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Public Health and Cooperative Group Partnership: A Colorectal Cancer Educational Intervention for Breast Cancer Survivors

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Abstract

Objectives—To describe the development of a multi-component colorectal cancer educational tool for female breast cancer survivors through a cooperative group and public health partnership.

Data Sources—PubMed, World Wide Web, published guidelines from professional organizations, and surveys and focus groups with breast cancer survivors.

Conclusion—Collaboration is at the core of cooperative group and public health research. This partnership has led to the development and tailoring of a colorectal cancer educational tool for breast cancer survivors. Focus groups revealed that female breast cancer survivors were receptive to education on colorectal cancer screening, liked the educational tool, and provided key information to make the tool more relevant and appealing to a broader audience.

Keywords

Survivors; Neoplasms; Screening; Education; Health disparities; Partnership; Cooperative group

A unique partnership between state and national public health partners and cooperative groups provides an important avenue and resources for nurse scientists to contribute to the cooperative group setting and outcomes of clinical trials. Established in 1955, the National Cancer Institute's Clinical Trials Cooperative Group Program has played a key role in developing new and improved cancer therapies.¹ In addition to new single and combination cancer treatments, the Clinical Trials Cooperative Group Program is designed to explore methods of cancer prevention and early detection, study quality-of-life and rehabilitation issues, and investigates cancer imaging that targets therapy, surveillance, and biomarkers of therapeutic responses.² Public health departments are charged with protecting and promoting the health of communities and the population as a whole, including cancer prevention and

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control.³ These shared goals provide the foundation for this unique partnership between public health and the cooperative groups.

This article describes the collaborative group approach to the development of a colorectal cancer (CRC) educational tool for female breast cancer survivors, including the development process, funding and manpower resources, and overall processes of tailoring and implementing the CRC educational intervention for breast cancer survivors. This article describes the study design process, literature review, protocol development, institutional review board outcome, survivor focus groups, and pilot testing of the educational tool.

Public Health and Cooperative Group Partnership

The Cooperative Groups conduct clinical trials through networks of cancer centers and community oncology practices across the country with the shared mission to develop and conduct high-quality multidisciplinary cancer control, prevention, and treatment trials. Clinical trials engage a comprehensive research network; further our understanding of the biological basis of the cancer process and its treatment, from discovery to validation; and provide a scientific and operational infrastructure for innovative clinical and translational research for the unified purpose of providing empirical evidence for transforming practice to improve patient outcomes.^{2,4}

As defined by The Committee for the Study of the Future of Public Health, “Public health is what we, as a society, do collectively to assure the conditions in which people can be healthy.”³ Public health professionals, like clinicians, rely on expert knowledge to guide practice. The information from epidemiology and biostatistics identify and direct resources to address the health needs of the population. While public health is responsible for the public’s health, its mission can only be achieved through widespread partnerships.

Public health research of population-based health problems, including biological, environmental, and behavioral issues, has to be conducted at the federal, state, and local levels.³ Public health agencies seek to develop and cultivate relationships with physicians and other private sector representatives to improve the health of the population.⁵ Further, concerns about health care expenditures have presented opportunities for innovative, multi-level approaches to improving health and health care. This project is just one example of a collaborative effort between a cooperative group and public health department focused on secondary prevention, ie, reducing the morbidity and mortality of a largely preventable chronic disease, CRC among breast cancer survivors.

Development of the Colorectal Cancer Intervention

Intervention Design Process

Nursing cooperative studies have been at the forefront of clinical trials in symptom interventions and quality-of-life in the legacy Cancer and Leukemia Group B (CALGB) Cooperative Group (now a part of the Alliance for Clinical Trials in Oncology) (see article by Lester elsewhere in this issue). Interest, support, and input on developing a colorectal intervention were sought from nurse researchers, physicians, public health practitioners,

epidemiologists, and research and prevention specialists. After attending the Oncology Nursing Society Foundation Interdisciplinary Multi-Site Research Training Program in 2006, the burden, effectiveness of screening for CRC, and screening recommendations were presented to the CALGB Oncology Nursing Committee and the Prevention Subcommittee at their fall meeting in 2007.

Burden of Breast and Colorectal Cancers

Breast cancer affects hundreds of thousands of women's lives and also occurs in men, but to a much lesser extent. In 2013, it is expected that 232,340 new cases of invasive breast cancer will be diagnosed among women in the United States (US) compared with the 2,240 new cases expected in men.⁶ Among women, breast cancer is the most common occurring cancer (29% of all cancer cases) and second only to lung cancer in the number of cancer deaths (26% vs 15%) in the US.⁷ Women have a 12% probability, or one in eight chance, of developing breast cancer in their lifetime and a 98% relative survival, if detected in a localized stage.^{6,8}

In the US there are approximately 13.0 million cancer survivors, of which 2.8 million (almost 22% of total survivors) are women who had a breast cancer diagnosis during their lifetime.^{8,9} The future well-being of women who are breast cancer survivors is crucial and affects the well-being of their families and society. For breast cancer survivors, reoccurrence is a distinct possibility. In addition to reoccurrence, new primary cancers may also occur in breast cancer survivors, with an approximate 10% or higher risk for developing colon cancer than the general population.^{10,11} Every opportunity should be made available to women who have dealt with one cancer to avoid a second. Offering CRC screening provides this opportunity.

