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ORIGINAL ARTICLE
Epidemiology and prevention

Short-term impact of cardiovascular screening by traditional risk assessment or coronary artery calcium score on health-related quality of life: the ROBINSCA trial

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Aims

Evidence on the impact of screening for cardiovascular diseases (CVDs) on health-related quality of life (HRQoL) is important for policy decisions about screening implementation and to uncover teachable moments to motivate healthy lifestyle choices. It is unknown whether screening by cardiac computed tomography (CT) scan has a stronger impact on HRQoL than screening by traditional risk prediction models. The study aims to investigate differences in HRQoL across the screening process between participants who were randomized to CVD risk estimation by coronary artery calcium score or Systematic COronary Risk Evaluation.

Methods and results

A subset of 2687 ROBINSCA participants filled in questionnaires at (T0) randomization, (T1) invitation, (T2) 1–3 days before screening, (T3) 1–3 days after, and (T4) screening result. Generic HRQoL (SF-12; EQ-5D) and anxiety (STAI-6) were measured. We investigated the differences in changes in HRQoL across the screening process with linear mixed models. We found comparable levels of HRQoL at all screening moments for the two intervention groups. Mental health scores were worse at invitation and randomization than at the later time points, irrespective of screening group (all $P < 0.001$). A result indicating a heightened CVD risk was associated with increased anxiety in the CT screening group.

Conclusion

Computed tomography screening for CVD risk has no detrimental impact on HRQoL and anxiety levels compared to screening by traditional risk assessment. Receiving an invitation to screenning or a result implying increased CVD risk could function as teachable moments for high-risk individuals.

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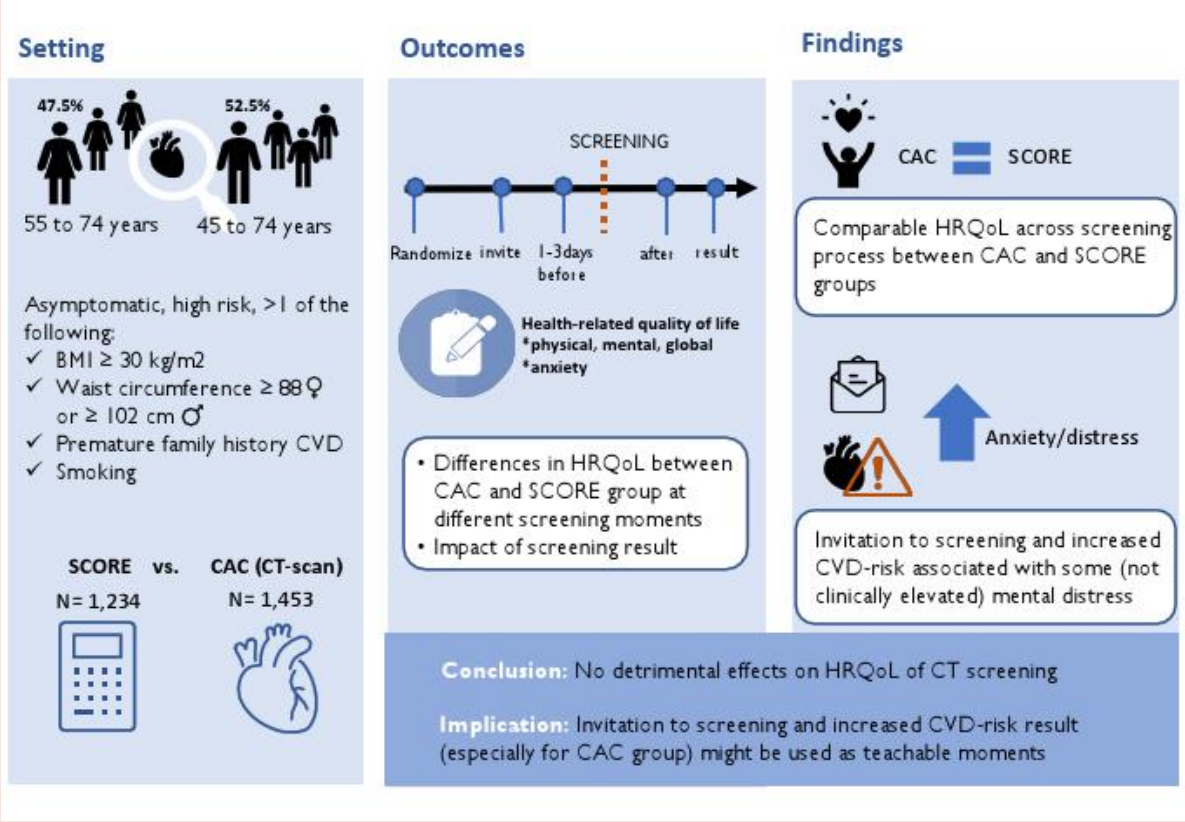
Registration ROBINSCA trial registration number: NTR6471 in Dutch Trial Register (NTR).

