# **Original Article**



# Short-term psychosocial outcomes of adding a non-contrast abdominal computed tomography (CT) scan to the thoracic CT within lung cancer screening

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## **Objectives**

To evaluate psychological, social, and financial outcomes amongst individuals undergoing a non-contrast abdominal computed tomography (CT) scan to screen for kidney cancer and other abdominal malignancies alongside the thoracic CT within lung cancer screening.

## **Subjects and Methods**

The Yorkshire Kidney Screening Trial (YKST) is a feasibility study of adding a non-contrast abdominal CT scan to the thoracic CT within lung cancer screening. A total of 500 participants within the YKST, comprising all who had an abnormal CT scan and a random sample of one-third of those with a normal scan between 14/03/2022 and 24/08/2022 were sent a questionnaire at 3 and 6 months. Outcomes included the Psychological Consequences Questionnaire (PCQ), the short-form of the Spielberger State–Trait Anxiety Inventory, and the EuroQoL five Dimensions five Levels scale (EQ-5D-5L). Data were analysed using regression adjusting for participant age, sex, socioeconomic status, education, baseline quality of life (EQ-5D-5L), and ethnicity.

## Results

A total of 380 (76%) participants returned questionnaires at 3 months and 328 (66%) at 6 months. There was no difference in any outcomes between participants with a normal scan and those with abnormal scans requiring no further action. Individuals requiring initial further investigations or referral had higher scores on the negative PCQ than those with normal scans at 3 months (standardised mean difference 0.28 sD, 95% confidence interval 0.01–0.54; P = 0.044). The difference was greater in those with anxiety or depression at baseline. No differences were seen at 6 months.

## Conclusion

Screening for kidney cancer and other abdominal malignancies using abdominal CT alongside the thoracic CT within lung cancer screening is unlikely to cause significant lasting psychosocial or financial harm to participants with incidental findings.

## **Keywords**

abdominal CT, kidney cancer, psychosocial harms, screening, anxiety

## Introduction

Screening for lung cancer using thoracic CT is beginning to be introduced in many countries. Using abdominal CT scanning to screen for kidney cancer and other abdominal pathology has been proposed as a means of identifying kidney and abdominal cancers at earlier stages of disease. The Yorkshire Kidney Screening Trial (YKST) is a feasibility study of adding a non-contrast abdominal CT scan to a low-dose thoracic CT scan in a population at risk of lung cancer [1].

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Central to the assessment of potential population screening programmes is ensuring that the benefit of screening for the small number in whom disease is detected earlier, outweighs any harm caused to the whole screened population [2]. Measuring the potential harms associated with non-contrast abdominal screening CT scans is therefore crucial when evaluating the feasibility and design of future screening trials incorporating abdominal CT [3,4].

There are a number of ways in which screening can cause harm [4–6]. These include: physical harm, resulting from both the screening test and/or follow-up procedures; psychological harm, including increases in anxiety or worry related to screening test results; treatment burden, including from subsequent invasive procedures and overdiagnosis; financial costs associated with travel and time off work to attend appointments and potential loss of earnings; social harm, resulting from social stigma or missing out on other activities; and dissatisfaction or lack of trust with healthcare.

Understanding and quantifying these potential harms amongst individuals with incidental findings is particularly important when considering potential new screening programmes for relatively uncommon conditions, such as kidney cancer, as a small harm to many participants may outweigh a large benefit to a small number of individuals. Potential physical harms and treatment burden are being captured for the entire study population within the YKST. This study aimed to evaluate psychological, social, and financial outcomes, and potential distrust of healthcare amongst a sub-group of participants.

### **Subjects and Methods**

Design

A longitudinal survey.

#### Participants and Recruitment

Participants were recruited from the YKST [1]. Participants for the YKST are recruited from the Yorkshire Lung Screening Trial (YLST) as they attend their second YLST study visit [7]. Participants who consent to take part in the YKST underwent a non-contrast abdominal CT scan in addition to the low-dose thoracic CT scan included within the YLST.

