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Psychosocial consequences of allocation to lung cancer screening: a randomised controlled trial

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ABSTRACT

Objective: To examine the psychosocial consequences of being allocated to the control group as compared with the screen group in a randomised lung cancer screening trial.

Method: The Danish Lung Cancer Screening Trial, a randomised controlled trial, ran from 2004 to 2010 with the purpose of investigating the benefits and harms of lung cancer screening. The participants in Danish Lung Cancer Screening Trial were randomised to either the control group or the screen group and were asked to complete the questionnaires Consequences Of Screening and Consequences Of Screening in Lung Cancer (COS-LC). The Consequences Of Screening and the COS-LC were used to examine the psychosocial consequences of participating in the study, by comparing the control and the screen groups' responses at the prevalence and at the incidence round.

Results: There was no statistically significant difference in socio-demographic characteristics or smoking habits between the two groups. Responses to the COS-LC collected before the incidence round were statistically significantly different on the scales 'anxiety', 'behaviour', 'dejection', 'self-blame', 'focus on airway symptoms' and 'introvert', with the control group reporting higher negative psychosocial consequences. Furthermore, the participants in both the control and the screen groups exhibited a mean increase in negative psychosocial consequences when their responses from the prevalence round were compared with their responses from the first incidence round.

Conclusions: Participation in a randomised controlled trial on lung cancer screening has negative psychosocial consequences for the apparently healthy participants—both the participants in the screen group and the control group. This negative impact was greatest for the control group.

ARTICLE SUMMARY

Article focus

- What are the psychosocial consequences of being allocated to the control group compared with the screen group in a randomised lung cancer screening trial?

Key messages

- Participation in a randomised controlled trial on lung cancer screening has negative psychosocial consequences for the apparently healthy participants —both the participants in the screen and the control groups.
- The negative psychosocial consequences was greatest for the participants in the control group.

Strengths and limitations of this study

- The study design was a randomised controlled trial.
- The questionnaire used to measure psychosocial consequences is a condition-specific instrument with high content validity and adequate psychometric properties for participants in lung cancer screening.
- The randomised design was disturbed by excluding those with true-positive (lung cancer) and false-positive screening results from the analysis.

INTRODUCTION

Screening for cancer is a double-edged sword.[1 2] It has the potential of resulting in beneficial effects, in some cases of early detection leading to better prognosis and less aggressive treatment. However, cancer screening also has the potentially harmful effect of detecting inconsequential cancer too early, which leads to overdiagnosis and overtreatment.[3] Furthermore, healthy screening participants may experience distress due to false-positive findings.[4–6]

Several aspects have been thoroughly examined within mammographic screening. Two studies reported that receiving a normal screen result might influence psychological well-being because women with normal findings, participating in breast cancer screening programmes, found this reassuring.[7 8] In addition, a recent study indicated that at the population level, women perceived breast screening as a reassuring and preventive

initiative and/or perceived a lack of the option for screening as insecure.[9] Moreover, women overestimated the beneficial effects and underestimated the harmful effects of screening mammography.[7 10] Important sources of information for the population about the benefits and harms of breast screening appear to be the media, together with family and friends.[11] A systematic review on scientific articles about breast cancer screening concluded that these articles tend to emphasise the benefits of screening over the harms.[12]

As screening is directed at apparently healthy individuals rather than patients, there is a particular ethical responsibility to ensure that participation in screening programmes is beneficial. During the last decades, there has been a rise in the implementation of cancer screening programmes in anticipation of benefits from the early diagnosis of cancer. Particularly in relation to lung cancer, which is now the leading cause of death among cancers,[13] there is a widespread interest in clarifying the benefits and harms of screening.[14–16] Previous non-randomised trials involving lung cancer screening with spiral CT scanning have indicated that lung cancer screening may lead to harm in the form of overdiagnosis of inconsequential lung cancer.[17 18]

