A Patient Decision Aid to Help Heavy Smokers Make Decisions about Lung Cancer Screening

Robert J. Volk, PhD[1]; Lisa M. Lowenstein, PhD, MPH[1]; Kamisha H. Escoto, PhD[2]; Scott B. Cantor, PhD[1]; Reginald F. Munden, MD, DMD, MBA[3]; Vance A. Rabius, PhD[4]; Linda Bailey, JD, MHS[5]; Paul M. Cinciripini, PhD[4]; Heather Lin, PhD[6]; Viola B. Leal, MPH[1]; Ashley J. Housten, OTD, MSCI[1]; Pamela Luckett, MA[7]; Angelina Esparza, RN, MPH[8]; Myrna Godoy, MD, PhD[9]; Therese B. Bevers, MD[10]

[1] Department of Health Services Research, The University of Texas MD Anderson Cancer Center, Houston, Texas
[2] Department of Health Disparities Research, The University of Texas MD Anderson Cancer Center, Houston, Texas
[3] Department of Radiology, Wake Forest School of Medicine, Winston-Salem, North Carolina
[4] Department of Behavioral Science, The University of Texas MD Anderson Cancer Center, Houston, Texas
[5] North American Quitline Consortium, Phoenix, Arizona
[6] Department of Biostatistics, The University of Texas MD Anderson Cancer Center, Houston, Texas
[7] Information & Quality Healthcare Inc, Ridgeland, Mississippi
[8] Houston Department for Health and Human Services, Houston, Texas
[9] Department of Diagnostic Radiology, The University of Texas MD Anderson Cancer Center, Houston, Texas
[10] Department of Clinical Cancer Prevention, The University of Texas MD Anderson Cancer Center, Houston, Texas

The University of Texas MD Anderson Cancer Center

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ABSTRACT

Background

Screening for lung cancer with low-dose computed tomography is recommended by the US Preventive Services Task Force with a Grade B and is reimbursed by the Centers for Medicare & Medicaid Services (CMS). Reimbursement by CMS requires use of a patient decision aid to support shared decision making prior to screening. Effective strategies are needed that provide high-quality decision support to patients eligible for lung cancer screening (LCS).

Objectives

We conducted a randomized controlled trial of a video patient decision aid, "Lung Cancer Screening: Is It Right for Me?" The aim of this study was to compare decision-making outcomes about LCS among patients recruited through state-based tobacco quitlines, where patients were randomly assigned to the decision aid or to standard educational materials about LCS.

Methods

Quitlines referred patients aged 55-77 to the project. After screening for eligibility, patients were randomized, stratified by state of origin, to the study groups. We assessed the primary outcomes (Preparation for Decision Making© Scale and Informed and Values Clarity subscales of the Decisional Conflict Scale©) after 1 week. We assessed knowledge of LCS at each follow-up period; we assessed screening intentions and behaviors at 3-month and 6-month follow-ups. We explored interactions between intervention group and race of the patient.

Results

Thirteen state quitlines contributed 516 patients to the study. Follow-up rates at the 1-week, 3-month, and 6-month assessments were 90.7%, 87.6%, and 85.9%, respectively. Among the patients, 370 (71.7%) were under 65 years of age, 320 (62.0%) were female, 138 (26.7%) identified as black or African American, 47 (9.1%) had no health insurance, and 226 (43.8%) had a high school education or less. At the 1-week follow-up, patients who received the decision aid, compared with those who received the standard education materials, were more prepared to make a screening decision (decision aid patients, mean = 79.4, 95% CI, 77.1-81.7; standard education patients, mean = 69.4, 95% CI, 66.4-72.4; $P < .0001$), felt more informed about the

screening options (decision aid patients, mean 27.1, 95% CI, 23.8-30.5; standard education patients, mean = 42.1, 95% CI, 38.0-45.9; *P* < .0001 [lower scores indicate better outcomes]), and were clearer about their values related to the harms and benefits of screening (decision aid patients, mean 17.6, 95% CI, 14.2-21.0; standard education patients, mean = 31.7, 95% CI, 27.3-35.8; *P* < .0001 [lower scores indicate better outcomes]). They were more knowledgeable than patients assigned to the standard education materials at each follow-up assessment (*P* < .0001). Intentions to be screened and scheduling a doctor's visit to discuss screening did not differ between groups. We observed no significant interactions of the intervention group and race of the patient.

Study Limitations

We collected data using patient self-reports. We were not able to collect and verify information about screening results and subsequent testing because the follow-up period was too short. We don't know the reasons some patients were not interested in screening or participating in the study. For patients who had a visit to discuss LCS, we do not have information about the quality of the decision-making process with the health care provider.

Conclusions

A decision aid delivered to patients of tobacco quitlines improved readiness to discuss LCS with a physician, reduced decisional conflict, and improved knowledge, when compared with standard education materials. The potential to reach large numbers of smokers through quitlines is great but would require carefully addressing the role of quitlines in dissemination, given their limited funding.

BACKGROUND

Lung cancer is the second-most-common cancer and the leading cause of cancer deaths in the United States.[1] Five-year survival rates are only about 16.6%, in part because many patients have advanced disease at the time of diagnosis.[2] Smoking is the most important risk factor for developing and dying from lung cancer and is thought to cause about 90% of all lung cancers in the United States.[1,3]

The National Lung Screening Trial (NLST) found 20% fewer lung cancer deaths among current and former heavy smokers screened with low-dose computed tomography (LDCT) compared with those screened with standard chest X-rays.[4] More than 12 000 lung cancer deaths could be prevented each year in the United States if eligible smokers were screened annually.[5] Yet, lung cancer screening (LCS) with LDCT is not without risks, including radiation exposure from screening and diagnostic imaging, and a high false-positive rate leading to subsequent follow-up and testing with its own associated harms. A recent systematic evidence review on the benefits and harms of LDCT screening for lung cancer confirmed the results of the NLST, while raising concerns about the potential harms of screening.[6]

Evidence-based guidelines that endorse LDCT scans for high-risk smokers have been released, emphasizing the importance of making an informed decision about screening within the context of receiving smoking cessation services.[6,7] The US Preventive Services Task Force (USPSTF) endorsed LCS with LDCT and stressed the need for shared decision making.[8] The Centers for Medicare & Medicaid Services (CMS) now covers screening with LDCT but requires a patient counseling and shared decision-making visit with the use of patient decision aids prior to referral for screening.[9] In addition, insurers are increasingly covering LDCT scans for LCS among patients who met criteria consistent with the NLST. We know from our previous research that patients are interested in the screening, yet they know very little about the potential harms and benefits.[10] There is a need for patient decision aids to support informed decision making for LCS with LDCT.[4,11] Few tools have been developed to support patients in making decisions about LCS, and none have been evaluated in comparative trials.

It is important to define *informed* and *shared decision making* as well as to clarify the role of patient decision aids in LCS. *Informed decision making* broadly refers to decisions made

by patients who understand key facts about the options and outcomes, but it does not necessarily occur in the context of a conversation with a health care provider. In contrast, *shared decision making* is a collaborative process in which patients and health care providers make decisions together, taking into account the best scientific evidence and what is important to patients.[12] The process honors the expertise of the clinician and the patient's right to be fully informed about his or her care and options, including any potential harms and benefits. By working together to explore the options, and the patient's values and concerns, the clinician and patient arrive at a decision most closely aligned with what is important to the patient (informedmedicaldecisions.org).

Patient decision aids are tools that support decision making by describing the decision-making context; providing information about options, including their harms and benefits; helping patients forecast what it might be like to experience the options and outcomes; and helping patients to consider what is important to them.[13] Patient decision aids represent the most common intervention strategy for supporting shared decision making, and more than 100 randomized trials are included in the most recent Cochrane Systematic Review.[14] In the case of LCS, patient decision aids promote shared decision making by providing patients with information about the benefits and harms of LCS, and help patients consider their values related to screening (in preparation for a conversation with a health care provider about screening).

Prior to referral and as a condition of reimbursement for LCS, CMS requires a visit that involves both patient counseling and shared decision making. The patient counseling aspect emphasizes the importance of smoking cessation and abstinence; the shared decision-making aspect involves a discussion of the harms and benefits of LCS and use of one or more patient decision aids. CMS does not endorse a specific decision aid, nor does CMS require that an aid be used during the visit. By extension, the patient decision aid is meant to support the visit but does not replace a conversation with an approved health care provider or ensure that a quality shared decision-making process occurs.

Here we describe a comparative effectiveness research study of a video-based patient decision aid for LCS that prepares high-risk smokers to discuss LCS with an approved health care

provider. In advance of the study, we updated our patient decision aid to reflect current clinical guidelines.[15] Our target population was persons seeking smoking cessation services through state-based tobacco quitlines who met screening eligibility criteria based on age and smoking history. By focusing on current smokers, we addressed an essential component of LCS programs: the importance of tobacco cessation for current smokers. The specific aim of this study was to evaluate patient-centered outcomes about LCS in a randomized trial of smokers recruited through state-based tobacco quitlines, where patients were randomly assigned to the patient decision aid or to standard educational materials about LCS. In testing this aim, we hypothesized that quitline patients who received the patient decision aid rather than standard educational materials would (1) be more prepared to make a decision about LCS, (2) feel more informed about the screening decision, and (3) be clearer about their values in terms of the tradeoffs between benefits and risks of LCS with LDCT. We further hypothesized that quitline patients who viewed the decision aid would be more knowledgeable about LCS than those patients who received the standard educational materials. We also collected patient data about screening intentions and screening behaviors up to 6 months after receiving the intervention materials but made no specific hypotheses about these latter outcomes, as the literature on the impact of decision aids on cancer screening uptake is mixed.[14]

PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS IN THE STUDY PLANNING AND DESIGN, CONDUCT OF RESEARCH, AND DISSEMINATION OF FINDINGS

Types of Stakeholders and Their Involvement

Our engagement strategy addresses the PCORI Methodology Standards (Appendix – Methodology Standards Checklist). To ensure that the study aims, methods, and intervention (ie, the patient decision aid) would benefit and reflect the needs of all end users, we sought guidance from stakeholders representing patients, primary care clinicians, advocacy groups, quitline service providers, and quitline support organizations. The principle of transparency was important throughout the project; decisions were made collaboratively and led by input from patient and stakeholder advisory groups.

