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## Interventions to Promote Colorectal Cancer Screening: An Integrative Review

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### Abstract

Behavior change interventions to promote colorectal cancer (CRC) screening have targeted people in community and primary care settings, health care providers, and health systems. Randomized controlled trials provide the strongest evidence of intervention efficacy. The purpose of this integrative review was to evaluate trials of CRC screening interventions published between 1997 and 2007 and to identify knowledge gaps and future directions for research. Thirty-three randomized trials that met inclusion criteria were evaluated using a modified version of the TREND criteria. Significant intervention effects were reported in six out of ten trials focused on increasing fecal occult blood testing, four of seven trials focused on sigmoidoscopy or colonoscopy completion, and nine of 16 focused on completion of any screening test. Several effective interventions to promote CRC screening were identified. Future trials need to use theory to guide interventions, examine moderators and mediators, consistently report results, and use comparable outcome measures.

### Keywords

Colorectal cancer; screening; randomized trials; fecal occult blood test; sigmoidoscopy; colonoscopy

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## INTRODUCTION

Despite the benefits of early detection and the availability of effective screening tests, colorectal cancer (CRC) remains the third leading cause of cancer death among Americans. The American Cancer Society estimates 1,596,670 new cases and 571,950 deaths from CRC in 2011.<sup>1</sup> About 90% of CRC is diagnosed in those age 50 or older and 75% of cases are diagnosed in people without any known risk factors.<sup>2</sup> A significant majority of deaths from CRC could be prevented by increasing the use of available screening tests. Tremendous progress has been made to reduce CRC incidence and mortality in recent years, and this progress has been attributed to prevention and early detection achieved through screening.<sup>3</sup> Continued progress is possible only if we increase access to, and utilization of, CRC screening tests. Currently, only about half of those aged 50 or older have received the recommended tests, with screening rates even lower among those who are less educated or lack insurance. Low rates of CRC screening, coupled with the fact that survival is inversely related to early detection, suggest the continued need for development, testing and translation of interventions to increase screening behavior. This critical need is supported by recommendations of the Oncology Nursing Society, the National Cancer Institute, and remains an objective in the Healthy People 2020 plan.<sup>4-6</sup> Interventions to increase CRC screening participation have focused on providers, health care systems, and individuals in both clinic and community-based settings. Effective interventions may need to be combined, focused on multiple targets or at multiple levels, and adapted to meet the needs of clients in different settings. Investigators who aspire to design effective interventions to promote CRC screening need to have a clear understanding of, and build upon, existing scientific evidence. The available evidence is presented in this integrative review of recent CRC screening intervention trials.

Numerous professional organizations have published CRC screening recommendations to guide clinical practice over the past two decades. Because recommendations from each organization differed, clinicians and patients were often confused about the most appropriate tests and testing intervals. In 2008, the major professional organizations came together to collaborate on a single set of updated consensus guidelines to promote evidence-based screening practice.<sup>7</sup> As shown in Table 1, these new guidelines differentiate tests that primarily detect cancer from those that detect both cancer and adenomatous polyps. This categorization of screening tests is accompanied by greater emphasis on cancer prevention, through removal of precancerous polyps, as the goal of CRC screening.

Because of the number of test options available, measurement of CRC screening outcomes is challenging. Some intervention trials have focused on participation in one specific CRC screening test as the outcome, whereas others have measured participation in any CRC screening test option as the outcome. A critical examination of interventions that have been tested to promote CRC screening will inform the development and design of future intervention trials so that further reductions in morbidity and mortality from this preventable cancer can be realized.

In 1997, Vernon conducted a comprehensive systematic review to evaluate the published literature on adherence to CRC screening with fecal occult blood testing (FOBT) and flexible sigmoidoscopy (FS), including interventions to promote screening.<sup>8</sup> In 2010, Holden and colleagues conducted a systematic review to summarize the evidence from interventions that influence CRC screening and strategies that increase the appropriate use and quality of CRC screening in general, rather than specific test use.<sup>9</sup> Even though these studies report on CRC screening evidence, to our knowledge, our study is the first systematic review to use established criteria to evaluate the quality of published CRC screening intervention trials. The purpose of this integrative review is to advance this

knowledge by describing CRC screening intervention studies that were published in the decade between 1997 and 2007 and to include trials that have been conducted to promote colonoscopy, an option that has now become the most frequently recommended CRC screening test among providers.<sup>10</sup> We further sought to identify gaps in knowledge about increasing screening behaviors by addressing the following aims: 1) Describe efficacious interventions to promote CRC screening; 2) evaluate intervention studies using a modified Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) criteria; and 3) discuss the quality of available evidence and implications for future research.

## METHODS

### Procedure

We conducted computer-based searches of several literature databases – PubMed, CINAHL, and Medline/Ovid using the following keywords: colon cancer screening, colorectal cancer screening, interventions, and randomized trials. Over 500 articles were identified, of which 33 met criteria for inclusion in this review. Inclusion criteria were: 1) at least one outcome variable must have focused on CRC screening behavior; 2) at least one intervention designed to increase CRC screening test completion was being tested; 3) a randomized trial design was used; and 4) published in English between 1997 and 2007. Only randomized trials were included in this review since our goal was to compare and contrast results of studies that evaluated the efficacy or effectiveness of a behavioral intervention.

Studies were divided into those with FOBT as the outcome (n=10), those with FS and/or colonoscopy as the outcome (n=7), and those with any CRC screening test as the outcome (n=16). Studies with FS or colonoscopy uptake as outcomes were combined as endoscopic screening. Studies with multiple screening outcomes, that is, more than one screening test, were categorized separately.

Three readers reviewed the studies – approximately 16 articles each. An additional two reviewers assessed a random sample of 10% of the articles. Agreement on scoring for each article was obtained through discussion until consensus was reached between the two reviewers and three readers. We found variations in coding on four articles, which were then resolved in a phone conference between all authors with reference to the specific sections of the article. We believe that using the standardized, easy to navigate criteria discussed below was largely responsible for the high inter-rater agreement. Criteria for evaluating studies were determined prior to reviewing articles after a comprehensive review and comparison of existing publishing guidelines. We developed a checklist based on the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) criteria.<sup>11</sup> In contrast to the CONSORT guidelines for reporting randomized trials, TREND guidelines emphasize more detailed reporting of theories used, descriptions of intervention and comparison conditions, and methods for adjusting for possible biases. Although designed for nonrandomized studies, we decided that modification of the TREND criteria provided the best framework to comprehensively evaluate behavioral intervention trials that promote CRC screening.

Of the original 22-category TREND checklist, we retained 10 major categories consisting of 20 individual criteria that represented critical components of behavioral intervention trials (Tables 6 through 8). The 10 categories were selected based on common design elements for RCTs (randomization, intervention delivery and fidelity, etc) and components emphasized in the CONSORT guidelines. Since the TREND guidelines were published in 2004, over 50% of the articles selected for review could have used TREND; therefore, all of the TREND components may not be entirely appropriate. Reviewers completed a TREND checklist for each article by indicating “Yes” or “No” with page numbers to specify whether the criterion

was addressed. Each “Yes” received 1 point and the total score was a sum of the “Yes” responses (See Tables 5, 6 & 7). Scores ranged from 0 (no criteria met) to 20 (all criteria met). For a criterion to be given a “Yes”, that criterion must have been described in the study. Descriptions ranged in the various studies from a brief statement about an issue (e.g., incentives were given to participants) to detailed paragraphs.

## RESULTS

### Interventions to Promote Fecal Occult Blood Testing

Of the 10 randomized trials of interventions to promote FOBT, nine were published since 2000 (Table 2). One study focused on a predominantly male population<sup>12</sup> and six included minority populations; four focused on African American samples<sup>13–16</sup> and two on Asian/Pacific Islanders.<sup>17,18</sup> Two studies were conducted outside of the U.S. Recruitment settings varied across studies with six trials conducted in primary care settings, two with community-based samples, and two in work-based settings.

