Impact of a Lung Cancer Screening Information Film on Informed Decision-making: A Randomized Trial

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Abstract

Rationale: Lung cancer screening has the potential to save lives, but it also carries a risk of potential harms. Explaining the benefits and harms of screening in a way that is balanced and comprehensible to individuals with various levels of education is essential. Although a shared decision-making approach is mandated by the Centers for Medicare & Medicaid Services, there have been no randomized studies to evaluate the impact of different forms of lung screening information.

Objectives: To evaluate the impact of a novel information film on informed decision-making in individuals considering participating in lung cancer screening.

Methods: A subset of participants from LSUT (Lung Screen Uptake Trial) were randomly allocated either to view the information film and receive a written information booklet or to receive the booklet alone. The primary outcome was the objective knowledge score after intervention. Secondary outcomes included subjective knowledge, decisional conflict, final screening participation, and acceptability of the materials. Univariate and multivariate analyses were performed to determine differences in pre- and postintervention knowledge scores in both groups and between groups for the primary and secondary outcomes.

Results: In the final analysis of 229 participants, both groups showed significantly improved subjective and objective knowledge scores after intervention. This improvement was greatest in the film + booklet group, where mean objective knowledge improved by 2.16 points (standard deviation [SD] 1.8) compared with 1.84 points (SD 1.9) in the booklet-alone group (β coefficient 0.62; confidence interval, 0.17–1.08; $P = 0.007$ in the multivariable analysis). Mean subjective knowledge increased by 0.92 points (SD 1.0) in the film + booklet group and 0.55 points (SD 1.1) in the booklet-alone group (β coefficient 0.32; CI, 0.05–0.58; $P = 0.02$ in the multivariable analysis). Decisional certainty was higher in the film + booklet (mean 8.5/9 points [SD 1.3], group than in the booklet-alone group (mean 8.2/9 points [SD 1.5])). Both information materials were well accepted, and there were no differences in final screening participation rates between groups.

Conclusions: The information film improved knowledge and reduced decisional conflict without affecting lung-screening uptake.

Clinical trial registered with clinicaltrials.gov (NCT02558101).

Keywords: lung cancer screening; informed decision-making; shared decision-making; educational video; information film

(Received in original form November 30, 2018; accepted in final form April 1, 2019)

This study was part of the Lung Screen Uptake Trial project, which was funded by a National Awareness and Early Diagnosis Initiative project grant awarded by Cancer Research UK (CRUK) and a consortium of funders (Department of Health [England]; Economic and Social Research Council; Health and Social Care R&D Division, Public Health Agency, Northern Ireland; National Institute for Social Care and Health Research, Wales; and the Scottish Government) (S.L.Q., J.W., and S.M.J.). The study and film production were funded by the Roy Castle Lung Cancer Foundation (M.R., S.L.Q., J.W., and S.M.J.). S.M.J. is a Wellcome Trust Senior Fellow in Clinical Science (WT107963AIA). S.M.J. is supported by the Rosetrees Trust, the Stonegate Trust, the Welton Trust, the Garfield Weston Trust, and the University College London Hospital (UCLH) Charitable Foundation. This work was undertaken at UCLH/UCL, which received a proportion of funding from the Department of Health's NIHR Biomedical Research Centre's funding scheme (N.N. and S.M.J.). J.W. is supported by a CRUK career development fellowship (C7492/A17219). B.G. and S.D. contributed to this work as part of the program of the Policy Research Unit in Cancer Awareness, Screening and Early Diagnosis, which receives funding for a research program from the Department of Health Policy Research Program. It is a collaboration between researchers from seven institutions (Queen Mary University of London, UCL, King's College London, London School of Hygiene and Tropical Medicine, Hull York Medical School, Newcastle University, and Peninsula Medical School). S.L.Q. is supported by a CRUK postdoctoral fellowship (C50664/A24460).

Author Contributions: M.R., S.L.Q., B.G., J.L.D., A.B., N.N., D.R.B., S.D., J.W., and S.M.J. contributed to the design and/or conduct of the study, and preparation of the manuscript. M.R., S.L.Q., B.G., S.D., and J.W. also contributed to the data analysis.

