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Aid-Assisted Decision-Making and Colorectal Cancer Screening:

A Randomized Controlled Trial

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Abstract

Background—Shared decision-making (SDM) is a widely recommended yet unproven strategy for increasing colorectal cancer (CRC) screening uptake. Previous trials of decision aids to increase SDM and CRC screening uptake have yielded mixed results.

Purpose—To assess the impact of decision aid–assisted SDM on CRC screening uptake.

Design—RCT.

Setting/participants—The study was conducted at an urban, academic safety-net hospital and community health center between 2005 and 2010. Participants were asymptomatic, average-risk patients aged 50–75 years due for CRC screening.

Intervention—Study participants (*n*=825) were randomized to one of two intervention arms (decision aid plus personalized risk assessment or decision aid alone) or control arm. The interventions took place just prior to a routine office visit with their primary care providers.

Main outcome measures—The primary outcome was completion of a CRC screening test within 12 months of the study visit. Logistic regression was used to identify predictors of test completion and mediators of the intervention effect. Analysis was completed in 2011.

Results—Patients in the decision-aid group were more likely to complete a screening test than control patients (43.1% vs 34.8%; *p*=0.046) within 12 months of the study visit; conversely, test uptake for the decision aid and decision aid plus personalized risk assessment arms was similar (43.1% vs 37.1%; *p*=0.15). Assignment to the decision-aid arm (AOR 1.48; 95% CI=1.04, 2.10),

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black race (AOR 1.52, 95% CI=1.12, 2.06) and a preference for a patient-dominant decisionmaking approach (AOR, 1.55; 95% CI=1.02, 2.35) were independent determinants of test completion. Activation of the screening discussion and enhanced screening intentions mediated the intervention effect.

Conclusions—Decision aid–assisted SDM has a modest impact on CRC screening uptake. A decision aid plus personalized risk assessment tool is no more effective than a decision aid alone.

Introduction

Colorectal cancer remains a leading cause of cancer-related morbidity and mortality, despite recent declines in both incidence and mortality.[1,2] A compelling body of evidence has accumulated to suggest that screening is the most effective and rational strategy for further reducing the public health burden of this deadly yet potentially preventable disease. Consequently, screening is now endorsed by most, if not all, authoritative groups, including the U.S. Preventive Services Task Force, American Cancer Society, and U.S. Multi-society Task Force on Colorectal Cancer.[3,4] These endorsements, combined with more-widespread coverage by medical insurers and heightened public awareness efforts, have contributed to a steady increase in screening prevalence in recent years. Nevertheless, more than one third of age-eligible Americans have never been screened.[5]

Eliciting patient preference within the context of shared decision-making (SDM) has been advocated as a potentially effective strategy for increasing patient acceptance and adherence to CRC screening recommendations.[3,4] Engaging patients to participate in the decision-making process when confronted with preference-sensitive choices related to CRC screening is also fundamental to the concept of patient-centered care.[6–8] CRC screening is ideally suited for this approach given the availability of multiple options with distinct advantages and disadvantages, the lack of consensus regarding an optimal cost-effective strategy, and limited effectiveness of the more-traditional paternalistic approach in which providers assume full responsibility for the decision-making process. Further support is derived from studies finding that both patients and providers hold distinct preferences for the various screening options,[9–14] that providers often misperceive patient preferences,[10] and that many patients endorse an SDM approach for CRC screening.[15,16]

Despite a compelling rationale, SDM has been difficult to implement in routine clinical practice in part due to lack of time, resources, clinician expertise and suitability for certain patients or clinical situations.[17,18] The use of patient-oriented decision aids has been proposed as a potentially effective strategy for circumventing several of these barriers.[8,19] Decision aids help patients make informed, value-concordant choices about a particular course of action based on an understanding of potential benefits, risks, probabilities and scientific uncertainty.[20] Studies to date have shown that decision aids for CRC screening enable users to identify a preferred screening option,[11,16,21–25] reduce decisional conflict[22,24] and increase interest in screening.[21,23,25,26] The authors have recently shown that decision aids can also facilitate SDM by increasing patient knowledge, increasing satisfaction with the decision-making process, enhancing screening intentions, and improving the quality and efficiency of the patient–provider encounter.[16,27]

The extent to which decision aids increase CRC screening uptake, however, is less well-defined.[21–25,28] Hence, the primary objective of this study was to test the hypothesis that decision-aid users were more likely to complete a CRC screening test than non-users. Unlike previous such studies, effectiveness was evaluated within the context of a shared rather than informed decision-making framework.[29] Based on evidence suggesting that individualized risk communication might also increase uptake of screening tests,[30] a secondary objective was to test the hypothesis that a modified version of the decision aid which incorporated a

validated personalized risk assessment tool for CRC would be more effective than the decision aid alone for increasing test completion. .

