

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

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## 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.<sup>1</sup> Its survival depends on tumour stage at diagnosis, which is around 56%–57% at 5 years.<sup>2</sup> That is why early detection of CRC using screening strategies can reduce the burden of this disease.<sup>3,4</sup>

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

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.<sup>12 13</sup> 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.

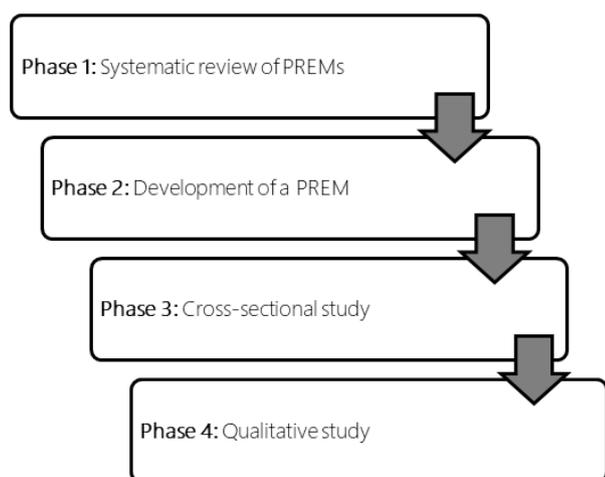
### Patient experience and satisfaction

Only when screening programmes have high participation do they achieve their expected efficacy and impact.<sup>5</sup> 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.<sup>14-16</sup> Similarly, in breast cancer screening, women's satisfaction with the screening process is related to good adherence to the programme.<sup>17-20</sup> 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.<sup>21 22</sup> Patient experience refers to how patients perceive the medical care received. However, patient satisfaction implies a subjective evaluation or rating of that experience,<sup>21</sup> comparing it to with previous patient expectations.<sup>22 23</sup> 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.<sup>21 24</sup>

### 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.<sup>25 26</sup>



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

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.<sup>27</sup> 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.<sup>28</sup> Shared decision-making processes must be individualised, since patients' preferences are not homogeneous and depend on personal factors such as age or gender.<sup>29</sup>

Published studies on patient satisfaction with CRC screening have focused mainly on some specific aspects of the whole screening process: the screening test used,<sup>30</sup> the conducting of a colonoscopy<sup>31 32</sup> or the most initial part of the screening process (invitation to and conducting of a screening test).<sup>33</sup> 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 study<sup>34</sup> 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,

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 CoConsensus-based Standards for the selection of health Measurement Instruments (COSMIN) methodology<sup>35 36</sup> and will report the results following the preferred reporting items for systematic review and meta-analysis statement.<sup>37</sup>

#### **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 checklist<sup>38</sup> and will rate the result of each measurement property against the updated criteria for good measurement properties based on Terwee *et al*<sup>39</sup> and Prinsen *et al*.<sup>40</sup> 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.

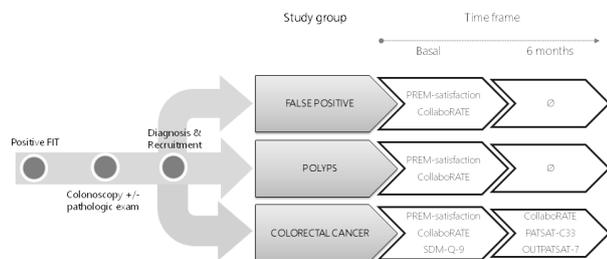
### **Phase 2: development of a patient-reported experience measure (PREM) questionnaire**

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.<sup>41–43</sup> 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 classification<sup>44</sup>). **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<sup>45–47</sup> and the 9-item Shared Decision-Making Questionnaire (SDM-Q-9),<sup>48 49</sup> 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)<sup>50 51</sup> for measuring patient

satisfaction with care delivery, two questionnaires based on the validated questionnaire IN-PATSAT32<sup>52 53</sup> 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  $\chi^2$  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  $\chi^2$  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).<sup>54</sup>

##### 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.<sup>54-56</sup> 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.<sup>54 57</sup> 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.<sup>58</sup> Individual interviews will be semistructured, based on an interview guide (online supplemental annex V), audio-taped and transcribed verbatim.<sup>59</sup> 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.<sup>60</sup> 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.<sup>61</sup> 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.

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**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.

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**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).

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