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Informed decision making does not affect health-related quality of life in lung cancer screening (NELSON trial)

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ABSTRACT

Background: It is believed that making an informed decision about (screening) participation is associated with better health-related quality of life (HRQoL) outcomes. This is the first study in cancer screening to explore this association in subjects participating in a lung cancer computed tomography (CT) screening trial.

Methods: Participants that made either an informed decision to participate ($n = 155$) or not ($n = 133$) were selected for this study. Differences in HRQoL, measured as generic HRQoL (Short Form 12 [SF-12] and EuroQol questionnaire [EQ-5D]), anxiety/distress (State-Trait Anxiety Inventory [STAI-6], Impact of Event Scale [IES] and Consequences of Screening-Lung Cancer [COS-LC]), were tested with Mann-Whitney U tests and ANOVA at three assessment points (when deciding about participation, before trial randomisation and 2 months after receiving the CT result).

Results: Subjects who made an informed decision to participate had no better scores than those who did not make an informed decision for 23 out of 24 HRQoL comparisons, except for a better mean score for mental health (Mental Component Summary (MCS) = 53.9 ± 9.2 versus 51.0 ± 10.1 , $p = 0.003$) before randomisation. For subjects with an indeterminate CT result ($n = 64$), no significant differences were found between subjects with ($n = 35$) or without ($n = 29$) an informed decision.

Conclusion: Subjects who did not make an informed decision to participate in lung cancer CT screening trial did not experience worse HRQoL during screening than subjects who did make an informed decision, either in general or after receiving an indeterminate result.

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1. Introduction

The number of screening offers is increasing. Even if the benefits of a screening programme at population level outweigh the disadvantageous side-effects, not all subjects will experience health gains from screening. Subjects eligible for screening should therefore be informed about the benefits and harms of the screening and should be supported to decide

about participation in a screening programme on the basis of an informed decision.^{1–3}

An informed decision (or informed choice) is a decision based on relevant knowledge, and the screening behaviour is consistent with the decision-makers' values.^{4,5} It is believed that making an informed decision is associated with better psychological and health outcomes, especially when receiving an unfavourable screening result.^{5,6} However, the relationship

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with making an informed decision or not and health-related quality of life (HRQoL) in screening is a relatively unexplored area of investigation and evidence is limited to prenatal screening.^{5,7} Recently, Kleinveld and colleagues reported that subjects whose participation in prenatal screening was based on an informed decision seemed to have less adverse emotional reaction when confronted with a positive screening test outcome.⁷

Studies on HRQoL in lung cancer computed tomography (CT) screening showed that receiving an unfavourable result caused a decrease in HRQoL.^{8–10} The purpose of the current study is to evaluate whether subjects who made an informed decision had a better HRQoL than subjects who did not make an informed decision, especially those receiving an indeterminate test result which required a follow-up CT scan.

2. Materials and methods

The current study was performed within the Dutch–Belgian randomised controlled trial for lung cancer screening in high-risk subjects (NELSON trial).

2.1. Characteristics of the study group

Details of the NELSON trial and the informed decision making (IDM) study have been described before.^{9,11–13} In brief, subjects aged between 50 and 75 years who smoke or have smoked heavily were selected for participation in the NELSON trial. The aim of the trial is to establish whether screening by low-dose CT can reduce lung cancer mortality with 25%. Subjects who gave informed consent were randomised (1:1) to a screen group with three subsequent CT screening rounds, or to a control group without screening. The outcome of the screening test at baseline could either be negative, indeterminate (requires follow-up CT after 3 months) or positive (work-up by pulmonologist).¹⁴ The trial was approved by the Dutch Ministry of Health and by the ethics committees of the participating centres. The Ministry of Health gave permission to start the trial after a positive test of the ‘comprehensibility’ of the trial information. Informed consent was obtained from all participants. The NELSON trial was registered at www.trialregister.nl with number ISRCTN63545820.