Methods

Study Population and Recruitment Process

The study sample was made up of average-risk primary care patients cared for at Boston Medical Center or the South Boston Community Health Center. Patients were deemed eligible if they were aged 50–75 years and due for CRC screening.[3,4] Patients meeting any of the following criteria were excluded: (1) prior CRC screening by any method other than fecal occult blood testing (FOBT); (2) high-risk condition (personal history of colorectal cancer or polyps, family history of colorectal cancer or polyps involving one or more first-degree relatives, or chronic inflammatory bowel disease); (3) lack of fluency in written and spoken English; or (4) comorbidities that preclude CRC screening by any recommended method, as determined by primary care provider (PCP). The decision to exclude patients with prior screening other than FOBT was based on concerns that such patients may be more likely to adhere to repeat testing than previously unscreened patients. Conversely, patients with prior FOBT were included because of institutional data suggesting that they were less likely to adhere to repeat testing and thus potentially more likely to consider alternative screening options after reviewing the decision aid.

Three different recruitment strategies were used during the course of the study. The vast majority of patients (*n*=796) were recruited using an "opt-out" approach in which patients due for screening were identified from monthly audits of the electronic medical record 2–4 weeks prior to a scheduled office visit and contacted directly by telephone by a research assistant if deemed appropriate by the patient's PCP. Those expressing interest were provided with a brief overview of the study, evaluated for eligibility and invited to participate. Two other PCP-mediated strategies, including an "opt-in" electronic flagging approach (*n*=12) and "opt-in" letter approach (*n*=17), were used initially but were discontinued after 6 months due to low enrollment. Details of each of these approaches and their relative cost effectiveness have been previously published.[31]

Setting

The study was conducted at two urban ambulatory care sites. The first, Boston Medical Center (BMC), is an urban, nonprofit academic medical center affiliated with the Boston University School of Medicine, which serves a mostly low-income, racially/ethnically-diverse patient population. The second, the South Boston Community Health Center (SBCHC), is a community health center affiliated with BMC, which serves a mostly non-Hispanic white, low-income patient population. Both sites use the same electronic medical record system (Centricity™). The study protocols were approved for both sites by the Boston University Medical Campus IRB.

Provider Characteristics and Training

Sixty-one primary care providers, including 47 board-certified general internists, 11 board-certified family physicians and three nurse practitioners, practicing at both BMC and the SBCHC participated in the study. Pre-trial training seminars and annual refreshers were conducted at both sites to educate providers about the current status of CRC screening highlighting the recommendation for SDM, provide an overview of the study design, and elicit support. The meetings also provided a venue for informing participating providers about the status of recruitment and addressing any logistic problems that they experienced related to the study. All providers attended at least one of the meetings. By design, no formal training in SDM was undertaken.

Study Design

An RCT was conducted between April 2005 and December 2010 to evaluate the impact of the decision aid on SDM and screening behavior. Eligible patients were instructed to arrive 1 hour before a prearranged chronic care visit with their primary care provider. Each received a pre-visit reminder call to ensure that the patient had no acute medical illnesses that would preclude the CRC screening discussion.

After informed consent was obtained, patients were administered a 10-minute, paper-based pretest that assessed knowledge, beliefs, attitudes and behaviors related to CRC screening, as well as level of desire for participating in decision-making related to CRC screening. The pretest was administered using a structured interviewer format by one of four trained research assistants in a private office located in one of the ambulatory care clinics of the participating sites. After completing the pretest, patients were randomized to one of two intervention arms (decision aid alone or decision aid plus *YourDiseaseRisk* (YDR; personalized risk assessment tool with feedback) or usual care with stratification by provider. Patients randomized to the usual care arm reviewed a modified online version of "9 Ways to Stay Healthy and Prevent Disease", which discussed generic lifestyle changes other than screening for minimizing risk of preventable diseases.

Immediately after completing the interactive computer session, patients met with their providers to discuss screening and identify a preferred screening strategy. Providers received written notification hand-delivered by all the patients acknowledging that they were participating in the "CRC decision aid study" at the time of the visit to ensure that screening was discussed; no information was provided regarding preferences or factors influencing choice for patients in the intervention arms. Before leaving the clinic, patients completed a 10-minute, paper-based post-test, again using a structured interviewer format, which assessed whether CRC screening was discussed, whether a screening strategy was chosen, patient satisfaction with the decisionmaking process, and screening intentions; the post-test also reassessed knowledge, beliefs, and attitudes related to CRC screening.

Decision Aid

Details of the decision-aid's theoretic framework, development, content and usability testing have been previously published[16] In brief, the DVD-formatted tool employed an audiovisual and touch-screen design to simplify use for individuals with limited literacy and/or computer skills. The tool consists of a series of modules, in which professional actors playing the role of a black, Hispanic female moderator and a white, non-Hispanic male physician convey relevant information via on-screen video, animation and/or graphics.