Lay summary

- Heart problems make up about a third of all deaths around the world. Detecting and treating heart issues early in people who are at high risk but do not show symptoms could help prevent serious health problems and death.
- This study is part of a bigger trial that was the first of its kind to compare two methods of screening for early signs of heart disease. The more traditionally method predicts how likely one is to develop heart problems based on age, sex, smoking, cholesterol levels, and blood pressure. The second method uses a CT scan to determine the build-up of calcium deposits in the heart's blood vessels or tissues.
- This study looked into how these two methods affect the anxiety and quality of life of participants.
- We did not find any harmful psychological effects from using CT scans for screening, compared to the usual risk calculation methods.
- Getting invited to a screening and learning about higher heart disease risk after a CT scan could cause some stress, but it is not too worrying. These moments could be good opportunities for motivating people to adopt healthy behaviours.

Graphical abstract



Keywords Cardiovascular diseases • Cardiovascular imaging • Early diagnosis • Mass screening • Quality of life • Psychological distress

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Introduction

Cardiovascular diseases (CVDs) are the leading cause of global mortality, accounting for 32% of all deaths with ~17.9 million people dying annually.[1] Early detection and treatment of CVD in high-risk asymptomatic individuals could reduce morbidity and mortality. Current methods to estimate CVD risk, such as the Systematic COronary Risk Evaluation (SCORE and SCORE2) in Europe and atherosclerotic CVD risk calculator or Framingham Risk Score in the USA, are based on risk factors such as age, sex, smoking status, cholesterol level, and blood pressure. However, evidence suggests that the coronary artery calcium (CAC) score obtained through cardiac computed tomography (CT) scans can more accurately predict CVD outcomes in asymptomatic individuals, particularly those at intermediate risk.[2–5] In order to compare these two methods to usual care, the randomized controlled trial 'ROBINSCA' (Risk Or Benefit IN Screening for Cardiovascular disease) estimated participants' CVD risk by either the SCORE risk model or CAC score.[6,7]

Assessing the impact of screening on health-related quality of life (HRQoL) is crucial for both policy decisions regarding implementation and individual decisions about participation. The possible adverse impact of screening on the subject's HRQoL should be minimal and justifiable given the benefits. Severe distress may cause avoidance of subsequent medical examinations and impact treatment compliance.[8,9] However, based on the health belief model, individuals are more inclined to adopt behaviour changes when they perceive themselves at risk of developing a condition with severe consequences.[10] Previous studies have demonstrated an inverted U-shape relationship between negative affect during screening and engaging in healthy behaviours.[11] Participants with too low levels of distress may not see the importance of changing their behaviour. On the other hand, participants with excessive worry may find that it hinders their ability to take healthy decisions and actions. Moderate stress, representing an appropriate response to a heightened CVD risk, might be harnessed for encouraging participants to adopt and maintain healthy behaviours, such as smoking cessation, physical activity, or pursuing a low-fat diet. Screening instances associated with moderate, but not clinically excessive distress might thus be used as so-called teachable moments, where participants are more receptive to lifestyle changes.