CRC is one of the three most common cancers for women (after breast and lung cancer) and men (after prostate and lung cancer) in the US.^{12,13} It is also the second leading cause of cancer death. CRC incidence and mortality have significantly declined in the US during the last decade, with the decline in incidence slightly greater in men (-2.9%) than women (-2.2%), but racial disparities persist, with African Americans having higher incidence and mortality rates than any other race/ethnic group.¹⁴

Effectiveness of Colorectal Cancer Screening

Early evidence from multiple well-conducted randomized trials support the effectiveness of the different screening modalities in decreasing colon cancer incidence and reducing mortality (Table 1).¹⁵⁻³⁴ In addition, a systematic review showed that screening by any of several methods is cost-effective compared with no screening.³⁵ However, all tests have risks, from mild mental and physical stress to perforation and, on rare occasions, death, which must be assessed against the benefits. Despite the risk, screening offers substantial benefit by preventing CRC from occurring and reducing its mortality. Although CRC screening among cancer survivors vary by state and demographic characteristics, and often exceed that of the non-cancer patients, many cancer survivors, including breast cancer survivors, for a variety of reasons are not receiving or engaging in CRC preventive care.³⁶⁻³⁸

The US Preventive Services Task Force recommends screening for CRC using high-sensitivity fecal occult blood testing, flexible sigmoidoscopy, or colonoscopy beginning at age 50 years and continuing until age 75.³⁹ In addition to the US Preventive Services Task Force recommended CRC screening modalities, the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, the American College of Radiology, and the National Comprehensive Cancer Network also provide the options of using high-sensitivity fecal immunochemical testing or fecal DNA test, double-contrast barium enema, or computed tomography colonography (virtual colonoscopy).^{40,41} Although all the screening approaches offer varying degrees of benefit and no single screening modality is supported in the guidelines, these organizations give preference for direct visualization compared with indirect methods.

Colonoscopy is often the criterion standard for CRC screening and is associated with a first exam sensitivity of > 90% for large polyps and about 75% for small polyps (<1 cm)¹⁶; lowers the incidence of colon cancer^{15,19}; lowers mortality^{17,18}; and is used for follow-up of positive screening results from other tests. However, other procedures, particularly noninvasive procedures, have an important role in CRC screening and may be more acceptable, especially among adults who do not engage in optical procedures or do not do as recommended. Nevertheless, colonoscopy offers substantial benefit over indirect methods, with greater sensitivity when considered as a single test,⁴² and is therefore the primary endpoint in the study design.

Concept Development

Through a multi-disciplinary, discussion-question approach and a series of literature and data reviews, the multi-intervention approach concept was formed to focus on a distinct group, female breast cancer survivors who may be at higher-than-average risk for CRC and benefit from the intervention.¹⁰ The concept continued to be refined by one of the two junior nurse researchers invited to join the CALGB oncology nursing committee, working with a nurse scientist in the Oncology Nursing Committee mentoring program and as liaison to the prevention subcommittee. In November 2008, the CRC cancer screening among breast cancer survivors concept was presented to both committees.

A thorough systematic review of effective interventions to increase CRC screening for the period January 1998 through September 2009 and categorized by patient, provider, and system/community levels is presented by Holden et al,⁴³ and informs this intervention along with the literature in Table 2.^{44–56} Effective individual interventions include patient reminders, one-on-one interactions, and eliminating barriers. Some types of small media/decision aids (eg, interactive Web site),⁴⁹ when combined into a multi-level intervention such as video, targeted brochure, and provider reminder,^{48,53} were also found to increase CRC screening. In addition, patient-specific provider prompts/reminders,^{50,52} provider assessment and feedback,⁵⁷ and system-level interventions that reduced structural barriers (eg, provided culturally and linguistically appropriate educational material, nurse counseling, or provided/facilitated access to screening) increased screening.^{53–56}

Predictors of CRC screening vary by many factors, including personal characteristics such as age, gender, race, education, marital status, and income; patient, provider, and organizational

barriers; and primary screening endpoints such as fecal occult blood testing, flexible sigmoidoscopy, and colonoscopy.^{58–62} However, the evidence shows that physician recommendation is a strong predictor of CRC screening.^{63–65} Additionally, May et al⁶⁶ investigated the influence and impact popular media has on medical decision-making for breast, colorectal, and prostate cancer screening. Focus group participants overwhelmingly trusted evidence-based decision aids over popular media information. Further, when deciding on screening, participants relied on personal experiences with providers, the health care system, and cancer; trust in the message source; and the ability to pay for the screening tests. It was concluded that there is a need for greater distribution of evidence-based decision support tools to aid patients in making decisions about cancer screening. The education tool and study design includes components shown to effectively increase CRC screening and reduce barriers. The CRC educational tool development, tailoring, and detailed project timeline schematic is depicted in Figure 1.

