Original Article

Medical Decision Making

Medical Decision Making
2018, Vol. 38(5) 614–624

DOI: 10.1177/0272989X18773713
journals.sagepub.com/home/mdm
SAGE

A Decision Aid to Promote Appropriate Colorectal Cancer Screening among Older Adults: A Randomized Controlled Trial

Carmen L. Lewis, Christine E. Kistler, Alexandra F. Dalton, Carolyn Morris, Renée Ferrari, Colleen Barclay, Noel T. Brewer, Rowena Dolor, Russell Harris, Maihan Vu, and Carol E. Golin

Abstract

Background. Concerns have been raised about both over- and underutilization of colorectal cancer (CRC) screening in older patients and the need to align screening behavior with likelihood of net benefit. **Objective.** The purpose of this study was to test a novel use of a patient decision aid (PtDA) to promote appropriate CRC screening in older adults. **Methods.** A total of 424 patients ages 70 to 84 y who were not up to date with CRC screening participated in a double-blinded randomized controlled trial of a PtDA targeted to older adults making decisions about whether to undergo CRC screening from March 2012 to February 2015. **Intervention.** Patients were randomized to a targeted PtDA or an attention control. The PtDA was designed to facilitate individualized decision making—helping patients understand the potential risks, benefits, and uncertainties of CRC screening given advanced age, health state, preferences, and values. **Outcomes.** Two composite outcomes, appropriate CRC screening behavior 6 mo after the index visit and appropriate screening intent immediately after the visit, were defined as completed screening or intent for patients in good health, discussion about screening with their provider for patients in intermediate health, and no screening or intent for patients in poor health. Health state was determined by age and Charlson Comorbidity Index. **Results.** Four hundred twelve (97%) and 421 (99%) patients were analyzed for the primary and secondary outcomes, respectively. Appropriate screening behavior at 6 mo was higher in the intervention group (55% v. 45%, $P = 0.023$) as was appropriate screening intent following the provider visit (61% v. 47%, $P = 0.003$). **Limitations.** The study took place in a single geographic region. The appropriate CRC screening classification system used in this study has not been formally validated. **Conclusions.** A PtDA for older adults promoted appropriate CRC screening behavior and intent.

Trial Registration: Clinicaltrials.gov, registration number NCT01575990. https://clinicaltrials.gov/ct2/show/NCT01575990?term=epic-d&rank=1

Keywords

appropriate screening, appropriate use, colorectal cancer screening, decision aid, overuse, underuse

Date received: October 4, 2017; accepted: March 23, 2018

Over the past several decades, there have been increasing concerns about both over- and underutilization of colorectal cancer (CRC) screening in older patient populations[1] and the need to align screening behavior with the likelihood of realizing a net benefit.[2] On one hand, the incidence of colon cancer increases with age, making

Corresponding Author

Carmen L. Lewis, Division of General Internal Medicine, Department of Medicine, University of Colorado School of Medicine, Mail Stop B180, Academic Office 1, Rm 8415, Aurora, CO 80045-2581, USA (carmen.l.lewis@ucdenver.edu).

older people a prime target for CRC screening.[3,4] On the other hand, screening multimorbid individuals can result in net harm due to increased colonoscopy risks related to age and health state.[4,5] These concerns led the US Preventive Services Task Force to recommend that CRC screening in older adults be individualized, taking into account health state and the potential to benefit from screening.[1,6,7]

Multiple observational studies have documented presumed overutilization of CRC screening in older people in poor health.[8–12] Recent data, however, also suggest concerns about possible underutilization of colon cancer screening in healthy older people who may benefit.[13] An approach to promote appropriate use of CRC screening that addresses both over- and underutilization in clinical practice is needed to maximize the benefit and minimize the harms of colon cancer screening in an older population.

Frameworks for individualized decision making suggest that adequately informing patients about risks and benefits along with a consideration of personal values will result in screening preferences that are aligned with the greatest potential to realize a net benefit.[2,14–16] Ideally, individualized decision making between physicians and patients results in appropriate CRC screening decisions and, ultimately, appropriate screening behavior. However, few studies have examined individualized decision making in clinical practice or interventions to promote appropriate CRC screening in older adults,[17,18] although there have been studies of decision making in older adults on other topics, such as mammography.[19]

Therefore, we tested the efficacy of a CRC screening decision aid for older adults to determine whether it promoted appropriate CRC screening behavior, which we define in this study as aligning screening intent or behavior with the likelihood of a net benefit. Traditionally, decision aids have been used for preference-sensitive decisions in which evidence is uncertain or no clear evidence exists regarding which option is best. Under such circumstances, patients are encouraged to make a decision based on their values and preferences regarding the risks and benefits.[20] Our trial examined a novel approach for the use of patient decision aids: to align CRC screening intent and behavior with the patient's potential to realize a net benefit—our definition of appropriate screening intent and behavior. Based on our preliminary work, we hypothesized that a targeted decision aid describing the risks and benefits of CRC screening in the face of increasing age and multimorbidity would prepare patients for individualized decision making and result in appropriate CRC screening intent and behavior.[21,22] Specifically, we hypothesized that the decision aid would promote cancer screening for patients in good health in whom screening is likely beneficial, discourage cancer screening in patients in poor health in whom screening is unlikely beneficial, and motivate patients in intermediate health to have discussions with their providers to determine what is best for them, a preference-sensitive decision-making approach.[23]

Methods

Our study was a double-blinded randomized controlled trial: researchers, research assistants (RAs), and patients were unaware of their assignment. We recruited participants from 14 community-based primary care practices affiliated with the Duke Primary Care Research Consortium. Enrollment and data collection began in March 2012 and ended in February 2015. The trial protocol is described in detail elsewhere.[24] Institutional review boards at both Duke University and the University of North Carolina approved the trial.

