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Randomized Trial of a Computerized Touch Screen Decision Aid to Increase Acceptance of Colonoscopy Screening in an African American Population with Limited Literacy

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Abstract

The goal of this study was to assess the effectiveness of a touch screen decision aid to increase acceptance of colonoscopy screening among African American patients with low literacy, developed and tailored using perceptual mapping methods grounded in Illness Self-Regulation and Information-Communication Theories. The pilot randomized controlled trial investigated the effects of a theory-based intervention on patients' acceptance of screening, including their perceptions of educational value, feelings about colonoscopy, likelihood to undergo screening, and decisional conflict about colonoscopy screening. Sixty-one African American patients with low literacy, aged 50-70 years, with no history of colonoscopy, were randomly assigned to receive a computerized touch screen decision aid (CDA; n = 33) or a literacy appropriate print tool (PT; n =28) immediately before a primary care appointment in an urban, university-affiliated general internal medicine clinic. Patients rated the CDA significantly higher than the PT on all indicators of acceptance, including the helpfulness of the information for making a screening decision, and reported positive feelings about colonoscopy, greater likelihood to be screened, and lower decisional conflict. Results showed that a touch screen decision tool is acceptable to African American patients with low iteracy and, by increasing intent to screen, may increase rates of colonoscopy screening.

Computerized decision aids (CDAs) include properties such as interactive features, visual cues, feedback to users, and ease of targeting to patient populations. Like other decision aids, they are believed to improve decision-making outcomes by increasing knowledge, improving accuracy of risk perceptions, enhancing values clarification, and reducing decisional conflict (Durand, Stiel, Boivin, & Elwyn, 2008; O'Connor, 2010; Sheehan & Sherman, 2012). Yet little is known about how well patients with low literacy accept health information from computerized decision aids compared to traditional types of health

Conflict of interest

Authors declare that they have no conflict of interest.

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education, and what is needed to have a positive effect on the decision-making process (Stacey et al., 2011).

We report on the results of a study grounded in Illness Self-Regulation and Information-Communication theories that used perceptual mapping methods to develop a touch screen CDA to educate about colorectal cancer (CRC) screening for African American patients with low literacy. The pilot randomized controlled trial investigated the effects of the CDA compared to a usual care print education tool (PT) on patients' acceptance of the education, feelings about colonoscopy, likelihood to undergo colonoscopy, and decisional conflict about colonoscopy.

Background

The 2003 National Assessment of Adult Literacy (White, 2003), the most recent national survey conducted and widely regarded as the most accurate assessment of literacy in the United States, reported that 24% of African Americans and 29% of all adults aged 65 and older have below basic health literacy. They are unfamiliar with medical terms and with how their bodies work, and do not know how to interpret numbers or risks to make a health care decision (Kutner, Greenburg, Jin, & Paulsen, 2006). These factors render the shift toward shared decision making particularly problematic for patients with low literacy, including CRC screening. The 2010 Health Interview Survey showed that African Americans were less likely than Whites to have been screened for colorectal cancer by any method (Centers for Disease Control and Prevention [CDC], 2012a). Between 1999 and 2009, the incidence of CRC remained highest in African Americans compared to all other groups (CDC, 2012b) and has led to calls for reducing this health disparity.

How to bridge low literacy is a critical health communication issue across the continuum of cancer care (Davis, Williams, Marin, Parker, & Glass, 2002). In African American populations, low literacy is thought to be a factor in low rates of preventive health practices and has spurred efforts to improve health education and communication. Despite some successes, communicating CRC risk to low-literacy patients, many of whom are older and racial/ethnic minorities, poses many challenges (Greiner, Born, Nollen, & Ahluwalia, 2005). Limited literacy has been associated with poorer knowledge about CRC screening (Miller, Brownlee, McCoy, & Pignone, 2007) and more barriers to completing screening (Peterson, Dwyer, Mulvaney, Dietrich, & Rothman, 2007). Miller et al. (2007) found that patients with less than a ninth grade reading level on the REALM (Rapid Estimate of Adult Literacy in Medicine) were significantly less likely than adequate literacy patients to be knowledgeable about CRC and CRC screening modalities, although screening rates were similar. Arnold et al. (2012) found that patients in federally qualified health centers who had less than a ninth grade reading level were less likely to be aware of CRC screening messages and complete screening than those with higher literacy. In a systematic review on health literacy and cancer screening, Oldach and Katz (2014) concluded that patients with lower literacy have cancer screening rates below established guidelines.

