Research Article

Impact of Risk Assessment and Tailored versus Nontailored Risk Information on Colorectal Cancer Testing in Primary Care: A Randomized Controlled Trial

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Abstract

Background: Colorectal cancer screening is effective but underused. Guidelines for which tests are recommended and at what intervals depend on specific risks. We developed a tablet-based Cancer Risk Intake System (CRIS) that asks questions about risk prior to appointments and generates tailored printouts for patients and physicians summarizing and matching risk factors with guideline-based recommendations.

Methods: Randomized controlled trial among patients who: (i) used CRIS and they and their physicians received tailored printouts; (ii) used CRIS to answer questions but received standard information about cancer screening while their physicians received a standard electronic chart prompt indicating they were age-eligible but not currently adherent for colorectal cancer screening; or (iii) comprised a no-contact group that neither used CRIS nor received any information while their physicians received

the standard prompt. Participation in testing was assessed via electronic medical record at 12 months.

Results: Participation in any colorectal cancer testing was three times higher for those who used the CRIS and received any printed materials, compared with no-contact controls (47% vs. 16%; $P < 0.0001$). Among CRIS users ages 50 and older, participation in any testing was higher in the tailored group (53% vs. 44%, $P = 0.023$).

Conclusion: Use of CRIS and receipt of any information facilitated participation in testing. There was more testing participation in the CRIS-tailored than nontailored group.

Impact: Asking patients questions about their specific risk factors and giving them and their providers information just prior to an appointment may increase participation in colorectal cancer testing. Tailoring the information has some added benefit. *Cancer Epidemiol Biomarkers Prev; 24(10); 1523–30. ©2015 AACR.*

Introduction

Colorectal cancer screening has been found to reduce incidence, morbidity, and mortality (1, 2), but is still underused (3–5). Several testing modalities are available; which ones are recommended and at what intervals depend on a person's specific risks. For example, guideline-based recommendations for average-age-risk individuals include options of stool-based testing repeated yearly or colonoscopy every 10 years (if results are normal). In contrast, some individuals with elevated risk should only choose colonoscopy and may need to undergo the procedure at an earlier age or more often than their average-risk counterparts (6, 7). However, delivery of risk-tailored recommendations is not easy. Identifying risk level and therefore appropriate test and schedule requires knowledge of multiple personal and familial factors [e.g., prior polyps or cancer, age at finding or diagnosis, and number and closeness of affected relatives (8) who are not routinely assessed and summarized in patients' medical records (9)].

To facilitate risk-tailored testing in the context of primary care, we developed a tablet-based Cancer Risk Intake System (CRIS) through which patients answer detailed questions about their colorectal cancer risk prior to an appointment. Tailoring algorithms in CRIS generate printed information for patients and their physicians summarizing their risk factors and matching them with guideline-based recommendations. CRIS also assesses patients' concerns about colorectal cancer testing so that they can be summarized in the physician's version of the tailored printout and briefly addressed in the patient's version.

CRIS was based on the Information–Motivation–Behavioral Skills model, which posits three fundamental determinants of risk avoidance behavior: (i) risk reduction information, (ii) motivation, and (iii) behavioral skills (10). To deliver risk and risk reduction information and enhance personal motivation, the printout was tailored to address personalized risks and perceived barriers to engaging in the recommended testing behavior. To increase social motivation, the intervention was designed to

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facilitate and supplement recommendation from the participant's physician in the context of the office visit. CRIS was also designed to be used and the information delivered just prior to an office visit to facilitate behavioral skills for engaging in testing (i.e., receipt of a stool test kit or referral for colonoscopy).

We conducted a three-group randomized controlled trial among patients in a university-based primary care practice to test hypotheses regarding the two major aspects of CRIS—its provision of risk-tailored testing information to patients and their physicians and its extensive assessment of risk factors.