About 288 participants of the NELSON trial were eligible for the current study: they completed the IDM questionnaire in our previous study (T0)¹¹ and made or made not an informed decision to participate in the NELSON trial; they were included in the HRQoL study⁹; and they were randomised to the screening arm. These 288 subjects further received questionnaires on HRQoL before trial randomisation (T1) and after the baseline result (T2). The T2 questionnaire was not sent to subjects with a positive test result ($n = 5$) or without baseline scan ($n = 4$).

2.2. Measures

2.2.1. Informed decision

In the definition regarding the informed choice (decision), we followed Marteau and colleagues.⁴ Accordingly, in our study an informed decision to participate was characterised by ade-

quate knowledge, a positive attitude towards lung cancer screening and actual participation (randomisation in the NELSON trial).¹¹ A decision to participate, but without adequate knowledge, and/or a negative attitude was regarded as uninformed. The knowledge and attitude scales were described elsewhere.¹¹ In brief, these scales were based on the Multidimensional Measure of Informed Choice, developed and validated by Marteau and Michie to quantify informed decisions in prenatal screening.^{4,5} Seven items on lung cancer screening were considered relevant for the decision regarding lung cancer screening participation^{4,15}: disorder being screened for, meaning of a normal CT result, percentage of positive and indeterminate CT results, follow-up after positive and indeterminate CT results and false-positive results (see van den Bergh and colleagues for the exact content of the knowledge items¹¹). A summary score was calculated by summing the correct responses (2), nearly correct responses (1) and incorrect and missing responses (0), resulting in a score ranging 0–14. Attitudes towards lung cancer screening were measured using six five-point Likert scales (bad–good, not reassuring–reassuring, beneficial–harmful, important–unimportant, unwise–wise and desirable–undesirable). The choice of items was based on Marteau et al. and van den Berg et al.^{4,16} The scale score ranged 6–30 with higher scores indicating a more positive attitude. Subjects with scores above the midpoint of the knowledge scale (>7) and the attitude scale (>18) were classified as having adequate knowledge and a positive attitude, respectively; others were classified as not having adequate knowledge and a negative attitude, respectively.⁵

Based on the definition of Marteau and colleagues 155 subjects (54%) made an informed decision to participate and 133 did not make an informed decision to participate (46%). This distinction was almost completely determined by knowledge, since almost all participants (98%) had a positive attitude towards lung cancer screening.¹¹

2.2.2. Health-related quality of life (HRQoL)

2.2.2.1. Generic HRQoL. The participant's generic HRQoL was measured with the 12-item Short Form (SF-12) and the Euro-QoL questionnaire (EQ-5D).^{17–20} The SF-12 is a shorter version of the SF-36 and consists of a Physical Component Summary (PCS) and a Mental Component Summary (MCS).²⁰ We used the acute (1-week recall) form of Version 1. A higher score indicates a better HRQoL. Respondents were also asked to rate their own health on the visual analogue scale (VAS) of the EQ-5D, ranging from 0 (worst imaginable health status) to 100 (best imaginable health status).^{17,18}

2.2.2.2. Generic anxiety. Generic anxiety was measured using the short form of the Spielberger State-Trait Anxiety Inventory (STAI-6).²¹ Six items related to anxiety (calm, tense, upset, relaxed, content and worried) were rated on a four-point scale. The total summary score was calculated in subjects with a maximum of three missing values and could range from 20 to 80, with higher scores indicating more anxiety.²² The STAI-6 is reported to have good reliability and validity and was found useful to evaluate the effectiveness of screening programmes on subjective anxiety levels.²¹

Table 1 – Respondent characteristics at T0.