Identification of Potential Participants

All patients ages 70 to 84 years old who had upcoming appointments in the next 4 to 6 weeks in a participating

Division of General Internal Medicine, Department of Medicine, University of Colorado School of Medicine, Aurora, CO, USA (CLL, AFD); Department of Family Medicine, School of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA (CEK); University of Colorado School of Medicine, Aurora, CO, USA (CM); Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA (RF, CB, RH, CEG); Department of Health Behavior, Gillings School of Global Health, and Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA (NTB); Division of General Internal Medicine, Department of Medicine, Duke School of Medicine, Durham, NC, USA (RD); Center for Health Promotion and Disease Prevention, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA (MV). This work was completed through the Sheps Center for Health Services Research at the University of North Carolina at Chapel Hill, the Duke Clinical Research Institute and Division of General Internal Medicine at Duke University, and the Division of General Internal Medicine at the University of Colorado School of Medicine. Portions of this work were presented at the 36th Annual North American Meeting of the Society for Medical Decision Making in Miami, FL, October 2014, and the 37th Annual North American Meeting of the Society for Medical Decision Making in St. Louis, MO, October 2015. This project was supported by the Agency for Healthcare Research and Quality (AHRQ) Research Centers for Excellence in Clinical Preventive Services, grant P01 HS021133-03. The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of AHRQ. Financial support for this study was provided entirely by a grant from AHRQ Research Centers for Excellence in Clinical Preventive Services. The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report.

clinic were initially assessed for eligibility via chart review. Patients were potentially eligible if they were not up to date with CRC screening, which included having no evidence of a fecal occult blood test (FOBT) within 1 y, sigmoidoscopy within 5 y, or previous negative colonoscopy within 10 y. We also included low-risk surveillance patients—individuals who had a colonoscopy 4 to 10 years ago and were due again based on standard surveillance recommendations[25–27] —because, like those undergoing screening, the risk of colon cancer is relatively small in this population.[27] We excluded patients who were in surveillance for high-risk lesions (recommended follow-up of 3 y of less) or who had a previous history of CRC or inflammatory bowel disease or possible dementia. The US Preventive Services Task Force recommends that individualized decisions start after age 75,[7,28] but because studies show limited life expectancy in patients ages 70 to 74 in the poorest health,[29] we included this age group.[30]

Patients who were potentially eligible by chart review were sent a letter explaining the study and an opt-out card. We called patients who did not return the opt-out card to further screen and recruit them for the study. Eligibility was confirmed by assessing CRC screening that may not have been documented in the electronic health record. In addition to being "not up to date" with screening, older adults needed to be fluent English speakers and able to use the paper-based tool without visual impairment. We used a 6-item screen to exclude persons with possible dementia.[31] Eligible patients were asked to arrive at the clinic 1 h before their scheduled appointment.

Randomization and Blinding

Patients were randomly assigned through a centralized computer process to the decision support intervention or attention control condition. Because our primary outcome was a combined outcome across 3 health states, we wanted to ensure adequate numbers in each health state. Therefore, we assigned participants to the intervention or control arm using permuted blocks stratified by health state. Allocation was concealed from the RAs through the use of opaque, sealed envelopes. Thus, the RAs, who administered surveys and collected data, were blinded to the patients' assignment. Patients were also blinded to their assignment, as they did not know whether they were in the intervention or control group. Providers, however, may have been aware of patients' assignment because patients in the intervention arm brought a paper cue into the provider visit.

Outcomes and Measures

Appropriate Colon Cancer Screening Behavior and Intent. The primary outcome of this study was a composite measure of appropriate screening behavior 6 months following the index visit. The secondary outcome was screening intent immediately after the index visit. Our composite outcomes were defined as "completed screening or intent to be screened" for patients in good health, "discussion about screening with their provider" for patients in intermediate health, and "no screening or intent to be screened" for patients in poor health. Appropriate CRC screening or intent was based on evidence that at least 5 y of life expectancy are needed to expect a net benefit from CRC screening.[8,25,32–38] Using this premise, we classified participants into good, intermediate, and poor health states[30,36,39] based on a combination of their Charlson Comorbidity Index (CCI) score and the individual's age (Figure 1). We used the Deyo adaption of the CCI (D-CCI),[40] which, like the original, assigns points to various comorbid conditions. Higher CCI or D-CCI scores are associated with a greater mortality risk.[41] In our study, participants in the best health state (age 70–74 y and CCI = 0–3 or age 75–79 y and CCI = 0) are expected to live >10 y and thus are expected to have a net benefit from screening. Participants in the intermediate health state (age 70–74 y and CCI $\geq$4, age 75–79 y and CCI = 1–3, or age 80–84 y and CCI = 0) are expected to live 5 to 10 y and the net benefit from screening is uncertain. Participants in poor health (age 75–79 y and CCI $\geq$4 or age 80–84 y and CCI $\geq$1) are expected to live <5 y[30] and are likely not to benefit from screening.

Decision-Making Outcomes. We also assessed several intermediate decision-making outcomes. First, using a measure developed during our preliminary work,[42] we determined whether participants were prepared for individualized decision making, defined as having adequate knowledge ($\geq$3 of 5 knowledge questions correct) and adequately clarified values (a score of $\leq$ 25 on the values clarity subscale, range 0–100).[42,43] We also assessed patients' preferences for screening after they reviewed the decision aid but before they saw their provider. Finally, we determined by patient report whether discussion about CRC screening occurred during the office visit and, if so, who initiated the discussion.