The efficacy of CT screening in reducing lung cancer mortality is being tested in five randomised controlled trials: one from the USA[19] and four European trials,[20–23] including the Danish Lung Cancer Screening Trial (DLCST).[22] The trial from the USA reported a 20% reduction in lung cancer mortality.[19]

Lay people seem to perceive cancer screening as predominantly beneficial and something that increases our safety and health. Comments from participants in the DLCST revealed that many of them think of the study as an ordinary screening programme rather than a scientific trial.[24] In general, studies on healthy persons' experience of participating in the control group are sparse. Cancer patients participating in psychological intervention research reported disappointment at having been randomised to the control group.[25] Other studies registered that subjects in the control group were more inclined to gain access elsewhere to the assistance they had hoped to obtain by joining the trial.[26 27] One study concerning apparently healthy smokers' experience of being allocated to the control group in a smoking cessation trial concluded that they were disappointed at being assigned to their group and had a higher dropout rate than subjects in the intervention group.[28] This could lead to the hypothesis that healthy individuals who are participating in a lung cancer screening trial and who are randomised to the control group will feel more worried and insecure.

Therefore, the objective of this study was to examine the psychosocial consequences of being allocated to the control group compared with the screen group in a randomised lung cancer screening trial.

MATERIALS AND METHODS

Our a priori hypothesis of this study was that being randomised to the control group in a lung cancer screening trial carries negative psychosocial consequences.

The DLCST was carried out from 2004 to 2010 and included 4104 participants, who were randomised to either annually low-dose CT scanning (screen group) or to the control group, whose members were not offered CT scanning.[22] Socio-demographic characteristics were collected at the prevalence round. In order to examine the psychosocial consequences of participating in the DLCST, all the participants were asked to complete the questionnaires Consequences Of Screening (COS) and Consequences Of Screening in Lung Cancer (COS-LC).[22] Further details about the DLCST can be found in the article regarding the prevalence round.[22]

The questionnaire COS was completed prior to the randomisation and before the first screening round. In the following incidence screening rounds, the participants were asked to complete the COS-LC annually. Thus, when completing the COS, none of the 4104 participants knew whether or not they were to be screened. In contrast, the participants were all aware of their randomisation status when they were asked to complete COS-LC the following years. Only the responses from the prevalence round and the first incidence round were analysed in the present study.

A longitudinal analysis was carried out by comparing the responses collected with the COS before the prevalence round with the responses collected with the COS-LC before the first incidence round (figure 1). In the analysis of the screen group, only those having normal screening results were included and those with true-positive and false-positive screening results were excluded. Hence, the development of psychosocial consequences after 1 year of participation in the trial was emphasised. Furthermore, cross-sectional analysis was conducted comparing the COS responses from the control group with the COS responses from the screen group, all responses having been collected before randomisation (figure 1). In addition, a cross-sectional analysis was conducted using data collected with the COS-LC before the first incidence round. In this latter analysis, the responses from the control group were compared with the responses from those in the screen group who had a normal CT scan result in the prevalence round (figure 1).

Questionnaires

The COS-LC is a multidimensional questionnaire measuring psychosocial consequences in lung cancer screening. The COS-LC has high content validity and adequate psychometric properties, statistically validated with the Partial Credit Rasch model for polytomous items.[24] The content of the COS-LC was developed on the basis of the questionnaire Consequences Of Screening in Breast Cancer: a condition-specific instrument measuring psychosocial consequences of screening mammography.[24 29] The COS is the common core questionnaire of the COS-LC and the Consequences Of Screening in Breast Cancer, and the COS has shown to