Funding

This project received support from the Missouri Department of Health and Senior Services and the junior researcher benefitted also from the mentoring by University of Missouri Sinclair School of Nursing faculty researchers who were also cooperative group members. Although reduced funding and out-of-state travel restrictions prevented travel to several group meetings, resulting in missed mentoring sessions, and slowed the progress of the intervention development, the intervention was developed and is being revised to reach a broader audience of breast cancer survivors.

The Colorectal Cancer Educational Intervention

The education tool, the “*Power of Prevention*,” and study design includes components shown to effectively increase CRC screening, including: targeted physician recommendation letter, evidence-based decision aid booklet with stage of change assessment-feedback, video, and one-on-one nurse interaction, and promotes the perception of screening as routine and convenient. The educational decision aid booklet was developed by the author in collaboration with a public health graphic artist and the oncology nursing committee, The “Get tested for colon cancer. Here’s how” DVD is used with permission from the American Cancer Society.

The decision-aid booklet was designed based on the Transtheoretical Model⁶⁷ and the Health Belief Model.⁶⁸ The Transtheoretical Model premise is that people are at different stages of motivational readiness for engaging in health behaviors. Interventions using this model, as applied to CRC screening, are most useful when they are matched to a person’s current stage of change, move the person along the continuum to change (ie, affect their decisional balance), and result in the behavior or behavior change.⁶⁹ The Health Belief Model suggests that a person’s belief in a personal threat to health (ie, susceptibility and severity), together with their perceived benefits of the proposed behavior (pros), barriers (cons), self-efficacy, and cues to action, will predict the likelihood of that behavior. These models provide guidance for developing and tailoring CRC interventions, as well as constructs for evaluating effectiveness.^{70–74}

The booklet presents an overview of CRC, as well as information on the various screening modalities, health improvement, and colonoscopy. It also addresses identified barriers to CRC screening, including lack of knowledge, perception of good health, fear of the test, embarrassment, and group targeted messaging. The protocol incorporates client reminders, nurse interaction, assessment, and feedback. It is anticipated that the Patient Protection and Affordable Care Act⁷⁵ will reduce some structural access-to-care barriers in terms of financial and cost-sharing.

Tailoring the Intervention

To tailor the *Power of Prevention* for breast cancer survivors, a series of four focus groups were held in Missouri, one in each of four cities – Columbia, Jefferson City, Kansas City, and Chesterfield located in St. Louis County. Before conducting the focus groups, the study was reviewed by the Missouri Department of Health and Senior Services Institutional Review Board and determined to be exempt from further review. A mixed-method design was used to gather information from breast cancer survivors. The focus groups were conducted using a standardized discussion protocol developed with the CALGB Oncology Nursing Committee. In addition, participants were asked to complete pre- and post-discussion surveys regarding attitudes, beliefs, and practices regarding CRC screening. The discussion survey instruments were comprised of validated questions from previous research on CRC screening,⁷⁴ behavioral risk factors,⁷⁶ and expert reviews and input.

Focus group participants were recruited from breast cancer support groups in the four areas and conducted between April and August 2011. Extensive notes and photos were taken during the focus groups by a registered nurse graduate student and public health graphic artist. To further tailor the educational tool, the breast cancer survivors who participated in the focus groups were invited to have their portraits taken by a professional photographer and provide quotes for encouraging other breast cancer survivors to participate in CRC screening for inclusion in the tool.

A total of 43 breast cancer survivors participated in the focus groups, including 10 (23%) African-American women. Eleven women consented, scheduled appointments for portraits, and provided quotes. One breast cancer survivor stated, “I think colorectal cancer screening is a very good thing and the reason why - I’ve lost two dear friends to colon and breast cancer... so I think it’s very, very important that we get that [screened].”

Overall, the focus group participants were receptive to education on CRC screening and liked the educational tool. The participants provided invaluable information and suggestions to make the intervention more relevant to breast cancer survivors, such as expressing recognition for being a cancer survivor early in the material. Overarching themes included the preference for gain-framed messages (ie, those that stress the benefits of the activity for promoting screening), that having a colonoscopy is very or extremely important, and the majority agreed or strongly agreed that colon cancer is preventable.

