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Design of a randomized clinical trial of a colorectal cancer screening decision aid to promote appropriate screening in community-dwelling older adults

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Abstract

Background—Appropriate colorectal cancer screening in older adults should be aligned with the likelihood of net benefit. In general, patient decision aids improve knowledge and values clarity, but in older adults, they may also help patients identify their individual likelihood of benefit and foster individualized decision making. We report on the design of a randomized clinical trial (RCT) to understand the effects of a patient decision aid on appropriate colorectal cancer screening. This report includes a description of the baseline characteristics of participants.

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Declaration of conflicting interests

The authors report no conflicts of interest in this work.

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Methods—English-speaking primary care patients ages 70–84 who were not currently up-to-date with screening were recruited into an RCT comparing a tailored colorectal cancer screening decision aid with an attention control. The intervention group received a decision aid that included a values clarification exercise and individualized decision-making worksheet, while the control group received an educational pamphlet on safe driving behaviors. The primary outcome was appropriate screening at six months based on chart review. We used a composite measure to define appropriate screening as screening for participants in good health, a discussion about screening for patients in intermediate health, and no screening for patients in poor health. Health state was objectively determined using patients' Charlson Comorbidity Index score and age.

Results—Fourteen practices in central North Carolina participated as part of a practice-based research network. Four hundred twenty-four patients were recruited to participate and completed a baseline visit. Overall, 79% of participants were white and 58% female, with a mean age of 76.8 years. Patient characteristics between groups were similar by age, gender, race, education, insurance coverage, or work status. Overall, 70% had some college education or more, 57% were married, and virtually all had Medicare insurance (90%). The three primary medical conditions among the cohort were a history of diabetes, pneumonia, and cancer (28%, 26%, and 21%, respectively).

Conclusion—We designed an RCT to test a novel use of a patient decision aid to promote appropriate colorectal cancer screening and have recruited a diverse study population that seems similar between the intervention and control group. The study should be able to determine the ability of a patient decision aid to increase individualized and appropriate colorectal cancer screening.

Keywords

Individualized decision making; appropriateness; elderly; colorectal cancer screening; randomized clinical trial

Introduction

Colorectal cancer screening can extend the lives of older adults but can also put them at risk for significant harm. To maximize the benefit and minimize the harms of colorectal cancer screening, guidelines for older adults ages 76 to 85 recommend against routine screening and endorse individualized recommendations using an assessment of life-expectancy^{1–4} based on age and health. Ideally, individualized screening in older adults would encourage screening for those in good health with the greatest life-expectancy and discourage screening for those in poor health with the shortest life-expectancy.⁵ Despite recommendations for individualized cancer screening, research suggests that inappropriate screening is problematic, resulting in underuse in older adults in good health and overuse in those in poor health.^{6–8}

Patient decision aids for colorectal cancer screening developed for younger adults have been shown to increase knowledge, reduce decisional conflict, and increase participation in decision making.^{9, 10} However, a recent systematic review found that among 21 existing colorectal cancer screening decision aids, none addressed screening in older adults.¹¹

Further, none to our knowledge have been designed specifically to promote individualized decision making.^{3, 12} Decision aids that adequately inform older adults may serve to achieve individualized decision making and result in more appropriate screening. Providing older adults with a better understanding of how age and health state affect the potential risks and benefits of colorectal cancer screening could align patient screening preference with the potential to benefit from screening. We anticipate the mechanism of action of this decision aid to be a “nudge” to encourage patients to consider their screening preference vis-à-vis their own health – a novel use of a decision aid. Nudges reduce the cognitive burden of decision making and provide a way to make more individualized decisions.¹³ Nudges make it easier for patients to weigh evidence and support their decisions.¹⁴

We have previously developed and preliminarily tested a colorectal cancer screening decision aid designed to improve individualized decision making for older adults.¹⁵ To fully test the effect of the decision aid on the appropriateness of cancer screening intent and test completion, we conducted a randomized clinical trial (RCT) of a colorectal cancer screening decision aid targeted to older adults ages 70 to 84. We hypothesized that the decision aid would prepare them for individualized decision making by improving knowledge and values clarity and promote appropriate screening. The primary outcome of this trial was appropriate screening determined 6 months after the index visit, where screening completion was determined by self-report via a phone interview and assessed for appropriateness by the research team using an individualized conceptual framework (below). The secondary outcome was appropriate screening intent immediately after the patient-provider visit, where screening intent was determined by a post-visit survey and assessed for appropriateness using the framework as well. This paper describes the design of the RCT, its rationale, and the baseline characteristics of the participants.