Ann Am Thorac Soc Vol 16, No 6, pp 744–751, Jun 2019

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DOI: 10.1513/AnnalsATS.201811-841OC

Internet address: www.atsjournals.org

Lung cancer screening (LCS) using low-dose computed tomography (LDCT) has the potential to save lives, although it also has the potential to cause harms. There is evidence that people want to be made aware of these harms and value the opportunity to make an informed decision (1, 2). However, the harms and benefits of cancer screening are often poorly understood (1, 2). They are also challenging to communicate, and this issue is exacerbated for individuals with lower levels of literacy, who are likely to be overrepresented among the LDCT-eligible population, given the higher incidence of lung cancer within lower-socioeconomic-status (SES) communities (3, 4). Indeed, research suggests that a high information burden could actually discourage individuals with lower health literacy from taking part in screening (5). This is important considering that only 1.9% of eligible individuals are estimated to have received an LDCT screen in the United States (6).

The use of illustrative materials is associated with improved understanding and perception of the risks involved (7). Graphics and animation are known to enhance knowledge and recall of facts related to specific healthcare interventions (8, 9). Several randomized studies that evaluated the use of “educational videos” in different healthcare settings found that video is an effective medium for enhancing knowledge and understanding without increasing anxiety or decisional conflict (10–15).

A shared decision-making process is mandated for LCS reimbursement by the Centers for Medicare & Medicaid Services (16), but few decision tools exist. Lau and colleagues found that a web-based interactive decision tool significantly increased knowledge and reduced decisional conflict among smokers and former smokers considering participation in LCS; however, as the authors acknowledged, web-based access may not be equitable (17). Mazzone and colleagues tested the impact of a shared decision-making visit that included a slide presentation about the benefits and harms, use of the above-described web-based tool, and the opportunity to have

questions answered by a health provider (18). The authors demonstrated a significant improvement in knowledge that partially persisted 1 month later. Two uncontrolled studies evaluated the impact of video (19, 20). Volk and colleagues developed a film and tested it with 52 participants in a tobacco treatment program, noting high acceptability, improved knowledge scores, and a high level of interest in LCS; however, patient demographics and screening attendance data were not provided (19). Reuland and colleagues also reported an improvement in knowledge with the use of a film in a single group of 50 participants (20).

Here, we present a randomized controlled study designed to understand the impact of an information film on decision-making and subsequent uptake of LDCT. Validation of such a tool could endorse its use in LCS. The information materials were designed to provide basic, standardized information on LCS and its harms and benefits (*see* Video E1 in the online supplement; also available at <https://www.roycastle.org/lungcancerscreeningguide>), and to be supplemented with a discussion with a healthcare professional (HCP) to support the decision-making process. We tested whether the film + information booklet enhanced objective and subjective knowledge compared with the booklet alone. We also evaluated additional impacts on decisional conflict and uptake of LDCT, and assessed the acceptability of both the booklet and film.

Methods

Participants and Setting

This was a nested randomized study within LSUT (Lung Screen Uptake Trial), the methods for which have been previously described (21). Briefly, LSUT invited smokers and former smokers (within 5 years of quitting) 60–75 years of age, identified from primary care records, to a lung health check (LHC) at a local London hospital using one of two sets of randomly allocated invitation materials. The primary aim of LSUT was to compare differences in uptake

to the LHC (where LDCT is offered) between the two invitation materials. Those who attended the LHC were invited to be enrolled in LSUT and offered an LDCT if they had no physical contraindication to LDCT scanning and met any of the following criteria: 1) ≥ 30 pack-year smoking history and quit < 15 years ago, in accordance with U.S. Preventive Services Task Force (USPSTF) recommendations (22); 2) $\geq 1.51\%$ 6-year lung cancer risk as per the PLCO_{m2012} model (23); and 3) $\geq 2.5\%$ 5-year lung cancer risk as per the LLP_{v2} model (24).

Between August 2016 and February 2017, LSUT enrollees were also invited to participate in the current study.

Individual, deidentified participant data are available from the corresponding author on reasonable request.

Study Design and Interventions

After they provided informed consent, the participants underwent simple parallel randomization without restriction, with 1:1 individual allocation to each group. Randomization was performed by the HCP via a computer-based randomization system.

Subjects who were randomized to the control group received the information booklet (*see* Figure E1) used for LSUT's control invitation materials (21). Those who were randomized to the intervention group were shown an information film and given the same information booklet. We developed the content and format of the film (*see* Video E1; also available at <https://www.roycastle.org/lungcancerscreeningguide>) using data from our qualitative work with screening-eligible participants and HCPs. Both interventions discussed lung cancer, the benefits and harms of LCS (including indeterminate pulmonary nodules and false positives, overdiagnosis, and radiation damage), the LDCT procedure, and the possible results after the scan. The booklet was 10 pages long and designed to be clear and comprehensible for individuals with a reading age of 11–13 years. The film was 5½ minutes long.