Patient Advisory Group

We convened a group of patient advisors whose chief role was to guide the refinement of the LDCT decision aid, give input about the study methods, and guide the eventual development of supplemental LDCT screening educational tools. Our patient advisory group (PAG) consisted of 5 former smokers (recruited from MD Anderson's Tobacco Treatment Program and the community) and a patient advocate (American Cancer Society [ACS]/City of Houston). Many of the PAG members had been involved with the current research team's earlier studies. The Center for Community-engaged Translational Research (CCETR), an institutional resource at MD Anderson, helped identify the patient advocate, and a CCETR staff member (Dr. Kamisha Escoto) led the PAG. Most PAG participants were relatively recent former smokers (quit within the past 5 years), and all were enthusiastic about being part of a project that would help educate patients about lung cancer and empower them to talk with their physicians about screening. We used the term *patient investigator* to clarify and reinforce their role as members of the research team as opposed to research subjects.

The PAG met 1 to 2 times per year in person, supplemented by quarterly email/postal mail updates and phone correspondence, as needed, to share project status and updates as well as to solicit feedback. We found mixed modes of communicating to be important for this group, as one member lacked email access, a few members lived a substantial distance from the MD Anderson campus, and several members worked full-time jobs. We needed to remain flexible to be respectful of the group's time and personal commitments. Each meeting lasted 60 to 75 minutes; light dinner was provided; and members received compensation (gift cards). We used the first meeting to set the stage for the project. We were intentional in conveying our goals of building a fair and honest partnership—that learning in the project would be bidirectional and that we would engage in decision making collaboratively—emphasizing the value of PAG members' experiences to the project. In addition to discussing the study and the nature of the research process, we discussed their roles as advisors in the project and answered any questions. Subsequent meetings involved reviewing and providing feedback on the intervention, study documents, and supplemental educational materials, in addition to

monitoring recruitment and study progress. We have shared and discussed early preliminary data with the group, including demographics and baseline LCS knowledge questions.

Stakeholder Advisory Group

We also formed a stakeholder advisory group (SAG) to provide key input about the intervention content, strategies for involving quitline service providers, patient recruitment approaches, interpretation of the study findings, and planning for the dissemination of the study results and the decision aid. The SAG included 2 primary care physicians, the director of a quitline service provider, the director of ACS's health equity program, and the president and CEO of the North American Quitline Consortium (NAQC). While we did not conduct our study in primary care settings, we felt it was important to have representation of primary care physicians because they are expected to implement the patient counseling and shared decision-making visit required by CMS for LCS. The patient advocate, also part of the SAG, was an asset to the group by providing advisement on literacy considerations and issues surrounding equity in access. Health equity was an important consideration in forming the SAG because of the unequal burden of tobacco use.

Based on our prior experience, we had the patient and provider stakeholder groups meet separately; this arrangement encourages patient members to freely voice their opinions and concerns, and it avoids the power dynamic that might be present with the addition of physicians and/or other stakeholder representatives. Meetings with the SAG were via conference calls in the first year of the study. In years 2 and 3, we attended the annual NAQC meetings to network with members of state departments of health, quitline service providers, and other tobacco researchers. In year 3, we met more frequently with the SAG via emails, phone calls, and an in-person meeting at the NAQC headquarters to discuss how best to make the research products available on a national level and engage other stakeholder groups in dissemination.

Impact of Stakeholder Involvement on the Research Project

Although we did not formally evaluate the impact of stakeholder engagement in this project, we feel that our successes—including trial recruitment, widespread interest in the LDCT

decision aid, and smooth study operations—confirm the significance of stakeholder involvement. From the first PAG meeting forward, group discussions validated the need for developing patient education about lung cancer and LDCT screening. No member had discussed screening or cancer risk with his or her physician. All members expressed the need for accurate information as a way to prepare them to talk with their doctors, and all responded positively to the decision aid. Similarly, members of the SAG indicated quitline service providers were generally unaware of LCS and not prepared to help interested patients with screening decisions.

Stakeholder involvement enhanced study quality. PAG members weighed in on major aspects of the project, particularly our LDCT decision aid and other materials. The PAG contributed to the refinement of the prototype decision aid, providing guidance on content and its use in the clinic visit and offering suggestions for additions to the aid (eg, course of screening, lung cancer symptoms, insurance coverage for screening). PAG members discussed the challenges the team might face in the study, brought up questions unique to the study population, and emphasized the need for physician engagement in screening decisions. We used this information to guide decision aid content, including reinforcing messages about discussing screening with the patient's doctor. These suggestions, along with input from the SAG, have been valuable to the final design of the decision aid.

PAG members were not active participants in study design planning; however, SAG members determined the scope of involvement of quitline staff in study recruitment. These decisions involved limiting the role of quitline staff to identifying eligible callers based solely on age and not calculating pack-year smoking history. Research staff assessed and confirmed eligibility when a patient contacted the team about participating in the study.

Patient recruitment was initially a significant challenge. We had a target enrollment of 500 quitline patients. Our original recruitment strategy required that quitline staff members identify potentially eligible callers and refer them to the project. It was clear from the outset that we could not ask call staff to assess patient eligibility for screening and provide informed consent for the project. We also found that accruals through our initial quitline service provider, Information & Quality Healthcare, were slower than anticipated. So, we refined the recruitment strategy, with input from our SAG members, in 2 important ways: (1) We increased

the number of participating states from 2 to 13; and (2) we added mailed invitations to the study for patients of selected quitline providers. These changes allowed us to rapidly boost referrals, complete recruitment earlier than expected, and complete 6-month follow-up assessments for the full sample.

We are including suggestions from the PAG as we devise plans for disseminating the decision aid into primary care practices. PAG members emphasized that the aid should be integrated into the physician visit (eg, patients could watch the video in the waiting room), as they saw it being present at the point of care as most effective. Importantly, they stressed the need for physician education, as their own personal experiences reflected that physicians were not always cognizant of screening guidelines. PAG members were very supportive of future interventions that would involve physician education on LDCT training. As the study was being completed, we worked with the SAG about planning dissemination of the study results and continued use of the decision aid. One key opportunity will be to nationally disseminate the patient decision aid and supporting materials through state quitlines.

METHODS

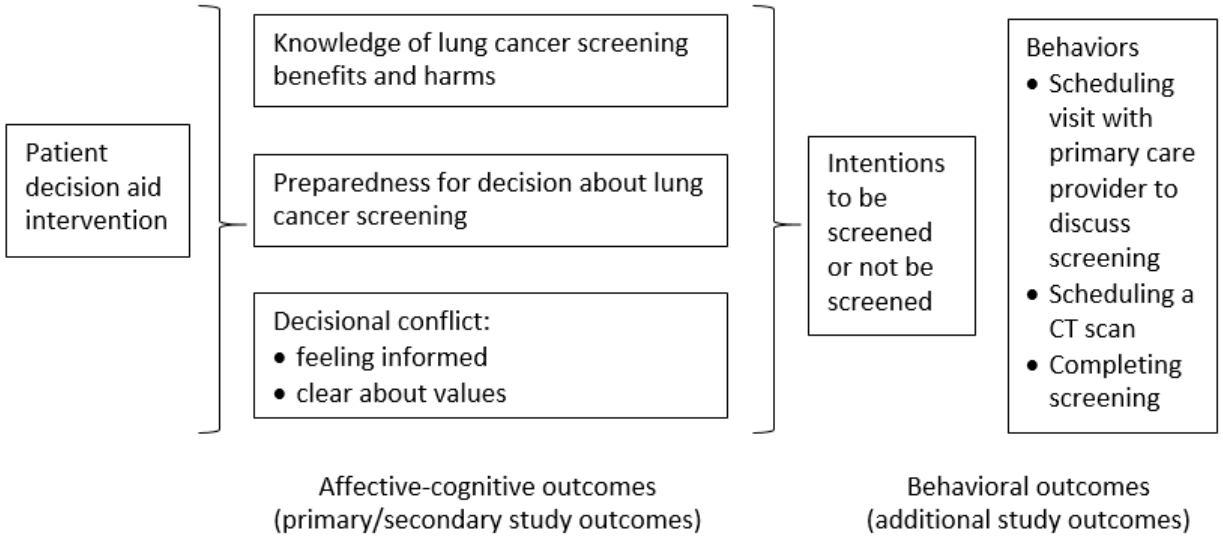
Study Overview

The aim of this study was to compare a video-based decision aid to standard educational materials on LCS decision making. We hypothesized that high-risk smokers eligible for LCS who received the decision aid would (1) be more prepared to make a decision about LCS; (2) feel more informed about the screening decision; and (3) have more clarity on how they value the benefits and harms of LCS with LDCT. We further hypothesized that eligible, high-risk smokers who viewed the decision aid would be more knowledgeable about LCS than would patients receiving the standard educational materials. We collected data about screening intentions and completion of screening, but we made no specific hypotheses about these additional outcomes because the literature on the impact of decision aids on cancer screening uptake is mixed.[16]

The causal model underlying this research reflects the impact of patient decision support interventions on patients' cognitive/affective outcomes and behavioral outcomes, and follows the adapted model offered by Shay and Lafata (see Figure 1).[17] Specifically, the model posits that a patient decision aid positively affects knowledge of the benefits and harms of LCS. Improved knowledge also leads to greater preparation for decision making and reduced decisional conflict. These affective/cognitive outcomes have the potential to affect intentions to be screened and subsequent downstream behavioral outcomes, including scheduling a visit with a doctor to discuss screening, scheduling a CT scan, and completing screening. The impact of the intervention on behavioral outcomes, though, is not specified because a fully informed patient may decline screening or decide to pursue screening.

