Title: Impact of a lung cancer screening information film on informed decision-making - a randomized trial

Mamta Ruparel MBBS, PhD¹, Samantha L. Quaife PhD², Bhagabati Ghimire PhD³, Jennifer L. Dickson MBBS¹, Angshu Bhowmik MBBS, MD⁴, Neal Navani MBBS, PhD¹, David R Baldwin MBChB, MD⁶, Stephen Duffy MSc³, Jo Waller PhD², Sam M. Janes MBBS, PhD¹

¹ Lungs for Living Research Centre, UCL Respiratory, University College London, London, U.K.
² Research Department of Behavioural Science and Health, University College London, U.K.
³ Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry, Queen Mary University, London, U.K.
⁴ Department of Thoracic Medicine, Homerton University Hospital, London, U.K.
⁵ Department of Thoracic Medicine, University College London Hospital, U.K.
⁶ Respiratory Medicine Unit, David Evans Research Centre, Nottingham University Hospitals, U.K.

CORRESPONDING AUTHOR:

Professor Sam Janes

Lungs For Living Research Centre, UCL Respiratory

Rayne Institute, 5 University Street

London, WC1E 6JF, UK

s.janes@ucl.ac.uk | (+44) 0203 549 5979
CONTRIBUTORS:

All the authors contributed to the design and/or conduct of the study, and preparation of the manuscript. MR, BG, SD, SLQ and JW also contributed to the data analysis.

FUNDING:

This study was part of the Lung Screen Uptake Trial project, which was funded by a National Awareness and Early Diagnosis Initiative (NAEDI) 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; Scottish Government) (S.L.Q, J.W. and S.M.J). The study and film production was 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 Stoneygate Trust, the Welton Trust, the Garfield Weston Trust and UCLH Charitable Foundation. This work was undertaken at UCLH/UCL who received a proportion of funding from the Department of Health’s NIHR Biomedical Research Centre’s funding scheme (N.N., 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 programme from the Department of Health Policy Research Programme. 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).

**DATA SHARING:** Individual, de-identified participant data are available from the corresponding author on reasonable request.

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

**WORDCOUNT:** 3627
ABSTRACT

Rationale: Lung cancer screening has the potential to save lives, but also carries risk of potential harms. Explaining the benefits and harms of screening in a way that is balanced and comprehensible to those with varying education is essential. Although a shared decision-making approach is mandated by the Centers for Medicare and Medicaid, 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 sub-set of participants from the 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 objective knowledge score post-intervention. Secondary outcomes included subjective knowledge, decisional conflict, final screening participation and acceptability of the materials. Univariate and multivariate analyses were carried out to determine differences in pre- and post-intervention 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 post-intervention. This improvement was greatest in the film + booklet group, where mean objective knowledge improved by 2.16 points (SD 1.8) in the film + booklet group compared with 1.84 points (SD 1.9) in the booklet
alone group (β coefficient 0.62, CI 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 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.

This article has an online supplement, which is accessible from this issue's table of contents online at [www.atsjournals.org](http://www.atsjournals.org)
Impact of a lung cancer screening information film on informed decision-making - a randomized trial

INTRODUCTION

Lung cancer screening (LCS) using low dose computed tomography (LDCT) has the potential to save lives, though also carries potential for harm. 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; an issue exacerbated for those 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 high information burden could actually disengage individuals with lower health literacy from taking part in screening (5). This is important when considering that only 1.9% of those eligible are estimated to have received a LDCT screen in the US (6).

The use of illustrative materials is associated with improved understanding and knowledge around risk perception (7). Graphics and animation are known to enhance knowledge and recall of facts related to specific health care interventions (8, 9). Several randomized studies evaluating the use of ‘educational videos’ in different health care settings have found video 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 and Medicaid Services (16), but few decision tools exist. Lau et al 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 et al tested the impact of a shared decision-making visit comprising of a slide presentation about the benefits and harms, use of the above described web-based tool, and the opportunity for having questions answered by a health provider. The authors demonstrated a significant improvement in knowledge which partially persisted one month later (18). Two uncontrolled studies evaluated the impact of video (19, 20). Volk et al, developed a film and tested it with 52 participants in a tobacco treatment program noting high acceptability, improved knowledge scores, and high level of interest in LCS; though patient demographics and screening attendance data were not provided (19). Reuland and colleagues also reported an improvement in knowledge with 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, Supplemental data 1), and to be supplemented with a health care professional (HCP) discussion to support the decision-making process. We tested whether the film plus information booklet enhanced objective and subjective knowledge over the booklet

1 Also available at https://www.roycastle.org/lungcancerscreeningguide
alone. We also evaluated additional impact on decisional conflict and uptake of LDCT, and assessed acceptability of both the booklet and film.