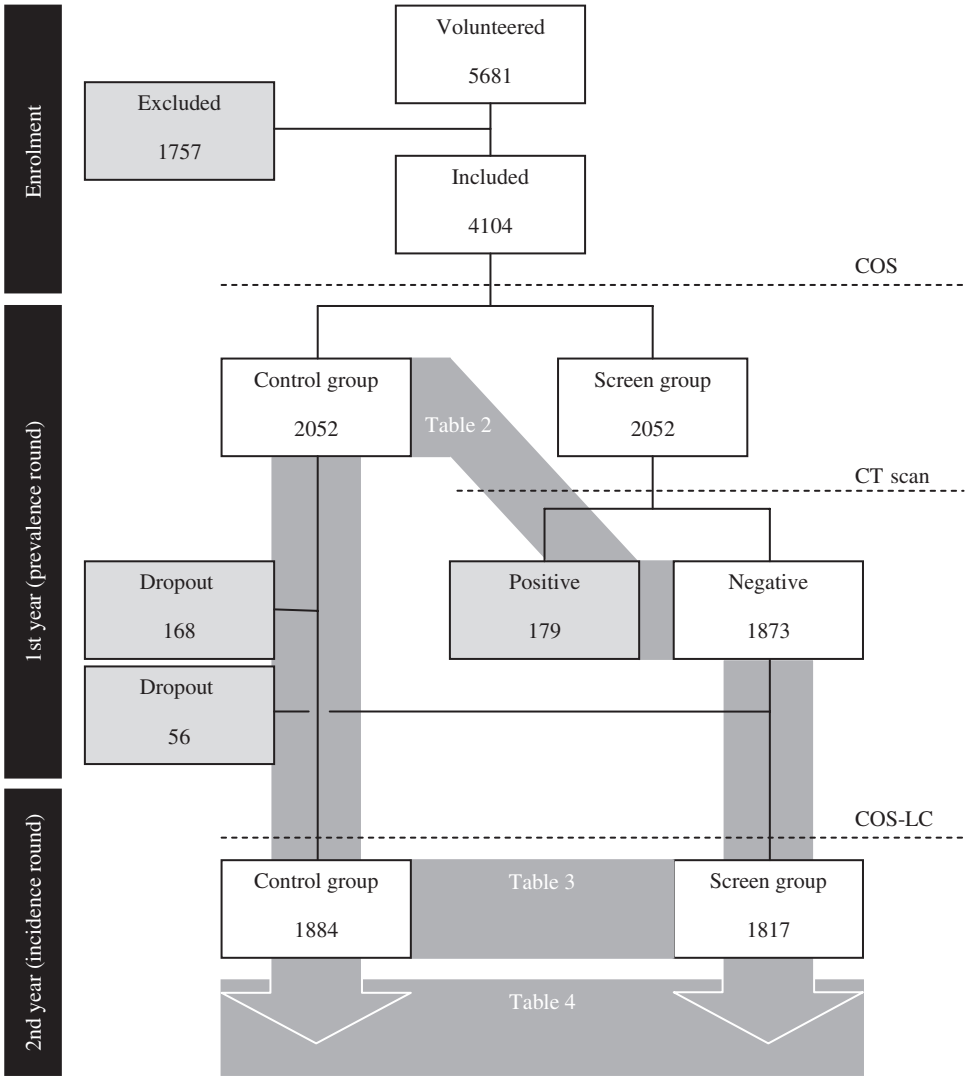

Figure 1 The recruitment, the prevalence round and the first incidence round in the Danish Lung Cancer Screening Trial.

be relevant for persons participating in both breast and lung cancer screening programmes.[24 29]

The COS and the COS-LC are multidimensional instruments consisting of two parts.[24 29] Part I of the COS-LC is measuring the psychosocial aspects relevant for potential screening participants and can be used before the potential participants are invited to lung screening, at invitation to screening, at screening and after screening.[24] In contrast, part II of the COS-LC is only applicable for participants after a final diagnosis: normal, false-positive and true-positive screening results.[24] This part is related to the long-term psychosocial consequences of cancer screening itself and is thereby only applicable to the screen group.[24 29] Therefore, only part I of the COS and the COS-LC, respectively, was used in the present study.

