STRATEGIES TO IMPROVE ADHERENCE TO COLORECTAL CANCER SCREENING

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THESIS

DECLARATIONS

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Date: 1st December 2018

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ACRONYMS

AEC	Australian Electoral Commission
AIHW	Australian Institute of Health and Welfare
ANZCTR	Australian New Zealand Clinical Trials Registry
BEACH	Bettering the Evaluation and Care of Health
CBA	Controlled Before After Study
CCT	Controlled Clinical Trial
CI	Confidence Interval
CRC	Colorectal Cancer
DALY	Disability Adjusted Life Years
EPOC	Effective Practice and Organisation of Care
FAP	Familial Adenomatous Polyposis
FOBT	Faecal Occult Blood Test
gFOBT	Guaiac-based Faecal Occult Blood Test
GP	General Practitioner
HNPCC	Hereditary Nonpolyposis Colorectal Cancer
iFOBT	Immunochemical Faecal Occult Blood Test

ITS	Interrupted Time Series
LOTE	Language Other Than English
NBCSP	National Bowel Cancer Screening Program
NCSR	National Cancer Screening Register
NHMRC	National Health and Medical Research Council
NSW	New South Wales
OR	Odds Ratio
PCP	Primary Care Provider
RACGP	Royal Australian College of General Practitioners
RCT	Randomised Controlled Trial
UK	United Kingdom
USA	United States of America
UTN	Universal Trial Number
YLL	Years of Life Lost

ABSTRACT

Colorectal cancer (CRC) is an important health problem globally and nationally. In Australia, every week, over 300 people are diagnosed with CRC, and 80 will die from this disease. When CRC is detected and treated early, there are high survival rates. CRC is amenable to screening as it has a long latency period during which microscopic traces of blood can be detected using a simple test called a faecal occult blood test (FOBT). To support CRC screening, Australians are offered biennial FOBT through the National Bowel Cancer Screening Program (NBCSP). Despite the proven benefits and accessibility of CRC screening in Australia, only 41% of those invited to screen by the NBCSP return completed FOBTs. Data collected from Australian general-practice- and population-based community surveys also suggest CRC screening rates are low. However, the most recent data were collected in 2011. Additionally, not all research assessed whether screening was adherent to Australian CRC screening guidelines.

Examining correlates of CRC screening behaviour can illuminate which groups are least likely to adhere to screening guidelines. Those in younger age groups, i.e. 50-59 years, are consistently reported to have higher rates of under-screening compared to those in older age groups. However, other correlates of under-screening for CRC vary depending on the source of data. For example, the NBCSP reports higher rates of under-screening for males, a finding that is contrary to general-practice- and population-based community studies which have reported that females are more likely to be under-screened. Ascertaining correlates of under-screening from healthcare settings can contribute to the current body of evidence and may be used to design

targeted interventions to increase CRC screening in those least likely to adhere to guidelines.

General practitioner (GP) endorsement of CRC screening is a positive predictor of screening behaviour, and GPs have a recognised role in promoting preventive health activities, including CRC screening. GPs can be integrated into population-based programs, thus potentially having a positive effect on uptake of screening within the program.

This thesis by publication consists of an introduction, six papers, a discussion of the key findings, implications and future directions, a review of the strengths and limitations of the research, and conclusions. The data-based papers report data collected from healthcare settings. The studies reported in papers 1 to 3 report new cross-sectional data on CRC screening practices of individuals attending these settings, and include both under- and over-screening, as well as knowledge of CRC risk factors and screening recommendations. Paper 4 reports a review of trends in general-practice-based research into CRC screening prevalence, using descriptive or intervention methodology, over time. The studies reported in papers 5 and 6 describe the protocol and delivery of a general-practice-based randomised controlled trial which aims to increase CRC screening uptake.

The results of this thesis suggest that there is an evidence-practice gap for CRC screening adherence in those attending healthcare settings in Australia, with both under- and over-screening reported. Males and those in younger age groups were more likely to report under-screening. Levels of knowledge of CRC risk factors and screening recommendations were low; less than one-third knew the correct age to commence CRC screening, and 40% knew that FOBT was the recommended test. This suggests that strategies may be required to reinforce CRC screening recommendations among patients attending healthcare settings.

A review of the peer-reviewed literature reveals that a high proportion of research effort has consistently been directed toward the evaluation of interventions to increase CRC screening in general practice, using robust study designs. Despite this, under-screening in this setting remains an area requiring improvement, suggesting that future research should focus on effectiveness trials, to determine which interventions are likely to be adopted into routine practice. Finally, we found that an intervention involving GP endorsement, and provision of point-of-care FOBT and printed information significantly increased CRC screening uptake among general practice patients. There is potential for the role of GPs in promoting CRC screening to be better integrated into the NBCSP. Effective general-practice-based interventions could be incorporated into routine practice to boost CRC screening participation rates.

THESIS OVERVIEW

This thesis is comprised of an introduction, six papers and a discussion. All papers have been published in peer-reviewed journals.

The first section of the introduction describes the aetiology, risk factors, incidence, lifetime risk, burden of disease, diagnosis, treatment and survival rates for colorectal cancer (CRC). The second section of the introduction describes the current evidence underpinning CRC screening guidelines, and how these are reflected in the National Bowel Cancer Screening Program (NBCSP). CRC screening data from other sources, including general practice and community settings, are reported. This leads to a commentary on the current evidence for general-practice-based strategies to increase CRC screening. The introduction concludes with the overall objectives of the thesis.

The study reported in paper 1 is a descriptive cross-sectional study of 197 participants, recruited from outpatient clinics of a major regional hospital. The objectives of this study were to examine the proportion of those at average risk of CRC, aged 50-74, who report being under- or over-screened for CRC, and the characteristics associated with under-screening. We also sought to establish the willingness of participants to receive CRC screening advice and the acceptability of different methods of receiving help. Approximately 40% of participants were under-screened for CRC. Of those reporting colonoscopy in the past five years (n=48), 21% (n=10) were potentially over-screened (i.e. they were at average risk and had undertaken colonoscopy for the purpose of screening). Males were more likely to be under-screened than females. Of those

under-screened, less than half were willing to receive screening advice. The majority were most interested in information being mailed to their homes. Papers 1 and 3 reported CRC screening rates that were higher than those reported by the NBCSP. This is most likely due to differences in the denominators used to determine screening uptake in the current study and that used by NBCSP. For example, the NBCSP reports screening uptake for all those invited to screening, some of whom are ineligible for screening, while this study excluded those ineligible for FOBT screening. Further, our study was able to capture screening conducted outside the NBCSP. Finally, we found that mailed CRC screening information is an acceptable method to provide CRC screening advice.

Higher levels of knowledge related to CRC may be associated with positive CRC screening behaviour. The study reported in paper 2 describes participant knowledge of CRC risk factors and CRC screening recommendations among 363 participants, aged 18-85, from five general practices, and the sociodemographic characteristics associated with higher knowledge levels. CRC risk factors were presented as five yes/no options. One-quarter of participants correctly identified all CRC risk factors, while 10% identified none. CRC screening recommendations were presented as four multiple-choice questions. Less than 10% of participants identified all the correct responses. Just over half knew that FOBT was the recommended screening test for those at average risk, and a smaller percentage (41%) could identify the recommended frequency for FOBT testing. Those with a tertiary education were more likely to score highly in both areas. The results suggest that there are gaps in CRC risk factor and

screening knowledge. It may be important for future intervention studies which aim to improve screening uptake to address gaps in knowledge.

To further explore CRC screening behaviour, the study reported in paper 3 presents cross-sectional data from 179 participants from five general practices in New South Wales, Australia. This study examined the proportion of those at average risk of CRC, aged 50-75, who report being under- or over-screened for CRC, the characteristics associated with under-screening, and the source of reported FOBTs. One-third of participants reported being under-screened for CRC. Of those who were up-to-date with screening using FOBT, one-quarter (n=22) reported sourcing this from their GPs. Of those reporting colonoscopy in the previous five years (n=66), 29% (n=19) were potentially over-screened. As age increased, there was less likelihood of under-screening. The findings of this paper suggest, as did those of paper 1, that although under-screening for CRC remains a problem, rates of CRC screening were found to be higher than those reported by the NBCSP. This, again, may be due to differences in denominators and the ability to capture screening occurring outside the NBCSP.

Over time, research efforts should progress from identifying the size of evidence-practice gaps, to strategies to address these gaps. If this occurs, there would be an increase in the number of interventions relative to descriptive research in this area over time. Paper 4 is a critical review which examines the trends in research effort across three lots of three-year time points since 1993. Publications reporting primary

data on CRC screening prevalence in general practice using an observational study design, or reported interventions delivered in general practice where CRC screening was the primary outcome, were included, yielding a total of 102 publications. Of these, 65 reported intervention studies, and 37 reported observational studies. The proportion of each study type did not change significantly over time. The majority of intervention studies met Effective Practice and Organisation of Care (EPOC) design criteria at each time point. Despite a high proportion of intervention studies which used robust study designs, under-screening for CRC in general practice continues. This indicates that further research in general practice is needed to establish interventions that are most likely to be adopted into routine practice.

Papers 5 and 6 describe a protocol and the outcomes, respectively, of a randomised controlled trial (RCT) which is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616001299493). The objectives of paper 6 were to examine, among under-screened general practice patients at average risk of CRC aged 50-74, the effectiveness of provision of point-of-care FOBT, printed CRC screening advice and face-to-face GP endorsement on: a) self-reported FOBT uptake; and b) CRC screening knowledge. The study was a multisite, 1:1 parallel-arm, cluster RCT conducted in four general practices. The intervention significantly increased FOBT uptake in the intervention group. Those in the intervention group were almost eight times more likely to complete FOBT when compared to usual care (39 vs 6%; OR 10.24; 95%CI 2.9-36.6, p=0.0006). The findings of the study reported in paper 6

suggest that general practice interventions may be an important adjunct to the NBCSP to boost CRC screening rates.

The discussion draws together the key findings of the papers within the thesis. Each finding is followed by implications and future directions related to the reported finding. Finding 1 reports rates of under- and over-screening for CRC and recommends that additional strategies are required to identify and address both under- and over-screening. Finding 2 explores correlates of under-screening, and highlights the need for specific intervention strategies for sub-groups that are less likely to be adherent to screening guidelines. Finding 3 reports general-practice-based interventions to improve CRC screening, and includes the effect that a multicomponent general-practice-based intervention, including GP endorsement, point-of-care FOBT and a printed information sheet, has on FOBT uptake. Recommendations for future research, including enhancing current study design and conducting cost analysis, are discussed.

Following this is a review of the strengths and limitations of the papers included within the thesis. Strengths of this thesis include: an updated snapshot of CRC screening behaviour; use of current Australian guidelines to detect under-screening; ability to detect over-screening; and use of an RCT study design to test the intervention. Some limitations are acknowledged: use of convenience samples which may limit the generalisability of findings; a simplified method to determine CRC risk

that may have led to some inaccuracies in risk estimation; and use of self-reported screening data that may have led to reporting bias.

Finally, the discussion concludes by summarising the most important findings of each paper and the overall thesis.

INTRODUCTION

PREVALENCE AND BURDEN OF COLORECTAL CANCER

What is colorectal cancer?

Colorectal cancer (CRC) is any cancer that occurs in the large bowel[1]. CRC generally develops from small benign growths called adenomatous polyps, located in the wall of the large bowel[2]. Adenomatous polyps can, over time, become malignant, with 95% of CRCs arising from these polyps[3]. Malignant CRC has the potential to metastasise, by invading the wall of the bowel and spreading to other parts of the body via the lymphatic system[1].

Morbidity, mortality, and lifetime risk of colorectal cancer in Australia is high

Globally, CRC cancer is the third most common cancer in males and second most common cancer in females, accounting for approximately 10% of all cancers diagnosed (746,000 cases)[4]. Each year there are close to 700,000 deaths from CRC (8.5% of all cancer deaths)[4]. CRC incidence is increasing in developing countries, however there is greater incidence of CRC in developed countries including Australia where it is the second most diagnosed and second most common cause of cancer death[5]. It is estimated that there will be 17,000 new cases of CRC diagnosed in 2018 and over 4,000 deaths from CRC[6]. The incidence of CRC increases exponentially from age 50, with 90% of CRCs being diagnosed in people aged 50 and over[7]. Australians have a lifetime risk of being diagnosed with CRC of 1 in 11 for men and 1 in 15 for women[6].

Burden of disease for colorectal cancer

Of all cancers, CRC accounts for 7.6% of global disability adjusted life years (DALYs)[8]. In 2016, 17.2 million DALYs were attributable to CRC, of which 97% came from years of life lost (YLLs)[9]. Globally, CRC ranks 44th of all disease types in terms of DALYs, and ranks 16th in the Australasian region [8].

CRC ranks 5th in Australia in terms of YLL, with an estimated 86,000 YLL per year[10]. Of all cancers in Australia, CRC has the second highest burden of cancer disease, accounting for 11% of cancer-related DALYs and is the second leading cause of fatal burden, representing 11% of YLL to cancer[11].

Risk factors for colorectal cancer

There is strong evidence that modifiable risk factors including being overweight or obese, red and processed meat consumption, consuming two or more alcoholic drinks per day and smoking tobacco increases the risk of colorectal cancer[12,13]. There is strong evidence that being physically active and consuming high-fibre foods decreases the risk of colorectal cancer[12, 14]. It is estimated that close to half of all CRCs could be avoided by addressing modifiable risk factors[15].

Non-modifiable risk factors include age, gender, history of inflammatory bowel disease and familial risk (genetic factors)[2, 13]. Males and those aged ≥50 have a greater risk of being diagnosed with CRC[6]. Those with inflammatory bowel disease such as Crohn's disease and ulcerative colitis have at least a two-fold increased risk of being diagnosed with CRC, compared to the general population[16]. Approximately 5-10% of CRCs are

caused by genetic abnormalities such as familial adenomatous polyposis (FAP) and hereditary nonpolyposis colorectal cancer (HNPCC), also called Lynch syndrome[17]. Those with FAP have a 100% lifetime risk of CRC, however FAP only accounts for 1% of all CRC[18]. HNPCC accounts for 2-3% of all CRC. The lifetime risk of those diagnosed with HNPCC is 10-47% depending on the particular genetic mutation carried[18].

How is colorectal cancer diagnosed and treated?

CRC is diagnosed via visualisation of the large bowel during colonoscopy and by histologic examination of biopsied tissue. CRC is then staged to determine the severity of disease and the most appropriate treatment pathway[2]. Several staging systems exist around the world, however in Australia, CRC is staged using the Australian Clinico-Pathological Staging system[14]. Stage A refers to cancer that is only found in the bowel wall. Stage B indicates that the cancer has spread to the outer surface of the bowel wall. Stage C represents cancer that has spread to the lymph nodes near the bowel. Stage D is the most advanced form of CRC and is the point where the cancer has metastasised to other organs in the body[1].

In general, Stage A is treated surgically and involves resection and repair of the affected area of bowel[2]. This is often done laparoscopically. Stage B is treated in a similar manner to Stage A, however, more serious cases may require post-surgical adjuvant therapy. Stage C always requires surgical resection and post-surgical adjuvant therapy. Stage D may or may not be amenable to surgical options, however, chemotherapy may be used to prolong survival[2].

The most recent Australian data suggests that those diagnosed at the latest stage (Stage D) have a 7-19% five-year survival rate. This compares to a five-year survival rate of 88-92% for those diagnosed with early stage disease (Stage A)[19, 20]. A large study reviewing 30 years (1980-2010) of CRC treatment and survival at major public hospitals in South Australia showed that just 13% of people were diagnosed at stage A, while 23% were diagnosed at stage D[21]. Stage A is the least costly to treat (~ AU $30,890 per individual). Stage C is the most costly to treat (~AU $74,225 per individual)[22]. Considering these data, early detection and treatment of CRC is advantageous.

SCREENING FOR COLORECTAL CANCER

Evidence-based guidelines recommend use of faecal occult blood testing for colorectal cancer screening

Australian CRC screening guidelines include the National Health and Medical Research Council (NHMRC) '*Clinical practice guidelines for the prevention, early detection and management of colorectal cancer'* [18] and the Royal College of General Practitioners (RACGP) '*Red Book Guidelines for preventive activities in general practice*' [23]. These guidelines make screening recommendations based on age, individual and familial history of CRC. Familial CRC risk can be quantified as: i) *average or slightly above average risk* (herein after referred to as average risk) - no strong personal or family history of CRC or inflammatory bowel disease (95-98% of the population is at average risk); ii) *moderately increased risk* - family history of CRC in one or two close relatives; iii) *potentially high risk* - strong family history of CRC including high risk features such as HNPCC, FAP or cancers of the endometrium, ovary or brain[18, 23]. For

those at moderately or potentially high risk, colonoscopy may be recommended for routine screening and surveillance[18, 23]. For those at average risk of CRC, aged 50-74 with no symptoms suggestive of CRC, a biennial immunochemical faecal occult blood test (iFOBT)[18]. This is in line with recommendations in other countries such as the UK[24] and Canada[25].

Adenomatous polyps and CRCs can have long latency periods during which microscopic traces of blood may be released into faecal matter[2]. FOBT tests faecal matter for these traces[26]. Evidence from several large randomised controlled trials shows that biennial FOBT screening reduces mortality from CRC by 13-33%[27-31]. A review by Hewitson et al. that included a meta-analysis of four large trials (combined n=327,0345) reported that participants attending at least two screening rounds (annual or biennial FOBT) had a 16% relative reduction of CRC mortality[32]. FOBT is an affordable, accessible test that can be performed by an individual in the privacy of their own home and involves obtaining 1-3 samples of faeces and sending these samples to pathology. FOBTs may be guaiac-based (gFOBTs) or immunochemical (iFOBTs)[26]. iFOBTs are a newer test that has demonstrated greater sensitivity when compared to gFOBT[26]. The sensitivity of iFOBT to detect adenomatous polyps and cancer ranges from 60-85%, with higher sensitivity reported where CRC is more advanced[18, 33]. These data highlight the need for recurrent screening (to maximise the opportunity to detect CRC). The specificity for iFOBT is approximately 95%[18]. False-positive results may lead to unnecessary procedures such as colonoscopy and emotional distress due to the possibility of CRC[26].

Positive FOBTs need to be followed up with general practitioners who may recommend additional investigation via colonoscopy, enabling adenomatous polyps or CRC to be directly visualised and removed[18]. In a few international guidelines, colonoscopy is recommended for routine screening[34, 35]. However, CRC screening via colonoscopy is currently not supported by high level evidence from randomised controlled trials[2, 36].

Risks and benefits of screening and informed consent

Screening for CRC has been shown to decrease mortality from this disease. However, the benefits of screening must be considered alongside the risks of screening. A data-linkage study between the NBCSP, cancer registries and national death index reported 83.4% sensitivity and 92.6% specificity for FOBT to detect CRC among 322, 340 NBCSP invitees between 2006-2008[37]. In this study 6.1% (n=256) of those diagnosed with CRC were considered to have 'interval' cancer (occurring within two years of a negative FOBT result) through the program, however, overall the study found a very low rate of false negatives (0.06%). False positive results can cause unnecessary psychological distress and can expose people to unnecessary diagnostic procedures such as colonoscopy which carry risks of bowel perforation, bleeding and complications form anaesthetic[38]. In the aforementioned study, for each 28 people returning positive FOBTs, one was diagnosed with CRC[37]. Considering these facts, it is important that general practitioners inform patients about both risks and benefits to facilitate informed consent. Informed consent, defined as permission granted in full knowledge of the possible consequences of a procedure, stands at the heart of patient-centred care and is ethically underpinned by the individual's right to autonomy[39].

POPULATION-BASED SCREENING PROGRAMS

Population-based screening globally

Originally published in 1968[40], and updated in 2008[41], the World Health Organisation provides guidelines for the key principles and practices of screening for disease. Key principles to identify conditions amenable to population-based screening include: a recognised need for screening, a defined target population, effectiveness of the program based on scientific evidence, equity and access to the entire target population and benefits which outweigh any harms[40, 41].

Across many parts of the world, CRC screening meets these criteria, which has led to the implementation of population-based screening programs[42]. A review of existing CRC screening programs identified 36 population-based screening programs across the world, the majority of which provide iFOBTs for those aged 50 and over[42]. A review of participation rates within fifteen population-based screening programs reported variable participation rates of between 7% (Belgium) to 67.7% (Finland)[43].

Population-based screening in Australia

The National Bowel Cancer Screening Program (NBCSP) is a vehicle to deliver CRC screening to all those in the recommended age range for screening in Australia[44]. The NBCSP is run by the Federal Department of Health and commenced as a pilot project in 2002-2004. Following the pilot phase, the program was introduced on a national level in 2006, initially inviting 50 and 55 year olds to participate in CRC screening[45]. Since that time the program has gradually increased the range of ages it targets. Once

the program is fully rolled out in 2020, biennial iFOBT will be offered to all adults aged 50-74[44]. Briefly, a list of eligible invitees is compiled by the NBCSP via the Australian Electoral Commission (AEC) roll, and invitations along with a FOBT kit, instructions and a reply-paid envelope are sent via regular post. Non-responders receive a reminder letter two months after the initial contact[44]. The NBCSP, upon request, provides information sheets to primary health care providers highlighting the importance of biennial FOBT screening recommendations and appropriate follow-up to a positive FOBT result[46].

Prevalence and correlates of screening within the NBCSP

CRC screening activity within the NBCSP is routinely captured and reported annually by the Australian Institute of Health and Welfare. The most recent report indicated that 41% of invitees returned a completed FOBT representing 1, 298 942 individuals (data from 2015-2016)[13]. This figure is higher than previously reported participation rates of 39% in 2014-2015[47] and 33.5% in 2012-2013[48]. There is no key performance indicator of 'participation rates' within the NBCSP[45], however, in comparison to CRC screening benchmarks from other developed countries of 65% (Europe)[24] and 70.5% (United States of America)[49], Australian participation rates are well below desirable levels. In the most recent screening round for which published data are available[13], females were more likely to participate in screening than males (43% vs 39%). Older age (70-74) was associated with higher screening than younger age (50-54) with participation rates of 53% and 28% respectively. Finally, those that had participated in a previous round were more likely to screen, with a 77% re-participation rate reported. Because the NBCSP uses the AEC to systematically identify and invite people who fall

in the target age range, the denominator for NBCSP participation is likely to include some individuals for whom FOBT is not recommended such as those with a previous diagnosis of CRC or those at greater than average risk of CRC[13]. Further, the NBCSP cannot capture screening occurring outside of the program, which may include colonoscopy in the absence of clinical indicators. Therefore, NBCSP participation rates may not necessarily equate to rates of adherence to CRC screening guidelines.

Impact of the NBCSP

Between 2006-2017, over 4.3 million Australians were screened through the NBCSP. Of these 18,280 were diagnosed with advanced adenomatous polyps and over 7,732 diagnosed with suspected or confirmed cancers[50]. Participating in the NBCSP can facilitate early diagnosis of CRC[37]. An observational study of 3481 South Australian patients admitted to hospital between 2003-2008 with a diagnosis of CRC, compared cancer stage between those that did (n=165) and did not (n=3316) participate in the NBCSP[51]. Those that participated in the NBCSP were more likely to be diagnosed at Stage A than those who did not (39% vs 19%) and were far less likely to be diagnosed at Stage D (3% vs 12%). The impact of the NBCSP could be improved if participation among invitees increased. A modelling study looking at the period from 2015-2040, predicted that an increase from the current 39% participation to 60% participation could result in an additional 37,300 cases of CRC being diagnosed and 24,800 less deaths from CRC[52]. The previously cited data-linkage study (NBCSP records, cancer registries and the National Death Index) reported bowel cancer diagnoses and deaths found that non-invitees had a 28% higher risk of bowel cancer death by 2015. Invitees

with screen-detected CRC had 171% higher odds of being diagnosed at an earlier stage than invitees who did not participate[53].

ADHERENCE TO COLORECTAL CANCER SCREENING GUIDELINES IN AUSTRALIA

Adherence to CRC screening refers to screening that aligns with recommendations contained within Australian CRC screening guidelines[18,23]. Non-adherence to guidelines can include both under- and over-screening.

Defining under- and over-screening

Under-screening. Under-screening means screening less frequently than is recommended in guidelines[18, 23]. For those at average risk, under-screening in the context of Australian guidelines refers to having had no FOBT in the past two years nor colonoscopy in the past five years. Colonoscopy is not recommended for routine screening in Australia, however, those that have had a colonoscopy in the past five years, such as surveillance following previous detection of adenomatous polyps or investigation of bowel symptoms, would not additionally require FOBT in the past two years, and therefore, can be considered up-to-date with CRC screening[18].

Over-screening. Over-screening is screening at greater than the recommended frequency or screening via a test method more intensive than recommended in guidelines[18, 23]. For those at average risk, over-screening in the context of Australian guidelines refers to FOBT at a frequency of <two years or colonoscopy in the absence

of increased familial or clinical risk[18, 23, 54]. Colonoscopy use in Australia has risen exponentially between the year 2000-2014 from 250,000 to 600,000[55, 56]. These data do not provide information on the reason/s people are referred for colonoscopy, however this dramatic increase may be attributed, in part, to colonoscopy being used as a routine screening method[57]. Over-screening via unnecessary colonoscopy can cause harms including individual injury (bowel perforation, bleeding and death)[58], increased public health-care expenditure on a low-quality screening item[59] and increase in waiting times for colonoscopy[59]. The latter may result in delayed diagnosis of CRC and subsequent delays in treatment[54].

Why focus on under-screening according to Australian guidelines among those at average risk of colorectal cancer?

Previous data collected from 2006[60]-2011[61] suggests that a large proportion of eligible Australians are under-screened for CRC[57, 61-63]. Adherence to CRC screening guidelines can lead to early diagnosis and treatment of CRC, reducing morbidity, mortality and economic costs associated with this disease[37]. The majority of the Australian population is at average risk of CRC[18], indicating improvement in the uptake of CRC screening in those at average risk could have the biggest impact on health and economic outcomes. There are no single comprehensive datasets reporting CRC screening behaviours in Australia. The annual NBCSP monitoring report[13] contains data from those who were invited into the program over the past two-year round. This may include people that are not overdue for screening, for whom FOBT is not appropriate or those that source FOBT outside of the NBCSP. Therefore, the focus of

this thesis is those that are under-screened for CRC according to CRC screening guidelines[18, 23].

What do community surveys tell us about adherence to colorectal cancer screening guidelines?

Several Australian cross-sectional studies have reported CRC screening behaviour, however because various definitions were used to determine screening adherence, reported prevalence did not align with CRC screening guidelines. Zajac et al.[57] (data collected 2010) surveyed 8, 762 participants aged 50-74 years identified through the AEC Roll in 2010 (18% consent rate). Those with a diagnosis of CRC were ineligible, however no further familial history was taken to determine risk category. They reported that 33% completed colonoscopy in the past five years and 21% had completed FOBT in the past 12 months. Those aged 50, 55 and 65, whom would have received FOBT from the NBCSP, were more likely to report completing FOBT in the past 12 months. Courtney et al.[62] (data collected 2009; 70% consent rate) reported lower participation rates in 777 NSW residents at average risk of CRC and aged 56-88[62]. Only 20% of those at average risk had screened with FOBT in the past two years and 16% had screened with colonoscopy in the past five years. Weber et al. conducted two studies through the 45 and Up Study (data collected 2006-2010; 34% consent rate)[60, 63], a large-scale Australian community cohort study of individuals aged 45 and over[64]. Risk category was not established for either study, however those with a history of CRC were ineligible to participate. The first study reported 18% (n=5,518) completed FOBT in the past five years[60]. The second study reported that 23% of men (n=20,127)

and 18% (n=18,541) of women had completed a FOBT in the past two years[63] (no familial history reported).

These studies report rates of under-screening up to 67-80%, however there are methodological weaknesses that make it difficult to determine if the reported screening was adherent to CRC screening guidelines[14, 18], and, if the results of these studies are generalisable. These weaknesses include no quantification of familial risk, screening intervals greater or less than recommended screening intervals and inclusion of those aged outside the target age range for screening. Cross-sectional studies may suffer from response bias and attrition in those most at risk of under-screening for CRC (low education and socio-economic status as well as those with unhealthy lifestyle behaviours)[65]. Different time frames for recall of screening were also used across studies, potentially leading to differences in the accuracy of self-reported screening behaviour[66, 67].

What do community surveys tell us about correlates of colorectal cancer screening?

Three published studies conducted in Australian community samples exploring the correlates of CRC screening behaviour can be found in the literature[57, 60, 63]. Zajac et al. reported those with higher levels of education were associated with FOBT and colonoscopy, some of the latter were likely to be over-screened, and included those residing in areas of higher socioeconomic advantage[57]. Weber et al reported that those who smoked, were sedentary, were aged 50-59, were female, that had no private health insurance or were not born in Australia were more likely to report being under-screened for CRC[60, 63]. A comprehensive review of barriers and facilitators to CRC

screening reported similar correlates of under-screening including female gender, younger age i.e. <60, current smokers, those with no private health insurance and those with lower levels of education[68]. None of the studies in Wools et al. review[68] were from Australia and the most recent data reporting correlates of screening behaviour was collected in 2010[57]. Identifying factors associated with under-screening is necessary to facilitate the development of interventions to target those most likely to be at risk of under-screening.

WHY FOCUS ON ADHERENCE TO COLORECTAL CANCER SCREENING GUIDELINES IN HEALTH CARE SETTINGS?

How is health care accessed in the Australian healthcare system?

Australia's healthcare system contains a mix of private and public facilities. Healthcare is managed across all three levels of government (Federal, State and Local)[69]. The Federal government is responsible for the management of Medicare, a national health insurance scheme which funds Australia's universal healthcare system. Medicare entitles citizens and residents of Australia to free treatment in public hospitals and subsidised treatment from healthcare providers including general practitioners (GPs). State governments manage hospitals and ambulance services and are responsible for community-based primary health services. Local governments deliver some public health/health promotion activities[70].

Primary care is usually the first port of call in the healthcare system and refers to care provided outside the hospital setting[71]. Primary care is delivered by a range of

providers including dentists, nurses, allied health and GPs across a range of settings including general practices, community health centres and allied health practices. GPs care for individuals across the lifespan and provide advice and education on a broad range of healthcare issues, including preventive health[23]. Patients are not required to register with a general practice and can elect to see any GP at any practice of their choosing[69]. Payment for GP visits is a fee-for-service system. GPs can 'bulk bill' which means that the Medicare subsidy covers patient fees in their entirety, or they may charge fees higher than the Medicare subsidy and patients pay an additional 'gap' fee[69, 72].