METHODS

Participants and setting

This is a nested randomized study within the Lung Screen Uptake Trial (LSUT), the methods for which, have been previously described (21). Briefly, LSUT invited smokers and former smokers (within 5 years of quitting) aged 60-75, 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 meeting any of the following three criteria and with no physical contra-indication to LDCT scanning:

- Meeting the US Preventative Services Task Force recommendation (USPSTF) (22), i.e. ≥30 pack-year smoking history and quit <15 years ago
- ≥1.51% 6-year lung cancer risk as per the PLCO\textsubscript{m2012} model (23)
- ≥2.5% 5-year lung cancer risk as per the LLP\textsubscript{v2} model (24)

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

Following informed consent, participants underwent simple parallel randomization without restriction, with 1:1 individual allocation to each group. Randomization was carried out by the HCP via a computer based randomization system.

Those randomized to the control group received the information booklet (see Figure S1, Supplemental data 2) used for LSUT’s control invitation materials (21). Those randomized to the intervention group were shown an information film and given the same information booklet. The film (see Video, Supplemental data 1²) content and format was developed 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 following the scan. The booklet was ten pages long and designed to be clear and comprehensible for those with a reading age of 11-13 years. The film was five and a half minutes long.

Participants were allocated ten minutes to read the booklet and/or watch the film in the presence of one of eight HCPs involved in the data collection for this study. HCPs were nurses or clinical trials practitioners who had been specifically trained in the consent process. Following a further knowledge assessment as described below, demographic, smoking and medical history data were collected to assess lung cancer risk and eligibility for LDCT. Participants were subsequently informed of elevated lung

² Also available at https://www.roycastle.org/lungcancerscreeningguide
cancer risk (if applicable) when compared to the general population and thus eligibility to LDCT, and prompted to ask any questions about the harms and benefits. At this point, if happy to proceed, written consent to undergo the LDCT was taken by the HCP, once again naming the potential harms of LDCT as per a ‘consent checklist’ (see Figure S2, Supplemental data 2).

Outcome measures

The primary endpoint was a post-intervention 10-point objective knowledge score that assessed facts relating to the benefits and harms of LCS contained in both intervention materials (see Table S1, Supplemental data 2). For the objective knowledge questions, a ‘not sure’ or incorrect answer were treated the same and not awarded any points, while only the correct answer received a score of one.

Secondary endpoints included a 5-point subjective investigator-designed knowledge assessment, adapted measures from the low literacy decisional conflict scale (DCS) (25) (see Table S1, Supplemental data 2), LDCT completion and feedback on the information materials. For the subjective questions a ‘yes’ response received one point, while a ‘no’ or ‘not sure’ 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 carried out at baseline and immediately post 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)
score. This is an “official measure of relative deprivation for small areas (or
neighbourhoods) 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 & statistical analysis

Three well designed studies using video decision aids, report intervention-related
improvements in knowledge scores by 24% (27), 21% (28) and 78% (19). Other studies
have failed to detect a significant effect, however, these 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 plus film group, with a standard deviation (SD) of 1.9 (2-sided testing at 5%
significance level).

Descriptive statistics were used to illustrate the demographic characteristics of both
groups and the acceptability data. Because we used both non-parametric and
parametric inferential analyses, we reported both means and medians. Noting that
the scores were not normally distributed, univariate analyses using the Wilcoxon
signed rank test were used to compare the primary outcome knowledge scores pre-
and post-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 were also used to assess group differences between individual items for knowledge, DCS and uptake to LDCT between the groups. Analyses were carried out using STATA v13 & v14.

**Ethics**

This study was part of the LSUT, which has had ethical approvals granted by the City Road and Hampstead NHS Research Ethics Committee (REC; reference: 15/LO/1186). LSUT has been registered by clinicaltrials.gov (NCT02558101) and the International Standard Registered Clinical/social sTudy Number (ISRCTN21774741).

**RESULTS**

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 so 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 following 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 index of multiple deprivation (IMD) score, the greater increases in the film group in objective and subjective knowledge scores remained significant (β coefficient 0.62, 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 score, and that the data were not normally distributed, we also carried out quantile (median) regressions with multiple imputation for IMD. Results were largely unchanged, with the film group showing significantly higher changes to both objective and subjective knowledge scores (details available from the authors).