Many breast cancer survivors indicated that they had previously or would engage in CRC screening with increased knowledge and support from their health care provider. The

frequent barriers to having a colonoscopy were the preparation required, being asymptomatic, and financial considerations. A detailed description of the outcomes of the focus groups will be discussed in another article now in preparation, but based on the key information gathered during the focus groups, the *Power of Prevention* tool and physician recommendation letter are in the re-design phase. Following re-design, pilot testing of the tool will be conducted with one to two clinical institutions. The cooperative group nursing and symptom prevention committees participated throughout the development and redesign process.

Nursing Implications

Nurses bring a unique patient-interaction experience to multi-disciplinary cooperative group research and can provide a wealth of information to address CRC prevention and other complex health issues, as well as critique and assist with concepts, protocols, accrual, and the many aspects of cooperative group clinical trials. With breast cancer survivors representing one of the largest groups of cancer survivors, it is imperative that efforts be made to promote health and well-being in this group. CRC screening provides this opportunity for health promotion. Nurses can provide comprehensive risk assessments and feedback regarding the appropriate CRC screening, taking into consideration each cancer survivor's individual needs, and provide the critical one-on-one interaction to promote action.

While it is documented that cancer reoccurrence is possible and new primary cancers may also occur, women previously diagnosed with breast cancer are at an increased risk of developing colon cancer. Therefore, public health and health practitioners should continue joint efforts to help survivors and the public understand the benefits of CRC screening. Cooperative group research can reach beyond cancer control to prevention through CRC screening research. Breast cancer survivors should be provided CRC education to make informed health care decisions and supported to participate in screening to reduce the morbidity and mortality associated with this disease. Findings from this cooperative group research can provide an evidence-based foundation for public health practices in cancer prevention.

Conclusion

There are currently accurate and effective CRC screening tools that are capable of decreasing the incidence and mortality of CRC. Formative research with breast cancer survivors provided valuable information for developing targeted messages and tailoring of the educational tool. Pilot testing will provide information regarding the feasibility of conducting a multisite clinical trial to determine the impact of a multilevel-component intervention to increase CRC screening among breast cancer survivors in the cooperative group setting. The existing cooperative group and community clinical oncology program infrastructure will permit rapid conduct of this study at a fraction of the cost of a population-based study and provide access to breast cancer patients rather than using a registry. This infrastructure also provides access to minority women through the minority-based community clinical oncology program and can help address the disparities that exist in CRC

incidence and mortality. Conducting the program through the clinical trials program will provide information relevant to public health and population-based screening and offers the potential for long-term sustainability.

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Implications for Nursing Practice

Nurses can be instrumental in research collaborations between cooperative groups and public health. The colorectal educational intervention for breast cancer survivors was developed through cooperative group efforts of the oncology nursing committee and prevention subcommittee. This study serves as an exemplar of public health and cooperative group partnerships leading to innovative research planning and implementation outcomes.