Conceptual Model. Our conceptual model is based on the premise of individualized decision making. In CRC

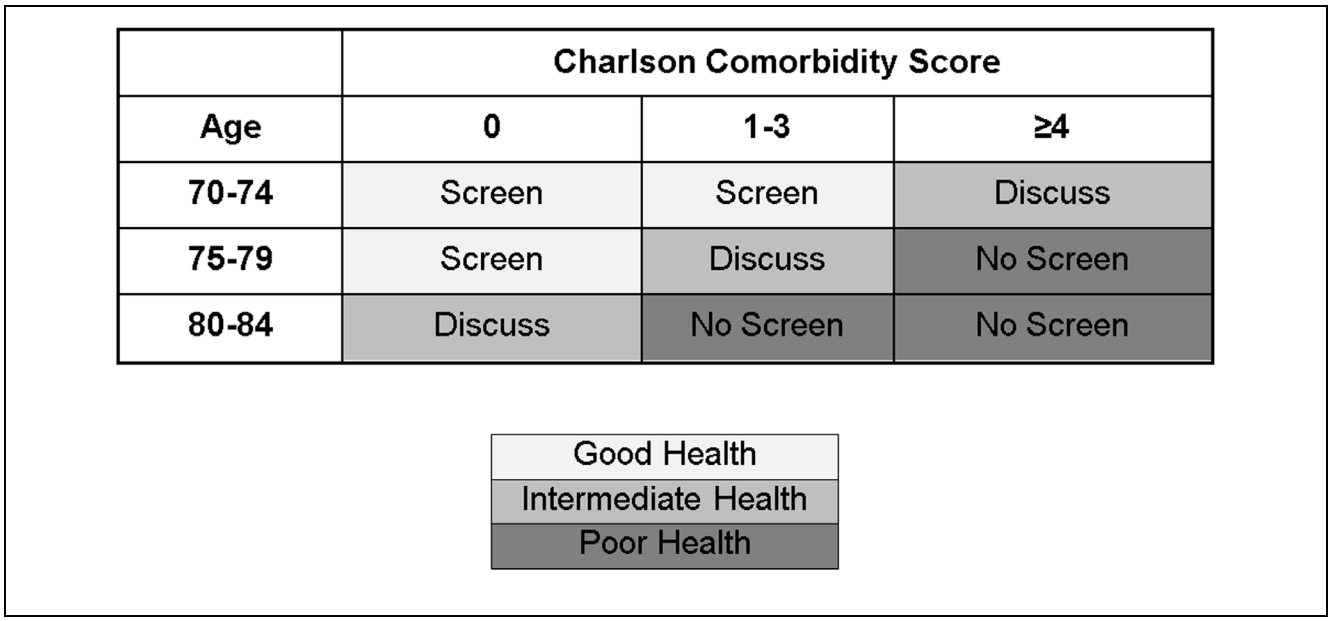

Figure 1 Appropriate screening behavior and intent based on health state derived from age and Charlson Comorbidity Score.

screening, individualized decision making typically involves considering a patient's life expectancy, risks, and potential to benefit from screening to determine whether it is appropriate to undergo CRC screening. Our decision aid modified the traditional choice architecture[44,45] about CRC screening. We provided additional information about competing risks, targeted the decision aid by age and gender, and provided information about the potential harms of undergoing colonoscopy. We did not directly provide information about patients' health state, given the uncertainty surrounding net benefit at the individual level. We hypothesized that this information would "nudge" older adults, thereby encouraging patients to consider their screening preference vis-à-vis their own health state, a novel use of a decision aid. The result is that older adults are open to individualized decision making—their screening intent and behavior align with their potential to benefit from screening and their individual screening preferences are respected.

Intervention. The decision aid, titled "Making a Decision about Colon Cancer Screening," is a 20-page paper-based tool with large font to accommodate visual difficulties and use of simple graphics and white space for easy readability. It is written at a seventh-grade reading level[46] and takes 5 to 15 min to read. The content of the decision aid was targeted to different age groups (70–74, 75–79, 80–84 y) and genders, resulting in 6 versions. It includes 6 basic components: 1) a description of FOBT, 2) a description of screening colonoscopy and its potential harms, 3) information explaining that all positive stool tests require follow-up diagnostic colonoscopy, 4) a description of the importance of competing mortality with targeted information based on age and gender, 5) why individualized decision making is necessary for older adults compared with younger people, and 6) the need to weigh the harms and benefits of CRC screening for each individual. Lastly, it includes a values-clarification exercise with 9 items that address patient values about screening that our formative work showed were important to older adults making decisions about cancer screening.[42,47] Patients were not provided any information about their health state. The decision aid was developed according to international standards for decision aid development[48] and based on the Ottawa Decision Support Framework.[49] The tool development was iterative, and the final product was tested in a pilot study.[42] The pilot, an uncontrolled trial of 49 participants, showed an increase in patients who were prepared for individualized decision making from 4% before the decision aid to 41% after the decision aid ($P < 0.01$). The pilot also increased the percentage of participants with adequate knowledge (4% v. 52%, $P < 0.01$). After reviewing the decision aid, 7 participants (15%) changed their screening intent.[42]

Control. Control group participants received an educational intervention developed by the AAA Foundation

for Traffic Safety, titled "Drivers 65 Plus: Check Your Own Performance." It contained information about driving, suggestions to increase safe driving, and a self-rating driving evaluation form. We did not assess whether participants drove, but most people in the study area do drive, as there are limited public transportation options available.

Sample Size Calculation and Data Analysis. In estimating the trial's sample size, we accounted for possible correlation among patients seen by the same physician. We conservatively estimated the intraclass correlation coefficient to be 0.0225. Based on prior work and the minimal important difference literature, we judged a clinically important increase in appropriate screening to be 10%.[50] We calculated the largest effective total sample size to be 413 and the smallest to be 282 to have 80% power to see a 15% increase in appropriate screening behavior. Because the primary and secondary outcomes were based on health state and age, it was important to recruit sufficient participants in each of the 3 health groups, as derived from their CCI score and age.[51] Therefore, once a health state reached 150 participants, it was closed to recruitment, and further patients in that health group were ineligible for the trial.

For the analysis, we first compared descriptive characteristics in the intervention and control groups to detect any between-group differences despite randomization. Means and standard deviations were calculated for continuous variables and compared between groups using t tests. Frequencies and percentages were calculated for categorical variables and compared between groups using χ^2 tests. For appropriate screening behavior and intent outcomes, we used mixed-effects logistic regression models with a random intercept for physician to account for correlation among patients who saw the same physician. Appropriate screening outcome was calculated and compared between health groups as a subgroup analysis, although we were not powered to detect significant statistical differences. The same approach was used to test the effect of the intervention on appropriate screening intent immediately following the provider visit. We did not adjust for clustering in calculating the intermediate outcomes, which occurred prior to the physician visit. All calculations were performed using SAS version 9.4.