We use the term *patient* to refer to the subjects in this study but note that quitline service providers often use the term *client*.

Figure 1. Causal Model Guiding the Study (Adapted From Shay and Lafata[17])

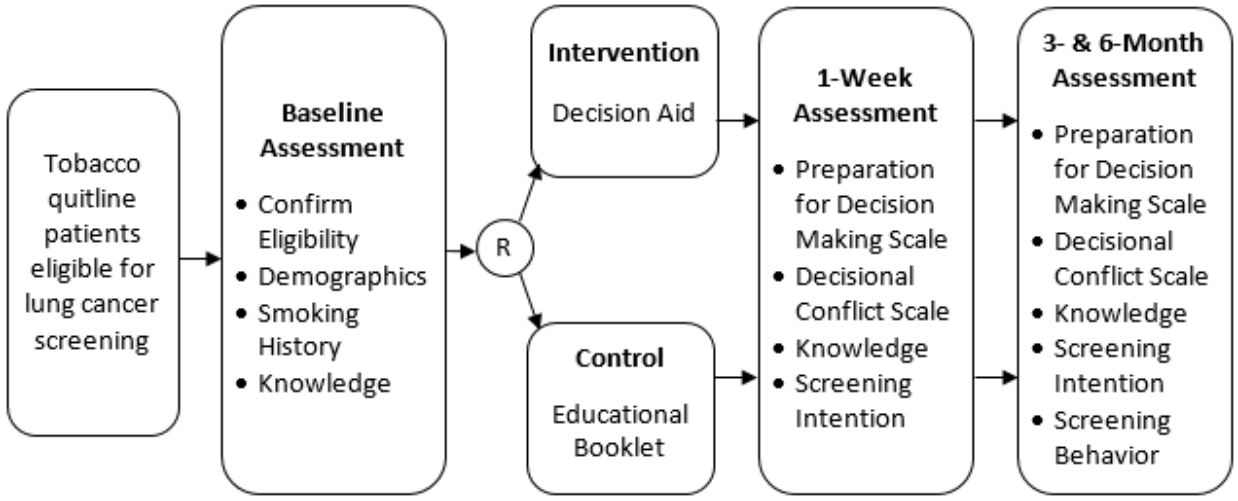


Study Design

The study was a randomized controlled trial to assess the effectiveness of a video-based patient decision aid compared with standard education materials for LCS with LDCT. Figure 2 depicts the study design and assessment schedule. The study design was selected to directly

compare the 2 intervention strategies, with randomization occurring at the level of the patient within each state quitline. We prestratified by state because state quitlines differ in the services they provide, and population demographics of each state differ as well. Following patients up to 6 months allowed them time to schedule a visit with a doctor to discuss referral for LCS and allowed us to test the model of the relationship between the effect of the decision aid on screening intention and screening behavior.

Figure 2. Design of the Study



Randomization of quitline patients was performed within each state.

After the baseline assessment, using a computer-generated randomization schedule with sealed envelopes containing each assignment, we randomized patients to receive the patient decision aid or standard educational materials. We performed randomization within each state organization (ie, prestratification by state quitline) to control for any systematic differences in services provided to quitline patients. It was not possible to blind patients to the intervention they received.

The design included an assessment at 1 week to collect data on the primary outcomes for the study and 3-month and 6-month follow-up assessments to determine how well patients retained the information and track any use of screening services. We also collected data about

the patient scheduling an office visit with a clinician to discuss LCS, scheduling a CT scan, and completing screening. We collected these latter outcomes via self-report, as verification by medical records was not feasible for this project.

Participants

Eligible patients were quitline patients aged 55-77 years, had at least a 30 pack-year smoking history, and spoke English. Eligibility criteria for the proposed study followed the high-risk categorization from the NLST that was also endorsed by ACS and the multisociety collaborative guideline published in 2012.[6,7]

Our protocol, approved by the MD Anderson Institutional Review Board (IRB), required that quitlines not provide names and contact information directly to the research team. Rather, patients were provided information about the study, with guidance on how to contact the research team about study participation.

Quitline staff identified potential patients from new referrals for smoking cessation services, including self-referrals and patients who were referred by primary care physicians and other health providers. Our initial plan was for quitline service staff to identify callers who had a 30+ pack-year smoking history; however, service providers indicated that this approach was not feasible because it would require additional staff time. Therefore, initial eligibility for the study was assessed based solely on patient age. For patients aged 55-77, the intake staff members assessed their interest in learning about LCS. Interested patients were sent recruitment materials, which included a toll-free number, an email address, and a postcard with information about how to contact the research team about study participation. Additionally, some of the state-based quitlines agreed to send out recruitment materials to those who had called the quitline over the past year and met the age eligibility criterion. This 2-pronged recruitment approach proved highly successful in meeting accrual targets.

Once potential study patients contacted the study team, the research staff provided more information about the study, assessed eligibility based on smoking history and no previous diagnosis of lung cancer, obtained verbal consent using a verbal consent script, and collected the study patients' demographic information.

Research staff instructed the study patients to review the study materials once they had received them. Intervention study patients could view the decision aid either on a DVD or the internet. If these options were not accessible, the research staff assisted patients in finding a location where they could have access locally (eg, public libraries).

Interventions and Comparators or Controls

Table 1 describes the video-based patient decision aid and the control intervention, using criteria adopted by the National Quality Forum[18] for determining if a patient intervention is a decision aid.

We updated a previous version of a video-based patient decision aid about LCS[15] to reflect the changes in guidelines from ACS, American College of Chest Physicians, American Society for Clinical Oncology, and National Comprehensive Cancer Network.[7,19-21] We refined and updated the decision aid with significant input from the PAG, tobacco users, primary care clinicians, and tobacco cessation experts. We iteratively refined the aid content following cognitive testing and usability testing. For cognitive testing, 10 smokers from MD Anderson's Tobacco Treatment Program were shown the updated content in PowerPoint slides and were asked to participate in "think aloud" exercises. They viewed the content and described what the content was trying to convey. Because the aid included new features (eg, how to calculate pack-years) and updated content, we conducted a small pilot study with 30 patients from the Tobacco Treatment Program to assess acceptability of its length, clarity of information, and balance of the information provided. We completed external peer review of the updated aid with 3 experts in decision aids and/or LCS. External peer review by experts who are not part of the development team is recommended by the International Patient Decision Aid Standards Collaboration and is an indicator of the tool's credibility.

Table 1. Patient Decision Aid Compared With Standard Education Materials, According to NQF Screening Criteria

NQF Screening Criteria	Patient Decision Aid	Standard Educational Materials
1. The patient decision aid describes the health condition or problem for which a decision is required.	Describes what lung cancer is, describes mortality (lung cancer specific and all cause), incidence, diagnosis, and risk factors	States lung cancer death as the health problem
2. The patient decision aid identifies the target user.	Uses USPSTF eligibility criteria for LCS	Uses NLST eligibility criteria for LCS
3. The patient decision aid explicitly states the decision under consideration.	Whether to be screened	Whether or not to be screened
4. The patient decision aid describes the options available for the decision, including nontreatment when appropriate.	Screening with LDCT versus not screening	Screening with LDCT versus not screening
5. The patient decision aid describes the positive features of each option.	States that LCS reduces the lung cancer–specific risk of dying by 16% to 20%; leads to fewer deaths from all causes; can find other health problems that may be treated earlier	States that screening for lung cancer may save your life
6. The patient decision aid describes the negatives features of each option.	Exposure to radiation; false positives with further testing (eg, higher radiation scans, biopsy) and associated complications; overdiagnosis	Radiation risk; need for additional tests and procedures
7a. The patient decision aid clarifies patient values for outcomes of options by: -Asking patients to consider or rate which positive and negative features matter most to them; and/or	Asks viewer to think about the reasons he or she would choose to be screened and the reasons he or shey would choose not to be screened	Not addressed
7b. The patient decision aid clarifies patient values for outcomes of options by: -Describing the features of options to help patients imagine the physical and/or social and/or psychological effects	Describes benefits (reduces lung cancer deaths and deaths from all causes) and harms (false positives, additional testing, radiation exposure, overdiagnosis)	Not addressed

Abbreviations: LCS, lung cancer screening; NLST, National Lung Screening Trial; NQF, National Quality Forum; USPSTF, US Preventive Services Task Force.

We used an active control condition for the study. The control was a brochure about LCS from a national lung cancer advocacy group. This approach is justified because educational materials about LCS are publicly available, and the study design was strengthened by comparing

the decision aid with existing educational materials rather than a standard-of-care approach that involved no patient education. We structured the 2-page brochure around questions a patient can ask a doctor about LCS; they addressed eligibility for screening, asking for a description of the harms and benefits of screening, what to expect from a CT scan, costs of screening, how to interpret the results, messages about the importance of smoking cessation, and where to find more information about lung cancer and screening. The benefits and harms were mentioned in the brochure, although no probabilities of outcomes were included. The brochure was printed as a 2-sided single sheet.

Study Outcomes

Primary Outcomes

Preparation for Decision Making© Scale

One of the primary outcomes for the study was preparation for decision making as measured by the Preparation for Decision Making© Scale.[22] This scale assesses a patient's perception of the usefulness of decision aids or educational materials for preparing the patient to communicate with his or her health care provider about making a screening or treatment decision.[22] Adapted for the LCS context, the 10-item scale uses a 5-point Likert response format, ranging from 1 (not at all) to 5 (a great deal). The Preparation for Decision Making© Scale has been shown to be unidimensional, based on principal components analysis with favorable Item Response Theory characteristics. It discriminates well between patients who do and do not find a decision aid helpful in making an informed choice. Internal consistency reliability of the scale is excellent, with alpha coefficients ranging from 0.92 to 0.96.

