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Low-Literacy Interventions to Promote Discussion of Prostate Cancer: A Randomized Controlled Trial

Sunil Kripalani, MD, MSc¹, Jyoti Sharma, MD¹, Elizabeth Justice, MD¹, Jeb Justice, MD¹, Cynthia Spiker, MPH², Larry E. Laufman, EdD², Terry A. Jacobson, MD¹, Megan Price, MS³, and Armin D. Weinberg, PhD²

1 Division of General Medicine, Department of Medicine, Emory University School of Medicine, Atlanta, GA

- 2 Chronic Disease Control and Prevention Research Center, Baylor College of Medicine, Houston, TX
- 3 Department of Biostatistics, Rollins School of Public Health, Emory University, Atlanta, GA

Abstract

Background—Professional organizations recommend that physicians discuss prostate cancer with patients to make individual screening decisions. However, few studies have tested strategies to encourage such discussions, particularly among high-risk populations. We examined the effects of two low-literacy interventions on the frequency of prostate cancer discussion and screening.

Design—Randomized, blinded, controlled trial with concealed allocation.

Setting/Participants—Inner city primary care clinic, serving a predominately African-American population. Participants were men age 45–70 with no history of prostate cancer, presenting for a regular appointment.

Interventions—While waiting to see their physician, patients received a patient education handout on prostate cancer screening (PtEd), a handout simply encouraging patients to talk to their doctor about prostate cancer (Cue), or a control handout. The interventions did not advocate for or against screening.

Main outcome measures—Patient-reported discussion of prostate cancer with the physician, and chart review to determine prostate specific antigen (PSA) test orders and performance of digital rectal examination (DRE). Adjusted odds ratios (aOR) and 95% confidence intervals (CI) were computed. Data were collected in 2003 and analyses completed in 2006.

Results—Most of the 250 subjects (90.4%) were African-American and 78.8% read below the 9th grade level. Overall, 48.4% reported discussing prostate cancer during the appointment. Compared to the control group (37.3%), discussions were significantly more common in the Cue group (58.0%, aOR=2.39 (1.26–4.52)), as well as in the PtEd group (50.0%, aOR=1.92 (1.01–3.65)).

Correspondence and reprint requests: Sunil Kripalani, MD, MSc, Emory University School of Medicine, 49 Jesse Hill Jr Dr SE, Atlanta, GA 30303, Phone: (404) 778-1627; Fax: (404) 778-1602; E-mail: skripal@emory.edu

Trial registered at ClinicalTrials.gov as "A randomized controlled trial to promote physician-patient discussion of prostate cancer screening" (NCT00208988, url: http://clinicaltrials.gov/ct/show/NCT00208988?order=1)

Study approved by the Emory Institutional Review Board, May 2003.

Dr. Kripalani had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

No financial conflict of interest was reported by the authors of this paper.

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When prostate cancer was discussed, patients in the intervention groups more commonly initiated the conversation (47.6% PtEd and 40.0% Cue, vs. 9.7% control, p<0.01 for each comparison to control). Compared to the control group (2.4%), PSA test orders increased in the PtEd group (14.1%, aOR=7.62 (1.62–35.83)) and in the Cue group (12.3%, aOR=5.86 (1.24–27.81)). Documentation of DRE did not change significantly (4.7% PtEd, 6.2% Cue, and 6.0% control).

Conclusions—Two simple low-literacy interventions significantly increased discussion of prostate cancer and PSA test orders, but not performance of DRE. Both interventions were effective in empowering low-literacy patients to initiate conversations about prostate cancer with their physician.

