 - 48 De las Cuevas C, Perestelo-Perez L, Rivero-Santana A, *et al.* Validation of the Spanish version of the 9-item shared decision-making questionnaire. *Health Expect* 2015;18:2143–53 <https://pubmed.ncbi.nlm.nih.gov/24593044/>
 - 49 Kriston L, Scholl I, Hölzel L, *et al.* The 9-item shared decision making questionnaire (SDM-Q-9): development and psychometric properties in a primary care sample. *Patient Educ Couns* 2010;80:94–9 <https://pubmed.ncbi.nlm.nih.gov/19879711/>
 - 50 Brédart A, Anot A, Young T, *et al.* Phase III study of the European organisation for research and treatment of cancer satisfaction with cancer care core questionnaire (EORTC PATSAT-C33) and specific complementary outpatient module (EORTC OUT-PATSAT7). *Eur J Cancer Care* 2018;27:e12786 <https://pubmed.ncbi.nlm.nih.gov/29094784/>
 - 51 Brédart A, Beaudeau A, Young T, *et al.* The European organization for research and treatment of cancer - satisfaction with cancer care questionnaire: revision and extended application development. *Psychooncology* 2017;26:400–4 <https://pubmed.ncbi.nlm.nih.gov/27546090/>
 - 52 Brédart A, Bottomley A, Blazeby JM, *et al.* An international prospective study of the EORTC cancer in-patient satisfaction with care measure (EORTC IN-PATSAT32). *Eur J Cancer* 2005;41:2120–31 <https://pubmed.ncbi.nlm.nih.gov/16182120/>
 - 53 Neijenhuis KI, Jansen F, Aaronson NK, *et al.* A systematic review of the measurement properties of the European organisation for research and treatment of cancer in-patient satisfaction with care

- questionnaire, the EORTC IN-PATSAT32. *Support Care Cancer* 2018;26:2551–60 <https://pubmed.ncbi.nlm.nih.gov/29732482/>
- 54 Berenguera A, Fernández MJ, Pons M. *Escuchar, observar Y comprender. Recuperando La narrativa en las Ciencias de la Salud. Aportaciones de la investigación cualitativa*. 1st ed. Barcelona: Institut Universitari d'Investigació en Atenció Primària Jordi Gol, 2014.
 - 55 Ruíz Olabuénaga Jde DU, ed. *Metodología de la investigación cualitativa*. Bilbao, 1995: 112–3.
 - 56 Teddlie C, Yu F. *Mixed methods sampling. A typology with examples*. Baton Rouge: Sage Publications, 2007: 1. 77–100.
 - 57 Green JTN. Interviews I-deph. In: *Qualitative methods for health research*. 4th ed. London: SAGE Publications Ltd, 2018.
 - 58 Braun V, Clarke V. To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales. *Qual Res Sport Exerc Health* 2021;13:201–16.
 - 59 Jefferson G. Glossary of transcript symbols with an introduction. In: *Conversation analysis studies from the first generation*. Amsterdam: Publishing JB, 2004: 13–31.
 - 60 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101 <https://www.tandfonline.com/doi/abs/>
 - 61 The Helsinki Declaration of the World Medical Association (WMA). Ethical principles of medical research involving human subjects. Available: <https://pubmed.ncbi.nlm.nih.gov/24964504/> [Accessed 6 Jul 2021].

ANNEX

Annex I. Search strategy

EMBASE Ovid Embase

- 1 exp patient satisfaction/
- 2 satisfaction.ti,ab.
- 3 satisfied.ti,ab.
- 4 patient experience.ti.
- 5 patients experience.ti.
- 6 participant experience.ti.
- 7 participants experience.ti.
- 8 preference*.ti.
- 9 discomfort.ti,ab.
- 10 burdensome.ti,ab.
- 11 acceptab*.ti.
- 12 willing*.ti.
- 13 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
- 14 exp screening/
- 15 exp early diagnosis/
- 16 screening.ti,ab.
- 17 early detection.ti.
- 18 14 or 15 or 16 or 17
- 19 exp colorectal cancer/
- 20 exp colonoscopy/
- 21 colorectal.ti.
- 22 f?ecal occult blood test.ti,ab.
- 23 f?ecal immunochemical test.ti,ab.
- 24 stool.ti,ab.