All but one FOBT interventions were delivered at the individual level, directed at primary care patients or people in the community. Interventions included mailed FOBT kits, stool sample collection containers, or invitations to request FOBT kits with letters from primary care practices;<sup>13,19,20</sup> non-tailored print materials/informational brochures;<sup>12,14,16–18,20</sup> educational videos;<sup>14,16,18</sup> computer programs;<sup>15</sup> group-based educational sessions;<sup>16,17</sup> tailored print materials;<sup>12</sup> as well as culturally targeted print, video and health educator-delivered interventions.<sup>16–18</sup> The office-based interventions were designed to simplify cancer screening processes for busy primary care practices and included cancer screening checklists, chart stickers, audits, and shared responsibilities for screening among office staff.<sup>21</sup> Only four of the 10 trials identified specific theories or conceptual frameworks; these included social learning theory<sup>17</sup>, social cognitive theory<sup>15</sup>, the health belief model, the precaution adoption process model, and social comparison theory.<sup>12</sup> Powe developed her own model to describe relationships between cancer fatalism and screening behavior.<sup>16</sup>

Effective interventions, or positive findings, were reported in six of 10 trials. Interventions resulting in higher FOBT completion rates included: 1) a culturally targeted, nurse-delivered educational program with free FOBT cards, instruction/demonstration, and a reminder call at one month<sup>17</sup>; 2) in-person, home delivery of stool sample collection containers;<sup>19</sup> 3) mailed FOBT cards with a letter from the provider practice sent to patients two weeks in advance of a visit;<sup>13</sup> 4) a tailored comprehensive print intervention with telephone counseling;<sup>12</sup> 5) screening education provided by a trilingual, bicultural health educator with language-appropriate video, pamphlets, FOBT cards and instructions;<sup>18</sup> and 6) a cancer screening office-based system intervention that included screening checklists, chart stickers, audits and shared responsibilities for screening among office staff.<sup>21</sup> Some trials reported intervention effects that were different for certain subgroups. An informational brochure accompanied by a letter from the medical practice offering free FOBT was more effective than a letter alone for men, but not for women.<sup>20</sup>

Two studies reported negative findings because the comparison group(s) received equally effective interventions. Providing an educational video to patients waiting to see their providers did not increase FOBT completion rates beyond rates achieved with an ACS screening brochure plus a note card for patients to give to the provider to order an FOBT.<sup>14</sup> Similarly, a computerized educational program did not outperform a nurse providing one-to-one instruction on completing FOBT.<sup>15</sup> With one exception, all studies examined one-time FOBT completion as the primary outcome, rather than annual, or repeat, screening. Lipkus and colleagues examined initial, yearly, and repeat FOBT in their four-group longitudinal

trial comparing basic and comprehensive print interventions with tailored and non-tailored messages.<sup>12</sup>

In summary, 60% of the studies that assessed FOBT as the outcome showed significant intervention effects; 5 studies that tested patient-directed interventions and 1 testing a system/provider intervention.

### Interventions to Promote Screening Endoscopy

Of the seven trials of interventions to promote FS and colonoscopy, publication dates ranged from 1999 to 2004 (Table 3). Settings for these studies were mainly primary care with one study in neighborhood community clinics.<sup>22</sup> One study was conducted outside the U.S., in Scotland.<sup>23</sup> The majority of interventions were targeted to patients, with only one study focused on providers.<sup>24</sup> Theoretical frameworks guiding the interventions were not reported in three studies;<sup>22,23,25</sup> those reporting frameworks used a combination of popular behavior change models with the most popular being the Health Belief Model. Interventions ranged from targeted informational letters or brochures<sup>23,25,26</sup> to videos or phone counseling<sup>27,28</sup> to provider seminars/lectures.<sup>24,29</sup>

In the majority of these trials, the targeted outcome was FS completion with only three studies focused on colonoscopy.<sup>24,25,28</sup> Differences in how screening completion was reported - from actual percent completing the test, to percent increase from baseline, to odds ratios - make comparisons across the seven studies problematic. Significant effects were reported in two studies on FS<sup>26,27</sup> and two studies on colonoscopy.<sup>25,28</sup> One study found significant intervention effects on the outcome of a complete diagnostic evaluation defined as a colonoscopy or combined FS plus barium enema X-ray.<sup>30</sup> Successful interventions reported were: 15-minute videos mailed to participants' homes,<sup>27</sup> mailed health information booklet,<sup>26</sup> and usual care plus an informational brochure.<sup>25</sup> In comparing motivational interviewing versus mailed brochures to usual care, significantly lower use of colonoscopy was observed in the usual care group; however no differences were found between intervention arms.<sup>28</sup> The only physician-directed education also found significant increases in complete diagnostic evaluation post-intervention.<sup>30</sup>

Intervention effects were not significant in two studies. The first compared an invitation to have a FS with an explanatory leaflet to a similar invitation and leaflet plus the option to discuss screening with a physician.<sup>22</sup> The second intervention comprised a comprehensive pre-education baseline survey of provider attitudes and practice patterns, a didactic seminar on the current status of screening, implementation of on-site FS services, procedural training for interested providers, and the establishment of a free-standing FS screening program staffed by primary care providers. This was compared to didactic seminars only.<sup>29</sup>

In summary, 80% of studies that assessed endoscopy as the outcome showed significant intervention effects. Colonoscopy was the outcome in 3 of 7 studies. Interventions with significant effects were all directed at patients.

### Interventions to Promote Any CRC Screening Test

Of the 16 reviewed randomized trials testing interventions to promote more than one CRC screening test, all but two were published after 2002 (Table 4). Five trials focused on minority populations; three recruited African Americans<sup>31,32</sup> and two enrolled Hispanics.<sup>33,34</sup> Ten trials were conducted with patient populations in primary care settings or health maintenance organizations, and six in community-based settings. One study conducted in Italy enrolled both general practice patients and members of the general population.<sup>35</sup>

All 16 trials tested interventions that were directed at the individual level to individual patients, employees, or community members. Three studies combined patient-directed interventions with health care system (provider or practice-directed) interventions.<sup>36-38</sup> Types of patient-directed interventions included non-tailored print materials/informational brochures,<sup>30,33,35-37,39,40</sup> tailored print materials,<sup>30,32,40,41</sup> tailored telephone counseling,<sup>31,33,39,41</sup> targeted videos,<sup>32,42</sup> interactive computer programs,<sup>43,44</sup> mailed FOBT kits,<sup>30,33,35,36,45</sup> lay health advisors,<sup>32</sup> prevention care managers,<sup>33</sup> or patient navigators.<sup>34</sup> Provider or practice-directed interventions included academic detailing,<sup>36</sup> systems for tracking overdue patients,<sup>38</sup> expanding office staff responsibilities for screening,<sup>38</sup> educational workshops,<sup>37</sup> performance feedback, and/or other types of quality improvement initiatives.<sup>36-38</sup> Eight of the 16 trials used a specific health behavior theory including: the health belief model,<sup>32,40,41</sup> transtheoretical model,<sup>32,40,42</sup> social cognitive theory,<sup>32,41</sup> precaution adoption process model,<sup>39</sup> analytic hierarchy process multicriteria decision theory,<sup>43</sup> preventive health model,<sup>30</sup> elaboration likelihood model,<sup>44</sup> theory of planned behavior,<sup>41</sup> and social support models.<sup>32</sup> Two studies used multiple health behavior theories but did not specify which were used.<sup>31,45</sup>

Significant intervention effects were reported in 9 of 16 trials. Effective interventions included: 1) tailored telephone counseling;<sup>31</sup> 2) non-tailored brochure plus telephone support calls from a prevention care manager;<sup>33</sup> 3) targeted video with non-tailored print information combined with a provider-directed education, performance feedback, and a quality improvement intervention;<sup>37</sup> 4) an ethnically-matched patient navigator;<sup>34</sup> 5) a brief educational message with multiple mailings of tailored print materials;<sup>40</sup> 6) tailored and non-tailored print materials mailed with FIT kit and 30-day reminders;<sup>30</sup> 7) an interactive web-based computer program designed to establish user preferences for CRCs;<sup>44</sup> 8) an annual mailed screening invitation with tailored education booklet plus follow-up phone call;<sup>41</sup> and 9) an academic detailing intervention combined with a letter from the provider, an educational brochure, and FOBT kit with instructions.<sup>36</sup> In two studies, subgroup analyses based on exposure to the intervention yielded significant results.<sup>32,39</sup> In a study testing both single and multiple mailings of tailored and non-tailored print materials with callers to the Cancer Information Service, intervention effects were moderated by age, gender, and prior screening history.<sup>40</sup>

Negative findings were reported in six trials.<sup>32</sup> In one study, FOBT adherence rates for two intervention groups that received mailed FOBT kits, with or without reminders, were 18% higher than rates for controls, but no significance tests were reported.<sup>45</sup> Similar to the FOBT trials, all but two studies examined one-time, as opposed to repeat, screening.<sup>38,41</sup>

In summary, 60% of the studies reviewed had significant intervention effects. Of these 9 studies, two were testing some component of system change/provider education while the remaining 7 tested patient-directed interventions.

### Evaluation of FOBT Intervention Trials Using TREND Criteria

The ten studies with FOBT participation or adherence as the primary outcome were evaluated against TREND criteria (Table 5). In general, most studies met intervention reporting criteria. All 10 trials described the study design; stated specific aims, goals or hypotheses; clearly defined outcomes; described eligibility criteria; provided details of the intervention(s) for each condition; described the intervention delivery method and setting; and included negative study findings. No studies met all 20 criteria primarily because none of the 10 trials had described activities to increase adherence (incentives); this is possibly because incentives were not used. Four trials met the remaining 19 (95%) criteria because they were the only studies that described the conceptual framework or theory used.

