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Final Results of a 3-Year Literacy-Informed Intervention to Promote Annual Fecal Occult Blood Test Screening¹

Connie L. Arnold, PhD¹, Alfred Rademaker, PhD², Michael S. Wolf, PhD, MPH³, Dachao Liu, MS², Geoffrey Lucas, MPP¹, Jill Hancock, BA¹, and Terry C. Davis, PhD¹

¹Department of Medicine, Louisiana State University Health Sciences Center, Shreveport, LA

²Department of Preventive Medicine and the Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, IL

³Division of General Internal Medicine & Geriatrics, Northwestern University, Chicago, IL

Abstract

Background—This three arm study was designed to make CRC screening with FOBTs more accessible, understandable and actionable for patients cared for in predominantly rural Federally Qualified Health Centers (FQHCs). Patients in an enhanced version of usual care received an annual CRC recommendation and FOBT kit; those in the education arm additionally received brief literacy and culturally appropriate education and those in the nurse arm received the education by a nurse manager who followed up by telephone. Baseline FOBT rates in this population were 3%. We evaluated if FOBT rates could be sustained over three years.

Methods—A three-arm, quasi-experimental evaluation was conducted among 8 clinics in Louisiana. Screening efforts included: 1) enhanced usual care, 2) literacy-informed education of patients, and 3) education plus nurse support. Overall, 961 average-risk patients, ages 50-85, eligible for routine CRC screenings were recruited. The primary outcome was completing three annual FOBT tests.

Results—Of 961 patients enrolled, 381 (39.6%) participants did not complete a single FOBT, 60.4% completed at least one FOBT of which 318 (33.1%) completed only one, 162 (16.9%) completed two and 100 (10.4%) completed three FOBTs over the three-year period (the primary study outcome). The primary outcome, return of three FOBT kits over the three-year period, was achieved by 4.7% in Enhanced Care, 11.4% in Education and 13.6% in the Nurse arm (p=0.005).

Conclusions—Overall three-year FOBT screening rates were not sustained with any of the three interventions, despite reports of promising interim results at years 1 and 2. New strategies for sustaining FOBT screening over several years must be developed.

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Corresponding Author: Connie L. Arnold, PhD, Associate Professor, Department of Medicine, Louisiana State University Health Sciences Center - Shreveport, 1501 Kings Highway, P.O. Box 33932, Shreveport, LA 71130-3932, Phone: 318-675-4324, Fax: 318-675-4348 (fax), carnol@lsuhsc.edu.

No conflicts are noted by the authors related to the work described.

Keywords

Health Literacy; Colon Cancer Screening; Annual screening; Federally Qualified Health Centers

Introduction

Colorectal cancer screening (CRC) with Fecal Occult Blood Tests (FOBTs) reduces mortality rates [1-5]. U.S. clinical guidelines recommend annual FOBTs [6, 7] yet sustaining yearly screening is challenging [8-10]. Innovative, evidence-based strategies are needed to promote continued longitudinal adherence to annual FOBT screening particularly among vulnerable populations cared for in resource limited safety-net clinics [9-14]. The National Colorectal Cancer Roundtable recently recommended focusing initiatives on Federally Qualified Health Centers (FQHCs) to address national screening challenges [15]. FQHCs provide primary care to over 22 million individuals regardless of insurance status [16] and have recently added CRC screening as a quality indicator.

Strategies to improve first-time rates of CRC screening included patient-directed interventions (written materials, DVDs, mailed FOBTs and reminders, telephone counseling), and physician-directed interventions (chart stickers, electronic reminders, academic detailing) [9-22]. Few studies promoting multi-year screening (focusing on FOBTs in particular) have been conducted in the US; most of these were with insured patients in large health systems [23]. The most effective strategies involve giving educational materials and FOBT kits during a clinic visit the first year with telephone follow up if needed and mailing the kits the second year, yet less than one in four patients were adherent with two rounds of screening [23].

Population based screening programs abroad where FOBTs are mailed by centralized health service to eligible individuals have higher repeat FOBT screening rates (39% to 55%) [24-27]. Interestingly, in these programs which eliminate geographic and cost barriers completion rates were lower in individuals from rural areas and those of lower socioeconomic status [28]. These programs also found barriers to completing one FOBT appeared to differ from those in sustaining FOBT screening over multiple years [24].