25 FOBT.ti,ab.
26 gFOBT.ti,ab.
27 colonoscop*.ti,ab.
28 colonography.ti,ab.
29 sigmoidoscopy.ti,ab.
30 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29
31 13 and 18 and 30
32 exp psychometry/
33 exp patient health questionnaire/
34 exp validation study/
35 questionnaire*.ti,ab.
36 psychometr*.ti,ab.
37 measure.ti,ab.
38 measures.ti,ab.
39 instrument*.ti,ab.
40 tool.ti,ab.
41 tools.ti,ab.
42 item.ti,ab.
43 items.ti,ab.
44 scale.ti,ab.
45 scales.ti,ab.
46 subscale*.ti,ab.
47 validation.ti,ab.
48 validity.ti,ab.
49 reliability.ti,ab.
50 internal consistency.ti,ab.
51 convergent.ti,ab.
52 discrimina*.ti,ab.

- 53 construct.ti,ab.
- 54 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46
or 47 or 48 or 49 or 50 or 51 or 52 or 53
- 55 31 and 54 (608) [hits related to instruments]
- 56 31 not 55 (610) [hits related to satisfaction as a measurable domain]

MEDLINE (PubMed)

- #1 "Patient Satisfaction"[Mesh]
- #2 "Patient Acceptance of Health Care"[Majr]
- #3 satisfaction[tiab]
- #4 satisfied[tiab]
- #5 patient experience[tiab]
- #6 patients experience[tiab]
- #7 participant experience[tiab]
- #8 participants experience[tiab]
- #9 experience*[ti]
- #10 preference*[ti]
- #11 discomfort[tiab]
- #12 burdensome[tiab]
- #13 acceptab*[tiab]
- #14 willing*[tiab]
- #15 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12
OR #13 OR #14
- #16 "Mass Screening"[Mesh]
- #17 "Early Detection of Cancer"[Mesh]
- #18 screening[tiab]
- #19 early detection[ti]
- #20 #16 OR #17 OR #18 OR #19

- #21 "Colorectal Neoplasms"[Mesh]
- #22 "Colonoscopy"[Mesh]
- #23 colorectal[ti]
- #24 fecal immunochemical test[tiab]
- #25 faecal immunochemical test[tiab]
- #26 fecal occult blood test[tiab]
- #27 stool[tiab]
- #28 FOBT[tiab]
- #29 gFOBT[tiab]
- #30 colonoscop*[tiab]
- #31 colonography[tiab]
- #32 sigmoidoscopy[tiab]
- #33 #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32
- #34 #15 AND #20 AND #33
- #35 "PSYCHOMETRICS"[Mesh]
- #36 "Patient Health Questionnaire"[Mesh]
- #37 "Behavior Rating Scale"[Mesh]
- #38 "Patient Reported Outcome Measures"[Mesh]
- #39 "Validation Studies"[pt]
- #40 questionnaire*[tiab]
- #41 psychometr*[tiab]
- #42 measure[tiab]
- #43 measures[tiab]
- #44 instrument*[tiab]
- #45 tool[tiab]
- #46 tools[tiab]
- #47 item[tiab]
- #48 items[tiab]

- #49 scale[tiab]
- #50 scales[tiab]
- #51 subscale*[tiab]
- #52 validation[tiab]
- #53 validity[tiab]
- #54 reliability[tiab]
- #55 internal consistency[tiab]
- #56 convergent[tiab]
- #57 discrimina*[tiab]
- #58 construct[tiab]
- #59 #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58
- #60 #34 AND #59 780 [hits related to instruments]
- #61 #34 NOT #59 1830 [hits related to satisfaction as a measurable domain]

PsycINFO PsycNET

- #1 Index Terms: {Satisfaction} OR {Client Satisfaction} OR {Consumer Satisfaction} OR {Job Satisfaction} OR {Life Satisfaction} OR {Marital Satisfaction} OR {Need Satisfaction} OR {Relationship Satisfaction} OR {Role Satisfaction} OR {Sexual Satisfaction}
- #2 Title: satisfaction OR Title: satisfied OR Abstract: satisfaction OR Abstract: satisfied
- #3 Title: patient experience OR Title: patients experience OR Title: participant experience OR Title: participants experience
- #4 Title: preference*
- #5 Title: discomfort OR Abstract: discomfort
- #6 Title: burdensome OR Abstract: burdensome
- #7 Title: acceptab*
- #8 Title: willing*
- #9 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8