Informed and Values Clarity Subscales of the Decisional Conflict Scale©

Adapted for the LCS context, we used the Informed and Values Clarity subscales (3 items each) of the Decisional Conflict Scale© (DCS)[23] to assess decisional conflict. The DCS is among the most widely used outcome measures in studies evaluating patient decision aids, with 38 of 105 randomized trials included in the most recent Cochrane Systematic Review reporting use of the measure.[13] The DCS Informed subscale assesses smokers' perceived awareness of

advantages and disadvantages of options; the DCS Values Clarity subscale assesses the perceived importance of the advantages and disadvantages of the options in making a screening decision. We used the statement format of the scale, with 5-point response options ranging from 0 (strongly agree) to 4 (strongly disagree).[24] Subscales were scored on a 0 to 100 scale following the user manual guidance, with lower scores indicating less decisional conflict. The DCS has been validated with Canadian and American patients for a variety of health care decision contexts and has excellent internal consistency reliability, discriminant validity, and construct validity.[24]

Secondary Outcome

Knowledge of Lung Cancer and LCS

To assess patients' knowledge of lung cancer and LCS, we used the LCS-12 measure developed by the research team.[25] The measure assesses understanding of risk of lung cancer, screening eligibility, benefits, and potential harms of screening including false-positive findings. It has excellent test–retest reliability (ICC = 0.84) and is responsive to change because of patients viewing a patient decision aid on LCS.[25,26] To provide an indication of patients' knowledge of LCS prior to receiving the intervention, patients answered 4 questions from the knowledge measure at the baseline. We chose to administer a subset of the knowledge measure items to minimize sensitizing effects where patients are keyed to certain information in the intervention materials because of the questions asked at the baseline. At each follow-up assessment, we used 9 items from the full scale. We administered the measure at 1-week, 3-month, and 6-month follow-up assessments. The scoring involved computing the percentage of questions answered correctly.

Additional Outcomes

Intentions to be Screened

We assessed intentions to be screened for lung cancer with LDCT at the 1-week assessment. Patients were asked the following question: "How likely is it that you will be tested for lung cancer with a CT scan this coming year?" Response options included the following: "Definitely will be tested," "Probably will be tested," "Probably won't be tested," "Definitely

won't be tested," and "Not sure." We collapsed response options to "Will be tested" and "Will not be tested or not sure" for the analyses.

Screening Behaviors/Screening Rates

We assessed screening behaviors/screening rates at the 3-month and 6-month follow-ups. Patients were asked if they scheduled or had a visit with their health care provider to discuss LCS. We also asked if they scheduled or had a LDCT scan since the time they enrolled in the study. Response options included "Yes," "No," and "Not sure."

Acceptability

We assessed acceptability of the decision aid at the 1-week follow-up with standard measures of acceptability adapted from the Ottawa Acceptability Measure (eg, ratings of the aid regarding length, clarity, balance of information).[27] Only participants assigned to the decision aid group answered these questions.

Study Setting

The setting for this study was tobacco quitline services operated by 13 states across the United States. We elected quitlines because (1) smoking cessation is an essential component of LCS programs, and (2) it is an effective way to reach individuals at high risk of lung cancer. We used a multipronged strategy to identify quitline service providers to participate in the study. We contacted both state departments of health and quitline service providers because quitline service providers contract with states to run their required state quitlines. We worked closely with our existing partners, such as ACS, to develop partnerships with state tobacco quitlines. We also partnered with NAQC and attended its annual conference to meet with our partners and recruit new partners in person.

States and quitline service providers were directly involved with patient outreach and recruitment. Each state/quitline service provider partnership is unique with specific requirements. Some service providers required financial support to participate in the study, while others did not. We included service providers regardless of the requirement to provide support for quitline staff to recruit patients.

Timeframe for the Study

We recruited patients beginning in March 2015 and continued through September 2016. Patients completed a baseline assessment at recruitment and were mailed intervention materials. Upon receipt of the materials, patients were given 1 week to review the materials and were then contacted to complete a 1-week follow-up. We selected this timeframe to allow patients sufficient time to seek an alternate location to the view the DVD if they did not have a DVD player or internet access to watch the video. We extended the follow-up period to 1 to 3 weeks, as it allowed time for us to reach patients while still being close enough to the initial review of materials to capture any changes in knowledge. Patients were then contacted at 3 months and 6 months to reassess the secondary outcomes and additional outcomes, including screening intentions and screening behaviors. We selected these time periods to examine decays in knowledge and to allow enough time for interested patients to schedule a visit with their primary care providers to discuss LCS. We were not able to follow patients beyond the 6-month period due to the project timeline and contract period of 3 years.

Data Collection and Sources

We collected data for this study via self-report from quitline patients. We used several strategies to enhance study retention. For example, patient compensation was offered after completion of each of the follow-ups. Payments were commensurate with the amount of time needed to complete the follow-up ($50 at the 1-week follow-up and $25 at the 3-month and 6-month follow-ups). We set a window of up to 3 weeks after the follow-up due date to complete that follow-up. We used a minimum of 3 call attempts to reach each patient for follow-up; we left messages for those we could not reach. If the patient did not respond after the second call, we mailed the surveys to the patient along with a postage-paid return envelope. If a person was lost to follow-up for a particular time point, we continued to attempt to reach him or her for subsequent follow-ups. Research coordinators recorded in a tracking database reasons for study withdrawal. The mode of data collection was tracked and considered in the analysis strategy.

Analytical and Statistical Approaches

Sample Size/Power Justification

The primary analysis compared the 3 primary outcomes (Preparation for Decision Making© Scale, DCS Informed subscale and Values Clarity subscale) between the intervention and control arms. Because the 3 primary outcomes were of equal significance, we controlled overall type 1 error rate at a significance level of 0.05 by comparing each of the 3 primary outcomes at a significance level of 0.017 (0.05/3). To control for multiple comparisons, the analysis used the Bonferroni multiple comparison adjustment.

From previous research with decision aids using the DCS, we estimated that the intervention arm would have a mean Informed subscale or Values Clarity subscale score of 30, while the control arm would have a mean Informed subscale or Values Clarity subscale of 25.[24,28] A sample size of 190 in each arm would have 80% power to detect a difference in means of 5 using a 2-group *t* test with a 0.017 2-sided significance level assuming a common standard deviation (SD) of 15 on the Informed subscale or Values Clarity subscale.[24] We calculated the effect size the study would be able to detect with the given sample size for the Preparation for Decision Making© Scale because we had limited preliminary data for this measure. A sample size of 190 in each arm would have 80% power for the study to detect an effect size of 0.332 using a 2-group *t* test with a 0.017 2-sided significance level. With an anticipated retention rate of 80% by the 3-month and 6-month follow-ups, we recruited about 500 patients for the study to allow for about a 20% dropout rate by the 6-month follow-up.

Analysis Plan and Testing for Heterogeneity of Treatment Effects

We summarized patients' demographic and clinical characteristics at baseline using descriptive statistics such as mean, SD, median, interquartile range (IQR), and frequency, where appropriate. We used Student *t* test/Wilcoxon test and Kruskal-Wallis test/ANOVA to compare continuous variables between the 2 groups, and the chi-square test or the Fisher exact test to assess the differences of categorical variables between the 2 groups.[29]

We performed 2-sided 2-group *t* tests to compare the differences of the 3 primary endpoints, Preparation for Decision Making© Scale, Informed subscale and Values Clarity subscale of DCS, between the 2 study groups. For these efficacy endpoints, we applied intent-

to-treat analysis to the patients. PCORI Methodology Standards address the importance of considering heterogeneity of treatment effects in planning the analyses (see Appendix – Methodology Standards Checklist). We tested for heterogeneity of treatment effects by examining subgroup differences in primary outcomes between white and African American patients. We assessed the interaction between intervention and race/ethnicity using a linear regression model to examine whether the decision aid has differential effects between African American and white participants. We conducted these analyses adjusting for multiple covariates, including age, gender, race, education level, insurance status, mode of administration, and quitline service provider.

Because we assessed LCS knowledge at postintervention (week 1), 3-month, and then 6-month follow-ups, we employed linear mixed effect models for longitudinal measures[30,31] to assess the change in the magnitude of LCS knowledge over time, adjusting for multiple covariates, including intervention indicator, age, gender, race, education level, insurance status, quitline service provider, and recruitment method.

We used logistic regression analysis[32] to assess the relationships between the additional endpoints (screening intentions, scheduled a visit with doctor to discuss screening, scheduled a CT scan for LCS, and being screened by the 6-month follow-up assessment) and the intervention, and to assess the interactions between intervention and race with and without adjusting for age, gender, race, education level, insurance status, quitline service provider, and recruitment method. For screening intentions, we grouped responses “Will not get screened” and “Not sure” for the logistic regression analysis. We also included in the analyses interaction terms for race and intervention group to test for any heterogeneity by racial subgroups in the additional outcomes.

Handling of Missing Data

The main data collection method was telephone interviews, with mailed questionnaires used for people we could not otherwise reach via telephone during a follow-up assessment time window. We used a structured tracking system to monitor completion of assessments and to trigger additional patient contacts when assessments were due.

The primary reason for missing data was subject attrition at the follow-up assessment. We compared characteristics of patients who did and did not complete follow-up assessments. In addition to giving us a clearer picture of patients who did and did not complete the follow-up assessments, these comparisons identified any additional covariates to be included in the analyses of study outcomes.

We initially proposed to account for missing data using a variety of multiple imputation techniques[33,34] to generate individual values for missing data fields. Because missing data among otherwise completed outcome instruments was so infrequent for patients who provided data (eg, only 8 patients in the decision aid group did not complete the Preparation for Decision Making© Scale), and the outcome differences were so large, imputation for missing values would not have affected the study findings. We therefore conducted analyses based on valid cases (ie, cases with at least partially completed follow-up surveys), without imputation for missing data.

Avoidance of Bias

We tested several assumptions made in the study using sensitivity analyses (Appendix – Methodology Standards Checklist). For the primary, secondary, and additional outcomes, we performed analyses with and without the following covariates: age (categorized as under 65 and 65+), gender, race, insurance status, education, quitline service provider, and recruitment methods. We selected age because older patients may have higher lifetime tobacco exposures. We included quitline service provider because the smoking cessation services provided to each state can differ. We also included recruitment method to account for patients who completed the assessments by phone (primary strategy) rather than through follow-up mailed surveys (secondary strategy). For the primary outcome measures, we used linear regression models and compared the intervention effects with and without the covariates. For the knowledge outcome, we used linear mixed effect models for longitudinal measures, with the intervention effects considered with and without the covariates in the model. Finally, for the additional outcomes, we conducted logistic regression analyses and examined the intervention effects with and without the covariates in the models.