N	Total group	Total group		Indeterminate result ^a	
	All 288	Informed decision 155	No informed decision 133	Informed decision 35	No informed decision 29
Sex: male: n (%)	142 (49)	74 (48)	68 (51)	20 (57)	16 (55)
Age (years): mean (SD), median (range)	57.3 (5.3), 56.1 (51–75)	57.2 (5.1), 55.8 (51–74)	57.6 (5.5), 56.5 (51–75)	57.9 (5.3), 56.7 (51–71)	58.0 (6.2), 56.3 (51–75)
Education					
(1) Primary education: n (%)	22 (8)	10 (7)	12 (9)	2 (6)	4 (14)
(2) Lower vocational or lower secondary general education: n (%)	114 (40)	62 (41)	52 (39)	12 (35)	11 (38)
(3) Intermediate vocational or higher secondary general education: n (%)	74 (26)	42 (27)	32 (24)	11 (32)	9 (31)
(4) Higher vocational education or university: n (%)	75 (26)	39 (25)	36 (27)	9 (27)	5 (17)
Smoking					
Current smokers: n (%)	140 (49)	76 (49)	64 (48)	18 (51)	14 (48)
Pack-years: mean (SD), median (range)	39.4 (16.0), 35.0 (21–96)	38.7 (15.1), 34.2 (21–92)	40.2 (17.1), 35.8 (21–96)	38.1 (13.5), 35.8 (21–72)	44.2 (18.9), 38.0 (21–92)
Amount of illnesses and chronic diseases: mean (SD), median (range)	0.8 (0.9), 1.0 (0–4)	0.8 (0.9), 1.0 (0–4)	0.7 (0.9), 0.0 (0–3)	0.6 (0.8), 0.0 (0–3)	1.0 (1.1), 1.0 (0–3)
Risk perception					
Cognitive					
For men (n (%) correct answer)	80 (28)	52 (34) ^b	28 (21) ^b	13 (37)	6 (21)
For women (n (%) correct answer)	91 (32)	58 (37) ^c	33 (25) ^c	15 (43)	8 (28)
Affective (n (%) high or very high)	47 (16)	27 (18)	20 (15)	5 (14)	7 (24)
SD = standard deviation					
^a No significant differences in indeterminate result group between subjects with and without an informed decision (chi-square and Mann–Whitney U test) ($\alpha = 0.05$).					
^b $p = 0.020$ (chi-square).					
^c $p = 0.024$ (chi-square).					

Table 2 – Unadjusted HRQoL scores (mean (SD), median (range)) at each assessment for subjects with and without making an informed decision.

