# **BMJ Open** Surveillance of indeterminate pulmonary nodules detected with CT in a Swedish population-based study (SCAPIS): psychosocial consequences and impact on health-related quality of life – a multicentre prospective crosssectional study

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# ABSTRACT

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**Objectives** To investigate whether surveillance of pulmonary nodules detected with low-dose CT (LDCT) impacted health-related quality of life and psychosocial consequences in the Swedish population-based study, Swedish CArdioPulmonary bioImage Study (SCAPIS). Design A prospective cross-sectional study. Settings and participants This multicentre (five sites) observational study, which included a cohort from SCAPIS, consisted of 632 participants with indeterminate pulmonary nodules detected with LDCT. These participants continued surveillance for up to 36 months, during which lung cancer was not detected (surveillance group). Additionally, 972 participants with a negative pulmonary LDCT scan were included as a control group. Matching criteria were LDCT date (±2 weeks), gender and site. Outcome measures All participants completed a healthrelated quality of life questionnaire (RAND-36) and the Consequences of Screening (COS) questionnaire, an average of 3 years after LDCT was conducted at entry into SCAPIS.

**Results** Participants were 51–70 years old at study commencement. Overall, the two groups did not differ in demographic or psychosocial variables, smoking habits or pulmonary medical history. Individuals from countries other than Sweden and those with low socioeconomic status were less likely to participate (p<0.001). No effects on health-related quality of life were observed via RAND-36. In COS, the surveillance group demonstrated a higher OR for anxiety about lung cancer (OR 3.96, 95% CI 2.35 to 6.66, p<0.001), experiencing a sense of dejection (OR 1.35, 95% CI 1.06 to 1.72, p=0.015) and thoughts about existential values (OR 1.30, 95% CI 1.04 to 1.60, p=0.018).

**Conclusions** Lung surveillance with LDCT contributed to significant experiences of sense of dejection, anxiety about lung cancer and development of thoughts about existential values among participants in the surveillance group compared with the controls. The risk of side effects should

# STRENGTHS AND LIMITATIONS OF THIS STUDY

- $\Rightarrow$  The sample was a population-based cohort for the surveillance group of indeterminate pulmonary nodules detected with low-dose computed tomography (LDCT) and matched controls (LDCT date (±2 weeks), gender and site) of negative LDCT.
- ⇒ The study investigated the risk of potential side effects after surveillance of pulmonary nodules was completed; that is, among people without a lung cancer diagnosis.
- ⇒ Participants from a country other than Sweden, those who lived alone and those with low economic status, were less likely to participate in the study.
- ⇒ The analysis of non-participant data demonstrated no other selection bias, indicating that the study sample was representative of the population.
- ⇒ Overall, no differences were found in baseline data between the surveillance group and controls, except for age.

be communicated for informed decision-making about (non-)attendance in lung cancer screening.