Part I of the COS encompasses four scales and two single items: 'anxiety', 'sense of dejection' and 'negative impact on behaviour and sleep' plus the items 'busy to take mind of things' and 'less interest in sex'. These four scales and two single items are also included in part I of COS-LC. In addition, part I of the COS-LC encompasses five additional lung cancer screening-specific scales: 'focus on airway symptoms', 'introvert', 'stigmatisation', 'harm of smoking' and 'self-blame'. The two single items and all the items in the nine psychosocial scales have four response categories: 'not at all', 'a bit', 'quite a bit' and 'a lot' scored 0, 1, 2 or 3, respectively. The higher the score of the outcome, the more negative psychosocial consequences the person has experienced.

Furthermore, the participants were asked to complete a single item about their self-rated health with five response categories going from very good health to very poor health with a score range from 0 to 4.

Statistics

Socio-demographic characteristics, smoking habits and psychosocial consequences of screening at the prevalence round and the first incidence round, respectively, were compared between the screen group and the control group either with t test (for interval scale variables) or χ^2 test (for categorical variables). Specifically, the COS and the COS-LC scales representing the dimensions of psychosocial consequences were viewed as interval scale variables and tested with t tests. The different developments in the responses to the COS

scales from the prevalence round to the first incidence round between the control and the screen groups were analysed in a linear regression model on the longitudinal COS data, using generalised estimated equations methods to account for repeated measurement on the same individual. From this model, t tests were derived to test whether these developments were different from zero for each randomisation group and different from each other between randomisation groups. The level of significance was $p<0.05$.

Ethical approval

The DLCST was approved by the Ethical Committee of Copenhagen County on 31 January 2003 and funded in full by the Danish Ministry of Interior and Health on 23 June 2004. Approval of data management in the trial was obtained from the Danish Data Protection Agency on 11 February 2005. The trial is registered in Clinical Trials.gov Protocol Registration System (identification no. NCT00496977).

RESULTS

Of the 4104 participants, 179 had a positive CT scan in the first round of screening (figure 1). Subsequent examinations concluded that 17 had lung cancer and 162 had a false-positive screening result.[22] The 179 participants were excluded from this specific study because abnormal CT scans have previously been shown to result in negative psychosocial consequences with the possibility of distorting the analysis.[24]

The screen group and the control group were compared regarding socio-demographic characteristics and smoking habits, to ensure that no systematic differences could be found (table 1).

There was no statistically significant difference in relation to gender, age, social group, education, employment, region of residence, living alone or smoking habits.

The comparison of the psychosocial aspects between the participants in the control group and the participants in the screen group with negative results measured with the COS before the prevalence round are listed in table 2.

After controlling for multiple testing, none of the COS scales or single items demonstrate any statistically significant difference between the control group and the screen group. The control group reported higher psychosocial aspects on all scales compared with the screen group. It is worth noting that randomisation had not yet been done at this stage.

One year later, at the incidence round, the same individuals completed the COS-LC (table 3).

Table 3 illustrates the cross-sectional analyses between the two groups at the incidence round. A statistically significant ($p<0.0001$) greater number of participants in the screen group showed up at the first incidence screening round (97.0%) compared with participants from the control group (91.8%)

The number of participants completing COS and COS-LC had fallen when comparing the prevalence and the incidence round.

Notable was the statistically significant difference between the two groups' responses on the scales: 'anxiety', 'behaviour', 'dejection', 'self-blame', 'focus on airway symptoms' and 'introvert'. There was no statistically significant difference in the scales and single items: 'sleep', 'stigmatisation', 'harm of smoking', 'busy to take mind off things', 'less interest in sex' and 'self-rated health'.

Table 4 shows the results from the statistical analysis of the longitudinal development in the responses on COS and COS-LC from the prevalence round to the incidence round.

As demonstrated in table 4, the participants in both the control and the screen groups had a mean increase in negative psychosocial consequences because there was a statistically significant difference between the prevalence and incidence rounds in the scales: 'behaviour', 'dejection', 'sleep', 'busy to take mind off things' and 'less interest in sex'. The mean increase in psychosocial consequences was also compared between participants in the control and the screen groups and no statistically significant differences were revealed.