Secondary care is medical care provided by a specialist or facility upon referral by a GP. Approximately 10% of general practice encounters resulted in a referral to a specialist[73]. Specialists can operate in private suites in the community or in private (n=612) or public (n=747) hospitals[70]. Specialists operating in public hospitals see patients through outpatient clinics where fees are largely or fully covered by Medicare[70].

Why examine colorectal cancer screening prevalence and correlates in primary care?

Australians see their GP 6.5 times per year, with those aged 65 years and older being more likely to see their GP ten or more times per year[73]. The majority of practising GPs in Australia are registered with the RACGP[73]. Their clinical practice is guided by documents such as the RACGP *'Guidelines for preventive activities in general practice'* (Red book 9)[23] which includes recommendations about provision of CRC screening advice and tests. Further, general practice patients expect their GPs to provide them

with information about preventive care[74]. Finally, the NBCSP Policy Framework (2015-2020)[75] focusses on the role of GPs to facilitate screening through the NBCSP. These factors suggest that general practice may be a valuable setting to deliver interventions to increase CRC screening as each general practice consultation represents a potential opportunity to deliver CRC screening advice.

There has been little research to examine CRC screening prevalence and correlates of under-screening in the primary care setting. Paul et al.[61] collected data in 2010-2011 from 12 general practice clinics and reported that approximately 40% of 5671 general practice patients aged ≥50 (any risk category) had completed FOBT within the past three years. Those that reported receiving a FOBT from the NBCSP were over five times more likely to have completed FOBT in the past three years, than those that could not recall receiving a FOBT. Younger age (50-59), female gender and being diagnosed with another kind of cancer were correlated with lower FOBT screening rates. Given the expansion of the NBCSP, there is a need to examine whether screening rates in this setting have changed. Further, examining correlates of under-screening could facilitate the development of interventions targeting those most at risk of being under-screened in this setting.

Why examine colorectal cancer screening in prevalence and correlates secondary care?

Australians are increasingly receiving care in secondary settings, such as outpatient clinics. Increasing levels of chronic diseases such as diabetes and cardiovascular disease[10] require specialist management and primary care appointments may be missed as specialist appointments are given higher priority by the patient[76]. This can

lead to fragmented healthcare delivery between primary and secondary care, an issue identified by the Australian government[76]. In the Australian outpatient setting, 33% of service events are for those in the target age range for CRC screening[77], yet there is only one study reporting prevalence and correlates of under-screening in this setting. Koo et al. conducted a cross-sectional study in outpatient clinics across 14 Asia-Pacific regions, including Australia (data collected in 2007)[78]. Of 311 Australian participants aged ≥50, 48% had ever undergone CRC screening. The authors did not report familial risk, or when the most recent CRC screening occurred, therefore it cannot be determined if the screening was adherent to CRC screening guidelines. Knowledge of CRC screening tests was a predictor of CRC screening uptake in high-participation countries which included Australia (OR 1.6; 95%CI 1.25-2.03). These factors highlight that the outpatient setting could be suitable to assess prevalence and correlates of CRC screening and potentially deliver targeted health promotion activities, including CRC screening.

HOW DOES THIS THESIS EXTEND THE CURRENT LITERATURE?

CRC is an important public health issue in Australia with high levels of morbidity and mortality compared to other cancer types[5]. Screening for CRC reduces morbidity and mortality associated with this disease[27-29]. The majority of the Australian population is at average risk of CRC[18], a substantial proportion of which are not adherent to CRC screening guidelines[13, 57, 60-62], despite the availability of biennial FOBT provided through the NBCSP[13]. Most Australians routinely attend healthcare settings, however, there has been little research conducted examining prevalence and correlates of adherence to CRC screening guidelines in Australian healthcare settings. Existing

research has several weaknesses including sampling of those outside the recommended age range for CRC screening[61, 62]; assessment of screening frequency and type not recommended in current guidelines[57, 60, 61], and; data collected prior to the expansion of the NBCSP[57, 61-63]. This thesis addresses these weaknesses.

The majority of research examining prevalence and correlates of under-screening has been observational. There have been few intervention studies to increase CRC screening in Australia, none of which have been conducted in the general practice setting. General practices have a high throughput of those in the target age range for CRC screening and GPs are expected to provide guideline adherent CRC screening advice[73]. Therefore, this thesis reports results of a randomised controlled trial delivered in general practice to increase CRC screening uptake in order to make recommendations for what kind of strategies might support the current population-based screening initiative.

The overall objectives of this thesis are to:

1. Using a cross-sectional methodology: to examine among people attending outpatient clinics at average risk of CRC:

a) The proportion who report: i) faecal occult blood test (FOBT) within the past two years; and b) colonoscopy within the past five years, including the reasons for undergoing colonoscopy;

b) Characteristics associated with under-screening;

c) For those that are under-screened, the proportion who are: i) willing to receive help, and the acceptability of different methods of receiving help, and; ii) unwilling to receive help, and reasons for this.

2. Using a cross-sectional methodology: to describe general practice patient's knowledge of:

a) CRC risk factors, and

b) CRC screening recommendations.

3. To examine, in a cross-sectional study, among Australian general practice patients at average risk of CRC, the proportion of patients who report:

a) FOBT within the past two years and the source of their most recent FOBT

b) Colonoscopy within the past five years and the reasons for undergoing this test, and

c) The extent to which patient sociodemographic characteristics and CRC knowledge are associated with being under-screened.

4. Review, by examining across three time-points changes in:

a) The proportion of observational and intervention research

b) The proportion of intervention studies that used an EPOC-accepted study design.

5. To examine using a randomised controlled trial, the effectiveness of an intervention including**:** provision of point-of-care FOBT, printed CRC screening advice and face-to-face GP endorsement on self-reported CRC screening uptake and CRC screening knowledge among under-screened general practice patients at average risk of CRC.

This thesis will present and discuss the findings of these objectives via a series of six papers which have been published in peer-reviewed journals.

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PAPER 1

PREVALENCE OF APPROPRIATE COLORECTAL CANCER SCREENING AND PREFERENCES FOR RECEIVING SCREENING ADVICE AMONG PEOPLE ATTENDING OUTPATIENT CLINICS

INTRODUCTION TO PAPER 1

Attendance for secondary care in settings such as public outpatient clinics may provide opportunities to assess and deliver preventive health care, including CRC screening. These settings have a high turnover of people in the target age range for CRC screening (50-74 years). In 2014-2015 there were nearly 33 million service events across 604 Australian public hospitals and 19 other services (local hospital networks and private hospitals). Of all outpatient episodes of care, 33% were for those within the target age range for CRC screening[1].

The only data reporting CRC screening behaviour in an Australian outpatient setting was collected in 2007[2]. As there has been further roll out of the NBCSP[3] it is likely that rates of screening have increased since these data were collected. Paper 1 describes the prevalence of under- and over-screening in those attending outpatient clinics, characteristics associated with under-screening and willingness to receive CRC screening advice.

A license agreement for publishing, participant information statement and survey instrument are contained in Appendices 1.1-1.3.

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Prevalence of appropriate colorectal cancer screening and preferences for receiving screening advice among people attending outpatient clinics

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Abstract

Objective: To examine among people attending outpatient clinics aged 50–74 at average risk of colorectal cancer (CRC): 1) The proportion who report: a) faecal occult blood test (FOBT) within the past two years; and b) colonoscopy within the past five years, including the reasons for undergoing colonoscopy; 2) characteristics associated with under-screening; 3) For those who are under-screened, the proportion who are: a) willing to receive help and the acceptability of different methods of receiving help, and; b) unwilling to receive help and reasons for this.

Methods: Cross-sectional survey of 197 participants attending a major regional hospital in New South Wales, Australia. Multivariable logistic regression was used to determine correlates of under-screening.

Results: A total of 59% reported either FOBT in the past two years or colonoscopy in the past five years. Of those reporting colonoscopy in the past five years, 21% were potentially over-screened. Males were more likely than females to be under-screened. Of those under-screened (41%), fewer than half were willing to receive screening advice.

Conclusions and implications for public health: A significant proportion of people attending outpatient clinics are under-screened for CRC, with some people also over-screened. There is a need to explore strategies to overcome both under- and over-screening.

Key words: colorectal cancer, early detection of cancer, outpatient

Colorectal cancer (CRC) is the third most common cancer in the world.[1] Each year, more than 16,000 Australians receive a diagnosis of CRC and over 4,000 die from the disease.[2] CRC mortality rates have declined significantly in Australia over the past 20 years.[3] This decline is in part attributed to screening for and subsequent treatment of CRC.[3] Screening for CRC using biennial faecal occult blood testing (FOBT) reduces mortality from this disease by 13% to 33%.[1,4-6] A meta-analysis of 11 observational studies suggests that screening with colonoscopy also reduces mortality from CRC when compared to not screening with colonoscopy (61% relative risk reduction).[7]

Australian CRC screening guidelines

Australian CRC screening guidelines, published by the National Health and Medical Research Council (NHMRC), provide screening recommendations based on level of risk, defined by personal and family history.[8] Those at average or slightly above average risk (herein after referred to as average risk) aged 50 and older are advised to screen for CRC using biennial faecal occult blood test (FOBT) and to consider five-yearly sigmoidoscopy.[8] More recent Australian guidelines recommend biennial FOBT only.[9] Approximately 98% of the Australian population is considered to be at average risk.[10] Colonoscopy may be recommended for: those at greater than average risk; symptoms suggestive of CRC; investigation of a positive FOBT; or if abnormalities have been previously detected during colonoscopy.[8]

Previous data on CRC screening rates

Australian data on screening rates has been provided by government reports and studies conducted in community and general practice settings.[11-14] The National Bowel Cancer Screening Program (NBCSP) is a population-based screening program that provides FOBT to Australians turning 50, 54, 55, 58, 60, 64, 68, 70, 72 and 74. The full roll-out will provide biennial FOBT to all those aged 50–74 by 2020.[11] Recent data from the NBCSP suggests that 39% of those invited to participate return a completed a FOBT.[11] However, the denominator used to calculate this rate may include individuals for whom FOBT may be inappropriate, such as those at greater than average risk of CRC. In addition, the data do not capture screening that occurs outside of the program such as via general practice, pharmacies or other community programs.

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Studies conducted in Australian community[12,14] and general practice settings[13] have shown variable screening rates, which may be due to differences between studies in age groups and risk categories included in the samples, as well as the time-period over which screening was examined. One community-based study including 699 asymptomatic, average-risk individuals aged 56–88 reported 20% of these as having an FOBT in the past two years,[12] while another community study of 8,762 participants from any risk category aged 50–74, reported 21% of participants had an FOBT in the past 12 months.[14] A study of 2,269 general practice patients (any risk category) aged 50 and older found that 40% of participants had completed FOBT in the past three years.[13,12] The most recent Australian study to assess CRC screening was collected in 2011.[15] Given the expansion of the NBCSP and increased promotion of bowel cancer screening,[16,17] it is timely to examine whether screening according to NHMRC guidelines has changed in this time.

Potential over-screening for CRC

Over-screening is screening more frequently than recommended, or via screening tests that are more intensive than recommended, such as colonoscopy in the absence of clinical indicators such as symptoms suggestive of CRC. Unnecessary colonoscopy places patients at undue risk of clinical complications, such as bleeding, bowel perforation and adverse reactions to anaesthetics.[18,19] Further, it reduces the capacity of the healthcare system to provide colonoscopy in a timely manner for those in clinical need.[20] Unnecessary colonoscopy is not quantifiable using Medicare Benefits Schedule data.[21] One previous Australian study of 699 average-risk individuals in a community setting showed that 14% are potentially over-screened for CRC.[12] Exploring the reasons for colonoscopy referral will provide insight into potential rates of over-screening.

Characteristics associated with under-screening for CRC

Examining the characteristics of individuals who are more likely to be under-screened can assist in the development of strategies to target specific sub-groups of the population.

Several factors appear to be associated with under-screening for CRC in Australia, including younger age and lower levels of education.[13,14] Contact with healthcare providers may also be a contributing factor, with studies in general practice settings identifying that continuity of care is associated with higher rates of CRC screening.[22] However, given the limited Australian data on factors associated with under screening, additional exploration is warranted.

Willingness to receive CRC screening advice

For individuals who are under-screened, provision of advice with screening can reduce knowledge gaps, which may encourage screening uptake.[23] However, individuals who are under-screened may vary in the extent to which they perceive they need help with screening. Exploring willingness of individuals attending outpatient clinics to receive specific CRC screening advice can establish if simple informational interventions are likely to be well-received among this population. Further, asking about a person's preferences for how they would like to receive this advice can provide information about the acceptability of different approaches. Previous studies suggest that there may be a number of reasons why people may be reluctant to receive screening advice. Commonly reported barriers include lack of knowledge about CRC and CRC screening recommendations,[23,24] lack of provider recommendation[25] and perception that they are not at risk of CRC.[25] Identifying the reasons why some individuals may be unwilling to receive screening advice can add to this evidence and assist in shaping intervention strategies to overcome these barriers.

Why examine CRC screening in an outpatient setting?

In 2014–2015, there were close to 35 million occurrences of non-admitted care across 610 Australian hospitals and 41 other services.[26] More than one-third of individual service events occurred in those within the NBCSP target age range of 50–74 years.[26] Further to this, many outpatients attend their appointments accompanied by support persons (e.g. friends or family) who may also be in the target age range for CRC screening. Therefore, exploring screening rates according to NHMRC guidelines among outpatients and accompanying support persons will provide an indication of screening rates in a broad cross-section of the community.

Objectives

To examine among people attending outpatient clinics aged 50-74 and at average risk of CRC:

1. The proportion who report: a) FOBT within the past two years; and b) colonoscopy within the past five years, and if so, the reasons for undergoing colonoscopy
2. Whether participant sociodemographic characteristics, frequency and continuity of GP visits are associated with under-screening (i.e. no FOBT in past two years nor colonoscopy in past five years)
3. For those who are under-screened, the proportion who are: a) willing to receive help, and the acceptability of different methods of receiving help, and; b) unwilling to receive help, and the reasons for this.

Methods

Design and setting

Cross-sectional survey conducted in outpatient clinics at one regional hospital in New South Wales, Australia. The outpatient clinics included a range of specialties such as cardiology, respiratory, gastroenterology, rehabilitation, orthopaedics, vascular and general surgery. The current study was conducted as part of a larger study examining health concerns and behaviours among people attending outpatient clinics. Data were collected from November 2016 to January 2017. This study received ethics approval from the Hunter New England (16/09/21/4.10) and the University of Newcastle (H-2016-0388) Human Research Ethics Committees.

Participant eligibility

Participants eligible for the larger study were: 1) aged 18 years and over; 2) English speaking; 3) able to provide informed consent; 4) an outpatient or support person accompanying an outpatient to an appointment; 5) mentally and physically well enough to complete a touchscreen survey.

Participants eligible for the current study were: 1) aged 50–74 years; 2) with no personal history of CRC or inflammatory bowel disease; 3) at average risk of CRC according to NHMRC criteria.[8] Those at average risk were identified as having: 1) no first degree relative diagnosed with CRC aged <55; 2) no more than two first degree relatives diagnosed with

CRC at any age on either side of the family; 3) no more than one first degree relative and one second degree relative diagnosed with CRC at any age from the same side of the family.[8]

Data collection

Consecutive patients and support persons were approached by a research assistant while they waited for their appointment and were assessed for eligibility for the larger study. The gender and age group of non-consenters was recorded. Consenting participants completed a web-based survey administered on a touch-screen computer in the outpatient waiting room. Consent was provided electronically at the commencement of the survey. Participants meeting the eligibility criteria for the current study were identified by a series of branching questions. Only those meeting the eligibility criteria for the current study received CRC questions. Participants who were called in to their appointment prior to completing the survey could complete this following their appointment.

Measures

Previous FOBT: Participants were asked: "When was the last time you had a faecal occult blood test?" A lay description of FOBT was provided. Response options included: Never had an FOBT; In the past year; 1–2 years ago; 2–3 years ago, 4–5 years ago; More than 5 years ago; Not sure.

Previous colonoscopy: Participants were asked: "When was the last time you had a colonoscopy?" A lay description of the colonoscopy procedure was provided. Response options included: <5 years ago; 6–10 years ago; >10 years ago; Not sure. Those who reported they had a colonoscopy in the past five years were asked: "Why were you referred for a colonoscopy?" Participants could select more than one option from the following: I have a family history of bowel cancer; I had symptoms suggestive of bowel cancer; I had a positive FOBT result; I had an abnormal X-ray or CT scan; I have previously had colorectal adenomas/polyps; Other.

Screening status: Participants reporting no FOBT in the past two years nor colonoscopy in the past five years were deemed under-screened. While guidelines do not recommend colonoscopy as a routine screening test for those at average risk, those receiving colonoscopy for other reasons are unlikely to require any additional screening tests such as FOBT within the years following colonoscopy. Therefore, in an effort to be conservative, people who had undergone colonoscopy regardless of the reason were considered screened regardless of the FOBT screening status.

Preferences for receiving CRC screening advice: Participants who were identified as not having FOBT in the past two years or colonoscopy within the past five years received the following question: "Your answers suggest that you may be overdue for bowel cancer screening. Would you be willing to receive help addressing this?" with response options: Yes; No; I am already addressing this. Participants who responded 'Yes' were asked: "How would you like to receive help to address this?" Participants could select more than one response from the following: Information mailed to my home; Information emailed to me; Notification sent to my GP; Other (please specify).

Participants who responded 'No' were asked: "Why would you be unwilling to receive help to address this?" Participants could select more than one response from the following: Bowel cancer is not relevant to me; I find the idea of bowel cancer screening unpleasant; I don't think bowel cancer screening is effective at detecting cancer; I can't afford bowel cancer screening; Worried I would not know how to do the test; Would rather not know if I had cancer; My doctor hasn't recommended I undertake bowel cancer screening; Other (please specify).

Explanatory variables: Sociodemographic items: Age, gender, whether they held private health insurance or a health care concession card, highest level of education, and employment status were self-reported. To determine frequency of GP care, participants were asked: "How many times have you seen your GP within the past 12 months?" Response options included: 0–3 times, 4–6 times, 7–9 times; 10 or more times. As an indicator of continuity of care participants were asked to select from the following: I always see the same GP; I usually see the same GP; I see whichever GP is available.

Data analysis

The characteristics of consenting participants and non-consenters were compared using chi-squared tests.

Descriptive statistics including frequencies and percentages were calculated for each variable of interest. Proportions were calculated (with 95% confidence intervals) of those reporting screening with: 1) FOBT within the past two years; 2) colonoscopy within the past five years, and the reason for this colonoscopy; and 3) preferences for receiving CRC screening advice.

Multivariable logistic regression analyses were performed to determine whether age, sex, private health insurance coverage, health care concession card holder, highest level of education, employment status, frequency and continuity of GP visits were independent predictors of under-screening. Missing data was handled using multiple imputation. All analysis variables were used as predictor variables in the imputation models and 50 imputed datasets were created. The multivariable logistic regression models were estimated on each of the imputed datasets, and regression coefficients pooled using Rubin's method. Pooled odds ratios, 95% confidence intervals and Wald based *p*-values are presented. All analyses were conducted using Stata IC 11.3 (Statacorp, College Station, TX). *P*-values of <0.05 were considered significant.

Results

A total of 663 people were invited to participate in the larger study, of whom 623 were eligible. Of these, 484 participants consented to participate in the study (consent rate=78%). There were no significant differences between consenters and non-consenters in relation to age ($X^2[3]=1.8$, $p=0.61$) or gender ($X^2[1]=0.42$, $p=0.51$).

Of the 484 consenting participants, 212 were eligible for the current study. A total of 272 were ineligible due to the following reasons: aged <50 or >74, (n=193); called away for appointment prior to answering initial eligibility screening questions (n=25); had a history of CRC/inflammatory bowel disease (n=11); or were at greater than average risk of CRC due to family history (n=43). A further 15 participants were excluded as they did not answer both the FOBT and colonoscopy questions, resulting in a final sample of 197 for analysis. The sample characteristics are reported in Table 1.

The proportion reporting FOBT within the past two years or colonoscopy within the past five years

A total of 92 (47%; 95%CI 40-54%) participants reported FOBT in the past

two years and 48 (24%; 95%CI 19-31%) participants reported colonoscopy in the past five years. Of these, 24 participants (21%; 95%CI 14-29%) completed both tests.

Self-reported reasons for undergoing colonoscopy in the past five years

Of those who had undergone colonoscopy in the past five years, 38 (79%) reported an appropriate reason for colonoscopy (see Table 2), including: symptoms that may indicate CRC (38%); other medical conditions (15%); follow-up of positive FOBT (13%); previous polyps/adenoma (13%). However, 10 (21%) of those reporting colonoscopy in the past five years indicated that this was done as a screening test rather than an investigative test. Eight (17%) participants reported having colonoscopy as part of routine screening and two (4%) participants reported that the colonoscopy was undertaken due to their family history of CRC, despite being classified as average risk for CRC based on their responses to family history questions in the survey.

Table 1: Participant sociodemographic characteristics (n=197).

Characteristic	Category	n (%)
Age group	50-59	85 (43%)
	60-74	112 (57%)
Gender	Female	123 (62%)
	Male	74 (38%)
Participant type	Outpatient	112 (57%)
	Support person	85 (43%)
Marital status	In a partnered relationship (married or living with partner)	132 (67%)
	Single (widowed, divorced, separated, never married)	40 (20%)
	Missing	25 (13%)
Education	Non-tertiary (high school, trade, diploma, vocation)	139 (71%)
	Tertiary	37 (19%)
	Missing	21 (11%)
Employment	Employed	61 (31%)
	Non-employed (unemployed, non-paid activities, carers, students, disability support)	42 (21%)
	Retired	73 (37%)
	Missing	21 (11%)
Private Health Insurance	Yes	77 (39%)
	No	96 (49%)
	Missing	24 (12%)
Healthcare concession card	Yes	108 (55%)
	No	65 (33%)
	Missing	24 (12%)
Frequency of GP visits in last 12 months	0-3	65 (33%)
	4 or more	107 (54%)
	Missing	25 (13%)
Continuity of GP visits in last 12 months	Always see the same GP	98 (50%)
	Usually see the same GP	60 (30%)
	I see whichever GP is available	14 (7%)
	Missing	25 (13%)

Variables associated with being under-screened for CRC

Eighty (41%; 95%CI 34-48%) participants reported not completing FOBT in the past two years nor colonoscopy in the past five years, and were deemed under-screened. Multivariable logistic regression with under-screening as the outcome showed that female participants had lower odds of being under-screened compared to males (OR 0.49; p =0.02). No other variables were significantly associated with being under-screened (see Table 3).

Preferences for receiving CRC screening advice

Of the 80 participants who were under-screened for CRC, 34 (43%; 95%CI 32-54%) were willing to receive help to address under-screening, 23 (29%; 95%CI 19-40%) were unwilling to receive help and 24 (30%; 95%CI 20-41%) said they were already receiving help with this.

For those willing to receive help to address under-screening, most preferred screening information mailed to their home, n=22 (65%). Smaller proportions of participants indicated they were willing to receive information emailed to them, n=9 (26%), or by notification sent to their GP, n=8 (24%).

For those unwilling to receive help to address under-screening, just over one-third n=8 (35%) selected 'My doctor hasn't recommended I undertake bowel cancer screening' as the reason for their choice to not receive screening advice. Other reasons included: 'I will wait until I receive FOBT from the NBCSP', n=3 (13%); 'I find the idea of screening for bowel cancer unpleasant', n=3 (13%); and 'Bowel cancer screening isn't relevant to me', n=2 (9%). The options: 'I don't think bowel cancer screening is effective at detecting cancer'; 'I can't afford bowel cancer screening'; and 'I would rather not know if I had cancer' each had one participant response (4%, respectively).

Table 2: Self-reported reasons for undergoing colonoscopy in the past five years (n=48).

Reason for colonoscopy	Responses n (%)
Symptoms suggestive of CRC	18 (38%)
Routine screening*	8 (17%)
Other medical conditions	7 (15%)
Previous polyps/adenoma	6 (13%)
Follow-up of positive FOBT	6 (13%)
Perceived strong family history of CRC*	2 (4%)
Abnormal CT/X-ray	1 (2%)

**indicates potential over-screening*

Discussion

Our study aimed to determine the CRC screening practices in those aged 50–74 and at average risk of CRC in an outpatient setting, including under-screening and potential over-screening, as well as willingness and preferences for receiving CRC screening advice.

FOBT in the past two years

Almost half the sample (47%) had completed a FOBT in the past two years. This rate is higher than rates reported in Australian research conducted between 2009–2011 (20%– 40%),[12-14] and by the NBCSP (39%).[11] In recent years, there has been increased promotion of CRC screening and increased age groups invited into the NBCSP.[27] Recent data from the NBCSP reported a 2% increase in screening with FOBT among invitees between January 2014–December 2015 (representing an increase of 177,870 people completing screening).[11,28] Therefore, increased awareness of and uptake of NBCSP invitations may have contributed to the higher FOBT completion rates found in our study.

Colonoscopy in the past five years

Forty-eight (24%) participants reported colonoscopy in the past five years. Of those, 21% (n=10) received potentially unnecessary colonoscopy (i.e. 5% of the sample). The majority of these indicated that they received a colonoscopy as routine screening. Previous Australian research reports a higher prevalence of potentially unnecessary colonoscopy in an asymptomatic average-risk sample (14%).[12] Given that holding private health insurance is associated with higher use of colonoscopy,[14] this finding may be at least partially explained by the lower proportion of individuals with private health insurance (40%) in our study sample as compared to the Australian population (56%).[29] Nevertheless, the finding that some participants may have undergone unnecessary colonoscopy, exposing them to unnecessary risk, suggests

that strategies are needed to ensure appropriateness of referrals for this test.

Variables associated with under-screening

The multivariable logistic regression showed that female participants were significantly less likely to be under-screened compared to males. This aligns with previous data that finds males are less likely to participate in CRC screening.[28,30,31] Given that males are more likely to be diagnosed and more likely to die from CRC,[32] interventions that specifically target males are needed. No other variables were significantly associated with being under-screened; however, this does not mean the other variables are not important. The confidence intervals of their effect sizes do include potentially important values; larger studies would be necessary to gain greater precision in these estimates. While previous research has found that lower levels of education may be associated with under-screening,[12,13] we did not find this in the current study. The proportion of those with tertiary education was comparatively lower than in previous studies,[12,13] which may explain why we did not find this association. Being younger did not correlate to a higher rate of under-screening, which is at odds with previous findings.[11,12] This may be due to differences in age categories used (only two age sub-groups in the current study) and/or because the NBCSP has added several younger age groups in the ongoing program expansion,[27] and overall participation in the NBCSP has increased in younger age groups.[11,28]

Preferences for receiving CRC screening advice

Fewer than half of those under-screened for CRC indicated that they would be willing to receive help to address under-screening. Of these, the majority preferred written information mailed to their home. The relatively high proportion of participants who were not interested in receiving help with screening is somewhat concerning. However, unwillingness to receive help to address under-screening did not necessarily indicate unwillingness to participate in screening. Some of those indicating unwillingness to receive help did so because they were waiting to screen through the NBCSP. One-third of these patients indicated that their doctor had not recommended they undertake screening. Although based on a small sample, this is consistent with the notion that physician endorsement is a key factor influencing positive screening CRC behaviours.[33,34] Considering this, interventions that involve general practitioner endorsement of screening should be considered for those who are under-screened.

Table 3: Multivariable logistic regression model determining factors associated with under-screening (n=197).

Participant characteristics		OR for being under-screened	P=value (95%CI)
Gender	Male	–	0.02*
	Female	0.49 (0.26–0.91)	
Age	50–59	–	0.59
	60–74	1.23 (0.58–2.58)	
Marital status	In a partnered relationship (married or living with partner)	–	0.85
	Single (widowed, divorced, separated, never married)	0.92 (0.40–2.12)	
Education	Non-tertiary (high school, TAFE/trade/diploma/ vocation)	–	0.17
	Tertiary	1.76 (.79–3.93)	
Employment	Employed	–	0.71
	Non-employed (includes unemployed, non-paid activities, disability support and students)	0.73 (0.68–1.75)	
	Retired	1.12 (0.44–2.9)	
Private health insurance	No	–	0.26
	Yes	0.66 (0.33–1.35)	
Healthcare concession card	No	–	0.86
	Yes	1.08 (0.47–2.50)	
Continuity of GP visits in last 12 months	Always see the same GP	–	0.06
	Usually see the same GP	0.67 (0.32–1.3)	
	I see whichever GP is available	0.21 (0.34–1.01)	
Frequency of GP visits in last 12 months	0–3 times per year	–	0.68
	4 or more times per year	0.86 (0.42–1.76)	

**statistically significant*

Implications for public health

Forty-one per cent of participants had not completed a FOBT in the past two years nor a colonoscopy in the past five years, suggesting that a significant proportion of people attending outpatient clinics are under-screened for CRC. Just under half of these were willing to receive screening advice, most of whom indicated they would like to receive written information posted to their home. This simple, affordable intervention is acceptable to many and similar print interventions have increased uptake of cancer screening.[35] Given that some participants cited lack of GP advice on screening as a reason for not wanting screening advice, general practitioner endorsement may increase the acceptability of receiving screening advice.

Limitations

Due to the brevity of family history questions used to determine CRC risk category, it is possible that a small number of participants at average risk may have been classified as greater than average risk and vice-versa. Self-reported screening may be affected by recall bias, however, a recent meta-analysis of the accuracy of self-report of FOBT and colonoscopy compared to medical records found good to excellent accuracy of self-report (area under the curve 0.87 and 0.95 respectively).[36] The sample representativeness may be limited as participants were recruited from one regional hospital. Self-reported sigmoidoscopy data was not collected, however, due to the low rates of sigmoidoscopy found in previous Australian research (<1%),[12,37] it is unlikely that this would affect our results. Finally, this study did not examine possible contraindications that may have made FOBT inappropriate, such as gastrointestinal symptoms, or the presence of late-stage disease. However, given that the proportion of individuals in our sample with these contraindications would have been low, it would not have had a significant impact on the screening rate identified.

Conclusion

FOBT screening rates in an outpatient sample were higher than those reported in the NBCSP data, however, 41% were under-screened. Females were less likely to be under-screened. Five per cent of the sample were potentially over-screened, having received a colonoscopy for screening

purposes. Fewer than half of those under-screened for CRC were willing to receive screening advice. Strategies involving general practitioners could be used to target those not interested in receiving written CRC screening advice.