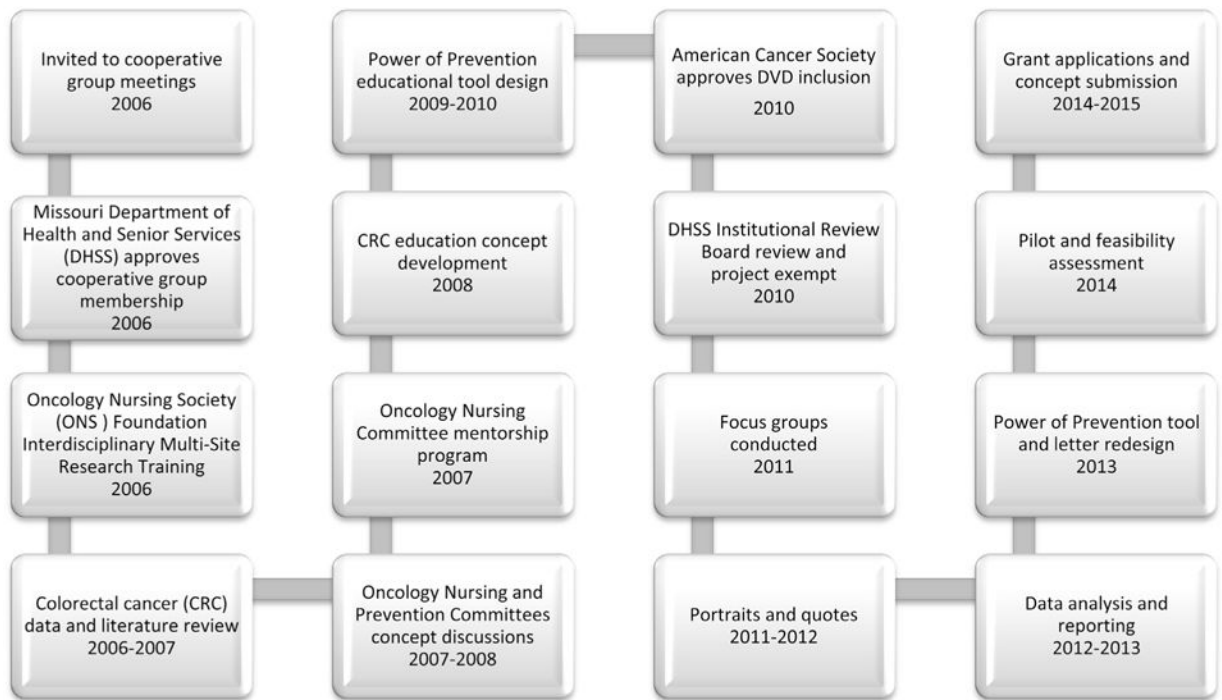


FIGURE 1.
Power of Prevention colorectal cancer screening educational tool research project development, tailoring, and pilot timeline.

TABLE 1

Literature Review of Colorectal Cancer Screening Modalities

| Screening modality/study | Sample and design | Measurement | Results and comments |
|---------------------------------------|---|---|---|
| Colonoscopy | | | |
| Citarida et al, 2001 ¹⁵ | 1,693 adults, aged 40–69 years Cohort study | CRC incidence | Colonoscopy with polypectomy reduced CRC incidence compared with that expected in the general population |
| Rex et al, 1997 ¹⁶ | 183 patients Indiana | Adenomas | Sensitivity 94% for large adenomas (> 1 cm), 87% for medium adenomas (6–9 mm) and 73% for small adenomas (< 5 mm); sensitivity slightly higher for left colon adenomas (79%) than right colon adenomas (73%); sensitivity for cancer probably exceeds 90% |
| Zauber et al, 2012 ¹⁷ | 2,602 patients referred for initial colonoscopy between 1980–1990 and with adenomas removed | CRC mortality | The standardized mortality ratio was 0.47 (95% CI 0.26 to 0.80), suggesting a 53% reduction in mortality |
| Muller et al, 1995 ¹⁸ | 4,411 US military veterans Case-control Study 1:4 living and 4 deceased match | CRC mortality | Reduced mortality OR 0.41 (95% CI 0.33 to 0.50) compared with living controls |
| Winawer et al, 1993 ¹⁹ | 1,418 patients compared with three reference groups (2 cohorts polyps not removed and 1-general population registry) National Polyp Study | CRC incidence | Reduced the incidence of colorectal cancer 76% to 90% ($P < .001$) |
| Flexible Sigmoidoscopy | | | |
| Weissfeld et al, 2005 ²⁰ | 77,465 adults, aged 55–74 years from 10 screening centers Prostate, lung, colorectal and ovarian (PLCO) randomized clinical trial US | Adenomas and cancer (60-cm flexible sigmoidoscopy) | The yields per 1,000 screened, depending on 5-year age group, were as follows: colorectal cancer, 1.1–2.5 in women and 2.4–5.6 in men; advanced adenoma, 18.0–30.4 in women and 36.1–49.1 in men; colorectal cancer or any adenoma, 50.6–79.6 in women and 101.9–128.6 in men |
| Atkin et al, 1998 ²¹ | 3,540 adults aged 55–64 years Randomized control trial United Kingdom | 60-cm flexible sigmoidoscopy | 7 cancers and 60 large or high-risk adenomas per 1,000 examinations |
| Selby et al, 1992 ²² | 261 adults Case-control study California | Rigid sigmoidoscopy | AOR 0.41 (95% CI 0.25 to 0.69) suggested screening reduced the risk of death by 59% for cancers within reach of the sigmoidoscope |
| Double Contrast Barium Enema | | | |
| Rockey et al, 2005 ²³ | 614 patients at risk for CRC North Carolina | CRC and polyps - compared ACBE with CTC and colonoscopy | Sensitivity for lesions > 10 mm: ACBE 48% (95% CI 35 to 61); CTC 59% (95% CI 46 to 71, $P = .1$ for CTC vs ACBE); colonoscopy 98% (95% CI 91 to 100, $P < .0001$ for colonoscopy vs CTC) Sensitivity for lesions 6–9 mm: ACBE 35% (95% CI 27 to 45); CTC 51% (95% CI 41 to 60, $P = .008$ for CTC vs ACBE); colonoscopy 99% (95% CI 95 to 100, $P < .0001$ for colonoscopy vs CTC) Specificity for lesions > 10: ACBE 0.90; CTC 0.96; colonoscopy 0.996 |
| Guaiac Fecal Occult Blood Test | | | |
| Jorgensen et al, 2002 ²⁴ | 30,967 adults, aged 45–75 years Randomized controlled trial Denmark | Randomly assigned to biennial screening | Compared with control group, risk of death from CRC was reduced to RR 0.85 (0.73–1.00) after 13 years and 7 screening rounds. RR 0.82 (0.68–0.99) after 10 years and 5 |