DISCUSSION

This study demonstrated that participation in a randomised controlled trial on lung cancer screening had negative psychosocial consequences for the apparently healthy participants—both the participants in the screen and the control groups. This negative impact was greatest for the participants in the control group.

The randomisation in the DLCST was successful since there was no statistically significant difference between the screen group and the control group in relation to socio-demographic characteristics and smoking habits. However, there was a statistically insignificant tendency in all scales and items in the COS, indicating that the participants in the control group experienced more negative psychosocial consequences than those in the screen group. This was surprising since no differences were seen in the socio-demographic characteristics and the smoking habits and because all the participants in the DLCST completed the COS before allocation to either the screen group or the control group. The scales and single items in the COS have previously been shown to be positively correlated in a confirmatory factor analysis.[30] Due to this positive correlation, it would be expected that a high mean score in one of the COS scales would also result in high mean scores in the remaining COS scales. This could explain the non-significant tendency of higher negative psychosocial mean scores in the control group compared with the mean scores in the screen group.

Another hypothetical cause of higher negative psychosocial mean scores in the control group could be that some of the participants had knowledge about their allocation before completing the COS. Therefore, we have scrutinised the COS responses from the prevalence round chronologically to see if any time periods were

Table 1 Comparisons of socio-demographic characteristics and smoking habits between the participants in the control group and the participants in the screen group with normal results in the prevalence round

Categories	n/n	Control group, n=2052 n (%)/mean (SD)	Screen group, n=1873 n (%)/mean (SD)	p Value*
Socio-demographics				
Gender				
Male	2052/1873	1120 (54.6)	1073 (57.3)	0.088
Female		932 (45.4)	800 (42.7)	
Age† (mean)				
	2052/1873	57.3 (4.8)	57.2 (4.8)	0.6433
Social group‡				
I	2040/1866	141 (6.9)	144 (7.7)	0.8508
II		410 (20.1)	370 (19.8)	
III		378 (18.5)	341 (18.3)	
IV		552 (27.1)	494 (26.5)	
V		282 (13.8)	242 (13.0)	
Employed, social group uncertain		168 (8.2)	171 (9.2)	
Outside the labour market		109 (5.3)	104 (5.6)	
School education				
7–9 Grade	2047/1870	716 (35.0)	633 (33.9)	0.1961
10 Grade		790 (38.6)	705 (37.7)	
Upper secondary school leaving exam		532 (26.0)	515 (27.5)	
Other		9 (0.4)	17 (0.9)	
Vocational education				
None	2048/1868	201 (9.8)	172 (9.2)	0.2943
Semi-skilled worker		27 (1.3)	19 (1.0)	
Vocational training		725 (35.4)	643 (34.4)	
Short further education		194 (9.5)	183 (9.8)	
Middle range training		539 (26.3)	463 (24.8)	
Long further education		225 (11.0)	240 (12.9)	
Other		137 (6.7)	148 (7.9)	
Employment status				
Employed	2046/1868	1325 (64.8)	1264 (67.7)	0.1338
Studying		12 (0.6)	8 (0.4)	
Job seeking		104 (5.1)	103 (5.5)	
Retired		605 (29.6)	493 (26.4)	
Region of habitat				
Capital region	2045/1862	1654 (80.9)	1493 (80.2)	0.8755
Region Zealand		349 (17.1)	329 (17.7)	
Region of Southern Denmark		28 (1.4)	30 (1.6)	
Central Denmark Region		11 (0.5)	7 (0.4)	
North Denmark Region		3 (0.2)	3 (0.2)	
Living alone				
No	2035/1865	1453 (71.4)	1331 (71.4)	0.9817
Yes		582 (28.6)	534 (28.6)	
Smoking habits				
Smoking status				
Current smoker	2052/1873	1579 (77.0)	1411 (75.3)	0.2353
Former smoker		473 (23.0)	462 (24.7)	
Smoking history§ (mean)				
	2048/1872	35.9 (13.4)	36.3 (13.4)	0.3229
Motivation for smoking cessation				
Very strong	2022/1856	224 (11.1)	174 (9.4)	0.3780
Strong		503 (24.9)	485 (26.1)	
Weak		492 (24.3)	437 (23.6)	
Very weak		159 (7.9)	133 (7.2)	
No wish to quit		171 (8.5)	165 (8.9)	
Current non-smoker		473 (23.4)	462 (24.9)	