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PAPER 2

KNOWLEDGE OF COLORECTAL CANCER RISK FACTORS AND SCREENING RECOMMENDATIONS: A CROSS-SECTIONAL STUDY OF REGIONAL AUSTRALIAN GENERAL PRACTICE PATIENTS

INTRODUCTION TO PAPER 2

Knowledge of CRC and CRC screening recommendations may be associated with positive CRC screening behaviours[1-3], however little research has been conducted in Australian healthcare settings. Given that a substantial proportion of outpatients surveyed were under-screened for CRC, it may be useful to explore knowledge gaps regarding CRC risk factors and screening recommendations. This may be useful to assist in the design of future interventions.

Primary care settings such as general practice may be useful settings to assess CRC knowledge and screening behaviour. General practices are well patronised and capture a broad cross-section of the community[4]. Further general practitioners have a recognised role in health promotion and patient education[5] therefore it may be expected that general practice patients have an understanding of CRC risk factors and CRC screening recommendations. Paper Two describes the results of a cross-sectional survey delivered in general practice that explored patient knowledge of CRC risk factors and screening recommendations.

A participant information statement, consent form and survey instrument are contained in Appendices 2.1-2.3.

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Brief report

Knowledge of colorectal cancer risk factors and screening recommendations: a cross-sectional study of regional Australian general practice patients

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Introduction

Higher levels of knowledge relating to colorectal cancer (CRC) are positively associated with CRC screening behaviour.[1] However, knowledge of CRC risk factors and screening recommendations is low.[1, 2]

The aim of this study was to examine knowledge of CRC risk factors and CRC screening recommendations among general practice patients aged 18–85 years, and the sociodemographic characteristics associated with knowledge.

Methods

This study was conducted in a convenience sample of five regional general practices in New South Wales (NSW), Australia, between December 2015 and March 2017. The practices had six to 18 practitioners and provided private and bulk-billing services. A consecutive sample of patients aged 18–85 years who spoke English and presented for a general practice appointment were invited to participate.

Data collection

Consenting patients completed a touchscreen survey in the waiting room. Ethics approval was received from the University of Newcastle Human Research Ethics Committee (H-2014-0198).

Measures

A 5-item survey, developed and piloted by the authors, assessed knowledge using a multiple-choice format. Participants were asked to identify which risk factors may increase a person's chance of developing CRC: smoking, being older than 50, being overweight, not eating enough fibre, and drinking alcohol regularly. Four questions assessed knowledge of CRC screening

recommendations for people at average risk of CRC (lay description provided). These included: 1) age to commence screening; 2) type of screening test recommended; 3) how often the faecal occult blood test (FOBT) should be done; and 4) what a positive FOBT result means. Participants could select one response for each of these questions. Correct responses aligned with Royal Australian College of General Practitioners guidelines for preventive activities in general practice.[3] Participants reported their age, gender, marital status, employment status and highest level of education.

Data analysis

Scores for risk and screening were analysed separately using logistic regression (binary for risk [>1 versus ≤1] and ordinal for screening) to model the odds of higher scores. All demographics were included in the model. The Brant test assessed the parallel regression assumption, the Pearson's goodness-of-fit test assessed the binary model, and each model fit adequately.

Results

A total of 510 patients (70% of those assessed) were eligible to participate. Of these, 411 patients consented to participate (81% consent rate). Those with missing data were removed, leaving 363 participants in the final analyses. There was no significant difference in gender between consenters and nonconsenters ($\chi^2(1)$ 1.29, $p = 0.254$).

Participant characteristics

More than half the sample was aged 50–74 years ($n = 208$; 57%), and similar proportions were aged 18–49 ($n = 65$; 18%), or 75–85 ($n = 90$; 25%). A total of 219 (60%) participants were female.

Colorectal cancer risk factors

Eighty-six participants (24%) correctly identified all risk factors (32% aged <50 versus 22% aged ≥50), and 35 (10%) identified none (15% aged <50 versus 8% aged ≥50). Higher proportions of those aged <50 identified smoking, alcohol consumption and being overweight as risk factors for CRC.

Those with a tertiary education had 2.1 times greater odds of identifying at least one risk factor (95% confidence interval [CI] 1.07, 4.3; $p = 0.03$). Those who were retired were less likely to identify at least one risk factor than those who were not retired (odds ratio [OR] 0.38; 95% CI 0.18, 0.82; $p = 0.01$).

Colorectal cancer screening

Less than 10% of participants identified the correct responses for all screening questions (12% aged <50 versus 9% aged ≥50); 11% selected no correct responses (17% aged <50 versus 9% aged ≥50). Just over half of the sample (53%) knew that FOBT was the recommended screening test (55% aged <50 versus 53% aged ≥50). Only 41% knew the recommended frequency of FOBT (26% aged <50 versus 44% aged ≥50). Less than one-third knew the recommended age to commence screening.

Those aged ≥50 years had 2.5 times greater odds of higher scores for screening knowledge ($p < 0.003$; 95% CI 1.37, 4.67) compared with those aged <50. Those with a tertiary education were more likely to score highly than those without (OR 2.02; $p < 0.002$; 95% CI 1.28, 3.17).

Discussion

Our data identified gaps in knowledge for CRC risk factors and screening recommendations. Several risk factors were poorly identified by participants; however, our study found higher knowledge scores in some areas compared with previous Australian research.[4] Ten per cent of participants in our study did not identify any risk factors, which was lower than the 34.8% of Australian participants in a 2012 study.[4] This may reflect differences in the study methods or populations, or an increase in knowledge of risk factors since this study. As expected, screening knowledge scores were higher for people aged 50 years and older compared with people aged younger than 50 years.

Table 1. Proportions selecting correct responses for colorectal cancer risk factors and screening questions ($N = 363$)

Category	Knowledge questions	Selected correct option, *n* (%)	
		<50 years ($n = 65$)	≥50 years ($n = 298$)
Risk factors	Smoking	44 (68)	167 (56)
	>50 years	38 (58)	176 (59)
	Overweight	42 (65)	156 (52)
	Low fibre	42 (65)	232 (78)
	Alcohol consumption	37 (57)	117 (39)
Screening	Age to commence screening	20 (31)	91 (31)
	Recommended screening test	36 (55)	159 (53)
	Frequency of FOBT	17 (26)	130 (44)
	Meaning of positive FOBT	42 (65)	225 (76)

FOBT = faecal occult blood test

Our data strongly suggest that there is a need to raise awareness of modifiable risk factors and CRC screening recommendations. Guidelines suggest that general practitioners routinely monitor patient body mass index; assess risky behaviour; promote healthy eating, drinking and physical activity; and recommend appropriate CRC screening.[3]

Given the complexity of opportunistic approaches, general practitioners should be better supported to perform preventive health activities. Strategies that could be implemented outside of the general practice setting could include population-based education interventions, as well as policies to reduce poor lifestyle decisions and incentives to foster positive lifestyle choices.[5]

Limitations

This study took place in five regional general practices, which limits the generalisability of our results to the broader Australian population. Further, non–English speaking patients were excluded.

Conclusion

Our results indicate gaps in the awareness of CRC risk factors and screening recommendations among a convenience sample of Australian general practice patients. Increasing patient knowledge may promote lifestyle changes and appropriate screening behaviour that could reduce individual risk of CRC.

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Competing interests

None declared

Author contributions

EM, MC and ND conceived the study. All authors contributed to the drafting of the manuscript or revising it critically for intellectual content.

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PAPER 3

ARE AUSTRALIAN GENERAL PRACTICE PATIENTS APPROPRIATELY SCREENED FOR COLORECTAL CANCER? A CROSS-SECTIONAL STUDY

INTRODUCTION TO PAPER 3

General practice guidelines recommend general practitioners provide regular CRC screening advice[1]. However, we found general practice patients in the target age range for CRC screening had low levels of knowledge related to several CRC screening recommendations (Paper 2), suggesting that it may be important to explore CRC screening rates among general practice patients.

Given the role GPs play in preventive care it may be expected that CRC screening prevalence is higher among general practice patients than in community samples. The most recent data from general practice, collected in 2010-2011 indicates that 40% of participants (n=2269) reported completing FOBT in the past three years[2]. A limitation of this study is a proportion of the sample may be under-screened as guidelines recommend CRC screening every two years, rather than three. Further, since the time of this study, additional age groups have been invited into the NBCSP[3].

Therefore, Paper 3 explores the rate of appropriate CRC screening in general practice patients and variable associated with under-screening. Participants included in this study are from the same dataset reported in Paper 2.

A license agreement for publishing is contained in Appendix 3.1. For participant information statement, consent form and survey instrument refer to Appendices 2.1-2.3.

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Are Australian general practice patients appropriately screened for colorectal cancer? A cross-sectional study

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RESEARCH

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ABSTRACT

Background
Australia has one of the highest rates of colorectal cancer (CRC) in the world. Data from the National Bowel Cancer Screening Program (NBCSP) suggests that only one third of Australians eligible for CRC screening are up-to-date with CRC screening; however screening occurring outside the program is not captured.

Aims
This study examines the self-reported CRC screening practices of general practice patients, and the factors associated with being under-screened for CRC.

Methods
A cross-sectional study conducted in five general practice clinics in NSW from 2015-2017. Participants were aged 50–75 and at average risk of CRC. Participants reported whether they had a faecal occult blood test (FOBT) in the past two years, including the source of FOBT; and whether they had a colonoscopy in the past five years and the reason for colonoscopy.

Results
Forty-nine per cent of participants completed a FOBT in the past two years. Of these, 62 per cent sourced their FOBT from the NBCSP and 25 per cent from their general practitioner. Thirty-seven per cent of participants reported colonoscopy in the past five years. Of these, 29 per cent received potentially inappropriate colonoscopy. Thirty-two per cent of the samples were classified as under-screened. Older adults were less likely to be under-screened.

Conclusion
CRC screening rates were higher than those reported by the NBCSP, however a significant proportion of participants remain under-screened. Over one-quarter of participants reporting colonoscopy in the past five years may have undergone unnecessary colonoscopy. These findings indicate that more needs to be done at a general practice level to facilitate risk-appropriate CRC screening.

Key Words
Colorectal cancer, screening, general practice

What this study adds:

1. What is known about this subject?
CRC is a leading cause of cancer mortality in Australia. CRC screening improves health outcomes. Reported CRC screening rates in Australia (37 per cent) are suboptimal.

2. What new information is offered in this study?
Thirty-two per cent of general practice patients in the sample were under-screened. Of those receiving

colonoscopy in the past five years, 29 per cent were potentially over-screened.

3. What are the implications for research, policy, or practice?

Under- and over-screening for CRC is an issue requiring urgent attention. Interventions to support general practitioners in promoting appropriate CRC screening are required.

Background

The problem

Australia has one of the highest rates of colorectal cancer (CRC) in the world.[1] CRC is the second leading cause of cancer death in Australia, with incidence predicted to increase in the coming years.[2] Early detection of CRC increases survival dramatically. Those diagnosed and treated at the earliest stage have a five-year survival rate of 90 per cent[3], while those detected in the later stages have a five-year survival rate of 5 per cent.[3]

Australian screening guidelines

The Australian National Health and Medical Research Council (NHMRC) guidelines recommend biennial faecal occult blood test (FOBT) for those aged 50 and over at 'average or slightly above average risk of CRC' (herein after referred to as average risk).[4] Those at average risk have no personal history of CRC, and, either no close relatives with CRC or one first-degree or second-degree relative diagnosed with CRC at age 55 or older.[4] The majority of Australians (98 per cent) are considered to be at average risk.[5] Colonoscopy is only recommended in limited circumstances for people at average risk, such as for those presenting with symptoms, or as a surveillance test following adenoma removal.[6]

Australia has had a population-based CRC screening program since 2006.[7] The program has been rolled out in phases with full roll-out expected by 2019.[7] The National Bowel Cancer Screening Program (NBCSP) mails individuals aged 50-74 an invitation to participate in the program and an immunochemical FOBT (iFOBT) with instructions. Completed tests are sent to a central processing laboratory.[8] Uptake rates in the program have plateaued at 37 per cent.[7]

No single data source exists that reports all CRC screening occurring in the Australian population. The uptake rate of 37 per cent refers only to those who complete a kit in response to an invitation from the NBCSP. Therefore this figure is likely to under-estimate screening uptake in the community. FOBTs may be obtained from a variety of sources outside of the NBCSP, including general practitioners (GPs), pharmacies and community organisations such as Rotary. Further, those for whom FOBT is unsuitable, such as those with a diagnosis of CRC, or those at greater than average risk of CRC are included in the denominator used to calculate uptake in response to a NBCSP invitation.[7]

Why examine screening in general practice?

The Royal Australian College of General Practitioners' guidelines recommend that GPs facilitate delivery of preventive care, including CRC screening.[9] GPs are well placed to provide screening advice given that they routinely see a high proportion of those in the target age range for CRC screening. On average, those aged 50 years and over see their GP 6.5 times per year, and those aged 65 years and over see their GP 10 or more times a year.[10] Therefore, we can be confident that general practice patients are representative of the target population for CRC screening. Furthermore, patients expect GPs to provide them with information about preventive care.[11] Given GPs' identified role in CRC screening, it may be expected that a large proportion of general practice patients would be up-to-date with screening.

What have previous studies found?

Previous Australian studies have assessed self-reported CRC screening participation rates in general practice and community settings. Data collected on CRC screening practices of 532 participants at average risk of CRC and aged 50 years and over from the Australasian Colorectal Cancer Family Register in 1999-2001 showed that only 0.75 per cent of this sub-sample screened in accordance with NHMRC guidelines.[12] More recently, Courtney et al.'s[13] community-based study reported that 20 per cent of average risk individuals aged 56–88 had undergone FOBT in the past two years (data from 2009); while another community study reported that 21 per cent of participants aged 50–74 years across all risk categories had undergone FOBT in the past three years (data from 2010).[14] A study of 5671 general practice patients aged 50 and older (data from 2010/11) found that 40 per cent[15] of participants reported that they had completed FOBT in the past three years. Given the increased attention on CRC screening in recent years as well as the continued roll out of the NBCSP, it is timely to assess current uptake rates of FOBT in the primary care setting.

Individuals who do not participate in CRC screening in accordance with guidelines may be under- or over-screened. Under-screening occurs when an individual

participates less often than recommended; over-screening is when screening occurs more frequently than recommended, or the screening test used is more intensive than recommended. For example, colonoscopy in the absence of heightened familial risk or clinical indicators such as symptoms or positive FOBT.[5] Courtney et al. found 14 per cent of those at average risk and asymptomatic had a colonoscopy in the past five years.[13] Zajac et al., found that 33 per cent of participants (no risk category defined) had completed colonoscopy within the past five years.[14] Exploring the reasons for colonoscopy referral will provide insight into potential rates of over-screening.

Demographic factors such as lower education level and younger age are associated with CRC under-screening.[14,15] Further exploration of the factors which are associated with CRC under-screening can assist in identifying the sub-groups of individuals where additional education and encouragement to screen may be required. International research has found higher levels of CRC knowledge relate to higher CRC screening rates.[16-18] The extent that CRC knowledge impacts CRC screening participation has not been examined in Australia. It may be expected that the increased public awareness and mass media campaigns focused on CRC screening in recent years have improved public knowledge, subsequently impacting on screening rates.

The purpose of the current study was to examine, among Australian general practice patients aged 50–75 and at average risk of colorectal cancer (CRC), the proportion of patients who report:

1) Completing a FOBT within the past two years and the source of their most recent FOBT;

2) Undergoing colonoscopy within the past five years and the reasons for undergoing this test; and

3) The extent to which patient sociodemographic characteristics and CRC knowledge are associated with undergoing neither FOBT within the past two years nor colonoscopy within the past five years.

Method

Study design

Cross-sectional survey conducted with general practice patients attending five general practice clinics in New South Wales, Australia. This study was conducted as part of a larger study examining knowledge and experiences in relation to CRC screening among general practice patients aged at least 18 years.

Recruitment methods

Practices: A convenience sample of general practice clinics was recruited. To ensure adequate throughput, eligible practices were required to have at least two full-time equivalent GPs. General practice managers were sent an invitation and information statement via email. Non-responding practices were followed up by telephone. Five of eight invited practices agreed to participate and provided informed written consent.

Participants: Consecutive eligible patients presenting for an appointment with their GP were invited by a research assistant to participate in the larger study. Patients were eligible for the larger study if they were: 1) aged between 18 and 85; 2) English speaking; 3) able to complete a touchscreen survey; and 4) provided written informed consent. Patients were ineligible if they were too unwell. The gender and age group of non-consenters was recorded.

Participants meeting the following criteria were asked to complete the questions on CRC screening which are the focuses of this study: 1) aged 50–75; 2) with no personal history of CRC or inflammatory bowel disease; 3) at average risk of CRC. Three survey questions determined average risk as defined by NHMRC criteria[4]: 1) Have any of your first-degree relatives been diagnosed with bowel cancer before age 55? (yes/no); 2) Have two or more of your first-degree relatives been diagnosed with bowel cancer at any age? These may be from either side of the family (yes/no); 3) Have one of your first-degree relatives and one of your second-degree relatives on the same side of the family been diagnosed with bowel cancer at any age? (yes/no). First degree relatives were described as mother, father, brother, sister, child. Second-degree relatives were described as grandparent, aunt, uncle, nephew, niece or half-sibling. Those responding 'no' to these questions were considered to be at average risk of CRC.

Measures

Previous FOBT: Participants were asked to report when they undertook their most recent FOBT. Response options included: never had an FOBT; in the last year; 1–2 years ago; 2–3 years ago, 4–5 years ago; more than 5 years ago; not sure.

Source of most recent FOBT: Participants who reported having an FOBT in the past two years were asked where they had obtained their most recent FOBT from: I received it in the mail from the National Bowel Cancer Screening Program; Rotary Bowelscan; my GP gave it to me; other – please specify.

Previous Colonoscopy: Participants were asked to report

their most recent colonoscopy: never had a colonoscopy; in the past five years; more than five years ago; not sure. Those that reported they had a colonoscopy in the past five years were asked: "why were you referred for a colonoscopy?" Participants could select multiple options from the following: I have a family history of bowel cancer; I had symptoms suggestive of bowel cancer; I had a positive FOBT result; I had an abnormal x-ray or CT scan; I have previously had colorectal adenomas/polyps; other – please specify.

Explanatory variables: *Sociodemographic items:* Age, gender, marital status, highest level of education, employment status, private health insurance coverage, health care concession card holder status were self-reported.

Knowledge items: CRC knowledge was assessed by five multiple choice questions. The questions were prefaced with: "The following questions use the term people at 'average risk' of bowel cancer. People at 'average risk' of bowel cancer will not have a personal history of cancer, and no strong history of bowel cancer in their family". Questions or responses regarding CRC screening tests included a description of each test in lay terms. Participants could select one response for each of the following questions: 1) "at what age do you think people at average risk of bowel cancer should start screening?" (40; 50; 60; 70; I don't know); 2) "what do you think is the recommended screening test for people at 'average risk' of bowel cancer?" (sigmoidoscopy; faecal occult blood test (FOBT); colonoscopy; I have not heard of these screening tests; I don't know).; 3) "how often do you think a person at 'average risk' of bowel cancer should have a faecal occult blood test (FOBT)?" (once only, every year; every two years; every five years; every ten years); 4) "a positive faecal occult blood test (FOBT) result means" (that a person has cancer; that a person does not have cancer; that traces of blood have been found in their faeces (poo); I don't know); 5) "the following may or may not increase a person's chance of developing bowel cancer. Please select all the option/s you might think increase risk of developing bowel cancer" (smoking; being over 50 years of age; being overweight; not eating enough fibre; drinking alcohol regularly; I don't know). For questions 1–4, one point was awarded for each correct response. For question five, one point was awarded for every risk factor selected (maximum of five points). The total maximum score possible was nine.

Data collection and analysis

Data were collected from December 2015–March 2017. Consenting participants completed a touch screen survey in the practice waiting room prior to their appointment. The survey was administered using QuON survey software.[19] Participants who were called in to their appointment prior to completing survey were logged out and were able to log in again after their appointment by using their unique identification code to complete the survey.

The gender and age group of consenting and non-consenting patients were compared using chi-squared tests.

Descriptive statistics including frequencies and percentages were calculated for each sociodemographic variable of interest. Individual knowledge scores were summed and expressed as a total score out of nine. Proportions were calculated (with 95 per cent confidence intervals) of those reporting screening with: 1) FOBT within the last two years, and the source of their FOBT kit, and 2) colonoscopy within the last five years, and the reason for this colonoscopy. Participants reporting neither FOBT in the past two years nor colonoscopy in the past five years were classified as under-screened.

Multivariable logistic regression analyses were performed to determine whether age, gender, marital status, highest level of education, employment status, private health insurance coverage, health care concession card holder, and knowledge scores were independent predictors of under-screening. Missing data were handled using multiple imputation. All analysis variables were used as predictor variables in the imputation models and 18 imputed datasets were created. The multivariable logistic regression models were estimated on each of the imputed datasets, and regression coefficients pooled using Rubin's method. Pooled odds ratios, 95 per cent confidence intervals and Wald based p-values are presented. All analyses were conducted using Stata IC 11.3 (Statacorp, College Station, TX). p-values of <0.05 were considered significant.

Results

A total of 727 participants were assessed for eligibility, of whom 510 were eligible for the larger study (70 per cent eligible). Of the eligible participants, 411 consented to participate (81 per cent consent rate). There was no significant difference in gender between the consenters and non-consenters ($x^2(1) = 1.29$, $p=2.54$). There were fewer consenters in the 55–64 year group and more consenters in the over 74 year group ($x^2(5)=12.36$, $p=0.03$). A further 221 of the consenting participants were excluded from the current study for the following reasons: 1) did not commence the survey (n=4); 2) were aged <50 or >75

(n=159); had a diagnosis of CRC of inflammatory bowel disease (n=19); were at greater than average risk of CRC (n=39). One-hundred and ninety participants commenced the survey, of these 179 responded to both the FOBT and colonoscopy questions and were included in the analyses. The demographic characteristics and knowledge scores of the sample are reported in Table 1.

The proportion who report being screened with FOBT within the past two years

87 (49 per cent; 95 per cent CI 41–56 per cent) participants reported completing an FOBT in the past two years. Of the remaining 92 participants, 44 (25 per cent; 95 per cent CI 18–32 per cent) had never completed a FOBT, 47 (26 per cent; 95 per cent CI 20–33 per cent) had completed a FOBT >2 years ago, 1 could not recall (0.5 per cent; 95 per cent CI 0.01–3 per cent).

Source of most recent FOBT

The majority of the 87 participants that completed FOBT in the past two years reported sourcing their FOBT from the NBCSP, n=54 (62 per cent; 95 per cent CI 51–72 per cent). A further 22 (25 per cent; 95 per cent CI 16–36 per cent) reported receiving their most recent FOBT from the GP. The remaining participants reported sourcing their FOBT from Rotary Bowelscan, n=5 (6 per cent; 95 per cent CI 2–13 per cent) and other sources n=6 (6 per cent; 95 per cent CI 2–13 per cent)(pathology n=2; pharmacy n=1; specialist n=2; research project n=1; unknown n=1).

Colonoscopy use within the past 5 years

66 (37 per cent; 95 per cent CI 30–44 per cent) participants reported colonoscopy in the past five years. All of these participants provided the reason they were referred for colonoscopy (see Table 2). 19 (29 per cent; 95 per cent CI 17–40 per cent) cited family history of CRC or routine screening as reasons for colonoscopy referral, indicating potential over-screening. However, one of these participants selected both symptoms suggestive of CRC and routine screening, so may possibly have been appropriately screened.

Variables associated with undergoing neither FOBT within the past two years nor colonoscopy within the past five years (Table 3).

58 (32 per cent; 95 per cent CI 26–40 per cent) participants were classified as under-screened (i.e., reported neither screening with FOBT in the past two years nor colonoscopy in the past five years). For every year increase in age there was an 8 per cent decrease in the odds of being under-screened (p=0.008).

Discussion

Nearly half of participants reported FOBT completion in the past two years (n=88, 49 per cent). This is substantially more than the 37 per cent FOBT completion rate reported by the NBCSP monitoring report[7] and previous Australian research investigating self-reported FOBT completion in general practice (40 per cent).[15] However, the latter study reported data which was collected between 2010 and 2011. Since that time there has been an increased focus on media campaigns to promote CRC screening such as 'a gift for living',[20] 'bowel cancer awareness month'[21] and 'red apple day'[22] and the Cancer Council's bowelcancer.org.au awareness campaign.[23] It is likely that these campaigns have increased public awareness of CRC and the need for CRC screening. Close to one third of those reporting FOBT in the past two years sourced their FOBT kit from outside of the NBCSP, with most of these obtaining a kit from their GP. This highlights the important role of the GP in promoting and providing CRC screening.

Thirty-seven per cent of participants reported colonoscopy in the past five years, a higher rate than that reported in previous research.[13,14] This could be due to the high proportion of participants with private health insurance (66 per cent) which has been found to be a predictor of unnecessary colonoscopy in other Australian research[12] and the general trend of increasing colonoscopy use in Australia.[24] Close to 1/3 (29 per cent) of participants reporting colonoscopy in the past five years (i.e., 11 per cent of our total sample) indicated that they received a colonoscopy due to routine screening and family history. Given that the inclusion criteria for our study required that all participants were at average risk, it is likely that those reporting colonoscopy as a routine screening test or due to family history were over-screened. Our results indicate a similar rate of potential over-screening as Australian data which reported 13 per cent of people aged 50–75 were over-screened using colonoscopy.[5] Australian Medicare Benefits Schedule data indicates that in the ten years from 2000/2001–2009/2010 the overall number of colonoscopies performed in Australia increased by 84 per cent.[24] We cannot determine appropriateness of colonoscopy from these data, however it is reasonable to expect that some of this increase is due to unnecessary colonoscopy, a pattern evident in other regions including Europe and the United States.[25] Unnecessary colonoscopy exposes patients to potential clinical and economic burden.[26,27] Further, it reduces the capacity of the health care system to provide

timely care to those with a genuine need for colonoscopy.[28] A GP educational intervention in Italy resulted in a three-fold decrease (p<0.001) of inappropriate colonoscopy.[29] Similar interventions may have potential to reduce the prevalence of inappropriate colonoscopy in Australia.

Just under one third of the sample were under-screened for CRC, reporting neither FOBT in the past two years nor colonoscopy in the past five years. The regression model identified increasing age as being significantly associated with a decrease in the odds of under-screening. This is consistent with published research.[16-18] GP recommendation of CRC screening is a consistent predictor of positive screening behaviours.[30,31] Strategies to support GPs to recommend CRC screening such as reminders embedded in practice software have increased screening participation in several studies.[32] In addition, the Australian government is in the process of building a national cancer register from which the NBCSP will operate.[33] The register is expected to support clinical-decision making by GPs by allowing direct access to their patients' CRC screening participation within the NBCSP via practice management software,[34] a function that is currently not available to GPs. In addition to this it is anticipated that GPs will be able to order and record FOBT via the register and receive reminders for patients that are overdue for CRC screening.[33] Finally, newer types of faecal testing are becoming available in Australia (such as faecal DNA). There is potential that these could lead to increased screening participation as early evidence suggests they may be more acceptable to screeners than iFOBT.[35]

Limitations

Self-reported screening may be affected by recall bias, however a recent meta-analysis found moderate agreement between self-reported and registered CRC screening.[35] Due to the brevity of familial history questions used to determine CRC risk category, it is possible that a small number of participants at average risk may have been classified as greater than average risk and vice-versa. We cannot determine the type of FOBT sourced outside of the NBCSP (i.e., guaiac or immunochemical), however the majority of pharmacies and pathology labs in Australia supply iFOBT.[36] These data were collected from a small number of general practices and therefore may not be generalizable to the broader population, however both rural and urban practices were represented in this study.

Implications and future directions

High rates of FOBT participation in general practice suggest the potential to further capitalise on the GP's role in CRC screening. Future research should focus on interventions that can be delivered in general practice to identify and target those overdue for CRC screening. This could include interventions such as tools to assess familial risk and screening status, point-of-care FOBT and GP endorsement of appropriate screening tests.

Our results suggest that there may be over-screening via colonoscopy among general practice patients. Strategies to support GPs to identify and manage those screening outside of guidelines may lead to decreases in unnecessary colonoscopy. Promotion of appropriate CRC guideline adherence amongst GPs may be facilitated by documents such as the National Prescribing Service MedicineWise initiative[5], as well as educational interventions[25,29].

Somewhat surprisingly, the odds of under-screening were not associated with CRC screening knowledge scores. This suggests that other factors besides knowledge may be stronger drivers for CRC screening. Future studies should explore whether other factors, such as attitudes towards screening, and personal experience with cancer among family or friends may be associated with screening.

Conclusion

Screening rates reported in the NBCSP have plateaued at 37 per cent. Our study indicates that CRC screening rates in the general practice setting may be higher than this but there is still room for improvement. 25 per cent of those completing FOBT in the past two years sourced their FOBT from their GP, highlighting the important role GPs have in providing screening advice. In addition, a substantial proportion of general practice patients appear to have undergone unnecessary colonoscopy. GPs need to be better supported to deliver appropriate CRC screening to their patients.

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PEER REVIEW

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

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ETHICS COMMITTEE APPROVAL

This study received ethics approval from the University of Newcastle Human Research Ethics Committee (H-2014-0198).

Table 1: Demographic characteristics and knowledge scores (n=179)

Characteristic	Category	n (%)
Age group	50-59	47 (26%)
	60-69	86 (48%)
	70-75	46 (26%)
Gender	Female	103 (58%)
	Male	76 (42%)
Marital status	Non-married (divorced/widowed/single)	53 (30%)
	Married (de-facto/living with partner)	123 (70%)
Education	Tertiary	54 (31%)
	Non-tertiary (high school or below/ trade/diploma/vocation)	122 (69%)
Employment	Employed (full-time and part-time)	54 (31%)
	Non-employed (carers, home duties, students, out of work)	16 (9%)
	Disability pension	14 (8%)
	Retired	92 (52%)
Private health insurance	Yes	96 (66%)
	No	50 (34%)
Healthcare concession card	Yes	88 (60%)
	No	58 (40%)
Knowledge scores	0	7 (4%)
	1	7 (4%)
	2	15 (8%)
	3	25 (14%)
	4	28 (16%)
	5	28 (16%)
	6	25 (14%)
	7	30 (17%)
	8	13 (7%)
	9	1 (0.5%)

nb: not all variables total 179 due to missing data.

