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The CRISP-P study: feasibility of a self-completed colorectal cancer risk prediction tool in primary care

Elena C Harty,[a,*] Jennifer G McIntosh,[a] Adrian Bickerstaffe,[b] Nadira Hewabandu[b] and Jon D Emery[a]

[a]Department of General Practice, Centre for Cancer Research, Faculty of Medicine, Dentistry and Health Sciences, Victorian Comprehensive Cancer Centre, University of Melbourne, Victoria 3010, Australia and [b]Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, University of Melbourne, Victoria 3010, Australia

*Correspondence to Elena C. Harty, Level 10, Victorian Comprehensive Cancer Centre, 305 Grattan Street, Melbourne, Victoria VIC 3000, Australia; E-mail: elenacharty@gmail.com

Abstract

Objective: Australia and New Zealand have the highest incidence of colorectal cancer (CRC) globally. Our research team has developed a CRC risk prediction tool for use in primary care to increase targeted screening. This study, Colorectal cancer RISk Prediction tool – patient ('CRISP-P'), aimed to determine the following to inform a future trial design: (i) the feasibility of self-reporting; (ii) the feasibility of recruitment methods; and (iii) the prevalence of CRC risk.

Methods: Participants aged between 40 and 75 years were recruited consecutively from three primary care waiting rooms. Participants input data into CRISP on a tablet without receiving clinical advice. Feasibility was evaluated using recruitment rate, timely completion, a self-reported 'ease-of-use', score and field notes. Prevalence of CRC risk was calculated using the CRISP model.

Results: Five hundred sixty-one (90%) patients agreed to use the tool and 424 (84%) rated the tool easy to use. Despite this, 41% of people were unable to complete the questions without assistance. Patients who were older, without tertiary education or with English as their second language were more likely to require assistance ($P < 0.001$). Thirty-nine percent of patients were low risk, 58% at slightly increased and 2.4% were at moderately increased risk of developing colorectal cancer in the next 5 years.

Conclusions: The tool was perceived as easy to use, although older, less educated people, and patients with English as their second language needed help. The data support the recruitment methods but not the use of a self-completed tool for an efficacy trial.

Key Words: family practice, general practice, humans, primary health care, self-report, tablets

Introduction

Australia and New Zealand have the highest incidence of colorectal cancer (CRC) in the world (1). In 2006, Australia started a free population–based screening program (the National Bowel Cancer Screening Program: NBCSP) providing a postal immunochemical faecal occult blood test (iFOBT) kit for all people aged 50 to 74 years old (2). In addition, clinical guidelines recommend screening based on individual family history and age (3). Despite the screening program and the guidelines, the NBCSP has a low uptake with only 41% of people returning completed kits (4). Further to this, many people who are at average risk of developing CRC are having more invasive and expensive colonoscopic screening instead of the iFOBT as per the

Key Messages

- It is not feasible for patients to self-complete CRISP without assistance.
- Older, less-educated and people with English as a second language needed help.
- High recruitment rate and timely completion suggest the methods are feasible.

recommendations (5, 6). Implementing risk-stratified screening provides a solution to reduce under-screening and over-screening, while still optimizing the early detection of CRC (7, 8).

An Australian CRC risk prediction tool—CRISP (Colorectal cancer RISk Prediction tool)—has been developed for use in primary care to increase risk-appropriate screening. CRISP is a web-based questionnaire that captures behavioural, environmental and family history risk factors. CRISP combines these risk factors, produces an absolute risk score and provides screening advice based on this risk score (9). CRISP was developed according to the Medical Research Council Guidelines for the development of complex interventions (10). This included gathering evidence (7), piloting a prototype tool (11), trialling methods for an efficacy trial (12) and conducting an efficacy trial (13).