A strategy to address the literacy gap is the use of literacy appropriate decision aids, including computerized ones with interactive features that reduce patient embarrassment

over lack of ability to read. Varying definitions of what constitutes a CDA make study results difficult to interpret. In one systematic review, Sheehan and Sherman (2012) found few CDA studies that specifically included patients with low literacy. In another, Thomson and Hoffman-Goetz (2007) found that out of 81 Web-based cancer CDAs that met their inclusion criteria (conforming to a Cochrane definition or similar standard), most were difficult to read. Only one (4%) was written at the eighth grade level, five (22%) were at the ninth grade level, and 17 (74%) were at the 10th–13th grade level. Only two targeted a specific cultural group.

Some CDAs for CRC screening have been shown to be more effective than non-tailored brochures at stimulating African American patients' discussions about CRC screening with their primary care providers and resulted in ordering more CRC screening tests, but have not resulted in statistically significant differences in rates of completed screening (Christy et al., 2013; Miller et al., 2011; Schroy et al., 2011). In a randomized trial of patients using "Colorectal Web" compared to a standard website, Ruffin, Fetters, and Jimbo (2007) found that the CDA group was more likely to choose a preferred screening test and be screened, but patient literacy level was not addressed. The Kim et al. (2005) CDA to promote CRC screening in primary care practice, studied in an uncontrolled trial, showed that most patients found it useful and reported improved knowledge of screening, and within 6 months, 43% completed screening tests.

Though Web-based health information is readily available, most does not reach patients with low literacy because of navigation and comprehension issues even if they have access. Kaphingst, Zanfini, and Emmons (2006) found the average SMOG formula reading grade level of 19 CRC websites was 12.8. Common problems included lack of review of key ideas, lack of illustrations, poor layout, small type size, and lack of interactive features, all barriers to patients with limited literacy. The lack of studies may reflect the expectation that decision aids help patients weigh the quantitative benefits and risks with their personal values when choosing among several screening or treatment options. For patients with low literacy, such tasks would be particularly difficult and may not reflect their cognitive decisional frameworks.

To address the needs of African American patients with limited literacy for educational support to undergo CRC screening, we undertook research to develop a theory-based, easy-to-use touch screen CDA using perceptual mapping methods to identify critical barriers and facilitators to move patients specifically toward colonoscopy screening. Though the U.S. Preventive Services Task Force specifies regular CRC screening for average-risk persons starting at age 50 years using colonoscopy, flexible sigmoidoscopy, or fecal occult blood testing (U.S. Preventive Services Task Force, 2002), colonoscopy was chosen based on the 2005 American College of Gastroenterology (ACG) Committee of Minority Affairs and Cultural Diversity recommendations, which advised that African Americans should begin CRC screening sooner, at age 45 years, with colonoscopy the preferred screening method because African Americans have lower CRC screening rates, more proximal lesions (best detected by colonoscopy), and higher rates of CRC mortality (Agrawal et al., 2005). In addition, although physicians in the clinic used in this study had developed a print educational tool describing all methods of screening, in practice they only encouraged

patients to have a colonoscopy unless medically contraindicated. Thus, we developed the CDA to be consonant with clinic practice.

Preliminary research and theoretical approach

We have previously published our systematic review of the literature on colonoscopy among African Americans (Ward et al., 2008), a formative assessment of the barriers and facilitators of colonoscopy for this clinic population (Ward et al., 2010) and quantitative assessment of perceptions of colonoscopy among both physicians and African American patients with limited literacy (Bass et al., 2011; Ruggieri et al., 2013).

We used perceptual mapping methods that are grounded in two theoretical frameworks: (a) Illness Self-Regulation Theory (Leventhal, Halm, Horowitz, Leventhal, & Ozakinci, 2004) and (b) Information-Communication Theory (Leventhal et al., 2004), both based upon the individual's conceptual map or model of health threatening situations. Illness Self-Regulation Theory contends that when confronted with a health crisis (disease or health threat), individuals form a mental representation of the condition, what caused it, what its effects might be, how long it might last, and how to control it. These conceptualizations are what Leventhal calls the individual's "common-sense model" of the illness (Leventhal et al., 2004). Based on this model, individuals then appraise various coping strategies. We posited that to undergo CRC screening, the individual forms a mental model of the benefits, risks, and barriers and on that basis makes the screening decision. If we have a valid representation of how people conceptualize the most salient factors associated with their likelihood of being screened, or with the cognitive and tangible barriers to initiation, we can more effectively develop decision aids to address them, and move the group toward the decision to screen.