Materials and Methods

Setting

Enrollment occurred in one Family Medicine and two General Internal Medicine practices affiliated with the University of Texas Southwestern (UTSW) Medical Center in Dallas (Dallas, TX). Nearly all patients had Medicare or commercial insurance that covered all or most of the costs of colorectal cancer testing. The UTSW Health System has a major colonoscopy program with timely access to this as a screening choice in addition to stool-based testing. The study was approved by the UTSW Institutional Review Board and registered on clinicaltrials.gov.

Eligibility criteria

A UTSW electronic medical records (EMR) system administrator developed a query to identify potentially eligible patients with upcoming appointments. We identified patients who, according to their records, were eligible for but not currently adherent to routine screening guidelines (i.e., no record of a stool test within the previous year, sigmoidoscopy within 5 years, or colonoscopy within the previous 10 years). We selected 75 years as the upper age limit, as testing is considered reasonable for people whose age and comorbid conditions do not limit life expectancy (11). For the lower age of patients using CRIS, we selected 25, the age by which the National Comprehensive Cancer Network then recommended beginning colonoscopy among carriers of mutations for the most common hereditary cancer (Lynch) syndrome (ref. 12; Newer NCCN guidelines now extend that age down to 20 years; ref. 13). For the tailored and nontailored CRIS groups, we invited patients ages 25 to 49 who were potentially eligible for colon cancer testing due to family history of colorectal cancer or a personal history of inflammatory bowel disease or adenomatous polyp based on patient self-report; whether they were actually in need of testing was determined through CRIS' more extensive risk questions. If patients of these ages used CRIS but no testing was recommended, they were thanked and received a gift card but were not included in the final sample for analyses. We excluded those previously diagnosed with colorectal cancer and, due to the nature of data collection and intervention, those who had no telephone access, were unable to speak or read English, or had severely impaired hearing or speech. For the no-contact control group, we did not select patients younger than 50 because there was no opportunity to ask questions to determine whether their risks warranted earlier-age colorectal cancer testing.

Study design: The study included three groups

Patients in group 1 used the CRIS and the patients and their physicians received tailored printouts summarizing their risk factors and recommendations based on these factors. Those in group 2 used CRIS to answer questions but received standard information about multiple types of cancer screening (e.g., content from an American Cancer Society cancer screening brochure), while their physicians received standard electronic chart prompts for those 50 and over indicating they were age-eligible but not currently adherent. Group 3 was a true no-contact group that neither used CRIS nor received any information and whose physicians received the standard electronic prompts during their visits. Because we did not collect risk data from the no-contact controls, we were not able to determine whether the tests they received were guideline-concurrent for their personal risk levels.

Analyses reported here were guided by our hypotheses that, within 12 months of the baseline visit: (i) The CRIS tailored recipients would have higher rates of risk-appropriate and any type of testing, compared to nontailored recipients (group 1 vs. 2), and (ii) those who used the CRIS and received any type of information (groups 1 and 2) would have higher participation in any type of testing, compared with controls (group 3).

CRIS' assessment of risk factors identified a small number of people in need of testing younger than the age of 50 years. Because it is possible that these subgroups, those with risks warranting testing at an earlier age as opposed to those in the normal screening age group, might react differently to tailored information, we assessed participation in testing separately for participants ages 50 years and older and those younger than 50 years.

Figure 1 shows details regarding patient identification, recruitment, and participation rates. Patients in the CRIS tailored and nontailored groups were contacted and consented to be in the study. They accepted invitations to arrive 30 minutes prior to their appointments to use CRIS to enter their risk factor data and receive information—either tailored or nontailored, depending on group assignment—about colorectal cancer testing. Patients in the no-contact control group had no interaction with the study team and received only usual care when they presented for appointments. They did not use CRIS to input data about their personal risk factors nor did they receive any printed information. Consistent with usual care at UTSW, Epic records for those 50 years and older displayed physician prompts indicating they were age-eligible but nonadherent for colorectal cancer screening. Therefore, their physicians received the same routine prompts as those in the nontailored CRIS group.