Evidence on the impact of CVD screening on HRQoL is scarce and mixed. Most recent studies did not find a clinically meaningful impact of cardiovascular screening by either traditional risk assessment or imaging-based techniques on HRQoL, worry, anxiety, or depression at 1–12 months follow-up or an hour after receiving the results.[12–17] However, several prospective studies found that an abnormal result following imaging based led to more worry or anxiety directly after receiving the results or 6–24 months post-screening.[18,19] There is however a lack of evidence comparing the impact of advanced screening methods, such as CAC score estimation, with traditional risk prediction models. Undergoing CT screening may be perceived as a more impactful experience compared to standard blood tests and risk calculations.

Therefore, this is the first study within a randomized controlled trial to investigate (i) differences in HRQoL and anxiety between CT and SCORE screening groups across specific screening moments and the (2) differences of impact of the screening result (estimated cardiovascular risk) between and within the two screening modality groups.

Methods

The details of the ROBINSCA trial are published elsewhere.[7] In brief, the ROBINSCA trial is a population-based trial performed in three Dutch regions, with the aim to investigate the effect of early detection of CVD risk, assessed by either the classical risk score (SCORE) or CT scan, compared to no screening (usual care), in a high-risk population. A total of $n = 394\,058$ men (45–74 years old) and women (55–74 years old) of the general population were invited. Inclusion criteria were (i) body mass index (BMI) ≥ 30 kg/m^2; (ii) waist circumference ≥ 102 cm for men or ≥ 88 cm for women; (iii) a family history of premature CVDs (before the age of 65); and/or (iv) current smoking. Exclusion criteria were (i) use of lipid-lowering drugs and antihypertensive drugs; (ii) a previous CVD diagnosis; (iii) a CAC measurement in the previous year; and/or (iv) not completed informed consent.

Participants were randomly (1:1:1) assigned to either no screening ($n = 14{,}519$), intervention group A (screening by Dutch SCORE risk calculation) ($n = 14{,}478$), or intervention group B (screening by CAC score) ($n = 14{,}450$). Participants in intervention group A underwent blood sampling and pressure measurement to estimate the 10-year risk of fatal and non-fatal CVD (SCORE) according to the guidelines in effect at that time.[20] This risk prediction is based on age, sex, smoking status, systolic blood pressure, and total cholesterol/high-density lipoprotein cholesterol ratio. The resulting risk could be either low (<10%), moderately increased (10–20%), or high (≥20%). Participants in intervention group B underwent a low-dose CT scan, which allowed measuring CAC, quantified by the Agatston score. The resulting risk could be either low (Agatston < 100), high (Agatston 100–399), or very high (Agatston ≥ 400). Screening only entailed very short contact (~10 min) with a screening employee. There was no further personal contact or interaction moment with a healthcare provider.

Participants and General Practicioners (GPs) received the screening result via letter. Participants with a low-risk result were informed that there was currently no need to further lower the risk of CVD. Participants with a medium and high (SCORE) or a (very) high risk (CAC) were advised to consult their GP to discuss preventive treatment (lifestyle changes and/or medication). In further analyses, we made a distinction between those who had a low-risk result vs. those advised to consult their GP.

From all trial participants, a subsample was randomly (computerized) selected for the HRQoL study. A total of 1577 participants were derived from intervention group A and 1723 participants from intervention group B (*Figure 1*). Only subjects who underwent screening were included in this study ($n = 2687$).

This subsample received Questionnaire 1 along with the letter informing them of their assigned group. They were then sent Questionnaire 2 along with the invitation for screening, ~1.5–2.5 weeks before the screening date. Questionnaire 3 was sent out 1–3 days before the screening, with participants asked to complete it no later than 1 day before the screening. Questionnaire 4 was to be completed within 5–7 days after the screening. Finally, participants received Questionnaire 5 along with the screening result, ~2.5–3 weeks after screening (*Figure 1*).

Measures

Health-related quality of life

Generic HRQoL was measured with the 12-item Short Form (SF-12) and the EuroQol questionnaire (EQ-5D-3L).[21,22] Both questionnaires are often used for assessing psychosocial impact of screening.[23–25] The SF-12 consists of a subset of 12 items from the longer SF-36[26] and has two components: a mental component summary (MCS) and a physical component summary (PCS). Internal consistency of the SF-12 summary scores was generally found to be high (Cronbach's $\alpha = 0.82$ for PCS scale and $\alpha = 0.75$ for MCS scale).[27] Scores on the SF-12 are standardized (i.e. mean = 50 and SD = 10), and higher scores indicate a better HRQoL.