The modules include: (1) an introductory segment that briefly discusse the importance of screening, purpose of the tool and instructions in its use; (2) a brief overview of the epidemiology of CRC, natural history, benefits of screening, availability of multiple screening options, and the lack of consensus regarding a best screening method; (3) brief descriptions of five screening methods (FOBT, flexible sigmoidoscopy, the combination of FOBT plus flexible sigmoidoscopy, DCBE and colonoscopy) endorsed at the time the study was initiated[32–34]; (4) audio and visual comparisons of each method with respect to individual test features; (5) a summary of the different test features for each method with optional links to additional information about the preparation or test itself, as well as vignettes from patients describing their experience with a particular test; and (6) a decision-making module where users are asked to identify a screening preference (including no screening) and rank-order test features influencing their selection; and (7) a concluding segment in which the narrator encourages the user to discuss screening and their preferences with their doctor.

A modified version of the decision aid was also created that incorporated the web-based YDR CRC risk assessment tool (www.yourdiseaserisk.wustl.edu), in order to assess whether personalized 10-year CRC risk feedback influenced decision-making. The risk estimate was conveyed using qualitative framing ("very much below average risk" to "very much above average risk") with accompanying suggestions for behavior modifications that might reduce risk, including a strong recommendation for screening, regardless of risk. The decision aid took between 20 and 30 minutes to complete, depending on which of the optional segments users chose to review.

Measures

The primary outcome measure was completion of a CRC screening test within 12 months of the study visit. Because of long waiting times (3 months) and high cancellation rates (>20%) at the start of the study, the 12-month time frame was selected a priori to allow sufficient time for patients who needed to cancel an endoscopic screening procedure to complete the rescheduled examination. Secondary outcomes included test uptake at 6 months and test ordering at 1, 3, 6 and 12 months post-study visit.

All outcomes were tracked using electronic clinical data reporting systems, which captured results for all endoscopic procedures, imaging studies and FOBT completed at the participating sites, and evaluated using an intention-to-treat analysis. Other outcomes of interest included the identification of predictors of test completion and mediators of the intervention effect. Mediators were defined as measures that: (1) significantly changed as a consequence of the intervention (e.g., screening intentions[16]); (2) had a significant independent effect on the primary outcome of interest (i.e., test completion); and (3) diminished the intervention's effect on the primary outcome in the adjusted model.[35]

Sample Size and Power Considerations

Sample size and power considerations focused on a two-group comparison of the decision aid alone versus control study arms for the primary outcome of CRC screening test completion at 12 months. Based on crude estimates of baseline test uptake, it was determined that a target sample of 275 subjects per arm provided greater than 80% power of detecting a 54% versus 40% difference in the percentage of patients completing a CRC screening test within 12 months of the study visit.

Statistical Analyses

Data analysis was completed in 2011. As a check on randomization, the three study groups were first compared on demographic characteristics, prior FOBT screening, risk perception and desired role in decision-making through the chi-square test of independence. Chi-square tests were also used to compare the percentage of patients in the decision aid –alone group to those in the control group or decision aid plus YDR group who either had a test ordered or completed at each of the designated time points. Logistic regression was used to identify patient-level determinants of test completion and mediators of the intervention effect. Details regarding measurement of patient knowledge, satisfaction with the decision-making process and screening intentions were previously published.[16] Variables exhibiting a significant association with test completion in univariate analyses at the two-tailed $p<0.05$ level were included as covariates in the multivariate analyses. Sobel tests were performed to assess significance for the mediation analyses.[36] All other analyses were conducted using SAS 9.2.

Results

Patient Characteristics

Of the 13,518 patients identified as potentially eligible for screening because of age, 7619 (56%) were deemed ineligible (mostly due to prior screening [*n*=6073]) and 5074 (38%) were excluded (Figure 1). Reasons for exclusion included: inability to contact (*n*=4321); disinterest (*n*=290); scheduling conflict (*n*=305); and failure to keep appointment (*n*=158). The remaining 825 patients (52% of eligible subjects contacted) were enrolled and randomized to decision aid–alone (*n*=269); decision aid plus YDR (*n*=280); or control (*n*=76) arms.

The three study arms were well-balanced with respect to all baseline characteristics, including patient age, gender, ethnicity, race, marital status, education, insurance coverage, prior FOBT, and decision-making preference (Table 1). Overall, the study group was mostly aged <65 years (84%); female (59%); non-Hispanic (95%); and black (62%), with at least a high-school degree (78%). Only 36% were married or living with a partner. Although most had some form of healthcare insurance (98%), nearly two thirds were covered by Medicare, Medicaid or Massachusetts' "Free Care" (now "Commonwealth Care") program. Most (87%) had no prior FOBT. The majority preferred a patient-dominant (27%) or shared-decision-making approach (53%) for selecting a preferred CRC screening option.