INTRODUCTION

Prostate cancer is the most common cancer in American men, with an estimated incidence of 234,460 cases and 27,360 deaths in 2006. Screening for prostate cancer remains controversial, ² due to insufficient evidence to recommend for or against screening. Many professional societies and experts recommend that patients be educated about the potential benefits and limitations of screening, so they may make a personal and informed decision. ^{3–9}

Researchers have tested many interventions to facilitate the decision-making process for prostate cancer screening. $^{10-17}$ Most of these studies have focused on providing balanced information about the possible advantages and disadvantages of screening, often through videotapes or other multimedia. However, patients with limited educational attainment or literacy skills have less knowledge about prostate cancer screening, 18 , 19 and they may experience difficulty acquiring information through multimedia decision-making interventions. 20 Other research has shown that low literacy presents an important barrier to the early diagnosis of prostate cancer. 21 Therefore, different strategies are needed to address prostate cancer screening among low-literacy patients.

In other clinical contexts, several techniques have proven effective in increasing patient activation and participation in the medical encounter. $^{22-25}$ One investigation, by Jacobson and colleagues, found that a low-literacy tool encouraging patients to ask their doctor about pneumococcal vaccination was effective in increasing the frequency of discussion and vaccination. 26 We designed two simple, low-literacy interventions to empower men to discuss prostate cancer with their physician, and tested their effect on the frequency of prostate cancer discussion and screening in a randomized controlled trial.

METHODS

Setting and population

The study was conducted in the primary care clinics of Grady Memorial Hospital, a large public teaching institution served by Emory University School of Medicine. Internal medicine residents in post-graduate year one, two, or three provide most of the care in the clinics under the supervision of board-certified Internal Medicine faculty members. In addition, the hospital employs several nurse practitioners who sign out to the same faculty, and some of the faculty follow their own patient panel. About 90% of the clinic patients are African-American, and approximately one-third are men.

Procedures

The study was approved by the Emory Institutional Review Board and the Grady Research Oversight Committee. A partial privacy waiver was authorized to assess patient eligibility.

Enrollment took place for seven consecutive weeks in June and July, 2003. The study timeframe and sample size were based on the availability of student research interviewers. During the enrollment period, all men age 45 to 70 who presented for a scheduled appointment with an Emory resident, faculty member, or nurse practitioner were considered for the study through a manual review of the clinic appointment schedule and patient sign-in logs. Patients were excluded if they had been enrolled previously, were in police custody, had arrived ill on a stretcher, or were not scheduled to see a primary care provider for a full visit (i.e., nurse-only visits, medical student appointments, and refill pickups were excluded); the exact number of men excluded for these reasons was not tracked. Men were also excluded on face-to-face screening if they could not converse fluently in English, had a corrected visual acuity worse than 20/60 as assessed by a pocket vision screening card, or had a history of prostate cancer, as determined by a focused review of the patient's electronic medical record. They were not excluded for prior PSA testing.

Men who remained eligible and were willing to receive a written handout were given one of three documents by the research interviewer. They were told, "Here is something for you to look at while you wait to see the doctor." No mention was made of prostate cancer or the purpose of the research study at that time. Health care providers (HCPs) were also not told about the study objectives.

Prior to their distribution, the handouts were stacked in random order, according to a computer-generated randomization sequence with permuted blocks of 6. Each handout was separated from the next by an opaque sheet of paper to maintain allocation concealment. Successive patients were always given the next handout in the pre-randomized stack, which effectively allocated them to one of the three study groups in accordance with the randomization sequence. A similar method was used in the study by Jacobson and colleagues, which took place in the same clinic. ²⁶

Interventions and Control

Each handout was a single page and printed in color (see Figures 1 and 2). The intervention handouts were written and designed by a multi-disciplinary team of physicians and educators with expertise in health literacy, cultural competency, cancer screening, prevention, and the design of patient education materials. The interventions were pilot tested with the intended audience and revised with patient feedback to maximize their clarity, cultural appropriateness, and content balance.