Because the study was nested in the wider randomized trial, half the participants in both groups (randomly allocated) would have seen the control information booklet prior to arriving at the LHC. A sensitivity analysis was therefore carried out by repeating the multivariable analysis adjusting for exposure to the control booklet prior to the LHC. This revealed that prior exposure to the information booklet did not have significant impact on knowledge scores, objective (p=0.33) and subjective (p=0.11).

**Individual knowledge items**

Of all 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 higher risk ratio 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 one year of background
radiation in the UK (RR 1.52, CI 1.03– 2.25) (Table S2, Supplemental data 2).

Decisional conflict
The adapted low literacy DCS score was high (reflecting low decisional conflict) in both
groups with a median of 9/9 (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 (see Figure S3, Supplemental data 2). 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 (α=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 groups respectively.

Feedback and acceptability of the information materials
The film and information booklet were both well accepted and felt to be useful,
comprehensible and 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 than booklet (96.5% vs. 85.9%, p<0.001) (figure 3).
The film group participants were asked for additional feedback, and 68.7% felt the film to be 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’, while 23.2% described it as ‘clearly slanted towards screening’.

**DISCUSSION**

We report the findings of a randomized study evaluating the impact of a novel decision tool on IDM in LCS. In this nested study of 229 participants from a larger cohort of individuals invited to an LHC by their GP and 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 numbers of individuals subsequently completing a LDCT examination; both information materials were well received.

Our findings that baseline objective knowledge was poor (median 5/10) is in keeping with other studies (2, 20), while 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 use of such tools enhances understanding of LCS. This is supported by other single group studies of decision tools in LCS (18–20, 29), though a reduction in knowledge at one month has been reported (18), thereby
emphasizing the need to repeat the ‘informing’ process at repeat screening visits. Our findings, particularly 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 an HCP consultation, whose role in shared decision-making is vital. Most conventional LCS information materials are written, but reliance on written communication materials have been noted to be problematic (5, 30). Web-based tools can be effective and personalized to the individuals’ needs but may be less accessible to older or lower SES populations who are the target for LCS. This study has shown a significant impact of the information film over the booklet alone on knowledge and decisional conflict, in a population that was eligible for LDCT screening and faced with the 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 better understanding of these concepts may in turn have an impact on the psychological responses to LCS and indeterminate (termed false positives) 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 into the development of information materials in LCS.
LCS has been proven to be an effective intervention that reduced lung cancer-specific mortality by 20% (34) and was recommended by the USPSTF in 2013 (22). Despite this, uptake to LDCT in the US 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 from data from the American College of Radiology LCS 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. low information burden) to individuals with varying levels of literacy, and that do not over-emphasize 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 that information materials incorporate such guidance.

The data from our study show that the film was well received and generally 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 it 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 people were ultimately satisfied with their decision and reinforces that the film should not replace the HCP discussion. The ultimate aim for IDM is for the individual to possess the relevant information on 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). Our aim was for the film to ensure that the harms were presented 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 where required.

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

**Strengths and Limitations**

The information film is not a decision aid as it does not meet all the criteria on the International Patient Decision Aid Standards (IPDAS) 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 HCP in their discussion, and not to replace it. Secondly, 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. Thirdly, both the interventions were delivered in the presence of a HCP and so 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 consultations were carried out by eight different HCPs. In addition, as described above the study was conducted in a group of individuals already attending a LHC and who may be more engaged in preventative 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 using similar eligibility criteria to those advised by the USPSTF (42) and a number of other projects internationally (43–46).

Future work could involve testing of the film prior to attendance at an LHC; and to assess longer-term knowledge and decisional conflict and satisfaction, as well assess the impact of such tools on the psychological morbidity associated with a diagnosis of an indeterminate pulmonary nodule following LCS. The research team have been approached by a number of centers in the UK and US 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 has 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.
ACKNOWLEDGEMENTS

We would like to 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.