Intervention Effects on Test Ordering and Completion

Patients in the decision aid–alone group were more likely to have a test ordered than the control group at the 1-month (69.1% vs 60.5%, *p*<0.035); 3-month (71.8% vs 62.3%, *p*=0.019); 6- month (77.0% vs 65.2%, *p*=0.002); and 12-month (80.7% vs 71.4%, *p*=0.011) time points (Table 2). The decision aid–alone group was also more likely to have a test ordered than the decision aid plus YDR group at each of these points, but here the differences were only significant at 1 month (69.1% vs 60.4%; *p*<0.031); 6 months (77.0% vs 67.1%, *p*<0.010); and 12 months (80.7% vs 73.6%, *p*=0.048). The pattern of test ordering was similar for the three groups; regardless of patient preferences, colonoscopy was the most commonly ordered test (range, 79%–81%) followed by FOBT (13%–19%); flexible sigmoidoscopy (<2%); and barium enema (<2%).

Among the 525 intervention patients expressing a preference, 322 (61%) had their preferred test ordered, 91 (17%) had an alternate test ordered, and 112 (21%) had no test ordered (Table 3). For individual tests, concordance between patient preference and test ordered varied from 81% for colonoscopy to 35% for FOBT, 28% for barium enema, 19% for flexible sigmoidoscopy and 19% for FOBT plus flexible sigmoidoscopy. Patients who preferred tests other than colonoscopy were less likely to have any test ordered than those who preferred colonoscopy (69% vs 85%, *p*<0.001).

Test completion, the primary outcome of interest, was higher for the decision aid–alone group than usual-care group at both the 6-month (34.2% vs 26.4%; *p*=0.049) and 12-month (43.1% vs 34.8%; *p*=0.046) time points (Table 2). Test completion for the decision aid–alone group and decision aid plus YDR group was similar at both time points (34.2% vs 30.0% at 6 months, *p*=0.292; 43.1% vs 37.1% at 12 months, *p*=0.153). Among the group of intervention patients who had a test ordered, 12-month uptake was similar when there was concordance or discordance between patient preference and test ordered (51% vs 58%; *p*=0.199; Table 3).

Associations Between Pre-Intervention Patient Characteristics and Test Completion

Table 4 depicts associations between baseline patient characteristics and test completion at 12 months. Assignment to the decision aid–alone study group (AOR 1.48, 95% CI=1.04, 2.10); black race (AOR 1.52, 95% CI=1.12, 2.06); and a preference for a patient-dominant decision-making approach (AOR 1.55; 95% CI=1.02, 2.35) were independent predictors of test completion. No associations were observed for site, age, gender, ethnicity, education, marital status, insurance status, or prior FOBT. Similar results were observed for test completion at 6 months (Appendix A, available online at www.ajpmonline.org), except that black race was no longer significant in the adjusted analyses (AOR 1.18, 95% CI=0.86, 1.63).

Mediators of Intervention Effects

Patients in the decision aid-alone group were more likely than controls to discuss screening at the study visit (93% vs 86%, p=0.008) even though all patients were given written prompts to hand to their providers acknowledging their participation in the study. As previously reported,[16] other measures of SDM including post-test knowledge, satisfaction with the decisionmaking process, and screening intention scores were also higher for the two intervention groups than they were for controls (Appendix B, available online at www.ajpmonline.org). Measures (Table 5) included: whether or not screening was discussed at the study visit (AOR 3.24, 95% CI=1.73, 6.05) and whether screening intentions (AOR 1.69, 95% CI=1.25, 2.28) were independent post-intervention determinants of test completion after adjustment for study group, race, and decision-making preference. Controlling for both determinants diminished the positive association for the decision aid–alone group (AOR, 1.30, 95% CI=0.90, 1.87), suggesting a mediation effect, which was confirmed using Sobel tests for significance (screening discussion, p=0.026; intentions, p=0.038). Post-intervention knowledge, satisfaction with the decisionmaking process, patient preferences and concordance between patient preference and test ordered showed no association with test completion.

Discussion

This study provides new evidence that decision aid–assisted SDM is an effective strategy for increasing CRC screening. Test completion uptake was ∼8% higher among decision-aid users than controls at both 6 and 12 months, suggesting a very modest but sustained impact on screening uptake. Unlike previous such studies, this study also explored the role of individual elements of SDM on screening behavior and found that the positive impact was mediated through activation of the screening discussion and heightened screening intentions rather than increased knowledge, satisfaction with the decision-making process, or concordance between patient preference and test ordered. Because providers received written notification of participation in the study from all patients, the authors speculate that enhanced activation of the screening discussion in the decision-aid group was the result of patient empowerment rather than differential provider behavior in response to the cue.