Table 2: Self-reported reasons for colonoscopy in the past five years (n=66 participants)

Reason for colonoscopy	Proportion*
Previous polyps/adenoma	14 (21%)
Symptoms suggestive of CRC	17 (26%)
Other medical conditions	9 (14%)
Follow-up of positive FOBT	7 (11%)
Abnormal CT/X-ray	1 (2%)
Perceived strong family history of CRC	6 (9%)
Routine screening	13 (20%)
Can't remember	2 (3%)

**Proportions sum to >100% due to some participants selecting more than one option*

Table 3: Multivariable logistic regression showing variables associated with under-screening (n=179)

Variable	Sub-group	OR for being under-screened (95% CI)	*p* value
Age	N/A (continuous)	0.92 (0.87-0.98)	0.008
Gender	Female	-	0.63
	Male	0.84 (0.41-1.72)	
Marital status	Non-married (divorced/widowed/single)	-	0.80
	Married (de-facto/living with partner)	1.11 (0.50-2.45)	
Education	Tertiary	-	0.95
	Non-tertiary (high school or below/ trade/diploma/vocation)	0.98 (0.45-2.12)	
Employment	Employed	-	0.65
	Unemployed (carers, home duties, students, out of work)	1.34 (0.38-4.72)	
	Disability	1.25 (0.31-5.00)	
	Retired	0.87 (0.34-2.2)	
Private Health	No	-	0.41
	Yes	0.70 (0.31-1.61)	
Health care card	No	-	0.55
	Yes	1.30 (0.55-3.07)	
Knowledge score	N/A (continuous)	0.87 (0.74-1.03)	0.10

PAPER 4

HAVE WE INCREASED OUR EFFORTS TO IDENTIFY STRATEGIES WHICH ENCOURAGE COLORECTAL CANCER SCREENING IN PRIMARY CARE PATIENTS? A REVIEW OF RESEARCH OUTPUTS OVER TIME.

INTRODUCTION TO PAPER 4

General practice CRC screening guidelines recommend GPs routinely provide CRC screening advice, however descriptive research frequently reports sub-optimal CRC screening rates in general practice settings[1-3]. In response to this evidence-practice gap, it may be expected that research efforts examining strategies to increase CRC screening in this setting has increased over time[4, 5]. Further, research must be of high enough quality so that the evidence generated has meaningful results and applications[6].

Paper 4 is a critical review of general practice-based research over the past twenty years which describes the volume and quality of descriptive and intervention research that reports CRC screening uptake. This paper provides a snapshot of the changes in research efforts to address this evidence-practice gap.

A license agreement for publishing, search strategy and list of included studies are contained in Appendices 4.1-4.3.

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Review Article

Have we increased our efforts to identify strategies which encourage colorectal cancer screening in primary care patients? A review of research outputs over time

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ABSTRACT

Globally, colorectal cancer (CRC) screening rates remain suboptimal. Primary care practitioners are supported by clinical practice guidelines which recommend they provide routine CRC screening advice. Published research can provide evidence to improve CRC screening in primary care, however this is dependent on the type and quality of evidence being produced. This review aimed to provide a snapshot of trends in the type and design quality of research reporting CRC screening among primary care patients across three time points: 1993–1995, 2003–2005 and 2013–2015.

Four databases were searched using MeSH headings and keywords. Publications in peer-reviewed journals which reported primary data on CRC screening uptake among primary care patients were eligible for inclusion. Studies meeting eligibility criteria were coded as observational or intervention. Intervention studies were further coded to indicate whether or not they met Effective Practice and Organisation of Care (EPOC) study design criteria.

A total of 102 publications were included. Of these, 65 reported intervention studies and 37 reported observational studies. The proportion of each study type did not change significantly over time. The majority of intervention studies met EPOC design criteria at each time point.

The majority of research in this field has focused on testing strategies to increase CRC screening in primary care patients, as compared to research describing rates of CRC screening in this population. Further research is needed to determine which effective interventions are most likely to be adopted into primary care.

1. Introduction

Globally, colorectal cancer (CRC) is the third most diagnosed cancer and the fourth most common cause of cancer death (Ferlay et al., 2013). CRC screening recommendations are reported in clinical practice guidelines in the developed world and include FOBT, sigmoidoscopy and colonoscopy (Australian Cancer Network Colorectal Cancer Guidelines Committee, 2005; European Commission, 2010; U.S. Preventive Services Task Force, 2008). Population-based CRC screening programs are recommended by the World Health Organisation (Wilson & Jungner, 1968) and several developed nations have implemented population-based screening (Benson et al., 2007). Reported CRC screening rates within these programs are suboptimal, ranging from 7% to 68% (Klabunde et al., 2015). This highlights the urgent need to find effective strategies to increase participation in CRC screening. There is increasing interest in the role of primary care providers (PCPs) to encourage participation in screening. Clinical practice guidelines suggest that PCPs provide risk-appropriate CRC screening advice (Australian Cancer Network Colorectal Cancer Guidelines Committee, 2005; European Commission, 2010; Sarfaty, 2008) and PCPs have a high-level of contact with those in the target age range for CRC screening (Britt et al., 2015).

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1.1. Research type and quality as an indicator of progression of the field

Published research can provide evidence to improve CRC screening in primary care, however this is dependent on the type and quality of evidence being produced. Observational research can provide prevalence data as well as factors associated with an outcome (Theise, 2014). Intervention research that has both internal and external validity can provide data to support causal inferences (Theise, 2014). Exploring the relative effort directed toward observational versus intervention research may help to inform future research directions. For example, if there is a dearth of research of any type, then the field may wish to focus on observational research in order to provide a base for subsequent intervention studies. If there is a predominance of observational research then it may be timely to consider whether efforts would better be focussed on intervention research.

The quality of intervention studies should also be considered. The quality of evidence generated by intervention studies is, in part, determined by the type of experimental design used. The Cochrane Effective Practice and Organisation of Care (EPOC) group specify four study designs which provide robust evidence of effectiveness for interventions: randomised control trials (RCTs), controlled clinical trials (CCTs), interrupted time series (ITS) and controlled before after studies (CBAs) (Cochrane Effective Practice and Organisation of Care Review Group, 2002). Results produced from studies using these designs are less likely to be susceptible to biases, including selection bias and confounding, than those produced from studies using other types of designs (Theise, 2014). While many criteria can be used to comprehensively assess methodological quality, research design provides an initial indicator of research quality.

Clinical practice guidelines report recommendations based on a hierarchy of evidence, with RCTs second only to meta-analyses and systematic reviews (Australian Cancer Network Colorectal Cancer Guidelines Committee, 2005; European Commission, 2010; Guyatt et al., 2015; Royal Australian College of Physicians, 2016). As such it might be expected that the scientific community has increased their research efforts over time from predominantly observational research to high-quality intervention research to inform evidence-based practice.

2. Aims

To examine across three time-points (1993–1995, 2003–2005 and 2013–2015), changes in:

- The proportion of observational and intervention research;
- The proportion of intervention studies that used an EPOC-accepted study design.

3. Methods

3.1. Literature search

Medline, Embase, The Cochrane Library and PSYCINFO databases were searched to identify studies reporting on CRC screening in primary care settings. A start point of 1993 was chosen for the following reasons: 1) Two landmark publications providing evidence that repeated screening with FOBT decreased mortality and that polypectomy via colonoscopy effectively prevented progression of polyps to CRC were published in 1993 (Mandel et al., 1993; Winawer et al., 1993); 2) the earliest mass CRC screening programs commenced in 1992–1993 (Benson et al., 2007). As the purpose of the review was to examine trends over time in the type of research, we examined all relevant publications for three time-points over the past twenty years: 1993–1995 (time point 1), 2003–2005 (time point 2) and 2013–2015 (time point 3).

The following search themes were combined: colorectal cancer, screening and primary care (for full search strategies for each database see Appendix 1). Reference lists of relevant articles were also manually searched to identify additional publications meeting inclusion criteria. The search was limited to include only English language publications and publications with an adult population.

3.2. Inclusion and exclusion criteria

All retrieved titles and abstracts were examined for relevance following removal of duplicates.

Publications were eligible for inclusion if they: 1) reported primary data on rates of CRC screening (any form) among primary care patients and used either; a) an observational study design, or; b) an intervention study design where CRC screening was a primary outcome; 2) were conducted either in the primary care setting or using primary care infrastructure/systems, such as electronic patient records; 3) included a sample aged ≥50; 4) were published in a peer-reviewed journal in the years 1993–1995, 2003–2005, 2013–2015; 5) were published in English; 6) had a full manuscript available. Publications that reported on mixed screening for a range of different conditions were included if results for CRC screening were reported separately. Publications that reported on a sample recruited from a variety of settings were included if the outcomes for the primary care sample were reported separately.

Publications were excluded if they: 1) involved participants who had a previous history of CRC, inflammatory bowel disease or those with hereditary disease such as Lynch syndrome or FAP, as people diagnosed with these diseases are at increased risk of CRC when compared to the general population and have differing CRC screening recommendations; 2) reported diagnostic procedures (symptomatic testing); 3) relied on PCP estimates of CRC screening rates; 4) were dissertations, commentaries, book reviews, reports, reviews, case studies, editorials, letters to the editor or conference proceedings.

3.3. Data coding

Publication titles and abstracts were initially assessed against the eligibility criteria by one author (ND) and excluded if the study did not meet inclusion criteria. A secondary screen of the abstracts by the same author led to additional publications being excluded. The full texts of the remaining publications were assessed for eligibility. A random subsample of 20% of full text publications were assessed against the inclusion criteria by another author (EM), with any discrepancies resolved via discussion.

All publications meeting the eligibility criteria were categorised according to whether they were: 1) observational studies which reported prevalence of CRC screening among primary care patients; or 2) intervention studies to assess the effectiveness of behavioural interventions to increase CRC screening among primary care patients. Intervention studies were further coded according to whether they met one of the four EPOC design criteria: RCTs, CCTs, CBAs, and ITS.

3.4. Analysis

The Kappa statistic was used to assess the level of inter-rater agreement between the authors who assessed the eligibility of full text articles.

To determine changes in proportions of study types over the three time periods we used generalised linear models with a binomial distribution and an identity link. Time was coded as 1, 2 or 3, representing 10 year increments, and assumed to have a linear effect (on the log scale). Coefficients from this model are interpreted as the absolute difference in proportions for each ten year increment in time.

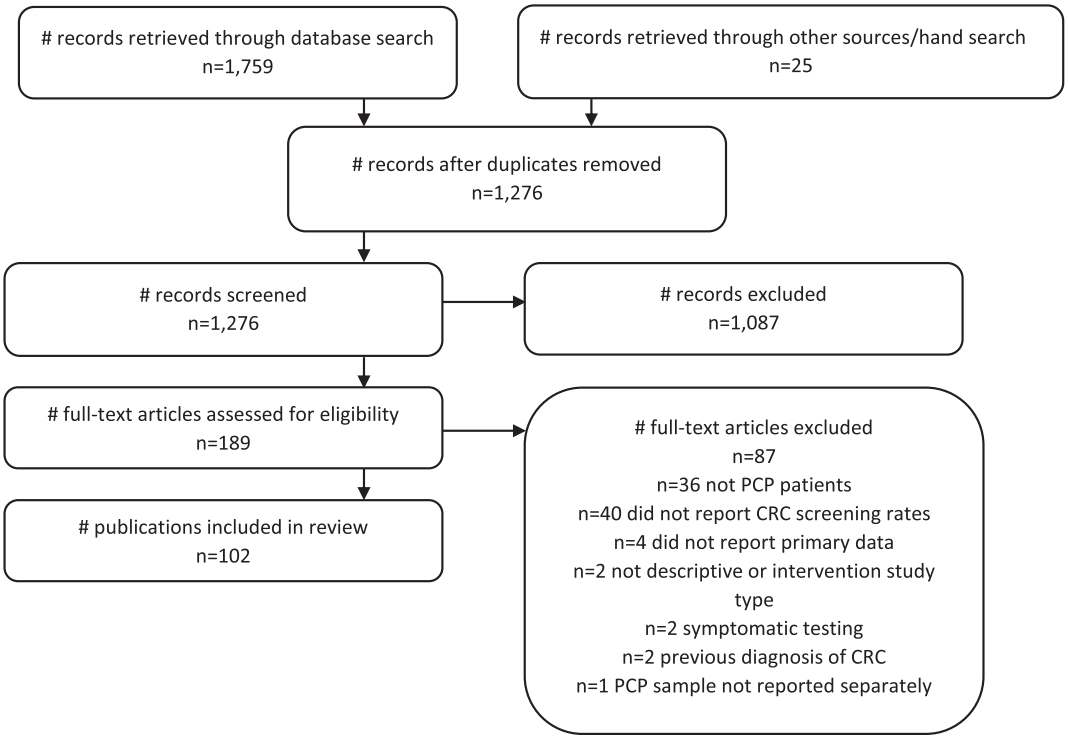

Fig. 1. Flow chart of steps and reasons for exclusion.

4. Results

4.1. Search results

A total of 1759 publications were retrieved from the searches (see Fig. 1). A further 25 publications were retrieved using a hand search. After duplicates were removed, 1276 publications were assessed against the eligibility criteria. Following initial abstract screening, full-text review was conducted on 189 publications. There were 102 full text publications which met eligibility criteria and were included in the review. The inter-rater agreement between the authors who assessed the eligibility of full text articles was very good (κ = 0.896; 95% CI 0.76–1.0). A full list of included references can be found in Appendix 2.

4.2. Changes in proportion of each type of research over time

Across the time-points, the proportion of studies that utilised an intervention design varied between 57% (time point 1) to 65% (time point 2) (see Fig. 2). The proportion of intervention relative to observational studies did not change significantly over time (risk difference −0.02; 95%CI −0.17–0.13, p = 0.83).

4.3. Changes in the proportion of intervention studies that used an EPOC-accepted study design over time

At the two most recent time points when the majority (94%) of intervention studies were published, between 78 and 85% of intervention studies used an EPOC-accepted study design. There were no significant changes in the proportion of studies meeting EPOC design criteria across the three time points (see Fig. 3; (risk difference 0.03; 95%CI −0.13–0.20, p = 0.83)).

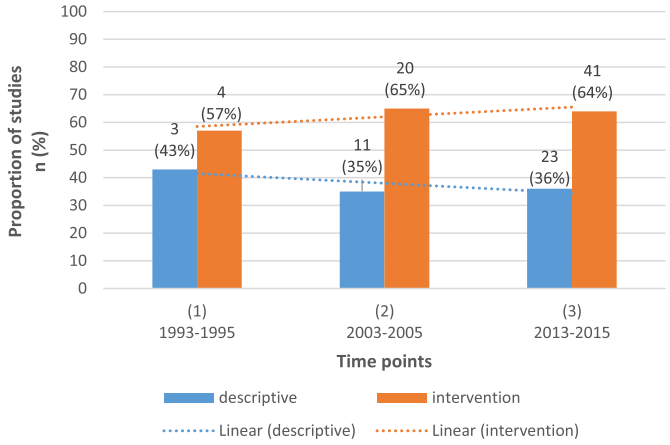

Fig. 2. Number and proportion of descriptive and intervention research over time.

5. Discussion

5.1. No statistically significant change in proportion of each type of research over time

The proportion of intervention research was larger than observational research across all time points (approximately 2/3 of studies were intervention at each time point). There was no significant change in the proportion of intervention vs observational research over time. This stands in contrast to previous reviews of the literature on evidence-practice gaps, which have found a higher volume of observational relative to intervention research, and that the proportion of observational research increased over time, relative to intervention research (Bryant et al., 2014; Goyet et al., 2015; Robertson et al., 2015; Mansfield et al., 2016; Waller et al., 2017). Given that intervention studies are often time and resource intensive when compared to observational studies, specifically for CRC screening (Dear et al., 2012) it is encouraging that

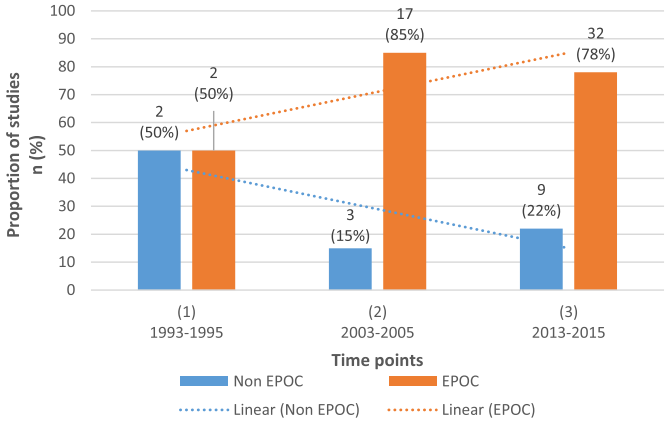

Fig. 3. Number and proportion of intervention studies that used an EPOC-accepted study design over time.

our results indicate a consistently high proportion of intervention studies being conducted to increase rates of CRC screening.

These findings may reflect a high level of awareness in the field of the need to develop evidence for effective strategies to increase screening uptake, which in turn can lead to improved health outcomes (Mandel et al., 1993; Winawer et al., 1993). National screening registers can provide observational data to describe current patterns of CRC screening behaviours (Klabunde et al., 2015; Australian Institute of Health and Welfare, 2017). However, these data sources are limited in their ability to capture screening which occurs outside of formalised screening programs, such as opportunistic screening in the community or general practice settings. Therefore, observational research remains important in general practice as it can inform the need for development of targeted interventions, and can serve to monitor the impact of changes in policies on current practice. Intervention research in turn, contributes new high-quality data which can be disseminated into practice via clinical practice guidelines (European Commission, 2010; Royal Australian College of Physicians, 2016).

5.2. High proportion of intervention studies using EPOC accepted study designs

The majority of intervention studies at the two most recent time points met the EPOC study design criteria (85%, 78% respectively). This high proportion suggests that the intervention research conducted has generally been of high methodological quality. These findings are in contrast to other reviews examining behavioural interventions (grief counselling and smoking cessation), which showed that lower proportions of intervention studies met EPOC design criteria (i.e. 59% (Waller et al., 2015) and 61% (Courtney et al., 2015)). The overall high proportion of intervention studies using EPOC-accepted designs may reflect that primary care settings are amenable to robust study designs such as RCTs due to the available units which can be potentially randomised, including patients, PCPs and practices. It may also reflect a high level of methodological and statistical expertise available in this area, allowing the conduct of high quality intervention trials and consequently the delivery of evidence-based medicine.

6. Limitations

These results should be considered in light of several limitations. Firstly, only three time points were included in the analyses. However each time point contained three years (covering 40% of the entire period 1993–2015), providing a reasonable snapshot of research efforts in this field. It is possible that there were extreme year to year variations in research outputs which were not captured by our purposeful sampling approach, leading to incorrect conclusions to be drawn in our review. However, given the range of studies at each time point and the range of three years selected at each time point, this is unlikely to be the case. We only included observational studies which reported the prevalence of screening. Therefore, studies which described attitudes, intentions and the acceptability of screening were omitted. This may have contributed to the lower proportion of observational relative to intervention studies found. Grey literature, including reports, policy documents, dissertations, reviews and protocol papers, were not included in our search. This may have resulted in some relevant studies being missed. As grey literature is not peer-reviewed, its omission may have biased the results toward higher quality studies. In addition, publication bias may limit the extent to which we can rely on publication metrics as a proxy for research effort. Studies with null results may not have been published, leading to an under-representation of the amount of research effort in this area.

7. Future directions

While a large proportion of research in this area consisted of high-quality intervention studies, a significant proportion of the population remain under screened for CRC (Navarro et al., 2017). Plateauing rates of CRC screening within some population-based programs (Klabunde et al., 2015) indicate that further research needs to continue exploring the effectiveness of strategies delivered in primary care and other settings in boosting CRC screening participation rates. Observational research indicates that low uptake of CRC screening among primary care patients may be attributable to several barriers, including inadequate time (Aubin-Auger et al., 2011; Guerra et al., 2007; Myers et al., 1999) lack of guideline clarity (Klabunde et al., 2003), lack of patient interest in conversations about CRC screening (Zapka et al., 2011) and cross-cultural issues (Martin et al., 2014). Appropriate primary care-based interventions which overcome these barriers are needed. Systematic reviews of intervention research show that a number of primary care-based strategies are effective in increasing CRC screening uptake (Camilloni et al., 2013; Ferroni et al., 2012; Rawl et al., 2012; Senore et al., 2015), particularly when delivered in conjunction with population-based CRC screening programs (Zajac et al., 2010; Federici et al., 2006; Hewitson et al., 2011; Cole et al., 2002). Multi-factorial systematic interventions have been shown to be most effective in primary care (Sabatino et al., 2012). Despite this research and the importance of the PCP's role in encouraging CRC screening uptake, US primary care studies indicate that only 17% (Malhotra et al., 2014) to 59% (Kern et al., 2014) of primary care patients are screened in accordance with guideline recommendations. Future research should focus particular attention on the feasibility of interventions in practice as well as long-term sustainability. Feasible approaches in this setting may include physician endorsement (Zajac et al., 2010; Hewitson et al., 2011), removal of financial barriers (Potter et al., 2011) and patient education (Senore et al., 2015). Future studies should therefore test these promising strategies using robust experimental designs. Where it is judged that there is sufficient evidence of efficacy for these strategies, studies should then focus on testing ways to effectively implement these into practice using a planned approach which addresses barriers to changing practice, such as stakeholder engagement (community and general practice) and tailoring messages to the target audience (Woolf et al., 2015).

8. Conclusion

This review examined trends over time in the proportion of observational and intervention research that explored CRC screening among primary care patients, and the proportion of intervention studies that met EPOC study design criteria. The proportion of intervention research was greater than observational research across all time points, and the proportion of intervention vs observational research did not change over time. The majority of intervention studies used an EPOC-

accepted study design, and this proportion did not change across time points. Implementing strategies that use feasible approaches is the next step to embed adoption in primary care and increase CRC screening rates.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2018.05.015.

Authors' contributions

EM, MC, ND and RSF conceived the study. CO advised on study design, sample size and statistical methods. All authors contributed to the drafting of the manuscript or revising it critically for intellectual content.

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Declaration of interests

The authors declare that they have no competing interests.

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PAPERS 5 AND 6

TESTING THE EFFECTIVENESS OF A PRIMARY CARE INTERVENTION TO IMPROVE UPTAKE OF COLORECTAL CANCER SCREENING: A RANDOMIZED CONTROLLED TRIAL

INTRODUCTION TO PAPERS 5 AND 6

Despite the majority of research reporting CRC prevalence in general practice is interventional and of high quality design, CRC screening rates in Australia remain suboptimal[1]. GP endorsement is associated with positive CRC screening behaviour[2-4]. This has mostly been demonstrated in the context of population-based screening programs, whereby GP letterhead and signature is attached to the invitation to the program[5]. This can only work in health care systems in which participants have a usual source of care and where the population-based program interacts with general practitioners and their patients. This is not the case in Australia, where the NBCSP operates without these facilitating factors[6]. Given low screening rates within the NBCSP, it is clear that additional strategies are required.

Papers 5 and 6 describe a multisite, 1:1 parallel-arm, cluster RCT delivered in a general practice setting. The intervention consists of provision of printed information, a faecal occult blood test and GP endorsement to complete the test. This intervention may be able to be incorporated into general practice and boost stagnant CRC screening participation rates. This RCT was registered with the Australian New Zealand Clinical Trials Registry on 15th September 2016 (ACTRN12616001299493).

A license agreement for publishing, patient consent form and survey instruments are contained in Appendices 5.1-5.7.

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Protocol

Testing the Effectiveness of a Primary Care Intervention to Improve Uptake of Colorectal Cancer Screening: A Randomized Controlled Trial Protocol

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Abstract

Background: Screening for colorectal cancer (CRC) significantly reduces mortality associated with this disease. In Australia, the National Bowel Cancer Screening Program provides regular fecal occult blood tests (FOBT) for those aged 50 to 74 years, however, participation rates in the program have plateaued at 36%. Given low uptake in the National Bowel Cancer Screening Program, it is necessary to explore alternate methods to increase CRC screening rates. Primary care is a promising adjunct setting to test methods to increase CRC screening participation. Primary care guidelines support the recommendation and provision of CRC screening to primary care patients. Those in the National Bowel Cancer Screening Program target age range frequently present to their primary care provider.

Objective: This study tests the effect that a multicomponent primary care–based intervention has on CRC screening uptake when compared to usual care.

Methods: Primary care patients presenting for an appointment with their primary care provider complete a touchscreen survey to determine eligibility for the trial. Those aged 50 to 74 years, at average risk of CRC, with no history of CRC or inflammatory bowel disease, who have not had an FOBT in the past 2 years or a colonoscopy in the past 5 years are eligible to participate in the trial. Trial participants are randomized to the intervention or usual care group by day of attendance at the practice. The intervention consists of provision of an FOBT, printed information sheet, and primary care provider endorsement to complete the FOBT. The usual care group receives no additional care.

Results: The primary outcome is completion of CRC screening 6 weeks after recruitment. The proportion of patients completing CRC screening will be compared between trial groups using a logistic regression model.

Conclusions: CRC screening rates in Australia are suboptimal and interventions to increase screening participation are urgently required. This protocol describes the process of implementing a multicomponent intervention designed to increase CRC screening uptake in a primary care setting.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12616001299493; https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=371136&isReview=true (Archived by WebCite at http://www.webcitation.org/6pL0VYIj6). Universal Trial Number U1111-1185-6120.

(JMIR Res Protoc 2017;6(5):e86) doi:10.2196/resprot.7432

KEYWORDS

clinical trial; colorectal cancer; early detection of cancer; general practice; primary care; primary care provider

Introduction

Globally, colorectal cancer (CRC) is the third most common cancer in men and the second most common cancer in women [1]. Overall, it is the fourth leading cause of cancer death [2]. Worldwide, 1.4 million people are diagnosed with CRC every year, and 694,000 die as a result [2]. In Australia, CRC is the second most diagnosed and second most common cause of cancer death [3]. In 2012, 14,958 Australians were diagnosed with CRC and in 2013, 4162 died as a result of CRC [3].

The effectiveness of CRC screening using a fecal occult blood test (FOBT) has been established in several large randomized controlled trials (RCTs) [4-7]. Biennial FOBT screening reduces mortality from CRC by 13% to 33% [4-8]. FOBT is an affordable, accessible form of screening that can be completed by an individual in the privacy of their own home. Studies in the United States [9] and Israel [10] have found that the majority of participants prefer FOBT compared to other screening methods such as colonoscopy. Participants report that they prefer FOBT because it is convenient, affordable, less time-consuming, less painful when compared to other screening modalities, and requires no bowel preparation [9-11]. In Australia, guidelines recommend biennial FOBT for people aged 50 years and above who are at average risk of CRC [12].

Given the benefits associated with CRC screening, many countries, including Australia, have implemented population-based screening programs [13]. Population-based screening programs can be defined as those that provide a simple test to detect early signs of disease to all individuals in a target group, usually defined by age [14]. In Australia, those aged 50 to 74 years are mailed an invitation and FOBT kit as part of the federally managed National Bowel Cancer Screening Program [13]. Briefly, the program mails individuals an immunochemical FOBT, instructions, and a reply paid envelope. Completed tests are sent to a central processing laboratory. A reminder letter is sent to those not returning a test within 8 weeks [13]. Invitees returning a completed FOBT are able to nominate their primary care provider to receive test results.

The impact of this and other population-based screening programs is dependent upon achieving high rates of initial uptake and repeat screening among invitees. However, the most recent National Bowel Cancer Screening Program monitoring report indicated that, of the 1.4 million people sent an FOBT in 2013-2014, only 36% returned a completed FOBT [13]. Given this, there is an urgent need to explore ways to improve engagement in CRC screening.

Primary care is a potential setting to increase CRC screening participation. Primary care providers have frequent contact with those in the target age group for CRC screening [15], and giving advice on preventive care is perceived by patients as a key part of the primary care provider's role [16]. Primary care guidelines [17-19] recommend that providers play a role in promoting CRC screening by assessing risk based on family history and providing screening advice and test referral. Despite this, a large proportion of primary care patients in Australia have not been screened at the recommended interval [20]. This suggests that in Australia, as in other countries, CRC screening advice is not routinely delivered in the primary care setting [21-23]. This may be due to a range of factors including limited time within the consultation [24-26], perceived lack of patient interest in conversations about CRC screening [21], and cultural barriers [27].

Systematic reviews have identified strategies that are effective for increasing CRC screening uptake in the primary care setting [28-31]. Two reviews concluded that supplying patients with free FOBT when they attended an appointment with their physician resulted in an increase in CRC screening uptake by 15% to 42% when compared to usual care [29,30]. Further, RCTs that included paper-based information on CRC screening using an FOBT also significantly increased CRC screening in the intervention group when compared to those that included no paper-based information or usual care [32,33]. RCTs have found that primary care provider endorsement (ie, recommendation to take part in screening) as part of an organized screening program invitation is associated with increased CRC screening uptake when compared to standard invitations [34,35]. Most studies, however, have evaluated primary care provider endorsement in the context of mail-based interventions [31,36]. Face-to-face endorsement within the context of a primary care consultation may have greater impact on screening uptake. While reviews have identified a number of potentially effective primary care–based strategies for increasing CRC screening, the majority of studies using opportunistic strategies have taken place in the United States [30,36]. Given that the United States has a different health care system than Australia, it is unclear how generalizable these findings are to the Australian primary care setting.

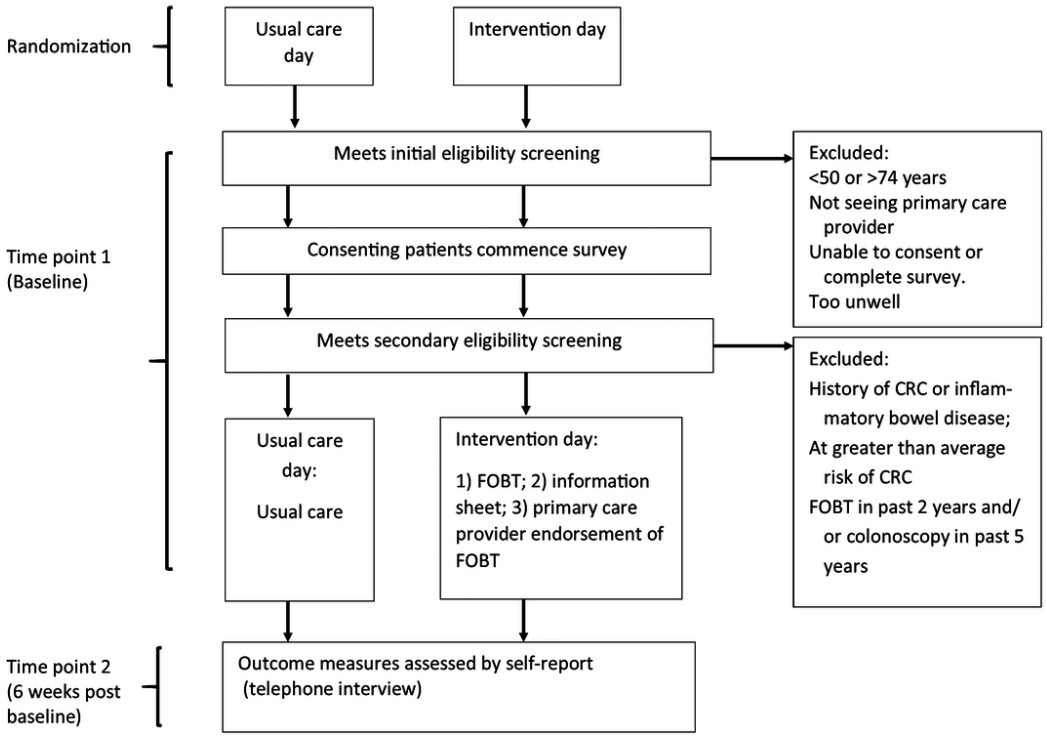
Building upon current evidence, this study incorporates effective strategies to deliver a multicomponent intervention to increase CRC screening in the Australian primary care setting. The intervention comprises a novel combination of printed information on screening, the provision of a free point-of-care FOBT, and face-to-face primary care provider endorsement of screening.