In reference to the Normalization Process Theory implementation framework (14) the CRISP pilot identified barriers to implementation (11). Although CRISP was acceptable to general practitioners (GPs), they did not have enough time during a standard consultation to complete the tool (11). The pilot also reported that GPs did not always assess their patient's risk accurately and often overestimated the risk of their patient population leading to increased referral for colonoscopy (11). Lack of time is a common barrier to implementing novel interventions in primary care (15, 16). Utilizing waiting room time for patients to self-complete CRISP could overcome this barrier. This allows more time in the consultation for the GP to focus on a discussion with the patient about appropriate CRC screening (17–20). Additionally, understanding the proportion of patients at low, average and moderately increased risk will be important data for the trial design.

The CRISP-P (Colorectal cancer RISk Prediction-Patient) study aimed to determine: (i) the feasibility of self-reporting as a part of intervention optimization; (ii) the feasibility of recruitment methods to inform a future trial design; and (iii) to estimate the prevalence of CRC risk, being important data for the trial design. CRISP-P specifically explored if it was feasible for patients between the age of 40 and 75 to enter their data in to the CRISP tool without assistance while waiting for their appointment.

Methods

Study design

This mixed methods study involved collecting observational and descriptive data to explore the feasibility of patients completing the CRISP risk tool in the waiting room prior to their doctor's appointment. Patients were recruited consecutively from three Melbourne primary care waiting rooms between May and August 2017 and invited to complete the risk tool while they waited for their appointment. One research assistant collected all the data.

This project received approval from the University of Melbourne Human Research Ethics Committee (ID: 1749281).

Study population

Three busy Melbourne clinics were recruited based on their high throughput of patients, locations and range of socioeconomic status. Eligible patients were aged between 40 and 75 who were waiting for an appointment with their GP, able to understand written and spoken English, competent to consent, and were well enough to complete the tool. People with a history of CRC were excluded from the study. As this was a pretrial mixed methods study to test trial feasibility, a formal sample size calculation was not appropriate. The final sample size was pragmatic, and related to the feasibility of recruitment.

Data collection

Recruited patients self-completed the questionnaire on a touchscreen tablet (Supplementary Material A). Minimal guidance was given by the researcher. Patients did not receive their risk information or any screening advice. Quantitative data included the number of eligible people recruited into the study, demographics, the proportion of people who completed CRISP before their doctor's appointment, the number of people who needed assistance and a self-reported 'ease-of-use' 5-point Likert scale ('really difficulty to use' to 'very simple to use').

Qualitative data were collected as field notes. Detailed notes were recorded by the researcher at the time documenting each participant's interaction with the tool including when and why they needed assistance.

Analysis

Feasibility of patients completing the tool was evaluated by the proportion of people who consented to the study, completed the data entry in time, and the 'ease-of-use' score. The number of people who required help completing the tool was calculated from the field notes. The qualitative data included detailed field notes taken by the researcher and described who needed assistance and why. The field notes were analysed for common themes. The mixed methods analysis allowed: (i) a description of the people who could use the self-completed tool; and (ii) an insight into how the tool could be optimized to enhance self-completion. As a result, the tool and methodology could be improved prior to a randomized control trial.

The CRISP algorithm was used to determine each patient's CRC risk (9). Prevalence estimates for each risk category were as follows: 'Low risk' was for an absolute 5-year risk of less than 0.33% 'average or slightly increased risk' was defined a 5-year risk greater than 0.33% and less than 2.5% and 'moderately increased risk' was an absolute 5-year risk greater than 2.5%. The risk thresholds were based on those set by the National Health and Medical Research Council recommendations (3).

Screening behaviour was assessed as 'appropriate' if the most recent screening test was consistent with the current guidelines. Appropriate screening in this study was defined as participants under 50 having no screening unless they reached the 0.33% risk threshold, and participants 50 and over screening with an iFOBT every 2 years. Any participant that reached the threshold of 2.5% or more should have had a screening colonoscopy. Inappropriate screening was considered as more or less screening than the guidelines recommend (3). All analyses were performed using STATA

Version 15 (21). Data were not collected from patients that did not complete the tool; hence, there were no missing data.