Those with normal abdominal scans received a letter within 4 weeks of the scan informing them that their scan was normal (Fig. 1, Group 1). All abnormal scans were reviewed in a weekly screening review meeting. Following that meeting, participants received a letter saying either: something had been found on the abdominal CT, but no further action is required (abnormal scan – no action required at screening review meeting, Group 2); or something had been found and

further investigations or a referral had been recommended by the clinical team (abnormal scan – needs further action at screening review meeting, Group 3). Where required, referrals to clinical specialities were made by the study team. From that point onwards participants were managed in line with usual clinical care. At 3 months all those with a normal scan or abnormal scan requiring no further action would have received the scan result. Those with an abnormal scan requiring further action would have all been referred to the relevant clinical speciality. Some may also have attended clinic appointments and/or had further investigations and been given a diagnosis and management options. The medical records of all participants with an abnormal scan requiring further action from the screening review meeting were reviewed by the study team at 6 months. By 6 months all participants had completed any necessary further investigations and received a diagnosis and management plan. Participants were classified at that point as either: abnormal scan - no further action (Group 3a); abnormal scan surveillance on-going (Group 3b); or abnormal scan treatment/surgery (Group 3c).

All participants who had an abnormal CT scan report between 14/03/2022 and 24/08/2022 and random sample of one third of those with a normal scan over the same period were invited to take part. Recruitment finished when 500 participants had been invited.

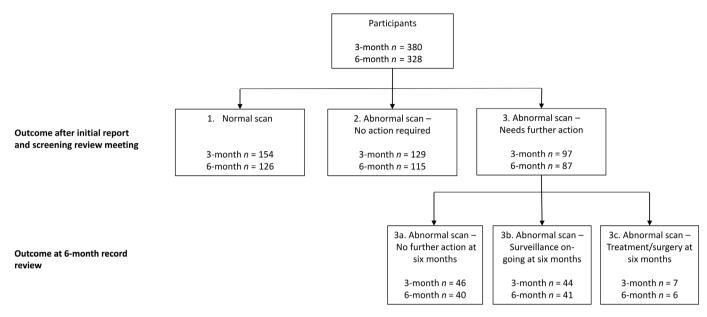
#### Data Collection

Data were collected via postal questionnaires at 3 and 6 months after the abdominal CT scan. Participants had the option to complete an on-line version of the questionnaire hosted on Qualtrics.

#### Measures

The questionnaires (Files \$1,\$2) included measures covering the impact of having the additional abdominal CT scan on the four key potential harms of screening. Validated measures were chosen where possible. The psychological and social impact was measured using the Psychological Consequences Questionnaire (PCQ) [8]. This is designed specifically to measure both the positive (positive PCQ) and negative (negative PCQ) psychological consequences. Anxiety was measured using the short form of the Spielberger State-Trait Anxiety Inventory [9] and health-related quality of life using the EuroQoL five Dimensions five Levels scale (EQ-5D-5L) and a single question asking how participants would rate their general health now compared to before they were invited to take part in the YKST. The financial consequences of having the scan were measured using five questions from a previous study [10] and trust with healthcare assessed using the abbreviated measure to assess trust in the medical profession [11].

#### Fig. 1 Categorisation of participant outcomes after the initial screening review meeting and at 6 months following record review.



Sociodemographic information (age, sex, socioeconomic status [index of multiple deprivation, IMD], education level, and ethnicity) and baseline (at the time of the scan) quality of life (EQ-5D-5L) were extracted from data already collected at entry to the YLST.

#### Consent

All participants provided written informed consent at the time of recruitment into the YKST. The participant information sheet included mention of this sub-study and return, or completion of the questionnaire was considered implied consent. A reminder questionnaire was sent 2 weeks after each questionnaire to all participants and the 6-month questionnaire sent to all participants.

#### Analysis

Descriptive statistics were used to summarise baseline characteristics and outcome measures amongst those invited and those who responded at both time points. Differences between those invited and those who responded were assessed using chi-squared tests.

At 3 months, we compared those with a normal scan to those with an abnormal scan requiring no further action (Group 1 vs Group 2) (Fig. 1) and those with an abnormal scan requiring further action (Group 1 vs Group 3). At 6 months, we compared those with a normal scan to those with abnormal scans requiring no further action either at the screening review meeting or at the 6-month review (Group 1 vs Group 2 and Group 3a) and those with abnormal scans requiring on-going surveillance at 6 months (Group 1 vs Group 3b). At 6 months, we additionally compared those with a normal scan with those who had an abnormal scan, which required further investigation initially at the screening review meeting but no intervention and no long-term follow-up or surveillance by 6 months (Group 1 vs Group 3a).