Because the decision whether to order colorectal cancer testing and which test to select is ultimately controlled by the primary care physician, to decrease the risks of contamination, we made physician the unit of randomization. This meant that patients were preidentified as potential CRIS-tailored intervention or nontailored group participants before they were invited, depending on the group to which their physician was assigned. There were a total of 14,080 patients with upcoming appointments with no evidence of screening adherence in their medical records. Of these, 3,864 were reserved for drawing the no-contact control sample and 10,216 received letters from the clinics signed by the medical director saying they might be invited for participation in a "study of beliefs and practices about cancer prevention and early detection" (but not specifically about colorectal cancer). Letters provided a toll-free number to opt out of contact ($n = 96$; ref. 14). One week after the mailing, research assistants began calling patients who received letters to explain the study, verify eligibility and, if the patient agreed, arrange a meeting at the clinic 30 minutes prior to the appointment.

As shown in Fig. 1, we reached and invited 2,989 patients who were potentially eligible. Of these, 1,032 agreed to participate and
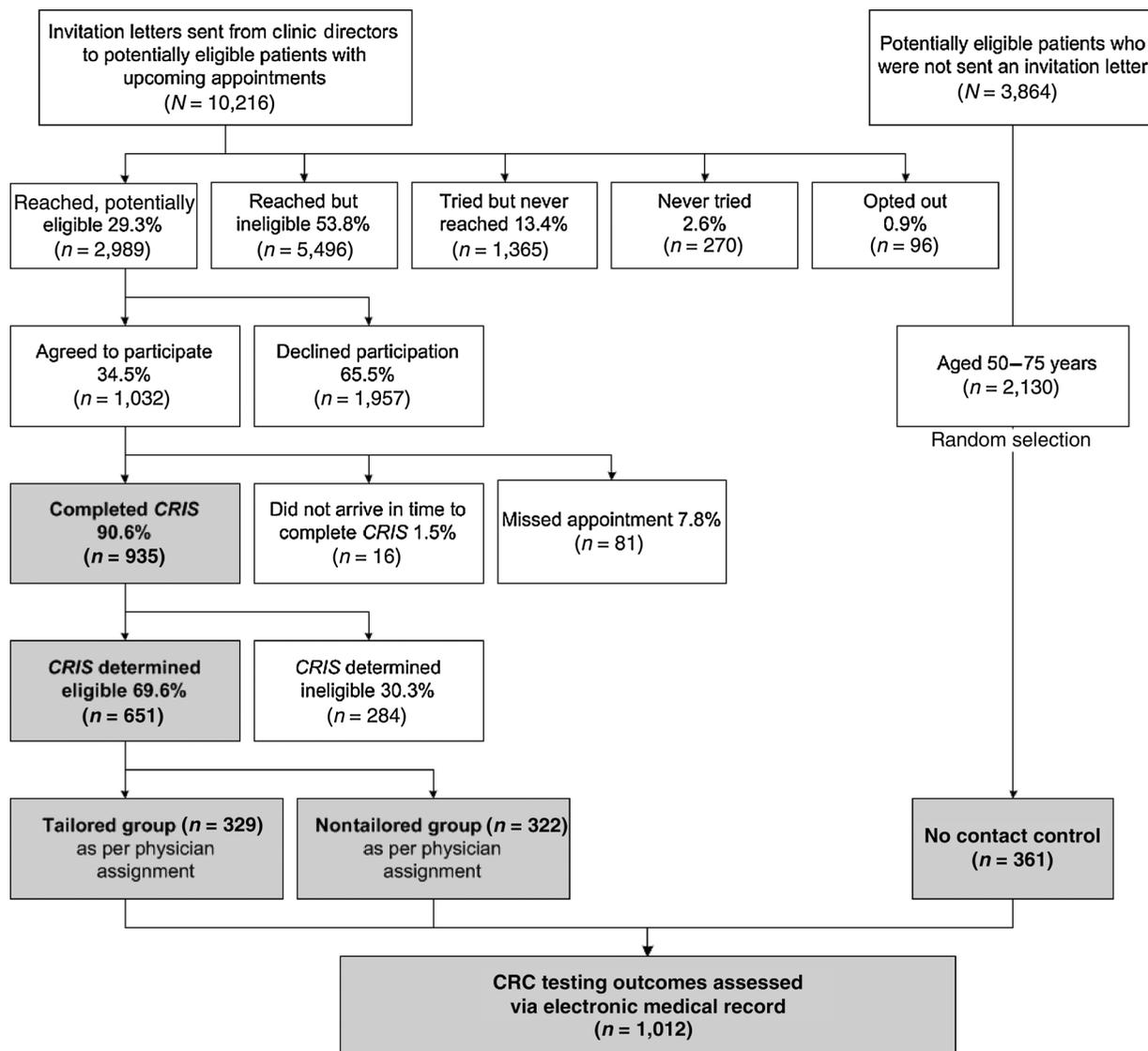
Figure 1.
CRIS study CONSORT diagram.