Methods

Hypotheses

Our first hypothesis is that compared to usual care participants, those allocated to the intervention group will report a 20% higher rate of CRC screening uptake at 6-week follow-up. Our second hypothesis is that compared to usual care participants, those in the intervention group will show a greater increase in knowledge from baseline to follow-up.

Figure 1. Flow of participants.



FOBT; fecal occult blood test: CRC; colorectal cancer

Trial Design and Setting

This study is taking place in 5 primary care practices in New South Wales, Australia. A cluster RCT design is being used with consenting participants allocated to the intervention or usual care group depending on the day they attend the practice (see Figure 1).

Practice Eligibility and Recruitment

A convenience sample of primary care clinics has been recruited for this study. To ensure adequate throughput of patients, eligible practices were required to have at least 2 full-time equivalent primary care providers. Primary care practice managers were sent an invitation and information statement via email. Nonresponding practices were followed up by telephone. Of 18 invited practices, 5 agreed to participate. Practice managers and primary care providers within each practice received an information statement and provided written informed consent.

Randomization

Using a computer-generated randomization table with block sizes of 4, recruitment days are randomly allocated using a 1:1 ratio to intervention or usual care. Randomization by day rather than individual participant was selected to minimize potential for contamination between experimental groups. The allocation cannot be concealed from the research assistant conducting participant recruitment; however, these staff do not have access to the assignment schedule and are only made aware of allocation the day prior to attending the practice.

Participant Eligibility Criteria

Those who (1) are aged 50 to 74 years, (2) have no personal history of bowel cancer or inflammatory bowel disease, (3) are at average risk of CRC, and (4) have not had an FOBT in the past 2 years or a colonoscopy in the past 5 years are eligible to participate in the trial.

Exclusion Criteria

Those who are (1) not seeing a primary care provider, (2) too unwell, (3) unable to complete the touchscreen survey, or (4) unable to speak and read English sufficiently are excluded from the trial.

Training of Staff

All training is delivered by one of the chief investigators prior to any recruitment. A training manual for research assistants developed by the research team is used for both training and as a reference during recruitment and follow-up. All research assistants receive face-to-face and on-site training in recruitment and data collection procedures. Reception staff are provided with an overview of the project as well as the process to identify eligible patients and how to refer them to the research assistant. A sign reminding reception staff to check patients for eligibility is placed at their workstation. One of the chief investigators attends a regular staff meeting at each practice to brief the primary care providers about the project and provide them with a dialogue sheet to encourage FOBT completion by patients assigned to the intervention group.

Procedure for Assessing Eligibility

A two-stage process determines trial eligibility. Initial patient eligibility screening begins when reception staff flag patients in the target age range to the research assistant, who invites patients in the waiting room to complete a touchscreen survey to assess trial eligibility, and if eligible, to take part in the trial. Patients are provided with an information statement and allowed time to ask any questions they may have about the trial. Those providing written consent complete a 10-minute touchscreen survey in the waiting room prior to their primary care appointment. Assistance to complete the touchscreen survey is provided by the research assistance as required. Study participants do not receive compensation for their time in the study.

Second-stage patient eligibility screening is performed during the touchscreen computer survey:

1. No personal history of bowel disease: Participants are asked whether they have ever received a diagnosis of bowel cancer or inflammatory bowel disease (yes/no). FOBT screening recommendations related to biennial FOBT are only relevant to asymptomatic individuals with no prior history of CRC. Therefore, those who respond "yes" are excluded.
2. Average risk for CRC: Participants are asked "How many of your first-degree relatives have ever been diagnosed with bowel cancer?" (0, 1, 2 or more) and "Were any of your relatives who have had bowel cancer diagnosed before the age of 55?" (yes/no). Based on criteria in the Australian National Health and Medical Research Council guidelines [12], those who report no relatives diagnosed with CRC aged younger than 55 years and up to one first-degree relative diagnosed with CRC at any age are classified as average risk for CRC. Those classified as at higher risk of CRC are excluded, as biennial FOBT recommendations do not apply to higher risk populations for whom more intensive methods of screening may be recommended. These participants receive a sealed envelope containing information about their survey results and are advised to discuss this with their primary care provider during their appointment.
3. Overdue for CRC screening: Average risk participants are asked to report whether they have ever had an FOBT or colonoscopy and, if so, when they had their most recent test. National Health and Medical Research Council guidelines recommend that average risk persons in the eligible age range undergo FOBT every 2 years [12]. Colonoscopy is not recommended as a routine screening test in Australia for those at average risk [12] but may be undertaken for other reasons (eg, the investigation of symptoms). Therefore, only those who report that they have not had an FOBT in the past 2 years or colonoscopy in the past 5 years are eligible for the trial.

The survey end screen contains a code that indicates to the research assistant if the participant is eligible for the trial. Eligible participants then receive the intervention if they attend the practice on an intervention day.

Intervention

Immediately after completing the touchscreen survey, those participants identified as eligible for the trial and attending the practice on an intervention day are provided with a large envelope by the research assistant and advised to take it into their appointment with the primary care provider. This contains an FOBT kit accompanied by a referral form, instructions and a postage paid envelope addressed to a commercial pathology laboratory and a printed information sheet. The information sheet is a single-page A4 sheet using bold colored boxes to separate the information. The information encompasses topics including the type of screening test they should complete and how often they should complete this, what to do with the FOBT, what a positive FOBT result means, and credible websites where further information about bowel cancer screening can be obtained. The information sheet has a Grade 8 Flesch-Kincaid reading level.

When the participant takes the envelope into their appointment, the primary care provider explains the importance of FOBT and encourages the participant to complete the test.

Usual Care

The usual care group receives no additional care. At the completion of the study, an information sheet similar to that provided to the intervention group is mailed to participants in the usual care group. This sheet contains additional information about how an FOBT can be sourced.

Ethics and Dissemination

Data Management

Baseline data is collected using QuON open source survey software [37]. QuON is a software system specifically designed for the development of scientific surveys that allows data collection and aggregation of data via a Web browser. QuON survey data is instantaneously transmitted to the University of Newcastle secure server. No data is stored on the touchscreen device. Data is downloaded from QuON as a .csv file and imported directly to Stata IC 11.2 (StataCorp LLC) for statistical analysis. This form of data collection reduces the risk of data inaccuracy. Follow-up data is collected via computer-aided telephone interview using the QuON software system. This involves a structured interview of each participant guided by a preprogrammed electronic survey. The research assistant reads each question on the electronic survey to the participants and records all responses directly into the online interface. For most questions prespecified response options are provided to the participant (eg, yes, no, not sure).

Monitoring

Due to the size and duration of the study a formal monitoring committee and interim analysis is not required. The study is subject to the conditions of the University of Newcastle's Human Research and Ethics Committee, including a random audit procedure to ensure the study is conducted in accordance with the approved ethics submission. This study has received ethical approval from the University of Newcastle Human Research and Ethics Committee (H-2014-0198) and has been registered with the Australian New Zealand Clinical Trials

Registry (ANZCTR) [ACTRN12616001299493]. Any protocol amendments that may affect the conduct of the study, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. The modifications will be approved by the University of Newcastle Human Research Committee and updated as a new protocol version with the ANZCTR.

Confidentiality and Access to Data

Consent forms are stored in a locked filing cabinet at the University of Newcastle and accessible by one member of the research team. Data collected via touchscreen survey is instantly uploaded to a secure University of Newcastle server accessible only by a password-protected access system. Data will be retained for at least 7 years under these conditions at the University of Newcastle. FOBT results processed by the commercial pathology laboratory are electronically conveyed to the patient's primary care provider by the password-protected online system. The pathology laboratory provides the researchers with the names of participants returning their FOBT but not individual test results. These details will be stored in a password-protected electronic file on the University of Newcastle server.

Data Collection

Baseline Survey

For participants meeting the trial eligibility criteria, the following measures are collected in the touchscreen computer survey:

1. Demographic characteristics: age, gender, marital status, employment situation, highest education level, current private health insurance, current health care concession card holder.
2. Primary care provider visit characteristics: Participants are asked how many times they have seen their primary care provider in the past 12 months and whether they always see the same primary care provider, usually see the same primary care provider, or see whichever primary care provider is available.
3. Perception of personal risk of bowel cancer: Australian data indicates that 1 in 10 males and 1 in 15 females will develop CRC in their lifetime [3]. Participants are asked to select a response to the following statement: "I think my chance of being diagnosed with bowel cancer in my lifetime is..." Responses are 1 in 15, 1 in 25, 1 in 50, and 1 in 100.
4. Attitudes and intentions regarding CRC screening: Participants are asked to indicate their level of agreement with the following statements: (1) "Fecal occult blood testing is an effective way to detect bowel cancer," (2) "I am confident I could complete an FOBT," (3) "Most of my family aged 50 and older screen for bowel cancer," and (4) "I intend to complete an FOBT in the next 2 years." Response options are "strongly disagree," "disagree," "neither agree nor disagree," "agree," and "strongly agree."
5. Knowledge of CRC screening recommendations: A 4-item study-specific instrument assesses knowledge of CRC screening recommendations using a multiple-choice format. The questions are prefaced by a description of average risk: "The following knowledge questions use the term 'people at average risk of bowel cancer.' Most people are at average risk of bowel cancer as they do not have a personal or strong family history of bowel cancer." Each question has 4-6 response options. The questions were derived from National Health and Medical Research Council CRC screening guidelines [12]. The questions are (1) "At what age do you think people at average risk of bowel cancer should start screening?" (2) "What do you think is the recommended screening test for people at average risk of bowel cancer?" (3) "How often do you think a person at average risk of bowel cancer should have an FOBT?" and (4) "A positive FOBT means?" One point is awarded for each correct response.

Follow-Up Survey

Follow-up data is collected by telephone interview 6 weeks after study enrollment. This time point was selected based on data from the National Bowel Cancer Screening Program showing that participation rates begin to plateau within 6 weeks of invitations being sent [13].

CRC screening: Participants are asked to self-report whether they have completed any form of CRC screening (FOBT, colonoscopy, other). If the patient indicates they completed an FOBT, they are asked where they obtained this.

Knowledge of CRC: The 4-item instrument to assess CRC screening knowledge at baseline is also delivered at follow-up to detect changes in CRC knowledge.

Intervention group only: Acceptability of feedback sheet is assessed by the following questions: (1) "Did you read the feedback sheet?" (yes/no), if yes, (2) "Do you have any suggestions about how the feedback sheet could be improved?" (free response), (3) "Did you access any of the websites listed on the feedback sheet?" (yes/no), if yes, (4) "Which websites did you access?" and (5) "Do you think it would be helpful to receive information sheets from your primary care provider about other health issues?" (free response). Reasons for not being screened: Participants who report no screening are asked if there was a particular reason they did not use the kit provided at their primary care provider appointment (free response).

Process Measure

The researchers receive electronic notification of the names of participants returning an FOBT from the commercial pathology laboratory; however, no results are provided. This process measure will be used for an analysis of the sensitivity of self-reported screening.

Analysis and Sample Size

The age and sex of consenters and nonconsenters will be compared using the chi-square test for categorical variables and the *t* test or nonparametric equivalent for continuous variables. The proportion of participants completing CRC screening at the follow-up time point will be compared using a logistic regression model, including treatment group and site as independent variables. The correlation of observations induced by the design of the study will be accounted for through cluster robust variance estimation. A logistic regression will determine

the characteristics associated with CRC screening. Differences in knowledge scores between the usual care group and the intervention group will be determined by ordinal logistic regression. For all tests, we will use 2-sided *P* values with a 5% significance level; exact *P* values will be reported. The primary analysis population will be all those who are randomized. Analysis will follow the intention-to-treat principle, with missing data imputed using multiple imputation. A sensitivity subanalysis of self-report versus pathology records in the intervention group will be conducted.

The sample size was calculated based on the primary aim. A sample size of 80 participants per arm will enable detection of a 25% increase in self-reported CRC screening for participants in the intervention group compared to 5% in the usual care group with 90% power at 5% significance. This calculation allows for a small design effect of 1.2 to allow for potential clustering by the design of the study (day of the week) and assumes on average 10 eligible participants will be available per day. Given that all participants eligible for randomization will have not participated in CRC screening via FOBT in the past 2 years or colonoscopy in the past 5 years, the underlying population prevalence of screening will not be considered in the sample size calculation.

Results

At the time of submission, 5 primary care practices have consented to participate, with 100 participants enrolled in the study. Follow-up of participants has commenced, and it is anticipated all data collection will be complete by August 2017. Data analysis is in the preliminary stages. The authors will disseminate trial results through peer-reviewed publications and presentations at conferences.

Discussion

Strengths and Limitations

Previous research has demonstrated that multicomponent interventions are more likely to increase CRC screening participation than singular interventions [28]. Our study will test a multicomponent intervention using a gold standard RCT design across 5 primary care clinics. Very few intervention studies to increase colorectal cancer have been conducted in an Australian primary care setting.

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Authors' Contributions

MC, EM, and ND conceived the study, wrote the project application for funding, and developed the study protocol. CO advised on study design, sample size, and statistical methods. All authors contributed to the drafting of the manuscript or revising it critically for intellectual content.

Conflicts of Interest

None declared.

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Abbreviations

ANZCTR: Australia New Zealand Clinical Trials Registry
CRC: colorectal cancer
FOBT: fecal occult blood test
RCT: randomized controlled trial

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Testing the effectiveness of a general practice intervention to improve uptake of colorectal cancer screening: a randomised controlled trial

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Abstract

Objective: Uptake of screening through the Australian National Bowel Cancer Screening Program remains low. General practice guidelines support the general practitioners' role to offer CRC screening. This study tests the effect that an intervention including point-of-care FOBT provision, printed screening advice and GP endorsement has on self-reported FOBT uptake.

Methods: A multisite, 1:1 parallel-arm, cluster-randomised controlled trial. Participants aged 50–74, at average risk of CRC and overdue for screening were recruited from four general practices in New South Wales, Australia, from September 2016 to May 2017. Self-report of FOBT up to eight weeks post baseline.

Results: A total of 336 participants consented to complete a baseline survey (64% consent rate), of which 123 were recruited into the trial (28 usual care days and 26 intervention days). Follow-up data was collected for 114 participants (65 usual care and 49 intervention). Those receiving the intervention had ten times greater odds of completing screening compared to usual care (39% vs. 6%; OR 10.24; 95%CI 2.9-36.6, p=0.0006).

Conclusions: A multicomponent intervention delivered in general practice significantly increased self-reported FOBT uptake in those at average risk of CRC.

Implications for public health: General practice interventions could serve as an important adjunct to the Australian National Bowel Cancer Screening Program to boost plateauing screening rates.

Key words: colorectal cancer, faecal occult blood test, general practice, early detection of cancer, randomised controlled trial

Colorectal cancer (CRC) is the second most diagnosed cancer and second most common cause of cancer-related death in Australia,[1] highlighting the need for prevention and early detection. Regular screening with faecal occult blood test (FOBT) has been shown to reduce CRC mortality by 13–33%.[2-5] Australian guidelines recommend biennial FOBT for those at average or slightly above average risk (herein after referred to as average risk) of CRC, who are aged 50 and over.[6,7] To support implementation of guidelines, the population-based National Bowel Cancer Screening Program (NBCSP) was developed. The program commenced using a phased approach in 2006.[8] When fully implemented, in 2020, the NBCSP will post FOBT kits biennially to all Australians aged 50 to 74.[9] The most recent NBCSP data suggest that only 41% of invitees returned a completed FOBT.[10] Similarly, cross-sectional data from Australian community studies report CRC screening rates from 21%[11] to 39%[12]. These data suggest there is a clear need to explore the effectiveness of additional strategies to increase appropriate CRC screening rates in the Australian population.

General practice is a promising setting for promoting uptake of CRC screening. General practitioners (GPs) have a recognised role in delivering preventive healthcare,[13] and evidence-based guidelines are available to facilitate preventive care delivery in general practice.[6] Recent cross-sectional data from five general practices in New South Wales, Australia, showed that one-third of average risk participants who completed a FOBT in the past two years sourced their kit from their GP.[14] This suggests that GPs are playing an active role in promoting screening participation among their patients.

Several strategies have been identified that demonstrate effectiveness at increasing CRC screening in general practice patients; these include reduction of structural barriers,[15] GP endorsement[16-18] and patient education.[15] Reduction of structural barriers includes the provision of free, accessible CRC screening, such as FOBT.[15] A review found this strategy, adopted in many population-based screening programs, is also effective when delivered opportunistically in general practice, with a 15–42% increase in CRC screening rates.[19] GP endorsement of CRC screening is a well-known predictor of CRC screening.[16-18] For example, written GP endorsement was more effective than no endorsement in increasing screening rates in an Australian community study[18] and with those eligible for population-based screening in England.[17] While GP

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endorsement is considered an important component of many interventions, it is often delivered in written format.[16,18] However, there is some evidence for the effectiveness of GP endorsement face-to-face. For example, in the French population-based screening program, face-to-face GP endorsement was shown to be effective in increasing CRC screening.[20] Sabatino et al.'s review found strong evidence to support one-to-one patient educational interventions that included delivery of printed information to patients from a medical professional.[15] It is likely that combining promising strategies as part of a multicomponent intervention may be more likely to result in increased CRC screening uptake.[21]

The majority of general practice interventions to increase CRC screening have been conducted outside Australia. Therefore, results may not be generalisable to the Australian setting. Given the low rates of CRC screening in Australia, it is timely to explore whether using a combination of evidence-based strategies may lead to increased CRC screening participation. This study aimed to test the impact that a general practice-based intervention including point-of-care FOBT, printed CRC screening advice and face-to-face GP endorsement has on CRC screening uptake among under-screened general practice patients.

Objectives

Aims

To examine, among under-screened general practice patients at average risk of CRC, the effectiveness of provision of point-of-care FOBT, printed CRC screening advice and face-to-face GP endorsement on: a) self-reported FOBT uptake and; b) CRC screening knowledge. Self-reported FOBT uptake was the primary outcome.

Hypotheses

We hypothesised that, compared to usual care participants, those allocated to the intervention group would report:

a) a 20% higher rate of self-reported FOBT uptake at six-week follow-up; and

b) a greater increase in knowledge from baseline to follow-up.

Methods

Study design: Details of the study method have been described elsewhere.[22] This was a multisite, 1:1 parallel-arm, cluster randomised controlled trial (RCT) conducted in four general practices in regional New South Wales, Australia, from September 2016to– May 2017. Recruiting a sufficient number of GP practices was not possible to enable randomisation by practice. Therefore, randomisation by day of recruitment was considered the best pragmatic alternative. Given the nature of the intervention, we identified a strong potential for contamination if randomisation was conducted at the patient-level.[23] This study received ethical approval from the University of Newcastle Human Research and Ethics Committee (H-2014-0198).

Practice sample: Practices with at least two full-time GPs were eligible to participate. A convenience sample of eligible practices was identified and invited by post to participate. Four of eighteen invited practices consented to participate. Non-responding practices were followed up by telephone; practices were not required to provide a reason for non-participation, therefore these reasons were not recorded. Written, informed consent was obtained from practice managers and GPs.

Randomisation: A randomisation schedule for each practice was computer-generated by a statistician using block sizes of four (i.e. every four-day block comprised two usual care days and two intervention days). Allocation was only revealed to the research assistant at the start of each day of recruitment. Patients, practice staff and research assistants were unaware of block size.

Eligibility screening: Eligibility was determined via a two-step process. Firstly, clinic staff assessed basic eligibility criteria (detailed below). Eligible patients were flagged to the research assistant who confirmed eligibility and obtained informed consent. Consenting patients completed a touchscreen computer survey to confirm trial eligibility (detailed below), which was assessed by a series of questions built into a 10-minute touchscreen survey.

Participant sample: All patients who met the following criteria were invited to complete a touchscreen survey to assess trial eligibility: 1) aged 50–74; 2) English speaking; 3) well enough to complete a touchscreen survey; 4) seeing their GP for an appointment; 5) able to provide written informed consent. Those meeting trial eligibility: 1) had no personal history of CRC or inflammatory bowel disease; 2) were at average or slightly above average risk of CRC (herein after referred to as average risk); and 3) were overdue for CRC screening (no FOBT in the past two years and no colonoscopy in the past five years). Those at average risk had: i) less than two first- or second-degree relatives diagnosed with CRC at any age, and: ii) no first or second-degree relatives diagnosed with CRC aged <55. Demographic data collected included age, gender, marital status, employment status, highest level of education, private health insurance status, healthcare concession card holder status.

Baseline survey: Participants meeting trial eligibility criteria were automatically presented with baseline survey questions on touchscreen computer. This included measures of socio-demographic characteristics and knowledge of CRC screening recommendations. Participants that did not complete the survey prior to their appointment were ineligible for the trial. A code appeared at the end of the survey to indicate participant trial eligibility to the research assistant. Eligible participants attending the practice on an intervention day then received the intervention.

Intervention: Patients attending the practice on a day allocated to the intervention condition received a multi-component intervention. Prior to their appointment, intervention participants received an envelope from the research assistant in the waiting room containing: i) one pre-paid immunochemical FOBT with return postage to a commercial pathology laboratory and a pre-filled pathology form; ii) one single page of CRC screening advice printed in colour (see Supplementary File 1) that included information about: recommended CRC screening tests and recommended testing frequency; the meaning of a positive FOBT; and information about government and non-government websites relating to CRC screening. The printed screening advice had a Grade 8 Flesch-Kincaid reading level. Participants were asked to show the envelope to their GP during their appointment. The GP explained the importance of FOBT and encouraged the participant to complete the test. GPs received a brief written script to assist them to endorse the importance of completing the FOBT. If, during the appointment, the GP decided FOBT was not suitable for the patient (e.g. if the patient was experiencing bowel symptoms), the GP advised the research assistant who then withdrew that patient from the study.

Usual Care: Those attending on usual care days received usual care from their GP. To provide an ethical standard of care, each participant received printed CRC screening

advice similar to that provided to the intervention group after follow-up data collection was completed. The printed CRC screening advice provided participants with additional information about how they could obtain a FOBT.

Follow-up data collection: A research assistant collected follow-up data up to eight weeks post-baseline via a computer-aided telephone interview.

Measures

Baseline

Knowledge of CRC screening recommendations: Four multiple-choice questions were derived from the National Health and Medical Research Council CRC screening guidelines.[7] They were: 1) *At what age do you think people at average risk of bowel cancer should start screening?*; 2) *What do you think is the recommended screening test for people at average risk of bowel cancer?*; 3) *How often do you think a person at average risk of bowel cancer should have an FOBT?*; and 4) *A positive faecal occult blood test (FOBT) means?* The questions were prefaced by lay descriptions of screening tests and the meaning of 'average risk'. One point was awarded for each correct response.

Follow-up

Self-reported CRC screening: For the primary outcome of self-reported CRC screening, participants were asked: *In the past six weeks have you had any tests for bowel cancer?* (Yes/No). Those who responded 'Yes' were asked: *Which test/s did you have?* Response options for the control group were: FOBT/ Colonoscopy/Other. Response options for the intervention group were: FOBT using the kit I received at my general practice; FOBT using a kit I received elsewhere; Colonoscopy.

Knowledge of CRC: The 4-item instrument to assess CRC screening knowledge at baseline was delivered at follow-up.

Process measures for intervention group: The accuracy of self-report was verified for participants allocated to the intervention against confirmation of FOBT test from pathology (the outcome of the FOBT was not provided to the researchers). Those in the intervention group were also asked: *Did you read the printed information sheet?* (Yes/No).

Sample size and statistical analysis

The sample size was originally calculated based on the primary outcome. It assumed a sample size of 80 participants per arm, and a 20% increase in self-reported FOBT uptake for participants in the intervention group compared to 5% in the usual care group, with 90% power at 5% significance. This calculation allowed for a small design effect of 1.2 to allow for potential clustering by the design of the study (day of recruitment, assuming 10 people recruited per day). Due to lower than expected participant numbers and because only two patients recruited per day over 26 days per arm, a post-hoc power calculation indicated that a similar effect size was detectable with 85% power.

Consent bias: The age and sex of consenters and non-consenters was compared using the chi-square test for gender and age. *Aim 1:* The odds ratio for self-reporting FOBT uptake at follow-up for intervention vs. usual care was obtained using logistic regression, including treatment (intervention) group and site as independent variables, with covariance structure accounting for participant ID nested within day of randomisation. Odds ratios, 95% confidence intervals (95% CI) and *p*-values are presented. *Aim 2:* Assessment of the change in knowledge score from baseline to follow-up was also assessed using mixed effects ordinal logistic regression, with covariance structure accounting for participant ID nested within day of randomisation. Knowledge score was the outcome and the independent variables included: the interaction of time point (follow-up vs. baseline) and study group (intervention vs. usual care), which allowed for different directions of change in knowledge score over time; the main effects for time point and study group; and site, to account for GP practice. Odds ratio, 95% confidence interval and *p*-value are presented, proportionality assumption was assessed using the Brant test.

Sensitivity and specificity of CRC screening status vs. pathology verification of testing: For those in the intervention group who self-reported completing the FOBT provided by the researchers, the sensitivity and specificity, with 95% confidence intervals, were calculated. Pathology evidence was considered the gold standard.

For all analyses, the correlation of observations induced by the design of the study was accounted for through cluster robust variance estimation for day of randomisation, and *p*-values <0.05 were indicative of statistical significance. Statistical analyses were programmed using Stata v14.0 (StataCorp Ltd, College Station, TX).

Results

A total of 1,671 people were screened for initial eligibility; of these, 1,335 were ineligible. Of the remaining 528, 336 (64%) agreed to participate in the survey to assess trial eligibility and 192 declined (see Figure 1). There were significant differences between consenters and non-consenters' age (x^2 (2, N=502) = 8.67, p=0.013) and gender (x^2 (2, N=518) = 11.79, p=0.0006) with females and those aged 50–59 more likely to consent to participate. Of the 336 consenting participants, 123 were eligible for the trial, with 53 allocated to the intervention group. No participants were withdrawn from the study based on GP decision during appointment. Nine participants were lost to follow-up, leaving 114 included in the final analysis.

Overall, there were more female than male participants (67% vs. 33%). Sociodemographic characteristics were similar for participants allocated to the intervention compared to the control group. Demographic characteristics are reported in Table 1.

Process measures for the intervention group

The sensitivity of self-reported FOBT compared against the gold standard of pathology results was 89.5%, CI: 61.2–97.9%, and the specificity was 93.3%, CI: 73.9–98.6%. Of the intervention participants, 51% (n=25), reported reading the printed CRC screening advice. Those who read the printed CRC screening advice were more likely to complete CRC screening than those who did not (84% vs. 30%).

Effect of the intervention on self-reported CRC screening

Nineteen out of 49 participants (39%) in the intervention group reported having completed screening at follow-up compared to four out of 65 (6%) in the usual care group. Those in the intervention group had more than ten times greater odds of self-reported FOBT uptake (OR 10.24; 95%CI 2.9–36.6, p=0.0006). Site was not significantly associated with the outcome (p=0.58). Almost all of the intervention participants who had completed screening (n=18) used the FOBT provided to them by the GP, while one sourced a FOBT from elsewhere. Four of the five screened participants in the usual care group reported completing FOBT and one reported receiving a colonoscopy.

Effect of the intervention on CRC screening knowledge.

Although there were slight increases from baseline in the proportion of participants selecting a greater number of correct responses, there were no statistically significant differences in group trends (*p* for interaction=0.61) or changes in knowledge scores between baseline and follow-up in either group (Usual Care OR 1.59 (0.8 to 3.1) *p*=0.18; Intervention OR 1.58 (0.5 to 4.9) *p*=0.43), estimated from the ordinal regression model (for regression co-efficients see Supplementary File 2).

Discussion

This study tested the effectiveness of a multicomponent intervention that included provision of point-of-care FOBT, printed CRC screening advice and face-to-face GP endorsement on self-reported FOBT uptake and CRC screening knowledge.