Additional findings were that use of a decision aid that incorporates a personalized risk assessment tool fails to increase test completion compared to a decision aid lacking the tool. Unlike for conditions where the benefits of screening are less certain, the primary goal of SDM for CRC screening is to enable patients to identify a preferred screening option rather than to decide whether or not to undergo screening.[4,7,8] Consequently, personalized risk feedback might have a detrimental effect without appropriate framing. Individuals deemed to be at higher risk may be fearful of the potential findings, whereas those at lower risk may feel that screening is unnecessary, especially if they overestimated their lifetime risk of cancer before receiving the feedback.[37]

Results of the current study contribute to a growing body of evidence suggesting that patient-level interventions alone have a relatively modest impact on CRC screening. The use of tailored educational approaches,[38–41] patient reminders,[42,43] activation strategies[44] and, as previously noted, decisions aids,[21–25, 28] have demonstrated either no effect or a slight increases in screening uptake that rarely exceed 20% compared to control groups. With the steady rise in screening prevalence nationally,[5] this limited effectiveness could partly reflect the challenges of trying to reach a more recalcitrant patient population. Regardless, this experience highlights the need for additional multilevel interventions that address not only patient- but also provider- and system-level barriers to participation.

Several clinical implications of the current study are notable. The findings and feedback from providers attest to the feasibility and validity of using decision aids as a point-of-contact intervention in clinical practice.[27] The observation that patients who preferred a patient-dominant decision-making style were more likely to complete screening provides new evidence supporting the importance of assessing a patient's desire to participate in the decision-making process prior to engaging in SDM.

Conversely, the lack of association between concordance and test completion suggests that complying with patient preferences may be less important in select patients than the provider's ability to effectively communicate his/her reasoning for recommending a preferred strategy. However, failure to comply with patient preferences negatively influenced test ordering and thus compromised the overall impact of SDM on screening uptake. The observation that blacks were more likely than whites to complete a screening test in a safety-net healthcare system corroborates previously published data suggesting that barriers to access and socioeconomic inequalities rather than cognitive factors may be largely responsible for racial disparities in screening rates.[45]

Limitations and Strengths

Limitations to this study include the fact that lack of provider blinding may have negatively influenced the magnitude of the interventions' effect on outcomes of interest. Second, no attempt was made to assess the quality of the patient–provider discussion. Even though satisfaction with the decision-making process was universally high (albeit higher in the intervention groups), recent data suggest that most patient–provider discussions related to CRC screening often fail to incorporate key elements of informed decision-making.[15,46]

Third, this study did not explore reasons for the large discrepancy between test ordering and test completion for each of the study arms. Although outcome assessment does not preclude the remote possibility that some patients may have completed tests elsewhere, the authors speculate that well-described patient- and system-level barriers to participation are largely responsible.[47] Lastly, no attempt was made to assess the cost effectiveness of the intervention from the perspective of the provider or healthcare center.

Despite these limitations, this study has several notable strengths. First, it is the largest study to date to demonstrate that the use of decision aids to promote SDM has a positive impact on screening behavior. Second, the use of an RCT study design, large sample size, and diverse study population enhances both the internal and external validity of its findings. Third, the randomization scheme after stratification by provider, and inclusion of mostly unscreened patients, minimizes potential confounding.

Conclusion

This study finds that decision aid–assisted SDM has a modest impact on CRC screening uptake, even when provider and patient preferences differ. The findings also suggest that