### Evaluation of Endoscopy Intervention Trials Using Modified TREND criteria

The evaluation of endoscopy intervention studies is presented in Table 6. Overall, most studies met intervention reporting criteria. Outcome variables were defined in all studies. Two criteria – theoretical frameworks and activities to increase adherence (incentives) – were met by very few studies. Research to increase endoscopic screening has several strengths. The majority of studies had clearly defined outcome variables, intervention content and procedures were described and generalizability and interpretation of findings in the context of current knowledge were discussed. Limitations of research in this area were related to lack of theoretical frameworks and information about incentives given to participants. Three interventions did not have significant effects. Those reporting odds ratios had small to moderate effects. A primary limitation, however, is related to the lack of standardized reporting of effects. Results of interventions were reported as percent increases<sup>25</sup> to odds ratios,<sup>30</sup> making comparisons of the effectiveness of interventions across studies difficult.

### Evaluation of Intervention Trials to Promote Any CRC Screening Using TREND Criteria

The 16 studies with any CRC screening adherence as the primary outcome were also evaluated using the TREND criteria (Table 7). Overall, most studies met intervention reporting criteria. All 16 trials met four criteria; investigators clearly defined the outcomes, described the settings and locations where data were collected, and provided details of intervention delivery method and the unit of delivery. Thirteen (81%) trials met 17 out of the 20 criteria. Although the use of theory was slightly higher than in trials of interventions to promote FOBT alone (40%), only 10 (62%) trials used conceptual frameworks or theories to design interventions. Criteria met by the fewest trials included descriptions of activities to increase adherence (incentives) (n=5), eligibility criteria (n=12), and who delivered the intervention (n=12).

## DISCUSSION

We sought to update the behavioral intervention literature on CRC screening since 1997. In the decade from 1997 to 2007, significant progress was made in developing innovative and effective interventions to promote CRC screening. Though early studies focused on individual CRC screening tests, such as FOBT or FS separately, more recent studies have addressed the complexity of CRC screening by examining completion of multiple test options, including colonoscopy. The inclusion of colonoscopy as an outcome reflects the increased utilization of that test for both screening and diagnostic purposes. Because the completion of a colonoscopy negates the need for annual FOBT and FS, the interdependence of these screening tests cannot be ignored. As a result, the majority of recent intervention trials examined multiple test outcomes.

In a comprehensive review of 23 CRC screening intervention studies published prior to 1997, Vernon reported on 18 studies focused on increasing adherence to FOBT; four designed to increase FS; and one on colonoscopy.<sup>8</sup> Five studies used behavior change theories or models in developing interventions. In contrast, almost half, 16 of 33 studies reviewed here used such a theory or model. Theories guide selection of intervention components, study design, sampling, and appropriate outcomes.<sup>46</sup> Theories allow investigators to specify the mechanisms of action of interventions and identify potential mediators. Without theory-based interventions, it is not possible to deconstruct intervention effects, to attribute outcomes to specific components, or to understand why an intervention was or was not effective. It is encouraging to note that a greater proportion of recent interventions are theory-based, but continued advancement in the refinement and application of theories that better explain CRC screening behavior is needed.

Effective interventions, reported in 19 of 33 trials, included culturally-matched in-person education and counseling, tailored print materials with and without telephone counseling, mailed informational brochures with letters/invitations from providers and FOBT cards, mailed videos, tailored phone counseling, and an interactive web-based computer program. Several provider or system interventions were effective especially when combined with the foregoing patient-directed interventions. Such interventions included academic detailing, screening reminders and prompts, audits, feedback and shared responsibility for CRC screening. Our findings are consistent with a recent review that graded the strength of the available evidence for CRC screening interventions.<sup>9</sup> These investigators considered the strength of the evidence to be high for interventions that reduced structural barriers to CRC screening, including one-on-one interactions, patient reminders, and small media without decision aids. Our results also support the need for interventions that eliminate structural and system-level barriers, especially those that include patient reminders or one-on-one interactions and that aim at making the screening process easier, especially for target populations.<sup>9</sup>

The CRC screening intervention trials reviewed here had numerous strengths, yet their limitations make it difficult to draw definitive conclusions about studies. Though the TREND criteria include reporting of negative findings, standardized reporting of results with appropriate statistical testing is not a criterion. Comparisons across studies would be enhanced if results had consistent statistical reporting. Many studies reported negative findings because the control or comparison condition was, in itself, an effective intervention. The current movement to conduct practical clinical trials and comparative effectiveness studies will likely result in increasing numbers of these types of study designs.

It was interesting to note that none of the trials evaluated met the TREND criterion related to describing activities to increase compliance or adherence, including incentives. While it is possible that no incentives were offered in any of these studies, the use of incentives to thank participants for their time and effort is quite common. Disclosure of such information is essential in reporting intervention trials since incentives have potential to influence behavioral outcomes such as CRC screening.

Few trials have examined adherence to annual (repeat) FOBT, but rather, most focused on one-time FOBT. The effectiveness of this CRC screening test is dependent on adherence to annual testing and this review does not enhance our understanding of effective interventions to promote repeat testing. A number of trials included people who were already adherent or up-to-date with CRC screening. Delivering interventions to individuals who do not need them not only wastes limited resources but also makes interpretation of results challenging.

Understanding for whom interventions are most and least effective is important but often goes unreported. Few trials examined moderators of intervention effects. Hart<sup>20</sup> reported that an informational brochure accompanied by a letter from medical practice offering free FOBT was more effective than a letter alone for men, but not for women. In two studies, degree of exposure (intervention dose) moderated effects of the intervention.<sup>32,39</sup> Campbell and colleagues found that, among participants who received four computer-tailored newsletters with targeted videotapes over a 9 month period, a higher proportion of those who read the newsletters completed FOBT compared to those who did not (35% vs. 12%,  $p<0.01$ ). Similarly, among those who received a lay health advisor intervention, more people who spoke directly with the lay health advisor completed FOBT (48% vs. 26%,  $p<0.01$ ). Costanza, et. al. reported that when they compared participants who received the tailored telephone counseling call with those who did not, a significant difference in adherence to any CRC screening test was observed ( $p<0.0001$ ).<sup>39</sup> In a study testing both single and multiple mailings of tailored and non-tailored print materials with callers to the Cancer



Information Service, intervention effects were moderated by age, gender, and prior screening history.<sup>40</sup>

Another notable limitation in this body of research is the inadequate inclusion of minority participants. Given the rapidly changing demographics in the U.S., with Latinos expected to reach 25% of the overall population,<sup>47</sup> it becomes imperative that adequate numbers of diverse participants are enrolled in studies to permit meaningful comparisons of intervention effects by race/ethnicity. Cancer screening disparities remain a considerable burden among certain racial/ethnic groups, particularly among those who receive a late-stage diagnosis leading to lower survival rates.<sup>48</sup>

Until recently, screening trials conducted in ethnically-diverse populations have relied on traditional models of behavior change such as the health belief model or social cognitive theory. Such models propose that increasing knowledge leads to behavior change and their application has led to widespread use of individually-focused, cognitively-based interventions. These theories and the interventions built on them do not consider cultural beliefs or the socio-cultural contexts that influence health behavior. Health care experiences and beliefs that are shaped from childhood - about causes of illness and perceptions of the body - need to be explored within the social context if we are to understand their influence on CRC screening behavior.<sup>49,50</sup> Religious or spiritual orientation, which varies by country of origin and is prominent among many African-American groups, has received limited attention despite being related to cancer screening.<sup>51</sup> Including meaningful numbers of diverse participants in studies, increasing our understanding of the social contexts in which people and providers make decisions about CRC screening, and learning how to leverage culture to optimize intervention effects<sup>51</sup> may well turn the tide in the ongoing struggle to increase CRC screening rates.

### Strengths and Limitations

To our knowledge, this is the first systematic review to use established criteria to evaluate the quality of published CRC screening intervention trials. Though we examined several recognized standards for reporting results of clinical trials, the TREND criteria were the most comprehensive and relevant for these types of interventions. It must be noted, however, that many of the articles reviewed were published prior to establishment of the TREND criteria in 2004. Publication bias that resulted in selective reporting of positive trials may have influenced our results and conclusions. In light of the substantial number of studies identified with negative findings, this is not considered to be a serious limitation. Despite use of comprehensive search strategies, it is possible that some trials were missed or inappropriately excluded.