935 arrived in time to use the CRIS program. Research assistants met patients, obtained consent, and facilitated use of the touch-screen tablet through which CRIS collected risk data and either informed they were not in need of screening ($n = 284$) or generated printouts recommending risk-based screening ($n = 651$). The research assistants handed participants tailored ($n = 329$) or nontailored ($n = 322$) printouts. Twenty-one patients had complicated medical histories for which programming in the CRIS algorithms could not recommend a specific testing regimen; therefore, the final analytic sample for risk-appropriate screening was $n = 630$.

Of the 2,130 patients in the no-contact group who were ages 50 to 75 years, we randomly selected 363. We defined baseline visit for the no-contact control group as the first appointment date when they became eligible for study participation. Two were excluded (one did not have an electronic medical record and one patient was a member of the study team). Final analytic sample for the no-contact group was 361 patients.

Interventions and measures

The CRIS touch-screen program collected demographics, personal medical history, including previous testing, detailed family history, and concerns about testing. Average time to complete CRIS was ≤ 10 minutes. CRIS then used these data to determine risk-appropriate testing option(s) and generate patient and physician printouts tailored to this information (or a nontailored printout for the comparison group and standard electronic chart prompts for their physicians). Algorithms linking responses to risk questions with guideline-based recommendations were developed in a structured process by an expert panel including representatives from primary care, gastroenterology, genetic counseling, and health communications and included extensive pretesting. We created iterative questions measuring risk factors such as family history of colorectal cancer and inflammatory bowel disease. For example, if the patient had inflammatory bowel disease, follow-up questions assessed disease duration (because guidelines recommend special testing for an 8- to

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10-year history) and, if she had family history, there were questions about degree of relation and age at diagnosis. For each risk category, we created recommendation messages based on national guidelines.

The one-page CRIS-tailored printouts included a summary of patients' personal risks, appropriate test(s) based on risk factors, and concerns about testing. The message for those at average risk was "you may choose to have a stool blood test, a colonoscopy, or another option your doctor recommends," whereas those whose risks warranted colonoscopy did not include the stool test option. The physician also received a version of the CRIS printout that summarized the patient's individual risk factors, the guideline-recommended testing option(s), and any concerns or barriers to screening that were reported. Patients in the CRIS nontailored group received nontailored content from an American Cancer Society brochure about cancer screening in general. Physicians of patients in the nontailored and no-contact control groups received our system's routine electronic chart prompts indicating patient age of 50 years and over, and no recent colorectal cancer testing was documented in the record.

Outcome assessment

All patients from the three groups ($n = 1,012$) had their EMRs audited 12 months postbaseline to determine whether they had received risk-appropriate colorectal cancer testing and any type of colorectal cancer testing (Hypothesis 1). We first performed analyses including all subjects in the tailored and nontailored groups, including those who were under the age of 50 years. Then, we ran a second set of analyses excluding the 57 patients under 50 in the tailored and nontailored groups, such that the age ranges in the three groups would be comparable. For these analyses, we created two yes/no variables. For risk-appropriate testing, the binary outcome values were: (i) participation in any risk-appropriate CRIS-recommended test, or (ii) either no testing or participation in a nonrecommended test (e.g., stool-based test for an individual whose risk profile indicated need for colonoscopy). For "any testing," values for the binary outcome were: (i) participation in any testing, or (ii) no participation in testing within 12 months.