This manuscript has been submitted with supplemental data files:

Supplemental data 1: information film (MP4 file)

Supplemental data 2: Tables S1 & S2 and figures S1-S3
REFERENCES


40. Wiener RS, Koppelman E, Bolton R, Lasser KE, Borrelli B, Au DH, Slatore CG, Clark JA, Kathuria H. Patient and Clinician Perspectives on Shared Decision-making in


Tables and Figures:

Table 1. Participant characteristics by group

Figure 1. Consort diagram for study participants

Figure 2. Knowledge scores by intervention group: a) change in objective knowledge scores, pre- and post-intervention (both groups); b) change in subjective knowledge scores, pre- and post-intervention (both groups)

Figure 3. Acceptability of film and information booklet: a) % of participants stating the information materials to be useful, not difficult to understand, informative, not too complicated, and not too little 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 felt the film helped them with their decision-making of whether or not to be screened; d) film group only: how balanced they perceived the film to be.
Table 1 Participant characteristics by group

% totals may not sum up due to rounding, or missing data. Figures expressed as number and (%) or median and (interquartile range). US equivalent education levels are: § less than high school education; §§ high school graduate; §§§ Post high school training; *Some college; **College graduate; *** Postgraduate/ professional education.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Groups n (%) or median (IQR)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention, n=120</td>
</tr>
<tr>
<td></td>
<td>(Film + Booklet)</td>
</tr>
<tr>
<td>Age (in years)</td>
<td></td>
</tr>
<tr>
<td>60 – 63</td>
<td>40 (33.33)</td>
</tr>
<tr>
<td>64 – 67</td>
<td>33 (27.50)</td>
</tr>
<tr>
<td>68 – 71</td>
<td>33 (27.50)</td>
</tr>
<tr>
<td>72 – 76</td>
<td>14 (11.67)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>65 (54.17)</td>
</tr>
<tr>
<td>Male</td>
<td>54 (45.83)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>98 (81.67)</td>
</tr>
<tr>
<td>Black/ African/ Caribbean</td>
<td>13 (10.83)</td>
</tr>
<tr>
<td>Asian</td>
<td>3 (2.50)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (5.00)</td>
</tr>
<tr>
<td>Level of Education</td>
<td></td>
</tr>
<tr>
<td>At or before 15§</td>
<td>61 (50.83)</td>
</tr>
<tr>
<td>CSEs, O-levels or equivalent §§</td>
<td>12 (10.00)</td>
</tr>
<tr>
<td>A-levels or equivalent §§§</td>
<td>20 (16.67)</td>
</tr>
<tr>
<td>Further education*</td>
<td>6 (5.00)</td>
</tr>
<tr>
<td>Bachelor degree**</td>
<td>12 (10.00)</td>
</tr>
<tr>
<td>Further higher degree***</td>
<td>8 (6.67)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.83)</td>
</tr>
<tr>
<td>Index of Multiple Deprivation (IMD) quintile</td>
<td></td>
</tr>
<tr>
<td>1 (most deprived)</td>
<td>69 (57.50)</td>
</tr>
<tr>
<td>2</td>
<td>35 (29.17)</td>
</tr>
<tr>
<td>3</td>
<td>3 (2.50)</td>
</tr>
<tr>
<td>4</td>
<td>0 (0)</td>
</tr>
<tr>
<td>5 (least deprived)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
</tr>
<tr>
<td>Average cig smoking (cig/day), median</td>
<td>16 (10.20)</td>
</tr>
<tr>
<td>Number of pack-years, median</td>
<td>38 (21.50)</td>
</tr>
<tr>
<td>Years smoked, median</td>
<td>47 (43.52)</td>
</tr>
<tr>
<td>Research Site</td>
<td></td>
</tr>
<tr>
<td>University College Hospital London</td>
<td>45 (37.5)</td>
</tr>
<tr>
<td>Homerton University Hospital</td>
<td>75 (62.5)</td>
</tr>
<tr>
<td>Invitation group (from primary randomization in LSUT)</td>
<td></td>
</tr>
<tr>
<td>Group A</td>
<td>52 (43.33)</td>
</tr>
<tr>
<td>Group B</td>
<td>68 (56.67)</td>
</tr>
</tbody>
</table>
1005 participants recruited to LSUT between Nov 2015 and July 2017

Eligibility for recruitment to film sub-study assessed in 252 participants between Aug 2016 and Feb 2017

Randomized (n = 246)

Intervention (n=126)
Film + booklet

120 included in analysis

Control (n=120)
Booklet alone

109 included in analysis

6 declined participation

6 withdrawn from analysis due to insufficient data

11 withdrawn from analysis due to insufficient data
Do you think the film helped your decision of whether or not to be screened?

- Helped a lot
- Helped a little
- Didn't help

Did you think the film provided a balanced view?