The content of the first intervention handout (PtEd, Figure 1) was based on the information that experts have recommended to be shared with patients to promote informed decision-making for prostate cancer screening. 2, 5, 7, 11, 27 The relatively high-detail handout described the function and location of the prostate gland, the prevalence and potential symptoms of prostate cancer, available screening tests, and the potential advantages and disadvantages of screening. It concluded with a message to ask the doctor for more information. This handout was printed front and back, in 14-point font, with patient-oriented questions for subheadings (e.g., "How can my doctor check for prostate cancer?"), simple text answers, and several illustrations. It was written at a 6th grade reading level, focused on the most important details, and followed other recommendations for the design of low-literacy patient education materials. 28, 29

The second intervention (Cue, Figure 2) was a one-sided handout that encouraged men to "Ask your doctor about prostate cancer **today!**" (emphasis in original). This low-detail handout contained less information, describing only the prevalence of prostate cancer (one in five men) and providing a picture of the gland's location. It did not provide information about screening tests. It was written at a 5th grade reading level.

The third handout (Control) pictured a traditional food pyramid.

Data Collection

After each randomized patient had seen the physician or nurse practitioner, research staff directed the patient to a private room, where an interviewer was waiting. The patient's handout was collected before entering the room, allowing the interviewer to remain blinded to the study group. Patients could not be blinded.

The interviewer then explained the research study and obtained written informed consent from willing patients. Consenting subjects completed a two-page, structured, interviewer-assisted questionnaire about what they had discussed during the clinic visit that pertained to prostate cancer. Most items involved a yes-no answer, such as whether prostate cancer or PSA testing were discussed. Patients also reported who initiated the conversation, how physicians counseled them about the PSA, and what role the handout played in the discussion. Patients self-identified their race, and they also took the Rapid Estimate of Adult Literacy in Medicine (REALM). 30 , 31 The REALM is a 66-item word pronunciation test that provides a valid and reliable measure of literacy in the healthcare setting. Scores are traditionally divided into four levels, corresponding to $\leq 3^{rd}$ grade (score 0–18), 4^{th} – 6^{th} grade (19–44), 7^{th} – 8^{th} grade (45–60), $\geq 9^{th}$ grade reading level (61–66). Subsequently, the research interviewer abstracted from the patient's chart whether the health care provider had ordered a PSA that day, or performed a DRE.

No data were collected on patients who could not be located after the clinic visit, or who did not provide consent. After data collection or refusal to participate, all patients received the PtEd handout before leaving the clinic.

Outcome Measures and Analysis

The primary outcome was patients' answer to the question, "Did you and your doctor talk about prostate cancer today?" Secondary outcomes, determined by chart abstraction, were whether or not a PSA test was ordered and whether or not DRE was documented. The sample size was determined by the number of patients who could be enrolled during the two-month period when the research interviewers were available.

Descriptive statistics, including simple proportions, frequencies, and means were performed. Differences in patient characteristics across the three study groups were evaluated using chi-square tests and t-tests. Chi-square tests, or Fisher's exact tests where appropriate, were used to test the hypothesis that the odds of prostate cancer discussion would be higher among patients who received either intervention, compared to the control handout. Chi-square tests were also used to compare results between the two intervention groups, though significant differences were not expected. A priori logistic regression analyses tested the intervention-outcome relationship while controlling for other potential covariates of interest – age, race, education level, literacy level, and health care provider – that were not balanced across study groups in spite of randomization. Adjusted odds ratios (aOR) and 95% confidence intervals (CI) were computed. The potential clustering effect of multiple patients being seen by one HCP was investigated using generalized estimating equations (GEE). Similar analyses were conducted on the two secondary outcomes – PSA test orders and DRE. Analyses were performed by intention to treat for all patients who consented to data collection.

Statistical analyses were performed in 2006 with SAS 9.1 (Cary, NC). For all analyses, alpha was set at 0.05.

RESULTS

Approximately 400 men age 45–70 were identified from administrative information contained in the clinic appointment and sign-in logs. (See Figure 3.) Excluding approximately 100 men who did not meet the eligibility criteria or refused the informational handout, 303 patients were randomized to one of the three study groups. However, 24 of these men were later found to be ineligible because they did not end up seeing a primary care provider or were too ill to participate. Among the 279 eligible patients who had been randomized, 11 could not be located after the appointment and 18 declined to participate in the study, making 250 patients available for data collection.