Statistical analysis

For Hypothesis 1 (participation between patients in the tailored vs. nontailored groups who used the CRIS), mixed-effects logistic regression models were fitted with group assignment as the main independent variable. Clinic physician was included as a random cluster effect. Multivariate analyses were conducted to identify significant factors associated with risk-appropriate screening and any screening using backward selection mixed-effect logistic regression. All the demographic variables and group assignment were included as covariates in multivariate analyses using physician as the random cluster effect.

For Hypothesis 2, comparing receipt of any colorectal cancer test between all patients who used the CRIS and received either a tailored or nontailored printout (groups 1 and 2, $n = 651$) vs. the no-contact group ($n = 361$), we fitted a mixed-effects logistic regression model, with group assignment as the main independent variable and physician as the random cluster effect. Age and gender were also included as covariates. $P \leq 0.05$ were considered to be statistically significant. Analyses were performed using SAS software, Version 9.2 of the SAS System for Windows (SAS Institute Inc.). PROC GLIMMIX in SAS was used to fit the mixed-effects logistic regression models.

Results

Patient characteristics

Sample characteristics are shown in Table 1 (for all ages) and Table 2 ($\geq$50 years). Overall, participants were 62.9% female, with no significant difference in gender among the three groups ($P = 0.08$). There was significant difference in mean age among the three groups ($P = 0.0002$) adjusting for multiple comparisons by Bonferroni correction ($\alpha = 0.017 = 0.05/3$), with the tailored group being slightly younger than patients in the no-contact control group ($P < 0.0001$, 57.5 vs. 60.3, respectively). The proportions of patients under the age of 50 years in the tailored and nontailored groups were small and did not differ significantly (10.6% and 6.8% respectively; $P = 0.086$). Although race/ethnicity and education level were similar in the tailored and nontailored groups, with the majority of participants being

Table 1. Patient characteristics (all ages)

	Tailored, N = 329, n (%)	Nontailored, N = 322, n (%)	No contact, N = 361, n (%)	Overall, N = 1,012, n (%)	P[a]
Age, y, mean (SD)[b]	57.5 (±8.6)	59.1 (±7.9)	60.3 (±6.5)	59.0 (±7.7)	0.04
Age, under <50	35 (10.6)	22 (6.8)	—	57 (8.8)	0.086
Sex, female	205 (62.3)	216 (67.1)	216 (59.8)	637 (62.9)	0.08
Race/ethnicity					
NH white	205 (62.3)	218 (67.7)	—	423 (65.0)	0.53
NH black	76 (23.1)	63 (19.6)	—	139 (21.4)	
Hispanic	31 (9.4)	26 (8.1)	—	57 (8.8)	
Asian/NA/Hawaiian/PI	13 (4.0)	10 (3.1)	—	23 (3.5)	
Other/refused	4 (1.2)	5 (1.6)	—	9 (1.4)	
Education					
<4 years of college	163 (49.5)	151 (46.9)	—	314 (48.2)	0.45
≥4 years of college	165 (50.2)	171 (53.1)	—	336 (51.6)	
Refused	1 (0.3)	0 (0.0)	—	1 (0.2)	
Employment					
Full-time or part-time	239 (72.6)	191 (59.3)	—	430 (66.1)	0.00
Unemployed	89 (27.1)	131 (40.7)	—	220 (33.8)	
Refused	1 (0.3)	0 (0.0)	—	1 (0.2)	

Abbreviations: NH, non-Hispanic; NA, Native American; PI, Pacific Islander.
[a]P value based on the comparison of the tailored and non-tailored groups with a generalized linear mixed-effects model.
[b]Measured at first eligible appointment date.