The EQ-5D-3L consists of a preference-based index score and a Visual Analogue Scale (VAS). The calculation of index scores was based on the Dutch tariff,[28] with a value of 1 for the best possible health state (11111) and −0.3 for the worst possible health state (33333). For the VAS, participants drew a line representing their health status on a scale from 0 (worst) to 100 (best imaginable health status).[28,29] A higher score indicates better HRQoL.

General anxiety

The short form of the Spielberger State-Trait Anxiety Inventory 6 (STAI-6) was used to measure general anxiety. Six items related to anxiety (i.e. calm, tense, upset, relaxed, content, and worried) were rated on a 4-point scale. The total summary score ranges from 20 to 80, with higher scores indicating more anxiety. The Dutch translation of the STAI-6 was reported to have good reliability (Cronbach's $\alpha = 0.83$) and highly correlated with the full version ($r = 0.95$).[30]

Statistical analysis

Differences in baseline characteristics between the CAC and the SCORE groups were tested with Mann–Whitney *U* tests and χ^2 tests. We analysed differences in HRQoL between the CAC and SCORE result group across several screening moments: (T0) randomization, (T1) invitation, (T2) 1–3 days before screening, (T3) 1–3 days after, and (T4) screening result. Linear mixed models (LMMs) were fitted with restricted maximum likelihood with the R package lmer; this also allowed the use of incomplete outcome variables under the assumption of missingness at random. The number of observations allowed for an unstructured covariance matrix. Assumptions were checked with diagnostic plots. To test whether the groups differed in HRQoL trajectories, the models included—next to the main effects of the categorical variables—a three-way interaction term between intervention group (SCORE vs. CAC), risk result (low vs. high), and screening moment. Several covariates were also used for controlling possible confounding variables (see passage below).

Since the time span between randomization and screening appointment significantly differed for the SCORE and the CAC groups, time passed since randomization (in days) was included as a covariate. A random intercept for