To do so, Information-Communication Theory (Borg & Groenen, 1997) provides methods for identifying optimum message strategies to address the barriers identified in the perceptual map. This theory posits that the individual's conceptual model of a situation is that individual's foundation for addressing that situation. The model is seen as representing the individual's "perceptions" and theorizes that to be effective, communication design methodology needs to identify optimum message strategies around specific conceptual frames. In this study, patients' conceptual models of colonoscopy were produced using perceptual mapping techniques. Based on a multidimensional scaling process, perceptual mapping produces dynamic three-dimensional models of complex cognitive and communication processes, critical for understanding the effectiveness of decision aids and studying how framing effects, perceptions of risks/benefits, and attitudes toward risk contribute to cognitive and affective dimensions of decision making. This method builds on the Galileo approach of Woelfel and Fink (1980), whose mathematical modeling tools can be used to identify optimum message strategies (based on principles of increasing the attraction to, or repulsion from, particular concepts or attributes). A recent review by the RAND Corporation lauded the approach, noting it "was the closest any social science approach came to providing a framework for thinking about how to affect attitude changes for planning, conducting, and assessing the impact of influence operations on attitudes and behaviors" (Larson et al., 2009, p. 20; for more information on health-related applications of

Details of the process used to develop the CDA have been published previously (Bass et al., 2013), as has the analysis of perceptual mapping variables used in it (Gordon et al., 2014). Using a k-means cluster analysis, perceptual mapping, and vector message modeling analysis we developed the CDA in collaboration with the Patient Education Institute (PEI). PEI has produced innovative interactive tutorials designed to enhance patient understanding of medical treatments (Ajam, 2001), which are available on MedLine Plus and licensed to health systems and medical practices. We worked with PEI to modify its "X-Plain" colonoscopy tutorial by reducing the reading/comprehension level from ninth to sixth grade, making the content specific to the clinic population by including graphics chosen to illustrate African American patients and health care providers. The most important change, however, was in selection of key messages based on findings from the vector modeling that emphasized that having a doctor's recommendation, having peace of mind, and knowing that family would want them to have the test were most important to this population (Gordon et al., 2014). The modeling enabled us to simplify messages and reduce the length by eliminating elements found unimportant (e.g., technical information on colon cancer, development of polyps, and anatomy of the digestive system) and focusing on those that were (e.g., importance of testing for family, colonoscopy's effectiveness at detecting cancer, why knowing results is important).

The touch screen included voice-over reading of the plain-language text to enhance understanding without requiring participants to acknowledge their lack of reading ability, a source of embarrassment to persons with low literacy. The CDA cued the user to touch the screen to move forward or backward through the CDA the way one navigates a bank ATM screen. These features gave users immediate feedback on their comprehension of information. We also added short video segments featuring African American patients from the clinic who had undergone colonoscopy and who volunteered to give testimonials about their experience to provide a personal, culturally grounded element to the CDA.

The control group education consisted of oral administration of a two-sided patient tool (PT), the information sheet that was developed for and routinely used in the internal medicine clinic. Written at a seventh grade reading level (Flesch–Kincaid), it described CRC, its warning signs, screening tests, and screening recommendations. The PT scored as "acceptable" on the Suitability Assessment of Materials (SAM) for patients with low literacy (Doak, Doak, & Root, 1996).

Our specific aim was to conduct a pilot study to demonstrate the feasibility of conducting a fully powered randomized controlled trial using a CDA for a population with low literacy. To warrant undertaking a fully powered trial, patients had to demonstrate that they could use the CDA. In addition, it had to be acceptable to patients in terms of being perceived as useful in making the decision to screen, have at least a moderate effect on likelihood to undergo colonoscopy (Cohen's d = .5), and reduce or not increase decisional conflict. Thus we examined the hypotheses that experimental subjects will be more likely than controls to report (a) intent to undergo colonoscopy, (b) less uncertainty and decisional conflict about

screening, and (c) that the decision aid was useful in the decision-making process. In addition to examining these hypotheses, qualitative data were collected to understand how patients with low literacy experienced the CDA compared to the PT.