Changes to the Original Study Protocol

Changes from the original study protocol included the addition of knowledge questions at the baseline assessment, a change in eligibility criteria, and the addition of recruitment sites. We added 4 knowledge questions to the baseline assessment to provide an indication of any group differences in knowledge about LCS before receiving the intervention materials. We initially changed the upper age limit for eligibility from 74 years (used in the NLST) to 80 years (recommended by the USPSTF).[8] Later, at the suggestion of PCORI, me modified the upper age limit to match the upper limit for Medicare coverage of LCS, at 77 years. To meet recruitment targets, we also increased the number of state-based quitline providers participating in the trial and allowed accrual to reach 516 to accommodate additional interested patients who called us after we reached our original target. The study protocol modifications were approved and renewed annually by the MD Anderson IRB (protocol number 2014-0628).

RESULTS

Sources of Participants

A total of 4 quitline service providers covering 13 states contributed patients to the study. Our first quitline partnerships were with the Tennessee Tobacco Quitline and Mississippi Tobacco Quitline, operated by Information & Quality Healthcare. They recruited patients through both new callers and mailings to previous callers. Then we expanded to the New York Tobacco Quitline, run by Roswell Park Cancer Institute. They mailed recruitment materials to patients who met inclusion criteria. We also worked with National Jewish Health and Alere Wellbeing (now Optum®) for state tobacco quitlines in Virginia, South Carolina, Washington, Alabama, Kentucky, Michigan, Pennsylvania, Ohio, Vermont, and Wyoming. A map showing participation by site is given in Figure 3, and the numbers of patients by state and service provider are given in Table 2.

Figure 3. Study Enrollment by State

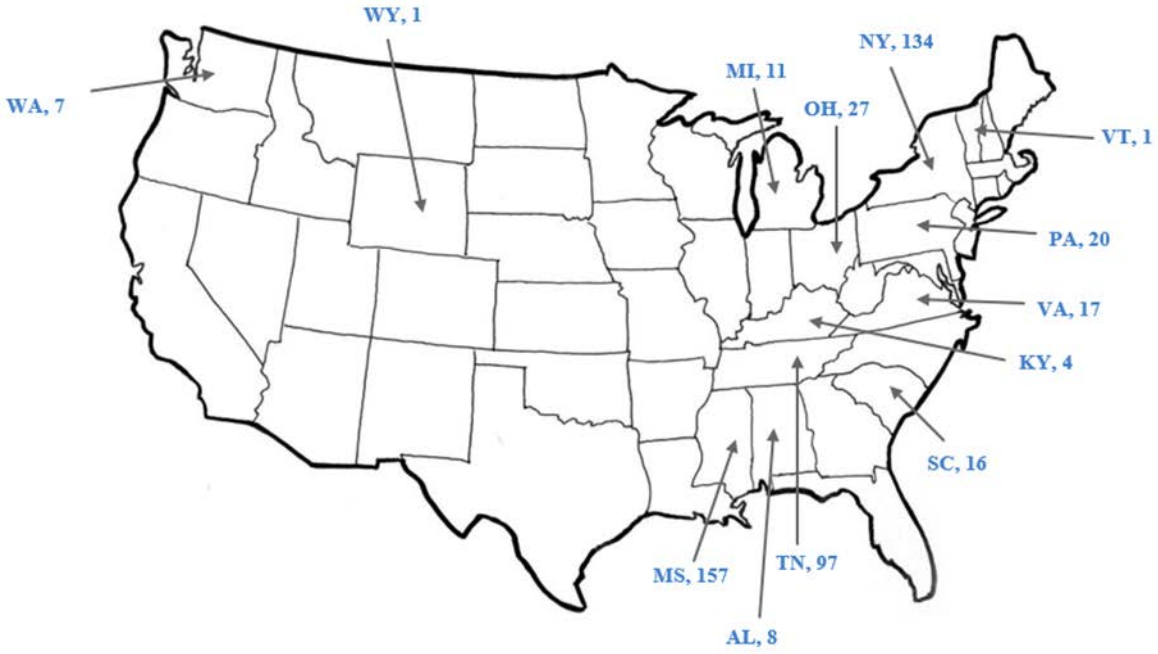


Table 2. Participating State Quitlines and Service Providers

State	Number of Participating Patients	Quitline Service Provider
Alabama	10	National Jewish Health
Kentucky	5	National Jewish Health
Michigan	12	National Jewish Health
Mississippi	160	Information & Quality Healthcare
New York	135	Roswell Park Cancer Institute
Ohio	28	National Jewish Health
Pennsylvania	25	National Jewish Health
South Carolina	16	Alere[a]
Tennessee	98	Information & Quality Healthcare
Vermont	2	National Jewish Health
Virginia	17	Alere[a]
Washington	7	Alere[a]
Wyoming	1	National Jewish Health

[a]Now part of Optum®.

Participant Flow

The study flow diagram is given in Figure 4. A total of 746 quitline patients contacted the research team about participating in the study. Reasons for ineligibility included not meeting inclusion criteria due to age or smoking history (184 patients), declining participation after learning about the study (35 patients), or being unable to view the decision aid video if assigned to that study arm (11 patients). From there, 516 patients were enrolled and randomized. The follow-up rates were 91% at 1 week (468 of 516), 88% at 3 months (452 of 516), and 86% at 6 months (443 of 516). Reasons for loss to follow-up can also be found in Figure 4. By the 6-month follow-up, 11 patients had withdrawn due to lack of interest or illness, and 5 were deceased. We attempted to recontact patients who did not participate in previous assessments, excluding patients who withdrew or were deceased. This resulted in 20 patients participating in the 3-month follow-up who did not participate in the 1-week follow-up, and 24 patients participating in the 6-month follow-up who did not participate in the 1-week follow-up.