Most (90.4%) subjects were African-American, with a mean age of 56.5. Patient characteristics were similar across the three study groups, except patients in the PtEd group had higher literacy skills (p=0.02 for comparison of literacy across the three study groups, Table 1). The patients were seen by a total of 127 health care providers, including 109 medical residents, 13 faculty physicians, and 5 nurse practitioners.

Overall, 48.4% of patients reported discussing prostate cancer with the HCP (Table 2). The frequency of discussion varied significantly across the three study groups (58.0% Cue, 50.0% PtEd, and 37.3% Control, p=0.03). In unadjusted analyses, men who received the Cue handout had more than twice the odds of prostate cancer discussion, compared to patients in the control group (OR=2.32, 95% CI=1.24–4.34). Compared to controls, a nonsignificant trend was seen toward increased discussion of prostate cancer in the PtEd group (OR=1.68, 95% CI=0.91–3.10). When prostate cancer was discussed, patients in the intervention groups more commonly initiated the conversation (40.0% Cue and 47.6% PtEd, vs. 9.7% Control, p<0.01 for comparison of each intervention to control).

Among patients who reported discussing the PSA test, 88.5% recalled that their physician said it was important to get the test, while fewer reported talking about the risks and benefits (29.5%) or that additional tests may be needed (45.9%). The content of the PSA discussion did not differ significantly across study groups.

Each intervention resulted in approximately a six-fold increase in PSA test orders (p<0.05 for comparison of each to control), although the frequency of testing was relatively modest overall (9.6%). Documented performance of DRE did not change significantly (Table 2).

When multivariable logistic regression models were constructed to control for differences in literacy across the study groups, the results were similar, except the effect of the PtEd handout on the primary outcome became statistically significant (Table 3). Compared to patients in the control group, those receiving the PtEd handout had greater odds of discussing prostate cancer with their HCP (aOR=1.92, 95% CI=1.01–3.65), as did patients in the Cue group (aOR=2.39, 95% CI=1.26–4.52).

There were no significant differences in study outcomes among patients in the Cue and PtEd groups. Analyses that tested for different intervention effects across literacy level produced similar findings, as did models that adjusted for clustering of multiple patients per health care provider (results not shown). Apart from treatment assignment, no other variables significantly predicted study outcomes.

Regarding how the handouts were used, nearly all patients (99.6%) reported looking over the handout, and 94.8% reported reading it. Few patients (28.0%) directly gave or showed the handout to the HCP, but when this occurred, 69.6% of patients indicated that the HCP reviewed it with them.

DISCUSSION

Two simple low-literacy interventions significantly increased the odds of discussing prostate cancer in a primary care setting. A low-detail cue handout and a high-detail patient education handout appeared equally effective in empowering patients to initiate the conversation with their physician. Patient education brochures are a mainstay of health education activities, and significant resources are dedicated to their development and testing. However, if the goal is to encourage patients to perform a certain action, such as talking to the physician, then this study suggests that providing a focused cue may be sufficient.

These findings also have implications for primary care practices, where strategies are needed to promote discussion of prostate cancer and personalized decisions about screening options. Prior research has examined multimedia aids and other interactive strategies to foster informed decision-making. $^{10-12}$, $^{15-17}$ While generally effective, such approaches may be difficult to implement on a large scale, particularly in health care settings that have limited resources, including many clinics that provide care to underserved minority populations. By contrast, the present approach appears simple and effective, and it could be scaled up at relatively low cost.

Similar research by Jacobson and colleagues demonstrated that a low-literacy educational handout, given to patients before the medical appointment, increased the frequency of pneumococcal vaccination several-fold. However, that study did not measure patients' literacy or assess how the tool was used. The present findings extend Jacobson's results by demonstrating that such patient interventions are effective across literacy levels, and they work primarily by empowering patients to raise the topic of discussion.

Poor literacy increasingly is recognized as an important barrier to care, 33 and low-literacy patients may be more passive in managing their health. $^{34-36}$ Based on the results of this study and the trial conducted by Jacobson and colleagues, 26 it appears that cueing or priming patients immediately before their medical appointment may be an effective technique to help low-literacy patients better engage in their health care. Further, this strategy could be applied in a variety of prevention or treatment contexts.