Methods

Sample

All subjects were patients who used the general internal medicine clinic at Temple University Hospital as their usual source of care and had Medicare or Medicaid insurance that covered the cost of colonoscopy. Because this pilot study was designed to establish whether or not the effect size of the CDA warranted conducting a fully powered trial, we made a priori estimates for the sample size that would be required to detect a moderate treatment effect (Cohen's d = .5) for the primary outcome variable, intent to screen. This was based in part on expected estimates of CRC screening outcomes reported by Ferreira et al. (2005) in subjects with literacy levels less than or equal to ninth grade level. We calculated that to detect a moderate treatment effect, 50 experimental and 50 control subjects would achieve 80% power to detect a difference of 27% between the null hypothesis that both group intent-to-screen proportions were 30% and the alternative hypothesis that the proportion in the experimental group was 57% using a one-sided Fisher's exact test with a significance level of $\alpha = .05$. Funding for the pilot study, however, limited the sample size to 60 subjects.

We invited patients whom clinic staff identified as African American, aged 50–70 years, and who were scheduled for routine visits during May through July 2009, to participate. Patients who had previously had a colonoscopy and/or were scheduled for a nonroutine condition were excluded. A trained research assistant orally administered all consent forms and instruments, which were tailored for patients with low literacy. Participants were randomized to receive the CDA (intervention; n = 33) or the PT (control; n = 28) by block randomization using the Bernoulli random value function with probability .5 (SPSS Version 14.0). A research assistant read the PT to control participants and gave CDA participants brief instruction on how to use the tutorial so that they could advance through it at their own pace, ranging from 15 minutes to one-half hour. Both interventions occurred in a private space in the clinic and took similar amounts of time. After completing the education, participants completed all outcome-measure instruments. The Temple University Insitutional Review Board (IRB) approved all instruments, education and procedures. Subjects received a \$20 gift card and \$5 in transit tokens.

Of the 84 eligible patients invited to participate, 61 (72.60%) consented and completed the protocol. Twenty-three (27.40%) declined, stating that they could not read, were not comfortable signing the consent form, were sick, or had to leave for other appointments. One deaf patient did not have an interpreter.

Preeducation instruments

Sociodemographic questionnaire—Participants were asked to self-report their race, Hispanic status, gender, age, and highest level of school completed on a fixed-choice protocol.

Literacy—We assessed literacy with REALM-R (Reading Estimate of Adult Literacy Medical–Revised), the word recognition test used widely in clinical settings, in which patients are asked to pronounce 11 medical words of increasing difficulty (Davis et al., 1993). The first three words are not scored, giving the test a scored range of 0–8. If a patient is unable to pronounce two words in succession, the test is ended. Patients unable to pronounce more the first three words have very low literacy skills, and those unable to pronounce more than six are at risk of having inadequate literacy for medical settings (Bass, Wilson, & Griffith, 2003).

Posteducation instruments

Ottawa decision framework outcome measures developed by the Ottawa Health Research Institute (OHRI) instruments are widely used to assess the outcomes of decision support tools (O'Connor, 2012). We adapted the instruments as recommended in the user manual for patients with limited literacy for specific use with CRC education. Because participants were randomized to education groups, it was appropriate only to administer these measures following the intervention. We assessed the hypotheses using the following instruments.

Choice predisposition and decision tool—The Choice Predisposition and Decision tool assessed feelings about colonoscopy (positive to negative) and likelihood to screen, each measured on a 15-point visual scale that appeared like a ruler across the page.

Decisional conflict scale (DCS)—The Decisional Conflict Scale and subscales designed for patients with low literacy included Feeling Informed (knowing the benefits and risks of having a colonoscopy); Values Clarity (being clear about which benefits matter most and which risks and side effects matter most); and Support (feeling enough support from others to make a choice, able to choose without pressure from others, and when meeting with the doctor will have enough information to make a choice about having a colonoscopy or not).

Acceptability of a specified DA—Acceptability of a specific decision aid was adapted from the OHRI instrument (2014), scored on a 5-point Likert-type scale. We added two open-ended questions: "What did you like about the education?" and "What would make this education better for patients at Temple?" The research assistant also observed and recorded difficulties participants had using the CDA.

Data analysis

Quantitative data were analyzed using SPSS Version 20. Scores were analyzed with twotailed statistical tests using *t*-tests for continuous data and Pearson's chi-squared or Fisher's exact test for categorical data with statistical significance set at $\alpha = .05$.