### Recommendations for Future Research

In many healthcare settings, system and patient-centered interventions have been put in place as evidence has accumulated. Health care reform is underway with a major emphasis on expansion of primary care services. Our ability to translate effective interventions into clinical or public health practice will require greater attention to the cost-effectiveness of interventions and the conduct of trials that move beyond efficacy. Given the mix of findings, a priority for future research should be to encourage comparative effectiveness research to understand which strategies work best with specific populations, and provide the greatest benefit in increasing CRC screening. Strategies to expedite translation of effective cancer screening interventions include: 1) greater attention to multilevel interventions that take the social contexts of CRC screening behavior into account; 2) more consistent reporting of results of intervention trials; 3) more extensive use of theory to guide intervention development; 4) examination of mediators and moderators to explain the mechanism of

intervention effects; and 5) use of research designs other than randomized trials to conduct implementation research.<sup>52</sup> Moving effective, culturally-appropriate, and sustainable interventions into practice is the necessary next step to eliminate health disparities and further reduce the burden of CRC for all.

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**Table 1**Guidelines for Colorectal Cancer Screening: 2008 <sup>(4)</sup>

Tests that detect both cancer and polyps	Tests that primarily detect cancer
Flexible sigmoidoscopy every 5 years Colonoscopy every 10 years Double contrast barium enema every 5 years CT (virtual) colonography every 5 yrs	Guiaac-based fecal occult blood test every year Fecal immunochemical test every year Stool DNA test (interval not known)

Table 2

Randomized Trials of Interventions to Promote Fecal Occult Blood Testing

Authors	Population/Target	Groups	Sample size	Adherence Post-Intervention (%)	Comments
Braun (2005)	Hawaiian Civic Clubs, HI 50+ years old 72% Female 90% Hawaiian	<b>Intervention:</b> Culturally-targeted group educational program provided by native Hawaiian physician and survivor; free FOBT cards; multiple reminder calls to non-completers during 4 months post-program to address barriers. <b>Control:</b> Culturally-targeted group educational program provided by non-Hawaiian nurse, brochure, free FOBT cards, instructions & reminder call at one month.	69 52	33 40	<b>Intervention:</b> Participants who received physician-directed program were less likely to be screened post-intervention than those in nurse-delivered program group (OR=0.36, 95% CI, 0.14–0.97). At baseline, 59% (n=41) in this group were up-to-date with CRC screening. <b>Control:</b> At baseline, 69% (n=36) in this group were up-to-date with CRC screening.
Courtier (2002)	Municipal employees, Barcelona, ES 50–74 years old 59% Male Ethnicity not reported	<b>Intervention 1:</b> Two containers for fecal sample collection delivered by mail with reminder phone call at 15 days. <b>Intervention 2:</b> Two containers for fecal sample collection delivered to home, and collected, by trained lay person with reminder phone call at 15 days.	1060 965	68 75	<b>Interventions 1 and 2:</b> Group 2 had a higher participation rate (57.7%; n=557) compared to Group 1 (36.5%; n=338; p<0.005). Use of correct specimen collection procedure also was higher in Group 2 (75.1%; n=419) than Group 1 (67.5%; n=262; p<0.014).
Friedman (2001)	Medical outpatient community clinic, Houston, TX 50+ years old 84% Female 88% AA	<b>Intervention 1:</b> Educational video describing CRC, early detection, treatment, and how to complete FOBT; ACS brochure on CRC prevention and screening; plus note card to give to PCP to order FOBT. All interventions delivered prior to PCP visit. <b>Intervention 2:</b> Same as above (but completed questionnaires before and after viewing the video). <b>Control:</b> ACS brochure on CRC screening plus note card to give to PCP to order FOBT.	110 50	44 36	<b>Interventions 1 and 2:</b> Differences in FOBT completion rates between intervention and control groups were not significant (44% vs. 36%) (n=90) of patients who viewed the video reported intention to get FOBT in next 2 months. <b>Control:</b> 50% (n=25) of control participants reported intention to get FOBT in next 2 months.
Goldberg (2004)	Primary care patients, Chicago, IL 50–80 years old 74% Female (Avg) 82% AA (Avg)	<b>Intervention:</b> FOBT cards with instructions and introductory letter signed by clinic director & staff mailed 2 weeks prior to scheduled appointment. <b>Control:</b> Usual care, no contact.	59 60	41 5	<b>Intervention:</b> Odds of FOBT return was thirteen-fold for patients in intervention group. FOBT return rate during 12 months post-intervention was 40.7% (n=24). OR=13.0, 95% CI, 3.6–45.5; p<0.001. <b>Control:</b> Rate of FOBT return was 5% (n=3).
Hart (1997)	Single physician group practice Leicestershire, UK 61–70 years old Male and Female Ethnicity not reported	<b>Intervention:</b> Letter from medical practice offering free FOBT with brochure containing information about CRC incidence, polyps, benefits of polypectomy, and symptomatic nature of the disease, screening, FOBT explained, and reasons for noncompliance. A pre-paid envelope was included to return request for FOBT. <b>Control:</b> Letter from medical practice offering free FOBT with a pre-paid envelope to return request for FOBT.	786 785	36 in men aged 61–65 39 in men aged 66–70 38 in women aged 61–65 31 in women aged 66–70 27 in men aged 61–65 23 in men aged 66–70 36 in women	<b>Intervention:</b> Intervention effects differed by gender. FOBT completion rates were higher among men who received the intervention compared to controls: 36% v 27% (p<.05) for men aged 61–65 and 39% v 23% (p<.01) for men aged 66–70. Among women, differences between intervention and controls were not significant <b>Control:</b> 27% of men aged 61–65 years and 23% of men aged 66–70 completed FOBT. 36% of women aged 61–65 and 31% of women aged 66–70 completed FOBT.

Authors	Population/Target	Groups	Sample size	Adherence Post-Intervention (%)	Comments
Lipkus (2004)	Carpentry workers, NJ 50+ years old 99% Male 95% White	<b>Intervention 1:</b> Non-tailored Basic Information: Four-page brochure discussing three "basic" CRC risk factors: age, family history, and polyps. <b>Intervention 2:</b> Non-tailored Comprehensive Information: Identical to group 1 intervention plus information on a comprehensive list of lifestyle and occupational risk factors. <b>Intervention 3:</b> Tailored Basic Information: Identical to group 1 intervention + tailored information highlighting which of the three "basic" risk factors increased their personal CRC risk. <b>Intervention 4:</b> Tailored Comprehensive Information: Identical to group 3 plus telephone counseling to discuss the effect of lifestyle and occupational factors on CRC cancer risk. <b>Control:</b> No control discussed.	216 212 218 214	aged 61–65 31 in women aged 66–70	<b>Intervention 1:</b> FOBT rates declined each year from 60% in year 1 to 41% in year 3. <b>Intervention 2:</b> By year 3, those who received the non-tailored comprehensive information had the highest yearly FOBT screening rates (59% vs. 41 vs. 49 vs. 51%; ( $p<.05$ )). <b>Intervention 3:</b> FOBT rates declined each year from 68% in year 1 to 49% in year 3. <b>Intervention 4:</b> Those receiving the Tailored Comprehensive information had the highest screening rate in Year 1 than any other group (74% vs. 68 vs. 60 vs. 60%; ( $p<.05$ )). <b>Comment:</b> Education was correlated with observed repeat screening ( $p<.00001$ ), age was correlated with initial screening ( $p<.00001$ ), yearly screening ( $p<.00001$ ), and repeat screening ( $p<.00001$ ).
Miller (2005)	Internal medicine patients, New Salem, NC 50+ years old 60% Female 72% AA	<b>Intervention:</b> Computerized educational program designed to teach patients about FOBT through computer animations, audio clips, digital photographs, and video segments. Website: <a href="http://nimedweb.wfubmc.edu/cai/fobt.htm">http://nimedweb.wfubmc.edu/cai/fobt.htm</a> <b>Control:</b> Participants met with office nurse in a private setting for instructions on how to complete FOBT.	93 101	62 63	<b>Intervention:</b> No significant differences observed between groups. 62% ( $n=58$ ) in computer group returned FOBT within 30 days; compared to 63% ( $n=64$ ) in nurse group ( $p=0.89$ ). Females (71% vs. 51% of males, $p<.001$ ) and those with prior screening history (79% vs. 54% with no prior screenings, $p<.001$ ) were more likely to return FOBT kits. <b>Control:</b> 64 (63%) returned FOBT. <b>Comment:</b> Gender was significantly associated with completion of the follow-up survey females vs. males (76% vs. 59%, $P<.001$ ).
Powe (2004)	Senior citizen center attendees No location 50–94 years old 88% female 84% AA	<b>Intervention 1:</b> Cultural & Self-empowerment Group received the 20-minute culturally targeted educational video, calendar, poster, brochure, and flier delivered over 12 months. <b>Intervention 2:</b> Modified Cultural Group received the 20-minute culturally targeted educational video alone. <b>Control:</b> A Traditional Group received a 13-minute video titled "Colorectal cancer: The cancer no one talks about"	54 39 41	61 46 15	<b>Intervention 1:</b> This group had the highest FOBT completion rates at 12 months (61%; $n=33$ ) and a greater increase in knowledge scores was observed over time ( $df=2$ ; $F=10.24$ ; $P<.0001$ ) compared to other groups. <b>Intervention 2:</b> 46% ( $n=18$ ) participated in FOBT. <b>Control:</b> 15% ( $n=5$ ) of the traditional group completed FOBT. <b>Comment:</b> Author stated group membership ( $df=1$ ; $p=0.13$ ) and 12 month knowledge scores ( $df=1$ ; $p=0.023$ ) were predictors of FOBT participation but NS statistic was reported. No test statistics of group differences in completion rates were reported.