Methods and analysis

Conceptual framework for appropriate colorectal cancer screening in older adults

The importance of individualized decision making has been established.⁵ Individualized decision making frameworks posit that screening preferences will better align with potential benefit when patients are adequately informed about risks and benefits and given the opportunity to consider their personal values.^{16, 17} An individualized framework for cancer screening has been described but not tested in clinical care.¹⁸ For the proposed research, we describe a conceptual model that is based in decision making theory and on clinical decision making models proposed by both Eddy and Deber (Figure 1).^{19, 20} We propose that the decision aid increases patient awareness of the need for individualized decision making and changes decisional balance by providing information about benefits and harms in the context of age and co-morbidities.^{21–23} Because older adults are prepared for individualized decision making, providers and patients can then engage in individualized decision making which leads to appropriate decision making about screening based on individuals’ likely potential benefit from colorectal cancer screening and their personal preferences.

Identification of potential participants

Patient participants were identified from the Duke University Health System practice-based research network. We recruited 14 primary care practices from the Duke research network in central North Carolina, and then recruited a maximum of 12 patients per provider. Recruitment finished in July, 2014. All patients aged 70 to 84 years old with scheduled appointments with their primary care provider within 4 to 6 weeks at one of the research network clinics were potentially eligible. Patients were potentially eligible if they were “not-up-to-date” with screening or surveillance colonoscopy, which included no history of any screening or no evidence of: fecal occult blood test within 1 year, sigmoidoscopy within 5 years, or negative colonoscopy within 10 years. We excluded patients who were in surveillance for high risk lesions (recommended follow up 3 years or less) but included older adults who were in surveillance but had low risk of colon cancer - those who had a colonoscopy between 4 to 10 years ago and were due again per gastroenterologists’ recommendations.^{24–26} We included these low risk surveillance patients because, similar to those undergoing screening, the risk of colon cancer is relatively small according to recent guidelines, relative to the potential harms for undergoing colonoscopy at advanced age in poor health.^{26, 27}

We initially reviewed patient charts for eligibility. Patients who remained eligible after chart review were sent a letter from their providers, explaining the study and provided them with an opt-out card to prevent further contact. We either called patients who did not return the opt-out card or approached them in the practice to recruit them for the study. For those contacted by phone, verbal informed consent and authorization to release medical information were obtained. We confirmed eligibility among patients who agreed to participate in the study by reviewing colorectal cancer testing that may have not been documented in the electronic health record. Eligible patients were then asked to arrive one hour prior to their scheduled clinic appointment to provide written consent to the study, receive their randomization packet, and complete the screening preference forms. 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. Other exclusion criteria included possible dementia via screener and history of colorectal cancer or inflammatory bowel disease per chart review and participant query. We used a 6-item screen (3-item recall and a 3-item temporal orientation) to identify and exclude older persons with probable cognitive impairment.²⁸ For patients approached within the clinic, we confirmed eligibility prior to their visit, had them provide written consent to the study, receive their randomization packet, and complete the screening preference forms at the time of first contact.

To examine the effect of the decision aid across the spectrum of health, we used purposeful sampling to recruit 150 participants in each of three health groups (good, intermediate, and poor) as derived from their Charlson Comorbidity Index^{29, 30} score and age (Table 1). Because our major outcome was *appropriate screening*, a composite outcome across health states, we wanted to ensure adequate numbers in each subgroup. Therefore, we used permuted blocks by health state to assign participants to intervention or control arm. Once 150 participants were recruited to a health state, further patients in that category were considered ineligible for the study. Participants received a total of 5 surveys across the study

timeline (Figure 2). The measures included in each survey varied by time point. The surveys conducted in the clinics took place in quiet research spaces available at each site. The procedures were identical for the control group except they were provided a written booklet on driving safety as an attention control instead of the colorectal cancer decision aid. Participants received a total of \$50 for participating (\$25 after the clinic visit, \$25 after the 6-month phone call).

Intervention

Underlying our framework for individualized decision making is the concept of informed decision making.^{31, 32} Based on the Ottawa Decision Support Framework and international standards for decision aid development, we developed two components for the intervention - education and values clarification.^{33, 34} The final result is the decision aid used in this trial: “Making a Decision about Colon Cancer Screening”.¹⁵ It was a 20 page paper-based tool with six versions targeted to patients’ according to their age and sex (70–74/Female, 70–74/Male, 75–79/Female, 75–79/Male, 80–84/Female, 80–84/Male). See Supplemental Materials for an example. It had large font to accommodate visual difficulties and was written at a 7th grade reading level,³⁵ taking between 5 and 15 minutes to read. It included 6 basic components, including: 1) a description of fecal occult blood testing; 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 sex; 5) why individualized decision making is necessary for older adults compared to younger people; and 6) the need to weigh the harms and benefits of colorectal cancer screening for each individual, including a visual demonstration of the balance of benefits and harms by overall health status. Lastly, it included a values clarification exercise entitled “Individualized Decision Making Worksheet” designed so that patients could bring it into their clinic visit as a paper cue for providers.