Our team designed, implemented and evaluated a multifaceted health literacy informed intervention to promote FOBT completion annually over three years in a vulnerable population served by predominately rural FQHCs in Louisiana. Our three arm study was designed to make annual CRC screening with FOBTs more accessible, understandable and actionable. Patients in an enhanced version of usual care received an annual recommendation and FOBT kit; those in the education arm additionally received brief literacy and culturally appropriate education, and simplified FOBT instructions; those in the nurse arm received the education materials by a nurse manager who followed up by telephone. The interim results, measured at the end of years 1 and 2, were promising, as reported previously [29, 30]. Baseline FOBT rates in this population were 3%. After year 1 of the intervention, initial FOBT rates improved to 39% with enhanced care, 57% with educational support, and 61% with nurse support. After year 2, repeat FOBT rates were 38% with enhanced care, 33% with educational support, and 59% with nurse support. We now

report on the overall results of all 961 patients who were enrolled in this three-arm intervention- FOBT completion study for three years.

Methods

Theoretical Framework

The Health Belief Model and Social Cognitive theory guided the framing of the intervention to highlight the benefit of FOBT screening and the need to take action annually [31-33]. Health literacy best practices were employed to help ensure the information was easy to understand and act on [34,35].

Study Design

A three-arm intervention was conducted among three FQHC networks in predominately rural areas of Louisiana between May 2008 and August 2011. Of the five FQHC networks in the area, three participated and were assigned to one of three arms by simple randomization (the other two network FQHCs were involved in cancer screening programs at the time). Each participating clinic was assigned to the same study arm as their parent FQHC network. This resulted in two clinics in enhanced care, two in the educational intervention, and three in nurse support arm. After the first study year, one additional clinic was enrolled in the enhanced care arm due to limited patient recruitment in this arm during the first year. The eight clinics were located in eight towns. Baseline CRC screening rates at each clinic ranged from 1% to 3%.

Patients aged 76-85 were included per the request of clinic directors. Further eligibility included: 1) English-speaking, 2) not requiring screening at an earlier age according to American Cancer Society guidelines [6], 3) not up-to-date with United States Preventive Services Task Force [7] CRC screening recommendations (i.e., an FOBT annually, flexible sigmoidoscopy every 5 years or colonoscopy every 10 years), 4) medical staff believing patients too ill to be interviewed. All participants were consented prior to data collection.

At enrollment (fig. 1), 1,055 patients were identified as meeting age criteria, of these 33 (3.1%) refused to participate and 61 (5.8%) were ineligible because they were up to date on CRC screening. A total of 961 patients were consented and enrolled, with a determined cooperation rate of 91.1%. A total of 512 patients completed a FOBT within three months, 51 had a positive test and received a provider referral for a colonoscopy and were therefore not eligible for a 2nd annual FOBT. In year 2, 461 patients were eligible for a repeat annual FOBT; of these, 210 (46%) completed screening and four had a positive test. In year 3, 206 patients were eligible for a 3rd annual screening test; of these, 99 (48%) completed screening and seven had a positive test.

The Louisiana State University Health Sciences Center – Shreveport Institutional Review Board approved the study. Each participant received \$10 for their participation in the baseline survey.

Study Instruments

A structured survey, including patient demographics, CRC screening items from validated questionnaires used previously by the authors, and a literacy assessment were administered at enrollment. A detailed description of the survey, which was administered orally, has been reported previously [36]. Literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM) [37].

Interventions

Enhanced Care—An enhanced version of usual care where patients waiting for a scheduled appointment with their provider received a recommendation for CRC screening by a clinic based research assistant (RA) and an FOBT kit with a stamped envelope addressed to the clinic. In year 2 and 3, twelve months after a patient's previous FOBT was returned or twelve months after the enrollment date if the FOBT hadn't been completed, a letter was sent by a central RA as a reminder that it was time for their annual FOBT and to inform them that a kit would be mailed the following week. The central RA mailed the FOBT with a stamped envelope addressed to the clinic. Patients returned FOBTs to the clinic by mail. Regular clinic protocol was followed for positive test results and referral for diagnostic testing.

Literacy-Informed Education—Patients in this arm *additionally* received brief education by a clinic based RA using literacy and culturally appropriate material (pamphlet, simplified FOBT instructions and video). The RA demonstrated how to perform the test and used 'teach back' to confirm patient understanding [34]. In years two and three, a central RA mailed a reminder letter and FOBT kit that also included simplified FOBT instructions and a pamphlet. Tracking and follow-up were the same as in the enhanced care arm.