- #10 Index Terms: {Health Screening} OR {Health Promotion}
- #11 Title: screening OR Abstract: screening
- #12 Title: early detection
- #13 #11 OR #12 OR #13
- #14 Title: colorectal
- #15 Title: "fecal occult blood test" OR Title: "faecal occult blood test" OR Abstract: "fecal occult blood test" OR Abstract: "faecal occult blood test"
- #16 Title: "fecal immunochemical test" OR Title: "faecal immunochemical test" OR Abstract: "fecal immunochemical test" OR Abstract: "faecal immunochemical test"
- #17 Title: stool OR Abstract: stool
- #18 Title: FOBT OR Title: gFOBT OR Abstract: FOBT OR Abstract: gFOBT
- #19 Title: colonoscop* OR Title: colonography OR Title: sigmoidoscopy OR Abstract: colonoscop* OR Abstract: colonography OR Abstract: sigmoidoscopy
- #20 #14 OR #15 OR #16 OR #17 OR #18 OR #19
- #21 #9 AND #13 AND #
- #22 Index Terms: {Questionnaires} OR Index Terms: {Test Construction}
- #23 Title: questionnaire* OR Abstract: questionnaire*
- #24 Title: psychometr* OR Abstract: psychometr*
- #25 Title: measure OR Title: measures OR Abstract: measure OR Abstract: measures
- #26 Title: instrument* OR Abstract: instrument*
- #27 Title: tool OR Title: tools OR Title: item OR Title: items OR Title: subscale* OR Abstract: tool OR Abstract: tools OR Abstract: item OR Abstract: items OR Abstract: subscale*
- #28 Title: validation OR Title: validity OR Abstract: validation OR Abstract: validity
- #29 Title: reliability OR Abstract: reliability
- #30 Title: "internal consistency" OR Abstract: "internal consistency"
- #31 Title: convergent OR Abstract: convergent
- #32 Abstract: discrimina* OR Abstract: discrimina*
- #33 Title: construct OR Abstract: construct
- #34 #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33

#35 #21 AND #34 26 [hits related to instruments]

#36 #21 NOT #35 49 [hits related to satisfaction as a measurable domain]

CINAHL EBSCOHost

S1 (MH "Consumer Satisfaction+")

S2 TI satisfaction OR AB satisfaction

S3 TI satisfied OR AB satisfied

S4 TI patient experience OR TI patients experience OR TI participant experience OR TI participants experience

S5 TI preference*

S6 TI discomfort OR AB discomfort

S7 TI burdensome OR AB burdensome

S8 TI acceptab*

S9 TI willing*

S10 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9

S11 (MH "Health Screening+")

S12 TI screening OR AB screening

S13 TI early detection

S14 S11 OR S12 OR S13

S15 (MH "Colorectal Neoplasms+")

S16 (MH "Colonoscopy+")

S17 (MH "Sigmoidoscopy")

S18 TI colorectal

S19 TI faecal occult blood test OR AB faecal occult blood test OR TI fecal occult blood test OR AB fecal occult blood test

S20 TI faecal immunochemical test OR AB faecal immunochemical test OR TI fecal immunochemical test OR AB faecal immunochemical test

S21 TI stool OR AB stool

S22 TI FOBT OR AB FOBT OR TI gFOBT OR AB gFOBT

S23 TI colonoscop* OR AB colonoscop*

- S24 TI colonography OR AB colonography
- S25 TI sigmoidoscopy OR AB sigmoidoscopy
- S26 S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25
- S27 S10 AND S14 AND S26
- S28 (MH "Psychometrics")
- S29 (MH "Questionnaires+")
- S30 (MH "Validation Studies")
- S31 TI questionnaire* OR AB questionnaire*
- S32 TI psychometr* OR AB psychometr*
- S33 TI measure OR AB measure OR TI measures OR AB measures
- S34 TI instrument* OR AB instrument*
- S35 TI tool OR TI tools OR AB tool OR AB tools
- S36 TI item OR TI items OR AB item OR AB items
- S37 TI scale OR TI scales OR AB scale OR AB scales OR TI subscale* OR AB subscale*
- S38 TI validation OR AB validation
- S39 TI validity OR AB validity
- S40 TI reliability OR AB reliability
- S41 TI internal consistency OR AB internal consistency
- S42 TI convergent OR AB convergent
- S43 TI discrimina* OR AB discrimina*
- S44 TI construct OR AB construct
- S45 S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38
OR S39 OR S40 OR S41 OR S42 OR S43 OR S44
- S46 S27 AND S45 166 [hits related to instruments]
- S47 S27 NOT S46 148 [hits related to satisfaction as a measurable domain]

Annex II. Scoring of questionnaires

CollaboRATE: This questionnaire consists of three questions with a score ranging from 0 to 9 for each one. The **CollaboRATE** Score should only be calculated when all three **CollaboRATE** items have been completed for at least 25 clinical encounters for each group of interest. Two scores can be obtained¹:

- a. The CollaboRATE mean score: a continuous variable from 0 to 9. After excluding cases where a response to one or more questions is missing, the mean of the three CollaboRATE responses is calculated for each encounter. Then, the mean of all encounters is calculated. Higher scores represent more shared decision-making.
- b. The CollaboRATE top score: a continuous variable from 0 to 100. After excluding cases where a response to one or more of the collaborate questions is missing, each encounter is coded as either "1" if the response to all three collaborate items is 9, or "0" if the response to any of the three CollaboRATE items is less than 9. Then, the percentage of all encounters that are coded as "1" is calculated. Higher scores represent more shared decision-making. This number also corresponds to the proportion of patients for whom there was 'gold standard' shared decision-making.

SDM-Q-9: This instrument consists of nine statements, which can be rated on a six-point scale from "completely disagree" (0) to "completely agree". We will add up all the items to a raw total score between 0 and 45. The authors of SDM-Q-9 suggest the imputation of up to two missing items using the mean of the items that were

¹ Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: A fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns*. 2013;93(1):102-107. doi:10.1016/j.pec.2013.05.009

filled out to calculate the raw score if required². No total score should be calculated if more than two items are missing. Multiplication of the raw score by 20/9 provides a score forced (transformed) to range from 0 to 100, where 0 indicates the lowest possible level of SDM and 100 indicates the highest extent of SDM.

PATSAT-C33 and OUT-PATSAT7: The instrument consists of four scales, each one with statements that can be rated on a five-point scale from “poor” (1) to “excellent” (5). The raw scores (from 1 to 5) for the individual items within a scale will first be added up, and then, for the multi-item scales, divided by the number of items in the scale. These scale scores will be linearly transformed so that all scales range from 0 to 100, with a higher scale score representing a higher level of satisfaction with care.

² Kriston L, Scholl I, Hölzel L, Simon D, Loh A, Härter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Educ Couns*. 2010;80(1):94-99. doi:10.1016/j.pec.2009.09.034

Annex III. Study variables

1. Patient identification number
2. Hospital centre.

Socio-demographic variables

3. Date of birth (dd/mm/yyyy):
4. Gender (F,M):
5. City/town of residence
6. People who live:
 - a. Alone
 - b. With a partner
 - c. With other family members
 - d. With other people
 - e. In a residential centre
7. Education:
 - a. No studies
 - b. Primary studies
 - c. Secondary studies
 - d. High school studies
8. Employment situation:
 - a. Working
 - b. Retired
 - c. Unemployed
 - d. Pension beneficiary
9. Last employment:

Clinical variables

10. Symptoms suggesting colorectal cancer:
 - a. Change in bowel rhythm
 - b. Rectal bleeding
 - c. Abdominal pain
 - d. Weight loss
 - e. Rectal tenesmus
 - f. Anal pain
 - g. Iron deficiency anaemia

11. Personal history of:
 - a. Colorectal cancer
-Date of diagnosis
 - b. Colorectal polyps
 - c. Ulcerative colitis
 - d. Crohn's disease
 - e. Other cancers:
-which ones and date of diagnosis
12. Comorbidities:
13. Previous diagnostic tests :
 - Colonoscopy. Date.
 - CT-colonography. Date.
 - Barium enema. Date.
 - Sigmoidoscopy. Date.
 - Stool blood test. Date.
14. Past participation in the colorectal cancer screening program.
15. Family history of cancer:
 - Colorectal cancer
-family member and age at diagnosis
 - For each cancer:
-family member and age at diagnosis
16. Date of first colonoscopy (dd/mm/yyyy)
17. Centre in which the colonoscopy is performed
18. Number of colonoscopies conducted in the current screening round
-Date of colonoscopies
19. Reason to repeat the colonoscopy:
 - bad bowel cleansing
 - piecemeal polyp resection
 - other: specify
20. Bowel cleansing preparation used:
 - Moviprep®
 - Bohm®
 - Citrafleet®
 - Lainco®
 - Casenglicol®
 - Enema