- Clearly slanted towards screening
- A little slanted away from screening
- A little slanted towards screening
- None
- Completely balanced
Table S1. Outcome measures for objective and subjective knowledge items and adapted low literacy decisional conflict scale

Table S2. Risk ratios (RR) for improving answers from an incorrect to correct response in the post intervention assessment for individual objective and subjective knowledge items in the film + booklet group (reference booklet only group)

Figure S1. The control information booklet

Figure S2. The checklist of points to be covered for standardization of the consent process

Figure S3. The frequency histograms of the adapted DCS by group

This article also has an online video data supplement (Supplementary Appendix 1)
Table S1. Outcome measures for objective and subjective knowledge items and adapted low literacy decisional conflict scale. *For the objective knowledge questions only the correct answer was awarded a point while incorrect or ‘not sure’ responses scored 0. **For the subjective knowledge questions, an answer of ‘yes’ was awarded a point, while ‘no’ and ‘not sure’ scored 0.

<table>
<thead>
<tr>
<th>Objective Knowledge questions*</th>
<th>Response options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Everyone in the population has the same risk of lung cancer</td>
<td>True/ False/ Not sure</td>
</tr>
<tr>
<td>Lung cancer screening is only for people with symptoms</td>
<td>True/ False/ Not sure</td>
</tr>
<tr>
<td>All lung cancers found by screening will eventually cause illness and death if they are not treated</td>
<td>True/ False/ Not sure</td>
</tr>
<tr>
<td>When lung cancer is picked up at screening, the chances of cure are higher than without screening</td>
<td>True/ False/ Not sure</td>
</tr>
<tr>
<td>Lung cancer screening will pick up every lung cancer</td>
<td>True/ False/ Not sure</td>
</tr>
<tr>
<td>If there is an unclear result at screening, the chance of having lung cancer is greater than 50%</td>
<td>True/ False/ Not sure</td>
</tr>
<tr>
<td>The amount of radiation from a screening CT scan is low and is similar to a year’s worth of radiation from the natural environment</td>
<td>True/ False/ Not sure</td>
</tr>
<tr>
<td>All people with suspected lung cancer on the screening CT scan, who go on to have tests, will have lung cancer</td>
<td>True/ False/ Not sure</td>
</tr>
<tr>
<td>Research has shown CT screening for lung cancer may save 20% more lives from lung cancer than chest x-rays</td>
<td>True/ False/ Not sure</td>
</tr>
</tbody>
</table>

If 100 smokers were screened for lung cancer, how many do you think would be found to have lung cancer? (please write number) ________________

<table>
<thead>
<tr>
<th>Subjective Knowledge questions**</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you understand who could benefit from lung cancer screening?</td>
<td>Yes/ No/ Not sure</td>
</tr>
<tr>
<td>Do you know your level of risk for lung cancer?</td>
<td>Yes/ No/ Not sure</td>
</tr>
<tr>
<td>Do you understand what the aims of lung cancer screening are?</td>
<td>Yes/ No/ Not sure</td>
</tr>
<tr>
<td>Do you understand what the risks of lung cancer screening are?</td>
<td>Yes/ No/ Not sure</td>
</tr>
<tr>
<td>Do you understand how often the risks of lung cancer screening occur?</td>
<td>Yes/ No/ Not sure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adapted decisional conflict scale questions:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you know the benefits of lung cancer screening?</td>
<td>Yes/ No</td>
</tr>
<tr>
<td>Do you know the risks and side effects of lung cancer screening?</td>
<td>Yes/ No</td>
</tr>
<tr>
<td>Are you clear about which benefits matter most to you?</td>
<td>Yes/ No</td>
</tr>
<tr>
<td>Are you clear about which risks and side effects matter most to you?</td>
<td>Yes/ No</td>
</tr>
<tr>
<td>Do you have enough support from others to make a choice about whether or not to be screened for lung cancer?</td>
<td>Yes/ No</td>
</tr>
<tr>
<td>Are you choosing without pressure from others?</td>
<td>Yes/ No</td>
</tr>
<tr>
<td>Do you have enough advice to make a choice about whether or not to be screened for lung cancer?</td>
<td>Yes/ No</td>
</tr>
<tr>
<td>Are you clear about whether being screened for lung cancer is the best choice for you?</td>
<td>Yes/ No</td>
</tr>
<tr>
<td>Do you feel sure about choosing whether to be screened or not?</td>
<td>Yes/ No</td>
</tr>
</tbody>
</table>
Table S2. Risk ratios (RR) for improving answers from an incorrect to correct response in the post intervention assessment for individual objective and subjective knowledge items in the film + booklet group (reference booklet only group)* the numbers represent changing the correct answer post into scores and not the absolute number of correct answers post. ** RR= risk ratio *** if P<0.05.