Three independent coders analyzed the open-ended qualitative data to develop the categories participants used to describe their experience using the CDA or PT. Once categories were agreed on, the independent coders resolved any differences in assignment of subject comments to categories through group discussion.

Results

Sample characteristics

Sociodemographics—There were no statistically significant differences between control (PT) and intervention (CDA) participants. All control (100%) and 97% of intervention participants self-reported their race as African-American; one intervention participant identified as mixed-race African-American by clinic staff reported "Other." No participants reported themselves Hispanic. Both groups had similar proportions of males (35.7% control, 30.3% intervention) and females (64.3 % control, 69.7% intervention), mean age (57.14 years control, 58.12 years intervention), and proportion who had completed high school (61% control, 64% intervention).

Literacy level

On the REALM-R, most control and intervention participants pronounced six or fewer words, an indicator of being at risk of inadequate literacy in a health care setting. There was no difference in REALM-R mean scores between the two groups (M= 3.51 control, 3.35 intervention; mean difference = .16, p = .79 t = 0.26, 95% confidence interval [CI] = -1.10 to 1.43). Because a score of 6 corresponds to a sixth grade reading level, both groups had low literacy.

Patient responses to educational interventions

There were no significant differences in how participants perceived the viewpoint of the education on the seven fixed-choice questions about the education (Fisher's exact test, df = 2, p = .505). More than half perceived the education as equal and balanced (57% control, 67% intervention patients); near equal numbers viewed it as slanted toward having a colonoscopy (39% control, 33% intervention). One control participant perceived it slanted toward not having a colonoscopy.

CDA users assessed the education more positively than PT users on all other measures: ease of use (p < .001); right length (p = .003); the right amount of information about colonoscopy (p < .001); and usefulness of the information on colonoscopy (p = .002; Table 1).

CDA users were also significantly more likely than PT users to report that the education would be helpful to a patient who wanted information to make a decision about screening for colon cancer (p = .002) and included enough information for a person to make a decision about whether or not to be screened (p = .001; Table 1).

Perception of colonoscopy and intent to screen

On the Choice Predisposition and Choice tool, participants reported how they felt about colonoscopy and how likely they are to be screened using two 15-point scales that ranged

from 1 (*most positive about colonoscopy/very likely to be screened*) to 15 (*most negative about colonoscopy/not likely to be screened*). CDA participants reported significantly more positive feelings about colonoscopy (M = 2.33) than PT participants (M = 5.39; t = 3.51, mean difference = 3.06, p = .001, 95% CI = 1.31–4.80). CDA participants also reported greater likelihood to be screened (M = 2.21) than controls (M = 5.36; t = 3.46, mean difference = 3.15, p = .001, 95% CI = 1.32–4.96; Table 2).

Effect size of intent to screen

Cohen's d(.90) was calculated using the means of the two groups and their standard deviations to assess the effect size of the difference in intent to screen between the two groups (two-tailed test, $\alpha = .05$, $\beta = .80$). A Cohen's d of .90 is a large effect (8/10 of a standard deviation unit) that is independent of sample size (Cohen, 1988).

Decisional conflict

Participants responded to a seven-item low-literacy version of the Decisional Conflict Scale (DCS) that included the subscales (Feeling Informed, Values Clarity, and Support) with *yes, no*, or *not sure*. Scores were standardized as recommended in the user manual to 100, with 0 being no decisional conflict to 100 being extremely high decisional conflict. CDA participants had significantly lower standardized overall decisional conflict scores (M= 0.65) compared to PT participants (M= 28.06; t= 5.88, p<.001, 95% CI = 17.86–36.97; Table 3).

CDA participants scored more positively on each of the DCS subscales: Feeling Informed (mean difference = 41.24, p < .001); Values Clarity (mean difference = 34.20, p < .001); and Support (mean difference = 13.70, p < .001; Table 3).

Satisfaction with the education

When asked to describe what they liked about the education, CDA users reported more features that they liked (68 comments) than PT users (39 comments). What they mentioned also differed. PT users most often mentioned information in general or about CRC (17 comments) or information on screening tests or options (9 comments). In contrast, those who received the CDA most often liked the picture–audio format and some said this was because they "didn't have to read" (20 comments). They also liked that it was short and gave them basic information that wasn't written in "doctor terms" (9 comments) and they liked the video testimonials with "real people" (9 comments). Four users liked that the CDA was interactive.