Results

We randomized 424 patients into intervention and control groups (Figure 2). The 2 study groups did not differ by age, gender, race, insurance coverage, education, or work status (Table 1). The mean age of the sample was 77 y (SD 4.2), with 58.5% of the sample female and 79.1% white. Almost 90% of participants reported previous CRC screening.

Appropriate Colon Cancer Screening Behavior and Intent

Fifty-five percent (54.8%) of all participants in the decision aid group exhibited appropriate screening behavior, as defined in this study, 6 mo after the intervention, compared with 45.1% in the control group (difference [95% confidence interval {CI}]: 9.7% [1.6%−20.9%], P = 0.023; Table 2). Breaking down the composite into its components, 27.0% of patients in good health were screened in the intervention group compared with 12.5% in the control group (difference [95% CI]:14.5% [5.1%−27.8%]), 53.3% of patients in the intermediate health state had discussions in the intervention group compared with 37.8% in the control group (difference [95% CI]: 15.5% [3.5%-33.0%]), and 91.5% of patients in poor health did not undergo screening in the intervention group compared with 94.8% in the control group (difference [95% CI]: −3.3% [−14.0% to 7.5%]). Although not part of the composite outcome measure, 9.0% of patients in intermediate health underwent screening: 11.1% in the intervention group and 6.9% in the control group.

The results were similar for the secondary outcome, appropriate screening intent, assessed immediately after the provider visit (Table 2). Of the patients in the intervention group, 60.5% reported appropriate screening intent, compared with 47.4% in the control group (difference [95% CI]: 13.1% [4.5%−22.9%], P = 0.003). We found similar differences in appropriate screening intent when we broke the composite into its components by health state, although the trial was not powered to examine statistically significant differences by health state.

Decision-Making Outcomes

The proportion of participants who were prepared to make an individualized decision was higher in the intervention group than in the control group (67.6% v. 31.9%; difference [95% CI]: 35.7% [26.8%− 44.6%]; $P < 0.001$; Table 2). This difference was driven primarily by higher knowledge in the intervention group compared with the control group (4.1 v. 2.3 of 5, $P < 0.001$). The intervention group also demonstrated lower scores

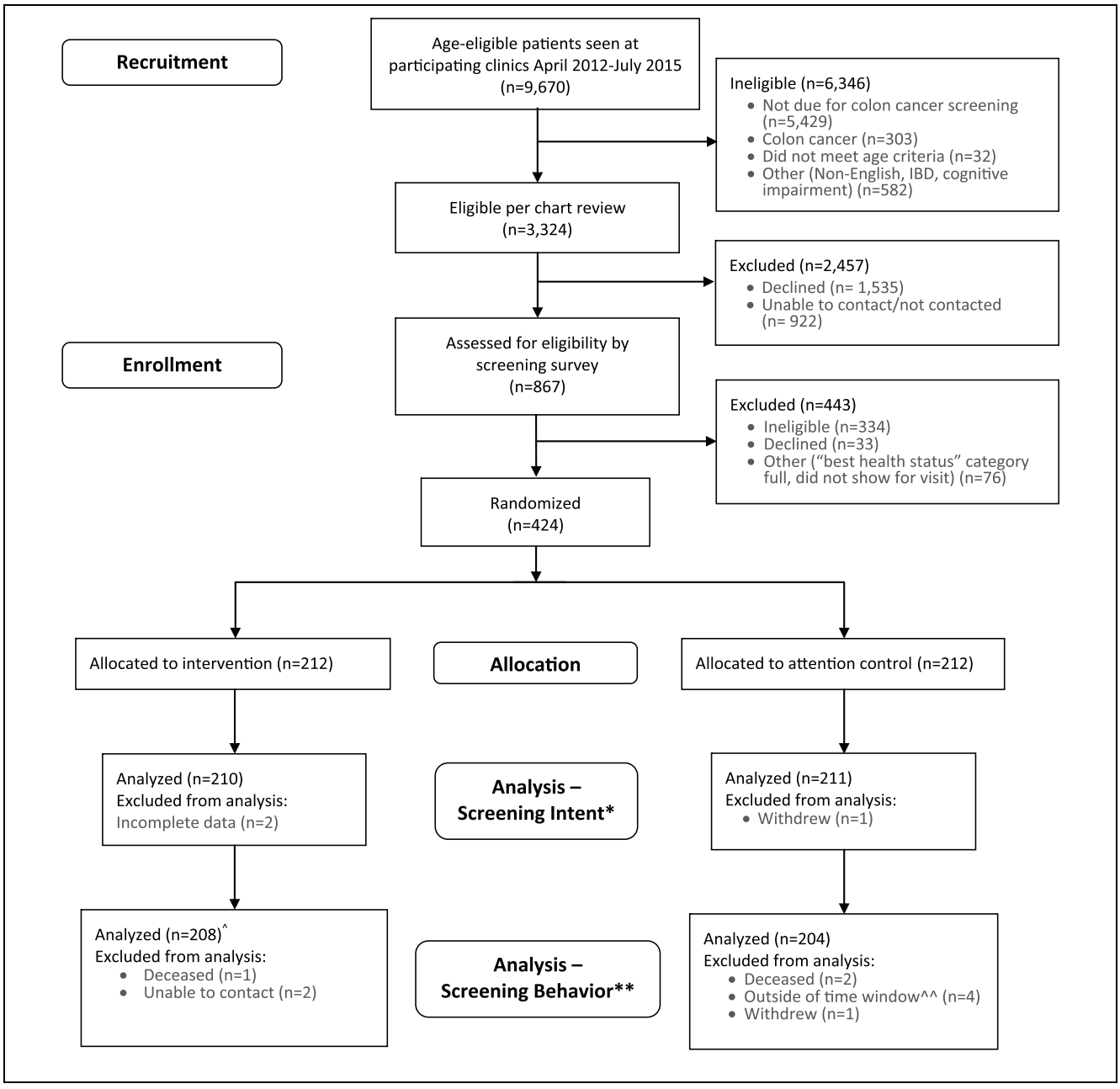

Figure 2 CONSORT Flow Diagram.