*p Value from a χ^2 test (categorical variables) or a t test (continuous variables).
†Age in years per 2 January 2010.
‡According to current or last job (when retired).
§Pack-years (cigarettes per day/20× smoking years).

Table 2 Comparisons at the prevalence round of the COS outcomes between the groups of the DLCST study

	Range of values	n/n	Control group, n=2052 Mean (SD)	Screen group, n=1873 Mean (SD)	p Value† ‡
COS scales					
Anxiety	0–18	1995/1823	1.61 (2.31)	1.48 (2.20)	0.0748
Behaviour	0–21	2018/1838	0.84 (2.08)	0.72 (1.78)	0.0456
Dejection	0–18	2024/1841	1.37 (2.17)	1.21 (1.99)	0.0254
Sleep	0–12	2019/1849	0.70 (1.72)	0.63 (1.56)	0.1957
Single items					
Busy to take mind of things	0–3	2036/1854	0.23 (0.62)	0.21 (0.58)	0.3066
Less interest in sex	0–3	2035/1858	0.48 (1.17)	0.45 (1.13)	0.2873
Self-rated health	0–4	2042/1865	0.97 (0.77)	0.95 (0.74)	0.5977

†p Value from a t test.
‡Controlling for multiple testing by setting the false discovery rate to maximum 5% with the method of Benjamini–Hochberg, the significance level was taken to be p<0.0071.
COS, Consequences Of Screening; DLCST, Danish Lung Cancer Screening Trial.

different from others. Thereby, we aimed to reveal a period of time in the prevalence round where participants' responses deviated, indicating a personnel bias. However, the COS responses in the two groups were found to be randomly distributed throughout the whole inclusion period.

A third explanation could be the exclusion of the 179 screen-positive participants since this violates the intention-to-treat principle. These participants may have had symptoms of lung cancer already and thereby concerns about their health and higher COS responses, leaving the included screen-negative participants with artificially lower COS scores than the control participants. However, an additional analysis including the 179 screen-positive individuals (results not shown) gave results similar to those in table 2.

One year later, at the incidence round, 222 had dropped out of the study, 54 from the screen group and 168 from the control group. Hence, the dropout rate was higher in the control group than in the screen group, which might be caused by disappointment at being allocated to the control group. Previous studies have registered disappointment of being randomised to the control group because participants joined the trial as they felt they needed the intervention offered to the intervention group.[28 31] The explanation could also be

Table 3 Comparisons at the incidence round of the Consequences Of Screening in Lung Cancer (COS-LC) questionnaire outcomes between the participants in the control group and the participants with normal screening results in the screen group of the DLCST study