decision aids not only enable patients to identify a value-concordant screening preference but also empower them to initiate the screening discussion and heighten screening intentions. Conversely, incorporating personalized risk feedback may have negative consequences on screening behavior in the absence of appropriate messaging that motivates patients to undergo screening regardless of risk. Despite its importance, however, SDM alone is unlikely to have a profound impact on CRC screening uptake unless strategies are in place to address patient- and system-level barriers to participation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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                    ┌─────────────────────────┐
                    │   13,518 prescreened    │
                    │      as eligible        │
                    └─────────────────────────┘
                              │
                              │        ┌──────────────────────────────────┐
                              │        │ 7619 ineligible                  │
                              │        │     6073 prior screening         │
                              │        │     503 no PCP permission        │
                              │        │     424 non-English speaking     │
                              │        │     310 inappropriate            │
                              │        │     207 high risk                │
                              │        │     98 screening test ordered    │
                              │        │     4 aged <50 years             │
                              │        ├──────────────────────────────────┤
                              │        │ 5074 excluded                    │
                              │        │     4321 could not be reached    │
                              │        │     290 not interested           │
                              │        │     305 scheduling conflict      │
                              │        │     158 did not keep appointment │
                              │        └──────────────────────────────────┘
                              │
                    ╭─────────────────────────╮
                    │ 825 enrolled and randomized │
                    ╰─────────────────────────╯
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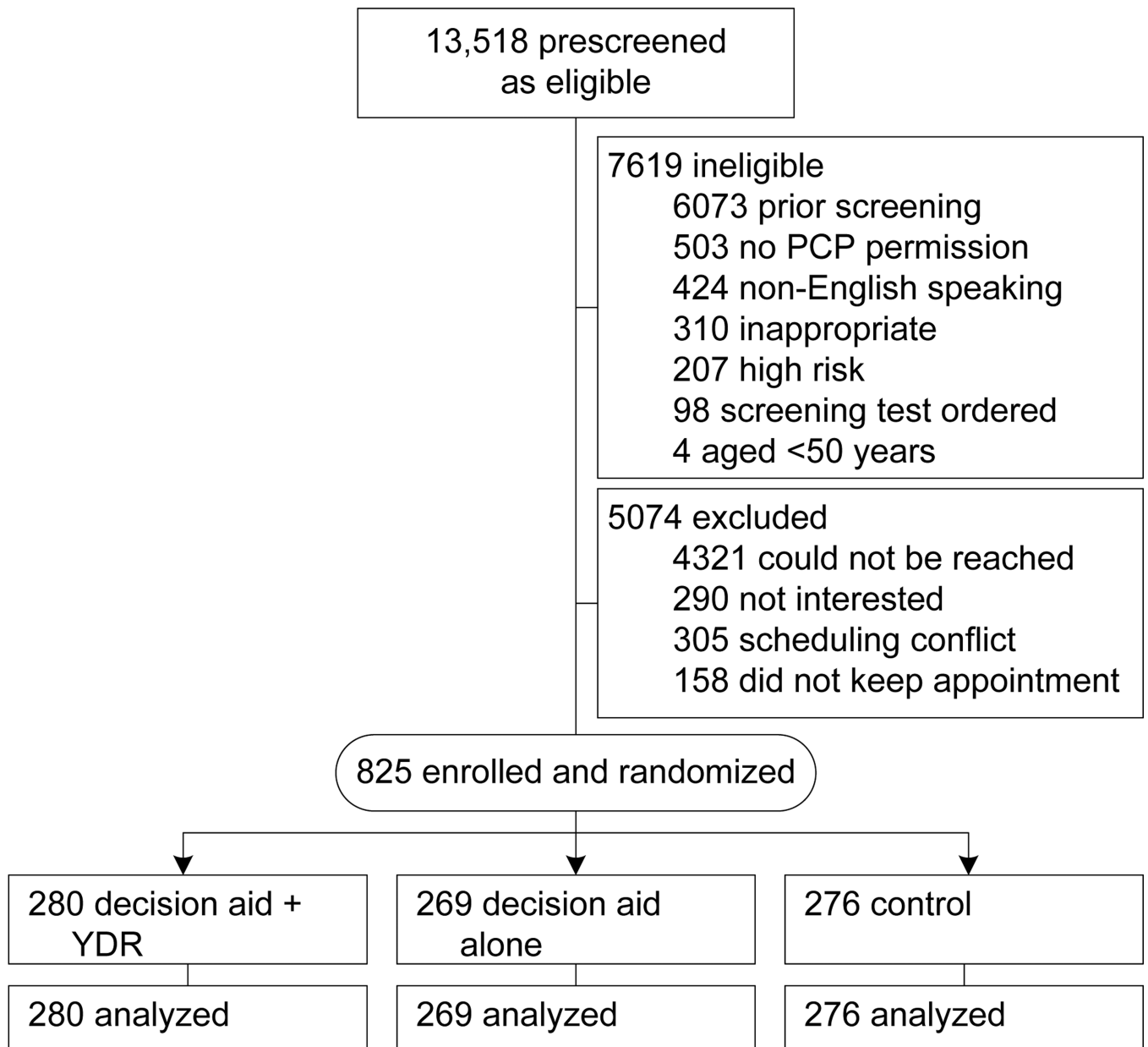| 280 decision aid + YDR	269 decision aid alone	276 control
280 analyzed	269 analyzed	276 analyzed

Figure 1. Study flow diagram
PCP, primary care provider; YDR, *YourDiseaseRisk* personalized risk assessment tool with feedback

Table 1

Characteristics of Study Participants (*n*=825), *n* (%)