*Screening intent outcome was collected immediately following the patient's visit with their provider.

**For patients in intermediate health, screening behavior was determined by whether they had a discussion with their provider during the clinic visit and was assessed immediately following the visit. In the other health states, screening behavior was assessed during the 6-month follow-up. Therefore, the "Analysis–Screening Behavior" numbers reflect patients who were lost to follow-up in the good and poor health states but not patients who were lost to follow-up in the intermediate health group.

^One patient in the intervention group was excluded from screening intent analysis (above) due to missing data but was included in the screening behavior analysis due to available screening data.

^^Patients not reached within 4 weeks of the follow-up survey date.

Table 1 Baseline Participant Characteristics

Participant Characteristic	Total ($N = 424$), *n* (%)	Intervention ($n = 212$), *n* (%)	Control ($n = 212$), *n* (%)	*P* Value
Age, mean (SD)	76.8 (4.2)	76.6 (4.1)	77.1 (4.3)	0.31
Female	248 (58.5)	130 (61.3)	118 (55.7)	0.24
Race				
White or Caucasian	335 (79.1)	173 (81.6)	162 (76.4)	0.17
Black or African American	76 (17.9)	35 (16.5)	41 (19.3)	
Asian American	8 (1.9)	1 (0.5)	7 (3.3)	
Native Hawaiian/Pacific Islander	1 (0.2)	0 (0)	1 (0.5)	
American Indian/Alaska	3 (0.7)	1 (0.5)	2 (0.9)	
Other	4 (0.9)	2 (0.9)	2 (0.9)	
Hispanic	7 (1.7)	3 (1.4)	4 (1.9)	0.71
Educational status				
Some high school or less	30 (7.1)	15 (7.1)	15 (7.0)	0.24
High school graduate	95 (22.4)	58 (27.4)	37 (17.5)	
Some college or associate's degree	97 (22.9)	44 (20.8)	53 (25.0)	
Bachelor's degree	90 (21.2)	40 (18.9)	50 (23.6)	
Advanced degree	112 (26.4)	55 (25.9)	57 (27.9)	
Marital status				
Married/cohabiting	241 (56.8)	117 (55.2)	124 (58.5)	0.49
Widowed	100 (23.6)	53 (25.0)	47 (22.2)	
Divorced	63 (14.9)	32 (15.1)	31 (14.6)	
Never married/other	20 (4.7)	10 (4.7)	10 (4.7)	
Primary health insurance				
Medicare	378 (90.2)	189 (89.6)	189 (90.9)	0.46
Medicaid	6 (1.4)	2 (1.0)	4 (1.9)	
Private	14 (3.3)	9 (4.3)	5 (2.4)	
Employee/union	13 (3.1)	6 (2.8)	7 (3.4)	
Other	8 (1.9)	5 (2.4)	3 (1.4)	
Work status				
Retired	354 (83.7)	174 (82.1)	180 (85.3)	0.80
Currently employed	58 (13.7)	32 (15.1)	26 (12.3)	
Unemployed	11 (2.6)	6 (82.1)	180 (85.3)	
Ever been screened for colorectal cancer?	377 (88.9)	187 (88.2)	190 (89.6)	0.64

on the values clarity subscale, indicating clearer values (23.3 v. 26.8, $P = 0.028$).

With respect to preferences assessed after viewing the intervention or control material but before interacting with their provider, patients in the intervention group were more likely to report that they were unsure about their screening preference (24.5% intervention v. 16.8% control; difference [95% CI]: 7.8% [0.1%−15.5%]; $P = 0.049$). After seeing their provider, patients in the intervention reported more discussions about CRC screening compared with the control group (58.4% intervention v. 41.6% control; difference [95% CI]: 16.6% [7.2%−26.0%]; $P < 0.001$). Among those patients who reported a CRC discussion, patients in the intervention group were more likely to report that they, rather than their doctor, brought up the topic (61.7% v. 41.4%, $P = 0.004$).

Discussion

In this randomized controlled trial, a decision aid for older adults increased appropriate screening intent immediately after the visit with the provider and appropriate screening behavior 6 mo after the intervention compared with the control group. With respect to components of the composite measure, a higher proportion of participants in good health, who were most likely to benefit, were screened in the intervention group compared with the control group, and a higher proportion of participants in intermediate health reported CRC discussions in the intervention group compared with the control group. We did not find differences between these groups in the poor health state, but more than 90% in both the intervention and control groups did not undergo CRC screening, so our intervention was hampered by a ceiling effect in this subgroup. The results also supported our

Table 2 Primary, Secondary, and Intermediate Outcomes

Primary Outcome: Percentage of Patients Reporting Appropriate Screening Behavior at 6 mo				
	Decision Aid (n = 208), % (n)[a]	**Control (n = 204), % (n)[a]**	**Difference (95% CI)[b]**	***P* Value[b]**
Overall	54.8 (114)	45.1 (92)	9.7 (1.6 to 20.9)	0.023
Good health	27.0 (20)	12.5 (9)	14.5 (5.1 to 27.8)	[c]
Intermediate health	53.3 (40)	37.8 (28)	15.5 (3.5 to 33.0)	[c]
Poor health	91.5 (54)	94.8 (55)	–3.3 (−14 to 7.5)	[c]
Secondary Outcome: Percentage of Patients with Appropriate Screening Intent after Provider Visit				
	Decision Aid (n = 210)[d]	**Control (n = 211)[d]**	**Difference (95% CI)[b]**	***P* Value[b]**
Overall	60.5 (127)	47.4 (100)	13.1 (4.5 to 22.9)	0.003
Good health	35.6 (26)	20.0 (15)	15.6 (0.55 to 30.1)	[c]
Intermediate health	53.3 (40)	37.8 (28)	15.5 (3.5 to 33.0)	[c]
Poor health	98.4 (61)	91.9 (57)	6.5 (–0.86 to 14.1)	[c]
Intermediate Outcomes				
	Decision Aid (n = 212)[e]	**Control (n = 212)[e]**		
	Mean (SD)	**Mean (SD)**	**Mean Difference (95% CI)**	***P* Value**
Knowledge score (0−5)	4.1 (1.1)	2.3 (1.2)	1.8 (1.6 to 2.0)	<0.001
Values clarity subscale score (0–100; lower scores indicate greater clarity)	23.3 (15.4)	26.8 (18.0)	3.6 (0.4 to 6.8)	0.028
	% (n)	**% (n)**		
Prepared for individualized decision making (knowledge + values clarity)	67.6 (144)	31.9 (67)	35.7 (26.8 to 44.6)	<0.001
Patient screening preference prior to provider visit: Unsure	24.5 (52)	16.8 (35)	7.8 (0.09 to 15.5)	0.049
Colorectal cancer screening discussion occurred	58.4 (122)	41.6 (87)	16.6 (7.2 to 26.0)	<0.001
Patient initiated screening discussion	61.7 (74)	41.4 (36)	19.9 (6.6 to 33.1)	0.004