Only two PT users compared to seven CDA users mentioned that information about the screening procedure helped them know what to expect. Three CDA users liked the focus on African Americans. Equal numbers mentioned preventive health practices (Table 4).

How patients felt the education could be improved

Negative feedback was solicited by asking how the education could be improved to overcome the known hesitancy of clinic patients to be critical of medical care. PT users cited more ways to improve the education (35 comments) compared to CDA users (10 comments).

Most CDA users (20 of 28) said there was nothing to improve and described it as "fine as it is" and "couldn't be better." Although seven PT users reported they could think of nothing to improve, they did not make the types of strong positive comments that CDA users reported.

Many PT users made specific comments about how to improve the education: fewer "big words" (7), shorter or just basic information (5), bigger print (5), pictures (6), more unspecified information (3), more about colonoscopy and what to expect (4), more information on treatment options and second opinions (3), and fewer options and/or more clarity about "what's best" (2). The CDA users mentioned the education could be improved with faster audio speed (2), putting it in the waiting room (2), and more cultural diversity (1). Two patients mentioned computer usability concerns and the need for help learning how to use it (Table 5).

Usability of the CDA

All CDA users completed the DA. The research assistants who administered the education described most users' response to the touch screen tutorial as positive, although some (12) had initial difficulty or appeared uncomfortable at first. A similar number (12) reportedly had no problems. A few participants raised content questions, appeared fidgety or annoyed, or skipped the videos. Although two participants initially anticipated difficulty, both learned to use it.

Discussion

Although we were aware of criteria that were under development for the International Standards for Patient Decision Aids (IPDAS; Elwyn et al., 2006), we did not include key elements involving a choice between three types of screening recommended by the U.S. Preventive Services Task Force (USPSTF) at that time because the clinic considered colonoscopy the standard of care (U.S. Preventive Services Task Force, 2008). Our decision to limit the CDA to a choice between having or not having a colonoscopy may also have increased acceptance of screening compared to the PT, which included other screening modalities. Physician recommendation of CRC screening is strongly associated with screening rates (Cairns and Viswanath, 2006; Partin et al., 2010), and compliance with CRC screening guidelines has been shown to increase when providers make specific screening test recommendations (Laiyemo et al., 2014).

This feasibility trial raises critical issues about how to improve patient care. At core, our work raises fundamental questions about innovation research (using theories and methods to come up with "what works" and then testing it) and where it should lead. The Cochrane Collaboration, the OHRI, and others have spurred action to assess decision aids that help patients weigh benefits, harms, and scientific uncertainties in value-based treatments/ screening. As Jimbo and colleagues (2013) noted, the IPDAS criteria are increasingly influential in shaping how DAs should be developed. We caution that while standards for decision aids may be useful for patients with adequate literacy and strong commitments to shared decision making, they may overlook certain needs of patients with low literacy.

The comments of control subjects that we could improve the education by offering "fewer choices" or telling them which tests doctors feel are "best" underscore this population's desire for clear guidance as a key element in their illness regulation cognition. Because our formative research had already shown that quantitative representations were not "what mattered" (Bass et al., 2011), the CDA only used the type of nonquantitative language that most doctors use when communicating about CRC screening (McQueen et al., 2009). We also chose not to include complex decision-making processes typically recommended for decision aids. CDA users reported that they liked having a tool that only gave them basic information in words they understood, not "doctor terms." Patient comments confirm the desirability of divergence from standards in the direction of patient-centeredness and effective communication.

There are several limitations to the study. We used intent to screen rather than actual completed colonoscopy as an outcome measure, a limitation common to CRC screening studies. A recent review of studies of decision aids showed that 11 of the 21 studies designed to increase rates of colorectal cancer screening included a screening behavior outcome measure (Jimbo et al., 2013). Given the established relationship between intention and behavior, and the large effect size of the CDA compared to the PT established in this study, additional research using rates of completed colonoscopy as the endpoint is warranted. Our results are important, given the consistent link found between intention and subsequent behavior. A meta-analysis (Webb & Sheeran, 2006) of health-related behaviors demonstrated that a change in intention produces some change in behavior, moderated by various intervention characteristics. This is consistent with earlier analyses, such as that conducted by Armitage and Connor (2001) in which a .47 sample-weighted average correlation was shown between measures of intention and behavior.