Participants were allocated 10 minutes to read the booklet and/or watch the film

The uncompressed video is accessible from this article's supplementary material page.

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This article has an online supplement, which is accessible from this issue's table of contents at www.atsjournals.org.

in the presence of one of eight HCPs involved in data collection for this study. The HCPs were nurses or clinical trial practitioners who had been specifically trained in the consent process. After a further knowledge assessment as described below, demographic, smoking, and medical history data were collected to assess lung cancer risk and eligibility for LDCT. The participants were subsequently informed of an elevated lung cancer risk (if applicable) compared with the general population and thus eligibility for LDCT, and prompted to ask any questions about the harms and benefits. At this point, if the participant was happy to proceed, written consent to undergo the LDCT was taken by the HCP, who once again described the potential harms of LDCT as per a “consent checklist” (see Figure E2).

Outcome Measures

The primary endpoint was a postintervention 10-point objective knowledge score that assessed facts relating to the benefits and harms of LCS contained in both intervention materials (see Table E1). For the objective knowledge questions, “not sure” and incorrect answers were treated the same and not awarded any points, and only the correct answer received a score of one.

Secondary endpoints included a five-point subjective investigator-designed knowledge assessment, adapted measures from the low-literacy decisional conflict

scale (DCS) (25) (see Table E1), LDCT completion, and feedback on the information materials. For the subjective questions, a “yes” response received one point, and a “no” or “not sure” answer received no points. Yes/no responses to the DCS questions were scored one point for “yes” and zero for “no.” Subjective and objective knowledge assessments (using the same questions) were performed at baseline and immediately after the intervention for both groups, and other secondary outcomes were assessed at the end of the consultation with the HCP.

Medical and smoking history and demographic data were also collected. This included collection of address postal codes, to categorize Index of Multiple Deprivation (IMD) scores. This is an “official measure of relative deprivation for small areas (or neighborhoods) in England” and covers the following domains: income, employment, health deprivation and disability, education skills and training, barriers to housing and services, crime, and living environment (26).

Sample Size and Statistical Analysis

Three well-designed studies using video decision aids reported intervention-related improvements in knowledge scores by 24% (27), 21% (28), and 78% (19). Other studies failed to detect a significant effect; however, these studies were heavily underpowered. For the present study, a sample size of 210

participants was calculated to confer 96% power to detect as significant a mean difference of 1.0 between the knowledge scores of the groups, anticipating a mean score of 4 in the booklet-only group and 5 in the booklet + film group, with a standard deviation (SD) of 1.9 (two-sided testing at a 5% significance level).

Descriptive statistics were used to illustrate the demographic characteristics of both groups and the acceptability data. Because we used both nonparametric and parametric inferential analyses, we reported both means and medians. Noting that the scores were not normally distributed, we performed univariate analyses using the Wilcoxon signed rank test to compare the primary outcome knowledge scores before and after intervention. Observations with missing values were excluded from the analysis. Multivariable analyses, using multiple linear regression (which assumes that residuals, not the raw scores, are normally distributed), adjusting for baseline scores, age, educational level, ethnicity, IMD score, and smoking duration (as these were factors with clinical and/or statistical relevance), were used to assess between-trial arm differences in overall knowledge scores. Risk ratios (RRs) were also used to assess group differences between individual items for knowledge, DCS, and uptake to LDCT between the groups. Analyses were performed using STATA v13 and v14.

Figure 1. Consort diagram of the study participants. LSUT = Lung Screen Uptake Trial.

Ethics

This study was part of the LSUT, which has received ethical approval from the City Road and Hampstead NHS Research Ethics Committee (reference 15/LO/1186). LSUT has been registered by clinicaltrials.gov (NCT02558101) and the ISRCTN (ISRCTN21774741).

Results

A total of 252 LSUT participants were invited to take part in the present trial: 246 participants agreed to participate and were randomized; 17 participants had incomplete baseline data, and thus 229 participants were included in the final analysis (Figure 1). The

demographics of the study participants are reported in Table 1.