For continuous outcomes, we used multivariable linear regression to derive estimates of the differences in means between the groups and corresponding confidence intervals. In these analyses the outcome of interest was the dependent variable and the groups included as a categorical independent variable. In the absence of an agreed minimum clinically important difference, the size of any differences was interpreted by comparison with the SD of all participants at that time point, with the criteria for clinically relevant difference being 0.5 sD [12]. We used linear regression with untransformed outcomes despite anticipating skewed distributions for many of the outcomes for comparability with other studies in this field and because no transformations would make the residuals normally distributed but would give estimates that no longer have a meaningful interpretation. For categorical outcomes we used logistic regression and derived estimates of the odds ratio and 95% CIs. All models included age (years), sex (male/female), education level (no qualifications, left school aged  $\leq$ 15 years/some qualifications), baseline EQ-5D, ethnicity (White/non-White) and socioeconomic status (IMD quintile).

For all analyses using the EQ-5D-5L, we used the visual analogue scale. This was chosen over the index value as we were interested in participants' perspectives of their health, not the societal perspective. The financial impact to the individual of having the abdominal scan and the participants' general health compared with before the study were analysed

#### Table 1 Characteristics of participants.

Characteristic	Invited	Completed 3-month questionnaire	Ρ	Completed 6-month questionnaire	P
N (%)	500	380 (76)		328 (66)	
Age, years, mean (sp)	69.03 (6.9)	69.66 (6.6)	0.008	70.05 (6.6)	0.001
55–64, n (%)	154 (31)	104 (27)		82 (25)	
65–74, n (%)	244 (49)	189 (50)		171 (52)	
>75, n (%)	103 (21)	87 (23)		75 (23)	
Sex, n (%)					
Male	311 (62)	241 (63)	0.3	216 (66)	0.02
Female	189 (38)	139 (37)		112 (34)	
Smoking status, <i>n</i> (%)					
Current smoker	112 (22)	74 (20)	0.005	58 (18)	<0.001
Ex-smoker	388 (78)	306 (80)		270 (82)	
Ethnicity, n (%)					
White	486 (97)	371 (98)	0.3	320 (98)	0.5
Other	14 (2.8)	9 (2.4)		8 (2.4)	
IMD quintile, %, <i>n</i> (%)					
1	109 (22)	76 (20)	0.2	60 (18)	0.004
2	85 (17)	62 (16)		48 (15)	
3	88 (18)	67 (18)		60 (18)	
4	107 (21)	83 (22)		76 (23)	
5	111 (22)	92 (24)		84 (26)	
Education, n (%)					
No qualifications, left school aged ≤15 years	283 (57)	208 (54)	0.14	178 (54)	0.15
Some qualifications	217 (43)	172 (45)		150 (46)	
Screening review meeting outcome, n (%)					
Normal scan	196 (39)	154 (41)	0.2	126 (38)	0.47
Abnormal scan – no further action	180 (36)	129 (34)		115 (35)	
Abnormal scan – needs further action	124 (25)	97 (25)		87 (27)	
6-month management outcome, <i>n</i> (%)					
Normal scan	196 (39)	154 (41)	0.3	126 (38)	0.46
Abnormal scan – no further action	241 (48)	175 (46)		155 (47)	
Abnormal scan – needs ongoing surveillance	55 (11)	44 (12)		41 (13)	
Abnormal scan – required treatment/surgery	8 (1.6)	7 (1.8)		6 (1.8)	
Negative beliefs about cancer outcomes	-	3.10 (0.88)		3.07 (0.87)	
Screening attendance amongst eligible, %, n (%)					
Abdominal aortic aneurysm screening	-	64 (32)		55 (31)	
Breast cancer screening	-	115 (83)		86 (77)	
Cervical cancer screening	-	75 (54)		56 (50)	
Bowel cancer screening	-	276 (80)		218 (73)	

Bold values statistically significant at P < 0.05.

as categorical outcomes (any negative financial impact vs no negative financial impact and 'A little worse' or 'Much worse' vs 'The same', 'A little better' or 'Much better').

We performed sensitivity analyses removing participants with abnormal thoracic CT scans and those who required treatment or surgery (Group 3c) from the 3-month analysis. We also performed a pre-specified sub-group analysis for psychosocial harms stratified by those responding 'not anxious or depressed' and those 'slightly/moderately/severely or extremely anxious or depressed' on the EQ-5D at baseline prior to the abdominal scan to explore if those with a pre-existing mental health condition are more vulnerable to psychosocial harms.