Authors	Population/Target	Groups	Sample size	Adherence Post-Intervention (%)	Comments
Roetzheim (2004)	Primary care clinics in Hillsborough County, FL, 50-75 years old 78% female 48% White, 29% AA, 22% Hispanic (Avg)	<b>Intervention:</b> Cancer-screening office system intervention included a checklist completed by patients, chart stickers indicating status of tests (due, ordered, completed), shared responsibility for screening among office staff, random chart audits. <b>Control:</b> Usual care.	1,196 baseline 1,237 at 12 mos.	40 12	<b>Intervention:</b> Odds of FOBT completion were more than doubled by the office-based intervention (OR = 2.56; 95% CI, 1.65-4.01; p<.0001). <b>Predictors of FOBT</b> included age (p=.03), Medicare insurance coverage (p=.047), lower Charlson comorbidity scores (p<.001) and number of PCP visits (p<.0001).
Tu (2006)	Community clinic patients, Seattle, WA 50+ years old 62% Female (Avg) 79% Cantonese-speaking (Avg)	<b>Intervention:</b> CRC screening education from a trilingual, bicultural health educator including a bilingual motivational video, a motivational pamphlet, an informational pamphlet, FOBT cards with written instructions in both Chinese and English. <b>Control:</b> Usual care.	105 105	70 28	<b>Intervention:</b> Odds of FOBT completion increased six-fold by the culturally and linguistically appropriate intervention. 69.5% (n=73) of patients in intervention group completed FOBT (OR = 5.98, 95% CI=3.29-10.85). <b>Control:</b> 27.6% (n=29) of participants received FOBT screening.



Table 3

Randomized Trials of Interventions to Promote Endoscopic Screening

Authors	Population/Target	Groups	Sample Size	Adherence Post-Intervention (%)	Test*	Comments
Denberg (2006)	Primary care patients 50+ years 60% female (Avg) >50% White (Avg) 30% unknown race (Avg)	<b>Intervention:</b> Usual care plus informational brochure <b>Control:</b> Usual care	781	71 5	COL COL	<b>Intervention:</b> 70.7% completed COL <b>Control:</b> 59% completed COL <b>Comment:</b> Rate of COL completion higher in intervention group by 11.7% percent (p<.001). OR for the intervention group was 1.20 (CI 1.09–1.33). Those with Medicaid or other low income insurance less likely to complete COL (OR .40, CI .21–.75)
Gray (2000)	General practice patients, Dundee, Scotland, UK 50–61 years old 43% Male (Avg) No ethnicity	<b>Intervention 1:</b> Invitation to have FS, along with an explanatory leaflet. <b>Intervention 2:</b> Invitation to have FS, an explanatory leaflet, and the option of discussing the test with their physician first.	165 154	27 21	FS FS	<b>Intervention 1:</b> 68.5% (n=113) replied to invitation to receive FS, 26.7% (n=44) of participants received screening. Differences between groups NS. <b>Intervention 2:</b> Significantly fewer people replied to the initial invitation (52.5%, n=81) and 21.4% (n=33) of participants received screening. Only 2% embraced option of physician consult.
Myers (2004)	Primary care physicians NJ + PA 50+ years old No gender No ethnicity	<b>Intervention:</b> Patient screening program (designed to make PCPs aware of patients who were eligible for CDE) and Physician-oriented educational and reminder program (included 2 visits to the practice, a tailored letter, and a telephone call to the PCP). <b>Control:</b> Patient screening program only.	120 198	63 54	CDE CDE	<b>Intervention:</b> CDE recommendation and performance rates were significantly higher for intervention group (OR = 2.28; 95% CI = 1.37 – 3.78) compared to controls (OR = 1.63; 95% CI = 1.06 – 2.5). During period 3 of the study, 63.3% (n=245) of intervention participants received CDE (OR=1.71; 95% CI= 1.21–2.40; P=0.03). <b>Control:</b> 53.7% (n=309) received CDE during period 3 of the study (OR= 1.05; 95% CI= 0.81–1.36; P=0.73). <b>Comment:</b> Complete diagnostic evaluation (CDE) defined as colonoscopy or combined FS + barium enema X-ray.
Schroy (1999)	Neighborhood health center PCPs, Boston, MA 50+ years old 52% Female 39% White (Avg)	<b>Intervention:</b> Pre-education baseline survey of provider attitudes and practice patterns plus a didactic seminar on the current status of CRC screening; implementation of on-site FS services; procedural training for interested providers; and inception of self-standing FS screening program staffed by primary care providers. <b>Control:</b> Didactic educational seminar consisting of 40-min. presentation on current status of CRC screening and 20-minute discussion period.	53 23	60 26	FS FS	<b>Intervention:</b> Of the forty-two providers who responded to the survey at baseline, 23.8% (n=10) of participants were compliant with FS. Of the fifty-three providers who responded to 1 year FU survey, 60.4% (n=32) were compliant with FS. <b>Control:</b> Of the 21 providers who responded to baseline survey, 19.0% (n=4) were compliant with FS. Of the 23 providers who responded to year 1 survey, 26.1% (n=6) were compliant with FS.
Turner (2008)	Primary care patients >50 years 69% female 62% AA	<b>Intervention 1:</b> Peer coach phone counseling using motivational interview Principles; call averaged 15 minutes 2 weeks before scheduled COL <b>Intervention 2:</b> Two mailed brochures one each from ACS and CDCP	275	69 58 82	COL COL COL	<b>Intervention:</b> No significant differences between 2 intervention arms. <b>Control:</b> Significant difference in COL attendance (P>.004). <b>Comment:</b> AA patients with Medicaid less likely to complete COL; In regression analysis, significant odds of completion only

Authors	Population/Target	Groups	Sample Size	Adherence Post-Intervention		Comments
				(%)	Test*	
Wardle (2003)	General practitioner patients, SCT 55–64 years old 50% female Ethnicity not reported	<b>Control:</b> No intervention	1,453	54	FS	for peer support (OR 2.14, $p<.05$ ) and no support needed groups (OR 2.68, $p<.04$ )  <b>Intervention:</b> 53.5% (n=777) of participants received FS ( $p<.05$ ). Participants had lower scores on negative attitudes (barriers, fear, and self-efficacy) compared to controls. The intervention resulted in higher scores on positive attitudes. <b>Control:</b> 49.9% (n=755) of participants received FS.
			1, 513	50	FS	
Zapka 2004	Primary care practice patients, MA 50–74 years old 57% Female Ethnicity not reported	<b>Intervention:</b> 15-minute videos were mailed to participants' homes. Each package contained a letter, signed by the primary care physician, encouraging the participant to view the video, which encouraged discussion of CRC screening with primary care physicians. <b>Control:</b> Received usual care.	450	26	FS	<b>Intervention:</b> Intervention dose (viewing at least half of the video) was significantly related to FS with or without another test (odds ratio, 2.81 [CI, 1.85 to 4.26]). 26.2% (n=118) of participants received FS with or without any other screening test (OR=1.22 95% CI=0.88–1.70). 28.9% (n=130) received a test combination other than FS (OR=0.84; 95% CI=0.63–1.14). <b>Control:</b> 21.3% (n=104) of participants received FS with or without any other screening test. 34.0% (n=166) of participants received a test combination other than FS.
			488	29	Other	
				21	FS	
				34	Other	