Total Knowledge Scores

There was an increase in objective knowledge scores after exposure to the information materials in both groups, with a change in median scores from 5/10 to 8/10, and 5/10 to 7/10 in the film + booklet and booklet-alone groups, respectively (both $P < 0.001$). Mean objective knowledge scores increased by 2.16 (SD 1.8) and 1.84 (SD 1.9) in the film + booklet and booklet-alone groups, respectively. There was also an increase in subjective knowledge scores in both groups (change in median scores from 4/5 to 5/5 in both groups, $P < 0.001$) (Figure 2). Mean subjective knowledge increased by 0.92 (SD 1.0) and 0.55 (SD 1.1) in the film + booklet and booklet-alone groups, respectively.

In multivariable analyses adjusted for age, education, ethnicity, years smoked, and IMD score, the greater increases in the film group in objective and subjective knowledge scores remained significant (β coefficient 0.62; confidence interval [CI], 0.17–1.08; $P = 0.007$; and β coefficient 0.32; CI, 0.05–0.58; $P = 0.02$, respectively) (see Figure 2). Recognizing the fact that 32 subjects had missing IMD scores and that the data were not normally distributed, we also performed quantile (median) regressions with multiple imputation for IMD. The results were largely unchanged, with the film group showing significantly higher changes in both objective and subjective knowledge scores (details available from the authors).

Because the study was nested in the wider randomized trial, half of the participants in both groups (randomly allocated) would have seen the control information booklet before arriving at the LHC. Therefore, we performed a sensitivity analysis by repeating the multivariable analysis adjusting for exposure to the control booklet before the LHC. This revealed that prior exposure to the information booklet did not have a significant impact on knowledge scores, objective ($P = 0.33$) or subjective ($P = 0.11$).

Individual Knowledge Items

Among all of the individual items in the subjective and objective knowledge questionnaires, only two items from the objective knowledge questions showed any statistically significant difference between the two groups. These two items showed a

Table 1. Participant characteristics by group

Variables	Groups n (%) or Median (IQR)	
	Intervention, $n = 120$ (Film + Booklet)	Control, $n = 109$ (Booklet Only)
Age, yr		
60–63	40 (33.33)	44 (40.37)
64–67	33 (27.50)	32 (29.36)
68–71	33 (27.50)	20 (18.35)
72–76	14 (11.67)	13 (11.93)
Sex		
Female	65 (54.17)	54 (49.54)
Male	54 (45.83)	55 (50.46)
Ethnicity		
White	98 (81.67)	92 (84.40)
Black/ African/Caribbean	13 (10.83)	8 (7.34)
Asian	3 (2.50)	4 (3.67)
Other	6 (5.00)	5 (4.59)
Level of education		
At or before 15*	61 (50.83)	52 (47.71)
CSEs, O-levels or equivalent†	12 (10.00)	15 (13.76)
A-levels or equivalent‡§	20 (16.67)	15 (13.76)
Further education§	6 (5.00)	2 (1.83)
Bachelor degree	12 (10.00)	16 (14.68)
Further higher degree¶	8 (6.67)	6 (5.50)
Other	1 (0.83)	3 (2.75)
Index of multiple deprivation quintile		
1 (most deprived)	69 (57.50)	50 (45.87)
2	35 (29.17)	37 (33.94)
3	3 (2.50)	3 (2.75)
4	0 (0)	0 (0)
5 (least deprived)	0 (0)	0 (0)
Smoking		
Average cigarette smoking (cigarettes/day), median	16 (10,20)	15 (10,20)
Number of pack-years, median	38 (21,50)	35 (21,51)
Years smoked, median	47 (43,52)	46 (42,51)
Research site		
University College Hospital London	45 (37.5)	59 (54.13)
Homerton University Hospital	75 (62.5)	50 (45.87)
Invitation group (from primary randomization in LSUT)		
Group A	52 (43.33)	59 (54.13)
Group B	68 (56.67)	50 (45.87)

Definition of abbreviations: CSEs = Certificate of Secondary Education; IQR = interquartile range; LSUT = Lung Screen Uptake Trial.

Percentage totals may not sum up due to rounding or to missing data. Figures are expressed as number and (%) or median and (interquartile range).

U.S. equivalent education levels:

*Less than high school education.

†High school graduate.

‡Post-high school training.

§Some college.

||College graduate.

¶Postgraduate/professional.

Figure 2. Knowledge scores by intervention group. (A) Change in objective knowledge scores, before and after intervention (both groups). (B) Change in subjective knowledge scores, before and after intervention (both groups).

higher RR for participants to improve their response from incorrect to correct in the film + booklet group compared with the booklet-alone group. The two significant items were the understanding that an “unclear” result at screening (i.e., an indeterminate pulmonary nodule) did not mean a high risk of cancer (RR, 1.51; CI, 1.07–2.13), and that the amount of radiation in an LDCT scan is equivalent to 1 year of background radiation in the United Kingdom (RR, 1.52; CI, 1.03–2.25) (Table E2).