Nurse Support—In this arm a designated clinic nurse provided the education and FOBT kit. If the patient did not mail the FOBT to the clinic within two weeks the nurse followed up by telephone within two weeks and again in one month to problem-solve barriers and motivate them to complete the test [28]. At the same specified dates for follow-up used in the other arms, the nurse mailed patients the *simplified* materials. If patients did not return their FOBT, the nurse followed up by telephone. Patients returned FOBTs to the clinic by mail. The nurse recorded and tracked results. If results were positive, the nurse called patients to discuss results, facilitate appointments with their primary care provider, and if indicated, schedule patients for a diagnostic colonoscopy.

Outcomes for the Intervention

The primary study outcome was completion of three FOBTs annually within the time frame of the study or having a positive FOBT that was followed up with colonoscopy. Secondary outcomes included completion of 0, 1, or 2 FOBTs during the three-year intervention period. Screening results were documented by the clinic nurse (enhanced care and education arms) or study nurse (nurse support arm).

Analyses

The denominator for analyses is the number of patients in each arm, eligible for the first year study (Enhanced Care $n = 275$, Education $n = 282$, Nurse $n = 404$). To examine whether patients in study arms differed on baseline characteristics, generalized estimating equations (GEE) accounting for clustering by clinic was used. Both global and pairwise tests for FOBT completion (0, 1, 2, 3 FOBTs) were calculated using GEE. Multivariate analyses adjusted for age, race, gender, and literacy level.

Results

Baseline characteristics are compared among groups in Table 1. Participants ranged in age from 50-89; 77% were female. The majority (67%) were African American; over half (56%) had low literacy (i.e. read 9th grade level). Almost all wanted to know if they had cancer (90%) and believed that an FOBT would find CRC early (96%). Although no patient was up-to-date with screening, 28% reported completing a FOBT sometime in the past. There were significant differences across groups for age, race/ethnicity, marital status, literacy, prior recommendation, previous FOBT, wanting to know if they had CRC and positive beliefs concerning FOBT efficacy.

Overall 62 (6.5%) of patients had a positive FOBT result. Most of these (82.3%) were found on the first FOBT, 6.5% were found on the second test, and 11.3% on the 3rd. Of the 51 patients that had a diagnostic colonoscopy, 4 had polyps, and 2 were diagnosed with colon cancer.

Discussion

While the interim results for this three-arm intervention focusing on improving FOBT rates among medically underserved persons in Louisiana who receive care at FQHCs were promising with FOBT rates that increased from a baseline of 5% to over two years as high as 59% (in the nurse support arm), the overall results at the end of three years are disappointing. After removing participants who had positive FOBT tests such that they became ineligible for the subsequent FOBTs from the total sample, FOBT completion rates at the end of the three years were 13% for the nurse intervention, 11% for the educational intervention, and 4% for the enhanced usual care arms.

The low rate of patients' completing FOBTs annually for three years demonstrates the challenge of sustaining annual FOBT completion among vulnerable populations. The pattern of FOBT compliance suggests that more intensive strategies, particularly after two years of FOBT screening, are needed to promote sustained annual FOBT screening or whether support for every ten-year colonoscopy needs to be considered. Whether the FOBT completion rate at fourth year would continue for the small numbers of persons who completed three FOBTs with or without continued interventions past the 3-year duration of the study is also unknown.

Limitations include differences between arms in sociodemographic characteristics (adjustments were made in the statistical analyses), and generalizability from a

predominantly African American and female population receiving care from FQHCs in one state. However, this is representative of FQHC populations in the southern United States. In addition, half of the sample had low literacy, which is more common in older, lower-income populations.

Conclusion

This study's findings illustrate the challenge in sustaining annual CRC screening over a three-year period by use of FOBTs. For FOBT screening to be effective it must be done annually – and hence strategies for improving repeat screening must be developed in resource challenged settings or strategies that support colonoscopy for persons in these settings should be developed. Compliance to repeat FOBT screening over time was improved three-fold by either education or nurse support, but overall rates were disappointing low (< 14%) in each of the three study arms. Helping disadvantaged populations with limited literacy will likely require more personal outreach and ongoing support if sustaining annual FOBT screening is to occur or strategies that allow for colonoscopy as a screening test should be developed.