# **INTRODUCTION**

Lung cancer (LC) is the deadliest cancer worldwide, including in Sweden.<sup>1 2</sup> LC symptoms occur late, but curative treatment is feasible at early disease stage.<sup>3</sup> A meta-analysis of studies on screening the lungs with lowdose computed tomography (LDCT) in smokers and former smokers demonstrated the possibility of early LC detection.<sup>4</sup> The purpose of medical screening is early detection of the disease in a population without symptoms, with a test to distinguish a group with suspicious findings.<sup>5</sup> Additional diagnostics provide further information, and some individuals are subsequently diagnosed with the disease (ie, had a true-positive screening test), while others are considered free from the disease (ie, had a false-positive test).<sup>5</sup> Detection of indeterminate lung nodules in the LDCT requires diagnostic follow-up because nodules can progress to LC; thus, when detected, these nodules should be monitored in a surveillance programme.<sup>67</sup> The Dutch and Belgian LC study (NELSON) and the US National Lung Screening Trial (NLST) confirmed screening-detected LC and also generated false-positive LDCT scans.<sup>8</sup> <sup>9</sup> A 10-year follow-up with four repeated LDCT among men, smokers and former smokers of ≥15 pack-years in the NELSON study found that 9.2% (n=2069) of 22 600 scans needed follow-up, of which 203 resulted in screening-detected LC.<sup>8</sup> The NLST trial demonstrated 24.2% positive scans out of 75 126 scans after three rounds of annual LDCT among people with a smoking status of  $\geq 30$  pack-years, and 96.4% of these scans were false-positive.<sup>9</sup> Surveillance of pulmonary nodules and false-positive CT scans can induce psychosocial side effects.<sup>10-12</sup> The psychosocial consequences in LC screening were defined as fear of LC, sense of dejection and thoughts on existential values, to mention some.<sup>13</sup> The UK LC Screening trial (UKLS) and the Pittsburgh LC study (PLUSS) reported increased cancer fear among individuals who required a follow-up CT, compared with those with a negative screening scan.<sup>10 11</sup> However, no long-term psychosocial effects between groups were reported (ie, 12 months after LDCT screening).<sup>10 11</sup> Likewise, the Danish LC screening trial demonstrated short-term psychosocial consequences following false-positive CT scans, but no long-term effects were observed.<sup>12</sup> However, people having smoked for many years are more likely to experience self-blame and exhibit nihilistic thoughts about their risk of getting cancer.<sup>13</sup> Health-Related Quality of Life (HROoL)<sup>14-16</sup> has also been investigated in the context of LC screening. The NELSON trial found that participants with inconclusive lung LDCT screening reported lower HRQoL, compared with those with negative LDCT scans.<sup>17</sup> At approximately 1.5 years of follow-up, the side effects returned to baseline level at study commencement.<sup>18</sup> The NLST showed no negative effects on HRQoL, either at 1-month or 6-month follow-ups after lung LDCT screening among individuals with false-positive scans.<sup>19</sup> Extensive information prior to screening was suggested as a potential explanation for those study results.<sup>19</sup> Similar results were reported in the Canadian PAN-CAN LC screening study showing no impact on HRQoL among participants having follow-up scans, neither following baseline LDCT nor after additional examinations.<sup>20</sup>

Studies on screening for LC among smokers and former smokers have shown reduced diseased-related mortality rates.<sup>489</sup> However, when introducing a screening programme, benefits and harms should be considered.<sup>57</sup> There are potential harms to be acknowledged including the psychological impact of surveillance of pulmonary nodules. Informed decision-making for (non-)attendance in screening requires evidenced-based knowledge about the pros and cons of screening. The effects of screening for LC in a Swedish population are unknown, but the potential risk of side effects has been acknowledged.<sup>7</sup> Moreover, both short-term and long-term psychosocial consequences of false-positive screening have been demonstrated for other types of cancer (eg, breast cancer) in a Swedish context.<sup>21</sup> LC screening is not available in Sweden. The National Board of Health and Welfare in Sweden emphasised that evidence of LC screening effects is scarce, and it has issued a call for additional studies.<sup>3</sup> Recently, the population-based Swedish CArdioPulmonary bioImage Study (SCAPIS) was performed to investigate predictors of cardiovascular disease and chronic obstructive pulmonary disease.<sup>22</sup> It performed lung LDCT scans, and pilot trial results and data from the first year of the main study at the Gothenburg site provided clues for the study surveillance programme of indeterminate pulmonary nodules.<sup>23</sup> Accordingly, SCAPIS provided a context for investigating the psychological side-effects of one round of lung screening in a Swedish population. The present study aimed to investigate the impact of surveillance for indeterminate pulmonary nodules on the HRQoL and psychosocial consequences in individuals that underwent surveillance, and no LC was found.

# METHODS

# Sample

Our study sample comprised a cohort from the main SCAPIS trial, which was described in detail elsewhere.<sup>22</sup> In brief, it was conducted in cooperation between six university hospitals and six universities in Sweden. The trial was initiated to reduce mortality and morbidity from cardiovascular disease, chronic obstructive disease and related metabolic disorders. The data collection included self-reported questionnaires about socioeconomic status, psychosocial well-being, medication and lifestyle, to mention some. Other procedures were, for example, imaging of carotid arteries with ultrasound and magnetic resonance tomography, lung function tests and imaging of the lungs with LDCT.<sup>22</sup> The trial closed in November 2018 and included 30 154 participants aged 50-64 years. These participants were randomly selected from a population registry that included six Swedish municipalities: Gothenburg, Linköping, Malmö, Stockholm, Umeå and Uppsala. A pilot trial of SCAPIS conducted in 2011 included 1111 participants from low (39.9%) and high (67.8%) socioeconomic areas.<sup>23</sup>