[a]The primary outcome (appropriate screening behavior) data for patients in intermediate health was collected immediately following their clinic visit, in contrast with patients in good and poor health whose primary outcome data were collected during the 6-mo follow-up call. Therefore, patients in intermediate health who were lost to follow-up at 6 mo are still represented in the primary outcome analysis.
[b]Confidence intervals and *P* values for the primary and secondary outcomes are adjusted to account for clustering by provider.
[c]The trial was not powered to examine statistically significant differences by health state.
[d]Secondary outcome data (appropriate screening intent) for all patients were collected at the time of the provider visit, so 6-mo survey data are not required for this analysis.
[e]The intermediate outcomes include all patients allocated and randomized at study enrollment.

hypotheses for the intermediate outcomes. A higher proportion of participants in the intervention group were prepared for individualized decision making, initiated discussions about CRC with their providers, and were more likely to report being unsure of their CRC screening preference. Previous work has shown that most older adults intend to continue screening regardless of age or health state[47] and would find it "strange" or uncomfortable to stop.[52] Placed in this context, our results showing an increase in participants who were unsure of their screening preference suggests that the decision aid successfully shifted these patients away from the default of screening—or, potentially, not screening, for those who have never been screened—and encouraged them to think about whether screening was the appropriate choice for them.

Our trial adds to the current literature in several ways. First, it is novel to develop and use a decision aid to

promote appropriate CRC screening. Traditionally, decision aids have been recommended and used for preference-sensitive decisions, in which the risks and benefits are a close call[53,54] or involve outcomes that patients may value differently.[23,54] The primary purpose is to promote high-quality decision making. Our study achieved our measure of decision quality by preparing participants for individualized decision making. Importantly, we also demonstrated efficacy in aligning CRC screening intent and behavior with individuals' potential to benefit from screening.

Our trial also adds specifically to the individualized decision-making literature. Although individualized decision making has been recommended to maximize the benefits and minimize the harms of screening in older adults,[2,7,14,28] implementation of this concept into clinical practice has been limited.[2,14–16,19,55] Further, to our knowledge, there is not a direct measure of individualized decision making. However, our intermediate outcomes suggest that the decision aid promoted individualized decision making by increasing the proportion prepared for it,[42,56] with the intervention group demonstrating increased knowledge and clearer values. Further, our previous work and that of others indicates that the default is for many older individuals to prefer screening, presumably because they have not had the opportunity to learn about the risks and benefits in the context of age and health state.[47,52,57] We demonstrated that the decision aid increased the proportion unsure about their preference for screening before their provider visit, opening them to the idea that undergoing screening may not always be beneficial. It emphasizes that CRC screening in older adults is actually a decision, not an obligation.[52] We chose not indicate to participants their health state or what we believed to be their appropriate CRC decision because of the uncertainty in predicting life expectancy and potential benefit or harm on an individual patient level. Instead, we chose a less prescriptive approach consistent with the behavioral economics principle of "nudging"[58,59] by altering the traditional choice architecture[44] around CRC screening decisions. In doing so, we offered a patient-centered approach to screening decision making that respected patients' screening preferences yet served to better align screening behavior with the potential to benefit from screening.

Finally, our study also introduces a classification scheme for appropriate CRC screening using health state to classify individuals based on their likely life expectancy and potential to benefit from screening. Patients, providers, and those who set guidelines could use this classification scheme for other screening or treatment decisions among older adults to maximize the benefits and minimize the harms for individuals in various health states.[60]

Our trial had some limitations. First, it was performed in the Southeastern United States among a relatively educated patient population, and thus, the generalizability of our findings to other areas of the United States or other populations remains to be established. Our appropriate CRC screening classification system, although based in the literature on life expectancy predictions, has not been formally validated. Further, our intermediate outcomes were designed to indicate whether the decision aid had the desired effect, but we did not directly measure individualized decision making. Finally, although composite measures of both appropriate CRC decision making and screening behavior differed overall and for patients in good and intermediate health, we did not find differences by intervention group among those in poor health. The potential effect of the decision aid was limited, however, because of low screening rates among patients in poor health in both the intervention and control groups. Therefore, we do not know whether the decision aid would reduce CRC screening in other populations in poor health with higher rates of screening.

In conclusion, the targeted decision aid promoted appropriate CRC screening behavior at 6 mo and appropriate CRC screening intent immediately after patients' visits with their providers. The intermediate outcomes indicate that the decision aid was effective in preparing patients for individualized decision making with providers. Patient decision aids may be an effective method to promote appropriate care in an older population across a spectrum of life expectancies.