Results

Participants

Recruitment occurred in May 2017 to August 2017. Three primary care clinics were recruited from different socio-economic areas in Melbourne Australia. From 707 people in the age group, 626 were eligible for the study and 560 (90%) consented (Fig. 1 and Table 1).

Feasibility

Out of 560 people recruited, 503 (90%) successfully completed the data entry in the time prior to being called into their consultation. Self-reported ease-of-use was high, 424 (84%) of patients found the tool 'very simple' or 'simple' to use and only 55 people (11%) found CRISP 'very difficult to use' or 'difficult to use'. However, 206 of 503 participants (41%) were unable to complete the CRISP tool without help. Older age ($P < 0.001$), less education ($P = 0.04$) and English as a second language ($P < 0.001$) were associated with requiring assistance (Table 2).

Thematic analysis of the field notes identified three barriers to completing the data entry without some assistance, these included: (i) question comprehension, (ii) self-reported health, and (iii) technology capability.

(i) Question comprehension

Patients either misunderstood questions or specifically asked for help interpreting the questions. Question one was often misunderstood with 47 out of 503 participants (9%) understanding the question: 'Have you had a previous CRC diagnosis', as 'Have you had any previous diagnostic testing for CRC'. Often they ticked 'yes' thinking they were being asked about being *investigated* rather than *diagnosed* for CRC.

> "*Yes, I have had a colonoscopy, so yes.* " [Clinic 2, male, 57 years]

Participants with a history of smoking (13 out of 256, 5%) did not understand the smoking questions, which were designed to determine pack-years smoked.

> "*Does this mean have I ever smoked, or currently smoke?*" [Clinic 3, female, 60 years]

Twenty-four participants (5%) asked the researcher to clarify what an iFOBT or colonoscopy was.

> "*Is that the one they send in the mail?*" [Clinic 3, male, 74 years] and "*Is that the poo test, oh yes I have done that*." [Clinic 2, male, 72 years]

Twenty-one participants (4%) did not know which medications were aspirin-based.

> '*…does aspirin include Panadol?*' [Clinic 2, female, 40 years] and '*…is panadeine forte an NSAID?*' [Clinic 2, female, 50 years]

(ii) Self-reported measures

Thirty-one participants (6%) did not know their height or weight (or both).

> '*Does 166cm sound, right?', 'I think it is 164cm…No idea…*' [Clinic 1, male 52 years] and
> '*I don't know when I last weighed myself…*' [Clinic 1, female, 50 years]

Seventeen of the 70 (24%) women on hormone replacement therapy did not know which hormones they were on.

> *'I don't know if it was oestrogen, or progesterone, or both, I think Mirena…*' [Clinic 2, female, 55 years]