Screening uptake

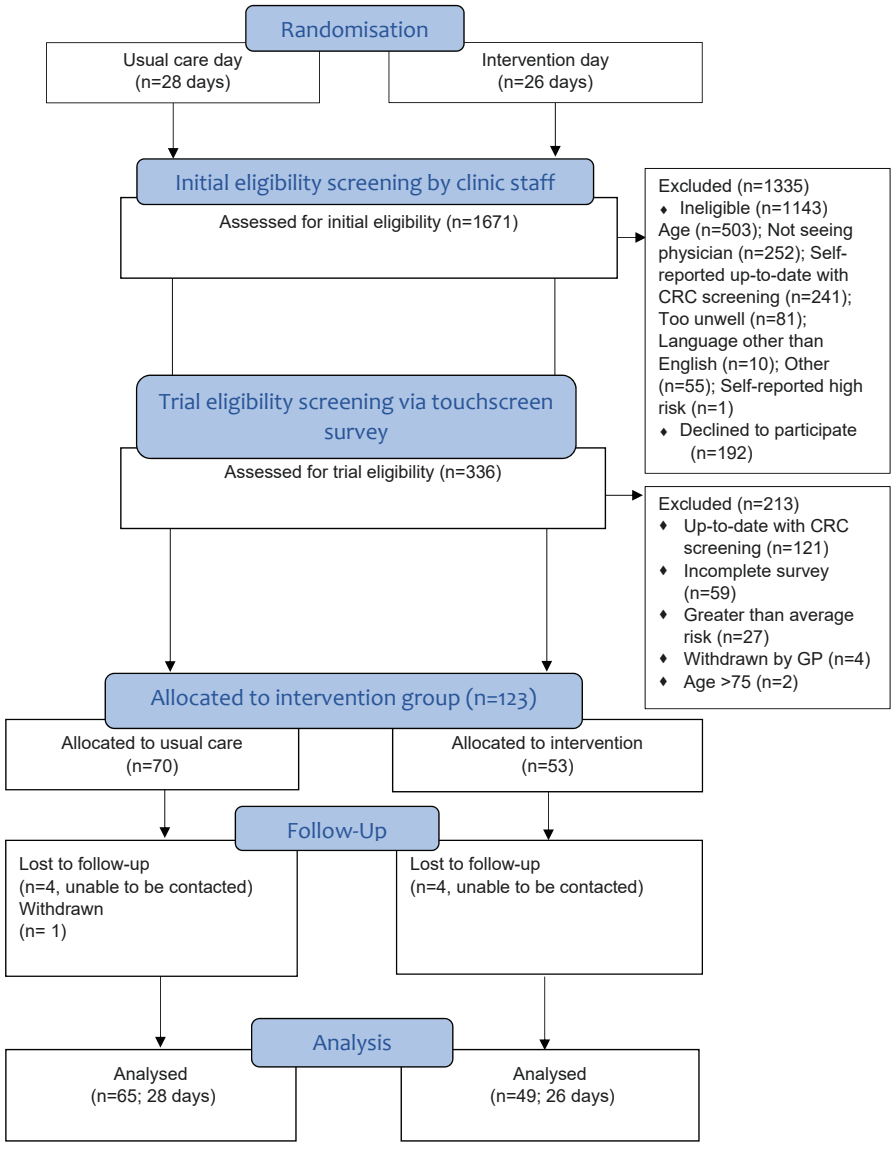
Delivering a multicomponent intervention targeting under-screened, average-risk Australian general practice patients significantly increased self-reported FOBT uptake when compared to usual care. Our results are consistent with findings of reviews that indicate reduction of structural barriers, including provision of screening kits,[15,19] GP endorsement[24,25] and printed educational materials,[15,26] can be effective at increasing uptake of FOBT. For example, in one US randomised controlled trial (n=21,860), Sequist et al. tested the impact of a mail-out containing printed CRC screening advice, FOBT and instructions to schedule sigmoidoscopy or colonoscopy (if they preferred this over FOBT) on screening uptake in general practice patients. Those receiving the mail-out had higher screening rates than usual care.[27] Potter et al.'s RCT, conducted in the US, demonstrated that providing FOBT to general practice patients attending a flu vaccination clinic resulted in a two-fold increase in uptake of screening compared to usual care.[28]

The use of a combination of strategies in our intervention may have had the advantage of addressing a number of known barriers to CRC screening in the general practice setting. Consultation times have been cited as a barrier to providing routine CRC screening advice.[29,30] Our intervention overcame this by providing printed information highlighting the importance of CRC screening and providing simple screening recommendations regarding the type and timing of test for average risk individuals. Further, automated reminder systems can act as a prompt for GPs to recommend CRC screening; however, performance issues with software systems can be a barrier to systems-based reminders.[31] Our intervention used the patient, FOBT and printed CRC screening advice as a prompt for GP endorsement of CRC screening. Further, GP endorsement was delivered face-to-face, rather than written, which may have further boosted screening uptake. A review of the effect of interventions to improve health literacy to encourage patients to make lifestyle changes found that brief interventions delivered by GPs had positive outcomes for physical activity and smoking cessation.[32] Our findings suggest that verbal advice may also be an effective strategy to encourage CRC screening.

CRC screening knowledge

Of those in the intervention group who had completed screening, the overwhelming majority (84%) had read the printed CRC screening advice, compared to about one-third of those in the intervention group who did not complete report completing FOBT. Despite this, and the impact of the intervention on screening behaviour, our results indicate that the intervention had no impact on CRC screening knowledge. This is surprising, given other studies that have shown a positive association between knowledge and screening behaviour.[33,34] This suggests that the intervention may have temporarily improved knowledge, but the effects were not sustained at the six-week

Figure 1: CONSORT Recruitment flow diagram.



follow-up time point. Alternatively, it may suggest that for this sample an improvement in knowledge above baseline levels was not necessary to facilitate the increase in screening uptake. The latter interpretation is consistent with a process evaluation of Ferreira's study,[35] which indicated no significant differences in screening uptake between patients who did and did not receive a patient educational strategy accompanied by FOBT (40% vs. 42%, p=0.61).

Strengths and limitations

This study used a robust RCT design and was prospectively registered with the ANZCTR. Apart from a slight reduction in sample size, the study was conducted as outlined in the ANZCTR. Our study adds to the current scientific literature; to our knowledge no multicomponent strategies to increase CRC screening have been conducted in an Australian general practice setting.

Results of this study must be viewed considering several limitations. Firstly, a convenience sample of practices was used, and cluster, rather than individual, randomisation was used. There were significantly more females and people in the younger age group who consented to the trial. These factors may reduce generalisability of the results. Due to low numbers of participants in the usual care arm reporting CRC screening, the results included wide confidence intervals, leading to lower precision in the estimate of effect size. Further, we did not measure GP adherence to the protocol and scripts provided to deliver screening endorsement. There may have been variability in how GPs delivered advice, which could have influenced uptake, although no statistical variation in outcome between GP practices was observed. Future studies could attempt to explore how practitioner adherence to intervention protocols influences screening uptake. Self-report of CRC screening was used to determine CRC screening for the usual care group. While this is not considered gold-standard, a meta-analysis found high levels of agreement between self-report and medical records.[36] The effectiveness of our intervention may have been increased with a longer follow-up time point. An Australian population-based three-arm RCT[16] tested interventions involving posted FOBT kits accompanied by differing invitation strategies (one of which included written GP endorsement). Cole et al. reported 38% of all those completing FOBT did so between the 6–12-week follow-up time points. Further, Cole et al.'s study used postal reminders for non-completers. Including reminders may have led to higher reported CRC screening rates in the intervention group of our study.

Table 1: Sociodemographic characteristics of sample (n=114).

Demographics	All (n=114)	Usual Care (n=65)	Intervention (n=49)
Gender			
Female	75 (66%)	42 (65%)	33 (67%)
Male	39 (34%)	23 (35%)	16 (33%)
Age			
50-54	30 (26%)	18 (28%)	12 (24%)
55-59	24 (21%)	15 (23%)	9 (18%)
60-64	17 (15%)	10 (15%)	7 (14%)
65-69	25 (22%)	13 (20%)	12 (24%)
70-74	18 (16%)	9 (14%)	9 (18%)
Education			
Tertiary	31 (27%)	17 (26%)	14 (29%)
TAFE/Trade	40 (35%)	25 (38%)	15 (31%)
Year 12 or below	43 (38%)	23 (35%)	20 (41%)
Employment status			
Employed (full-time/part-time/self-employed)	50 (44%)	31 (48%)	19 (39%)
Unemployed	5 (4%)	3 (5%)	2 (4%)
Student	1 (1%)	1 (2%)	0
Retired	48 (42%)	26 (40%)	22 (45%)
Home duties/carer	10 (9%)	4 (6%)	6 (12%)
Private health insurance			
Yes	31 (27%)	20 (31%)	11 (22%)
No	83 (73%)	45 (69%)	38 (78%)
Healthcare card			
Yes	62 (54%)	37 (57%)	25 (51%)
No	52 (46%)	28 (43%)	24 (49%)

Implications for public health

Our study indicates that GPs can effectively promote CRC screening and achieve increased CRC screening among their patients; however, larger trials are needed to estimate the effect size more precisely. There are several factors that could increase the likelihood of future adoption of an intervention such as the current study. Previous research has demonstrated that electronic screening in general practice waiting rooms is both feasible and acceptable.[37] Further, pre-prepared risk-appropriate printed screening advice accompanied with an electronic screening tool can decrease the time burden for GPs.[38] Thus, our findings could support the implementation of national strategies such as the incorporation of the NBCSP into National Cancer Screening Register. It is anticipated the Register, which is currently being developed, will interface with general practice software systems and allow GPs to directly interact with the NBCSP. This will allow GPs to receive automated reminders of patients that are overdue for screening, order FOBTs and follow-up on FOBT test results.[39] This may help GPs to identify those who have not responded to NBSCP invitations to screen and offer proactive advice and support to screen.[37] It is noteworthy that there are currently no practice incentive payment for CRC screening, as there are for cervical cancer screening in Australia.[40] This may act as a disincentive for practices to implement similar strategies.

A large proportion of those who participate in CRC screening once will screen again,[10] highlighting the importance of supporting people to make positive choices around CRC screening. Future research should focus on developing effective interventions to capture those who have never screened. This may include increased detection prior to GP appointments of those who have never screened for CRC, which requires further testing through robust intervention studies.

Conclusion

A general practice-based intervention consisting of point-of-care FOBT, printed CRC

screening advice and general practitioner endorsement can significantly increase self-reported FOBT in those overdue for screening, for whom FOBT is appropriate. This type of intervention may serve as a useful adjunct to population-based screening methods in Australia.

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Trial registration

This study was registered with the Australian New Zealand Clinical Trials Registry on 15 September 2016 (ACTRN12616001299493). The Universal Trial Number (UTN) for this trial is U1111-1185-6120.

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Supporting Information

Additional supporting information may be found in the online version of this article:

Supplementary File 1: Bowel cancer screening: Saving lives.

Supplementary File 2: Regression co-efficients.

DISCUSSION

THESIS OVERVIEW

This thesis is comprised of six papers all of which have been published in peer-reviewed journals. The studies reported in papers 1 to 3 examined the prevalence and correlates of under-screening in those at average risk of colorectal cancer (CRC) attending healthcare settings. The study reported in paper 1 was a cross-sectional study exploring rates of CRC screening among participants from an outpatient setting (n=197). The study reported in paper 2 was a cross-sectional study exploring knowledge of CRC risk factors and screening recommendations from general practice participants aged 18 and over (n=363). The study reported in paper 3 was a cross-sectional study exploring rates of CRC screening among general practice patients (n=179). The study reported in paper 4 was a critical review providing a snapshot of research that reported CRC screening prevalence, and intervention research in general practice settings over the past twenty years. Paper 5 was a protocol paper which described an intervention delivered in general practice and designed to increase CRC screening uptake, the results of which were presented in paper 6. One hundred and fourteen participants were included in the final analyses for the intervention.

The discussion of findings, implications and future directions from this thesis are organised within three key themes: rates of under- and over-screening for CRC; correlates and potential determinants of under-screening; and interventions to improve CRC screening. This is followed by an analysis of strengths and limitations of the thesis and a conclusion summarising the main findings of this thesis.

1. RATES OF UNDER- AND OVER-SCREENING FOR COLORECTAL CANCER

Finding 1.1. A substantial proportion of participants in healthcare settings were under-screened for colorectal cancer

Substantial under-screening for CRC was reported among those in the target age range for CRC screening and at average risk of CRC attending primary and secondary healthcare settings (papers 1 and 3). Forty-one per cent (n=97) of people attending outpatient clinics were under-screened (paper 1). Lower rates of under-screening were found for general practice participants (32%; n=58) (paper 3).

The rates of under-screening reported in papers 1 and 3 are considerably lower than Australian studies reporting data from 2009 to 2011 in both general practice (60%)[1] and community settings (79%)[2]. However, these past studies may not be directly comparable to the current studies due to methodological differences and sample sizes, For example, prior studies had larger sample sizes, indicating that their estimates of screening rates are likely to be more precise[1-3]. There were also differences in the age ranges of sample frames[1, 2] and CRC risk categories included[1, 3], and the definitions and timeframes of under-screening[1, 2] used in previous studies did not align completely with Australian CRC screening guidelines[4-6].

However, the substantially lower rate of under-screening compared to previous data suggests that this change cannot solely be attributed to methodological differences. It is likely that this reduction can be explained at least partly by the increased opportunity to screen since 2011. One of the most important sources of CRC screening

in Australia is the National Bowel Cancer Screening Program (NBCSP). In Phase 1 of the NBCSP (2008-2011) approximately 800,000 Australians were invited to participate in the NBCSP[7]. More recently (2015-2016) approximately 3.2 million Australians were invited to participate in the NBCSP[8]. The increasing number of age groups invited into the program has directly increased the number of invitees each year and has likely resulted in greater exposure to CRC screening.

Although there appears to be an increasing number of Australians participating in CRC screening, a substantial proportion of attendees at healthcare settings remained under-screened. CRC screening for those at average risk is affordable and accessible, and decreases mortality associated with this disease[9-12]. Therefore, additional strategies to improve CRC screening uptake in these settings are needed.

Finding 1.2. A proportion of people were over-screened for colorectal cancer via colonoscopy

Over-screening by unnecessary colonoscopy places patients at undue clinical risk[13]. Further, as colonoscopy services are finite, over-screening can reduce the capacity of the healthcare system to provide timely services to those requiring diagnostic colonoscopy[14]. The studies reported in papers 1 and 3 suggested that a minority of people may have undergone colonoscopy as routine screening test for CRC, indicating these participants might be over-screened (n=29; 8% of combined samples). Due to the low numbers of participants reporting colonoscopy in these studies (n=114; 30% of combined samples), the results should be interpreted with caution. However, our results are consistent with a previous Australian study, which found that 14% (n=699)

of participants were potentially over-screened, defined as having had a colonoscopy in the past five years in the absence of clinical indicators[2].

The current results suggest that there is a need to systematically assess the appropriateness of colonoscopy, to minimise the likelihood of individuals undergoing an unnecessary procedure. A small controlled before-after study (sample size n=100), conducted in South Australia, tested the effectiveness of a clinical nurse consultant within an endoscopy unit in increasing the proportion of colonoscopies which were in accordance with clinical practice guidelines[4]. The proportion of colonoscopies deemed unnecessary reduced from 14% at baseline to 0% at follow-up[15]. Many publicly funded endoscopy units in Australia now use a similar model to this intervention[16, 17]. The exponential increase in colonoscopy procedures in Australia over the past decade, some of which represent over-screening[18, 19], suggests that more intervention research using robust randomised controlled trial (RCT) designs are needed to establish additional strategies which effectively reduce unnecessary colonoscopy.

2. EXPLORING CORRELATES OF UNDER-SCREENING FOR COLORECTAL CANCER

Finding 2.1. Gaps remain in knowledge of colorectal cancer risk factors and screening recommendations

Knowledge of CRC risk factors and screening recommendations is associated with greater intention to screen and higher rates of CRC screening[20-22]. The study in paper 2 found gaps in knowledge for CRC risk factors and screening recommendations. For

example, among the 363 general practice patients aged 18-85, less than half knew the correct age to commence CRC screening or the correct frequency of faecal occult blood testing (FOBT). More participants were aware of all CRC risk factors assessed (24%) compared to all CRC screening recommendations assessed (10%). There were differences in knowledge across age groups. Those aged ≥50 had 2.5 times greater odds of higher scores for CRC screening knowledge than those aged <50. This may reflect the impact of greater exposure to CRC screening information and experience among those in older age groups. However, for those aged ≥50 there were important gaps in CRC screening knowledge, most notably the correct age to start screening and the correct frequency of FOBT. Further, lower proportions of those aged ≥50 correctly identified all CRC risk factors (smoking, aged >50, being overweight, low-fibre diet, alcohol consumption) compared to those aged <50 (22% vs 32%). Knowledge of CRC risk factors is important across all age groups, especially those aged <50. Understanding risk factors may facilitate patterns of protective behaviours, such as healthy diet and regular exercise, that can confer long-term benefits by reducing the risk of chronic diseases, including CRC[5].

These findings indicate that there is potential to increase knowledge of CRC risk factors and screening recommendations in all age groups, especially those aged ≥50, for whom CRC screening is an imminent issue. Knowledge of CRC screening recommendations is considered important for facilitating screening uptake. Patients who have greater knowledge of CRC are more likely to initiate screening discussions with their GPs[23, 24].

However, the study reported in paper 3 showed that higher rates of knowledge were not associated with higher self-reported screening rates in a general practice sample. Previous research reporting an association between knowledge and under-screening[21, 25], included Koo et al.'s cross sectional study, which showed that among 311 Australian outpatients, better knowledge was significantly associated with greater likelihood of self-reported CRC screening uptake (OR 1.6; 95%CI 1.25-2.03). Koo et al. did not report CRC screening within the recommended time interval; rather, participants were asked if they had undergone previous screening tests (yes/no)[21]. In contrast, the current study used Australian guidelines to determine under-screening. Differences in the wording of knowledge questions and stricter criteria to define under-screening may explain why knowledge levels were not associated with screening behaviour in the current study.

Finally, paper 6 reported that knowledge levels did not increase significantly in the intervention group, although CRC screening uptake was significantly higher. Future studies could consider exploring motivations to undertake CRC screening and the extent to which knowledge is an important factor compared to other factors, such as GP endorsement or decreasing structural barriers to screening.

Finding 2.2. Male gender was significantly associated with under-screening

The study reported in paper 1 highlighted that male gender was significantly associated with under-screening (OR 2.04; 95% CI 1.08-3.84, p=0.02). This finding is consistent with results from the NBCSP in 2015-2016 which showed that 39% of male invitees returned a completed FOBT compared to 43% of female invitees[8].

Previous Australian research has reported that male gender is associated with lower prevalence of screening[26,27]. However, a study of 16,433 South Australian residents invited into the NBCSP found that although females were initially more likely to participate, males, after initial screening, were more likely to report ongoing participation[28]. Australian males are more likely than females to be diagnosed with CRC (66.9/100,000 versus 48.7/100,000 age-standardised incidence) and are more likely to die from CRC (18.6/100,000 versus 13.0/100,000 age-standardised mortality)[29]. These data highlight that engaging males in CRC screening is of particular importance.

Strategies to increase CRC screening, such as provision of FOBT[30-32] and general practitioner (GP) endorsement[33-35], have been shown to increase screening uptake in both males and females. These strategies could be further tailored to increase the likelihood of screening uptake in males. For example, GP endorsement could include emphasis on the greater incidence and mortality from CRC for males[29], to further close the gap in screening uptake.

Finding 2.3. Younger age was significantly associated with under-screening

In the sample of general practice participants aged 50-75 reported in paper 3, there was an 8% increase in the odds of being under-screened with each year decrease in age (OR 0.91; 95% CI 0.86-0.98, p= 0.008). Data from the NBCSP also suggest that screening uptake is lower in younger age groups (50-54 years)[8]. Between 2015 and 2016, 28% of invitees aged 50–54 returned a completed FOBT, while 53% of invitees

aged 70–74 returned a completed FOBT[8]. These findings suggest that interventions are needed to increase screening uptake in younger age groups.

In Australia, all those aged between 45-49 years old are entitled to a free, comprehensive health check with their GPs[6]. This health check typically covers smoking, nutrition, alcohol and physical activity risk factors, blood pressure, lipids, weight, and risk of diabetes and cardiovascular disease[6], as well as advice about mammograms for females. It has been recommended that this health check be used as an opportunity for GPs to 'prime' patients for the need to commence biennial CRC screening from their 50th birthday[36]. However, longitudinal or intervention research is needed to assess whether this 'priming' is effective in encouraging individuals to commence screening at a younger age.

The studies reported in papers 1 and 3 found, respectively, that males and those in younger age groups were more likely to be under-screened. This information, viewed with other research reporting predictors of screening behaviour[37], could be used to develop specific interventions to target those most at risk of being under-screened for CRC. Future interventions could include messages which are targeted to at-risk sub-groups, such as males and younger people. For example, printed information sheets or GP scripts could be tailored to suit the demographic characteristics of the participant. Noar et al.'s meta-analysis of tailored print-based health behaviour change interventions found that tailored printed messages were more effective than a comparison message (r=.058), suggesting that framing screening messages to target individual characteristics may successfully engage at-risk sub-groups[38].

3. GENERAL-PRACTICE-BASED INTERVENTIONS TO IMPROVE COLORECTAL CANCER SCREENING

Finding 3.1. The quality of colorectal cancer interventions has remained high but low rates of colorectal cancer screening persist

Paper 4 presented a snapshot of research reporting CRC screening prevalence in general practice at three time points since 1993. The majority of studies across the three time points were intervention studies (57%, 64% and 65%, respectively). Additionally, the majority of intervention research across the three time points utilised an Effective Practice of Organisation of Care (EPOC) accepted study design, i.e. were either an RCT, a controlled before and after study, a controlled clinical trial, or an interrupted time series (50%, 78% and 85% of the intervention studies at the three time points, respectively).

Despite the consistently strong focus on development and testing of interventions in this area, and the high quality of the intervention studies, CRC screening rates remain suboptimal in general practice[39-41]. One possible reason for this may be that strategies which are efficacious have not yet been identified. However, recent systematic reviews indicate that provision of FOBT, reminder systems and physician endorsement show promise. Therefore, another possible reason for persistently low screening rates is that efficacious strategies have been identified but have not been translated into routine practice. A lack of intervention research to identify strategies which improve uptake of evidence-based practice has been identified in other areas of health services research[42,

[43]. Future systematic reviews could explore efforts to implement effective strategies into general practice settings.

Finding 3.2. A multicomponent general-practice-based intervention is effective in increasing colorectal cancer screening uptake

Although the number of age groups invited to participate in the NBSCP has increased over time, participation rates in the NBCSP are stagnant[8, 44, 45], suggesting that additional strategies to encourage CRC screening are required. GPs have frequent contact with those in the target age range for screening[46]. The study reported in paper 6 tested an intervention delivered in general practice that aimed to increase CRC screening rates in those aged 50-74, at average risk of CRC and identified as being under-screened for CRC. The intervention included point-of-care FOBT, printed CRC screening information and face-to-face GP endorsement. Participants in the intervention group were significantly more likely to complete CRC screening compared to the usual care group at the six-week follow-up time point (39% versus 8%; OR 7.89, p=0.0007). The majority of those in the intervention group completing CRC screening used the FOBT provided to them as part of the intervention (95%). While these results are encouraging, it is important that the current findings are replicated using a larger and more representative sample of general practices. This would give greater confidence regarding the generalisability of the results and allow effect size to be estimated with a greater degree of accuracy.

Enhancing current intervention design

The finding that a multi-component GP-based intervention was effective in improving screening uptake highlights the important role GPs can play in promoting CRC screening. Future studies could test whether additional features could be added to the intervention to enhance its impact on screening uptake. Such features could include advance notification that an invitation to participate in CRC screening may be provided at an upcoming general practice appointment, and follow-up reminders to non-responders. Population-based studies in The Netherlands and Australia have shown that advance notification of screening invitation significantly increases CRC screening uptake[47-49]. Post-intervention patient reminders to complete screening should also be considered in future research. A population-based study tested the effectiveness of posting an FOBT and invitation letter on CRC screening uptake. Non-responders were sent reminder letters at six weeks, with 38% of all those completing FOBT doing so after the six-week time point[33]. Future general-practice-based interventions should consider incorporating these strategies.

Integration with the National Bowel Cancer Screening Program

Despite guidelines highlighting the importance of GP involvement[5, 50] in population-based screening programs, available evidence suggests that few programs integrate GPs in their programs[51]. In Australia, the formal role of GPs within the NBCSP is limited to discussing the results of positive FOBTs with patients and planning the next steps in care. The current findings suggest that increased involvement of GPs in the NBCSP may have a beneficial effect on screening rates. The potential for translation and long-term impact of an intervention such as that reported in paper 6 may be

enhanced by integration with the NBCSP, or other general practice systems, staff or infrastructure. Currently, Australia is in the process of integrating the NBCSP into the National Cancer Screening Register (NCSR)[52], a 'national electronic infrastructure that collects, analyses and reports information about the cervical cancer screening history of eligible Australians'[53]. When the NBCSP is added to the NCSR, GPs will be able to access information regarding their patients' screening status from the register[30, 54]. As an alternative, general practices may also be able to provide point-of-care NBCSP FOBT for those who do not respond to screening invitations, as recommended in a review of the NBCSP[55]. Therefore, future studies could examine how GPs can best be integrated into the NBCSP to promote CRC screening uptake in this setting.

Cost-effectiveness

The study reported in paper 6 did not include an analysis of cost-effectiveness of the intervention. A recent review of opportunistic and population-based screening strategies to increase CRC screening uptake included 44 studies, of which only five included cost-effectiveness analysis of general practice interventions[56]. This suggests that cost-effectiveness analyses are currently overlooked in many studies. There has been some Australian research reporting cost-effectiveness analysis and economic modelling related to the NBCSP. One study examined the cost-effectiveness of an advance notification letter in a hypothetical cohort within the NBCSP. The study reported that an advance notification letter could have a significant impact on life years gained (AU$3,976/life year gained) at an acceptable cost to the program[57]. A more recent modelling study of the NBCSP in its current form with a participation rate of 40%, reported that each year of life saved due to detection and treatment of CRC

cost AU$3014[58]. Future Australian general practice studies could use the existing studies reporting economic modelling of the NBCSP[57, 58] to serve as a benchmark for determining whether GP-based interventions can value-add to the NBCSP in a cost-effective manner.

STRENGTHS AND LIMITATIONS OF THE BODY OF THIS WORK

The findings of this body of work should be considered in light of the following strengths and limitations.

STRENGTHS

Provides an updated snapshot of current colorectal cancer screening rates

The studies reported in papers 1 and 3 are timely and important, as they provide a current snapshot of risk-appropriate CRC screening behaviour of those at average risk of CRC in healthcare settings. Prior to publication of these papers, the most recent published Australian data on screening in general practice and community samples were collected seven years ago (2011). In 2011, only three age groups (50, 55 and 65) were invited into the NBCSP, whereas, at the time of data collection for papers 1 and 3, eight age groups received invitations to screen from the NBCSP (50, 55, 60, 64, 65, 70, 72 and 74). The findings from these studies provide an update on screening rates in Australia and suggest that the increase in number of age groups invited to the NBCSP has had a positive impact on screening uptake.

Approach to detecting under-screening used current Australian guidelines

Prior Australian research in healthcare and community settings has not quantified CRC screening in a manner that aligns with National Health and Medical Research Council (NHMRC) guidelines[5]. For example, some studies included age groups outside the target range for CRC screening[1, 2], did not specify whether CRC screening was risk-appropriate[3], or reported CRC screening frequency outside the recommended screening interval[1] (e.g. reported FOBT screening within 3 years rather than 2). The studies reported in papers 1 and 3 overcame these weaknesses, utilising NHMRC guidelines to assess under- and over- screening[5].

Studies were able to detect over-screening

The studies reported in papers 1 and 3 assessed screening using colonoscopy among people at average risk for CRC, allowing for an estimation of the proportion who were potentially over-screened. Two previous Australian papers have reported rates of over-screening in those at average risk[2, 59], the most recent of which collected data in 2009[2]. The studies reported in papers 1 and 3 provide recent data regarding potential over-screening among average-risk participants in primary and secondary healthcare settings.

Use of robust randomised controlled trial study design

The studies reported in papers 5 and 6 included an RCT protocol and results of this RCT. The RCT is the gold standard for evaluating the effectiveness of an intervention[60]. The use of this design increases confidence that the intervention effect observed was due to the intervention, as opposed to other factors. The protocol

reported in these papers was prospectively registered with the Australia and New Zealand Clinical Trials Register (ACTRN12616001299493). There was a small reduction in sample size after registration, but the study remained adequately powered.

Addressing known barriers to colorectal cancer screening

The current intervention included multiple strategies designed to take a comprehensive approach to overcoming known barriers to CRC screening: affordability and access[61, 62] (provision of FOBT); lack of time during consultations[62, 63] (education leaflet and referral completed pre-appointment); and lack of reminder systems[63] (patient and kit acted as a prompt for GP endorsement).

LIMITATIONS

Sampling frame is not directly comparable to previous Australian studies.

There are few Australian studies investigating the prevalence of CRC screening, each study used a different sampling frame to our general practice and outpatient studies. For example, Zajac et al. recruited participants via the Australian electoral roll[3], Courtney[2] et al. sampled through a community-based research cohort, therefore our results may not be directly comparable to the results of these prior studies. Further, those attending general practice appointments are more likely to participate in preventive health care behaviours including CRC screening[54], this may in part, explain differences observed in screening rates between the current and previous studies.

Sampling methods may limit generalisability of findings

Practice samples

The study reported in paper 1 reports on data collected from outpatient clinics in one major regional hospital. The studies reported in papers 2, 3 and 6 report on data from a convenience sample of general practices in rural and regional areas of New South Wales. For papers 2 and 3, five of thirteen practices consented to participate. For paper 6, four of twenty-one practices consented to participate. This non-random sampling technique may limit the generalisability of our results to other practices[64]. A further limitation is that the practice characteristics of consenting and non-consenting practices were not collected. Therefore, it cannot be determined if the participating practices were broadly representative of the national practice sample reported by *Bettering the Evaluation and Care of Health* (BEACH) (general practice activity data from a large sample of Australian general practitioners n=965)[46], or if the non-participating practices were comparable to participating practices.

Participant samples

Consecutively sampled patients that met initial eligibility criteria were included in the studies reported in papers 1, 2, 3 and 6. This non-probability sampling technique is preferential to other non-probability samples such as convenience sampling because it includes all subjects that are available, thus making the sample more representative of the entire population[65]. Some individual participant characteristics reported in these papers can be compared to broader population samples. For example, in the general practice sample (paper 3), 58% of our participants were female compared to 56.6% in the BEACH general practice activity data, which reported 97, 398 patient encounters[46], suggesting that the sample was representative of the broader population in relation to gender. The outpatient sample included slightly more females than

recent national outpatient data (62% versus 56%)[66]. However, the age brackets and variables used when reporting national outpatient data[66] differ when compared to the current studies, limiting direct comparison to assess representativeness of the current sample.

Whilst our sample sizes were small and may be subject to sampling bias due to non-random sampling, high consent rates obtained at an individual participant level (81% and 78%) were reported in papers 1, 2 and 3, indicating participants may be reasonably representative of patients attending the clinics from which they were recruited. Further, there were no significant differences between consenters and non-consenters. Nevertheless, findings should be interpreted in light of this limitation. Utilising random sampling approaches in future may limit potential biases and improve the accuracy with which screening behaviours and knowledge are measured. The RCT (paper 6) reported a moderate consent rate of 64%. Additionally, females were significantly more likely to consent to participate than males, as were those aged 50-59. This is consistent with previous RCTs testing interventions to increase CRC screening in general practice, which have reported higher participation among females[67-69], and is in line with findings from paper 1 which indicated that males may be more reluctant to participate in screening than females.