Acknowledgments

The authors are grateful for the participation of the clinicians and staff at the 14 DukeHealth practices—Duke Outpatient Clinic, Duke Primary Care (DPC) Brier Creek, DPC Butner-Creedmoor, DPC Croasdaile, DPC Harps Mill, DPC Henderson, DPC Hillsborough, DPC Mebane, DPC Pickett Rd, DPC Timberlyne, Durham Medical Center, Oxford Family Physicians, Sutton Station Internal Medicine, and Triangle Family Practice. The authors are also grateful for the data collection by the coordinators and trial assistants at Duke Primary Care Research Consortium (Bethany Grim Appleborne, Luis Ballon, Kathlene Chmielewski, Devon Clark, Lynn Harrington, Lori Hendrickson, Beth Patterson, Liz Schmidt, Stephanie Smith, Erica Suarez, Nicholas Walter, Neha Ranadive, Sarah Ricker, Jessica Stratmon, and Jennifer Talbert) and the personnel at the UNC Sheps Center (Lisa Werner, Byron Raines, Mary Brinson, Bob Schwartz, Anupama Sundaram, Christopher DeLeon, Leonard Williams, and Jane Darter).

References

1. Holden DJ, Jonas DE, Porterfield DS, Reuland D, Harris R. Systematic review: enhancing the use and quality of colorectal cancer screening. *Ann Intern Med*. 2010;152: 668–676.
2. Walter LC, Covinsky KE. Cancer screening in elderly patients: a framework for individualized decision making. *JAMA*. 2001;285:2750–2756.
3. Howlader N, Noone A, Krapcho M, et al. SEER Cancer Statistics Review, 1975-2012. Available from: http://seer.cancer.gov/csr/1975_2012/browse_csr.php?sectionSEL=6&pageSEL=sect_06_table.11.html
4. Garcia-Albeniz X, Hsu J, Bretthauer M, Hernan MA. Effectiveness of screening colonoscopy to prevent colorectal cancer among Medicare beneficiaries aged 70 to 79 years: a prospective observational study. *Ann Intern Med*. 2017;166(1):18–26.
5. Warren JL, Klabunde CN, Mariotto AB, et al. Adverse events after outpatient colonoscopy in the Medicare population. *Ann Intern Med*. 2009;150:849–857, w152.
6. US Preventive Services Task Force. Recommendation summary. Available from: http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/colorectal-cancer-screening
7. US Preventive Services Task Force. Screening for colorectal cancer: US Preventive Services Task Force recommendation statement. *JAMA*. 2016;315:2564–75.
8. Kahi CJ, Azzouz F, Juliar BE, Imperiale TF. Survival of elderly persons undergoing colonoscopy: implications for colorectal cancer screening and surveillance. *Gastrointest Endosc*. 2007;66:544–50.
9. Bellizzi KM, Breslau ES, Burness A, Waldron W. Prevalence of cancer screening in older, racially diverse adults: still screening after all these years. *Arch Intern Med*. 2011;171:2031–7.
10. Heflin MT, Oddone EZ, Pieper CF, Burchett BM, Cohen HJ. The effect of comorbid illness on receipt of cancer screening by older people. *J Am Geriatr Soc*. 2002;50: 1651–8.
11. Sima CS, Panageas KS, Schrag D. Cancer screening among patients with advanced cancer. *JAMA*. 2010;304:1584–91.
12. Powell AA, Saini SD, Breitenstein MK, et al. Rates and correlates of potentially inappropriate colorectal cancer screening in the veterans health administration. *J Gen Intern Med*. 2015;30:732–41.
13. Saini SD, Vijan S, Schoenfeld P, Powell AA, Moser S, Kerr EA. Role of quality measurement in inappropriate use of screening for colorectal cancer: retrospective cohort study. *BMJ*. 2014;348:g1247.
14. Breslau ES, Gorin SS, Edwards HM, Schonberg MA, Saiontz N, Walter LC. An individualized approach to cancer screening decisions in older adults: a multilevel framework. *J Gen Intern Med*. 2016;31:539–47.
15. Eckstrom E, Feeny DH, Walter LC, Perdue LA, Whitlock EP. Individualizing cancer screening in older adults: a narrative review and framework for future research. *J Gen Intern Med*. 2013;28:292–8.
16. Salzman B, Beldowski K, de la Paz A. Cancer screening in older patients. *Am Fam Physician*. 2016;93:659–67.
17. Jimbo M, Rana GK, Hawley S, et al. What is lacking in current decision aids on cancer screening? *CA Cancer J Clin*. 2013;63:193–214.
18. Dolan JG, Frisina S. Randomized controlled trial of a patient decision aid for colorectal cancer screening. *Med Decis Making*. 2002;22:125–39.
19. Schonberg MA, Hamel MB, Davis RB, et al. Development and evaluation of a decision aid on mammography screening for women 75 years and older. *JAMA Intern Med*. 2014;174:417–24.
20. Stacey D, Legare F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2014;1:CD001431.
21. Lewis CL, Esserman D, DeLeon C, Pignone MP, Pathman DE, Golin C. Physician decision making for colorectal cancer screening in the elderly. *J Gen Intern Med*. 2013;28:1202–7.
22. Lewis CL, Moore CG, Golin CE, Griffith J, Tytell-Brenner A, Pignone MP. Resident physicians' life expectancy estimates and colon cancer screening recommendations in elderly patients. *Med Decis Making*. 2008;28:254–61.
23. O'Connor AM, Llewellyn-Thomas HA, Flood AB. Modifying unwarranted variations in health care: shared decision making using patient decision aids. *Health Aff (Millwood)*. 2004;(Suppl Variation):Var63–72.
24. Kistler CE, Golin C, Morris C, et al. Design of a randomized clinical trial of a colorectal cancer screening decision aid to promote appropriate screening in community-dwelling older adults. *Clin Trials*. 2017;14(6):648–58.
25. Winawer SJ, Zauber AG, O'Brien MJ, et al. The National Polyp Study. Design, methods, and characteristics of patients with newly diagnosed polyps. The National Polyp Study Workgroup. *Cancer*. 1992;70:1236–45.
26. Atkin WS, Morson BC, Cuzick J. Long-term risk of colorectal cancer after excision of rectosigmoid adenomas. *N Engl J Med*. 1992;326:658–62.
27. Winawer SJ, Zauber AG, Fletcher RH, et al. Guidelines for colonoscopy surveillance after polypectomy: a consensus update by the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society. *Gastroenterology*. 2006;130:1872–85.
28. US Preventive Services Task Force. Screening for colorectal cancer. Available from: http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm
29. Royce TJ, Hendrix LH, Stokes WA, Allen IM, Chen RC. Cancer screening rates in individuals with different life expectancies. *JAMA Intern Med*. 2014;174(10):1558–65.
30. Kistler CE, Kirby KA, Lee D, Casadei MA, Walter LC. Long-term outcomes following positive fecal occult blood test results in older adults: benefits and burdens. *Arch Intern Med*. 2011;171:1344–51.
31. Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. Six-item screener to identify cognitive impairment