| Screening modality/study | Sample and design | Measurement | Results and comments |
|--|--|---|---|
| Mandel et al, 1999 ²⁵ | 46,551 adults, aged 50 to 75 years Randomized controlled trial Minnesota | Randomly assigned to annual screen, a biennial screen, or a control group with G-FOBT | screening rounds. Reduced risk of death after 13 years attributed to decreasing proportion of the screening group actually being screened Compared with control group, 33% reduction in colorectal cancer mortality among annual screening group (rate ratio 0.67, 96% CI 0.51 to 0.83); 21% lower in the biennial group (rate ratio, 0.79, 95% CI 0.62 to 0.97). |
| Hardcastle et al, 1996 ²⁶ | 152,850 adults, aged 45–74 years Randomized controlled trial United Kingdom | Randomly assigned to G-FOBT screening or control group | Compared with control group, 15% reduction in colorectal cancer mortality in screening group (OR 0.85, 95% CI 0.74 to 0.98, <i>P</i> = .026) |
| Guaiac Fecal Occult Blood Test/Fecal Immunochemical Test | | | |
| van Rossum et al, 2008 ²⁷ | 20,623 individuals random sample (n = 6,157 I-FOBT and 4,836 G-FOBT) aged 50–75 years Dutch population-based study | Participation in screening All polyps and cancer Advanced adenomas (≥ 10 mm, high-grade dysplasia, or ≥ 20% villous component) and cancer | Participation 59.6% (95% CI 58.7% to 60.6%) vs 46.9% (95% CI 46.0% to 47.9%), and detection rates for all polyps and cancer 2.1% (95% CI 1.8% to 2.4%) vs 0.8% (95% CI 0.6% to 0.9%) and advanced adenomas and cancer 1.4% (95% CI 1.2% to 1.6%) vs 0.6% (95% CI 0.4% to 0.7%) were significantly higher in the group tested with I-FOBT compared with G-FOBT. Three times as many people tested with the I-FOBT were referred for a negative colonoscopy while 3 times as many patients with advanced adenomas and 2 times more patients with cancer were undetected in the G-FOBT, which resulted in similar positive predictive values |
| Allison et al, 2007 ²⁸ | 5,841 adults from a group-model managed care organization California | Advanced neoplasms (cancer and adenomatous polyps ≥ 1 cm) left-side | FIT compared with G-FOBT had high sensitivity (81.8%, 95% CI 47.8% to 96.8% vs 64.3%, 95% CI 35.6% to 86.0%) and specificity (96.9%, 95% CI 96.4% to 97.4% vs 90.1%, 95% CI 89.3% to 90.8%) for detecting left-sided colorectal cancer. For detecting advanced adenomas, greater sensitivity for G-FOBT 41.3% (95% CI 32.7% to 50.4%) than FIT 29.5% (95% CI 21.4% to 38.9%) but greater specificity by FIT 97.3% (95% CI 96.8 to 97.7%) than G-FOBT 90.6% (95% CI 89.8% to 91.4%) |
| DNA Fecal Occult Blood Test | | | |
| Ahiquist et al, 2008 ²⁹ | 4,482 average risk adults Blinded, multicenter, cross-sectional study | Screen relevant neoplasia (curable stage), high-grade dysplasia or adenomas >1 cm | Stool DNA test 2 (a novel test targeting three markers) detected significantly more neoplasms than Hemoccult (<i>P</i> < .001) or Hemoccult Sensa (<i>P</i> < .001) but with significantly more false-positives than Hemoccult (<i>P</i> = .01) and Hemoccult Sensa (<i>P</i> = .03) |
| Imperiale et al, 2004 ³⁰ | 5,486 average risk adults enrolled, 2,507 included in analysis Indianapolis | 21 DNA panel mutations for cancer | The DNA fecal test detected significantly more invasive cancers (51.6%) than the Hemoccult II (12.9%); <i>P</i> = .003. Among a subset with tubular adenoma ≥ 1 cm, villous histologic or high-grade dysplastic polyp or cancer (n = 418), the DNA panel was positive for 18.2% compared with Hemoccult II 10.8%. The majority of neoplastic lesions identified by colonoscopy were not detected by either test |
| Tagore et al, 2003 ³¹ | 292 participants in case control study (80 with advanced CRC and 212 controls) California | 21 DNA panel mutations other genes, an instability marker and an integrity marker in adenomatous polyps and cancer | The multi-target panel detected 63.5% (95% CI 49.0% to 76.4%) with invasive colorectal cancer Of the subsample with tubular adenoma ≥ 1 cm, villous histologic or high-grade dysplastic polyp or cancer (n = 28) 57.1% (95% CI 37.2% to 75.5%) were detected by the DNA assay panel. The DNA |