Sample Size

The sample size for this study was constrained by the practicalities of the YKST. Based on the final recruited

numbers and baseline mean and sD for the negative PCQ, we had 80% power to detect a difference of 0.35 sD at 3 months and 0.34 sD at 6 months between those with a normal scan and those with an abnormal scan requiring no further action, both smaller than the 0.50 sD used as criterion for a clinically important effect.

## Results

In all, 380/500 (76%) of the participants returned the questionnaire at 3 months and 328 (66%) at 6 months (Table 1). Older YKST participants and ex-smokers were more likely to return the 3-month questionnaire and at 6 months older YKST participants, ex-smokers, men, and those in the least deprived quintile were more likely to respond. There was no evidence of differences in response rates between those with normal and abnormal scans.

Of the 380 participants who completed the 3-month questionnaire, 154 (41%) had a normal scan (Group 1), 129 (34%) had an abnormal scan that required no further action (Group 2), and 97 (26%) had an abnormal scan requiring further action following the screening review meeting (Group 3). The majority of those who had an abnormal scan that required no further action had a renal cyst. The most common findings requiring further action were renal stones, abdominal aortic aneurysms, and adrenal adenomas. There was no evidence of differences in any of the outcomes between those with a normal scan and those with abnormal findings requiring no further action (Fig. 2 and Table S1). Those requiring further investigations or referral to clinics had higher scores on the negative PCQ (indicating more negative psychosocial thoughts) than those with normal scans (difference in means 1.20 [95% CI 0.05–2.35], P = 0.044; standardised mean difference [SMD] 0.28 sp [95% CI 0.01-0.54]). There was no evidence of differences between those groups in any of the other outcomes.

Of the 328 participants who completed the 6-month questionnaire, 126 (38%) had a normal scan (Group 1). Nearly half, 155 (47%) had an abnormal scan requiring no further action either at the screening review meeting or by 6 months (Groups 2 and 3a), of which 40 (12%) had an abnormal scan requiring further action at the screening review meeting but no further action by 6 months (Group 3a), and 41 (13%) had an abnormal scan at the screening review meeting that required on-going surveillance at 6 months (Group 3b). The most common findings in those requiring on-going surveillance were renal stones and abdominal aortic aneurysms. There was no evidence of differences in any of the outcomes between those with a normal scan and any of the groups with abnormal scans, including the sub-group (Group 3a) of those with an abnormal scan with no further action at 6 months that required further action at the screening review meeting (Fig. 3, Fig. S1 and Tables S2,S3).

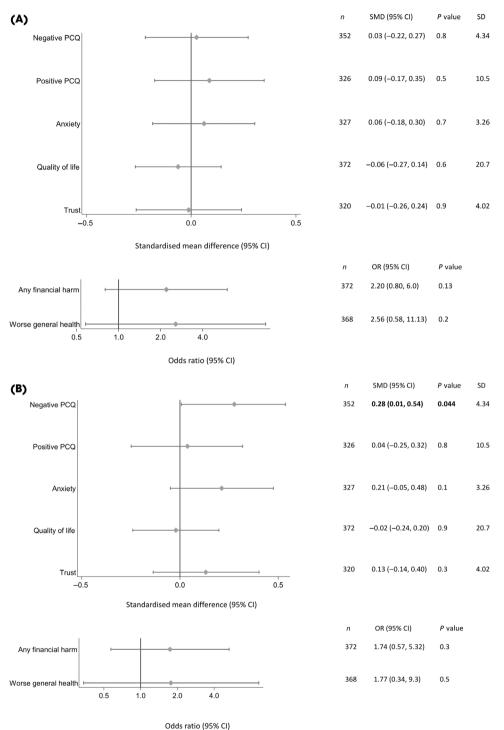
The results from the sensitivity analyses were consistent with the main analysis (Tables S4–S7). Specifically, there were no differences in the overall findings after removing those with an abnormal thoracic scan or after removing those who required treatment or surgery from the 3-month analyses. There was evidence of an interaction between anxiety or depression at baseline and the impact of having an abnormal scan on the negative PCQ at 3 months (P value for interaction 0.019). The difference between those with normal and abnormal scans requiring further action was no longer statistically significant for either group alone once the interaction was taken into account. However, the difference in negative PCQ between those with abnormal scans requiring further action and those with normal scans was greater at 3 months in those with baseline anxiety or depression (SMD 0.69 [95% CI -0.02, 1.41] for those with anxiety or depression at baseline vs 0.18 [95% CI -0.12, 0.48] for those without). No other significant interactions were seen (Tables 58,59).