Table 2. Patient characteristics (age ≥50)

	Tailored, N = 294, n (%)	Nontailored, N = 300, n (%)	No contact, N = 361, n (%)	Overall, N = 955, n (%)	Pa
Age, years, mean (SD)b	59.2 (±7.2)	60.2 (±6.9)	60.3 (±6.5)	59.9 (±6.9)	0.102
Sex, female	180 (61.2)	197 (65.7)	216 (59.8)	593 (62.1)	0.697
Race/ethnicity					
NH white	181 (61.6)	205 (68.3)	—	386 (65.0)	0.319
NH black	67 (22.8)	56 (18.7)	—	123 (20.7)	
Hispanic	30 (10.2)	26 (8.7)	—	56 (9.4)	
Asian/NA/Hawaiian/PI	12 (4.1)	8 (2.7)	—	20 (3.4)	
Other/refused	4 (1.4)	5 (1.7)	—	9 (1.5)	
Education					
<4 years of college	151 (51.4)	142 (47.3)	—	293 (49.3)	0.290
≥4 years of college	142 (48.3)	158 (52.7)	—	300 (50.5)	
Refused	1 (0.3)	0 (0.0)	—	1 (0.2)	
Employment					
Full-time or part-time	220 (71.4)	177 (59.0)	—	387 (65.2)	0.001
Unemployed	83 (28.2)	123 (41.0)	—	206 (34.7)	
Refused	1 (0.3)	0 (0.0)	—	1 (0.2)	

Abbreviations: NH, non-Hispanic; NA, Native American; PI, Pacific Islander.
aP value based on the comparison of the tailored and non-tailored groups adjusting for cluster effect (clinic provider) with a generalized linear mixed-effects model.
bMeasured at first eligible appointment date.

non-Hispanic white and having four or more years of college, employment was significantly higher among tailored than non-tailored recipients (72.6% vs. 59.3%; $P = 0.0003$; because the control group provided no patient-reported data, we do not have information about their race/ethnicity, educational attainment, or employment.)

Hypotheses 1, that there would be significantly higher participation in risk-appropriate or any type of colorectal cancer testing at 12 months post appointment in the CRIS-tailored versus the nontailored group, was partially upheld among participants ages 50 years and older. As shown in Table 3, the full CRIS tailored and nontailored groups had similar participation in risk-appropriate testing (47.9% and 41.6%, respectively; $P = 0.11$) and in any type of testing (50% and 44%, respectively; $P = 0.3$). In the tailored and nontailored groups combined, only 3.3% of those screened had a test that differed from what the CRIS intervention recommended (e.g., they had a stool-based test when, according to the guidelines, they should have had a colonoscopy). Among those at average risk for colorectal cancer who could have chosen either test option, 77.1% had a colonoscopy.

However, as shown in Table 4, when analyses included only those ages 50 years and older in the two CRIS groups, participation in any type of testing was significantly higher among the tailored than the nontailored group (53% vs. 44%; $P = .023$). Although participation in risk-appropriate testing approached significance in univariate analysis (51% vs. 43%; $P = 0.068$), the P value was 0.11 when age entered the stepwise regression.

Table 5 shows results for the very small group ($n = 57$) of tailored and nontailored group members younger than 50 years, between which no differences in testing were found.

Hypotheses 2, that there would be significantly higher participation in any testing among patients who used CRIS and received any printout (e.g., tailored and nontailored groups) versus those in the no-contact control group, was confirmed. Participation in any type of testing by 12 months after visit was only 16% in the no-contact control group. There were significant differences in the proportion of having any type of testing between CRIS users and no-contact controls in all patients ($P < 0.0001$) and patients with ages 50 to 75 years ($P < 0.0001$).