Control

Participants not randomized to the intervention received an attention control developed by the AAA Foundation for Traffic Safety, entitled, “Drivers 65 Plus: Check Your Own Performance”. It contained education about driving, suggestions to increase safe driving and a self-rating driving evaluation form. It was a 20-page tool including 14 personal questions about driving such as, “How many traffic tickets, warnings, or “discussions” with law enforcement officers have you had in the past two years?” and “I find it difficult to decide when to merge with traffic on a busy interstate highway.” The tool was not tailored to either patient gender or age. We chose this control because the driving tool contains materials about the decision to stop driving, just as the intervention contained materials about the decision to stop cancer screening. There were also no other cancer screening decision aids for all older adults that might constitute “usual care” and a natural control. See Supplemental Materials.

Randomization and blinding

Participants were randomly assigned through a centralized computer process to either the intervention or control. They received a pre-labeled, opaque, sealed packet that was sorted

and assembled by research assistants not involved with data collection. The packet did not indicate to participants their group assignment. Participants were asked to put the intervention or control back in the manila envelope and seal it after viewing it, to ensure RAs were also blinded to study arm. In addition to blinding for the intervention and control, participants were also blinded to their health state as were the research assistants who assessed the primary outcome. However, the research assistants who performed the eligibility, baseline, post-visit and post-intervention surveys were not blinded to the participant's health state.

Measures

We collected information on the participants' colorectal cancer screening history, knowledge of colorectal cancer screening harms and benefits, and other measures of informed decision-making. We also collected information on demographics, functional status, and other characteristics that may influence screening behavior (see Table 2). In order to assess eligibility and health state, the eligibility survey measures included the patient's age, colorectal cancer screening history, and Charlson Index score. The baseline survey included measures of demographic characteristics, as well functional status³⁶ and self-reported health.³⁷ Participants also rated their preference for or against cancer screening prior to receiving the intervention. After receiving either the intervention or control but before their visit with providers, we assessed measures that might be influenced by the intervention. Participants again rated their preference for or against cancer screening. They also reported their colorectal cancer screening knowledge and values, and completed the values clarification exercise. They were also asked about their decisional conflict³⁸ and preference for shared decision making.³⁹ We also assessed perceived life-expectancy. We assessed participants' intentions about screening in a post-visit survey after they had received the intervention/control and participated in their visit with their provider. We included health literacy⁴⁰ and a timed sit-to-stand test⁴¹ in the post-visit survey. We also asked open-ended questions about screening discussions that occurred during the visit to understand the content important to those discussions and thus their decisions. Six-months after the index study visit, patients received a telephone survey to assess their completion of cancer screening, colorectal cancer screening knowledge and values, preparedness for decision making,⁴² activities of daily living,³⁶ general health status (using the SF-1),³⁷ and any new health conditions.

Outcome measures—The primary outcome of this study was a dichotomous variable of whether or not *appropriate screening* had occurred by 6 months after the index visit. The presence of screening was measured by self-report of screening completion at the 6-month follow-up survey. We defined the presence of appropriate screening as: screening for participants in the good health state, a patient-provider discussion about screening during the office visit for patients in the intermediate health state, and no screening in the poor health state. Based on prior studies,^{8, 43, 44} we used a combination of the widely used Charlson Comorbidity Index score⁴⁵ and the individual's age to categorize health states: good health—the youngest and healthiest patients (age 70–79 and Charlson score = 0 or age 70–74 and Charlson score=1–3) who were expected to live >10 years; intermediate health—the younger patients with increasing comorbidity and the oldest, healthiest patients (age 70–74

and Charlson score ≥ 4 , age 75–79 and Charlson score = 1–3, or age 80–84 and Charlson score = 0) who were expected to live 5–10 years; and poor health—the oldest, sickest patients (age 75–79 and Charlson score ≥ 4 or age 80–84 and Charlson score > 0) who were expected to live < 5 years.⁸ Based on the literature suggesting at least 5 years of life expectancy is needed to benefit from screening,^{24, 46–49} this classification system was done because it easily performed and correlates well with other mortality indices.⁴³ The secondary outcome was the appropriateness of the cancer screening intent measured by patient report immediately following the provider visit. The definition of appropriate screening intent and screening completion depended on the patient's initial health state classification. For patients classified in good health, appropriate intent and screening completion were to decide in favor of screening and receive screening. For patients classified in poor health, appropriate intent and screening were to decide NOT to receive screening and to not receive screening. Those in the intermediate group health group were considered to have appropriate screening if a discussion of cancer screening occurred during the office visit, regardless of the final screening intent or completion (Figure 3). Occurrence of a discussion was determined through direct questioning of the participant during the post-visit survey. Additional outcome measures included the change in cancer screening knowledge and values clarity.