<table>
<thead>
<tr>
<th>Item questions</th>
<th>Correct scores post* booklet only, n (%)</th>
<th>Correct scores post* booklet + film, n (%)</th>
<th>RR** (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Everyone in the population has the same risk of lung cancer</td>
<td>17(15.60)</td>
<td>9(7.50)</td>
<td>0.48 (0.22-1.03)</td>
<td>0.06</td>
</tr>
<tr>
<td>2. Lung cancer screening is only for people with symptoms</td>
<td>19(17.43)</td>
<td>25 (20.83)</td>
<td>1.20 (0.70 – 2.04)</td>
<td>0.51</td>
</tr>
<tr>
<td>3. All lung cancers found by screening will eventually cause illness and death if they are not treated</td>
<td>22(20.18)</td>
<td>29(24.17)</td>
<td>1.20 (0.73 – 1.95)</td>
<td>0.47</td>
</tr>
<tr>
<td>4. When lung cancer is picked up at screening, the chances of cure are higher than without screening</td>
<td>7(6.42)</td>
<td>9(7.50)</td>
<td>1.16 (0.45 – 3.03)</td>
<td>0.75</td>
</tr>
<tr>
<td>5. Lung cancer screening will pick up every lung cancer</td>
<td>35(32.11)</td>
<td>47(39.17)</td>
<td>1.22 (0.86–1.74)</td>
<td>0.27</td>
</tr>
<tr>
<td>6. If there is an unclear result at screening, the chance of having lung cancer is greater than 50%</td>
<td>33(30.28)</td>
<td>55(45.83)</td>
<td>1.51 (1.07 – 2.13)</td>
<td>0.02***</td>
</tr>
<tr>
<td>7. The amount of radiation from a screening CT scan is low and is similar to a year’s worth of radiation from the natural environment</td>
<td>28(25.69)</td>
<td>47(39.17)</td>
<td>1.52 (1.03–2.25)</td>
<td>0.03***</td>
</tr>
<tr>
<td>8. All people with suspected lung cancer on the screening CT scan, who go on to have tests, will have lung cancer</td>
<td>26(23.85)</td>
<td>30(25.00)</td>
<td>1.05 (0.66 – 1.65)</td>
<td>0.84</td>
</tr>
<tr>
<td>9. Research has shown CT screening for lung cancer may save 20% more lives from lung cancer than chest x-rays</td>
<td>16(14.68)</td>
<td>24(20)</td>
<td>1.36 (0.77–2.43)</td>
<td>0.29</td>
</tr>
<tr>
<td>10. If 100 smokers are screened for lung cancer, how many do you think would be found to have lung cancer?</td>
<td>41(37.61)</td>
<td>43 (35.83)</td>
<td>0.95(0.68 – 1.34)</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Subjective</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Do you understand who could benefit from lung cancer screening?</td>
<td>2(1.83)</td>
<td>7(5.83)</td>
<td>3.18 (0.67 – 14.98)</td>
<td>0.12</td>
</tr>
<tr>
<td>2. Do you know your level of risk for lung cancer?</td>
<td>19(17.43)</td>
<td>23(19.17)</td>
<td>1.10 (0.63 –1.90)</td>
<td>0.73</td>
</tr>
<tr>
<td>3. Do you understand what the aims of lung cancer screening are?</td>
<td>7(6.42)</td>
<td>13(10.83)</td>
<td>1.69 (0.70 – 4.07)</td>
<td>0.24</td>
</tr>
<tr>
<td>4. Do you understand what the risks of lung cancer screening are?</td>
<td>25(22.94)</td>
<td>37(30.83)</td>
<td>1.34 (0.87 – 2.08)</td>
<td>0.18</td>
</tr>
<tr>
<td>5. Do you understand how often the risks of lung cancer screening occur?</td>
<td>33(30.28)</td>
<td>44(36.67)</td>
<td>1.21 (0.84 –1.75)</td>
<td>0.31</td>
</tr>
</tbody>
</table>
Need more information before your appointment?
For more information call our freephone advice service on 0808 281 9525 or call/text 07469 118 308 or email us at lungscreen@ucl.ac.uk

Lung Health Check:
Information on what’s involved
A new NHS Lung Health Check is being offered to people aged 60 to 75 who smoke or used to smoke.

This booklet is designed to help you decide whether to have a lung health check. It is your choice whether you attend.

It aims to answer the following questions:

- Why am I being invited?
- What happens when I arrive at the appointment?
- What are the different tests?
- What are the possible benefits and risks?
- What is lung cancer?
- Who can I contact if I have a question?