The present study included participants from Gothenburg, Linköping, Malmö, Stockholm and Umeå. The surveillance group consisted of participants who had an inconclusive LDCT scan in SCAPIS that required surveillance of pulmonary nodules and, following surveillance, were considered free from LC at least 1 month prior to inclusion into our study. Figure 1 shows the surveillance programme for monitoring pulmonary nodules in the



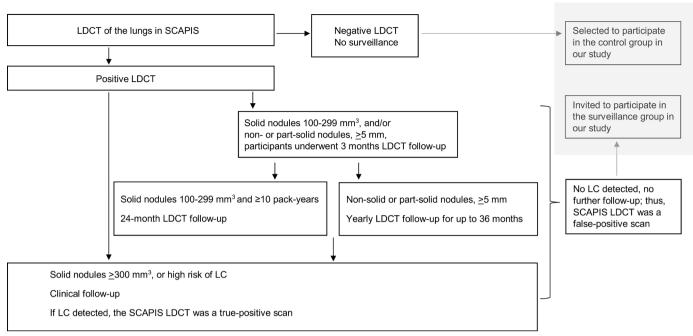


Figure 1 The surveillance programme of monitoring indeterminate pulmonary nodules according to SCAPIS guidelines. The boxes in grey show the selection of participants for the present study. LC, lung cancer; LDCT, low dose CT; SCAPIS, Swedish CArdioPulmonary bioImage Study. n pack-years: the number of packs of cigarettes (one pack=20 cigarettes) smoked per day, multiplied by the number of years of smoking or previous smoking.

main SCAPIS trial.<sup>23</sup> In total, 953 individuals fulfilled the criteria for the group and were invited to participate in the present study. Online supplemental tables 1 and 2 show the characteristics of the nodules and the surveillance, respectively, for the surveillance group. The control group consisted of participants with negative LDCT in SCAPIS (figure 1). To compensate for the expected non-participation rate, we matched two control individuals to each individual invited to participate in the surveillance group. The matching criteria were LDCT date (±2 weeks), gender and site, which provided 1889 eligible controls. The exclusion criteria for both groups were no consent to participate in further studies after SCAPIS, no registered address in Sweden, death and diagnosis of LC. Those continuing surveillance at the start of our study were also excluded. The study report is based on the guidelines for reporting observational studies (Strengthening the Reporting of Observational Studies in Epidemiology(STROBE)).

# **Questionnaires and baseline data** RAND-36

RAND-36, a questionnaire on self-reported HRQoL, comprised 36 items grouped into seven scales about physical, mental and general health and social functioning, and one item regarding perceived health relative to 12 months earlier.<sup>24</sup> Ordinal response categories were converted to a scale score between 0 (low HRQoL) and 100 (high HRQoL). The questionnaire scores demonstrated good reliability among patients in Sweden.<sup>25</sup> The Chronbach  $\alpha$  of the scales in our study was 0.81–0.88.

# **Consequences of Screening**

The Consequences of Screening (COS) questionnaire measures self-reported psychosocial consequences of cancer screening.<sup>13 26</sup> It was proposed to be applicable to all types of cancer screens,<sup>15</sup> and its psychometric properties were previously investigated in LC and breast cancer screening.<sup>13 26</sup> COS consists of two parts, with 26 and 23 items, respectively. Item scores in part 1 reflected agreement to having experiences due to thoughts about LC, scored as: 'not at all' (0 points), 'a bit' (1), 'quite a bit' (2), 'a lot' (3). The scores were summed for the scales: 'Sense of dejection', 'Anxiety', 'Behavioural' and 'Sleep'.<sup>13</sup> Item scores in part 2 reflected comparisons to baseline, scored as: 'much less' (2 points), 'less' (1), 'the same as before' (0), 'more' (1) and 'much more' (2).<sup>13</sup> The scores indicated the prevalence of consequences, regardless of whether they were positive or negative. The scores were summed for the scales: 'Existential values', 'Relaxed/calm', 'Social relations', 'Impulsivity' and 'Empathy'. The items related to the scale 'Reassurance/ Anxiety about LC' were recoded.<sup>13</sup> To reflect 'Reassurance about not having LC', the scores were recoded as: 'much more reassurance' (2 points), 'more reassurance' (1) and 'the same as before' (0). The remaining responses reflected anxiety and were coded as missing. To reflect 'Anxiety about having LC', the scores were recoded as: 'much more anxiety' (2 points), 'more anxiety' (1) and 'the same as before' (0). The remaining responses reflected reassurance and were coded as missing. Then, the scores for each part of the scale were summed to give two separate scores for 'Reassurance about not having LC' and 'Anxiety about having LC'. COS was adapted to Swedish, and its psychometric properties were tested in breast cancer screening. Those results provided support for the scales in part 1 and the 'Existential values' in part 2.<sup>27</sup> The results provided a Rasch model fit and a Chronbach  $\alpha \ge 0.7$ .<sup>27</sup> In the present study, the Chronbach  $\alpha$  values for the scales were  $\ge 0.70$ , except for 'Reassurance about not having LC' and 'Relaxed/calm', which demonstrated Chronbach  $\alpha$  values of 0.62 and 0.67, respectively.