**Table 4**  
Randomized Trials of Interventions to Promote Any Colorectal Cancer Screening Test

Authors	Population/Target	Groups	Sample Size	Adherence		Comments
				Post-Intervention (%)	Test	
Basch (2006)	Members of a single health plan, NY 52+ years old 71% Female 63% AA	<b>Intervention:</b> Tailored telephone counseling to increase CRCS motivation based on readiness to screen, reduce barriers, provide social emotional support, and elicit commitment to screen. <b>Control:</b> Mailed CRC screening brochure.	226	13	FOBT	<b>Intervention:</b> At 6 months, screening with any CRC test was increased more than 4-fold in intervention group (OR=4.4, 95% CI=2.6, 7.7). 27% of intervention group had completed a CRCS. <b>Control:</b> 6% (n=14) had completed a CRCS test. No analyses comparing differences on individual tests were reported. <b>Comment:</b> 3% of intervention and 6% of controls completed office-based FOBTs.
			230	13	COL	
Campbell (2004)	Members of rural churches, NC 50+ years old 74% Female 99% AA	<b>Intervention 1:</b> Four computer-tailored newsletters with four targeted videotapes mailed to participants bimonthly for first 6 months after baseline; 4 <sup>th</sup> mailing at 9 months post-baseline. Materials focused on dietary change, physical activity and CRCS. <b>Intervention 2:</b> Trained lay health advisors provided information through existing networks, 3 church-wide events related to healthy eating, physical activity and CRCS. <b>Combined Intervention 3:</b> Received both interventions 1 and 2. <b>Control:</b> Health education sessions on topics unrelated to study objectives	76	37	FOBT	<b>Intervention 1:</b> At 1 year, this group demonstrated the greatest increase in the proportion (36.8%) of participants who completed FOBT, but differences across groups was NS (p=0.08). Those who read tailored newsletters were more likely to get FOBT than those who did not read (35% vs. 12%, p<0.01). <b>Intervention 2:</b> Individuals who spoke with a lay health advisor (LHA) were more likely to have obtained an FOBT test than those who did not (48% vs. 26%, p<0.01). <b>Intervention 3:</b> FOBT completion rates similar to other intervention groups and higher than controls, but NS. <b>Control:</b> Control churches were offered intervention materials (training manuals and sessions, newsletters, and videos) after study was completed.
			51	21	Other CRCS	
Church (2004)	Community members, Wright County, MN 50+ years old 53% Female Ethnicity not reported	<b>Intervention 1:</b> Invitation letter from investigator and mailed FOBT kits with no reminders <b>Intervention 2:</b> Invitation letter from investigator and mailed FOBT kits with reminder at 1 month. Non-responders received second FOBT kit one month later, plus reminder call one month after that. <b>Control:</b> No direct contact. County-wide CRCS promotion/awareness campaign was simultaneously conducted using newspaper articles, public service announcements, radio shows, and public presentations.	434	17	FOBT	<b>Intervention 1:</b> At 1 year, change in FOBT adherence rate was 16.9% and 13.2% were adherent to any CRCS. Half of this group erroneously received reminders at 1 month. <b>Intervention 2:</b> At 1 year, change in FOBT adherence rate was 23.2% and 14.1% were adherent to any CRCS. <b>Control:</b> At 1 year, change in FOBT adherence rate was 1.5% and 7.8% were adherent to any CRCS. <b>Comments:</b> For both intervention groups 1 & 2 combined, FOBT adherence rates increased 18.4% more than controls and rates of adherence to any CRCS increased 5.9% more than controls. Results were reported as significant, but statistical tests were not provided. Differences between intervention groups were NS.
			404	13	Any CRCS	
			417	23	FOBT	
				14	Any CRCS	
				2	FOBT	
				8	Any CRCS	

Authors	Population/Target	Groups	Sample Size	Adherence		Comments
				(%)	Test	
Costanza (2007)	Primary care practice patients, MA 50-75 years old Male and Female 92% non-Hispanic White	<b>Intervention:</b> Mailed informational brochure followed at 3 months by computer-based tailored telephone counseling providing education, barriers reduction and motivational interviewing. <b>Control:</b> Usual care.	1,187	9	FOBT	<b>Intervention:</b> No significant differences observed in percentages of those up-to-date with FOBT, FS, COL or any CRCS test between intervention and control groups. Subanalyses comparing rates of any CRCS between those who received tailored telephone counseling (n=553) and those who were not called, including controls, was significant (p<0.0001).
			1,261	<1	FS	
Dietrich (2006)	Community health centers, New York City, NY 50-69 years old 100% Female 63% Spanish-speaking	<b>Intervention:</b> <i>Put Prevention into Practice</i> brochure plus telephone support calls from a trained prevention care manager who assessed readiness to screen, provided motivational support, addressed barriers, scheduled appointments, mailed FOBT kits, sent reminders & directions, and arranged transportation. <b>Control:</b> Single telephone call where study staff answered questions about preventive care and advised women to obtain needed preventive care from their primary care clinician.	696	43	FOBT	<b>Intervention:</b> Changes in rates of any CRCS from baseline were 60% higher in intervention group compared to control (p<0.001). 23.8% of intervention group had FOBT in past 18 months at baseline, increasing to 42.5% at 18-month follow-up. 39% of intervention group had any CRCS in past 18 months at baseline, increasing to 62.9% at 18-month follow-up. <b>Control:</b> 25.5% had FOBT in past 18 months at baseline increasing to 30.7% at 18-month follow-up. 39% had any CRCS at baseline increasing to 50.0% at 18-month follow-up. <b>Comment:</b> Interventions for both groups focused on breast, cervical and CRC screening.
			694	63	Any CRCS	
				31	FOBT	
				50	Any CRCS	
Dolan (2002)	Internal medicine practice patients, Rochester, NY 50+ years old 52% Female 98% White	<b>Intervention:</b> Decision aid consisting of a detailed analysis of CRC screening options using the Analytic Hierarchy Process. <b>Control:</b> Brief in-person description of CRC and 5 screening test options with encouragement to discuss CRCS with provider.	45	48	FOBT	<b>Intervention:</b> Fewer intervention patients chose the no screening "wait & see" option (p=0.06), but differences in numbers who complete planned screening tests between groups were NS (p=1.0). Of 45 intervention patients, 82% (n=37) planned to be tested. Of the 37 who planned to be tested, 48.6% (n=18) completed a CRCS test. <b>Control:</b> Of 43 in the control group, 27 (62.8%) planned to be tested and 37% chose the no screening "wait & see" option. Of the 27 who planned to be tested, 51.9% (n=14) completed a CRCS test.
			43	4	FOBT+FS	
				9	FS	
				2	COL	
				40	Any CRCS	
				14	FOBT	
				16	FOBT+FS	
Ferreira (2005)	Providers + veterans in two clinic firms at VAMC, Chicago, IL 50+ years old 100% Male 50% AA	<b>Intervention:</b> HCPs attended 2 hour workshop on CRCS and QI workshops every 4-6 months with feedback on group screening rates, individual rates, and training to improve communication. Patients received informational brochure, video on CRCS, FOBT instructions, messages to overcome barriers and increase self-efficacy. <b>Control:</b> Usual care, no intervention.	60 PCPs	29	FOBT	<b>Intervention:</b> At 18 month follow-up, 29.1% (n=295) of veterans had returned FOBTs and 18.7% (n=190) had FS or COL. 41.3% of patients completed either a FOBT, FS or colonoscopy compared to 32% of controls (p<0.01). Among patients with literacy levels below 9th grade, 56% of intervention group had any CRCS compared to 30% of controls (p=0.002) <b>Control:</b> 17.1% (n=165) of veterans returned FOBTs and 18.1% (n=174) had FS or COL. 32.4% completed either FOBT, FS or colonoscopy.
			1,015	19	FS/COL	
			53 PCPs	41	Any CRCS	
			963	17	FOBT	
				18	FS/COL	
				32	Any CRCS	
Jandorf (2005)	Single primary care practice patients, East Harlem, NY 50+ years old	<b>Intervention:</b> Ethnically-matched PN provided education, support, advocacy, encouraged CRCS with written reminders, telephone calls, and scheduling assistance.	38	42	FOBT	<b>Intervention:</b> Significant intervention effect observed for endoscopy but not FOBT screening. At 3 months, 42.1% (n=16) had completed FOBT compared to 25% of controls
			40	24	FS or COL	
				25	FOBT	
				5	FS or COL	