With regard to the secondary study outcomes, PSA test orders increased significantly in the intervention groups, even though the handouts were designed to not advocate for or against screening. Because most patients recalled their physician saying it was important to get the test, it is likely that physicians' attitudes toward PSA impacted test orders. The reluctance of many African-American men to undergo digital rectal examination may have contributed to the infrequent performance of DRE.³⁷

Among the methodologic strengths of this investigation are randomization, concealment of treatment allocation, and blinding of outcome assessors. The study design, which involved consenting patients for data collection after randomization and the physician visit, served to minimize confounding of study results by limiting patients' knowledge of the study objectives prior to seeing the physician. Statistical analyses were performed to assess the possible confounding effects of other patient characteristics, as well as possible physician-level clustering of data, and these were found to not significantly affect the results. Finally, most of the research participants were African-American and had low literacy skills. Such patients arguably have the greatest need for interventions targeting cancer awareness, informed decision-making, and early detection, given the increased burden of prostate cancer and later stage of presentation in this group. ²¹

Several limitations were present. First, because the investigation was conducted at a single center, it is unknown how the results would generalize to other health care settings. Second, despite randomization, patients' literacy was imbalanced across study groups, which required

us to adjust for literacy in multivariable analyses. Third, the primary outcome assessment relied on patient self-report; the treating physicians were not interviewed, and patient visits were not audiotaped to confirm that prostate cancer was discussed. However, the structure of the patient questionnaire was straightforward, consisting primarily of yes/no items, and it was administered immediately after the physician visit, which should have maximized the accuracy of patient reported outcomes. Fourth, because the primary goal of the study was to promote discussion of prostate cancer and screening, details of the decision-making process about whether or not to undergo screening were not fully assessed. Based on the available information, it appears that fully informed decision-making frequently did not occur. ³²

Future research should test this intervention strategy among a wider spectrum of patients in other health care settings. Modifications could be tested as well, such as combining patient empowerment techniques with training physicians to appropriately counsel patients about the potential advantages and disadvantages of prostate cancer screening.

In summary, this study showed that two low-literacy interventions, including a patient education handout and a cue to talk to the doctor about prostate cancer, approximately doubled the odds of discussing prostate cancer in primary care visits. The interventions appeared effective in empowering patients to initiate these conversations, even though most had limited literacy skills. Cueing or priming patients at the point of care may represent an effective general strategy to promote greater participation by low-literacy patients.

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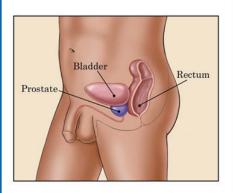
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Prostate Cancer

What You Should Know...

What is my prostate and where is it?

Your **prostate** is a small part of your body that sits next to your bladder. Only men have a prostate. It makes semen, which is the liquid that carries sperm when you have sex. A normal prostate is about the size of a walnut or a small lime.



What is prostate cancer?

Cancer can start growing in any part of your body. When it grows in your prostate, it's called prostate cancer. Prostate cancer is not the same thing as having a "big prostate" or an "enlarged prostate."

Who can get prostate cancer?

Prostate cancer is one of the most common kinds of cancer. About 1 out of every 5 men will get it.



You have a higher chance of getting prostate cancer as you grow older. Your chances are also higher if you are African-American, or if your brother or father had prostate cancer.

Would I feel anything wrong if I had prostate cancer?

Prostate cancer grows slowly. Most of the time, men don't feel anything wrong, but there are some things you can watch for. Keep an eye out for blood in your urine or semen. Also tell your doctor if you have back pain that won't go away.

How can my doctor check for prostate cancer?

There are 2 main ways to check for prostate cancer – a **blood test** and a **rectal exam**. The blood test is called the **PSA**.

(Continued on back)

This information may be copied and given to patients.

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Prostate Cancer What You Should Know...(Continued)



The rectal exam is when your doctor puts his finger inside your bottom to see if your prostate feels normal.