**Signs and symptoms of lung cancer**

In the very early stages of lung cancer, there are often no symptoms. This is partly because the lungs are large and do not feel pain.

Warning signs to look out for include:

- a persistent cough or change in an existing cough
- feeling short of breath
- coughing up blood
- pain or ache when breathing or coughing
- unexplained tiredness or weight loss
What is lung cancer?
Lung cancer begins when cells in the lungs, windpipe (trachea) or airways (bronchi) start to grow abnormally.
The cells form a cluster (known as a nodule), which grows bigger and turns into a tumour.
In most cases this happens slowly and (without screening) can take up to five years before it is diagnosed.

How common is it?
Lung cancer is the second most common cancer in the UK. Survival from lung cancer improves the earlier it is found. Over eight out of ten lung cancers are caused by smoking. Risk of lung cancer is also increased in those who are older, have been exposed to other people’s smoke, have been exposed to asbestos, or have been diagnosed with a lung problem like COPD (which includes chronic bronchitis and emphysema).

What can I do to reduce my risk?
The single best thing you can do to prevent lung cancer is not smoke. If you do smoke and would like to stop there is lots of help out there.
Ask your GP about free local support available, or contact NHS smokefree on 0800 0224 332 or visit www.nhs.uk/smokefree

What is a lung health check?
Lung health checks test for the early signs of lung conditions. Lung conditions and lung cancer are easier to treat when found early, and there is now good evidence that screening for early stage lung cancer using CT scans saves lives.

Why am I being invited?
Lung health checks are being offered to people aged 60 to 75 who smoke or used to smoke. These people are most likely to benefit because they are more at risk of lung disease. Medical records indicate that you are either a smoker or have smoked in the past.
It does not matter if you already have a lung problem. Please let the nurse know about this at your appointment.

What happens when I arrive at the appointment?
A nurse will greet you, discuss all the different tests and answer any questions. The nurse will help you choose which tests you would like by explaining how you might benefit from them. You can choose when you want to have the tests - then or at a later date. You may not be offered a CT scan if it is not suitable for you and the nurse will discuss this with you.
What are the different tests?

Lung function test

This is a simple test (called spirometry) for which you blow into a hand-held machine. The test checks for problems with the lungs that may be caused by conditions like asthma, lung tissue scarring, sarcoidosis and COPD (which includes chronic bronchitis and emphysema). It measures:

- How much air you can take into and blow out of your lungs
- How strong your breathing muscles are

CO (carbon monoxide) test

The nurse will ask you to hold your breath for 15 seconds (or as long as you can) and then blow into a hand-held machine. It measures the level of carbon monoxide in your breath, to find out how much there is in your blood. Carbon monoxide is a poisonous gas produced by tobacco smoke, unsafe gas boilers and pollution.

Samples of blood, breath, sputum and cheek cells

We are carrying out research to see whether the early signs of lung disease can be found in the blood, breath, cells from the lining of the cheek and sputum samples. These tests are not part of your lung health check and it is completely up to if you want to have them.

- Samples of breath are taken by breathing normally into a machine
- Cheek cells are collected by rubbing a swab (which looks a bit like a large cotton wool bud) against the inside of the cheek
- Any sputum brought up by an existing cough is collected in a pot

How reliable is lung cancer screening?

Like all cancer screening tests, lung cancer screening is not completely accurate and some cancers will be missed. Nodules found in the middle of the chest and some small cancers are harder to see. Some cancers start to grow after screening.
What are the possible benefits?

When found early, lung conditions are easier to treat and lung cancer is more likely to be cured.

A study in North America has shown that using CT scans to find lung cancer early saves lives of people aged 55 to 75 who smoke or used to smoke. Screening using CT scans prevented 20% more deaths from lung cancer than using chest x-rays.

What are the possible risks?

The low dose CT scan will expose you to a small amount of radiation. It is the same as about one year’s worth of radiation from the natural environment. The risk of a CT scan causing a cancer is very low compared with the benefits of detecting lung cancer early. If a further CT scan is needed then this will expose you to more radiation.

In some cases, people will be diagnosed and treated for lung cancer that would never have caused the person harm. If they had not been screened, they would never have known about the cancer or have had any treatment.

Waiting for the results of these tests can be worrying. People with an unclear result will need to be monitored and have a further scan. This can be a worrying time and in most cases they will not have lung cancer. If you are confused about any of the tests or have any concerns at any point, please contact the lung clinic and we will help.