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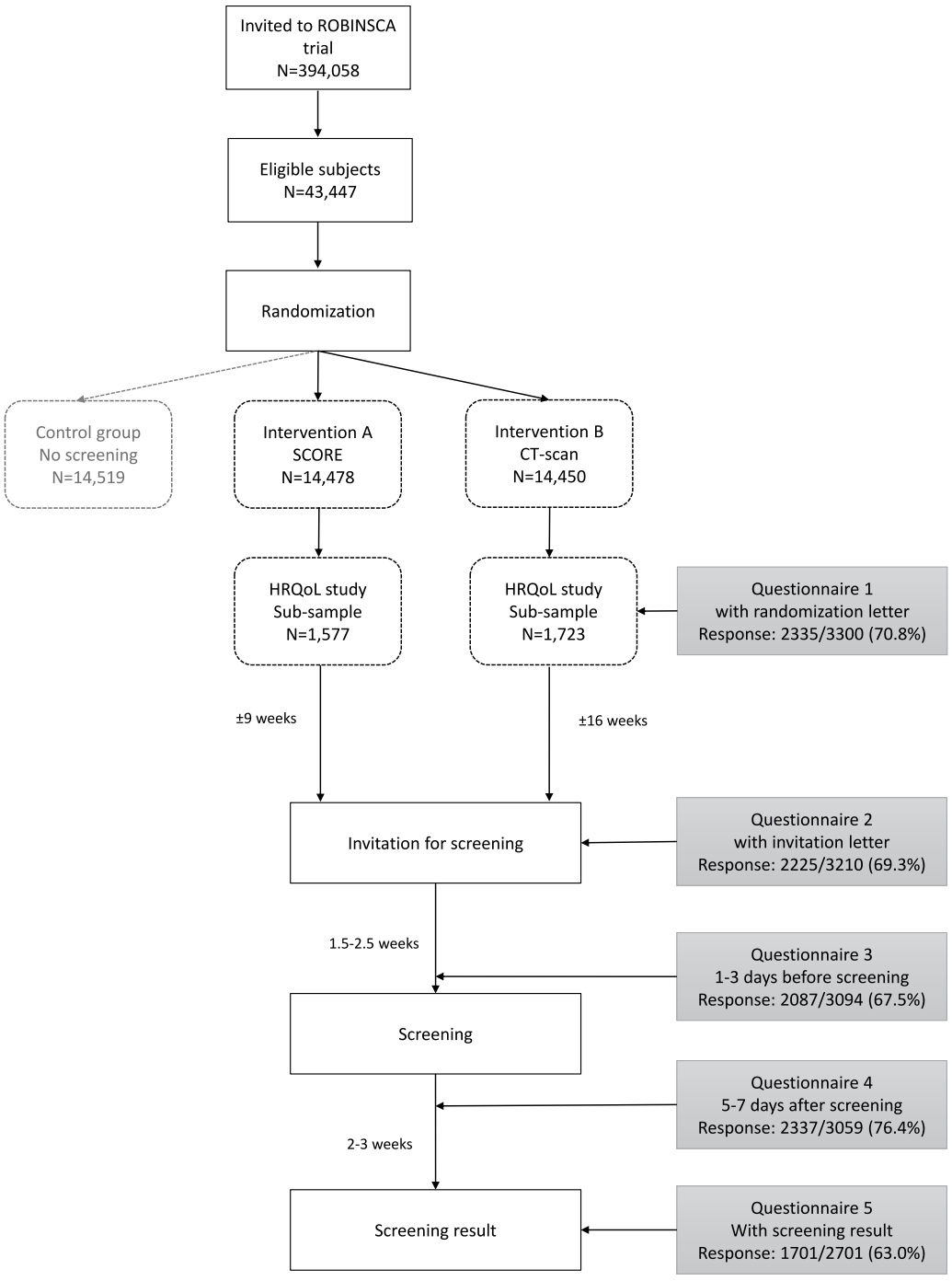

Figure 1 Flowchart of the health-related quality of life substudy within the ROBINSCA randomized controlled trial. A subsample of the ROBINSCA trial participants from the screening groups who either received screening by Systematic COronary Risk Evaluation or coronary artery calcium filled in health-related quality of life questionnaires at five different moments of screening (randomization, invitation, before screening, after screening, and at result). Response rates at each assessment moment are shown.

the individual participants allowed for differences of the outcome variables between individuals at baseline.

We were especially interested in the change in HRQoL between risk groups when having received the risk result (T4) compared to before screening (T2). The following planned contrasts were made to test the impact of a higher CVD risk compared to a lower risk: SCORE low- SCORE high, CAC low- CAC high. The following contrasts were made to test for the impact of receiving a result in the SCORE vs. CAC group: SCORE low- CAC low and SCORE high- CAC high. For the dichotomous classification into low and high scores, any SCORE risk of 10% or higher or a CAC score of 100 or greater was categorized as a high score; all other values were considered low.

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To correct for multiple comparisons (family-wise error rate), the Holm–Bonferroni method was employed for the interaction contrasts.

A $P < 0.05$ was considered statistically significant. To determine clinically meaningful differences, we used the minimal important difference (MID), defined as half of the standard deviation (SD) of the mean.[31] The pooled SD of the two groups at a specific time point was used for intergroup differences, while the SD at the first assessment of the compared time points was used for changes over time.

Covariates and missing data analysis

The following covariates were entered into the models to correct for possible confounding effects on HRQoL: age, sex, education, smoking duration (in years), country of origin, BMI, waist circumference, types of medication used, number of chronic diseases, and family history of CVD. The covariates at baseline were either complete or only 1–3% were missing due to erroneous filling in of the questionnaire (e.g. skipping a line) or difficulties to estimate the value (i.e. for smoking duration). For the repeated HRQoL outcome variables, missing data across all time points ranged between 29 and 31%. Further inspection of the data revealed that individuals who use a greater number of medication types, current smokers, male, sedentary, from non-Western origin, and assigned to the SCORE screening arm had a higher amount of missing HRQoL data.