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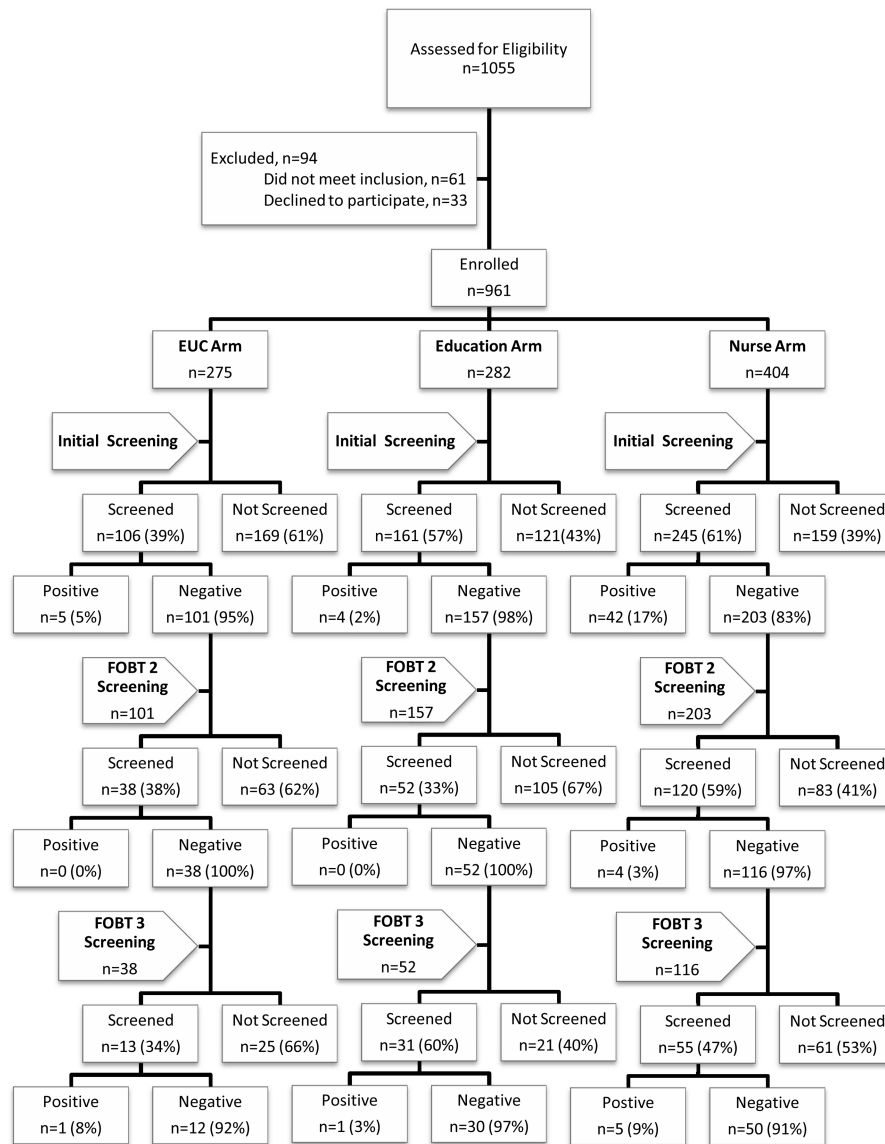


Figure 1. Flowchart of Initial and Repeat Screening (those who completed initial screening)

Table 1
Characteristics of Study Sample at Baseline, Stratified by Study Arm

Characteristic	All Patients (n=961)		Study Arm		p-value
	N (%)	N (%)	Enhanced Usual Care (n=275)	Nurse (n=404)	
Age, Mean (sd)	58.4 (7.3)	57.7 (7.5)	57.8 (6.5)	59.2 (7.5)	0.014
Age Categories					
50-59	611 (64)	190 (69)	181 (64)	240 (59)	0.11
60-69	265 (28)	63 (23)	80 (28)	122 (30)	
70-85	85 (9)	22 (8)	21 (7)	42 (10)	
Female	740 (77)	207 (75)	224 (79)	309 (77)	0.50
Years of Education					
Less than high school	313 (33)	98 (36)	92 (33)	123 (31)	0.26
High school grad	435 (45)	109 (40)	139 (49)	187 (47)	
Some College	157 (16)	50 (18)	40 (14)	67 (17)	
College Graduate	53 (6)	18 (7)	11 (4)	24 (6)	
Race					
African-American	645 (67)	199 (72)	114 (40)	332 (83)	<0.0001
Caucasian/Hispanic	313 (33)	76 (28)	168 (60)	69 (17)	
Marital Status					
Single	276 (29)	62 (23)	55 (20)	159 (40)	<0.0001
Married	330 (34)	101 (37)	142 (50)	87 (22)	
Separated	66 (7)	22 (8)	14 (5)	30 (7)	
Divorced	155 (16)	47 (17)	38 (13)	70 (17)	
Widowed	131 (14)	43 (16)	33 (12)	55 (14)	
Literacy Level					
Limited (0-60)	537 (56)	188 (68)	98 (35)	251 (62)	<0.0001
Adequate (61-66)	424 (44)	87 (32)	184 (65)	153 (38)	
Seen Doctor in Past 12 months	849 (89)	236 (86)	258 (91)	355 (89)	0.09
Prior Recommendation	357 (39)	96 (35)	83 (29)	178 (48)	<0.0001
Ever Completed an FOBT	262 (28)	62 (23)	26 (9)	174 (47)	<0.0001