Rectal Exam



The PSA test and rectal exam are usually done together. Both tests are easy to do, and they don't cost much. We call them "screening tests" because they can give you a pretty good idea whether or not you have prostate cancer.

What will the tests tell me?

Unfortunately, the tests aren't perfect, especially the PSA. Sometimes, it may look like you have cancer when you're really okay. And sometimes, the tests look okay, but you may really have cancer. If one of the tests is abnormal (bad), your doctor will talk to you about doing another test to double-check. He might suggest another blood test, an ultrasound, or a biopsy. An ultrasound takes a picture of your prostate, and a biopsy uses a needle to get small pieces of your prostate.

What happens if I have prostate cancer?

Prostate cancer grows slowly.

Sometimes, it doesn't cause any problems. Many men (especially older men) decide to just keep an eye on things with their doctor. Other men decide to get treated with surgery, radiation, or hormones. If you have prostate cancer, your doctor will help you decide what to do next.

Should I try to find out if I have prostate cancer?

Even though prostate cancer is very common, we aren't sure whether or not every man should get tested. Some doctors say that it doesn't really help. But other doctors say that you should get tested once a year after you turn 50. If you are African-American or have a brother or father with prostate cancer, they say you should get tested once a year, starting at age 45.

Ask your doctor about prostate cancer

It's your choice whether or not to get tested. Your doctor can help you make that decision.



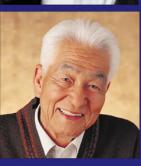
Figure 1.
Patient education handout (PtEd)
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Figure 2 - (1/4 page size)

If you are a man age 45 or older...



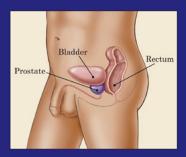






Ask your doctor about prostate cancer today!

- About 1 out of every 5 men will get prostate cancer.
- If you want more information about prostate cancer:
 - 1. Give this handout to your doctor.
 - 2. Ask about prostate cancer today.



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Figure 2. Talk to doctor handout (Cue)

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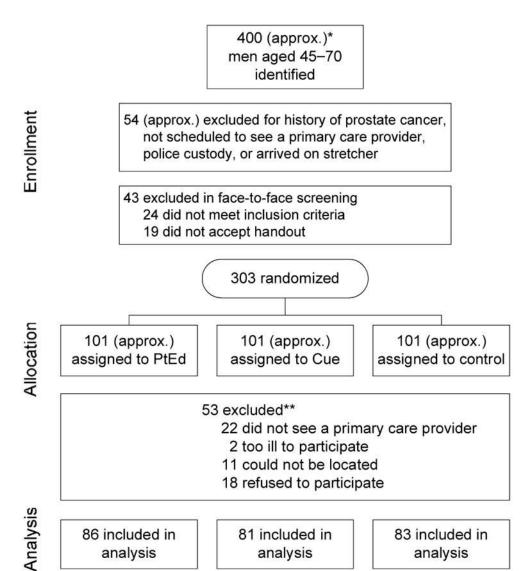


Figure 3. Study flow diagram

analysis

analysis

analysis

PtEd = Patient education handout, Cue = Talk to doctor handout, Control = Food pyramid

^{*} Numbers are approximate because the exact number of men who were excluded was not tracked.