Figure 4. Study Flow Diagram

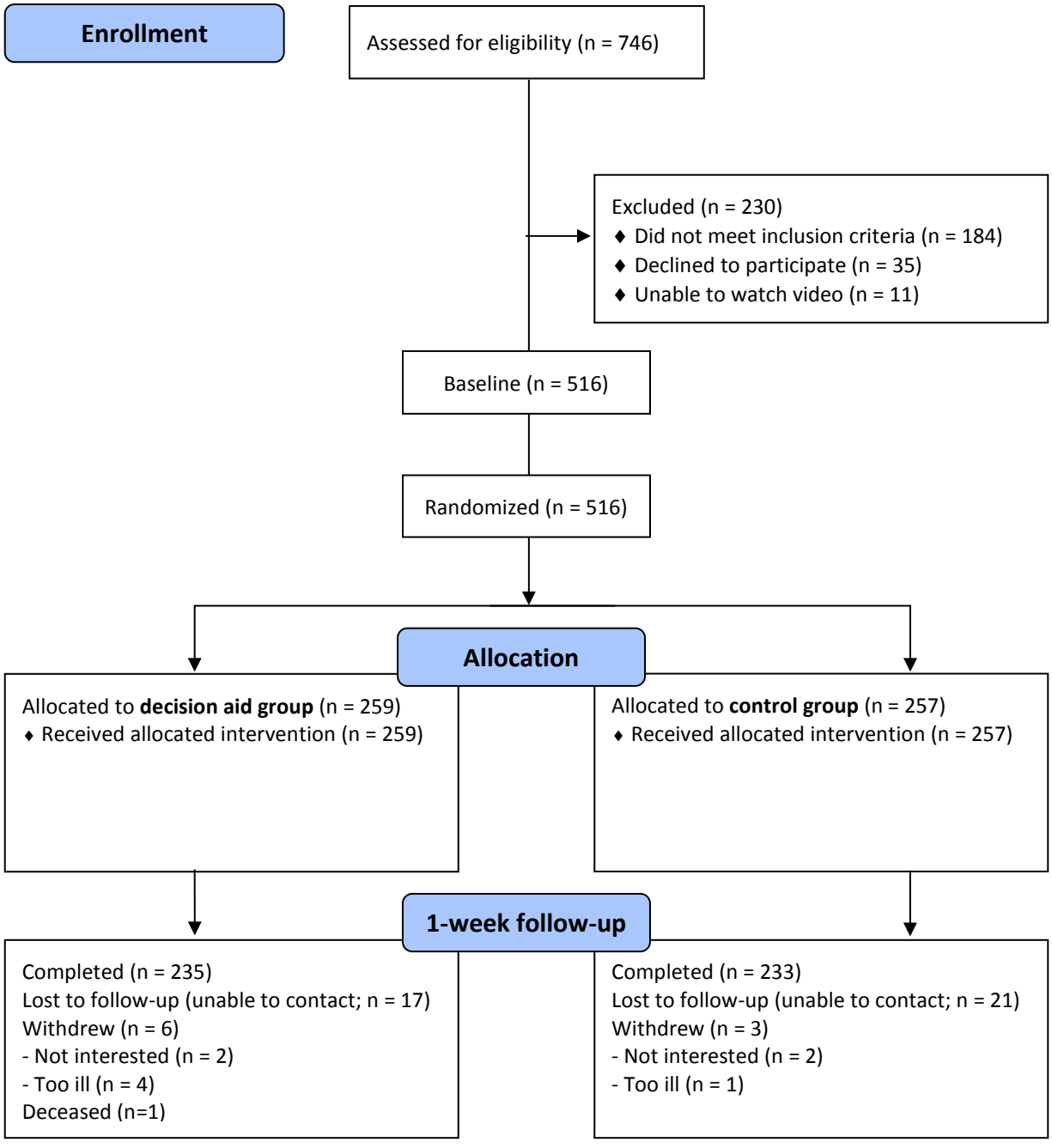
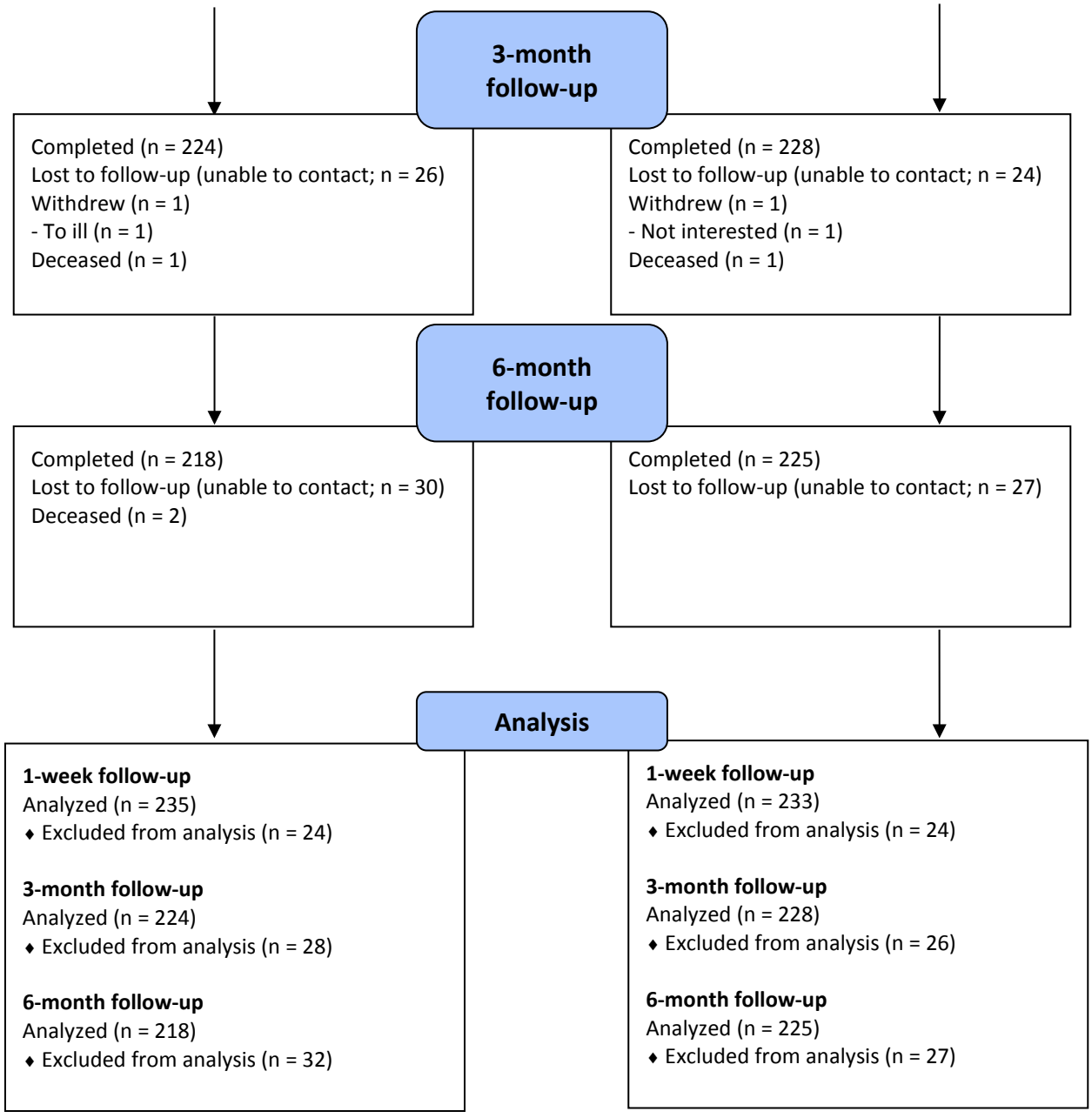


Figure 5. Study Flow Diagram (continued)



Characteristics of the Study Patients

Characteristics of the study patients by intervention group are given in Table 3.

Table 3. Comparison of Patients' Characteristics by Study Group (n = 516)

	Decision Aid Group		Standard Education Group		Total		*P* Value
	n	(%)	n	(%)	n	%	
Age							
65+ years	69	26.6	77	30.0	146	28.3	.4025
Under 65 years	190	73.4	180	70.0	370	71.7	
Gender							
Male	102	39.4	94	36.6	196	38.0	.5114
Female	157	60.6	163	63.4	320	62.0	
Race/ethnicity[a]							
American Indian or Alaska Native	2	0.8	0	0.0	2	0.4	.2273
Asian	0	0.0	0	0.0	0	0.0	
Black or African American	62	23.9	76	29.6	138	26.7	
Native Hawaiian or other Pacific Islander	0	0.0	1	0.4	1	0.2	
Hispanic or Latino	7	2.7	1	0.4	8	1.6	
White	185	71.4	177	68.9	362	70.2	
Refused	0	0.0	1	0.4	1	0.2	
More than one category	1	0.4	1	0.4	2	0.4	
Other	2	0.8	0	0.0	2	0.4	
Insurance							
Yes	239	92.3	230	89.5	469	90.9	.2718
No	20	7.7	27	10.5	47	9.1	
Education							
Less than high school	41	15.8	36	14.0	77	14.9	.9181
Graduated high school/GED	72	27.8	77	30.0	149	28.9	
Some college/ trade school	107	41.3	105	40.9	212	41.1	
Graduated college or more	39	15.1	39	15.2	78	15.1	
Quitline service provider							
Alere	21	8.1	19	7.4	40	7.8	.9737
Information & Quality Healthcare	130	5.2	128	49.8	258	50.0	
National Jewish Health	40	15.4	43	16.7	83	16.1	
Roswell Park	68	26.3	67	26.1	135	26.2	
Method of recruitment							
Callers to quitline	103	39.8	107	41.6	210	40.7	.6662
Previous clients	156	60.2	150	58.4	306	59.3	
Data collection method at 1 week							
Phone	211	89.8	211	90.6	422	90.2	.7795
Mail	24	10.2	22	9.4	46	9.8	
Data collection method at 3 months							
Phone	200	89.3	200	87.7	400	88.5	.6018
Mail	24	10.7	28	12.3	52	11.5	
Data collection method at 6 months							
Phone	189	86.7	194	86.2	383	86.5	.8839
Mail	29	13.3	31	13.8	60	13.5	

[a]Statistical test for race is based on comparison of white and African American patients.

Overall, we found no significant differences in patient characteristics between patients randomized to the decision aid or to the standard education group. Patients' average age was 61.6 years (SD = 5.4 years). More than 70% of the patients were under age 65. More than 60% of the patients were female, more than 90% had health insurance (including coverage through CMS), and about 40% had a high school education or had not graduated high school. Of the patients, 26.7% were black or African American and 70.2% were white.

Smoking history indicators for the patients are given in Table 4. Study patients had smoked for an average of more than 40 years and more than 1 pack of cigarettes per day. The average pack-year smoking history of about 54 years well exceeded the screening eligibility threshold of 30 pack years.

Table 4. Smoking History at Enrollment by Study Group

	Decision Aid Group			Standard Education Group			*P* Value
	n	Mean (SD)	Median (IQR)	n	Mean (SD)	Median (IQR)	
Number of years smoked	259	43.4 (7.2)	42.0 (40.0-49.0)	257	43.8 (8.2)	44.0 (40.0-50.0)	.641
Average number of cigarettes smoked per day	259	25.0 (9.1)	20.0 (20.0-30.0)	257	25.6 (10.3)	20.0 (20.0-30.0)	.448
Pack-year smoking history[a]	259	54.6 (23.8)	47.0 (40.0-63.0)	257	55.6 (23.5)	49.0 (40.0-63.8)	.650

Abbreviations: IQR, interquartile range; SD, standard deviation.
[a]One pack year is equivalent to smoking 1 pack of cigarettes (20 cigarettes in a pack) for 1 year.

Comparisons of Patients Who Did and Did Not Complete the Follow-up Assessments

Table 5 compares patients who completed and did not complete the 1-week, 3-month, and 6-month follow-up assessments. We conducted these analyses to identify any potential biases in the follow-up data from missing cases and to inform the analysis plan for addressing missing cases. We examined differences in follow-up across patient characteristics, quitline service provider, and method of recruitment. Patients under 65 years of age were slightly more likely than patients 65 years of age and older to complete the 1-week follow-up (*P* = .0308).