| Screening modality/study | Sample and design | Measurement | Results and comments |
|---|---|-------------------------------------|--|
| FOBT with Sigmoidoscopy Winawer et al, 1993 ³² | 21,756 patients, aged 40 years and older New York | CRC Rigid sigmoidoscopy | panel had similar specificity reported for the Hemoccult II More cases of colorectal cancer were detected on initial examination in intervention patients than in control patients (4.5 vs 2.5 per 1,000 participants). Incidence rates (cancer detected after the initial examination) were similar between groups (0.9 per 1,000 person-years in each group). Deaths from colorectal cancer was 0.36 per 1,000 patient-years in the intervention group and 0.63 per 1,000 patient-years among controls ($P = .053$) |
| Computed Tomographic (Virtual) Colonography Wessling et al, 2005 ³³ | 78 patients, 83% were asymptomatic Germany | Polyps and CRC Virtual colonography | Colonoscopy identified 49 polyps in 26 patients and 3 carcinomas. All 3 carcinomas and 39 polyps (80%) were identified by CTC; low specificity with small polyps (14 false-positive findings, 10 of which were 5 mm in diameter) |
| Van Gelder et al, 2004 ³⁴ | 249 consecutive patients at increased risk for CRC Amsterdam, The Netherlands | Polyps CTC and colonoscopy | Thirty-one patients had large polyps at colonoscopy. CTC identified 84% of patients (26/31) with large polyp(s) and had a specificity of 92% (200–201/218) |

Abbreviations: CRC, colorectal cancer; CI, confidence interval; OR, odds ratio; AOR, adjusted odds ratio; ACBE, air contrast barium enema; CTC, computed tomographic colonography; RR, relative risk; G-FOBT, guaiac fecal occult blood test; I-FOBT, immunochemical fecal occult blood test; FIT, fecal immunochemical test.

TABLE 2

Literature Review of Colorectal Cancer Screening Interventions

| Study | Sample and Design | Intervention | Results |
|------------------------------------|---|--|--|
| Individual | | | |
| Khankari et al, 2007 ⁴⁴ | 154 screening-eligible primary care patients in federally qualified health center. Single arm, pre- and post-test design | Tracking eligible patients. Mailing patients physician letter and brochure prior to visit. Training physicians in health literacy Monitoring patient compliance | At 1 year follow-up, any colorectal screening increased from 11.5% to 27.9% ($P < .001$) Physician recommendation increased from 31.6% to 92.9% ($P < .001$) Factors related to non-adherence: patient readiness (60.7%), competing health problems (11.9%), and fear or anxiety toward procedure (8.3%) |
| Myers et al, 2007 ⁴⁵ | 1,546 primary care practice patients and randomized to 4 study groups | Control group (usual care) SI – screening invitation letter, informational booklet, stool blood test, and reminder letter TI – tailored “message pages” TIP – targeted intervention, tailored message pages and telephone reminder | Screening rates were 33% control group, 46% SI group, 44% TI group, and 48% TIP group. Screening was significantly higher In all 3 intervention groups compared with control group: SI OR 1.7 (95% CI 1.3 to 2.5, TI OR 1.6 (95% CI 1.2 to 2.1) and TIP OR 1.9 (95% CI 1.4 to 2.6) No significant difference across intervention groups |
| Sequist et al, 2011 ⁴⁶ | 1,103 patients, 50 to 75 years of age with an active electronic health record and overdue for CRC screening from 14 ambulatory health centers | Patients randomly assigned to receive a single electronic message highlighting overdue CRC screening status and a link to a Web-based tool to assess their personal risk of colorectal cancer | At 1-month follow-up, screening rates were higher for patients who received electronic messages than for those who did not (8.3% vs 0.2%, $P < .001$), but the difference was no longer significant at 4 months (15.8% vs 13.1%, $P = .18$) |
| Weinberg et al, 2013 ⁴⁷ | 904 women unscreened at average risk for CRC from 2 large health care systems Randomized to intervention or control group | CRC screening information delivered via Web or print vs control group (usual care) | No significant difference in screening uptake in the Web (12.2%), print (12.0%), or control group (12.9%) Participant factors associated with greater screening: higher income ($P = .03$), stage of change ($P < .001$) and physician recommendation to screen ($P < .001$) |
| Pignone et al, 2000 ⁴⁸ | 249 adults patients 50 to 75 years of age in randomized control trial | Intervention group – CRC screening video, targeted brochure and chart marker Control group – Automobile safety video and brochure | FOBT or flexible sigmoidoscopy was ordered for 47.2% of intervention participants and 26.4% of controls Screening tests were completed by 36.8% of the intervention group and 22.6% of control group |
| Ruffin et al, 2007 ⁴⁹ | 174 adults, 50 years and older with no previous CRC screening were randomized | Intervention group – Colorectal Web, interactive electronic tool Control group – Standard Web site on colorectal cancer screening | At 24 weeks post-intervention, 89 participants had completed CRC screening. Probability of being screened for intervention group compared with control group OR = 3.23 (95% CI 2.73 to 3.50) |
| Provider | | | |
| Fortuna et al, 2013 ⁵⁰ | 1,008 adults, 50 to 74 years of age randomized to 4 groups | Reminder letter Letter and automated telephone message Letter, automated telephone message, and patient-specific provider prompt Letter and personal telephone call | Compared with reminder letter alone (12.2%), letter plus personal phone call improved CRC screening rates (21.5%) AOR 2.0, 95% CI 1.1 to 3.9 Letter plus automated message plus provider prompt also improved CRC rates (19.6%) AOR 1.9, 95% CI 1.0 to 3.7 Letter and autodial was not more effective than reminder letter alone |
| Sequist et al, 2009 ⁵¹ | 21,860 patients 50 to 80 years of age overdue for CRC screening 110 PCPs | Patients randomly assigned to receive educational pamphlet, FOBT kit, and instructions for direct scheduling of flexible sigmoidoscopy or colonoscopy Physicians were randomly assigned to receive electronic reminders during an office visits with patients overdue for screening | Screening rates higher for patients who received mailings compared with those who did not (44.0% vs 38.1%; $P < .001$) Screening rates were similar among patients of physicians receiving electronic reminders and the control group (41.9% vs 40.2%) |
| Avanian et al, 2008 ⁵² | 717 patients with previous colorectal adenomas removed | Patient-specific reminders for surveillance colonoscopy | At 6 months, of the 358 patients whose physicians received a reminder, 33 (9.2%) completed colonoscopy compared with 16 (4.5%) of 359 patients whose physicians did not receive reminders ($P = .009$) |