^{**} Treatment assignment not recorded

Table 1

Baseline characteristics

[[Characteristics]]	Overall $(n = 250)$	PtEd (<i>n</i> =86)	Cue (<i>n</i> =81)	Control (<i>n</i> =83)
Age, mean (SD), y [[Race, no. (%)]]]	[[56.5 (6.8)]]	[[56.3 (6.6)]]	[[58.1 (7.3)]]	[[55.0 (6.0)]]
[[African-American]]	[[226 (90.4)]]	[[72 (83.7)]]	[[74 (91.4)]]	[[80 (96.4)]]]
[[Caucasian]]	[[20 (8.0)]]]	[[12 (14.0)]]	[[5 (6.2)]]	[[3 (3.6)]]]
[[Other]]	[[4 (1.6)]]	[[2 (2.3)]]	[[2 (2.5)]]]	[[(0)(0)]]
Education, mean (SD), y	[[10.9 (2.5)]]	[[11.3 (2.6)]]	[[10.4 (2.6)]]	[[10.9 (2.1)]]
Reading level, no. (%) ^a *				
< 3 rd grade	[[94 (37.6)]]	[[30 (34.9)]]]	[[31 (38.3)]]	[[33 (39.8)]]]
4 th -6 th grade	[[46 (18.4)]]	[[9 (10.5)]]	[[18 (22.2)]]	[[19 (22.9)]]]
7 th -8 th grade	[[57 (22.8)]]]	[[18 (20.9)]]]	[[20 (24.7)]]]	[[19 (22.9)]]
\leq 3 rd grade 4^{th} - 6^{th} grade 7^{th} - 8^{th} grade \geq 9 th grade	[[53 (21.2)]]	[[29 (33.7)]]	[[12 (14.8)]]	[[12 (14.5)]]

 $^{^{\}it a}{\rm Determined}$ by Rapid Estimate of Adult Literacy in Medicine (REALM)

PtEd = Patient education handout; Cue = Talk to doctor handout, Control = Food pyramid

^{*}Chi-square test of literacy level across the 3 study groups: p =0.02

Prostate cancer discussion and screening by study group (unadjusted)

[[Group]]]	Discussed prostate cancer, no. (%)	[[OR (95% CD)]]]	p value	PSA ordered, no. (%)	[[OR (95% CD)[]]	p value	DRE documented, No. (%)	[[OR (95% CI)]]]	p value
[[Control]]] [[Cue]]]	[[31 (37.3)]] [[47 (58.0)]]	[[]] [[2.32 (1.24- 4.34)]]	[[]] [[0.008]] *	[[2 (2.4)]]] [[10 (12.3)]]]	[[]] [[5.70 (1.21– 26 01311 **	[[]]] * [[0.03]]] *	[[5 (6.0)]] [[5 (6.2)]]	[[]] [[1.03 (0.29- 3 60)11	[[]]] [[0.97]]
[[PtEd]]]	[[43 (50.0)]]]	4.54)[]] [[1.68 (0.91– 2.10)[]	[[0.10]]	[[12 (14.1)]]]	20.21)]]] [[6.66 (1.44– 30.74)]]	[[0.02]]	[[4 (4.7)]]]	[[0.77 (0.20– 2.08711	[[0.71]]
[[Total]]]	[[121 (48.4)]]			[[24 (9.6)]]	30.74/JJJ [[]]]		[[14 (5.6)]]]	2.30/III [[]]]	

*
For chi-square comparison of intervention to control group

Table 3 Prostate cancer discussion and screening by study group (adjusted for literacy)

[[Group]]	Discussed Prostate Cancer, No. (%)	[[aOR (95% CI)]]	p value	PSA Ordered, No. (%)	[[aOR (95% CI)[]]	p value	DRE Documented, No. (%)	[[aOR (95% CI)[]]	p value
[[Control]] [[Cue]]	[[31 (37.3)]]] [[47 (58.0)]]]	[[]] [[2.39 (1.26–	[[]]] [[0.008]] *	[[2 (2.4)]]] [[10 (12.3)]]]	[[]] [[5.86 (1.24– 27.81)]]	[[]]] [[0.03]]] *	[[5 (6.0)]] [[5 (6.2)]]	[[]] [[1.04 (0.29- 3.76/11]	[[]]] * [[0.95]]]
[[PtEd]]]	[[43 (50.0)]]]	1.92 (1.01– 2.65)]]	[[0.05]]	[[12 (14.1)]]]	[[7.62 (1.62– 25.92)]]	[[0.01]]	[[4 (4.7)]]	2.70)]] [[0.85 (0.21– 3.27)]]	[[0.81]]
[[Total]]	[[121 (48.4)]]]	3.05. [[]]]		[[24 (9.6)]]]	[[]]		[[14 (5.6)]]	[[]]	

* For comparison of intervention to control group