#### **Baseline data**

Data from SCAPIS that might have an influence on the study outcomes were included in the current study as follows. Demographics (gender, country of origin); socioeconomic variables (education, accommodation, marital status and economic status); smoking habits; status of chronic obstructive pulmonary disease, asthma, tuberculosis and other pulmonary diseases; cancer history and first-degree relatives who contracted or died of LC. The data were collected in SCAPIS through a questionnaire at entry into the trial.<sup>22</sup> We also recorded the age at entry into our study, follow-up data (online supplemental table 2) and the date of LDCT conducted in SCAPIS.

# **Data collection**

Baseline data were acquired from SCAPIS. We mailed invitations to participate in our study in June 2019, and a reminder was sent in September. The invitations were sent simultaneously to all eligible people in both groups. They included information about our study, a consent form, RAND-36 and COS questionnaires and a stamped reply envelope. Both groups responded to the same questionnaires on one single occasion.

#### Statistical analysis

Questionnaire data were entered into an SPSS IBM V.25 spreadsheet, and we performed a quality control analysis of the data file. Missing responses were randomly distributed and  $\leq 5\%$ , so no imputation of the scores was applied. The reliability of questionnaire data (ie, the Cronbach  $\alpha$ ) was investigated. It is recommended that a Chronbach  $\alpha$  should be  $\geq 0.70$ ,<sup>28</sup> with it being a rule of thumb that this is sufficient for group-level measurements in research. Baseline data were included in the file and the independent Student's t-test and Fisher's exact test were applied to evaluate between-group differences at baseline and differences between the participants and non-participants. Between-group differences in RAND-36 scale responses were analysed with the Mann-Whitney U test. Total COS scores were dichotomised as 0 for not experiencing or >0 for experiencing psychosocial consequences due to thoughts of LC. Univariate logistic regression was performed to investigate the odds of experiencing psychosocial consequences based on group affiliation. Two-tailed p values ≤0.05 were considered significant.

# RESULTS

The study included 1604 participants who provided signed, informed consent to participate, including 844 (52.6%) men and 760 (47.4%) women. Participants were between 51 and 70 years old (mean: 61.0 years, SD 4.56). The first LDCT in SCAPIS was performed an average of 3.1 (SD 1.2) and 3.2 (SD 1.2) years prior to study entry, for the surveillance and control groups, respectively.

## **Characteristics of baseline data**

The surveillance group (n=632, 66.3%) and control group (n=972, 51.5%) had similar baseline characteristics (table 1), except for age (p<0.001), despite the similarity in mean ages (mean (SD): surveillance group: 58.5 years (4.3) vs control group: 57.5 years (4.4)).

The analysis of baseline data for non-participants is presented in table 1. Most variables were not significantly different between participants and non-participants in both the surveillance and control groups. Individuals from a country other than Sweden were less represented in the study (p<0.001). The groups also showed significant differences in some socioeconomic variables, including difficulty in meeting expenses over the previous 12 months (p<0.001), accommodations (p<0.001) and marital status (p=0.023). Rented accommodations were less common among participants than among nonparticipants (table 1). Additionally, fewer participants were single, widowed or separated, compared with nonparticipants (table 1).

# HRQoL

The RAND-36 questionnaire data demonstrated no differences in HRQoL between the surveillance and control groups, except for 'Social functioning' (extent of social limitations) (p=0.032) and 'Role functioning' (extent of limitations at work and other activities) (p=0.029) (table 2). However, the medians (IQR) were equivalent between groups for both 'Social functioning' (surveillance: 100 (78.13–100) and control: 100 (75–100)) and 'Role functioning' (surveillance and control: 100 (100–100)).