Analysis

For this paper, we conducted an analysis of the baseline data to examine randomization. Descriptive statistics for demographics and other health measures were calculated overall and by treatment group. Means and standard deviations were reported for continuous measures, and frequencies and percentages were reported for categorical variables. These measures were compared between treatment groups using t-tests for continuous variables and chi-square tests for categorical variables to confirm randomization. All analyses were conducted using SAS v9.3. We anticipated that the analysis and results of the primary and secondary outcomes of this study will be reported at a later time.

Sample size

Because of the hierarchical structure of the study, we had to account for the correlation among patients within a physician and practice. We conservatively estimated this intra-class correlation coefficient to be 0.0225. Based on prior work, the smallest meaningful increase in percent of appropriate screening was judged to be 10 to 15%.^{50, 51} Given this information, the largest effective total sample size was 413 and the smallest is 282 (equivalent to 206 to 141 per arm). We calculated that we needed 180 patients per arm to have 80% power to see a 15% increase in appropriate screening.

Ethical approval and trial registration

The study protocol was approved by both the Duke University and University of North Carolina at Chapel Hill Institutional Review Boards. We will publish our findings regardless of the results and will follow the CONSORT guidelines for reporting RCTs. The trial is registered at clinicaltrials.gov (NCT01575990). This project was supported by the Agency for Healthcare Research and Quality Research Centers for Excellence in Clinical Preventive Services, grant number P01 HS021133. The content was and is solely the responsibility of

the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.

Results

Participants were enrolled from January 2012 through June 2014 in 14 practices from a practice-based research network in central North Carolina. A total of 872 older adults were assessed for inclusion; 448 were ineligible for the study, including 33 who declined participation. Four hundred twenty-four participants enrolled in the study and completed the eligibility and baseline surveys. Overall, 79.1 % of participants were white and 58.5% female with a mean age of 76.8 years (Table 1).

No differences were found between the intervention and control group. In total, 70% had some college education or more, 57% were married, and virtually all of them had Medicare insurance (90%). The three primary medical conditions of the cohort were a history of diabetes, pneumonia, and cancer (28%, 26%, and 21%, respectively). Nearly one-fifth (18%) of the population reported their health as fair or poor, and 33% had difficulties with at least 1 activity of daily living.

Discussion

This paper presents the protocol and baseline results for a randomized clinical trial evaluating a decision aid based on a conceptual framework for individualized decision. Our decision aid was designed to promote individualized and appropriate colorectal cancer screening. We were able to successfully recruit older patients to participate in the study, with roughly equal participation across health states. Our baseline findings suggest the sample is similar to older adults in the United States. The top three medical conditions of the cohort were diabetes, cancer, and pneumonia, which rank seventh, second, and eighth, respectively, in leading causes of death in adults 65 and older in the United States.⁵²

The primary outcome of our trial was appropriate cancer screening. Few decision aids for patients have examined how these tools help clarify patients' values, let alone improve the alignment between those values and appropriate care.¹⁰ A systematic review found that only half of cancer screening decision aids examined screening behavior as an outcome.¹¹ Of those studies, none examined appropriate screening as an outcome. One decision aid targeting women age 70 and older about mammography screening increased preparation for individualized decision making, but did not change self-reported screening test completion at one month.⁵³ It did not evaluate appropriate screening in regards to health state. Our review of the literature found one breast cancer screening decision aid that increased appropriate breast cancer screening in older women.⁵⁴ This tool reduced mammography in those unlikely to benefit, but showed no significant change in those likely to benefit. However, it at least attempted to examine the appropriate cancer screening as an outcome. The preliminary testing of the decision aid we used in this study found that it increased older adults' preparedness for individualized decision making, though that study lacked sufficient numbers of participants to examine appropriate colorectal cancer screening.¹⁵