Simplified method to determine colorectal cancer risk categories may have led to some inaccuracies in risk estimation

Determining CRC risk categories is a complex undertaking, as several familial and individual factors needs to be taken into account[70]. However, these were unable to be

incorporated into our study as it was not feasible to administer a lengthy survey, given the short duration participants spend in the waiting areas of these settings. For these reasons CRC risk was determined by three brief family history questions, modelled on existing guidelines[5, 6]. While this may have resulted in some participants being incorrectly categorised, it is likely that the proportion of incorrectly categorised participants would have been small. In the current RCT (paper 6), the GP was able to withdraw participants from the study if they had been categorised incorrectly and FOBT was not considered appropriate, but there was no occurrence of this during the study.

Self-reported screening data may have led to reporting bias

The studies reported in papers 1, 3 and 6 relied on self-reported CRC screening. Using self-report to measure health behaviours may result in reporting bias[71]. Participants are more likely to over-report normative behaviour, such as exercise, and under-report counter-normative behaviour, such as drug use[72]. Pathology results and medical records are considered the gold standard for clinical outcome measures[73]. Paper 6 reported high levels of sensitivity and specificity for self-report compared to pathology records (90%; 95%CI 61.2-97.9 and 93%; 95% CI 73.9-98.6, respectively). Similarly, a recent meta-analysis reported high accuracy of self-reported FOBT compared to medical records (sensitivity of 95% and specificity of 95%)[74]. These findings are reassuring in that they suggest that the self-report method represented actual screening with a high degree of accuracy.

CONCLUSION

CRC is an important public health issue in Australia. Mortality and morbidity from CRC can be reduced by early detection. While population-based screening programs are an ideal method for systematically inviting all those eligible for screening, participation in the Australian NBCSP remains sub-optimal. This thesis provides new data on CRC screening prevalence in accordance with clinical practice guidelines, in both primary and secondary healthcare settings. The studies reported in papers 1 and 3 highlight that CRC screening rates are higher than those reported by the NBCSP. These higher rates reflect both the capture of screening occurring outside the NBCSP, as well as the impact of using a denominator which excludes those who are ineligible for FOBT due to a strong family history of CRC or due to their personal medical history (e.g. having been diagnosed with CRC). Despite this, under-screening for CRC remains an ongoing concern, especially among males and those at the younger end of the target age range for screening. These factors suggest that strategies which can complement the existing NBCSP should be considered.

A logical setting to test and deliver strategies to increase CRC screening is general practice. This thesis presents new Australian data regarding the impact of a multi-component intervention delivered in a general practice setting on CRC screening uptake. These results suggest that there should be further exploration of how general-practice-based strategies, such as provision of screening advice and point-of-care FOBT, can be integrated into the NBCSP in order to boost low CRC participation rates.

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Manuscript number: ANZJPH-2017-196

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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Participant Information Sheet

Health concerns and preferences among hospital outpatients and their support persons

Project Number: HREC/16/HNE/351

Location: John Hunter Hospital

Research Team: L/Prof Rob Sanson-Fisher, Dr Elise Mansfield, Dr Mariko Carey, Ms Natalie Dodd and Ms Rochelle Smits from the School of Medicine and Public Health at the University of Newcastle.

You are invited to participate in a research study being conducted by researchers from the School of Medicine and Public Health at the University of Newcastle. All patients and their accompanying support persons attending outpatient clinics in the North and South block of the Royal Newcastle Centre are being invited to complete this study.

This information sheet tells you about the research project. Knowing what is involved will help you decide if you want to take part. Please read the information carefully and ask questions about anything you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your doctor.

Why is the research being done?

This research will explore individuals' health care concerns and preferences across a range of areas, including cancer screening, diagnosis of disease, and access to services. This research may help to identify areas where improvements could be made in the care that people receive.

Who can participate in the research?

We are inviting patients attending an outpatient appointment at the Royal Newcastle Centre and their support person to participate in this research. A support person might be a partner, family member or friend of the patient. Participants must be aged 18 years and over and have sufficient English to be able to complete the survey.

Do I have to take part in this research project?

Participation in any research project is entirely your choice. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you can stop participating at any stage without giving a reason. Only those people who give their informed consent will be included in the project. Your decision about whether to take part will not affect the care provided to you or the person you support, or your relationship with the health care team.

What would you be asked to do?

If you are willing to take part, you will be asked to complete one survey on an iPad (touch screen computer) in a private room or in the clinic waiting room while you wait for your appointment. Help to use the iPad will be provided. Depending on your age and gender, you may receive questions about bowel cancer screening, your views about diagnosis of dementia and a range of other diseases, access to and use of the internet, care provided in hospital, and aged care. We are interested in your views even if you have no experience with these areas. These questions have nothing to do with your current or future expected health status, or your reason for visiting the clinic today. You will also be asked if you agree to be contacted again about future research. It is completely up to you whether you agree to any future contact.

At the end of the survey, the research assistant may ask you what you thought about the survey and if you found it easy to complete. Please feel free to give your honest opinions as all feedback is helpful.

The iPad survey is expected to take around 15 minutes to complete. If you are called for your appointment during the survey, you can stop the survey straight away. You may be able to continue with the survey after your appointment if you would like to. Please just let the research assistant know. Unfortunately we cannot guarantee that an iPad will be available for you to continue after your appointment. If you need to stop the survey, you will have the option of withdrawing the information you have entered, or allowing us to use this information in our study.

What are the possible benefits of taking part?
There are no costs to you associated with participating. There are no benefits to you from participating. The research will allow hospital outpatients and their support persons to express their concerns and preferences about a range of health issues. This information may help to identify how care might be improved in the future.

What are the possible risks and disadvantages of taking part?
We do not expect any significant risks from participating. It is possible that participation may cause you to reflect on any personal experiences you have had with the conditions included in the survey. We recommend you discuss any questions or concerns with your doctor. You can also contact the NSW Mental Health Line on 1800 011 511. The NSW Mental Health Line is staffed by health professionals, and gives NSW residents access to expert health advice, support and referrals for people dealing with health problem and their families and carers.

What if I want to stop participating in this research project?
If you want to stop participating in the project, please let the research assistant know. You can stop participating at any stage without giving a reason.

How will your privacy be protected?
All information collected will be de-identified. This means that a number will be used instead of your name to store your survey answers. Your name and contact information, if you provide it, will be stored separately from your survey answers, and will only be able to be re-linked by the ID code. Any identifying information will be stored securely in a password protected file on the University of Newcastle server. This information will only be accessed by the researchers unless you give permission for your personal details to be provided to others, except as required by law. Data will be retained for at least 7 years in a locked filing cabinet and password protected files at the University of Newcastle.

How will the information collected be used?
The information collected will be reported in scientific journals and in a peer-reviewed theses for Ms. Dodd and Ms. Smits as part of their degree. Additionally, the information collected may be presented at national and international conferences. Only grouped data will be presented in any reports of publications arising from this research. No individual will be identifiable and your privacy will be protected. At the end of the study we can send you a summary of the key findings of the project. If you would like this information sent to you, please call the research team on 1800 084 755.

What do you need to do to participate?
Please read this Information Statement and be sure you understand it before you agree to participate. Please ask the research assistant any questions you have or if there is anything you do not understand. If you are willing to take part in this study, please let the research assistant know when they come to talk to you in the waiting room.

Further information and who to contact
The person you may need to contact will depend on the nature of your query. If you have any questions or want more information about this project you can talk to the research assistant or contact the research team on **1800 084 755**.

Complaints about this research
This research has been reviewed and approved by the Hunter New England Human Research Ethics Committee reference number 16/09/21/4.10. If you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email hnehrec@hnehealth.nsw.gov.au.

You are also free to discuss any concerns about this study, not only with your family, friends, health care professionals or legal advisors.

Thank you for taking the time to consider this study.
This information sheet is for you to keep.

Attachment 3. Outpatient survey V2 28/09/2016

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Thank you for taking part in this survey.
Your answers may help to improve health care delivery in the future.

Please touch 'NEXT' to continue.

Note for HREC: The survey is tailored to suit gender and age requirements. Participants will not be required to complete all questions. Branching is shown in RED and won't be visible to participants

CONSENT

Please read the information statement and the information below carefully.

By providing consent to take part in this study:

- *I understand that I am being asked to complete this iPad survey that asks about my health and preferences for care*
- *I understand that my decision about whether to participate will not affect my medical care in any way, or the care of the person I am here supporting*
- *I understand that I can choose to stop taking part at any time without providing a reason*

Do you consent to participate in this study?

☐ yes ☐ no

1. Please select the block you are currently in:

1=North Block

2=South Block

If North Block:

1a. Which type of clinic are you, or the person you are accompanying, attending today?

- Cardiology
- Respiratory
- Neurology
- Gastroenterology
- Endocrinology
- Immunology
- Rehabilitation
- Minor procedures (biopsy, skin clinic)
- I'm not sure
- Other (please specify)

If South Block:

1b. Which type of clinic are you, or the person you are accompanying, attending today?

- Orthopaedics
- Ear, nose, throat or eye
- General surgery
- Vascular surgery
- Urology
- Rehabilitation
- Dental
- Endoscopy
- Bariatric surgery
- I'm not sure
- Other (please specify)

MODULE 1

We will use the following information to ensure you are only asked questions that are relevant to your gender and age.

1. Are you?

- Male
- Female

2. What is your age?

- 18-49 years
- 50-59 years
- 60-74 years
- Over 75 years

3. Do you have a partner/spouse

- Yes
- No

4. Are you attending this outpatient clinic today as a:

- Patient → Answer 4a, then skip to 5
- Person accompanying a patient → Skip to 4b

5. What is your relationship to the patient?

- Partner
- Child
- Parent
- Friend
- Other

6. How often have you visited this out-patient clinic in last three months?

- This is my first time at this clinic
- 1-2 times
- 3-4 times
- 5-6 times
- 7 or more times
- I have not visited this clinic in the past 3 months, but I have visited this clinic previously

MODULE 2 (If 50-74)

This section is about your personal and family history of bowel cancer and tests that you may have had to screen for bowel cancer.

2a. Have you had a previous diagnosis of bowel cancer or an inflammatory bowel disease (e.g. Crohn's Disease, ulcerative colitis)?

- ○ Yes — Skip to Module 3
- ○ No

2b. Have any of your first degree relatives (i.e mother, father, brother, sister, child) been diagnosed with bowel cancer before age 55?

- ○ Yes — Skip to 2
- ○ No — Go to 1c

2c. Have 2 or more of your first degree relatives (i.e mother, father, brother, sister, child) been diagnosed with bowel cancer at any age?

(These may be from either side of the family)

- ○ Yes — Skip to 2
- ○ No — Go to 1d

2d. Has <u>one of your first degree relatives</u> (i.e mother, father, brother, sister, child)

and

<u>one of your second degree relatives</u> (i.e grandparent, aunt, uncle, nephew, niece or half-sibling) <u>on the same side of the family</u> been diagnosed with <u>bowel cancer at any age?</u>

- Yes
- No

For males and females aged 50-74 with no personal history of bowel cancer

2e. When was the last time you had a Faecal Occult Blood Test (FOBT)?

A FOBT involves collecting a small sample of faeces (poo). The sample is tested for tiny amounts of blood.

- Never had a FOBT
- 1-2 years ago
- 2-3 years ago
- 3-4 years ago
- 4-5 years ago
- More than 5 years ago
- Not sure

3. Have you ever had a colonoscopy?

A colonoscopy is usually a day procedure in hospital where the inside of your bowel is examined while you are sedated

- ○ Yes, I have had a colonoscopy — Go to 3a
- ○ No, I have never had a colonoscopy — Skip to 4
- ○ Not sure — Skip to 4

3a. When was the last time you had a colonoscopy?

- ○ <5 years ago — Go to 3b
- ○ 6-10 years ago — Skip to 4
- ○ >10 years ago — Skip to 4
- ○ Not sure — Skip to 4

3b. Why were you referred for a colonoscopy?

- I have a family history of bowel cancer
- I had symptoms which indicated I may have bowel cancer
- I had a positive FOBT result
- I had an abnormal X-ray or CT scan
- I have previously had colorectal adenomas (polyps)
- Not sure
- Other (please specify)

For those with no FOBT in past 2 years or no colonoscopy in the past 5 years

Your answers suggest that you may be overdue for bowel cancer screening.

4. Would you be willing to receive help to address this?

- ○ Yes Go to 4a
- ○ No Go to 4b
- ○ I am already addressing this

4a. How would you like to receive help to address this?

- ○ Information mailed to my home
- ○ Information emailed to me
- ○ Notification sent to my GP
- ○ Other (please specify)

4b. Why would you be unwilling to receive help to address this?

- Bowel cancer screening is not relevant to me
- I find the idea of bowel cancer screening unpleasant
- I don't think bowel cancer screening is effective at detecting cancer
- Can't afford bowel cancer screening
- Worried I would not know how to do the test
- Would rather not know if I had cancer
- My doctor hasn't recommended I undertake bowel cancer screening
- Other (please specify)

MODULE 8

We would like to ask you a bit more about yourself.

8a. What is the highest level of schooling you have completed? *Please select one answer only.*

- ○ High school or below
- ○ Trade or vocational training (e.g. TAFE or college)
- ○ University or postgraduate degree
- ○ Other – Please specify _____

8b. How would you best describe your employment situation at the moment?

- ○ Employed full time
- ○ Employed part time/casual
- ○ Unemployed
- ○ Disability pension
- ○ Retired
- ○ Home duties
- ○ Student
- ○ Other – Please specify _____

8c. What is your current marital status?

- Married or living with partner
- Divorced or separated
- Widowed
- Never married

8d. Do you have private health insurance?

- Yes
- No

8e. Do you have a healthcare card?

- Yes
- No

MODULE 9

9a.	For your medical care, how many times in the last 12 months have you:					
		0 times	1-3 times	4-6 times	7-10 times	More than 10 times
a.	Used a family general practice clinic	○	○	○	○	○
b.	Used a 24-hour medical clinic	○	○	○	○	○
c.	Used emergency services at a hospital	○	○	○	○	○
d.	Had an after hours home visit from a general practitioner	○	○	○	○	○

9b. Please select the statement that reflects your GP visits.

- ○ I always see the same GP
- ○ I usually see the same GP
- ○ I see whichever GP is available

NEXT

You have now finished the survey. Thank you for your time.

If this survey has raised any issues you are concerned about, please discuss these with your doctor.

Laureate Professor Rob Sanson-Fisher
School of Medicine and Public Health, University of Newcastle
University Drive, Callaghan NSW 2308
Ph: 02 4042 0713 Fax: 02 4042 0040
Rob. Sanson-Fisher@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Patient Information Statement for the Research Project:
Bowel cancer screening
Document Version 4; dated 30/09/15

Why is the research being done?

Bowel cancer is one of the most common types of cancer in Australia. However, only about 35% of those invited to participate in screening via the National Bowel Cancer Screening Program return a completed Faecal Occult Blood Test (FOBT). This study aims to explore individuals' knowledge, attitudes and practices regarding bowel cancer screening.

Who can participate in the research?

We are seeking English-speaking patients between 18 – 85 years of age to participate in this study.

What choice do you have?

Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your routine care at this medical practice will not be affected. If you do decide to participate, you may withdraw from the project at any time without giving a reason and have the option of withdrawing any data identified as yours.

If you are between 50 and 75 years of age, you will also be asked if you consent to data on your history of bowel cancer screening being accessed from the National Bowel Cancer Screening Program (NBCSP). We will ask the NBCSP to provide us with your data from the last 2 years on: whether you were mailed an invitation to participate in bowel cancer screening; the address that the NBCSP sent your invitation letter to; and if you returned a bowel cancer screening kit. We are seeking this information to assess how many people receive invitations from the NBCSP and how many people complete the screening. This information will help us understand how we can improve how bowel cancer screening is delivered.

What would you be asked to do?

If you agree to participate, you will be asked to complete a touchscreen computer survey before your appointment with your GP. If there is a more private area available than the waiting room, you will be offered this option. The survey will include questions about you, such as your age, gender and medical history, your family's history of bowel cancer, your bowel cancer screening history as well as your attitudes and knowledge about bowel cancer and bowel cancer screening.

How much time will it take?

It is expected that the survey will take approximately 10 minutes to complete. You may get called into your appointment before finishing the survey. If this happens, you will not be able to participate in the study at this time, but may be approached to participate at a later date. However, we cannot guarantee that you will be able to participate at a later date.

What are the risks and benefits of participating?

The risks of participating in the study are low, however, there is a slight risk that the survey may cause you to reflect on any personal experiences you have had with cancer. If you have any cancer-related concerns, you should discuss these with your GP. You may also wish to contact the Cancer Helpline by phoning 131120. The Cancer Helpline is staffed by experienced cancer nurses and who can provide support and information about cancer.

We cannot promise that you will receive a direct benefit from participating in this pilot. However, participation may provide you with a greater awareness of bowel cancer screening and the different tests which may be used to screen for this cancer type.

How will your privacy be protected?

Information collected will be de-identified upon receipt. This means that a unique identification code (ID) will be stored with your survey results. If you provide your name and contact information it will be stored separately from your survey data, and will only be able to be re-linked by the ID code. Any identifying information will be stored securely in a password protected file on the University of Newcastle server. This information will only be accessed by the researchers unless you consent otherwise, except as required by law. Data will be retained for at least 7 years in a locked filing cabinet and password protected files at the University of Newcastle.

How will the information collected be used?

This research is being conducted by the University of Newcastle. This research will be used to conduct a larger trial and to inform policy regarding bowel cancer screening methods. The information collected may be presented at national and international conferences and published in scientific journals. Only group data will be presented in any reports of publications arising from this research. In this way, no individual can be identified in any publications. Some of the research being conducted is part of Natalie Dodd's post-graduate studies at the University of Newcastle, supervised by L/Prof. Rob Sanson-Fisher, Dr Mariko Carey and Dr Elise Mansfield from the School of Medicine and Public Health. The information collected will be reported in a peer-reviewed thesis for Ms. Dodd's degree.

What do you need to do to participate?

Please read this Information Statement and be sure you understand all its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact the researchers, whose details are below. If you would like to participate, please inform the Research Support Person, complete the consent form and complete the survey now.

Further information

If you would like further information, please contact Ms Natalie Dodd on 02 40420425 or Dr. Elise Mansfield on 1800 084 755.

Thank you for considering this invitation.

Laureate Professor Rob Sanson-Fisher

School of Medicine and Public Health, University of Newcastle

Complaints about this project

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2014-0198.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

Laureate Professor Rob Sanson-Fisher

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Ph: 02 4042 0713 Fax: 02 4042 0040
Rob.Sanson-Fisher@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Patient Consent Form for the Research Project:

Bowel cancer screening – pilot study

Document Version 4; dated 30/09/15

The Research Team:
University of Newcastle: Dr. Mariko Carey, Prof. Rob Sanson-Fisher, Dr. Jamie Bryant, Dr. Christopher Oldmeadow, A/Prof. Lyndal Trevena, Dr Elise Mansfield, Ms Natalie Dodd

Please tick (✓) ONE BOX to indicate if you would like to take part in the study.

( ) YES, I agree to participate in the above research project and give my consent freely

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to completing an electronic health questionnaire.
I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

I would like to receive a summary of the project results. Yes No

*Please fill in **your details** in the box below:*

Title *(please circle one):* Mr / Mrs / Miss / Ms / Dr / Other _____		
Name:		
Postal Address:		
Suburb:	State:	Postcode:
Preferred phone:	Alternate phone:	
Preferred contact day/time:	Signature:	Date:

( ) NO, I would not like to take part (*N.B. Ticking the 'No' box and returning this consent form is optional*)

Research Assistant Only

I believe that the participant has understood what participation involves.
I have confirmed that the participant meets all of the eligibility requirements.

Full name of research assistant who obtained informed consent:

_____

Research Assistant Signature: _____

Date: _____

Thank you for participating in this research project conducted by the University of Newcastle. Your information will help us develop better ways to provide information to people about bowel cancer screening.

Please touch the screen when you are ready to commence the survey.

Note: Survey is tailored according to question responses so participants will not be required to complete all questions.

MODULE 1: All about you (All consenting patients)

What is your current age?
Enter response in years

Are you:
1=Male
2=Female

3. What is your current marital status?
1=Married or living with partner
2=Divorced or separated
3=Widowed
4=Never married

4. How would you best describe your employment situation at the moment?
1=Employed full time
2=Employed part time/casual
3=Unemployed
4=Disability pension
5=Retired
6=Home duties
7=Student
8=Other – Please specify

5. What is the highest level of schooling you have completed?
1 =High school or below
2=Trade or vocational training (e.g. TAFE or college)
3=University or postgraduate degree
4= Other – Please specify

6. Do you have private health insurance?
1=Yes
2=No

7. Do you have a healthcare card?
1=Yes
2=No

8. How many times have you seen a GP in the past 12 months?
1=0-3 times
2=4=6 times
3=7-10 times
4= More than 10 times

9. Please select the statement that reflects your GP visits.
1= I always see the same GP
2= I usually see the same GP
3= I see whichever GP is available
Primary school response removed and combined to this response
All new questions

10. Have you had a previous diagnosis of bowel cancer or an inflammatory bowel disease (e.g. Crohn's Disease, ulcerative colitis)?
1=Yes (end survey)
2=No

11. Have any of your first degree relatives (i.e mother, father, brother, sister, child) been diagnosed with bowel cancer before age 55?
1=Yes (Potentially Risk Category 2 or 3) go to Module 2
2=No

12. Have 2 or more of your first degree relatives (i.e mother, father, brother, sister, child) been diagnosed with bowel cancer at any age? (These may be from either side of the family)
1=Yes (Potentially Risk Category 2 or 3) go to Module 2
2=No (Potentially Risk Category 1) go to Module 2

13. Has one of your first degree relative (i.e mother, father, brother, sister, child and one of your second degree relative (i.e grandparent, aunt, uncle, nephew, niece or half-sibling on the same side of the family?
1=Yes (Potentially Risk Category 2 or 3) go to Module 2
2=No (Potentially Risk Category 1) go to Module 2

MODULE 2: FOBT screening history (All eligible patients)
The following questions are about your history of cancer screening.

1. When was the last time you had a Faecal Occult Blood Test (FOBT)?

A FOBT, involves collecting a small sample of faeces (poo). The sample istested for tiny amounts of blood.

1= Never had a FOBT	If aged 50-75 go to Question 2, all others go to Module 3
2= In the last year	Go to question 1a
3= 1-2 years ago	Go to question 1a
4= 2-3 years ago	If aged 50-75 go to Question 2, all others go to Module 3
5= 3-4 years ago	If aged 50-75 go to Question 2, all others go to Module 3
6= 4-5 years ago	If aged 50-75 go to Question 2, all others go to Module 3
7= > 5 years ago	If aged 50-75 go to Question 2, all others go to Module 3
8= Not sure	If aged 50-75 go to Question 2, all others go to Module 3

1a. How did you obtain your last FOBT kit?

1=I was sent it in the mail from the National Bowel Cancer Screening Program (NBCSP)	Go to 1b
2=Rotary Bowelscan	If aged 50-75 go to Question 2, all others go to Module 3
3=My GP gave it to me	If aged 50-75 go to Question 2, all others go to Module 3
4=Other (please specify)	If aged 50-75 go to Question 2, all others go to Module 3

2. Have you ever received an FOBT kit in the mail as part of an invitation to participate in the National Bowel Cancer Screening Program (NBCSP)?

Please touch your response and then touch 'NEXT'

1= Yes

2= No Go to Module 3

3= Not sure Go to Module 3

2a. Did you complete the test?

Yes Go to Question 3

No

2b. Why didn't you complete and return the FOBT kit received from the National Bowel Cancer Screening Program (NBCSP)?

Please select all that apply

1=Went to my GP instead as I have a family history of bowel cancer

2=Went to my GP instead as I thought I had symptoms of bowel cancer

3=Wasn't worried about having bowel cancer

4=Found the idea of completing the test unpleasant

5=Would have been embarrassed to discuss the test result with my doctor

6=Did not want to go through the stress of waiting for a result

7=Did not want to find out the test result 8= Forgot about it

9= Lost the test

10= I obtained a FOBT from another source 11=Other (please specify)

MODULE 3. Previous history of colonoscopy

These questions ask about whether you have previously had a colonoscopy.

A colonoscopy is usually a day procedure in hospital where the inside of your colon is examined while you are sedated.

1. Have you ever had a colonoscopy?

1=Yes, I have had a colonoscopy	Answer Question 2 & 3
2=No, I have never had a colonoscopy	Go to Module 4
3=Not Sure	Go to Module 4

2. When was the last time you had a colonoscopy?

1= <5 years ago
2=6-10 years ago
4= >10 years ago
7= Not sure

3. Why were you referred for a colonoscopy?

Please touch at least one response and then touch ‘NEXT’ (you can select more than one response)

1= Family history of bowel cancer
2 = Symptoms which indicated I may have bowel cancer
3= A positive FOBT result
4= An abnormal x-ray or CT scan
5= Previously had colorectal adenomas (polyps)
6= Other

Module 4: Knowledge and attitudes toward screening

The following knowledge questions use the term 'people at average risk of bowel cancer'. Most people are at average risk as they do not have bowel disease or a strong family history of bowel cancer.

1. At what age do you think people at average risk of bowel cancer should start screening?

a) 40
b) 50
c) 60
d) 70
e) I don't know

2. What do you think is the recommended screening test for people at average risk of bowel cancer?

a) Sigmoidoscopy (with definition)
b) Colonoscopy (with definition)
c) Faecal occult blood test (FOBT) (with definition)
d) I have not heard of these screening tests
e) I don't know

3. A faecal occult blood test (FOBT) is a bowel cancer screening test where you are asked to provide a sample of faeces (poo). The sample is then tested for tiny amounts of blood.

How often do you think a person at average risk of bowel cancer should have a FOBT?

a) Once only
b) Every year
c) Every two years
d) Every five years
e) Every ten years
f) I don't know

4. A positive faecal occult blood test (FOBT) means:

a) That a person has cancer
b) That a person does not have cancer
c) That traces of blood have been found in their faeces (poo)
d) I don't know

5. The following may or may not increase a person's chance of developing bowel cancer. Please select the option/s you think might increase your risk of developing bowel cancer.

a) Smoking
b) Being over 50 years of age
c) Being overweight
d) Not eating enough fibre
e) Drinking alcohol regularly
f) I don't know

MODULE 5: Information and encouragement to participate in bowel cancer screening (Ages 50-75 and not screened within last 2 years)

1. Please indicate how much you agree with the following statements:

If I was provided with an information sheet on bowel cancer screening by my GP, I would like it to include:

Strongly disagree/Disagree/Agree/Strongly agree

a. Minimal, basic information
b. Very detailed and specific information
c. Information provided in diagrams and pictures
d. A list of additional resources, including websites I can go to if I would like more information

2. Imagine you were offered a faecal occult blood test (FOBT) kit from your doctor. A FOBT involves collecting a small sample of faeces (poo). The sample is tested for tiny amounts of blood. Would you complete the FOBT?

1=Yes	END
2=No	Go to Question 3

3. Why wouldn't you take the test from your doctor?
1= think it would be unpleasant to do the test
2=I think it would be embarrassing to discuss the test with anyone
3=I think I would find waiting for the results would be too stressful
4=I would not like to find out the result
5=I'm not worried about getting bowel cancer
6=Other

Thank you for completing this survey. If this survey has caused you any concern, please discuss this with your doctor . Or call the Bowel Cancer Australia Hotline on 1800 555 494

Natalie Dodd

From: AMJ Editor <editor@amj.net.au>
Sent: Friday, 27 July 2018 4:20 PM
To: Natalie Dodd
Subject: RE: Please reply asap: Authority to post journal article to an institutional repository

Dear Natalie Dodd,

Thank you for the mail.

Apologies for the mishap, it's just an example of attribution I mentioned. You can mention as the final published version in the attribution.

Loyalty charges usually are applicable if the institutional repositories as services intended to make a commercial gain which include charging fees for access, distribution and advertising of user data.

With regards,

Rick Steves
Managing Editor
AMJ

From: Natalie Dodd [mailto:natalie.dodd@newcastle.edu.au]
Sent: 27 July 2018 08:16
To: AMJ Editor
Subject: Re: Please reply asap: Authority to post journal article to an institutional repository

Dear Rick,

Thank you so much for your reply. I am slightly confused by your email:

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E.g., This is a pre-copyedited, author-produced version of an article accepted for publication in ***Australasian Medical Journal*** *following peer review. The version of record [insert complete citation information here] is available online at: xxxxxxx [insert URL and DOI of the article].*

It seems on one hand I can include the final PDF with proper attribution and on another I can include a pre-copyedited version with proper attribution. Could you please clarify?

I am also unsure what the loyalty charge means and why a maximum amount is not specified. Could you please clarify?

Sorry I am not understanding. I want to make sure I am doing the right thing by your journal and my institution.

Kind regards,

Natalie

From: AMJ Editor <editor@amj.net.au>
Sent: Thursday, 26 July 2018 2:55:58 PM
To: Natalie Dodd
Subject: RE: Please reply asap: Authority to post journal article to an institutional repository

Dear Natalie Dodd,

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*E.g., This is a pre-copyedited, author-produced version of an article accepted for publication in **Australasian Medical Journal** following peer review. The version of record [insert complete citation information here] is available online at: xxxxxxx [insert URL and DOI of the article].*

A minimum of $500 USD loyalty charges will be levied to enter into this additional contractual agreement.

If you have more queries please revert.

Regards,

Rick Steves
Managing Editor
AMJ

From: Natalie Dodd [mailto:natalie.dodd@newcastle.edu.au]
Sent: 26 July 2018 05:59
To: AMJ Editor
Subject: Please reply asap: Authority to post journal article to an institutional repository
Importance: High

Dear Editor,
I write once again as I am nearing completion of my PhD thesis by publication. I would like to include the following publication in my thesis which will be posted in the University of Newcastle's repository.

> *Dodd N, Mansfield E, Carey M, Oldmeadow C. Are Australian general practice patients appropriately screened for colorectal cancer? A cross-sectional study. AMJ 2017;10(7):610–619. https://doi.org/10.21767/AMJ.2017.3041*

I understand that: "Authors are able to enter into separate, additional contractual arrangements for the non-exclusive distribution of the journal's published version of the work (e.g., post it to an institutional repository or publish it in a book), with an acknowledgement of its initial publication in this journal".
Could I please enter into an additional contractual agreement to permit me to do this?
I look forward to your reply.
Kind regards,
Natalie

Natalie Dodd

Associate Lecturer of Medical Education
PhD Candidate, Health Behaviour Research Collaborative
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Faculty of Health and Medicine

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Appendix 4.1

JOURNAL PUBLISHING AND LICENSING AGREEMENT

Elsevier Inc.