- Fosfosoda®
- Klean-Prep®
- Nulitely®
- Pleinvue®
- 21 Use of other laxative
- 22 Maximum insertion
- 23. Bowel cleansing (Boston scale): X-X-X
- 24. Withdrawal time (in minutes):
- 25. Additional diagnostic tests and date:
 - CT-colonography. Date.
 - Barium enema. Date.
 - Sigmoidoscopy. Date.
- 26. Complications of colonoscopy in the first 30 days.
 - bleeding
 - bowel perforation
 - cardio-respiratory complications
 - other
- 27. If any complication, what was the consequence?
 - hospital admission ≤3 nights
 - hospital admission from 4 to 10 nights
 - long hospital admission > 10 nights
 - admission to ICU >1 night
 - surgery
 - medical consultation
 - death
 - permanent disability (specify)
 - interrupted colonoscopy due to adverse event
 - interventionist radiology due to adverse event
 - Repetition of colonoscopy due to adverse event
 - respiratory support
 - transfusion
- 28. Final diagnosis of screening:
 - Normal colonoscopy
 - Hyperplastic or inflammatory polyps.
 - High risk lesion
 - Intermediate risk lesion
 - Low risk lesion
 - Polyposis
 - Colorectal cancer

Only for colorectal cancer:

- 29 Pathologic stage (TNM classification)
 - If neoadjuvant treatment, identify yp
- 30. Clinical stage (TNM classification) in case of neoadjuvancy
- 31. Treatment
 - endoscopic resection only
 - surgery
 - surgery + adjuvant chemotherapy
 - surgery + adjuvant radiotherapy
 - surgery + chemotherapy + radiotherapy
 - neoadjuvant chemo/radiotherapy + surgery
 - neoadjuvant chemo/radiotherapy + surgery + adjuvant chemotherapy
 - radiotherapy
 - chemotherapy
 - chemo/radiotherapy

Care process variables

- 32. Date of faecal blood test analysis.
- 33. Date of pre-colonoscopy nurse visit
- 34. Date of first colonoscopy
- 35. Date of pathology report
- 36. Date of result-communication visit
- In colorectal cancer:
- 37. Date of presentation to the tumour committee
- 38. Date of first medical visit after extension study
- 39. Date of first treatment
- 40. Treatment centre

Scores of questionnaires (see Annex II)

Annex IV: Statistical analysis

Bivariate analysis:

For categorical variables, we will use cross tables and χ^2 test or F-Fisher when necessary. For quantitative variables, we will use the Student's t-test (or U Mann-Whitney for variables with no normal distribution) to compare means between two groups and the ANOVA test (or Kruskal-Wallis for variables with no normal distribution) to compare means between more than two groups. A two-sided alpha level of 0.05 will be considered statistically significant.

Multivariate analysis:

In addition to the analysis proposed for the main variable, we will also perform a logistic regression analysis to determine which covariates are associated with: 1. Proportion of patients that are satisfied according to the PREM-satisfaction; 2. Rating of shared decision-making according the SDM-Q-9 (ordinal logistic regression); 3. Satisfaction with cancer care according to PATSAT-C33 and OUT-PATSAT7. In all cases, we will consider as covariables those that were statistically significant in the bivariate analysis at p value of <0.10 and those that are not, are relevant from a clinical point of view.

Annex V: Interview topic guide

Topic explored	Example of questions	Question order
General Satisfaction	What do you think about your participation in the CRC screening program? Why?	1
Decision Making	What made you decide to participate in the CRC screening Program?	2
	Did you talk to other people (family, friends, GP, pharmacist) about the possibility of participating in the screening Program? Did that influence your decision?	3
Experience: professional dealing	What did you think about the dealing provided by professionals of the screening program? (pharmacists, nurses, endoscopy professionals)	4
Experience: information received	Did you understand everything that these professionals explained to you?	5
	Do you think you have been able to clarify with the different professionals all the doubts that you have had during your participation in the screening Program?	6
Experience: reaction to positive screening result	What did you think when you knew that the screening test result had been positive?	7
Experience: information received	Remember the time you had the visit with the nurse after knowing that the screening test result had been positive. What did you think of that visit? What did you think of the information the nurse gave you? Did you miss something?	8
	Do you think you could ask anything you wanted? Were you able to clear up any doubts you might have?	9
Decision making	You decided to have the colonoscopy; what was the most influential to decide to do it?	10
Experience: colonoscopy	Think about the day you underwent the colonoscopy. How was that day?	
Experience: information received	Once you know what a colonoscopy is, what information would you like to receive about this procedure?	11
	What do you think of the information you received on your diagnosis and the recommended follow-up? Would you have liked to know anything else?	12
Experience: surveillance	You had a result of (normal colonoscopy/colonoscopy with polyps) and a follow up was recommended to you. What do you think of the recommended follow-up?	13
	Do you remember anything in particular about your participation in the CRC screening program that you have experienced especially badly? And especially good?	14
Experience: waiting times	Is there a time that has been especially long during your participation in the CRC screening program?	15
Closing question	How do you rate your participation in the Program? Has it been as expected?	16