Characteristic	Decision Aid + YDR (*n*= 280)	Decision aid (*n*=269)	Control (*n*=276)	*p*-value [a]
Age, years				0.35
< 65	232 (83)	234 (87)	230 (83)	
65	48 (17)	35 (13)	46 (17)	
Gender				0.70
Female	163 (58)	164 (61)	159 (58)	
Male	117 (42)	105 (39)	117 (42)	
Ethnicity				0.35
Non-Hispanic	262 (94)	259 (96)	261 (95)	
Hispanic	18 (6)	10 (4)	15 (5)	
Race				0.52
Black	172 (61)	160 (59)	180 (65)	
White	99 (35)	96 (36)	88 (32)	
Asian	3 (1)	7 (3)	2 (1)	
Other	6 (2)	6 (2)	6 (2)	
Education[b]				0.12
High school	221 (79)	213 (80)	200 (74)	
< High school	58 (21)	52 (20)	72 (26)	
Marital Status [b]				0.40
Married	89 (32)	72 (27)	85 (31)	
Living with a partner	12 (4)	20 (7)	14 (5)	
Other	176 (64)	175 (66)	174 (64)	
Insurance				0.06
Private/HMO	85 (33)	95 (39)	76 (30)	
Medicare	79 (31)	58 (24)	86 (34)	
Medicaid	70 (28)	76 (31)	63 (25)	
Free care	14 (6)	11 (5)	16 (6)	
None	6 (2)	2 (1)	10 (4)	
Prior FOBT [b]				0.90
Yes	33 (12)	35 (13)	36 (13)	
No	243 (88)	232 (87)	239 (87)	
Desired role in decision-making				0.54
Mostly patient	75 (27)	66 (25)	81 (29)	
Shared	151 (54)	149 (55)	134 (49)	

Characteristic	Decision Aid + YDR (*n*= 280)	Decision aid (*n*=269)	Control (*n*=276)	*p*-value [a]
Mostly doctor	54 (19)	54 (20)	61 (22)	

[a] Chi-square test of independence

[b] Missing data: education, *n*=9; marital status, *n*=8; prior FOBT, *n*=7.

YDR, *YourDiseaseRisk* personalized risk assessment tool with feedback; FOBT, fecal occult blood testing.

Table 2

Patient outcomes by study group, n (%) or % (95% CI)

Outcome	Decision aid vs Control			Decision aid vs Decision aid +YDR		
	Decision aid alone	Control	Difference	Decision aid alone	Decision aid + YDR	Difference
Test Ordered						
1 month	186 (69.1)	167 (60.5)	**8.6 (0.7, 16.6)** *	186 (69.1)	169 (60.4)	**8.8 (0.8, 16.7)** *
3 months	193 (71.8)	172 (62.3)	**9.4 (1.6, 17.3)** *	193 (71.8)	180 (64.3)	7.5 (−0.3, 15.2)
6 months	207 (77.0)	180 (65.2)	**11.7 (4.2, 19.3)** *	207 (77.0)	188 (67.1)	**9.8 (2.4, 17.3)** *
12 months	217 (80.7)	197 (71.4)	**9.3 (2.2, 16.4)** *	217 (80.7)	206 (73.6)	**7.1 (0.1, 14.1)** *
Test Completed						
6 months	92 (34.2)	73 (26.4)	**7.8 (0.1, 15.4)** *	92 (34.2)	84 (30.0)	4.2 (−3.6, 12.0)
12 months	116 (43.1)	96 (34.8)	**8.3 (0.2, 16.5)** *	116 (43.1)	104 (37.1)	6.0 (−2.2, 14.2)

Note: Bold indicates significance.

YDR, *YourDiseaseRisk* personalized risk assessment tool with feedback

*
p<0.05 by chi-square test of independence

Table 3

Concordance between patient preference and test ordered or completed at 12 months (intervention groups only [a]).

Outcome	Patient Preference, n (%)					
	Colonoscopy (n=323)	FOBT (n=134)	Flexible Sigmoidoscopy (n=27)	DCBE (n=25)	FOBT + Flexible Sigmoidoscopy (n=16)	Overall (n=525 [a])
Test Ordered [b]						
Any	264 (85) [d]	93 (69)	19 (70)	16 (64)	11 (69)	413 (79)
Same	260 (80)	47 (35)	5 (19)	7 (28)	3 (19) [e]	322 (61)
Different	14 (4)	46 (34)	14 (52)	9 (36)	8 (50)	91 (17)
None	49 (15)	41 (31)	8 (30)	9 (36)	5 (31)	112 (21)
Test Completed [c]						
Same	138 (53)	17 (36)	3 (60)	3 (43)	2 (67)	163 (51)
Different	7 (50)	31 (67)	7 (50)	4 (44)	4 (50)	53 (58)

[a] Intervention patients with no preference (n=19) or missing data (n=5) not included

[b] Denominator for percentage is number of patients with a particular preference

[c] Denominator for percentage is number of patients with a particular preference who had same or different test ordered

[d] p<0.05 by chi-square test of independence for comparison of colonoscopy (85%) versus tests other than colonoscopy (69%)

[e] "Same" indicates that at least one of the two preferred tests was ordered.

FOBT, fecal occult blood testing; DCBE, double-contrast barium enema.