Article:	**Have we increased our efforts to identify strategies which encourage colorectal cancer screening in primary care patients? A review of research outputs over time**
Corresponding author:	**Ms. Natalie Dodd**
E-mail address:	**natalie.dodd@newcastle.edu.au**
Journal:	**Preventive Medicine Reports**
Our reference	**PMEDR666**
PII:	**S2211-3355(18)30092-5**
DOI:	**10.1016/j.pmedr.2018.05.015**

YOUR STATUS

» I am one author signing on behalf of all co-authors of the manuscript

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Appendix 4.1

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Search	Query Medline
#1	exp Colorectal neoplasms/
#2	(colo* cancer* or bowel cancer* or rect* cancer* or sigmoid cancer* or anus cancer* or anal cancer*).tw.
#3	(colo* neoplas* or bowel neoplas* or rect* neoplas* or sigmoid neoplas* or anal neoplas*).tw.
#4	(colo* malignanc* or bowel malignanc* or rect* malignanc* or sigmoid malignanc* or anal malignanc*).tw.
#5	(colo* tumo* or bowel tumo* or rect* tumo* or sigmoid carcinoma* or anal tumo*).tw.
#6	1 or 2 or 3 or 4 or 5
#7	Mass screening/ or screen*.tw.
#8	"Early detection of cancer"/
#9	Occult blood/
#10	(FOBT or "f?ecal occult blood test*").tw.
#11	("Guaiac f?ecal occult blood test" or gFOBT).tw.
#12	("immuno* f?ecal occult blood test" or iFOBT).tw.
#13	"f?ecal immuno* test*".tw.
#14	(Colonoscop* or flexible sigmoidoscop*).tw.
#15	(stool test* or stool sample or DNA stool).tw.
#16	exp colonoscopy/ or proctoscopy/ or colonography, computed tomographic/
#17	((early adj3 detect*) or (early adj3 prevent*)). tw.
#18	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
#19	general practitioners/ or physicians, family/ or physicians, primary care/
#20	exp General Practice/
#21	Primary Health Care/
#22	((general or family) adj1 (practice* or practitioner)).tw.
#23	(primary care or primary healthcare or primary health care or primary health service*).tw.
#24	19 or 20 or 21 or 22 or 23
#25	"clinical trial".pt. or controlled clinical trial.pt. or "multicenter study".pt. or "randomized controlled trial".pt. or double-blind method/ or exp clinical trials as topic/ or ((randomi?ed adj7 trial*) or (controlled adj3 trial*) or (clinical adj2 trial*) or ((single or doubl* or tripl* or treb*) and (blind* or mask*))).ti,ab,tw. or ("4 arm" or "four arm").ti,ab,tw.
#26	Intervention Studies/ or evaluation studies/ or evaluation studies as topic/ or program evaluation/ or validation studies as topic/ or ((pre- adj5 post-) or (pretest adj5 posttest) or (program* adj6 evaluat*)).ti,ab. or (effectiveness or intervention).ti,ab.
#27	27 or 28
#28	6 and 18 and 24 and 27
#29	limit 28 to (english language and yr="1993 -Current")

Search	Query (Ovid, Embase,)
#1	exp colon cancer/ or exp colon tumor/ or exp rectum tumor/
#2	(colo* cancer* or bowel cancer* or rect* cancer* or sigmoid cancer* or anus cancer* or anal cancer*).tw.
#3	(colo* neoplas* or bowel neoplas* or rect* neoplas* or sigmoid neoplas* or anal neoplas*).tw.
#4	(colo* malignanc* or bowel malignanc* or rect* malignanc* or sigmoid malignanc* or anal malignanc*).tw.
#5	(colo* tumo* or bowel tumo* or rect* tumo* or sigmoid carcinoma* or anal tumo*).tw.
#6	1 or 2 or 3 or 4 or 5
#7	Mass screening/ or screen*.tw.
#8	Early diagnosis/
#9	Occult blood/
#10	(FOBT or "f?ecal occult blood test*").tw.
#11	("Guaiac f?ecal occult blood test" or gFOBT).tw.
#12	("immuno* f?ecal occult blood test" or iFOBT).tw.
#13	"f?ecal immuno* test*".tw.
#14	(Colonoscop* or flexible sigmoidoscop*).tw.
#15	(stool test* or stool sample or DNA stool).tw.
#16	colonoscopy/ or computed tomographic colonography / or rectoscopy
#17	((early adj3 detect*) or (early adj3 prevent*)). tw.
#18	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
#19	general practitioner/
#20	General Practice/
#21	Primary Health Care/
#22	((general or family) adj1 (practice* or practitioner)).tw.
#23	(primary care or primary healthcare or primary health care or primary health service*).tw.
#24	19 or 20 or 21 or 22 or 23
#25	exp "clinical trial (topic)"/ or double blind procedure/ or (clinical trial or randomized controlled trial or controlled clinical trial or multicenter study or phase 1 clinical trial or phase 2 clinical trial or phase 3 clinical trial or phase 4 clinical trial).ct. or ((randomi?ed adj7 trial*) or (controlled adj3 trial*) or (clinical adj2 trial*) or ((single or doubl* or tripl* or treb*) and (blind* or mask*))).ti,ab,tw. or ("4 arm" or "four arm").ti,ab,tw.
#26	Intervention study/ or evaluation study/ or program evaluation/ or validation study/ or ((pre-adj5 post-) or (pretest adj5 posttest) or (program* adj6 evaluat*)).ti,ab. or (effectiveness or intervention).ti,ab.
#27	25 or 26
#28	6 and 18 and 24 and 27
#29	limit 28 to (english language and yr="1993 -Current")

Search	Query (Cochrane)
#1	MeSH descriptor: [Colorectal Neoplasms] explode all trees
#2	colo* cancer* or bowel cancer* or rect* cancer* or sigmoid cancer* or anal cancer*
#3	colo* neoplas* or bowel neoplas* or rect* neoplas* or sigmoid neoplas* or anal neoplas* :ti,ab,kw (Word variations have been searched)
#4	colo* malignanc* or bowel malignanc* or rect* malignanc* or sigmoid malignanc* or anal malignanc* :ti,ab,kw (Word variations have been searched)
#5	colo* tumo* or bowel tumo* or rect* tumo* or sigmoid carcinoma* or anal tumo*:ti,ab,kw (Word variations have been searched)
#6	#1 or #2 or #3 or #4 or #5
#7	MeSH descriptor: [Mass Screening] explode all trees
#8	Screen*:ti,ab,kw (Word variations have been searched)
#9	MeSH descriptor: [Early Detection of Cancer] explode all trees
#10	MeSH descriptor: [Occult Blood] explode all trees
#11	FOBT or "f?ecal occult blood test*"
#12	"Guaiac f?ecal occult blood test*" or gFOBT
#13	"immune* f?ecal occult blood test" or iFOBT
#14	"f?ecal immuno* test*"
#15	Colonoscop* or flexible sigmoidoscop*
#16	stool test* or stool sample or DNA stool
#17	MeSH descriptor: [Colonoscopy] explode all trees
#18	MeSH descriptor: [Proctoscopy] explode all trees
#19	(early detect* or early prevent*):ti,ab,kw (Word variations have been searched)
#20	#7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19
#21	MeSH descriptor: [General Practitioners] explode all trees
#22	MeSH descriptor: [Physicians, Family] explode all trees
#23	MeSH descriptor: [Physicians, Primary Care] explode all trees
#24	MeSH descriptor: [General Practice] explode all trees
#25	MeSH descriptor: [Primary Health Care] explode all trees
#26	((general or family) n/1 (practice* or practitioner*))
#27	primary care or primary healthcare or primary health care or primary health service* :ti,ab,kw (Word variations have been searched)
#28	#21 or #22 or #23 or #24 or #25 or #26 or #27
#29	#6 and #20 and #28

Search	Query (Ovid, Psychinfo)
#1	exp colon disorders/ and neoplasms/
#2	(colo* cancer* or bowel cancer* or rect* cancer* or sigmoid cancer* or anus cancer* or anal cancer*).tw.
#3	(colo* neoplas* or bowel neoplas* or rect* neoplas* or sigmoid neoplas* or anal neoplas*).tw.
#4	(colo* malignanc* or bowel malignanc* or rect* malignanc* or sigmoid malignanc* or anal malignanc*).tw.
#5	(colo* tumo* or bowel tumo* or rect* tumo* or sigmoid carcinoma* or anal tumo*).tw.
#6	1 or 2 or 3 or 4 or 5
#7	Cancer screening/ or screen*.tw.
#8	((early adj3 detect*) or (early adj3 prevent*)).tw.
#9	(FOBT or "f?ecal occult blood test*").tw.
#10	("Guaiac f?ecal occult blood test" or gFOBT).tw.
#11	("immuno* f?ecal occult blood test" or iFOBT).tw.
#12	"f?ecal immuno* test*".tw.
#13	(Colonoscop* or flexible sigmoidoscop*).tw.
#14	(stool test* or stool sample or DNA stool).tw.
#15	(colonoscopy* or proctoscopy*).tw.
#16	((early adj3 detect*) or (early adj3 prevent*)). tw.
#17	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
#18	general practitioners/
#19	Family medicine/ or family physicians/
#20	Primary Health Care/
#21	((general or family) adj1 (practice* or practitioner)).tw.
#22	(primary care or primary healthcare or primary health care or primary health service*).tw.
#23	18 or 19 or 20 or 21 or 22
#24	clinical trials/ or "treatment outcome clinical trial".md. or ((randomi?ed adj7 trial*) or ((single or doubl* or tripl* or treb*) and (blind* or mask*)) or (controlled adj3 trial*) or (clinical adj2 trial*)).ti,ab,id.
#25	program evaluation/ or ((pre- adj5 post-) or (pretest adj5 posttest) or (program* adj6 evaluat*)).ti,ab,id. or (intervention or effectiveness).ti,ab,id.
#26	27 or 28
#27	6 and 17 and 26
#28	limit 27 to (english language and yr="1993 -Current")

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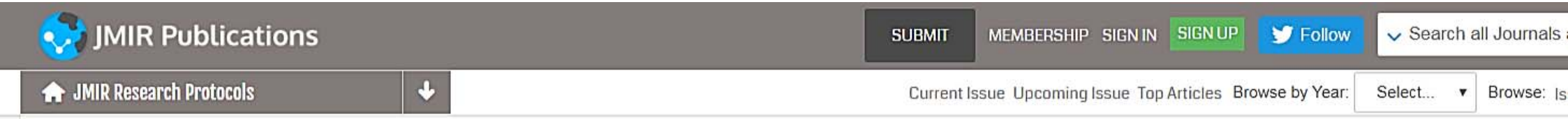

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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Patient Information Statement for the Research Project:
Bowel cancer screening

Who is conducting this research?
This study is being conducted by Dr Mariko Carey, Dr Elise Mansfield, Laureate Professor Rob Sanson-Fisher, Dr Jamie Bryant, Mr Justin Walsh and Ms Natalie Dodd from the School of Medicine and Public Health at the University of Newcastle, Associate Professor Lyndal Trevena from the University of Sydney, and Dr Christopher Oldmeadow from the Hunter Medical Research Institute.

Why is the research being done?
Bowel cancer is one of the most common types of cancer in Australia. Screening using a Faecal Occult Blood Test (FOBT) is recommended for most people aged 50-75 every 2 years. This is a simple test that you can do at home. Early detection of bowel cancer through screening greatly improves outcomes. This study is being conducted to pilot test the feasibility and acceptability of a new strategy to increase the uptake of screening for bowel cancer in those aged 50-75 years.

Who can participate in the research?
We are seeking English-speaking patients between 50-75 years of age to participate in this study.

What choice do you have?
Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your routine care at this medical practice will not be affected. If you do decide to participate, you may withdraw from the project at any time without giving a reason and have the option of withdrawing any data identified as yours.

What would you be asked to do?
If you agree to participate, you will be asked to complete a touchscreen computer survey before your appointment with your GP. If there is a more private area available than the waiting room, you will be offered this option. The survey will include questions about you, such as your age, gender, medical history, and bowel cancer screening history. The survey also includes questions about history of bowel cancer in your first and second degree blood relatives. A first-degree relative is defined as a close blood relative which includes the individual's parents, full siblings, or children. A second-degree relative is defined as a blood relative which includes the individual's grandparents, grandchildren, aunts, uncles, nephews, nieces or half-siblings.

Your survey answers will be used to determine if you are eligible to continue on with the study. If you are *not* eligible to continue with the study, we will give you some information about your tests that may be appropriate for you based upon your survey answers.

If you *are* eligible to continue on with the study you will be randomised to receive usual care or an intervention, depending on the day you attend your GP clinic. Usual care means you receive the care usually provided by your doctor. If you are randomised to the intervention, you will be offered an FOBT kit to take home, an information sheet about bowel cancer screening. This kit contains simple instructions and a reply paid envelope. You will also be asked to give permission for the researchers to access information about whether you have completed the FOBT kit through Dorevitch pathology. The researchers will not be given any information about your test result, but will be informed about whether you have returned the test to Dorevitch. Your GP will be able to access your FOBT results and can advise you if further investigation is necessary.

Regardless of the group you are allocated to, you will be asked to take part in a follow up telephone interview in 6 weeks.

How much time will it take?

It is expected that the survey will take approximately 10 minutes to complete. You may get called into your appointment before finishing the survey. If this happens, you will not be able to participate in the study at this time, but may be approached to participate at a later date. However, we cannot guarantee that you will be able to participate at a later date. If you are asked to participate in a follow up interview, this will take approximately 10 minutes.

What are the risks and benefits of participating?

The risks of participating in the study are low. If using the FOBT kit, there is a small risk of a false positive or a false negative reading. If your FOBT returns a positive result, your doctor may order some extra tests for you. If you have negative results, your doctor will not order any follow up, however, it is recommended that you screen with the FOBT every 2 years. If you have any cancer-related concerns, you should discuss these with your GP. You may also wish to contact the Cancer Helpline by phoning 131120. The Cancer Helpline is staffed by experienced cancer nurses and who can provide support and information about cancer.

We cannot promise that you will receive a direct benefit from participating in this pilot. However, participation may provide you with information about your risk of bowel cancer and appropriate screening for your level of risk. The FOBT kit (if appropriate for you) is free and simple to use.

How will your privacy be protected?

Your responses within the survey will not be shared with your doctor or the general practice. However, we may provide you with a generic feedback sheet regarding bowel cancer risk that we encourage you to share with your doctor during your appointment. Information collected will be de-identified upon receipt. This means that a unique identification code (ID) will be stored with your survey results. If you provide your name and contact information it will be stored separately from your survey data, and will only be able to be re-linked by the ID code. Any identifying information will be stored securely in a password protected file on the University of Newcastle server. This information will only be accessed by the researchers unless you consent otherwise, except as required by law. Data will be retained for at least 7 years in a locked filing cabinet and password protected files at the University of Newcastle.

How will the information collected be used?

This research is being conducted by the University of Newcastle. This research will be used to conduct a larger trial and to inform policy regarding bowel cancer screening methods. The information collected may be presented at national and international conferences and published in scientific journals. Only group data will be presented in any reports of publications arising from this research. In this way, no individual can be identified in any publications. Some of the research being conducted is part of Natalie Dodd's post-graduate studies at the University of Newcastle, supervised by L/Prof. Rob Sanson-Fisher, Dr Mariko Carey and Dr Elise Mansfield from the School of Medicine and Public Health. The information collected will be reported in a peer-reviewed thesis for Ms. Dodd's degree.

What do you need to do to participate?

Please read this Information Statement and be sure you understand all its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact the researchers, whose details are below. If you would like to participate, please inform the Research Assistant, sign the consent form and complete the survey now.

Further information

If you would like further information, please contact Dr Elise Mansfield (02) 40420705, elise.mansfield@newcastle.edu.au or Ms Natalie Dodd (02) 40420425, Natalie.dodd@newcastle.edu.au.

Thank you for considering this invitation.

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Fax: 02 4042 0044
Mariko.Carey@newcastle.edu.au

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2014-0198

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

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THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Patient Consent Form for the Research Project:

Bowel cancer screening – RCT

Document Version 4; dated 19/07/2016

The Research Team:
University of Newcastle: Dr. Mariko Carey, Dr Elise Mansfield, Prof. Rob Sanson-Fisher, Dr. Jamie Bryant, Dr. Christopher Oldmeadow, A/Prof. Lyndal Trevena, Ms Natalie Dodd

Please tick (✓) ONE BOX to indicate if you would like to take part in the study.

( ) Yes, I agree to participate in the above research project and give my consent freely

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to:

- completing an electronic health questionnaire
- being randomised to one of two study groups
- receiving a feedback sheet and a faecal occult blood test (FOBT) kit if appropriate
- my GP providing me with brief advice about bowel cancer screening
- self-administering an FOBT kit and forwarding the used kit to Dorevitch Pathology if indicated
- the researchers being informed by Dorevitch Pathology about whether I have completed the FOBT kit (but not the test result)
- completing a follow-up telephone interview in about 6 weeks

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

I would like to receive a summary of the project results. Yes No

*Please fill in **your details** in the box below:*

Title *(please circle one):* Mr / Mrs / Miss / Ms / Dr / Other _____		
Name:		
Postal Address:		
Suburb:	State:	Postcode:
Preferred phone:	Email:	
Preferred contact day/time:	Signature:	Date:

*Please fill in the details of a **secondary contact person** (family member or friend) who does not live at the same address as you:*

Title *(please circle one):* Mr / Mrs / Miss / Ms / Dr / Other _____			
Name:			
Postal Address:			
Suburb:		State:	Postcode:
Phone:	Signature:		Date:

( ) No, I would not like to take part (*N.B. Ticking the 'No' box and returning this consent form is optional*)

Research Assistant Only

I believe that the participant has understood what participation involves.
I have confirmed that the participant meets all of the eligibility requirements.

Full name of research assistant who obtained informed consent:

_____

Research Assistant Signature: _____

Date: _____

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Thank you for participating in this research project conducted by the University of Newcastle. The information you provide will help us determine the feasibility and acceptability of an intervention to improve uptake of bowel cancer screening among general practice patients.

Please touch the screen when you are ready to commence the survey.

Note: Survey is tailored according to question responses so participants will not be required to complete all questions.

MODULE E: Eligibility (All consenting patients)

1. How old are you?

_____ years If age ≠ 50-75end of survey

2. Have you had a previous diagnosis of bowel cancer or an inflammatory bowel disease, such as ulcerative colitis?

1=Yes If yes, end of survey

2=No

3. How many of your first or second degree relatives have ever been diagnosed with bowel cancer?

A first degree relative is a 'blood relative' and includes parents, full siblings or children. A second degree relative is a 'blood relative' and includes grandparents, grandchildren, aunts, uncles, nephews, nieces or half-siblings.

1=None	Average risk
2=One	Go to Q2
3=More than two	Go to Mod 3 – Higher Risk Category

4. Were any of your relatives who have had bowel cancer diagnosed before the age of 55?

1=No	Average risk
2=Yes	Go to Mod 3 – Higher risk category

MODULE 1. About you

5. What is your current marital status?

1=Married

2=Living in a de-facto relationship

3=Divorced

4=Married, but separated

5=Widowed

6=Never married

6. How would you best describe your employment situation at the moment?

1=Employed full time

2=Employed part time/casual

3=Unemployed

4=Student

5=Retired

6=Home duties

7=Other – Please specify _____

7. What is your country of birth?

Please touch your response and then touch 'NEXT'

1=Australia

2=Other – Please specify_____

8. What is the highest level of schooling you have <u>completed</u>? *Please select only one.*

Please touch your response and then touch 'NEXT'

1=University degree

2=TAFE or trade certificate or diploma

3=Year 12, Higher School Certificate, or Leaving Certificate

4=Year 10, School Certificate, or Intermediate Certificate

5=Primary School

6= Other – Please specify _____

9. Do you have private health insurance?

1=Yes

2=No

10. Do you have a healthcare card?

1=Yes

2=No

11. How many times have you seen a GP in the past 12 months?

1=0-3 times

2=4=6 times

3=7-10 times

4= More than 10 times

12. Please select the statement that reflects your GP visits.

1= I always see the same GP

2= I usually see the same GP

3= I see whichever GP is available

MODULE 3: Screening history

The following questions are about your history of cancer screening.

13. When was the last time you had a Faecal Occult Blood Test (FOBT)?

For an FOBT, you would have been asked to provide samples of faeces. The samples would have been tested for tiny amounts of blood.

Please touch your response and then touch 'NEXT'

1= Never had an FOBT

2= In the last 2 years

3= More than 2 years ago

4= Not sure

14. When was the last time you had a colonoscopy?

A colonoscopy is usually a day procedure in hospital where the inside of your colon is examined while you are sedated.

1= Never had a colonoscopy

2= In the last 5 years

3= More than 5 years ago

4= Not sure

15. When was the last time you had a sigmoidoscopy?

For a sigmoidoscopy only the rectum and lower part of the colon are examined. This is a short procedure which lasts about 5-10 minutes. Sedation is not usually required and you can usually go straight home after the procedure.

1= Never had a sigmoidoscopy

2= In the last 5 years

3= More than 5 years ago

4= Not sure

If patients have had an FOBT in the last 2 years, or colonoscopy/sigmoidoscopy in the last 5 years, skip to end of survey. All other patients go to Module 4.

The following knowledge questions use the term 'people at average risk of bowel cancer'. Most people are at average risk as they do not have bowel disease or a strong family history of bowel cancer.

16. At what age do you think people at average risk of bowel cancer should start screening?

a) 40

b) 50

c) 60

d) 70

e) I don't know

17. What do you think is the recommended screening test for people at average risk of bowel cancer?

a) Sigmoidoscopy (a 5-10 minute procedure in hospital where the inside of your rectum and colon is examined, usually without sedation)

b) Colonoscopy (a day procedure in hospital where the inside of your colon is examined under sedation)

c) Faecal occult blood test (FOBT) (a test which involves providing a small sample of faeces which is then tested for small amounts of blood)

d) I have not heard of these screening tests

e) I don't know

18. A faecal occult blood test (FOBT) is a bowel cancer screening test where you are asked to provide a sample of faeces (poo). The sample is then tested for tiny amounts of blood.

How often do you think a person at average risk of bowel cancer should have an FOBT?

a) Once only
b) Every year
c) Every two years
d) Every five years
e) Every ten years
f) I don't know

19. A positive faecal occult blood test (FOBT) means:

a) That a person has cancer
b) That a person does not have cancer
c) That traces of blood have been found in their faeces (poo)
d) I don't know

MODULE 5 – Behavioural items

<Males only>

20. I think my chance of being diagnosed with bowel cancer in my lifetime is:

1= 1 in 15

2= 1 in 30

3= 1 in 50

4= 1 in 100

<Females only>

21. I think my chance of being diagnosed with bowel cancer in my lifetime is:

1= 1 in 25

2= 1 in 50

3= 1 in 100

4= 1 in 200

Please indicate how much you agree with the following statements

22. I think faecal occult blood testing (FOBT) is an effective way to detect bowel cancer.

23. I am confident that I could complete a faecal occult blood test (FOBT).

24. Most of my family aged 50 and older complete screening tests for bowel cancer

25. I intend to complete bowel cancer screening in the next 2 years

<Likert response>

1=Strongly disagree

2=Disagree

3=Unsure

4=Agree

5=Strongly agree

Thank you for completing this survey. If this survey has caused you any concern, please discuss this with your doctor. Or call the Bowel Cancer Australia Hotline on 1800 555 494

(A small letter will be displayed in the top right hand corner of the screen – either P for eligible for pilot study, S for average risk patients who are appropriately screened, H for potentially moderately increased risk or potentially high risk patients).

END OF SURVEY

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Patient Follow-up Interview Guide – Intervention Group

Introduction

Good morning/afternoon. My name is <insert name> and I'm calling on behalf of the University of Newcastle a*s part of your participation in a study to improve rates of bowel cancer screening among general practice patients. You may recall completing a touchscreen survey at your general practice and receiving a feedback sheet. The final part of this study involves completing a follow-up telephone interview, which I am hoping to conduct with you today.*

Your participation is voluntary and you have the option of terminating this interview at any time without giving me a reason. The interview should take about 10 minutes to complete. Are you happy to proceed with the interview?

(If participant agrees)

Thank you. I will be asking some questions about the feedback sheet you received.

Do you have any questions? Are you ready to begin?

The following questions relate to any bowel cancer screening you may have had in the past 6 weeks

FOBT – For a FOBT, you would have been asked to provide samples of faeces. The samples would have been tested for tiny amounts of blood.

Colonoscopy – A colonoscopy is usually a day procedure in hospital where the inside of your colon is examined while you are sedated.

Do you have any questions? Can we continue?

Questions:

1. **In the past 6 weeks have you had any tests for bowel cancer?**
   a) Yes …*[GO TO Question 2]*
   b) No …*[SKIP Questions 2-4, GO TO Question 5]*

2. **Which test(s) did you have?**

   [Participant may provide more than one answer]

   a) Faecal Occult Blood Test (FOBT) using the kit I received at my general practice …*[Be sure to include Question 3]*
   b) Faecal Occult Blood Test (FOBT) using a kit I received elsewhere …*[Be sure to include Question 3]*
   c) Colonoscopy
   d) Other (please specify)_____

3. Did you have a follow-up colonoscopy?

a) Yes, I had a colonoscopy [GO TO Question 6]
b) No, but I am currently waiting for a colonoscopy [*GO TO Question 6*]
c) No, but I will be arranging a colonoscopy soon [*GO TO Question 6*]
d) No, I won't be having a follow-up colonoscopy (please explain)

If the patient has completed their kit (determined through pathology records or this interview) ask the following:

4. Why did you decide to complete the FOBT provided at your GP appointment? (free response)

If the patient has <u>not</u> completed their kit (determined through pathology records or this interview) ask the following:

5. Was there a particular reason you didn't use the FOBT kit provided at your GP appointment? (free response)

<u>The following questions relate to bowel cancer screening recommendations for those at average risk of bowel cancer</u>

6. At what age do you think people at average risk of bowel cancer should start screening?
a) 40
b) 50
c) 60
d) 70
e) I don't know

7. What do you think is the recommended screening test for people at average risk of bowel cancer?
a) Sigmoidoscopy (a 5-10 minute procedure in hospital where the inside of your rectum and colon is examined, usually without sedation)
b) Colonoscopy (a day procedure in hospital where the inside of your colon is examined under sedation)
c) Faecal occult blood test (FOBT) (a test which involves providing a small sample of faeces which is then tested for small amounts of blood)
d) I have not heard of these screening tests
e) I don't know

8. A faecal occult blood test (FOBT) is a bowel cancer screening test where you are asked to provide a sample of faeces (poo). The sample is then tested for tiny amounts of blood.

How often do you think a person at average risk of bowel cancer should have an FOBT?
a) Once only
b) Every year
c) Every two years
d) Every five years
e) Every ten years
f) I don't know

9. A positive faecal occult blood test (FOBT) means:

a) That a person has cancer
b) That a person does not have cancer
c) That traces of blood have been found in their faeces (poo)
d) I don't know

The following questions relate to how you used the feedback sheet

10. Did you read the feedback sheet?

Yes – Q12
No – Q11

11. Why didn't you read the feedback sheet? (free response)

12. Do you have any suggestions about how the feedback sheet could be improved? (free response)

13. Did you access any of the websites listed on the feedback sheet (If 'yes', indicate which ones)

www.bowelcanceraustralia.org

www.cancercouncil.com.au/bowelsymptoms

www.bowel-cancer.canceraustralia.gov.au/

14. Do you think it would be helpful to receive information sheets from your GP about other health issues? (free response)

If you have any questions or concerns about the study please don't hesitate to call me. Would you like the number?
IF YES*: The number is {provide interviewer contact number}. You may also call a toll free number on 1800 084 755.*

Once again, thank you very much for your help. END INTERVIEW

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Patient Follow-up Interview Guide – Usual Care

Introduction

Good morning/afternoon. My name is <insert name> and I'm calling on behalf of the University of Newcastle as part of your participation in a study to improve rates of bowel cancer screening among general practice patients. You may recall completing a touchscreen survey at your general practice recently. The final part of this study involves completing a follow-up telephone interview, which I am hoping to conduct with you today.

Your participation is voluntary and you have the option of terminating this interview at any time without giving me a reason. The interview should take about 10 minutes to complete. Are you happy to proceed with the interview?

(If participant agrees)

Thank you. I will be asking some questions about the feedback sheet you received.

Do you have any questions? Are you ready to begin?

The following questions relate to any bowel cancer screening you may have had in the past 6 weeks

FOBT – For a FOBT, you would have been asked to provide samples of faeces. The samples would have been tested for tiny amounts of blood.

Colonoscopy – A colonoscopy is usually a day procedure in hospital where the inside of your colon is examined while you are sedated.

Do you have any questions? Are you ready to begin?

Questions:

1. **In the past 6 weeks have you had any tests for bowel cancer?**
   a) Yes …[GO TO Question 2]
   b) No …[SKIP Questions 2-3, GO TO Question 4]

2. **Which test(s) did you have?**
   [Participant may provide more than one answer]
   a) Faecal Occult Blood Test (FOBT) [*Be sure to include Question 3]*
   b) Colonoscopy
   c) Other (please specify)_____

3. **Did you have a follow-up colonoscopy?**
   a) Yes, I had a colonoscopy
   b) No, but I am currently waiting for a colonoscopy
   c) No, but I will be arranging a colonoscopy soon
   d) No, I won't be having a follow-up colonoscopy (please explain)

The following questions relate to bowel cancer screening recommendations for those at average risk of bowel cancer.

4. At what age do you think people at average risk of bowel cancer should start screening?

a) 40
b) 50
c) 60
d) 70
e) I don't know

5. What do you think is the recommended screening test for people at average risk of bowel cancer?

a) Sigmoidoscopy (a 5-10 minute procedure in hospital where the inside of your rectum and colon is examined, usually without sedation)
b) Colonoscopy (a day procedure in hospital where the inside of your colon is examined under sedation)
c) Faecal occult blood test (FOBT) (a test which involves providing a small sample of faeces which is then tested for small amounts of blood)
d) I have not heard of these screening tests
e) I don't know

6. A faecal occult blood test (FOBT) is a bowel cancer screening test where you are asked to provide a sample of faeces (poo). The sample is then tested for tiny amounts of blood.

How often do you think a person at average risk of bowel cancer should have a FOBT?

a) Once only
b) Every year
c) Every two years
d) Every five years
e) Every ten years
f) I don't know

7. A positive faecal occult blood test (FOBT) means:

a) That a person has cancer
b) That a person does not have cancer
c) That traces of blood have been found in their faeces (poo)
d) I don't know

If you have any questions or concerns about the study please don't hesitate to call me. Would you like the number?
IF YES: The number is {provide interviewer contact number}. You may also call a toll free number on 1800 084 755.

Once again, thank you very much for your help. END INTERVIEW

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Contributor name: Natalie Dodd

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