N	T0, when deciding about trial participation		T1, before randomisation		T2, after receipt of baseline result ^a			
	Total group		Total group		Total group		Indeterminate result	
	Informed decision (155)	No informed decision (133)	Informed decision (143)	No informed decision (124)	Informed decision (135)	No informed decision (113)	Informed decision (30)	No informed decision (25)
SF-12								
PCS	–	–	49.4 (7.8), 52.3 (23–67)	49.3 (9.2), 52.9 (11–63)	50.6 (7.9), 53.2 (22–69)	50.1 (8.1), 52.5 (23–66)	48.5 (8.8), 52.4 (29–60)	48.0 (7.4), 51.0 (26–55)
MCS	–	–	53.9 (9.2), 56.2 (22–66) ^b	51.0 (10.1), 54.1 (21–65) ^b	51.2 (12.6), 55.9 (9–67)	51.4 (11.0), 55.9 (16–65)	54.4 (9.3), 56.3 (25–66)	53.5 (8.2), 56.0 (31–63)
EQ-5D VAS	78.5 (12.1), 80.0 (40–100)	76.4 (14.6), 80.0 (20–100)	80.5 (12.6), 80.0 (50–100)	78.7 (13.6), 80.0 (40–100)	79.3 (11.9), 80.0 (35–100)	78.0 (12.1), 80.0 (33–99)	75.8 (12.9), 75.0 (50–95)	76.1 (9.2), 80.0 (60–95)
STAI-6	33.8 (9.0), 33.3 (20–63)	35.0 (8.4), 33.3 (20–67)	31.5 (7.8), 30.0 (20–60)	33.4 (8.4), 33.3 (20–70)	32.6 (10.1), 30.0 (20–77)	33.4 (9.3), 30.0 (20–67)	33.0 (7.0), 33.3 (20–47)	34.8 (10.5), 33.3 (20–67)
IES								
IES intrusive	–	–	1.5 (3.2), 0.0 (0–25)	1.6 (2.8), 0.0 (0–14)	1.3 (3.2), 0.0 (0–19)	1.4 (3.7), 0.0 (0–30)	3.2 (4.9), 1.0 (0–19)	4.1 (6.8), 1.0 (0–30)
IES avoidance	–	–	2.0 (4.1), 0.0 (0–22)	2.3 (4.5), 0.0 (0–22)	2.3 (4.9), 0.0 (0–29)	2.0 (4.6), 0.0 (0–29)	4.6 (6.3), 2.0 (0–26)	5.1 (7.8), 1.0 (0–29)
IES total	–	–	3.6 (6.5), 0.0 (0–35)	3.9 (6.9), 0.0 (0–36)	3.6 (7.2), 0.0 (0–42)	3.4 (7.8), 0.0 (0–59)	7.8 (10.1), 4.0 (0–42)	9.3 (13.9), 5.0 (0–59)
COS-LC								
Anxiety	–	–	–	–	1.9 (2.8), 1.0 (0–15)	1.8 (2.1), 1.0 (0–12)	2.0 (2.1), 1.5 (0–7)	2.3 (2.8), 2.0 (0–12)
Behavioural	–	–	–	–	2.4 (3.0), 1.5 (0–16)	2.3 (2.5), 2.0 (0–10)	2.5 (2.3), 2.0 (0–8)	2.0 (2.3), 2.0 (0–10)
Worry	–	–	–	–	1.5 (1.6), 1.0 (0–8)	1.7 (1.6), 1.5 (0–6)	1.8 (1.3), 2.0 (0–4)	2.2 (1.9), 2.0 (0–6)
Depression	–	–	–	–	1.2 (2.0), 1.0 (0–9)	1.0 (1.4), 1.0 (0–6)	0.9 (1.2), 0.5 (0–4)	1.0 (1.6), 0.0 (0–6)
Sleep	–	–	–	–	1.2 (1.3), 1.0 (0–6)	1.6 (1.5), 1.5 (0–6)	1.0 (1.2), 1.0 (0–5)	1.4 (1.6), 1.0 (0–6)
Self-blame	–	–	–	–	1.2 (2.0), 0.0 (0–11)	1.1 (1.9), 0.0 (0–8)	1.5 (1.7), 1.0 (0–4)	2.2 (2.5), 1.0 (0–8)
Introvert	–	–	–	–	0.9 (1.5), 0.0 (0–9)	0.9 (1.2), 0.0 (0–7)	1.0 (1.0), 1.0 (0–3)	1.2 (1.5), 1.0 (0–7)
Tobacco	–	–	–	–	1.0 (1.2), 1.0 (0–6)	1.0 (1.3), 0.5 (0–6)	1.6 (1.2), 2.0 (0–4)	1.6 (1.7), 1.0 (0–6)

SD = standard deviation, SF-12 = Short Form 12 (generic HRQoL), PCS = Physical Component Summary, MCS = Mental Component Summary, EQ-5D VAS = self-reported health status, STAI-6 = anxiety, IES = lung cancer-specific distress, COS-LC = Consequences of Screening-Lung Cancer.

^a No significant differences in SF-12, EQ-5D, STAI-6 and IES scores between subjects with and without an informed decision at T2 when corrected for the SF-12, EQ-5D, STAI-6 or IES scores respectively at T1 (ANOVA).

^b MCS score was significantly higher (i.e. better) in the group with an informed decision than in the group without an informed decision ($p = 0.003$) (Mann–Whitney U test).

2.2.2.3. Lung cancer-specific distress. Lung cancer-specific distress was measured using the Impact of Event Scale (IES).^{23,24} The 15 IES items were tailored to lung cancer as the specific stressor. Each item was scored on a four-point scale: not at all (score of 0), rarely (score of 1), sometimes (score of 3) and often (score of 5). The total score and subscales (avoidance and intrusion) were calculated for those who completed 75% of the questions on each subscale, and were corrected for the total number of questions on the subscale. The total summary score could range from 0 to 75 (intrusive scale 0–35, avoidance scale 0–40), with a higher score indicating more lung cancer-specific distress.