Decisional Conflict

The adapted low-literacy DCS score was high (reflecting low decisional conflict) in both groups, with a median of 9/9 (interquartile range [IQR], 9–9) and mean of 8.5 (SD 1.25) in the film + booklet group, and a median of 9/9 (IQR, 8–9) and mean of 8.24 (SD 1.49) in the booklet-alone group (Figure E3). The film + booklet group had higher adapted DCS than the booklet-alone group in the adjusted multivariable analysis ($P = 0.007$), reflecting greater decision certainty in the film + booklet group. A Cronbach’s test for internal validity of the adapted scale

showed acceptable internal consistency ($\alpha = 0.78$).

LDCT Completion

LDCT completion rates did not significantly differ across groups ($P = 0.66$), with 76.7% and 78.9% proceeding to LDCT in the film + booklet and booklet-only groups, respectively.

Feedback and Acceptability of the Information Materials

The film and information booklet were both well accepted and believed to be useful and comprehensible, and to contain the correct level of information, though more participants watched the entire film than read the entire booklet (100% vs. 62%, $P < 0.001$), and understood all or most of the film compared with the booklet (96.5% vs. 85.9%, $P < 0.001$) (Figure 3). The film group participants were asked for additional feedback, and 68.7% believed that the film was memorable, 64.3% found the film helpful for their decision-making, and 79.4% would have watched the film if it had been available to them before the LHC. In addition, 59.8% described the film as

“completely balanced,” and 23.2% described it as “clearly slanted toward screening.”

Discussion

We report the findings of a randomized study evaluating the impact of a novel tool for informed decision-making (IDM) in LCS. In this nested study of 229 participants from a larger cohort of individuals who were invited to an LHC by their general practitioner and were participating in LSUT, an information film plus written information booklet improved objective and subjective knowledge, and reduced decisional conflict more than the booklet alone, with no significant impact on the number of individuals who subsequently completed an LDCT examination. Both information materials were well received.

Our finding that baseline objective knowledge was poor (median 5/10) is in keeping with other studies (2, 20), whereas subjective knowledge was better (median 3/5), suggesting that individuals’ perception of their knowledge about LCS may be somewhat optimistic. The changes in the mean scores need to be interpreted with caution given the discrete rather than continuous nature of the scores. Both groups significantly improved their knowledge scores after exposure to the information materials, which demonstrates that the use of such tools enhances understanding of LCS. This is supported by other single-group studies of decision tools in LCS (18–20, 29), although a reduction in knowledge at 1 month has been reported (18), emphasizing the need to repeat the “informing” process at repeat screening visits. Our findings, particularly from the comparison of the randomized arms, support the use of the film, which contained graphics and animation as an engaging and effective means to enhance understanding. The film was designed to be used as an adjunct to consultation with an HCP, whose role in shared decision-making is vital. Most conventional LCS information materials are written, but reliance on written communication materials has been noted to be problematic (5, 30). Web-based tools can be effective and personalized to an individual’s needs, but may be less accessible to older or lower-SES populations that are the target for LCS. In this study, the information film had a more significant impact than the booklet alone on knowledge

Figure 3. Acceptability of the film and information booklet. (A) Percentage of participants stating that the information materials were useful, not difficult to understand, informative, not too complicated, and provided enough information (including responses to film [film group only] and information booklet [both groups]). (B) Amount of the information materials read/watched and understood in both groups. (C) Film group only: how much participants believed the film helped them decide whether or not to be screened. (D) Film group only: how balanced they perceived the film to be.

and decisional conflict in a population that was eligible for LDCT screening and faced with a decision about undertaking an LDCT. This makes the results directly generalizable to the target population.

The film had a greater impact than the booklet on two aspects of specific knowledge: the significance of radiation exposure from LDCT and the fact that an “unclear” result (signifying an indeterminate pulmonary nodule) carries a low overall risk of malignancy. This is of value, as a better understanding of these concepts may in turn have an impact on the psychological responses to LCS and indeterminate (termed false-positive) results (31, 32). Certainly, improved communication has been reported to be associated with improved adherence to CT surveillance, and reduced distress in the context of non-LCS-detected pulmonary nodules (33), and it is imperative that we

translate these findings to the development of information materials in LCS.