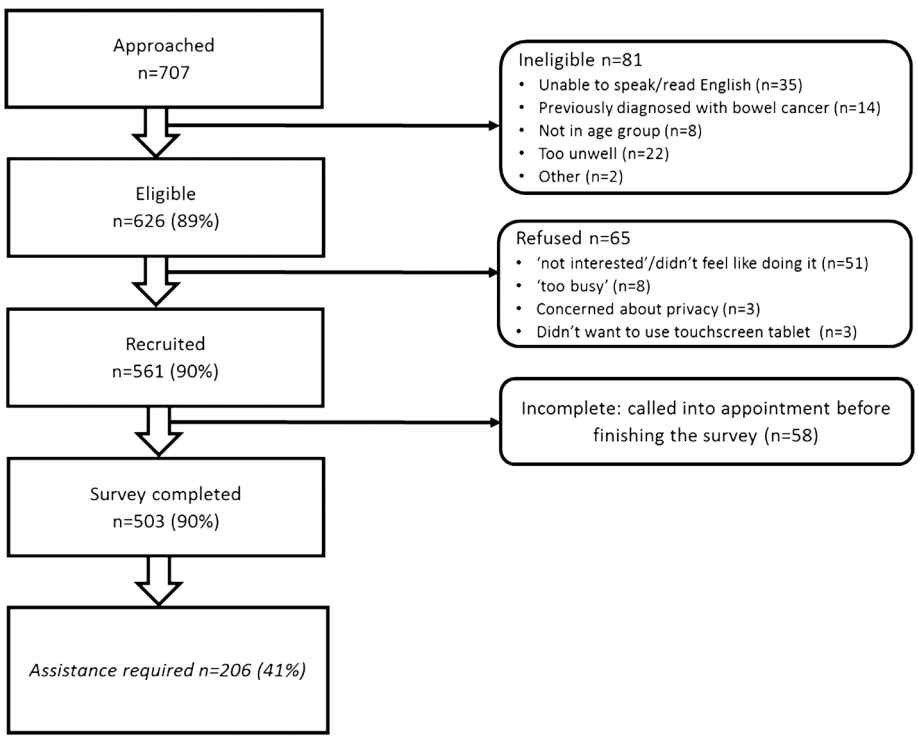

Figure 1. Patients recruited from May 2017 to August 2017 from three Melbourne General Practice Clinics.

Table 1. Description of the sample recruited from May 2017 to August 2017 from three Melbourne General Practice clinics

Demographic characteristic	Clinic 1 *n* (%)	Clinic 2 *n* (%)	Clinic 3 *n* (%)	Total *n* (%)
Age (years)				
40–50	38 (24)	51 (28)	49 (30)	138 (27)
50–60	61 (39)	61 (34)	42 (25)	164 (33)
60–70	42 (27)	41 (23)	40 (24)	123 (24)
70–74	15 (10)	28 (15)	35 (21)	78 (16)
Sex				
Male	70 (45)	77 (43)	71 (43)	218 (43)
Female	86 (55)	104 (57)	95 (57)	285 (57)
Education				
<Bachelor degree	116 (74)	112 (62)	69 (42)	297 (59)
≥Bachelor degree	30 (20)	63 (35)	85 (51)	178 (35)
Missing	10 (6)	6 (3)	12 (7)	28 (6)
English as a second language				
No	111 (71)	144 (80)	143 (86)	398 (79)
Yes	45 (29)	37 (20)	23 (14)	105 (21)
Family history of CRC[a]				
No	16 (10)	20 (11)	18 (11)	54 (11)
Yes	140 (90)	161 (89)	148 (89)	449 (89)
Total	156 (31)	181 (36)	166 (33)	503 (100)

[a]Family history of CRC is defined as the participant having one or more first degree relative(s) diagnosed with CRC.

Table 2. Association between the demographics of participants recruited from May 2017 to August 2017 and needing assistance to complete CRISP in three Melbourne General Practice clinics

	Unadjusted OR[a] (95% CI[b])	*P*	Adjusted OR[c] (95% CI)	*P*
Age (years)				
40–50	1		1	
50–60	2.4 (1.4, 4.1)	<0.001	2.4 (1.4, 4.2)	0.002
60–70	6.0 (3.4, 10.5)	<0.001	5.5 (3.0, 9.9)	<0.001
70–74	10.2 (5.3, 19.4)	<0.001	8.6 (4.3, 17.1)	<0.001
Sex				
Male	1		1	
Female	1.2 (0.8, 1.7)	0.33	1.2 (0.8, 1.8)	0.49
Education				
≥Bachelor degree	1		1	
<Bachelor degree	2.3 (1.6, 3.5)	<0.001	1.9 (1.2, 2.9)	0.004
English as a second language				
No	1		1	
Yes	2.4 (1.6, 3.7)	<0.001	2.7 (1.6, 4.5)	<0.001
Family history of CRC[d]				
No	1		1	
Yes	0.7 (0.4, 1.3)	0.26	0.8 (0.4, 1.5)	0.45

[a]OR = odds ratio.
[b]CI = 95% Confidence Interval.
[c]Adjusted odds ratio: adjusted for age, sex, education, English language, and family history of CRC.
[d]Family history of CRC is defined as the participant having one or more first-degree relatives diagnosed with CRC.