Authors	Population/Target	Groups	Sample Size	Adherence		Comments
				Post-Intervention (%)	Test	
Marcus (2005)	74% Female 82% Hispanic	<b>Control:</b> Received usual care.				(p=0.09). At 6 months, 23.7% (n=9) had completed endoscopy compared to 5% of controls (p=0.02). <b>Control:</b> 25% (n=10) completed FOBT by 3 months and 5.0% (n=2) had completed endoscopy by both 3- and 6-month follow up.
	Regional CIS callers, USA 50+ years old 83% Female 85% White	<b>Intervention 1 (SU):</b> Brief education message encouraging CRCS + single untailored booklet mailed 7 days post-enrollment. <b>Intervention 2 (ST):</b> Brief education message encouraging CRCS + single 16-page tailored booklet mailed 7 days post-enrollment. <b>Intervention 3 (MT):</b> Brief education message encouraging CRCS + multiple tailored print materials using tailoring information obtained only at baseline. Materials were mailed at 7 days, 6 months, 9 months and 12 months post-enrollment. <b>Intervention 4 (MRT):</b> Brief education message encouraging CRCS + multiple retailored print materials were tailored to information obtained both at baseline as well as at 6-month follow-up. Materials were mailed at 7 days, 6 months, 9 months and 12 months post-enrollment.	380 377 424 419	42 44 51 48	Any CRCS Any CRCS Any CRCS Any CRCS	<b>Interventions:</b> Overall significant trend across groups showing higher CRCS rates with increased intensity of tailoring (p=0.05). At 14-month follow-up, adherence to any CRCS was 9% higher in MT intervention (Group 3) compared to SU intervention (Group 1): 51% vs. 42%; p=0.03. No other group differences were significant. Moderators of intervention effects included age, gender and prior CRCS history. Among females, both longitudinal interventions were different than the control condition. Adherence was 12% higher in MT (Group 3) and 13% higher in MRT (Group 4) compared to SU (Group 1). SU vs. MT (p=0.03) and SU vs. MRT (p=0.02). For younger participants (aged 50-59), all three tailored interventions showed higher CRCS rates compared to the SU group. Adherence rate was 12% higher in ST (Group 2) compared to SU (Group 1) and almost 20% higher in MT (Group 3). SU vs. ST (p=0.048) and SU vs. MT (p=0.003), SU vs. MRT (p=0.008). Among those with prior screening history, adherence was 12% higher in MRT (Group 4) compared to SU (Group 1); p=0.04.
Myers (2007)	Primary care practice patients 50-74 years old 67% female 58% AA	<b>Intervention 1 (SI):</b> Mailed CRCS invitation letter, screening informational booklet, FIT kit and reminder letter at 30 days and 1 year post-baseline. <b>Intervention 2 (TI):</b> Standard intervention described above + 2 tailored message pages on personal barriers to FIT and FS. <b>Intervention 3 (TIP):</b> Standard intervention + tailored intervention + reminder phone call from health educator. <b>Control:</b> Usual care.	387 386 386 387	46 44 48 33	Any CRCS Any CRCS Any CRCS Any CRCS	<b>Intervention 1:</b> At 24 months, adherence to any CRCS test was higher in all three intervention groups compared to controls, but not different from each other. 46% of SI (Group 1) was adherent to any CRCS compared to 33% of controls; OR=1.68, 95% CI= 1.25, 2.53 (p=0.003). <b>Intervention 2:</b> 44% of TI (Group 2) was adherent to any CRCS compared to 33% of controls; OR=1.58, 95% CI=1.18, 2.12 (p=0.01). <b>Intervention 3:</b> 48% of TIP (Group 3) was adherent to any CRCS compared to 33% of controls; OR=1.91, 95% CI= 1.42, 2.56 (p=0.001). <b>Control:</b> 33% were adherent at 24 months
Pignone (2000)	Community primary care practice patients, NC 50-75 years old 61% Female 87% White	<b>Intervention:</b> 11-minute video on CRC with color-coded brochures indicating patients' stage of readiness to be screened. Color-coded laminated cards indicating patient's readiness were attached to clinic chart before seeing provider. <b>Control:</b> Generic brochure and video on automobile safety.	125 124	28 18 37 20 5 23	FOBT FS Any CRCS FOBT FS Any CRCS	<b>Intervention:</b> Intervention increased any CRCS by 14% (36.8% vs. 22.6%) but no p-values were reported. Crude (unadjusted) OR=2.14, 95% CI=1.20, 3.79 for intervention effect was reported. After adjusting for clustering of providers, OR=2.14, 95% CI=0.94, 4.84, 28.5% (n=36) completed FOBT and 17.6% (n=22) completed FS. <b>Control:</b> FOBT was completed by 20.2% (n=25) of control group and FS was completed by 4.8% (n=6).

Authors	Population/Target	Groups	Sample Size	Adherence Post-Intervention (%)	Test	Comments
Ruffin (2004)	Community primary care practices + patients in MI 50+ years old Male and Female 51%–67% Caucasian	<p><b>Intervention 1 (Practice-directed):</b> At every patient encounter, past screening history &amp; screening recommendations made available to all staff members, with cues and changes to staff responsibilities for screening.</p> <p><b>Intervention 2 (Patient-directed):</b> Wallet-sized calendar and prevention guide with past screening tests complete and screening recommendations relevant to age &amp; gender.</p> <p><b>Intervention 3 (Combined):</b> Both interventions 1 &amp; 2 above.</p> <p><b>Control:</b> Usual care, no intervention</p>	5 sites, 4,212 patients 6 sites, 4,160 patients 6 sites, 4,286 patients 5 sites, 557 patients	24 13 34 16 34 8 41 11	FOBT FS, COL, or BE FOBT FS, COL, or BE FOBT FS, COL, or BE FOBT FS, COL, or BE	<p><b>Intervention 1:</b> No significant differences were observed between groups at 1 or 3 year follow-up. At baseline, 34.9% were adherent to FOBT and 15.9% adherent to endoscopy or barium enema. At 3 year follow-up, 24.0% were adherent to FOBT and 13.0% adherent to endoscopy or barium enema.</p> <p><b>Intervention 2:</b> At baseline, 38.0% were adherent to FOBT and 16.0% adherent to endoscopy or barium enema. At 3 year follow-up, 33.9% were adherent to FOBT and 16% adherent to endoscopy or barium enema.</p> <p><b>Combined:</b> At baseline, 31.0% were adherent to FOBT and 10.0% adherent to endoscopy or barium enema. At 3 year follow-up, 34.0% were adherent to FOBT and 8.0% adherent to endoscopy or barium enema.</p> <p><b>Control:</b> At baseline, 38.1% were adherent to FOBT and 12.9% adherent to endoscopy or barium enema. At 3 year follow-up, 40.9% were adherent to FOBT and 11.0% adherent to endoscopy or barium enema.</p>
Ruffin (2007)	General population, MI 50–70 years old 55% Female (Avg) 55% White (Avg)	<p><b>Intervention:</b> Colorectal Web, an interactive program designed to assist adults to establish preferences among CRCS test options using a preference clarification activity based on patient values. (Website: <a href="http://www.colorectalweb.org">www.colorectalweb.org</a>)</p> <p><b>Control:</b> Existing CRC website with standard non-interactive format. Content similar to intervention but not interactive and it did not promote establishing a CRCS test preference. (Website: <a href="http://www.preventcancer.org">http://www.preventcancer.org</a>)</p>	87 87	48 18 34 64 49 15 36 38	FOBT FS COL Any CRCS FOBT FS COL Any CRCS	<p><b>Intervention:</b> At 24 weeks, 64.4% of intervention group completed any CRCS compared to 37.9% of controls (p=0.035). No significant differences in type of CRCS test completed were observed by group.</p> <p><b>Control:</b> 37.9% completed any CRCS with FOBT, FS, or COL.</p>
Segnan (2005)	Patients in GP practices and general population, Italy 55–64 years old 55% Female	<p><b>Intervention 1:</b> Mailed letter inviting patient to complete biennial FOBT, leaflet explaining test and side effects, FOBT with instructions (OR instructions to contact GP to obtain kit), reminder letter, plus additional invitations at 12 and 24 months to nonresponders.</p> <p><b>Intervention 2:</b> Biennial FOBT delivered by GP or screening facility.</p> <p><b>Intervention 3:</b> Mailed letter inviting patient to choose FOBT or “once-only” FS and all materials &amp; contacts described in Intervention 1 above.</p> <p><b>Intervention 4:</b> Mailed letter inviting patient to “once-only” FS with all materials &amp; contacts described in Intervention 1 above.</p> <p><b>Intervention 5:</b> Mailed letter inviting patient to “once-only” FS followed by biennial FOBT 2 years after sigmoidoscopy with all materials &amp; contacts described in Intervention 1 above.</p>	2,266 5,893 3,579 3,650 10,867	30 28 27 28 28	FOBT FOBT FOBT or FS FS FS + FOBT	<p><b>Interventions:</b> Overall, a 28% participation rate was observed across groups with no differences by group observed.</p> <p>Multivariate analyses showed that significantly higher completion rates were observed in groups who were mailed FOBT kits compared to those in the FS + FOBT group; OR= 1.11, 95% CI= 1.00, 1.22 (p=0.049).</p> <p>Completion rates in the FS groups was higher among men than women (OR=1.22, 95% CI=1.14, 1.32) and higher among older (60–64 year olds) compared to younger (55–59 year old) subjects (OR=0.89, 95% CI=0.82, 0.95).</p> <p>Among subjects who were sent FOBT kits, fewer men than women completed the test; (OR=0.82, 95% CI=0.74, 0.90).</p>