The small sample size and subject characteristics limit generalizability. Although this sample of African American patients had very low literacy, all patients had medical insurance (Medicare and/or Medicaid) and a usual source of care, both of which are associated with use of preventive health practices. A CDA is unlikely to have as large an effect in a population without similar access to medical care and insurance. In addition, selection bias could have overinflated the intent to screen outcome measure. Patients who agreed to participate may be more likely to be receptive to patient education in general and to learning to use a CDA than those who refused.

We acknowledge our inability to differentiate features of the CDA that were most important in increasing intent to screen. As with many studies, the content of the education and targeting for specific populations differed between the control and intervention groups (Jerant et al., 2014; Jimbo et al., 2013). Although physicians in the clinic for this specific patient population wrote the control PT and used it routinely prior to this study, many physicians who were asked to assess the tool made observations similar to those PT users reported.

Despite these limitations, the randomized design ensured there were no significant differences in the characteristics or literacy levels of subjects who received the CDA versus the PT. This study clearly documents the feasibility of using a CDA in a population with

limited literacy by including literacy-appropriate interactive features, visual cues, and feedback to users.

Because the CDA used the PEI's programming, it could be modified easily for use by other groups that have low rates of CRC screening and low health literacy. The extensive and well-documented process by which the CDA was developed has both practical and theoretical significance.

This study extends our understanding of how Illness Self-Regulation and Information-Communication theories can be tested using perceptual mapping to develop specifically targeted messages. A challenge is to document how individuals gather information about the identity, causes, patterns, consequences, and controllability of health problems, to form major components of their "representations" or mental models of a health problem (Leventhal et al., 2004), and then to demonstrate how prevention methods crafted to reflect these models increase preventive health practices. This study links these processes and has documented the process by which the CDA was developed from the models (Bass et al., 2013). The large effect size of the CDA in terms of intent to screen provides empirical evidence that using this theoretical formulation can yield important clinical outcomes. The Cohen's effect size of .90 for the intent to screen variable is so large that we calculated post hoc that a fully powered study in the future would need only an n of 40 (with 20 in each group) to have sufficient power (80% probability, $\alpha = .05$) to detect it (Fritz, Morris, & Richler, 2012). This demonstrates that efficacy could be established with a relatively small, and thus feasible, sample size. Such a study could also establish an effect size for a harder outcome measure such as completed colonoscopy screening.

In sum, this study supports the theorized relationship between the individual's representations of a health threat and self-protective coping efforts, that is, the propensity to seek advice and adhere to medical recommendations, such as colonoscopy. Because our results are consonant with the core theorized relationships between individuals' representations of health threats and their health protective behaviors, it is likely that decision aids grounded in the best available epidemiological evidence will support optimal decision making only if they frame evidence in ways that are also consistent with and targeted to the risk–benefit conceptual frames of the target population. We believe that the theory-based perceptual mapping and vector message design techniques used in this study demonstrate the importance of including salient motivators for perception and intent/ behavior change for a specific population. This differs from approaches that assume that all people use the same types of information to weigh positives and negatives to make a screening decision.

Conclusion

This study demonstrates that a CDA developed with perceptual mapping methods and grounded in Illness Self-Regulation and Information-Communication theories can be used and accepted by older African American patients with limited literacy. Participants rated the CDA significantly higher than the PT on all indicators of acceptance, including the helpfulness of the information for making a screening decision, and reported more positive

feelings about colonoscopy, greater likelihood to be screened, and lower decisional conflict. CDA users reported more positive features of the education compared to PT users, who commonly said the education could be improved for patients in the clinic. Most CDA users reported it did not need to be improved. Thus, all study hypotheses were supported.

Our results have broad implications for health communication practice. Our preliminary research confirmed the need to develop a CDA that broke some rules of what kind of information needs to be included in all decision aids. Thus, we focused on including only what this patient group perceived was needed to make a decision, and eliminated much of the "noise" (information on the anatomy of the colon, exactly what colon cancer is and how it progresses, etc.). This approach addressed the specific patient group's cognitive framework, shaped by subcultural factors and limitations posed by low literacy. Given the promise of CDAs for patients with limited literacy, we recommend guarding against imposing standards prematurely that might cut off valuable innovations for patients at highest risk of health disparities.

The practical implications of using perceptual mapping methods based on their theoretical underpinnings can potentially reduce health disparities and overturn the view that low-literacy, minority patients are uninterested in health-protective behavior. The CDA could be a particularly useful tool in primary care settings where engaging patients in decision making and increasing preventive health practices are difficult.