(iii) Technology capability

Three people refused to do the survey as they were not comfortable with using technology and 83 (16%) participants had some difficulty using the technology.

> *"I need a pen to use…old fingers don't work as well!"* [Clinic 1, Male, 72 years] and "*Don't make me do the [touchscreen] it will make my blood pressure go up*!! " [Clinic 2, Female, 72 years]

Prevalence of CRC risk

Most participants (*n* = 293, 63%) were calculated as being at 'average or slightly above average risk', 198 (39%) participants were categorized as being at 'low risk', and 12 (2%) or people at moderately increased risk (Supplementary Material B). Younger participants were more likely to be at 'low risk' (91% of 40–49 year olds were at low risk) and only 12 participants (2%) were at moderately increased risk, 10 of whom were over 70 years old. Thirteen participants aged between 40 and 49 years old were identified as moderately increased risk, and therefore should have undergone screening.

Estimates of the number of participants who had appropriate screening were calculated based on age and risk category. An estimated 63% of participants identified as low risk had inappropriate screening—either unnecessary iFOBT (8%), unnecessary

colonoscopy (23%) or both (32%). Additionally, 81% of participants at average risk had inappropriate screening—unnecessary colonoscopy/iFOBT and colonoscopy (43%) or no screening (38%). Participants at moderately increased risk also had inadequate screening, with 34% having only iFOBT or no screening at all (Table 3).

Discussion

This was a pretrial study of a complex intervention designed to address the following aims: (i) The feasibility of self-reporting as a part of intervention optimization; (ii) The feasibility of recruitment methods to inform a future trial design; and (iii) To estimate the prevalence of CRC risk, important data for the trial design.

Feasibility of CRISP

The CRISP-P study explored the feasibility of primary care patients self-completing CRISP while sitting in the waiting room prior to an appointment with their clinician. The results of this study strongly suggest that it is not feasible for primary care patients to accurately self-complete CRISP without assistance principally because 41% of people who used CRISP required assistance. Importantly, this was more common in people who were older, less educated and had English as a second language. We surmized that for risk based screening advice to be accurate, the CRISP data entry requires some level of assistance.

The CRISP-P results are comparable to other clinical decision support tool studies. Wu et al. explored the experience of patients using a family health history self-collecting tool in primary care ('MeTree©'). Similarly to CRISP-P, older people needed assistance filling out the MeTree risk questions; of the 26% of patients who needed assistance, 77% were over 60 years old (19). In direct contrast to this, the Your Health Snapshot (YHS) study found that older people were more likely to complete the tool without assistance (20). Utilizing the time in the waiting room worked well with CRISP-P but still 10% failed to complete all the questions before being called in to their appointment. In the YHS study, time was a major barrier with 64% of people unable to complete the questions in time (20). Willingness to complete the study was less of a problem for the CRISP-P participants: 90% of eligible patients agreed to do the tool while waiting for their appointment unlike the MeTree and YHS studies which had recruitment rates of 28% and 10%, respectively (19, 20).

This study supports the results from our initial original exploratory research conducted with clinic staff. In a useability study testing the first iteration of CRISP, we found that doctors, nurses and administrative staff did not think that CRISP would be feasible for patients to self-complete. Administrative staff were wary of patients self-completing CRISP as they felt the responsibility of answering patients' questions would fall to them (11). This is supported by a recent systematic review that reported that risk tool uptake is substantially increased with a dedicated research assistant (or clinician) to assist with the risk tool (7). In the final CRISP trial, we therefore elected not to attempt patient self-completion but to incorporate data entry as part of the trial consultation with the research nurse.