#### **Psychosocial consequences**

Psychosocial consequences, measured with the COS questionnaire, are presented in table 3. The OR of experiencing 'Sense of dejection' was higher in the surveillance group (n=161, 26.3%) than in the control group (n=190, 20.9%); OR 1.35 (p=0.015). Additionally, the surveillance group was more likely to have thoughts about 'Existential values' (n=234, 38.1%) than the control group (n=292, 32.2%); OR 1.30 (p=0.018). 'Anxiety about LC' was at least three times higher in the surveillance group (n=52, 15.9%) than in the control group (n=22, 4.5%); OR 3.96 (p<0.001).

# DISCUSSION

This multicentre study demonstrated that surveillance of indeterminate pulmonary nodules after one round of screening did not significantly impact HRQoL. However,

Baseline data	Surveillance group (n=632)	Control group (n=972)	Total participants (n=1604)	Non-participants (n=1235)
Demographic variables				
Gender				
Male	331 (52.4)	513 (52.8)	844 (52.6)	653 (52.9)
Female	301 (47.6)	459 (47.2)	760 (47.4)	582 (47.1)
Age, years; mean (SD)				
Male	58.4 (4.3)	57.5 (4.5)	57.8 (4.4)	57.0 (4.3)
Female	58.6 (4.3)	57.5 (4.4)	57.9 (4.4)	57.1 (4.3)
Country of origin*				
Sweden	531 (85.8)	836 (87.3)	1367 (86.7)	956 (80.0)
Other country	88 (14.2)	122 (12.7)	210 (13.3)	239 (20.0)
Socioeconomic variables				
Education†				
Secondary school/college/higher education	551 (89.3)	883 (92.2)	1434 (91.0)	1064 (89.2)
Compulsory school/no school	66 (10.7)	75 (7.8)	141 (9.0)	129 (10.8)
Can raise 20 000 kronor in 1 week, when needed‡§				
No	40 (6.5)	52 (5.5)	92 (5.9)	91 (7.8)
Yes	573 (93.5)	897 (94.5)	1470 (94.1)	1069 (92.2)
Difficulties in meeting expenses in the last 12 months	\$¶**			
No	589 (95.5)	923 (96.5)	1512 (96.1)	1103 (93.2)
Yes	28 (4.5)	33 (3.5)	61 (3.9)	81 (6.8)
Accommodation††				
Own a house or apartment	480 (77.5)	744 (77.7)	1224 (77.6)	844 (70.7)
Rent/other accommodation	139 (22.5)	214 (22.3)	353 (22.4)	350 (29.3)
Marital status‡‡				
Single/widowed/separated	151 (24.4)	229 (24.0)	380 (24.1)	334 (28.0)
Married/cohabitant	467 (75.6)	727 (76.0)	1194 (75.9)	858 (72.0)
Smoking habits, pulmonary status, cancer history				
Smoking§§				
Non-smoker	301 (49.3)	483 (50.9)	784 (50.3)	583 (49.2)
Smoker/former smoker	310 (50.7)	465 (49.1)	775 (49.7)	601 (50.8)
COPD chronic bronchitis/emphysema¶¶	10 (1.6)	12 (1.3)	22 (1.4)	15 (1.3)
Asthma¶¶	36 (5.9)	63 (6.7)	99 (6.4)	104 (8.9)
TB¶¶	1 (0.2)	0 (0.0)	1 (0.1)	5 (0.4)
Other pulmonary disease¶¶	11 (1.8)	13 (1.4)	24 (1.5)	15 (1.3)
Cancer history¶¶***	29 (4.7)	53 (5.6)	82 (5.3)	53 (4.5)
First-degree relatives with primary LC++++++	49 (8.2)	68 (7.3)	117 (7.6)	81 (7.1)
Years between first LDCT in SCAPIS and entry to the current study, mean (SD) range	3.1 (1.2) 0.6–5.5	3.2 (1.2) 0.7–5.5		

Data are given as n (%), unless otherwise noted.

Missing data in a total of participants/non-participants: \*27/40, †29/42, ‡42/75.

\$If you were suddenly confronted with a situation where you must raise 20 000 kronor within a week, would you be able to do so?.

¶31/51.