2.2.2.4. Psychological consequences of lung cancer

screening. The psychological consequences of lung cancer screening test results were measured using part 1 of the Consequences of Screening-Lung Cancer questionnaire (COS-LC). This questionnaire was based on the COS-Breast Cancer questionnaire,²⁵ but adapted for lung cancer screening into the COS-LC.²⁶ With a formal procedure the COS-LC was adapted from Danish into Dutch with two panels: a bilingual panel and a lay people panel.²⁷ After that it was field-tested in the NELSON population.

Respondents rated experiences of the last week on a four-point scale (score 0–3): not at all, a bit, quite a bit and a lot. These 29 items were organised into eight dimensions: anxiety (6 items, e.g. I have felt scared/nervous/terrified), behavioural (6 items, e.g. have been quiet/have had difficulty meeting work or other commitments), worry (3 items, e.g. I have been worried about my future), depression (3 items, e.g. I have felt sad/unable to cope), sleep (2 items, e.g. I have slept badly), self-blame (4 items, e.g. I have felt guilty/disappointed, because I smoked for so many years), introvert (3 items, e.g. I have felt not confident/change of moods) and tobacco (2 items, e.g. I have felt regret, because I smoked for so many years). A higher score indicates more unfavourable psychological consequences of lung cancer screening. The COS-LC was only used at T2.

2.2.2.5. Demographic and other data. Educational level, smoking status and smoking pack-years were derived from the NELSON questionnaire used to determine eligibility for the NELSON trial.¹² The number of self-reported conditions such as asthma and hypertension (0–9) and risk perceptions were measured at T0. Cognitive risk perception was measured with two population risk estimations for men and for women on a six-point scale: 'How do you estimate the chance of an average man/woman getting lung cancer during his lifetime in the Netherlands?' (approximately 1 in 5, 1 in 15, 1 in 25, 1 in 50, 1 in 100, 1 in 250). For a man the correct answer was 'approximately 1 in 15' and for a woman 'approximately 1 in 50'. Affective risk perception was measured with 1 item on a five-point scale to evaluate how a person feels about his or her risk: 'What do you feel your chance of developing lung cancer is?' (very low–very high).²⁸

2.3. Statistical analysis

Differences in respondent characteristics between subjects who made an informed decision or made not an informed

decision were analysed with chi-square tests for nominal and ordinal variables, and with Mann–Whitney *U* test for continuous variables. Differences in HRQoL between subjects with and without an informed decision were tested with Mann–Whitney *U* tests for T0, T1 and T2, because the data were not normally distributed. Since the non-parametric analyses (Mann–Whitney *U* tests) did not differ from the parametric analyses (*T*-tests), analyses of variance (ANOVA) analyses were used to test differences in HRQoL at T2 for subjects with and without an informed decision, corrected for the T1 HRQoL assessment. As a result of possible type-1 errors due to multiple testing in the HRQoL comparisons, a *p*-value <0.01 was considered statistically significant.

3. Results

3.1. Response and respondent characteristics

The questionnaire response was 93% (267/288) (95% confidence interval (CI) = 89–95%) for the assessment before randomisation (T1) and 89% (248/279) (95% CI = 85–92%) for the assessment after the baseline result (T2). About 215 subjects (75%) had a negative baseline test result, 64 subjects (22%) had an indeterminate result, 5 (2%) a positive result and 4 subjects did not undergo baseline screening. Of the total group, 49% was male and the respondents were on average 57.3 (SD = 5.3) years old (Table 1). No significant differences in respondent characteristics were found between subjects with and without an informed decision either in the total group or in the group that received an indeterminate baseline

Table 3 – Parameter estimates of parameter estimates (Beta (SE)) health-related quality of life.