The recruitment of patients from the waiting room was very successful and supports the recruitment process for a randomized controlled trial to test the efficacy of the CRISP tool in general practice. The time prior to the doctor's appointment was adequate to complete the recruitment and the tool without disrupting the clinical flow. This is consistent with other trials conducted in general practice (22) and reinforces our decision to recruit patients from the waiting room for our efficacy trial (13).

Prevalence of CRC risk

The CRISP-P study has provided the first opportunity to estimate the distribution of CRC risk using the CRISP model on an Australian primary care population.

Using the predefined threshold for risk, we identified that 13 participants between the age of 40 and 49 years were at moderately increased risk of developing CRC. This demonstrates the potential utility of CRISP in primary care to identify people who are at increased risk and would not be screened until 50 years old through the NBCSP (2). This is particularly important considering the growing incidence of CRC in people below 50 years old (23, 24). Comprehensive risk-stratified screening offers the opportunity to target screening for those who might not be screened using the current guidelines based on their age and family history alone (16).

Most patients in the study either over-screened or under-screened for colorectal cancer. Two-thirds of low-risk participants were being over-screened, 81% of participants at average or slightly increased were being either over or under-screened, and a third of participants at moderately increased risk were being under-screened. The inappropriate screening supports previous findings that patients and GPs do not necessarily follow the guidelines (11), and that it is common for inappropriate screening in the absence of a risk-stratified screening program (5, 25). Currently, we are conducting a randomized controlled trial to test the efficacy of using CRISP in a primary care population (13).

Strengths and limitations

The CRISP-P results were strengthened by having a large sample size (n = 503) from three clinics in very different socio-demographic areas in Melbourne, Australia. The sample included a broad demographic range, in particular, older patients (median age of 57 years), patients who had had less education (59% were not tertiary educated) and patients whose first language was not English (21%). Despite not being representative of the entire Australian population, it was very important to test patient competence to complete CRISP in these more vulnerable populations. In contrast, the MeTree and

Table 3. Current screening behaviour of patients recruited from three Melbourne General Practice Clinics in 2017 and risk groups[a] [*n* (%)]

Absolute risk of developing colorectal cancer in 5 years (%)	iFOBT *n* (%)	Colonoscopy *n* (%)	iFOBT and colonoscopy *n* (%)	No screening *n* (%)	Total
<0.33	15 (8)	41 (23)	59 (32)	67 (37)	182
≥0.33 <0.25	52 (4)	56 (21)	61 (22)	104 (38)	273
≥0.25	2 (17)	5 (41)	3 (25)	2 (17)	12
Total	69	102	123	173	467

[a]Thirty-six people did not know if they had an iFOBT or a colonoscopy.

YHS studies involved more privileged populations. The MeTree participants were highly educated (72% USA 'College' graduates), white (91%), and high income earners (55% earnt more than US$75K per annum) (19), and the YHS participants predominantly white (89%) and most had private health insurance (86%) (20).

Future research and development of risk tools that are direct to consumer should test question comprehension, patient self-health knowledge and technology capacity of the population. To increase accuracy of data input, CRISP and other similar risk tools would benefit from having a member of the clinical team double checking risk information (such as type of medication) from patient records, or better still auto-populating data from patients' records directly into the tool. Having a clinic staff member assisting with the tool also removes the challenge of relying on technology such as touch screens that many people found difficult.

The CRISP-P study has provided important information about the feasibility of using CRISP as a self-completed tool in the waiting rooms of primary care clinics and has provided some of the first prevalence data on CRC risk in the primary care population. The high proportion of both over and under-screening for colorectal cancer supports the implementation of a risk tool in the primary care context to both reduce unnecessary and potential harmful screening and identification of patients who are at increased risk but are not covered by the population-based screening programs offered in Australia.

This research has contributed to the development of the CRISP tool trial, which is currently being tested in an RCT in primary care and has provided essential data to inform future models of implementation of CRISP in primary care.

Supplementary material

Supplementary material is available at *Family Practice* online.

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Declaration

Conflict of interest: none.

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