| Study | Sample and Design | Intervention | Results |
|------------------------------------|--|---|---|
| Aragones et al, 2010 ⁵³ | Pairs of 65 PCPs and 65 Latino immigrant patients, with randomization at the physician level | Intervention – Video in Spanish, brochure and patient-delivered paper-based reminder for physician Control group – Usual care | CRC screening for intervention group (55%) and control group (18%), $P = .002$ Physicians recommended CRC screening for 61% of patients in intervention group vs 41% in control group ($P = .08$) Of those receiving a physician recommendation, 90% adhered to it vs 26% in the control group ($P = .007$). |
| System | | | |
| Hudson et al, 2012 ⁵⁴ | 975 patients from 25 primary care practices New Jersey | Facilitated team-building, organizational change process intervention focused on vision, mission, learning, and reflection | At 1 year follow-up, patients reported receiving CRC screening or receiving a screening recommendation (82%). Patients who were up-to-date in CRC screening were assumed to have received physician-initiated recommendations, so percent receiving screening recommendation may be inflated because of the inability to exclude patients requesting CRC screening |
| Ling et al, 2009 ⁵⁵ | 599 screen-eligible patients, 50 to 79 years of age in 10 PCP practices | Tailored vs non-tailored physician recommendation letter Enhanced vs non-enhanced physician office and patient management support to develop and implement CRC screening programs | During a 1-year period, lower endoscopy was highest among the group that received the non-tailored letter and enhanced management (54.2%) and lowest in the group that received the non-tailored letter and non-enhanced management (37.9%) Enhanced office and patient management increased the odds of completing a colonoscopy or flexible sigmoidoscopy by 1.63-fold (95% CI 1.11 to 2.41; $P = .1$). Tailored letter alone did not significantly increase the odds of lower endoscopy completion ($P = .71$) |
| Lasser et al, 2011 ⁵⁶ | 476 primary care patients from 4 community health centers and 2 public hospital-based clinics who were not up-to-date with CRC screening | Patients were randomly selected to receive patient navigation-based intervention or usual care Intervention included introductory letter from their PCP with educational material followed by telephone calls from navigator who offered FOBT or colonoscopy screening | During a 1-year period, intervention patients were more likely to undergo CRC screening than control patients (33.6% vs 20%; $P < .001$) and to be screened by colonoscopy (26.4% v 13.0%; $P < .001$) |

Abbreviations: SI, standard intervention; TI, targeted intervention; TIP, tailored intervention plus phone; CRC, colorectal cancer; CI, confidence interval; OR, odds ratio; AOR, adjusted odds ratio; FOBT, fecal occult blood test; PCP, primary care physician.