Results

Baseline characteristics of this study population are summarized in *Table 1*. The median age was 62 years, and almost half of the sample (47.5%) was female. The number of questionnaires sent decreased over time since participants could go off-screen (e.g. already under treatment, no longer interested, and lack of time), off study (e.g. death or emigration), or did not show up for screening.

No statistically significant differences were observed between subjects in intervention group A and intervention group B in all demographic variables (*Table 1*). As these covariates were well balanced between the two randomized screening groups, the interpration of results of the LMMs, both with and without covariate adjustment, did not differ. The subsequent passages report the results with adjustment for covariates, while the unadjusted values can be found in the Supplementary material (see Supplementary material online, *Tables S2* and *S3*).

Differences in health-related quality of life and anxiety between Systematic COronary Risk Evaluation and coronary artery calcium screening groups across time

For a global comparison of impact on HRQoL between screening by CT or SCORE, we first only looked at the interaction term of screening modality and moment of time, averaging over the CVD risk results. A significant interaction ($P = 0.008$) indicated that the intervention groups differed in PCS scores depending on the screening moment. Specifically, simple effects analysis indicated that the CAC group had lower estimated means in PCS scores compared to the SCORE group shortly before screening at T2 [$t(5685) = 2.34$, $P = 0.019$, see *Table 2*]. The statistically significant difference in physical health before screening between SCORE and CT ($b = 0.91$, SE = 0.39) did not represent a clinically meaningful difference, as it did not meet the minimal important cut-off of 4.5. The groups did not differ at other screening moments in their ratings of physical health.

The CT and SCORE groups showed no statistically significant differences in mental health scores (MCS) as measured by the SF-12 at any of the time points. Both groups had the lowest mental health scores at invitation (see *Table 2*), and the scores at invitation were significantly

Table 1 Baseline characteristics of total respondents and by intervention group

	Intervention A: SCORE ($n = 1234$)	Intervention B: CAC ($n = 1453$)	*P*-value
Sex, male (%)	640 (51.9)	772 (53.1)	0.512
Median age at randomization in years (IQR)	62.0 (10)	62.0 (10)	0.420
Educational level			0.113
Low (%)	446 (36.3)	533 (36.8)	
Medium (%)	331 (25.3)	408 (28.2)	
High (%)	473 (38.5)	506 (35.0)	
Country of birth			0.818
The Netherlands (%)	1149 (93.1)	1340 (92.2)	
Other Western country (%)	39 (3.2)	54 (3.7)	
Non-Western country (%)	32 (2.6)	40 (2.8)	
Unknown/don't know (%)	14 (1.1)	19 (1.4)	
Median BMI, kg/m^2 (IQR)	26.0 (5)	26.0 (5)	0.194
Median waist circumference in cm (IQR)	102.0 (15)	102.0 (14)	0.749
Family history of CVD (%)	524 (42.5)	603 (41.5)	0.614
Number of chronic diseases (IQR)	1.0 (2) min = 0, max = 7	1.0 (2) min = 0, max = 9	0.425
Median smoking duration in years (IQR)	10 (29)	10 (30)	0.885
Physical activity level			0.355
Sedentary (%)	11 (0.9)	20 (1.4)	
<30 min/day, ≤5 days/week (%)	372 (30.5)	458 (31.9)	
≥30 min/d, ≥5 days/week (%)	835 (68.6)	958 (66.7)	

Differences in non-normally distributed continous variables are tested by Mann–Whitney *U* test. Differences in frequencies are tested by χ^2 test.
IQR, interquartile range.