Authors	Population/Target	Groups	Sample Size	Adherence		Comments
				(%)	Test	
Tilley (1999)	Employees from an automobile industry; 28 worksites in MI, OH, IN, NY, & PA 96% Male 94% Caucasian	<b>Intervention:</b> Annual mailed screening invitation with educational booklet tailored to employees' screening history and recommendations + follow-up phone call to highlight messages from the Colo-record intervention, answer questions, and encourage screening appointments. Quarterly newsletter with nutrition & screening information + interviews of employees who had participated in the program. <b>Control:</b> Standard worksite screening program.	15 work sites; 2,261 employees	36	Compliance (SR)	<b>Intervention:</b> After adjusting for baseline and worksite characteristics, significant intervention effects were observed at 24 months. For self-reported (SR) compliance: OR=1.46, 95% CI=1.1, 2.0; p=0.006. For medical record (MR) verified compliance: OR=1.71, 95% CI=1.1, 2.7; p=0.012. For self-reported (SR) coverage: OR=1.33, 95% CI=1.1, 1.6; p=0.002. For medical record (MR) verified coverage: OR=1.57, 95% CI=1.2, 2.0; p<0.001 Among employees who were screened in the first year of the trial, percentage with repeat tests increased to 71% compared to 68% of controls. <b>Comments:</b> Compliance is defined in this study as having had all three CRCS tests (FOBT, FS and DRE). Coverage is defined as having had at least one of these tests. Both compliance and coverage outcomes were measured using self-report (SR) and verified using medical records (MR).
			13 work sites; 2,827 employees	61	Compliance (MR)	
Walsh (2005)	Primary care physicians + patients in a managed care organization in San Francisco, CA 50-79 years old 57% Female 59% White, 19% Asian	<b>Intervention:</b> Physicians received educational seminars and "academic detailing" intervention. Patients mailed a personalized letter from PCP encouraging CRCS, educational brochure, FOBT kit with instructions and stamped return envelope. <b>Control:</b> Usual care, no intervention.	50 PCPs	59	FOBT	<b>Intervention:</b> At 1 year, among patients who had been continuously enrolled for the past 2 years, a significantly greater increase in percentage of intervention patients who completed FS from baseline was observed, compared to controls (7.4% vs. 4.4%, P<0.01). No significant difference in percentage who completed any CRCS (9.7% vs. 8.6%, P=.45). <b>Control:</b> A significantly greater increase in FOBT completion was observed in the control group compared to intervention (13.1% vs. 11.4%, p=0.05).
			4, 276 patients	38	SIG	
			44 PCPs	77	Any CRCS	
			3, 717 patients	65	FOBT	
				28	SIG	
		78	Any CRCS			

Table 5

## FOBT Trials Meeting TREND Criteria

Content	Criterion Description	FOBT Studies Meeting Criteria
<b>Design</b>	Study design stated (n=10)	12-20,53
<b>Objectives</b>	Specific objectives/aims/goals or hypotheses stated (n=10)	12-20,53
<b>Outcome</b>	Outcome variables defined (n=10)	12-20,53
<b>Theoretical framework</b>	Conceptual framework or theories used in designing interventions (n=4)	12,15-17
<b>Methods Participants</b>	Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities./clinics, subjects) (n=10)	12-20,53
	Methods of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented (n=9)	12-14,16-20,53
	Recruitment setting (n=9)	12,13,15-20,53
	Settings and locations where the data were collected (n=9)	12-19,53
	Sample description/characteristics includes flow of participants through the study (n=6)	12,13,15-17,53
<b>Interventions</b>	Details of the interventions intended for each study/condition and how and when they were actually administered, specifically including: Content: what was given? (n=10)	12-19,53,54
	Delivery method: how was the content given? (n=9)	12-17,19,53,54
	Unit of delivery: how were subjects grouped during delivery? (n=8)	12-19
	Deliverer: who delivered the intervention? (n=9)	12,13,15-20,53
	Setting: where was the intervention delivered? (n=10)	12-20,53
	Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? Time span: how long was it intended to take to deliver the intervention to each unit? (n=7)	12-16,19,20
	Activities to increase compliance or adherence (e.g., incentives) (n=0)	No studies met this criterion
<b>Results</b>	Study results include negative findings (n=10)	12-20,53
<b>Limitations</b>	Limitations acknowledged (n=7)	12-15,17,18,53
<b>Generalizability</b>	Generalizability (external validity) of the trial findings is described (for example, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues) (n=4)	13,15,16,53
<b>Overall evidence</b>	General interpretation of the results in the context of current evidence and current theory (n=6)	12,13,16-18,53



**Table 6**

## Endoscopy Screening Trials Meeting TREND Criteria

Content	Criterion Description	Endoscopy Studies Meeting Criteria
<b>Design</b>	Study design stated (n=5)	24,25,27-29
<b>Objectives</b>	Specific objectives/aims/goals or hypotheses stated* (n=5)	23-26,28
<b>Outcome</b>	Outcome variables defined (n=7)	23-29
<b>Theoretical framework</b>	Conceptual framework or theories used in designing interventions (n=4)	24,26-28
<b>Methods Participants</b>	Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities./clinics, subjects) (n=6)	23-28
	Methods of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented (n=6)	23-28
	Recruitment setting (n=6)	23-28
	Settings and locations where the data were collected (n=6)	23-28
	Sample description/characteristics includes flow of participants through the study (n=4)	24,25,27,28
<b>Interventions</b>	Details of the interventions intended for each study/condition and how and when they were actually administered, specifically including: Content: what was given? (n=7)	23-29
	Delivery method: how was the content given? (n=6)	23-28
	Unit of delivery: how were subjects grouped during delivery? (n=6)	23-28
	Deliverer: who delivered the intervention? (n=5)	24-28
	Setting: where was the intervention delivered? (n=6)	23-28
	Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? Time span: how long was it intended to take to deliver the intervention to each unit? (n=7)	23-29
	Activities to increase compliance or adherence (e.g., incentives) (n=0)	No studies met criterion
<b>Results</b>	Study results include negative findings (n=6)	23,25-29
<b>Limitations</b>	Limitations acknowledged (n=6)	23-28
<b>Generalizability</b>	Generalizability (external validity) of the trial findings is described (for example, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues) (n=5)	24-28
<b>Overall evidence</b>	General interpretation of the results in the context of current evidence and current theory (n=6)	23-28

**Table 7**

## Trials Promoting Any CRC Screening Test Meeting TREND Criteria

Content	Criterion Description	Any CRC Screening Studies Meeting Criteria
<b>Design</b>	Study design stated (n=15)	30-37,39-45
<b>Objectives</b>	Specific objectives/aims/goals or hypotheses stated* (n=14)	30-35,37-41,43-45
<b>Outcome</b>	Outcome variables defined (n=16)	30-45
<b>Theoretical framework</b>	Conceptual framework or theories used in designing interventions (n=10)	30-34,39,40,42-44
<b>Methods Participants</b>	Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities./clinics, subjects) (n=12)	30-34,36,37,39-45
	Methods of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented (n=14)	30-37,40-45
	Recruitment setting (n=14)	30-37,40-45
	Settings and locations where the data were collected (n=16)	30-45
	Sample description/characteristics includes flow of participants through the study (n=15)	30-35,37-45
<b>Interventions</b>	Details of the interventions intended for each study/condition and how and when they were actually administered, specifically including: Content: what was given? (n=13)	30-38,40-45
	Delivery method: how was the content given? (n=16)	30-45
	Unit of delivery: how were subjects grouped during delivery? (n=16)	30-45
	Deliverer: who delivered the intervention? (n=12)	30-35,38,40-42,44,45
	Setting: where was the intervention delivered? (n=15)	30-35,37-45
	Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? Time span: how long was it intended to take to deliver the intervention to each unit? (n=13)	30-35,37,38,40-42,44,45
	Activities to increase compliance or adherence (e.g., incentives) (n=5)	32,39,43-45
<b>Results</b>	Study results include negative findings (n=13)	30,32-36,38-43,45
<b>Limitations</b>	Limitations acknowledged (n=13)	30-34,36-38,40,42-45
<b>Generalizability</b>	Generalizability (external validity) of the trial findings is described (for example, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues) (n=14)	30-36,38,40-45
<b>Overall evidence</b>	General interpretation of the results in the context of current evidence and current theory (n=13)	30-38,40-42,45