\*\*During the past 12 months, have you had any difficulties in meeting your current expenses for food, rent, bills etc.?. +++27/41. +++30/43.

§§45/51.

 $^{33}_{\rm PI}$  46/60.

†††69/88.

HTTG/Job Co. ###HAve your father, mother or siblings contracted or died of LC?. COPD, chronic obstructive pulmonary disease; LC, lung cancer; LDCT, low-dose CT; SCAPIS, Swedish CArdioPulmonary bioImage Study; TB, tuberculosis.

we did observe psychosocial consequences due to concerns about LC, including a sense of dejection and thoughts about existential values. In addition, anxiety about LC was at least three times higher among individuals who required surveillance compared with matched controls.

RAND36*	Surveillance group (n=632)	Control group (n=972)	P value†
PF	95/80–100	95/85–100	0.147
RP	100/100–100	100/75–100	0.697
BP	90/67.50–100	90/67.50–100	0.780
GH	75/60–85	75/65–85	0.060
VT	75/60–85	75/55–85	0.458
SF	100/78.13–100	100/75–100	0.032
RE	100/100–100	100/100–100	0.029
MH	84/75.25–92	84/72-92	0.180

Data are given as the median/q1-3 (IQR) unless otherwise noted. The number of responses for these scales ranged from 1591 to 1602.

\*BAND36, generic questionnaire for measuring HRQoL.

†Mann-Whitney U test.

BP, body pain; GH, general health; HRQoL, Health-Related Quality of Life; MH, emotional well-being (mental health); PF, physical functioning; RE, role functioning/emotional; RP, role functioning/physical; SF, social functioning; VT, energy/fatigue (vitality).

Our findings that surveillance of pulmonary nodules had no effect on HRQoL are consistent with the findings of other studies. Indeed, the NELSON trial found that participants with inconclusive lung LDCT screens experienced lower HRQoL, compared with individuals with negative LDCT screens, but the effects did not persist over the long term.<sup>17 18</sup> Also, the NLST showed no negative effects on HRQoL at either a 1-month or 6-month follow-up after a false-positive LDCT screen.<sup>19</sup> A potential explanation for these findings could be that extensive information was provided at entry into the study.<sup>19</sup> In support of that argument, the participants in our study were informed about the SCAPIS study procedure and the potential risk of detecting pulmonary nodules.<sup>23</sup> On the other hand, an investigation of how SCAPIS participants perceived the cardiovascular risk information showed that they found the information difficult to understand.<sup>29</sup>

The present study showed that surveillance of indeterminate pulmonary nodules was associated with a sense of

 Table 3
 Consequences of Screening questionnaire results

 showing the odds of psychosocial consequences

snowing the odds of psychosocial consequences						
Psychosocial consequences	Odds ratio (95% CI)	P value				
Sense of dejection	1.35 (1.06 to 1.72)	0.015				
Anxiety	1.22 (0.97 to 1.54)	0.087				
Behavioural	1.21 (0.95 to 1.54)	0.119				
Sleep	1.17 (0.93 to 1.45)	0.189				
Existential values	1.30 (1.04 to 1.60)	0.018				
Social relations	1.13 (0.73 to 1.75)	0.593				
Relaxed/calm	1.10 (0.85 to 1.40)	0.483				
Impulsivity	1.23 (0.95 to 1.68)	0.111				
Empathy	1.03 (0.81 to 1.30)	0.828				
Anxiety about LC*	3.96 (2.35 to 6.66)	<0.001				
Reassurance about LC	1.07 (0.86 to 1.32)	0.551				

Univariate logistic regressions for each scale (dependent variable) were dichotomised as: no psychosocial consequences, when the total score was=0, or psychosocial consequences, when the total score was >0.

The number of responses for these scales ranged from 1518 to 1523.