### Discussion

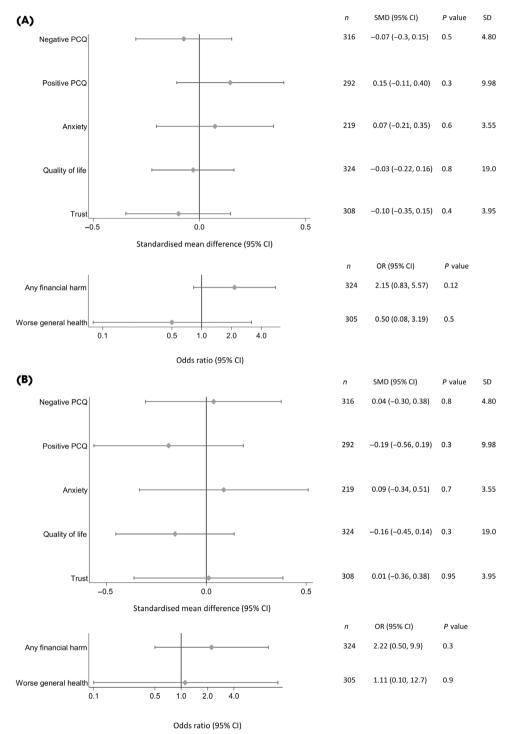
This study suggests that using abdominal CT to screen for kidney cancer and other abdominal malignancies is unlikely to cause significant psychosocial or financial harm to participants with incidental findings. There may be a small initial negative effect on well-being, as indicated by higher negative PCQ scores at 3 months in those with abnormal scans requiring further action or investigations when compared with those with normal scans. This is not accounted for by a negative effect on well-being for those ultimately requiring treatment or surgery and resolves by 6 months. Perhaps most importantly, there was no evidence of differences in any of the outcomes at 6 months between those with a normal scan and those who had an abnormal scan that required further investigation initially but required no intervention and no long-term follow-up or surveillance. These individuals are those of greatest concern within the context of screening programmes as they have been informed of an abnormality that, by virtue of not requiring any treatment, follow-up, or surveillance, being aware of is unlikely to benefit them but they are at risk of harm. Even a small harm to these individuals could potentially outweigh any benefits to those with significant findings amenable to intervention.

This absence of any evidence of significant negative psychological effects at 6 months is consistent with findings from lung cancer screening [13]. Short-term increases in anxiety and cancer distress have also been reported within lung screening trials amongst those with indeterminant scan results [14] or individuals with a positive initial scan who require a repeat scan [15]. Particularly in the context of this study, where many of those with abnormal scans require further investigations to determine the significance of the finding, this short-term effect may be due to uncertainty. This highlights the importance of clear communication up-front and streamlined processes for timely follow-up and further investigation. Our findings also suggest that individuals with a background of anxiety or depression may benefit from additional offers of support or information when informed of any findings.

To our knowledge this is the first study to measure nonphysical harms of abdominal CT scans in the context of screening. Although we used validated scales, our measures of psychosocial harms are, however, generic rather than diseasespecific measures. Cancer-specific measures have been shown to be more sensitive than generic anxiety measures [16]. Consequently, we cannot exclude the possibility that a cancer-specific measure would yield different results. However, we, like others [13] believe that while Fig. 2 Questionnaire outcomes at 3 months in those with: (A) abnormal scans requiring no further action at the screening review meeting and those with normal scans; and (B) abnormal scans requiring further action at the screening review meeting and those with normal scans. OR, odds ratio. Positive values for SMD indicate higher scores in those with abnormal scans compared with those with normal scans and an OR >1 indicates a greater odds of each outcome in those with abnormal scans compared with normal scans.



disease-specific measures are relevant when planning counselling programmes, global measures are more useful for comparisons across groups with different outcomes and when making decisions on the appropriate allocation of healthcare resources. We also did not have baseline values for participants and so cannot exclude that any differences Fig. 3 Questionnaire outcomes at 6 months in those with: (A) abnormal scans requiring no further action at either the screening review meeting or 6-month review and those with normal scans; and (B) abnormal scans on-going surveillance at 6 months and those with normal scans. OR, odds ratio. Positive values for SMD indicate higher scores in those with abnormal scans compared with those with normal scans and an OR>1 indicates a greater odds of each outcome in those with abnormal scans compared with normal scans.