Table 4

Associations between pre-intervention patient characteristics and test completion at 12 months

	n	Test Completion n (%)	Unadjusted OR (95% CI) [a]	AOR (95% CI) [ab]
Study group				
Decision aid only	269	116 (43)	1.42 (1.01 , 2.01)	1.48 (1.04, 2.10)
Decision aid + YDR	280	104 (37)	1.11 (0.78 , 1.57)	1.13 (0.80, 1.61)
Control	276	96 (35)	---	---
Site				
BMC	763	297 (39)	---	
SBCHC	62	19 (31)	0.69 (0.40 , 1.21)	
Age, years				
< 65	696	268 (39)	---	
65	129	48 (37)	0.95 (0.64 , 1.40)	
Gender				
Female	486	188 (39)	1.04 (0.78 , 1.38)	
Male	339	128 (38)	--	
Race				
White	283	92 (33)	---	---
Black	512	214 (42)	1.49 (1.10 , 2.02)	1.52 (1.12, 2.06)
Asian/Other	30	10 (33)	1.04 (0.47 , 2.31)	1.00 (0.45, 2.23)
Ethnicity				
Hispanic	43	16 (37)	0.95 (0.50 , 1.80)	
Non-Hispanic	782	300 (38)	---	
Education				
< high school graduate	182	65 (36)	---	
High school graduate	634	247 (39)	1.15 (0.82 , 1.62)	
Marital Status				
Married/Living with partner	246	100 (41)	1.15 (0.85 , 1.56)	
Unmarried/Living alone	571	213 (37)	---	
Insurance, n(%)				
Private/HMO	256	111 (43)	---	
Medicare	223	81 (36)	0.74 (0.52, 1.08)	
Medicaid	209	78 (37)	0.78 (0.54, 1.13)	
Free care	41	18 (44)	1.02 (0.53, 1.99)	
None	18	8 (44)	1.04 (0.40, 2.74)	
Prior FOBT				
Yes	104	40 (38)	1.01 (0.66, 1.54)	

	n	Test Completion n (%)	Unadjusted OR (95% CI) [a]	AOR (95% CI) [ab]
No	714	273 (38)	---	
Decision-making preference	222	97 (44)	1.52 (1.01 , 2.31)	1.55 (1.02, 2.35)
Patient	434	162 (37)	1.17 (0.80 , 1.70)	1.15 (0.79, 1.68)
Shared	169	57 (34)	---	---
Doctor				

YDR, *YourDiseaseRisk* personalized risk assessment tool with feedback; BMC, Boston Medical Center; SBCHC, South Boston Community Health Center; FOBT, fecal occult blood testing; CRC, colorectal cancer

[a]Logistic regression analysis

[b]Adjusted for study group, race and decision-making preference.

Table 5

Associations between potential mediators of intervention effect and test completion at 12 months.

	n	Test Completion *n* (%)	Unadjusted OR (95% CI) [c]	AOR (95% CI) [c,d]
Study group				
Decision aid only	269	116 (43)	1.42 (1.01, 2.01)	1.30 (0.90, 1.87)
Decision aid + YDR	280	104 (37)	1.11 (0.78, 1.57)	1.03 (0.72, 1.48)
Control	276	96 (35)	---	---
Discussed screening at study visit				
Yes	740	302 (41)	3.71 (2.02, 6.83)	3.24 (1.73, 6.05)
No	83	13 (16)		---
Knowledge Post, quartile				
1	234	83 (35)	---	
2	120	51 (42)	1.34 (0.86 , 2.11)	
3	189	72 (38)	1.12 (0.75, 1.67)	
4	282	110 (39)	1.16 (0.81, 1.67)	
Satisfaction with decision-making process, quartile				
1	218	79 (36)	---	
2	186	77 (41)	1.24 (0.83 , 1.86)	
3	237	95 (40)	1.18 (0.81, 1.72)	
4	153	60 (39)	1.14 (0.74, 1.74)	
Intention (How sure are you that you will complete a CRC screening test?)				
Completely Sure	447	194 (43)	1.63 (1.22 , 2.17)	1.69 (1.25, 2.28)
Less Sure	362	116 (32)	---	---
Patient Preference [a]				
Colonoscopy	324	145 (45)	---	
FOBT	134	49 (37)	0.71 (0.47, 1.08)	
Other screening test(s) [b]	68	23 (34)	0.63 (0.36, 1.09)	
Concordance[a]				
Patient/Provider Preference Same	329	164 (50)	---	
Patient/Provider Preference Different	100	53 (53)	1.13 (0.72 , 1.78)	

[a]Intervention patients only (Decision aid only and Decision aid +YDR)

[b]Other screening tests include flexible sigmoidoscopy, flexible sigmoidoscopy plus FOBT and double-contrast barium enema.

[c]Logistic regression analysis

[d]Adjusted for study group, whether screening discussed at study visit, intentions, race and decision-making preference

YDR, *YourDiseaseRisk* personalized risk assessment tool with feedback; BMC, Boston Medical Center; FOBT, fecal occult blood testing