LCS was shown to be an effective intervention that reduced lung cancer-specific mortality by 20% (34), and it was recommended by the USPSTF in 2013 (22). Despite this, uptake to LDCT in the United States has been low, with only 1.9% of the 7.6 million eligible smokers having undergone a LDCT examination as part of LCS according to a recent report using data from the American College of Radiology Lung Cancer Screening Registry (6). The likely barriers to uptake are multifactorial and complex (35). However, once an individual is considering LCS, it is vital that we communicate the benefits and harms using information resources that are engaging and accessible (i.e., with a low information burden) to individuals with varying levels of literacy, and that do not overemphasize either the harms or benefits. Individuals have been

noted to have a desire to hear an “expert opinion” (36) or “clinician guidance” (37) when making medical and screening-related decisions, and it is important for information materials to incorporate such guidance.

The data from our study show that the film was well received and generally the participants found it to be helpful and balanced, though a proportion found it to be biased in favor of screening, which may reflect the impressive 20% relative reduction and the positive patient testimonial included in the information materials. A significant proportion also found that it was not helpful for decision-making, perhaps in view of the difficult balance of benefits and harms. However, the low decisional conflict observed by the end of the consultation suggests that people were ultimately satisfied with their decision, and reinforces that the film should not replace discussion with an

HCP. The ultimate aim of IDM is for individuals to possess the relevant information regarding harms, benefits, and the options available to them, and then to be able to process that information to make a decision that is in line with their personal beliefs and values (38). In developing the film, our aim was to ensure that we presented the harms fairly and accurately while still making the benefits clear. The film can aid the IDM process, and the HCP can further help individuals arrive at an informed decision when required.

An important point in this study is that the participants were already attending an LHC and thus were somewhat engaged in the screening process. The findings endorse the use of the film, for example, to be played on a loop in the waiting room before a pre-LDCT consultation with an HCP. Given recent reports of poor performance with respect to shared decision-making for LCS in the United States (39, 40), this could be an important use for a valuable tool. The likely impact of the film if an individual viewed it before attending an LHC or screening visit was not tested in the present study. Given that almost no participants believed it was biased against screening, the film may not deter those who are inclined to engage in preventive health behaviors from taking part in LCS; however, further studies are needed to address this issue.

Strengths and Limitations

This study has several limitations that should be noted. First, the information film

is not a decision aid, because it does not meet all the criteria on the International Patient Decision Aid Standards checklist, which is a detailed list of specifications that we were unable to comprehensively address in a short film (41). Our intention was for the film to be used to provide information that would facilitate the discussion with an HCP, and not to replace it. Second, we used an adapted version of the low-literacy DCS scale (25), which has not been validated but showed acceptable internal validity. The impact of the information film is likely to be understated, as a ceiling effect was observed with both the DCS and the subjective knowledge scores. Third, both the interventions were delivered in the presence of an HCP and thus did not imitate a “real-world” setting where there may be variability in the amount of information material watched or read. However, some real-world variability may have been simulated in light of the fact that the consultations were performed by eight different HCPs. In addition, as described above, the study was conducted in a group of individuals who were already attending an LHC and may have been more engaged in preventive health behaviors; nevertheless, the study is strengthened by the likely generalizability of the results to the target population. The study participants were invited to participate according to eligibility criteria similar to those advised by the USPSTF (42) and used in a number of international projects (43–46).

Future work could involve testing the film on individuals before they attend an LHC, and assess longer-term knowledge and decisional conflict and satisfaction, as well as the impact of such tools on the psychological morbidity associated with a diagnosis of an indeterminate pulmonary nodule after LCS. The research team has been approached by a number of centers in the United Kingdom and United States for use of the information film in their local LCS projects, and a strength of this medium is that it can be easily adapted for local needs and preferences.

Conclusions

This nested randomized study has demonstrated that the developed information film positively impacted knowledge and decisional conflict more than the booklet alone without reducing uptake of LDCT. We propose that use of the film, as an adjunct to the HCP role in shared decision-making, standardizes and enhances knowledge about LCS benefits and harms, and improves knowledge and decisional conflict associated with LCS. ■

Author disclosures are available with the text of this article at www.atsjournals.org.

Acknowledgment: The authors acknowledge the substantial intellectual contribution made by Professor Jane Wardle, who sadly passed away prior to publication and is deeply missed by all of her co-authors, colleagues, and students.

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