	Intercept	HRQoL score at T2 ^a	Informed decision (yes)
<i>Total group</i>			
PCS	26.5 (2.8)	0.5 (0.1) ^b	0.4 (0.9)
MCS	11.5 (3.5)	0.8 (0.1) ^b	–1.8 (1.2)
EQ-5D VAS	31.4 (3.9)	0.6 (0.0) ^b	0.4 (1.2)
STAI-6	8.0 (2.2)	0.8 (0.1) ^b	0.2 (1.0)
IES intrusion	0.8 (0.3)	0.4 (0.1) ^b	–0.1 (0.4)
IES avoidance	0.8 (0.4)	0.6 (0.1) ^b	0.3 (0.5)
IES total	1.5 (0.7)	0.5 (0.1) ^b	0.3 (0.9)
<i>Indeterminate result group</i>			
PCS	31.7 (5.6)	0.4 (0.1) ^b	–0.7 (2.4)
MCS	21.4 (9.0)	0.6 (0.1) ^b	1.2 (2.5)
EQ-5D VAS	46.1 (8.4)	0.4 (0.1) ^b	–0.3 (2.8)
STAI-6	13.3 (3.8)	0.7 (0.1) ^b	–1.2 (1.9)
IES intrusion	3.3 (1.3)	0.4 (0.3)	–1.0 (1.6)
IES avoidance	3.3 (1.4)	0.7 (0.2) ^b	–0.0 (1.8)
IES Total	6.2 (2.6)	0.7 (0.2) ^b	–0.8 (3.1)

HRQoL = health-related quality of life, PCS = Physical Component Summary, MCS = Mental Component Summary, EQ-5D VAS = self-reported health status, STAI-6 = anxiety, IES = lung cancer-specific distress.

^a HRQoL at T2 depends on the outcome measure, e.g. if the outcome measure is PCS, HRQoL at T0 is PCS.

^b *p* < 0.01.

result. Subjects who made an informed decision provided the correct response to the cognitive risk perception items more often correct than subjects without an informed decision (risk perception for men: $p = 0.020$ and risk perception for women 0.024, Table 1).

3.2. HRQoL differences between subjects with and without an informed decision

Subjects of the total group who made an informed decision had better scores for MCS than subjects who did not make an informed decision (53.9 (9.2) and 51.0 (10.1)) before randomisation ($p = 0.003$) (Table 2). For subjects with an indeterminate baseline result, no differences were found between the subjects with and without an informed decision at each assessment (Table 2). At T2, the ANOVA analyses in which was adjusted for the T1 HRQoL measure, no differences were found in SF-12, EQ-5D, STAI-6 and IES scores between subjects with and without an informed decision in the total group and in the indeterminate result group (Table 3). For the ANOVA analyses in the total group and in the indeterminate result group, the T1 HRQoL measure was significantly associated with the outcome measure except from IES intrusion (Table 3).

4. Discussion

This first study on the effect of informed decision making on HRQoL in cancer screening showed that subjects who made an informed decision to participate in a lung cancer CT screening trial in general did not experience better HRQoL compared with subjects who had not made an informed decision. We did not find differences in HRQoL between subjects who made an informed decision to participate or who made not an informed decision to participate after receiving an indeterminate baseline test result that required follow-up screening.

Only one out of 24 HRQoL comparisons between subjects who made an informed decision and subjects who did not make an informed decision was significantly different. Because the absolute differences were small and this is possibly a result of multiple testing we did not consider these differences relevant.

Michie and colleagues evaluated the effect of informed decision making on post-test anxiety (STAI-6) in subjects in prenatal screening.⁵ They did not find differences between subjects with and without an informed decision in the group with a low-risk (i.e. favourable) outcome following serum screening for Down syndrome. This is in accordance with our findings in the total group with mainly negative (i.e. favourable) outcomes. In another prenatal screening study, Kleinveld and colleagues found that subjects who made an informed decision seemed to have a less adverse emotional reaction when confronted with an unfavourable screening outcome (i.e. an increased risk of having a child with Down syndrome) than subjects who did not make an informed decision.⁷ This result was not confirmed in our study, because we did not find HRQoL differences in the subjects with and without an informed participation decision who received an unfavourable

(i.e. indeterminate) CT result. The differential result may be partly attributable to the choice of anxiety measures: Kleinveld and colleagues used items on the emotional reaction specifically relating to the screening outcome whereas we used more generic scales.