	Range of values	n/n	Control group, n=1884 Mean (SD)	Screen group, n=1817 Mean (SD)	p Value† ‡
COS scales					
Anxiety	0–18	1437/1749	1.71 (2.79)	1.50 (2.52)	0.0263*
Behaviour	0–21	1426/1741	2.02 (3.04)	1.76 (2.85)	0.0129*
Dejection	0–18	1451/1760	1.88 (2.98)	1.61 (2.71)	0.0085*
Sleep	0–12	1454/1765	1.79 (2.57)	1.64 (2.47)	0.1032
COS-LC scales					
Self-blame	0–15	1468/1756	2.62 (3.75)	2.32 (3.53)	0.0202*
Focus on (airway) symptoms	0–24	1446/1749	3.80 (3.93)	3.30 (3.58)	0.0002*
Stigmatisation	0–12	1458/1760	1.25 (2.41)	1.16 (2.26)	0.2821
Introvert	0–18	1453/1763	2.22 (2.96)	1.89 (1.76)	0.0007*
Harm of smoking	0–6	1473/1785	1.63 (1.75)	1.53 (1.66)	0.0880
Anxiety+§	0–21	1431/1743	1.77 (2.93)	1.55 (2.67)	0.0238*
Single items					
Busy to take mind off things	0–3	1456/1758	0.30 (0.66)	0.27 (0.63)	0.0799
Less interest in sex	0–3	1465/1774	0.66 (1.29)	0.66 (1.33)	0.9221
Self-rated health	0–4	1476/1780	0.97 (0.80)	0.93 (0.80)	0.1592

†p Value from a t test.
‡Controlling for multiple testing by setting the false discovery rate to maximum 5% with the method of Benjamini–Hochberg, the significance level was taken to be p<0.0269 (indicated by*).
§The COS anxiety scale with an extra item: shocked.
COS, Consequences Of Screening; DLCST, Danish Lung Cancer Screening Trial.

Table 4 Mean increase from the prevalence round to the incidence round in the Consequences Of Screening in Lung Cancer (COS-LC) questionnaire outcomes in the participants in the control group and the participants with negative screening results in the screening group of the DLCST study

		Control group, n=2052		Screen group, n=1873		
	Range of values	Mean increase (SE)	p Value† ‡	Mean increase (SE)	p Value‡ §	p Value¶
COS scales						
Anxiety	0–18	0.1275 (0.0689)	0.0644	0.0299 (0.0657)	0.6493	0.3056
Behaviour	0–21	1.1962 (0.0770)	<0.0001*	1.0535 (0.0690)	<0.0001*	0.1681
Dejection	0–18	0.5371 (0.0750)	<0.0001*	0.4076 (0.0686)	<0.0001*	0.2031
Sleep	0–12	1.1025 (0.0651)	<0.0001*	1.0271 (0.0585)	<0.0001*	0.3887
Single items						
Busy to take mind off things	0–3	0.0760 (0.0189)	<0.0001*	0.0539 (0.0173)	0.0019*	0.3903
Less interest in sex	0–3	0.1811 (0.0348)	<0.0001*	0.2253 (0.0318)	<0.0001*	0.3490
Self-rated health	0–4	0.0196 (0.0185)	0.2898	−0.0270 (0.0165)	0.1018	0.0605

†p Value from a t test pertaining to the increase in the control group.
‡Controlling for multiple testing by setting the false discovery rate to maximum 5% with the method of Benjamini–Hochberg, the significance level was taken to be p<0.0238 (indicated by*).
§p Value from a t test pertaining to the increase in the screen group.
¶p Value from a t test pertaining to the difference in increase between the control and the screen groups.
COS, Consequences Of Screening; DLCST, Danish Lung Cancer Screening Trial.

that the participants in the screen group felt more obliged to participate in follow-up assessments, whereas participants in the control group felt less obliged to do so.[32] In a mammographic study, it was found that those who dropped out were less able to cope with anxiety and had higher levels of fatalism.[33] Another cohort study in urologic disease concluded that men who dropped out were more likely to have moderate/severe symptoms and lower socioeconomic status.[34]

If the participants who dropped out in the DLCST were accordingly different when compared with those who continued to attend the screening trial, this might have underestimated the differences in the negative psychosocial consequences between the control group and the screen group.

A substantial participation bias was identified in a study where the 4104 participants in the DLCST were comparable with current and former smokers in the general population.[35] Generally, the DLCST participants had a different socio-demographic make-up, higher socioeconomic status and reported fewer negative psychosocial aspects compared with the ordinary heavy smokers from the general population.[35] This might also have biased the results in the present study. In addition, the participants who dropped out in the first incidence round might have been persons with more morbidity and lower socioeconomic status. Therefore, the negative psychosocial consequences of the randomisation to the control group might have been even greater in a representative group of former and current smokers.