Further tests and treatment all carry risks as well as benefits. Should you be offered any of these, a specialist NHS doctor will discuss the risks and benefits. If you would like to know more information about these before having a CT scan, please speak to the nurse during your appointment.

Low dose chest CT (computed tomography) scan

A chest CT scan is a type of x-ray which takes detailed pictures of the lungs. These pictures are processed by a computer and then checked for the early signs of lung cancer by specially trained doctors (known as radiologists).

Whether or not you are offered a CT scan will depend on your lifestyle, medical and family history. The nurse will help you to choose whether the test is right for you and you may want to postpone it to a different day.
What is having a chest CT scan like?

The CT scan will take about **10 minutes**. You will be asked to lie flat on the bed of the scanner. The bed will move slowly backwards and forwards while the scanner circles your chest. Specially trained staff will sit the other side of a screen where they can talk to you and control the scanner.

Only your chest will be scanned and you will not go into a tunnel (this is for a different scan called an MRI scan). The scan is pain free and you will not need an injection. If you do have any concerns about the scan then please contact the lung clinic or speak to the nurse at your appointment.

RESULTS WILL BE SENT TO YOU & YOUR GP IN 2 WEEKS

**Normal result** This means that no signs of lung cancer or other abnormalities could be seen on the scan. Approximately three quarters of people will have a normal result. While this is good news, it is still possible that lung cancer could develop in the future or that the scan may have missed it. It is important to be aware of the symptoms of lung cancer and to go to your GP quickly if you have any concerns.

**Unclear result** This usually means the scan has shown a small area of white shadowing in the lung. This is probably something harmless but there is a chance it might be something serious. You will be invited to an appointment with a specialist doctor to discuss the result. The best way to make sure that there is nothing to worry about is to have another scan after an interval to make sure there are no signs of lung cancer. Most people with an unclear result will not have lung cancer.

**Abnormal result** This means there is something abnormal on the scan that needs more tests to find out what it is. It could be cancerous or it could be harmless. You will be invited to an appointment with a specialist doctor who will discuss the results and arrange further tests.

**Incidental finding** This means there are signs of other problems on the scan that may need treatment or medical advice. If you already have a lung problem, this might be why and you may not need any extra care. You may be advised to make contact with your GP to make an appointment to find out more.
**Figure S2. The checklist of points to be covered for standardization of the consent process**

<table>
<thead>
<tr>
<th>Consent checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If appropriate- tell them they have a higher than average risk of lung cancer due to their age, smoking and other history and that they are eligible to be offered a CT scan</td>
</tr>
<tr>
<td>• CT scan is a 3d x-ray test, not painful, like a big doughnut.</td>
</tr>
<tr>
<td>• Takes about 10 minutes with perhaps a little waiting before hand</td>
</tr>
<tr>
<td>• Important to hold their breath for a short time but they will be instructed.</td>
</tr>
<tr>
<td>• But before they decide whether to go ahead, they should be aware of the pros and cons and make their own mind up whether its right for them to go ahead.</td>
</tr>
<tr>
<td>Pros:</td>
</tr>
<tr>
<td>• Currently lung cancer is often <strong>diagnosed late</strong> due to symptoms occurring late. With screening we aim to <strong>detect lung cancer earlier</strong> which offers a <strong>higher chance of cure</strong>.</td>
</tr>
<tr>
<td>• A US study showed <strong>we might save 20% of lives</strong> that could have been lost from lung cancer if we screen high-risk individuals</td>
</tr>
<tr>
<td>Cons:</td>
</tr>
<tr>
<td>• <strong>Radiation</strong>- the amount of radiation in 1 scan is about the same as what you’d get from the environment in a year, and isn’t too harmful. However many scans over a lifetime especially when young, can cause harm.</td>
</tr>
<tr>
<td>• <strong>Indeterminate results</strong>- about a quarter of all patients undergoing screening will have a “spot”. This will mean the need for further tests to check for growth. This can cause anxiety. If this does happen to you, try not to worry as about 90% of those with spots, will turn out not to have cancer. I.e. only 2 in every 100 screened will have cancer.</td>
</tr>
<tr>
<td>• <strong>Overdiagnosis</strong>- The screening test may pick up slow growing cancers that you may end up having tests or treatments, when they may be so slow growing that without the screening tests you may have gone on another 15-20 years without knowing there was cancer, and it may not cause symptoms.</td>
</tr>
<tr>
<td>• Very rarely, the test may <strong>miss small cancers</strong></td>
</tr>
</tbody>
</table>
Figure S3. The frequency histograms of the adapted DCS by group