\*n=812 after recoding

LC, lung cancer.

dejection due to thoughts about LC and anxiety about LC. In the context of cancer screening, a sense of dejection reflects feelings like sadness, worry, uneasiness, depression and a reduced ability to cope due to thoughts about LC. Anxiety about LC reflects a feeling of doubt about the negative tests and anxiety about having LC.<sup>13</sup> To the best of our knowledge, these findings have not been shown in previous studies after participants completed surveillance. However, findings of LC anxiety were observed during follow-up of pulmonary nodules. For example, the UKLS and PLUSS studies observed increased cancer fear and anxiety among participants who required a follow-up CT, compared with those with negative screens.<sup>10 11</sup> Additionally, the Danish LC screening trial demonstrated that psychosocial consequences occurred at 1 week and 1 month after tomography among participants with falsepositive scans, but no significant long-term consequences were observed.<sup>12</sup> These results were similar to the experiences of psychosocial consequences observed among people having LC.<sup>12</sup> We also investigated the consequences of surveillance in terms of thoughts about existential values, which emerged in more than a third of the participants who required follow-up. In-depth interviews with participants in the surveillance group might provide clues to a comprehensive understanding of those experiences; this study is planned for a future publication. The Danish LC screening trial, in which participants underwent five annual rounds of lung CT scans, showed that participation in screening per se introduced psychosocial consequences.<sup>30</sup> Between the first and second screening rounds, it observed increases in psychosocial consequences, including a sense of dejection and anxiety, and the increases persisted throughout the study.<sup>30</sup> However, the participants who underwent CT screening experienced less severe psychosocial consequences compared with controls (no CT). That result might be explained by the fact that the study sample had negative CT scans.

## Strengths and limitations of the study

The main strength of our study was that the sample was a population-based cohort, and we found no differences in baseline data, except for age, between participants who underwent surveillance and the matched controls. However, the mean and SD values for age were similar between the groups; thus, it was reasonable to conclude that the age difference detected was due to a sample size effect. Nevertheless, our results were limited to a rather narrow age group: 51-70 years. Another limitation was that participants from a country other than Sweden, those who lived alone and those with low economic status, tended not to participate in the study. This type of selection bias was also observed in previous studies that investigated how LDCT screening for LC impacted HRQoL and psychological consequences.<sup>10 11 19</sup> In addition, the SCAPIS pilot trial also showed lower participation rates among individuals from areas of low socioeconomic status; one reason for non-participation in those areas was difficulty in communicating in Swedish.<sup>31</sup> On the other hand, our analysis of non-participant data demonstrated no other selection bias, which indicated that, except for the variables mentioned, the study sample was representative of the population.

Another potential limitation was that some SCAPIS participants had cardiovascular findings that might have influenced their well-being and, thus, could have affected the outcome of our study. On the other hand, it might be anticipated that participants in both study groups had equivalent frequency of cardiovascular diseases. However, due to ethical considerations, we chose not to collect those data, aware that this choice could potentially limit the interpretation of our results. Nevertheless, it should be noted that the COS questions about psychosocial consequences were explicitly related to thoughts of LC and lung surveillance.

SCAPIS aimed to investigate predictors of cardiovascular disease and chronic obstructive pulmonary disease; thus, it was not a study on LC screening effects. Nevertheless, the context of lung LDCT screening in a large population provided a good basis for studying the effects of one round of screening and the surveillance of indeterminate pulmonary nodules that mostly led to falsepositive LDCT scans.<sup>89</sup> Previous studies investigated the longitudinal development of HRQoL and psychosocial consequences during surveillance.<sup>10</sup> <sup>12</sup> <sup>18-20</sup> In contrast, our intention was to investigate the risk of potential side effects after the surveillance was complete among participants without an LC diagnosis. Accordingly, we studied individuals who did not necessarily benefit from screening.<sup>32</sup> Further research might investigate potential predictors of a low capability to cope with surveillance such as sociodemographic characteristics or surveillance procedures. Furthermore, studies are needed to investigate the psychosocial well-being of individuals with screening-detected pulmonary nodules but who are not referred to a surveillance programme due to the small size of the nodules, but when the nodules are detected, it presumably influences the well-being of the individual. These studies could lead to providing tailored preventive information throughout the surveillance programme.

# CONCLUSION

This study, conducted in a Swedish population, contributed to existing knowledge based on international studies about the effects of lung LDCT screening on the risks of psychosocial consequences. The study results showed that surveillance of the lungs with LDCT contributed to significant experiences of a sense of dejection, anxiety about LC and development of thoughts about existential values among participants in the surveillance group compared with the controls, despite the negative result of the surveillance. However, no effects on HRQoL were observed. When introducing an LC screening programme, screening side effects should be kept in mind. We advise providing screening candidates with objective information on the pros and cons of screening to promote an informed decision about attendance. Such information would support sound awareness of the potential effects of screening while respecting the autonomy of the individual.

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# **Open access**

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