among potential subjects for clinical research. *Med Care*. 2002;40:771–81.
32. Hardcastle JD, Chamberlain JO, Robinson MH, et al. Randomised controlled trial of faecal-occult-blood screening for colorectal cancer. *Lancet*. 1996;348:1472–77.
33. Mandel JS, Bond JH, Church TR, et al. Reducing mortality from colorectal cancer by screening for fecal occult blood. Minnesota Colon Cancer Control Study. *N Engl J Med*. 1993;328:1365–71.
34. Kozuka S, Nogaki M, Ozeki T, Masumori S.Premalignancy of the mucosal polyp in the large intestine: II. Estimation of the periods required for malignant transformation of mucosal polyps. *Dis Colon Rectum*. 1975;18: 494–500.
35. Chen X, White MC, Peipins LA, Seeff LC. Increase in screening for colorectal cancer in older Americans: results from a national survey. *J Am Geriatr Soc*. 2008;56:1511–6.
36. Walter LC, Lindquist K, Nugent S, et al. Impact of age and comorbidity on colorectal cancer screening among older veterans. *Ann Intern Med*. 2009;150:465–73.
37. Fisher DA, Galanko J, Dudley TK, Shaheen NJ. Impact of comorbidity on colorectal cancer screening in the veterans healthcare system. *Clin Gastroenterol Hepatol*. 2007;5: 991–6.
38. Royce TJ, Hendrix LH, Stokes WA, Allen IM, Chen RC. Cancer screening rates in individuals with different life expectancies. *JAMA Intern Med*. 2014;174:1558–65.
39. Kistler CE, Zimmerman S, Ward KT, Reed D, Golin C, Lewis CL. Health of older adults in assisted living and implications for preventive care. *Gerontologist*. 2017;57(5): 949–54.
40. Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. *J Clin Epidemiol*. 1992;45:613–9.
41. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis*. 1987;40:373–83.
42. Lewis CL, Golin CE, DeLeon C, et al. A targeted decision aid for the elderly to decide whether to undergo colorectal cancer screening: development and results of an uncontrolled trial. *BMC Med Inform Decis Mak*. 2010;10:54.
43. Mathieu E, Barratt A, Davey HM, McGeechan K, Howard K, Houssami N. Informed choice in mammography screening: a randomized trial of a decision aid for 70-year-old women. *Arch Intern Med*. 2007;167:2039–46.
44. Quigley M. Nudging for health: on public policy and designing choice architecture. *Med Law Rev*. 2013;21: 588–621.
45. Johnson EJ, Shu SB, Dellaert BGC, et al. Beyond nudges: tools of a choice architecture. *Market Lett*. 2012;23: 487–504.
46. Doak CC, Doak LG, Root JH. Teaching patients with low literacy skills. *Am J Nurs*. 1996;96:16M.
47. Lewis CL, Kistler CE, Amick HR, et al. Older adults' attitudes about continuing cancer screening later in life: a pilot study interviewing residents of two continuing care communities. *BMC Geriatr*. 2006;6:1–8.
48. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006;333: 417.
49. O'Connor AM, Tugwell P, Wells GA, et al. A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Educ Couns*. 1998;33:267–79.
50. Barrett B, Brown D, Mundt M, Brown R. Sufficiently important difference: expanding the framework of clinical significance. *Med Decis Making*. 2005;25:250–61.
51. Katz JN, Chang LC, Sangha O, Fossel AH, Bates DW. Can comorbidity be measured by questionnaire rather than medical record review? *Med Care*. 1996;34:73–84.
52. Torke AM, Schwartz PH, Holtz LR, Montz K, Sachs GA. Older adults and forgoing cancer screening: "I think it would be strange." *JAMA Intern Med*. 2013;173: 526–31.
53. Sheridan SL, Harris RP, Woolf SH. Shared decision making about screening and chemoprevention: a suggested approach from the U.S. Preventive Services Task Force. *Am J Prev Med*. 2004;26:56–66.
54. Lewis CL, Adams J, Tai-Seale M, et al. A randomized controlled effectiveness trial for PSA screening decision support interventions in two primary care settings. *J Gen Intern Med*. 2015;30(6):810–6.
55. Sajid S, Mohile SG, Szmulewitz R, Posadas E, Dale W. Individualized decision-making for older men with prostate cancer: balancing cancer control with treatment consequences across the clinical spectrum. *Semin Oncol*. 2011;38: 309–25.
56. Hersch J, Barratt A, Jansen J, et al. Use of a decision aid including information on overdetection to support informed choice about breast cancer screening: a randomised controlled trial. *Lancet*. 2015;385:1642–52.
57. Schonberg MA, McCarthy EP, York M, Davis RB, Marcantonio ER. Factors influencing elderly women's mammography screening decisions: implications for counseling. *BMC Geriatr*. 2007;7:26.
58. Purnell JQ, Thompson T, Kreuter MW, McBride TD. Behavioral economics: "nudging" underserved populations to be screened for cancer. *Prev Chronic Dis*. 2015;12:E06.
59. Blumenthal-Barby JS, Cantor SB, Russell HV, Naik AD, Volk RJ. Decision aids: when 'nudging' patients to make a particular choice is more ethical than balanced, nondirective content. *Health Aff (Millwood)*. 2013;32:303–10.
60. Kutner JS, Blatchford PJ, Taylor DH Jr, et al. Safety and benefit of discontinuing statin therapy in the setting of advanced, life-limiting illness: a randomized clinical trial. *JAMA Intern Med*. 2015;175:691–700.