between recipients of different screening results might have existed before screening [17]. While our response rate to the questionnaires was high (76% at 3 months and 66% at 6 months), older participants and ex-smokers were more likely to return the questionnaires. We cannot exclude other factors that may contribute to responder bias. However, importantly, we found no evidence of a difference in response rates from those with normal and abnormal scans. The participants of this study were additionally those already engaged in a lung screening trial and already had experience of receiving thoracic CT scan results. They were also older individuals (mean age 70 years), predominantly men, all smokers, and over half with no educational qualifications. The findings are therefore only directly applicable to this group and may not be generalisable to the general population or those being invited for the first time for an abdominal CT scan. A further limitation is that, while all participants requiring further action had received a diagnosis and management plan by 6 months, some of those in the group requiring further action following the screening review meeting would have had further investigations and been given a diagnosis by the time of the 3-month questionnaire while others may have still be waiting for further care. The participants in the 3-month analysis who required further action were therefore heterogenous both in terms of the severity of the abnormality and stage of the diagnostic pathway. As participants were managed in line with usual clinical care from the point of the screening review meeting onwards, the comparison between those individuals and those with a normal scan does, however, reflect the differences between these groups if such a screening programme were to be introduced. The non-normality of residuals of the continuous outcome measures further means we should interpret the one statistically significant finding in this group with caution.

Overall, this study suggests that screening for kidney cancer and other abdominal malignancies using abdominal CT is unlikely to cause significant non-physical harm to participants with incidental findings in the short term. Given the difficulty in accounting for the costs and benefits and harms associated with incidental findings in screening programmes, these results should provide reassurance that there are no significant individual-level non-physical harms associated with the additional abdominal scan, and therefore only the additional cost needs to be accounted for amongst those with incidental findings. Further trials are now needed to assess the potential benefits to those with clinically important findings.

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## **Disclosure of Interests**

Grant D. Stewart has received educational grants from Pfizer, AstraZeneca, and Intuitive Surgical; consultancy fees from Pfizer, BMS, Merck, EUSA Pharma, and CMR Surgical; travel expenses from BMS and Pfizer; and speaker fees from Pfizer. The other authors have no conflicts of interest to declare.

# **Ethical Approval**

This study was granted approval by the North West – Preston Research Ethics Committee (reference 21/NW/0021).

# Data Availability Statement

Anonymised data are available for access *via* the University of Cambridge data repository (https://www.repository.cam.ac. uk). Formal requests for access will be considered via a data-sharing agreement that indicates the criteria for data access and conditions for research use and will incorporate privacy and confidentiality standards to ensure data security (https://doi.org/10.17863/CAM.104612).

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Abbreviations: EQ-5D-5L, EuroQoL five Dimensions five Levels; IMD, index of multiple deprivation; PCQ, Psychological Consequences Questionnaire; SMD, standardised mean difference; YKST, Yorkshire Kidney Screening Trial; YLST, Yorkshire Lung Screening Trial.

## **Supporting Information**

Additional Supporting Information may be found in the online version of this article:

**Fig. S1.** Questionnaire outcomes at 6 months in those with abnormal scans requiring further action at the screening review meeting but then no further action at the 6-month review and those with normal scans.

File S1. Participant 3-month questionnaire.

File S2. Participant 6-month questionnaire.

 Table S1. Questionnaire outcomes at 3 months compared

 between groups based on the initial screening review meeting

 outcome.

**Table S2.** Questionnaire outcomes at 6 months comparedbetween groups based on the 6-month management outcome.

**Table S3.** Questionnaire outcomes at 6 months compared between those with normal scans and those requiring further action at the initial screening review meeting but no further action at the 6-month management outcome.

**Table S4.** Questionnaire outcomes at 3 months compared between groups based on the initial screening review meeting outcome amongst those with normal lung CT scans.

**Table S5.** Questionnaire outcomes at 6 months comparedbetween groups based on the 6-month management outcomeamongst those with normal lung CT scans.

**Table S6.** Questionnaire outcomes at 6 months compared between those with normal scans and those requiring further action at the initial screening review meeting but no further action at the 6-month management outcome in those with normal lung CT scans.

**Table S7.** Questionnaire outcomes at 3 months compared between groups based on the initial screening review meeting outcome, excluding those participants who required treatment or surgery.

**Table S8.** Questionnaire outcomes at 3 months compared between groups based on the initial screening review meeting outcome stratified by the presence or absence of anxiety or depression at baseline.

**Table S9.** Questionnaire outcomes at 6 months compared between groups based on the initial screening review meeting outcome stratified by the presence or absence of anxiety or depression at baseline.