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

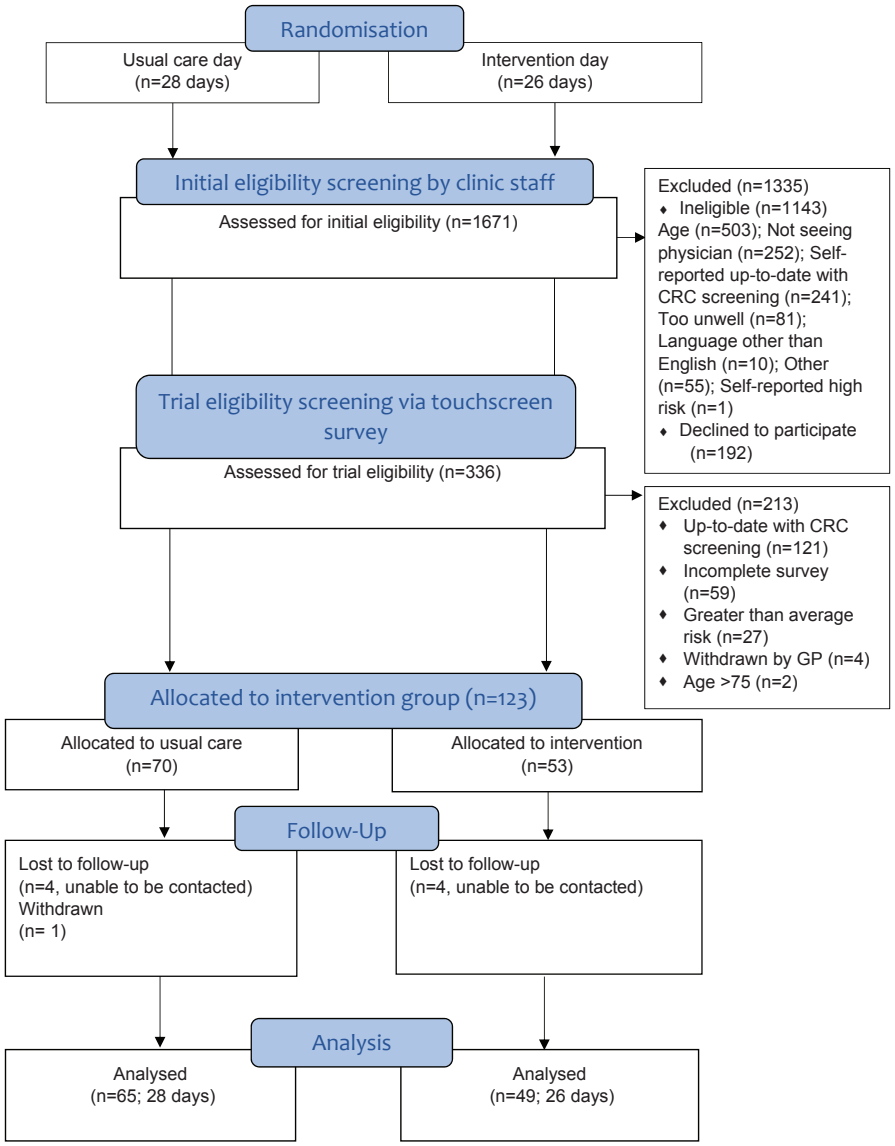
This study tested the effectiveness of a multicomponent intervention that included provision of point-of-care FOBT, printed CRC screening advice and face-to-face GP endorsement on self-reported FOBT uptake and CRC screening knowledge.

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.

Figure 1: CONSORT Recruitment flow diagram.



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

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.