Discussion

CRIS is not the first tailored intervention to promote colon cancer testing within the context of primary care (15–22). Most of these previous colorectal cancer screening promotion interventions have assessed multiple behavioral determinants and delivered tailored messages developed to enhance perceived benefits and reduce barriers to undergoing any of the US Preventive Task Force-recommended screening options. None of which we are aware have assessed risks thoroughly enough to determine whether resulting test participation is risk-appropriate. The unique focus of CRIS is its extensive assessment of risk factors and complex algorithms tailoring risk information to guidelines for specific test modality and schedule rather than a "one-size-fits-all" approach that recommends the same test for everyone regardless of risk level. The strategy is to encourage either stool-based or endoscopic screening for individuals at average risk, but only colonoscopy for those with elevated risks, perhaps starting earlier or repeating more often, depending on specific risk factors.

Table 3. Mixed-effects logistic regression model analysis of CRIS group effect on colorectal cancer testing within 12 months of baseline visit (all ages)

12-Month colorectal cancer testing outcome	Tailored, N = 329, n (%)	Nontailored, N = 322, n (%)	Pa
			0.11
Risk-appropriate testingb	150 (48)	132 (42)	
No risk-appropriate testing	163 (52)	185 (58)	
			0.13
Any testing	164 (50)	141 (44)	
No testing	165 (50)	181 (56)	

aP value tested the group effect on the colorectal cancer testing while adjusting for cluster effect (clinic provider).
bTwenty-one patients had complicated medical histories for which programming in the CRIS algorithms could not recommend a specific testing regimen; therefore, the final analytical sample for risk-appropriate testing was $n = 630$.

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Table 4. Mixed-effects logistic regression model analysis of CRIS group effect on colorectal cancer testing within 12 months of baseline visit (age ≥50)

12-Month colorectal cancer testing outcome	Tailored, N = 294, n (%)	Nontailored, N = 300, n (%)	P^a
			0.11
Risk-appropriate testing[b] ≥ 50	144 (51)	128 (43)	
No risk-appropriate testing ≥ 50	141 (49)	170 (57)	
			0.023
Any testing ≥ 50	156 (53)	131 (44)	
No testing ≥ 50	138 (47)	169 (56)	

[a]P value tested the group effect on the colorectal cancer testing while adjusting for cluster effect (clinic provider).
[b]Eleven patients had complicated medical histories for which programming in the CRIS algorithms could not recommend a specific testing regimen; therefore, the final analytical sample for risk-appropriate testing was n = 630.

Our unique study design allowed us to compare three groups of patients: those who (i) used the CRIS to answer questions and they and their physicians received tailored information before their visit, (ii) used CRIS and received nontailored information while their physicians received standard electronic prompts, and (iii) did not use CRIS or receive any information and whose physicians received the standard prompts. We were therefore able to compare the effect of tailored versus nontailored information as well as using the CRIS and receiving any information versus no contact or information for patients.

Findings showed a benefit in using CRIS and receiving any information. Patients in the tailored and nontailored groups were roughly three times more likely to undergo any type of testing than were members of the control group. There may be several reasons why there was such a large difference between those who actively participated in the study and used CRIS versus those who were not contacted. Researchers have previously suggested that recruitment into screening studies and data collection may interact with an intervention, such that the intervention effect, assessed at follow-up, may be influenced by or even depend upon the presence of a pretest (23).

Participating in the study may have produced a Hawthorne effect (24) in which patients who received information about screening and gave permission for their records to be evaluated by study staff behaved differently because they knew they would be observed. Another potential explanation for differences between the CRIS groups and the no-contact group is that answering multiple questions about risk factors and previous testing history may have acted as an intervention or had a priming effect prior to the visit. Indeed, previous studies have shown that mere measurement may promote health behaviors (25), and a number of randomized intervention trials have found changes in cancer screening outcomes among individuals in comparison groups who completed data collection but did not receive tailored interventions (16, 26, 27).

Patients' use of the CRIS right before the office visit and getting any printed information about screening may have prompted them to think more about screening before their visits and this, rather than whether their information was tailored, may explain why active study participants who used the CRIS were so much more likely to receive testing than were the no-contact controls. CRIS users may have also been more likely to talk with their providers about screening or be more open to physician recommendations. In our evaluation of an earlier version of CRIS that addressed multiple risks, screening, and prevention behaviors, CRIS users reported more screening-related discussions with their providers (28), compared with a usual-care group. Whatever the explanation, these findings highlight the importance of including a true control group in experimental designs.