Some hypothesise that former smokers may not be aware of their continuing risk of developing lung cancer. If they are made aware of this risk by the screening invitation, they may not be interested at all in potential disadvantageous effects of screening. However, in our previous paper, we found that former smokers were more often aware that their risk of developing lung cancer is still higher than of someone who has never smoked (data not shown).¹¹

4.1. Limitations

In the indeterminate screening result group, the groups with and without an informed participation decision seemed to differ in some demographic characteristics (e.g. education level and smoking history) in an absolute sense, although these differences did not reach statistical significance, probably due to the small groups. However, larger groups would probably show differences in demographic characteristics, but not in finding differences in HRQoL since the absolute differences in HRQoL scores were very small.

Psychometric analyses for the COS-LC found differential item functioning (DIF) for screening result or gender for three subscales. We have not corrected for DIF because it would not have changed the conclusions.

A decision about participating in a screening programme is different from deciding to participate in a screening trial. Therefore, the results of the present study may not be generalised to the situation when lung cancer screening may be implemented in a population-based screening programme.

4.2. Implications

Although we did not find differences in HRQoL, this does not imply that we should stop informing potential screenees. Those who want to be informed should have easy access to honest, complete and balanced information about the favourable and unfavourable aspects of participation in (lung) cancer screening. In a previous study¹¹ we showed that uninformed participation decision making in lung cancer screening was almost completely determined by lack of knowledge: If adequately informed, subjects can decide whether undergoing the screening is best for themselves.^{2,3,29} Previous research in other health care contexts showed unfavourable effects of uninformed participation decisions in domains that may be related to HRQoL, for example, more decisional conflict.⁵ Research in other cancer screening groups on the effects of informed decision making on HRQoL is recommended, especially in groups with unfavourable screening results.

In conclusion, subjects who made an informed decision to participate in a lung cancer CT screening trial, in general, and after receiving an indeterminate CT result, do not differ in health-related quality of life during screening from the subjects who did not make an informed decision.

Conflict of interest statement

None declared.