Table 5. Comparisons of Patients' Characteristics by Status of Follow-up Assessments

	Completed 1-week Follow-up?					Completed 3-month Follow-up?					Completed 6-month Follow-up?				
	Yes		No		*P*	Yes		No		*P*	Yes		No		*P*
	n	(%)	n	(%)	Value	n	(%)	n	(%)	Value	n	(%)	n	(%)	Value
Age															
65+ years	126	86.3	20	13.7	.0308	128	87.7	18	12.3	.9743	130	89.0	16	11.0	.1917
Under 65 years	342	92.4	28	7.6		324	87.6	46	12.4		313	84.6	57	15.4	
Gender															
Male	178	90.8	18	9.2	.9421	174	88.8	22	11.2	.5250	171	87.2	25	12.8	.4776
Female	290	90.6	30	9.4		278	86.9	42	13.1		272	85.0	48	15.0	
Race[a]															
White	327	90.1	36	9.9	.9492	311	85.7	52	14.3	.3515	306	84.3	57	15.7	.2472
Black of African American	131	94.9	7	5.1		128	92.8	10	7.2		125	90.6	13	9.4	
Other	10	66.7	5	33.3		13	86.7	2	13.3		12	80.0	3	20.0	
Insurance															
Yes	428	91.3	41	8.7	.1663	412	87.8	57	12.2	.5869	403	85.9	66	14.1	.8776
No	40	85.1	7	14.9		40	85.1	7	14.9		40	85.1	7	14.9	
Education															
Less than high school	69	89.6	8	10.4	.5906	71	92.2	6	7.8	.2158	67	87.0	10	13.0	.6410
Graduated high school/GED	134	89.9	15	10.1		127	85.2	22	14.8		128	85.9	21	14.1	
Some college/ trade school	191	90.1	21	9.9		182	85.8	30	14.2		178	84.0	34	16.0	
Graduated college or more	74	94.9	4	5.1		72	92.3	6	7.7		70	89.7	8	10.3	
Quitline service provider															
Alere	37	92.5	3	7.5	.1075	37	92.5	3	7.5	.1456	34	85.0	6	15.0	.3534
Information & Quality Healthcare	230	89.1	28	10.9		220	85.3	38	14.7		215	83.3	43	16.7	

Table 5. Comparisons of Patients' Characteristics by Status of Follow-up Assessments

	Completed 1-week Follow-up?					Completed 3-month Follow-up?					Completed 6-month Follow-up?				
	Yes		No		*P*	Yes		No		*P*	Yes		No		*P*
	n	(%)	n	(%)	Value	n	(%)	n	(%)	Value	n	(%)	n	(%)	Value
National Jewish Health	81	97.6	2	2.4		78	94	5	6.0		73	88.0	10	12.0	
Roswell Park	120	88.9	15	11.1		117	86.7	18	13.3		121	89.6	14	10.4	
Method of recruitment															
Callers to quitline	196	93.3	14	6.7	.0877	191	91.0	19	9.0	.0554	180	85.7	30	14.3	.9404
Previous clients	272	88.9	34	11.1		261	85.3	45	14.7		263	85.9	43	14.1	

[a]Statistics tests include only white and African American categories because few patients endorsed a different racial category.

Also, patients recruited from new quitline clients were slightly more likely to complete the 1-week (*P* = .0877) and 3-month follow-ups (*P* = .0554) than patients recruited from previous quitline clients. We observed no other differences. We therefore retained age and method of recruitment, along with the other study covariates, in the models to adjust for their effects on the study outcomes.

Primary Outcomes

We hypothesized that patients assigned to the decision aid group, compared with the standard education group, would report being more prepared to make a decision about LCS; feel more informed about the options, harms, and benefits of screening; and be clearer about which harms and benefits mattered most to them. Results for the primary outcome analyses are given in Table 6. We observed significant differences between the study groups for each of the 3 primary outcomes at the 1-week assessment. The Preparation for Decision Making© Scale scores were higher in the decision aid group (*P* < .0001), indicating that these patients were more prepared to make a decision about LCS than were the standard education group patients. The subgroup analyses testing for an interaction effect of intervention group and race (white or African American) were not statistically significant (*P* = 0.7065 for the interaction term), indicating that the intervention effect was similar across race groups. The main effect for the intervention group remained significant after including age, gender, race, education level, insurance status, quitline service provider, and recruitment method as covariates in the model. None of the covariates were predictive of the Preparation for Decision Making© scores at the 1-week follow-up.

Table 6. Scores for Primary Outcome Measures by Intervention Group

Outcome Measure	Decision Aid Group				Standard Education Group				*P* Value
	n	Mean	95% CI	SD	n	Mean	95% CI	SD	
Preparation for Decision Making© Scale	227	79.4	77.1-81.7	17.7	224	69.4	66.4-72.4	22.7	<.0001
Decisional Conflict Scale©: Informed subscale[a]	234	27.1	23.8-30.5	25.9	233	42.1	38.0-45.9	30.8	<.0001
Decisional Conflict Scale©: Values Clarity subscale[a]	234	17.6	14.2-21.0	26.2	232	31.7	27.3-35.8	32.8	<.0001

Abbreviations: CI, 95% confidence interval for the mean; SD, standard deviation.

[a]The Decisional Conflict Scale© and subscales are scored on 0-to-100 scales, with lower scores indicating lower decisional conflict about LCS.

We observed significant differences between the study groups for the DCS Informed and Values Clarity subscales. Decision aid patients felt more informed about the screening options (to be screened or not) and the benefits and harms of the options, and they were clearer about which benefits and harms mattered most to them (*P* values < .0001). The subgroup analyses testing for an interaction effect of intervention group and race (white or African American) were not statistically significant for either subscale. The main effects for the intervention group remained significant after including the covariates in the models. Of note, in the model predicting the Informed subscale scores, the only significant covariate was education, suggesting that more educated patients also reported being more informed.

Secondary Outcome: Knowledge of Lung Cancer Screening

We hypothesized that patients assigned to the patient decision aid group, compared with patients assigned to the standard education group, would have greater knowledge of LCS at each follow-up assessment period. Comparisons of knowledge outcomes at each follow-up assessment period are given in Table 7 as the percentage of correct responses to the knowledge measure. Knowledge was significantly higher among the decision aid patients than the standard education patients at each follow-up assessment period (*P* values < .0001). Knowledge was highest at the 1-week follow-up for patients who received the decision aid, with an average score of 57.5% correct responses. Among the decision aid patients, knowledge was significantly lower at the 3-month and 6-month assessments compared with the 1-week assessment (*P* values < .0001). Among the standard education patients, knowledge was significantly lower at the 3-month assessment (*P* = .0038) but did not differ from scores at the 6-month follow-up assessment (*P* = .9442). We adjusted these results for the study covariates (ie, age, gender, race, education level, insurance status, quitline service provider, and recruitment method).

Table 7. Percentage Correct Responses to Lung Cancer Screening Knowledge Measure by Study Group

Assessment Period	Decision Aid Group				Standard Education Group				*t* Test	*P* Value
	n	Mean	95% CI	SD	n	Mean	95% CI	SD		
1 week	235	57.5	54.7-60.3	21.8	233	40.1	37.9-42.3	17.1	9.93	.000
3 months	224	44.4	41.9-47.0	19.6	228	35.9	33.7-38.1	16.9	4.61	.000
6 months	218	49.9	47.5-52.3	17.8	225	40.0	37.6-42.4	18.1	5.37	.000

Abbreviations: CI, 95% confidence interval for the mean; SD, standard deviation.

Additional Outcomes Related to Screening Intentions and Behaviors

We offered no specific hypotheses about the impact of the patient decision aid, compared with that of the standard education materials, on intentions to be screened or screening behaviors. Group comparisons for the 4 additional outcomes are given in Table 8. Intentions to be screened for lung cancer were high in both groups, with 165 (70.8%) of patients in the decision aid group and 151 (65.1%) of patients in the standard education group planning to be screened in the following year. These differences were not statistically significant in unadjusted and adjusted analyses. The findings about scheduling a visit with a doctor to discuss LCS were similarly high, with 150 (63.0%) of decision aid patients and 158 (66.4%) of standard education patients having scheduled a visit by the 6-month follow-up assessment. These differences were not statistically significant in the unadjusted or adjusted analyses.

Rates of scheduling a CT scan by the 6-month follow-up assessment were lower; however, these findings should be viewed with caution because some patients who scheduled a visit with a doctor to discuss screening may not have had that visit by the 6-month follow-up assessment. Among patients assigned to the decision aid group, 70 (29.5%) had scheduled a CT scan for LCS, compared with 89 (37.4%) of standard education patients (adjusted OR = 0.70; 95% CI, 0.47-1.03).

Rates of scheduling a CT scan for LCS among those patients who scheduled a visit with a health care provider to discuss screening were fairly high; however, these findings should be viewed with caution because some patients may have scheduled a CT scan beyond the 6-month follow-up window. Among patients assigned to the decision aid group who scheduled a CT scan, 57 (85.1%) had been screened by the 6-month follow-up assessment, compared with 68 (80.8%) of standard education patients (adjusted OR = 1.27; 95% CI, 0.52-3.11).

Table 8. Additional Outcomes Related to Screening Intentions and Behaviors by Study Group

	Decision Aid Group		Standard Education Group		Not Adjusted for Covariates		Adjusted for Covariates[b]	
	n	%	n	%	Odds Ratio (95% CI)	*P* Value	Odds Ratio (95% CI)	*P* Value
Intentions to be screened within 1 year (1-week assessment)[a]								
Will get screened	165	70.8	151	65.1	1.30	.1860	1.25	.2860
Will not get screened	28	12.0	32	13.8	(0.88-1.92)		(0.83-1.89)	
Not sure	40	17.2	49	21.1				
Scheduled a visit with doctor to discuss lung cancer screening by 6-month follow-up								
Yes	150	63.0	158	66.4	0.86	.4430	0.87	.4664
No	88	37.0	80	33.6	(0.59-1.26)		(0.59-1.28)	
Scheduled a CT scan for lung cancer screening by 6-month follow-up								
Yes	70	29.5	89	37.4	0.70	.0700	0.70	.0677
No	167	70.5	149	62.6	(0.48-1.03)		(0.47-1.03)	
Screened by lung cancer, among those who scheduled a CT scan, by 6-month follow-up assessment								
Yes	57	85.1	68	80.0	1.43	.4179	1.27	0.5983
No	10	14.9	17	20.0	(0.61-3.36)		(0.52-3.11)	

Abbreviation: CI, 95% confident interval for odds ratio.

Percentages are within study group, reported as column percentages.

[a]Odds ratio of "Will get screened" to "Will not get screened" or "Not sure."

[b]Covariates include age, gender, race, education level, insurance status, quitline service provider, and recruitment method.

Acceptability of the Patient Decision Aid

Patients assigned to receive the patient decision aid assessed its acceptability at the 1-week follow-up (see Table 9). Acceptability ratings were quite favorable. Of note, only 10 (4.4%) of the patients felt the decision aid was too long, while 53 (23.2%) wanted more information. Patients saw the aid either as favoring patients being screened for lung cancer (122, 53.3%) or as balanced in its presentation of the options (103, 45.2%). Finally, 198 (87.2%) patients felt the aid included enough information to help a person decide about LCS, while 29 (12.8%) indicated that it did not include enough information or were not sure.