The difference we found between participation in testing among those 50 years and older in the tailored versus nontailored groups was real but much smaller. These findings suggest that CRIS' extensive assessment of risk factors was more important than its provision of risk-tailored information to patients and physicians.

Strengths and limitations

Findings of the study highlight the importance of including a true control group, which minimizes threats to validity from pretest sensitization and Hawthorne effects (29). Whereas the expense of data collection often precludes use of such a design, our use of electronic medical records for drawing the sample and assessing the outcomes enabled us to employ it. However, although the no-contact control group is an important and strong feature of the research design, it was not perfect. For the no-contact group, we could not select and include patients younger than 50 years because there was no opportunity to ask questions to determine whether their risks warranted earlier age colorectal cancer testing. Therefore, findings from this group can only be generalized to those ages 50 years and over.

Limitations of the study also include the clinical setting in which it was conducted. All patients were insured, with ready access to colonoscopy and physicians inclined to recommend the procedure. Because the vast majority of those screened had colonoscopies, which are guideline-concordant with any risk level, there was little opportunity to find differences in receipt of nonrecommended tests. From these findings, we cannot determine whether, in lower-resource settings or those with a "FIT-first"

Table 5. Mixed-effects logistic regression model analysis of CRIS group effect on colorectal cancer testing within 12 months of baseline visit (age <50)

12-Month colorectal cancer screening outcome	Tailored, N = 35, n (%)	Nontailored, N = 22, n (%)	P^a
			0.852
Risk-appropriate screening[b] <50	6 (21)	4 (21)	
No risk-appropriate screening <50	22 (79)	15 (79)	
			0.146
Any screening <50	8 (23)	10 (45)	
No screening <50	27 (77)	12 (55)	

[a]P value tested the group effect on the colorectal cancer testing while adjusting for cluster effect (clinic provider).
[b]Ten patients had complicated medical histories for which programming in the CRIS algorithms could not recommend a specific testing regimen; therefore, the final analytical sample for risk-appropriate screening was 47.

strategy, receipt of tailored recommendations would have resulted in different rates of any screening and guideline-concordant testings, driven by stool testing.

Another feature of the clinical setting is that the prevalence of screening was already relatively high and growing (from 62% in 2012 to 81% in 2014 in the General Internal Medicine practice). Patients eligible for the trial due to nonadherence might have over-represented the most recalcitrant who have previously refused or failed to complete colorectal cancer testing. From this study, we cannot determine whether rates would have been triple among those who used the CRIS or the tailored/nontailored difference in testing would have been similarly in a more "screening-naïve" setting.

Another limitation is that risk factor assessment and generation of tailored screening recommendations occurred in "real time" just prior to a primary care visit. Had the CRIS assessment been completed days or weeks prior to the appointment, the difference between groups who did versus did not use CRIS might not have been as strong, or the difference between those receiving tailored versus nontailored information may have been stronger.

Among participants ages 50 to 75 years, participation in any testing was significantly higher among the tailored group and difference in risk-appropriate testing approached significance. We looked separately at this age group for two reasons. First, they were mostly different in size. Also, because one's risk level had to be higher-than-average to qualify for receipt of a testing recommendation, we thought that the under-50 individuals might differ meaningfully from their counterparts in the routine-screening age group. Our study was limited by the fact that we had enough power to identify significant differences in the over-50, but not the younger-than-50 sample.

Conclusions

In our study setting, asking patients specifics about their family and personal risk factors and giving them and their providers any information about testing just prior to an appointment increased their likelihood of participation in colorectal cancer testing after the visit. Among those 50 years and over, risk-tailored colorectal cancer testing information given to patients and their physicians seems to have an additional benefit.

Disclosure of Potential Conflicts of Interest

S. Gupta is a scientific advisory board member for Exact Sciences. No potential conflicts of interest were disclosed by the other authors.

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