Characteristic	All Patients (n=961)			Study Arm			p-value
	Enhanced Usual Care (n=275)	Education (n=282)	Nurse (n=404)	Enhanced Usual Care (n=275)	Education (n=282)	Nurse (n=404)	
Would want to know if have CRC?							
Yes	837 (90)	242 (90)	334 (89)	261 (93)	15 (5)	29 (8)	0.03
No	56 (6)	12 (4)	11 (3)	6 (2)			
Don't know	34 (4)	17 (6)					
FOBT finds CRC early							
Strongly Agree/Agree	889 (96)	255 (94)	358 (96)	276 (98)	4 (1)	12 (3)	0.24
Disagree/Strongly Disagree	9 (1)	3 (1)		2 (1)			
Don't know	29 (3)	13 (5)		4 (1)			
FOBT decreases chances of dying from CRC							
Strongly Agree/Agree	742 (80)	194 (72)	305 (82)	243 (86)			0.0001
Disagree/Strongly Disagree	109 (12)	43 (16)	37 (10)	29 (10)			
Don't know	76 (8)	34 (13)	32 (9)	10 (4)			
Barrier Index, Mean (sd)	8.98 (2.29)	9.42 (2.24)	9.38 (2.26)	8.04 (2.11)			<0.0001

Table 2

Return of no, 1, 2 or 3 FOBTs over a three-year period

	Study Arm					p-value
	All Patients (n=961)	Enhanced care (n=275)	Education (n=282)	Nurse (n=404)	N (%)	
Return of no FOBTs	N (%)	N (%)	N (%)	N (%)	N (%)	
Screening Ratio	381 (40)	157 (57.1)	107 (37.9)	117 (29.0)	0.58	0.006
95% Confidence Interval		1.00	0.83	(0.41 – 0.81)		
p-value			0.33	0.001		
Screening Ratio			1.00	0.70		
95% Confidence Interval				(0.47 – 1.03)		
p-value				0.07		
Return of 1 FOBT	318 (33)	74 (26.9)	112 (39.7)	132 (32.7)	1.25	0.25
Screening Ratio		1.00	1.37			
95% Confidence Interval			(0.94 – 1.99)	(0.95 – 1.65)		
p-value			0.10	0.11		
Screening Ratio			1.00	0.92		
95% Confidence Interval				(0.75 – 1.11)		
p-value				0.37		
Return of 2 FOBTs	162 (17)	31 (11.3)	31 (11.0)	100 (24.8)	2.10	<0.0001
Screening Ratio		1.00	0.96			
95% Confidence Interval			(0.55 – 1.70)	(1.20 – 3.69)		
p-value			0.89	0.01		
Screening Ratio			1.00	2.18		
95% Confidence Interval				(1.65 – 2.89)		
p-value				<0.0001		
Return of 3 FOBTs	100 (10)	13 (4.7)	32 (11.4)	55 (13.6)	2.65	0.005
Screening Ratio		1.00	2.39			
95% Confidence Interval			(1.21 – 4.72)	(1.47 – 4.77)		
p-value			0.01	0.001		
Screening Ratio			1.00	1.11		

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Study Arm				
	All Patients (n=961)	Enhanced care (n=275)	Education (n=282) Nurse (n=404)	p-value
95% Confidence Interval			(0.76 – 1.62)	
p-value				0.59

* Screening ratios and p-values control for age (in years), race (African American vs Caucasian and Hispanic), gender and literacy (limited vs adequate).