The present study established a statistically significant difference between the control group and the screen group regarding experiences of participating in the screening trial. The results of these analyses seemed to confirm our a priori hypothesis that healthy individuals who were participating in a lung cancer screening trial and who were randomised to the control group would gain feelings of worry and insecurity.

The level of negative psychosocial consequences was higher in the control group compared with the screen group. However, responses collected before the prevalence round indicated a non-significant tendency that individuals in the control group experienced more negative psychosocial consequences, which might have influenced the statistically significant differences found in data collected before the incidence round.

The longitudinal analyses revealed that both the control group and the screen group reported statistically significantly more negative psychosocial consequences when their responses before the prevalence round were compared with their responses 1 year later. This increasing negative psychosocial impact during 1 year of participation was not statistically significantly different when the two groups were compared. Nevertheless, the control group reported a higher increase in negative psychosocial scores during this year on all COS scales. This indicated that the participants in the control group experienced more negative psychosocial consequences in the first year of participation in the DLCST compared with those in the screen group. Negative psychosocial consequences were likewise reported from women not having the option to participate in an implemented breast cancer screening programme.[9] Conversely, a CT scan with a negative result could have the benefit of reassuring the participants that they were healthy. In cervical cancer screening, women participated to acquire feelings of confidence and security and they returned to regular screening to confirm that they were healthy.[36] However, the present study demonstrated that participants in the screen group who had a normal CT scan also experienced negative psychosocial aspects.

It is worth noticing that the control group in this trial completed the COS and the COS-LC annually and performed spirometry after completing the COS and the COS-LC. This intervention could be the cause of the reported negative psychosocial consequences in the control group. The intervention might have made the participants anxious because their lung function might have dropped as a well-known complication of smoking. In contrast to the screen group, they did not obtain the knowledge of having a normal CT scan. However, the analyses of COS cannot distinguish the reasons for the reported negative psychosocial consequences.

The COS and COS-LC are condition-specific multidimensional questionnaires where the content of the scales and the items were found highly relevant in focus group interviews with participants from the DLCST.[24] It is well known that condition-specific questionnaires are more sensitive than generic questionnaires.[37] Furthermore, generic questionnaires might lack content validity in a setting of cancer screening.[38] In addition, generic questionnaires can have inadequate psychometric properties when they are used in other settings than they were developed for.[39] This might explain why we have been able to identify that participation in lung cancer screening has negative psychosocial consequences in contrast to the Belgium–Dutch lung cancer screening trial that mostly have used generic Health Related Quality of Life questionnaires.[40 41]

At the first incidence round, statistically significant differences of 0.2–0.7 in the mean scores were identified between the participants in the control group and the participants with normal screening results in the screen group (see table 3). This corresponds to every fifth to every second participant in the control group responding 'a bit' to one item in each scale compared with the response 'not at all' among the same number of participants in the screen group having a normal result. The statistically significant mean increase in scores from the prevalence round to the first incidence round in both the control group and the screen group were from 0.4 to 1.2 (see table 4). This corresponds to a shift in responses from 'not at all' to 'a bit' in one item in each scale for every second participant to all participants. We regard these differences as relevant because none of the persons have experienced a trauma in relation to lung cancer screening programme, for example, diagnosis of lung cancer or a false-positive screening result. We also think that a negative impact illustrated by a change from 'not at all' to 'a bit' in one item in each psychosocial scale for 2000 to 4000 healthy screening participants may well have social significance.

CONCLUSIONS

Participation in a randomised controlled trial on lung cancer screening has negative psychosocial consequences for the apparently healthy participants—both the participants in the screen and the control groups. This negative impact was greatest for the participants in the control group.

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