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Comparison of perceptions of educational tools between intervention and control participants.

Perceptions of educational tools	Control (PT), <i>n</i> = 28 (%)	Intervention (CDA), <i>n</i> = 33 (%)	Significance (two-tailed)*
Length of education			
Too long	12 (43)	3 (9)	
Too short	0	2 (6)	
Just about right	16 (57)	28 (85)	.003
Amount of information on colonoscopy			
Too much	1 (3)	0 (0)	
Too little	12 (43)	1 (3)	
Just right	15 (54)	32 (97)	<.001
How useful the information was on colonoscopy			
Very useful	16 (57)	31 (94)	
Somewhat useful	7 (25)	1 (3)	
Not very useful	5 (18)	1 (3)	.002
Found the presentation			
Slanted toward not having colonoscopy	1 (4)	0 (0)	
Slanted toward having colonoscopy	11 (39)	11 (33)	
Equal and balanced between two options	16 (57)	22 (67)	.505
How hard or easy to use the education			
Very easy	7 (25)	31 (94)	
Somewhat easy	10 (36)	1 (3)	
Somewhat hard	9 (32)	1 (3)	
Very hard	2 (7)	0 (0)	<.001
Education would be helpful to a patient who wanted information to make a decision about screening for colon cancer			
Yes	19 (68)	32 (97)	
No	6 (21)	0 (0)	
Not sure	3 (11)	1 (3)	.002
Included enough information to help a person make a decision about whether or not to be screened			
Yes	17 (61)	31 (94)	
No	7 (25)	0 (0)	
Not sure	4 (14)	2 (6)	.001

^{*}Fisher's exact test.

Comparison of feelings about colonoscopy and intent to screen between intervention and control participants.

Screening intentions	Control (PT), $n = 28$	Intervention (CDA), <i>n</i> = 33	p Value [*]
How I feel about colonoscopy screening (1 most positive-15 most negative)			
Mean (SD)	5.39 (3.64)	2.33 (3.05)	.001
How likely I am to decide to be screened with colonoscopy (1 very likely- 15 not likely)			
Mean (SD)	5.36 (3.93)	2.21 (3.00)	.001

* Independent samples *t*-test, two-tailed.

Comparison of decisional conflict about colonoscopy screening (standardized seven-item scale) between intervention and control participants.

Decisional conflict	Control (PT), $n = 28$	Intervention (CDA), $n = 33$	p Value*
Overall decisional conflict			
Mean (SD)	28.1 (24.58)	.65 (2.08)	<.001
Feeling Informed subscale			
Mean (SD)	42.0 (36.68)	.76 (4.35)	<.001
Values Clarity subscale			
Mean (SD)	35.7 (35.63)	1.5 (6.06)	<.001
Support subscale			
Mean (SD)	13.7 (15.75)	.00	<.001

* Independent samples *t*-test, two-tailed.

What participants liked about the PT versus the CDA.

Themes	Control (PT), $n = 28$	Intervention (CDA), $n = 33$
Content		
Information (about CRC or unspecified)	17	8
Information on screening tests/options	9	0
Information on test procedure and what to expect	2	7
Preventive health practices	5	5
Format and readability		
Video testimonials with real people	NA	9
Q & A format	4	1
Picture-audio format (so didn't have to read)	NA	20
Easy to read	1	0
Large print	0	2
Short, understandable/basic information/"not doctor terms"	NA	9
Interactive	NA	4
Cultural specificity		
Focus on African Americans	NA	3
Total number of positive comments	39	68

What participants reported would improve the PT versus the CDA.

Themes	Control (PT), $n = 28$	Intervention (CDA), $n = 33$
More information		
Unspecified information	3	0
On signs, symptoms of CRC	0	1
More information on colonoscopy procedure, what to expect	4	0
More information on second opinions, treatment options for CRC	3	0
Less information		
Fewer options, clearer on what's best	2	0
Shorter, more basic information	5	1
Format		
Fewer words or big words, more basic, easier words	7	0
Bigger print	5	0
More pictures (unspecified, procedures, people)	6	0
Usability—computer	NA	2
Audio speed slow-should be faster	NA	2
Other		
Cultural diversity	0	1
Put it in the waiting room	0	2
Use of CRC survivor	0	1
Nothing—"fine as it is," "couldn't be better"	7	20
Total number of comments	42	30