Some argue that patients need decision aids only when decisions are preference-sensitive.⁵⁵ However, with ongoing issues of over-screening and under-screening in older adults, the goal of decision aids in older adults should be to individualize decisions. A focus on appropriate cancer screening that provides targeted messages about harm and benefits may allow decision aids in older adults to more closely adhere to the international criteria for decision aids.⁵⁶ Even research into patient decision aids acknowledges the need to clarify the role of a decision aid in the clinical encounter.⁵⁷ The efficacy of the decision aid should be measured in terms of how it changes the harms and benefits of screening across the population, increasing screening for some and decreasing screening for others as appropriate for the individual. Thus, we believe that this study of a decision aid designed to promote individualized decision making through the provision of information and opportunity for values clarification, represents an important contribution to the field of decision making research. This study provides an opportunity to gain insight into the interactions between patient values and appropriate screening, and may provide a way to respect patients' values and decrease the harms of screening, including over-diagnosis and overtreatment.⁵⁸

Conclusion

We designed an RCT to evaluate a novel decision aid to promote appropriate colorectal cancer screening. We have recruited a diverse study population. The study will allow us to examine the effect of the decision aid on appropriate cancer screening.

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Figure 1.
Conceptual Framework

Figure 2.
Trial Design and Activities

		Charlson Comorbidity Score		
		0	1-3	≥ 4
Age	70-74	Screen	Screen	Discuss
	75-79	Screen	Discuss	No Screen
	80-84	Discuss	No Screen	No Screen

Figure 3. Appropriate Screening
Outcome Measure

Table 1**Baseline Participant Characteristics by Intervention and Control**

Participant Characteristics	Total (N=424)	Intervention (N=212)	Control (N=212)
Age, mean (SD)	76.8 (4.2)	76.6 (4.1)	77.1 (4.3)
Charlson Comorbidity Score, mean	1.9 (2.1)	1.9 (1.7)	2.0 (2.4)
Health State			
Good	149 (35.1)	74 (49.7)	75 (50.3)
Intermediate	150 (35.4)	76 (50.7)	74 (49.3)
Poor	125 (29.5)	62 (49.6)	63 (50.4)
Female	248 (58.5)	130 (61.3)	118 (55.7)
Race			
White or Caucasian	335 (79.1)	173 (81.6)	162 (76.4)
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)
Educational Status			
Some High School or Less	30 (7.1)	15 (7.1)	15 (7.0)
12 th Grade Graduation	95 (22.4)	58 (27.4)	37 (17.5)
Some College or Associate's Degree	97 (22.9)	44 (20.8)	53 (25.0)
College Degree	90 (21.2)	40 (18.9)	50 (23.6)
Masters, PhD, JD, or MD	112 (26.4)	55 (25.9)	57 (27.9)
Marital Status			
Married/Cohabiting	241 (56.8)	117 (55.2)	124 (58.5)
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)
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)
Currently Employed	58 (13.7)	32 (15.1)	26 (12.3)

Participant Characteristics	Total (N=424)	Intervention (N=212)	Control (N=212)
Unemployed	11 (2.6)	6 (82.1)	180 (85.3)
Diabetes requiring medications	121 (28.5)	67 (31.6)	54 (25.5)
History of Pneumonia	109 (25.7)	61 (28.9)	48 (22.6)
Cancer, other than skin, leukemia, lymphoma	88 (20.8)	40 (18.9)	48 (22.6)

Table 2**Study Measures**

Eligibility Measures	Survey Timing
Dementia Screen ²⁸	Eligibility
Not up to date with CRC screening ⁵⁹	Eligibility
Measures to Classify Patients into Health States	
Charlson Comorbidity Index ²⁹	Eligibility
Age group	Eligibility
Patient Characteristic Measures	
Demographics: Age, race/ethnicity, gender, education, etc.	Baseline
Functional status: activities of daily living, ³⁶ their general health status (the SF-1) ³⁷	Baseline
Sit-to-Stand test ^{41,60}	Post-visit
Previous colorectal cancer screening (ever)	Baseline
Health literacy ⁴⁰	Post-visit
Visit type	Post-intervention
Saw regular physician	Post-intervention
Decision Making Measures	
Decisional conflict ³⁸ (Knowledge score+ Values Clarification subscale)	Baseline, Post- intervention
Preparation for decision making ⁴²	Post-intervention
Preference for shared decision making ³⁹	Baseline
Screening preference ¹⁵	Baseline, Post- intervention
Balance of harms and benefits (decisional balance) ¹⁵	Post-intervention
Intent to discuss screening during the visit ⁶¹	Post-intervention
Outcomes	
Primary Outcome- Appropriate screening 6 months after index visit ^{8,44,62}	6 month
Secondary Outcome- Appropriate screening decisions after index visit ^{8,44,62}	Post-visit