Table 9. Acceptability of the Patient Decision Aid (1-week Assessment)

	n	%
The length of the materials was:		
Too long	10	4.4
Too short	45	19.7
Just right	173	75.9
The amount of information was:		
Too much	8	3.5
Too little	53	23.2
Just right	167	73.2
I found the materials:		
Favored getting screened with a CT scan	122	53.5
Favored not getting screened with a CT scan	3	1.3
Balanced, did not favor one option over the other	103	45.2
Do you think we included enough information to help a person decide whether to be screened for lung cancer?		
Yes	198	87.2
No	23	10.1
Not sure	6	2.6

Completed only by patients assigned to the decision aid group; percentages do not total 100 due to rounding.

DISCUSSION

Decisional Context

The dilemma facing current and former smokers eligible for LCS is whether to be screened with LDCT given the tradeoffs between a reduction in lung cancer mortality; a potential reduction in all-cause mortality; and the harms of screening, including a high false-positive rate, harms from invasive diagnostic procedures and cumulative radiation exposure, and possible overdiagnosis. Recommendations about LCS emphasize the importance of a shared decision-making process and—in the case of CMS—the use of patient decision aids in preparing patients to make decisions about screening.[6,8,9] LCS for high-risk smokers with LDCT is the only secondary preventive strategy shown to lower lung cancer deaths.[4,8] Screening with LDCT is also associated with potential harms to patients, as mentioned above; yet, smokers generally are not aware of the benefits and harms of LCS, and tools are needed to support their screening decisions.[25]

We recruited patients for this study from state-based tobacco quitlines. Quitlines provide smoking cessation services, thereby addressing a key component of a successful LCS program. We found that patients assigned to the decision aid group were more prepared to make a decision about LCS than those patients assigned to the standard education group. The decision aid helped patients recognize that a decision needed to be made, weigh the pros and cons of screening, consider how involved they wanted to be in the screening decision, and devise questions to ask their doctors about screening.

Decisional conflict was lower among patients who received the decision aid rather than the standard educational materials. Decision aid patients felt more informed about the benefits and harms of LCS and reported being clearer about their values related to the tradeoffs between harms and benefits. These outcomes matter to patients, and it is encouraging that a video decision aid mailed to patients had a positive impact on readiness to be screened and decisional conflict about screening.

We found that patients who received the decision aid had greater knowledge of LCS than did patients who received the standard education materials, and we observed these

differences at each follow-up assessment. Improvements in knowledge associated with patient decision aids is a consistent finding in randomized trials.[14] While patients in the decision aid group scored higher than standard education group patients on the knowledge measure, their overall scores may be seen as less than desirable. Furthermore, there is no consensus on the minimal key facts a patient should have in making a decision about LCS. These findings reinforce the importance of a conversation with a clinician to address knowledge deficits and enduring misconceptions about screening. Knowledge scores declined by the 6-month follow-up assessment, suggesting a "booster" might be needed when the screening decision is reconsidered the following year for patients who have a normal screening result. Of note, CMS does not require additional patient counseling and shared decision-making visits for subsequent annual screenings for lung cancer.[9]

The decision aid was highly acceptable to patients, who felt the aid prepared them to decide about LCS. Of interest, about 1 in 4 patients wanted more information from the aid; this highlights the importance of a conversation with a health care provider about LCS.

Interest in LCS was high among patients in this study and did not differ between the 2 intervention groups. We observed similar rates of visits scheduled with a doctor to discuss LCS between the groups. We made no specific hypotheses about the impact of the decision aid on intentions to be screened or screening behavior. While it might be argued that an effective patient decision support intervention should lead to an increase in LCS because national rates of LCS are low,[35] the role of patient decision aids is to prepare patients to make informed decisions and support shared decision making, not necessarily increase or decrease patients' choices about screening.

Study Results in Context

Few studies have examined the impact of patient decision aids on LCS decision making, and only one used a comparison group.[36] All studies were conducted in the United States. The results from these previous studies largely confirm our findings related to increased knowledge and reduced decisional conflict because of the patient decision aid. In addition, patients'

reports of the acceptability of the patient decision aid interventions were universally high in our study and in other studies.

Using a pre–post design, we conducted a pilot study of an earlier version of our video-based patient decision aid with 52 patients from a tobacco treatment program.[15] Knowledge scores increased after patients viewed the decision aid, and decisional conflict scores were low at postassessment. Interest in screening was also high, with 78.8% of patients more interested in screening after viewing the decision aid. The web-based patient decision aid www.shouldiscreen.com was evaluated in a before–after study of 60 current and former smokers by Lau et al.[37] The aid provides individualized estimates of lung cancer risk, using text and graphs about LCS and its benefits and harms. Similar to our study's findings, the study found large improvements in knowledge and reductions in decisional conflict.

Mazzone et al developed a centralized patient counseling and shared decision-making visit for LCS implemented in the pulmonology setting.[38] Their intervention included a narrated slide show, individualized risk assessment, and time for discussion about screening. Large increases in knowledge were observed related to the benefits and harms of LCS, similar in magnitude to those found in our study at the 1-week follow-up. Also, knowledge scores dropped by the 1-month assessment, a finding consistent with our study. In the only other comparative trial to date, Studts et al reported on a small trial comparing a web-interactive decision aid to the national Cancer Institute web pages on LCS.[36] While they found reductions in decisional conflict and increases in knowledge across preintervention to postintervention assessments in both study arms, they observed no group differences. Similarly, there were no group differences in preparedness for decision making. The study included patients who were not eligible for screening (eg, under the 55-year age threshold to begin screening), which may explain, in part, the mixed findings.

Reuland et al[39] recently published a pre–post evaluation of a patient decision aid for LCS implemented in a large US academic primary care practice. They also observed gains in knowledge of LCS because of viewing the aid. Preferences for screening were largely unchanged, with about 50% of patients indicating a preference to be screened.

Implementation of Study Findings

We conducted this study through state-based tobacco quitlines that serve many heavy smokers. NAQC estimates that 350 000 to 400 000 smokers use its services annually, and about 165 000 are within the age range for LCS (data provided by Linda Bailey, JD, MHS, president and CEO of NAQC and a member of our SAG). There is great potential to reach many eligible smokers by broadly implementing the study findings through quitlines—with several important caveats. Quitline service providers are funded, in part, through contracts with state departments of health. Some have resources to explore new initiatives, such as supporting LCS, while others have very limited budgets and are cautious about adding new responsibilities for the call staff. We found it was important to limit the role of quitline call staff to assessing eligibility for LCS based on age alone. For broader implementation of the patient decision aid, patients will need clear guidance on the importance of determining eligibility for screening and on discussing LCS with their doctors. Quitlines can play a key role in alerting patients to LCS and directing them to high-quality decision support materials, such as the decision aid evaluated in this study.

Generalizability of the Findings

We drew patients from 13 state quitlines in the United States. Study participants were similar to clients served by quitlines nationally, according to statistics provided by the NAQC (http://www.naquitline.org/). In addition, our patients were similar to NLST subjects based on age and pack-year smoking history.[40] The benefits and harms of LDCT screening observed in the NLST can likely be applied to patients in our study based on similar smoking histories of patients in the 2 studies. Patients in this study were more likely to be female (62% versus 41%), be African American (27% versus 4.4%), and have less than a high school education (44% versus 30%) than subjects in the NLST, respectively. Our study was also underrepresented for other groups, including Hispanic and Asian American smokers.

Subpopulation Considerations

The primary subgroup addressed in this study was African American smokers because of the unequal burden on lung cancer among African American men. Their representation in this study exceeded that of the NLST and is likely because of the demographic composition of the states that participated in subject recruitment. ACS reports that non-Hispanic black males had the highest lung cancer incidence and mortality from 2008 to 2012, followed by non-Hispanic white males.[41] We tested for interaction effects between race (white and African American) and intervention group assignment for the primary outcomes and additional outcomes, and found no significant effects. Therefore, the decision aid had equally strong impact on improving patient decision making in both races.

Study Limitations

The study has several important limitations. We collected all data using patient self-report. This was appropriate for patient-centered outcomes, but we were not able to collect and verify information about screening outcomes because the follow-up period was too short. Patients in this study had to express an interest in LCS when asked by quitline call staff, and they had to contact the research team about participation. While delivering decision support to only patients who are interested in learning more about LCS is appropriate, we don't know the reasons some patients were not interested in screening or participating in the study. Many patients in this study intended to be screened for LCS and had scheduled appointments with their doctors to discuss screening. For patients who had a visit to discuss LCS, we do not have information about the quality of the decision-making process with the health care provider.

Future Research

Many future research directions are apparent from this study. Multilevel interventions should be evaluated that target patients with tools like our patient decision aid, training of primary care providers, and complementary methods that can be used during the clinical encounter. The added value of providing decision support prior to the clinical encounter should be considered, as patients may enter the encounter better prepared to discuss screening with a

health care provider, thus leading to a higher-quality decision-making process. Given the decay in knowledge observed in our study, future research should also consider the role of providing a decision support "booster" prior to annual screenings. Adapting the patient decision aid for non-English speakers—and testing its impact on decision-making outcomes—is a high priority for future research. Finally, the downstream outcomes of providing patient decision support, such as the impact on smoking behaviors, adherence to annual screening, and follow-up on abnormal results, are important areas for future consideration.

CONCLUSIONS

We found that a patient decision aid delivered in video format to patients of tobacco quitlines improved readiness to discuss LCS with a physician; led to patients feeling more informed and clearer about their values related to the screening decision; and improved knowledge of LCS up to 6 months after the intervention, when compared with standard education materials. It had no impact on intentions to be screened or scheduling a visit with a doctor to discuss screening, as patients in both groups were generally favorable about screening. The decision aid was meant to support but not replace a conversation with a health care provider. Distributing the decision aid to quitline patients was feasible. The aid proved highly acceptable to patients. The potential to reach large numbers of smokers engaged in smoking cessation services provided by quitlines across the United States appears great. Carefully addressing the role of quitlines in distributing patient decision support for LCS, given their limited funding, is necessary for broader dissemination and greater impact of the intervention.

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