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REFERENCES

- Entwistle VA, Carter SM, Trevena L, et al. Communicating about screening. *BMJ* 2008;**337**:a1591.
- General Medical Council. *Seeking patients' consent: the ethical considerations*. London: GMC; 1998. p. 1.
- Jepson RG, Hewison J, Thompson AG, Weller D. How should we measure informed choice? The case of cancer screening. *J Med Ethics* 2005;**31**(4):192–6.
- Marteau TM, Dormandy E, Michie S. A measure of informed choice. *Health Expect* 2001;**4**(2):99–108.
- Michie S, Dormandy E, Marteau TM. The multi-dimensional measure of informed choice: a validation study. *Patient Educ Couns* 2002;**48**(1):87–91.
- Green JM, Hewison J, Bekker HL, Bryant LD, Cuckle HS. Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review. *Health Technol Assess* 2004;**8**(33). iii, ix–x, 1–109.
- Kleinvelde JH, Ten Kate LP, van den Berg M, van Vugt JM, Timmermans DR. Does informed decision making influence psychological outcomes after receiving a positive screening outcome? *Prenat Diagn* 2009;**29**(3):271–3.
- Byrne MM, Weissfeld J, Roberts MS. Anxiety, fear of cancer, and perceived risk of cancer following lung cancer screening. *Med Decis Making* 2008;**28**(6):917–25.
- van den Bergh KA, Essink-Bot ML, Borsboom GJ, et al. Short-term health-related quality of life consequences in a lung cancer CT screening trial (NELSON). *Br J Cancer* 2010;**102**(1):27–34.
- Vierikko T, Kivistö S, Järvenpää R, et al. Psychological impact of computed tomography screening for lung cancer and occupational pulmonary disease among asbestos-exposed workers. *Eur J Cancer Prev* 2009;**18**(3):203–6.
- van den Bergh KA, Essink-Bot ML, van Klaveren RJ, de Koning HJ. Informed participation in a randomised controlled trial on CT screening for lung cancer. *Eur Respir J* 2009;**34**(3):711–20.
- van Iersel CA, de Koning HJ, Draisma G, et al. Risk-based selection from the general population in a screening trial: selection criteria, recruitment and power for the Dutch–Belgian randomised lung cancer multi-slice CT screening trial (NELSON). *Int J Cancer* 2007;**120**(4):868–74.
- van Klaveren RJ, Oudkerk M, Prokop M, et al. Management of lung nodules detected by volume CT scanning. *N Engl J Med* 2009;**361**(23):2221–9.
- Xu DM, Gietema H, de Koning H, et al. Nodule management protocol of the NELSON randomised lung cancer screening trial. *Lung Cancer* 2006;**54**(2):177–84.
- Wald N. Information leaflets in medical screening. *J Med Screen* 2006;**13**(3):109.
- van den Berg M, Timmermans DR, Ten Kate LP, van Vugt JM, van der Wal G. Are pregnant women making informed choices about prenatal screening? *Genet Med* 2005;**7**(5):332–8.
- Essink-Bot ML, Stouthard ME, Bonsel GJ. Generalizability of valuations on health states collected with the EuroQolc-questionnaire. *Health Econ* 1993;**2**(3):237–46.
- Gandek B, Ware JE, Aaronson NK, et al. Cross-validation of item selection and scoring for the SF-12 health survey in nine countries: results from the IQOLA project. International quality of life assessment. *J Clin Epidemiol* 1998;**51**(11):1171–8.
- Kind P, Brooks R, Rabin R. *EQ-5D concepts and methods: a development history*. Dordrecht: Springer; 2005.
- Ware Jr J, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;**34**(3):220–33.
- van der Bij AK, de Weerd S, Cikot RJ, Steegers EA, Braspenning JC. Validation of the Dutch short form of the state scale of the Spielberger state-trait anxiety inventory: considerations for usage in screening outcomes. *Community Genet* 2003;**6**(2):84–7.
- Maissi E, Marteau TM, Hankins M, et al. The psychological impact of human papillomavirus testing in women with borderline or mildly dyskaryotic cervical smear test results: 6-month follow-up. *Br J Cancer* 2005;**92**(6):990–4.
- Brom D, Kleber RJ. De Schok Verwerkings Lijst [the Dutch version of the impact of event scale]. *Nederlands Tijdschrift voor de Psychologie* 1985;**40**:164–8.
- Horowitz M, Wilner N, Alvarez W. Impact of event scale: a measure of subjective stress. *Psychosom Med* 1979;**41**(3):209–18.
- Brodersen J, Thorsen H. Consequences of screening in breast cancer (COS-BC): development of a questionnaire. *Scand J Prim Health Care* 2008;**26**(4):251–6.
- Brodersen J, Thorsen H, Kreiner S. Consequences of screening in lung cancer: development and dimensionality of a questionnaire. *Value Health* 2010.
- Swaine-Verdier A, Doward LC, Hagell P, Thorsen H, McKenna SP. Adapting quality of life instruments. *Value Health* 2004;**7**(Suppl. 1):S27–30.
- Bunge EM, van den Bergh KA, Essink-Bot ML, van Klaveren RJ, de Koning HJ. High affective risk perception is associated with more lung cancer-specific distress in CT screening for lung cancer. *Lung Cancer* 2008;**62**(3):385–90.
- Rimer BK, Briss PA, Zeller PK, Chan EC, Woolf SH. Informed decision making: what is its role in cancer screening? *Cancer* 2004;**101**(5 Suppl.):1214–28.