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Table 2 Marginal estimated means for the Systematic COronary Risk Evaluation vs. coronary artery calcium screening groups by moment of screening, adjusted for covariates

Outcome (group)	T0 (estimated marginal means, 95% CI)	T1 (estimated marginal means, 95% CI)	T2 (estimated marginal means, 95% CI)	T3 (estimated marginal means, 95% CI)	T4 (estimated marginal means, 95% CI)
SF-12 PCS					
SCORE	48.2 (46.4–50.1)	48.3 (46.5–50.1)	48.7 (46.9–50.5)	48.7 (46.9–50.4)	48.5 (46.7–50.3)
CAC	48.5 (46.7–50.4)	48.2 (46.4–49.9)	47.8 (46.0–49.5)	48.4 (46.6–50.2)	48.7 (46.9–50.5)
SF-12 MCS					
SCORE	49.0 (47.0–51.1)	47.4 (45.5–49.3)	49.9 (47.9–51.8)	50.1 (48.2–52.0)	50.7 (48.8–52.7)
CAC	48.5 (46.7–50.4)	46.7 (44.4–48.6)	50.4 (48.4–52.3)	50.1 (48.2–52.0)	50.1 (48.1–52.0)
EQ-5D-3L					
SCORE	0.801 (0.769–0.832)	0.821 (0.791–0.852)	0.819 (0.788–0.849)	0.823 (0.793–0.853)	0.827 (0.796–0.857)
CAC	0.811 (0.779–0.842)	0.812 (0.782–0.842)	0.824 (0.794–0.855)	0.826 (0.796–0.856)	0.838 (0.807–0.868)
EQ-5D VAS					
SCORE	75.9 (73.2–78.6)	76.7 (74.1–79.3)	76.7 (74.1–79.3)	76.6 (74.0–79.2)	76.9 (74.3–79.5)
CAC	75.8 (73.2–78.5)	76.2 (73.7–78.8)	76.6 (74.0–79.2)	76.8 (74.2–79.4)	76.7 (74.1–79.3)
STAI-6					
SCORE	36.6 (34.6–38.5)	36.6 (34.7–38.5)	36.4 (34.5–38.3)	36.0 (34.2–37.9)	35.5 (33.6–37.4)
CAC	36.8 (34.9–38.8)	36.5 (34.7–38.4)	36.1 (34.2–38.0)	35.8 (33.9–37.4)	36.6 (34.7–38.5)

Adjusted for age, sex, education, country of origin, BMI, waist circumference, types of medication, types of chronic diseases, family history of CVD, physical activity, smoking duration (all at baseline), and averaged over screening result.
T0, trial randomization; T1, invitation to screening; T2, 1–3 days before screening; T3, after screening; T4, result; CI, confidence interval; SF-12, Short Form 12 (generic HRQoL); PCS, physical component summary; MCS, mental component summary; EQ-5D-3L, EuroQoL 5 dimensions 3 levels; VAS, Visual Analogue Scale; STAI-6, Spielberger State-Trait Anxiety Inventory 6.

lower than at later time points, irrespective of intervention group (all $P < 0.001$). None of the statically significant differences in SF-12 mental health scores between invitation and the other time points reached the clinically MID (≈4.5).

The EQ-5D index or VAS scores were not statistically different between the SCORE or CAC screening group at either time point (see *Figure 2D*).

A significant interaction ($P = 0.001$) indicated that the SCORE and CT groups differed in anxiety depending on the screening moment. Specifically, anxiety decreased over time for both groups, until the CT group experienced an increase in anxiety after having received the results. The CT group showed higher anxiety scores at result [$t(6070) = -2.805$, $P = 0.005$]. This statistically significant difference ($b = 1.17$, SE = 0.42) did not reach the clinically meaningful difference cut-off score of 4.3.

Differences in health-related quality of life and anxiety depending on the screening result

The distribution of screening results within the two intervention groups (*Table 3*) reflects the distribution of the complete trial.[32] The risk result groups did not differ in their trajectory over time in physical health (PCS), mental health (MCS), or general HRQoL as measured by the EQ-5D index (*Figure 2A–C*, and for underlying data, see Supplementary material online, *Table S1*). There was an effect of CVD risk result on EQ-5D VAS scores at results (T4). The high CAC group had significantly lower VAS scores than those with a low-risk result [$t(4953) = 3.29$, $P = 0.006$] after adjustment for multiple comparisons. This difference ($b = -2.67$, SE = 0.81) did not represent a clinically significant difference (MID = 5.9). SCORE low- and high-risk result groups did not statistically differ in their VAS scores at result (T4).

The effect of CT screening on anxiety that was mentioned in the passage before is primarily driven by the high CAC group. Compared to before screening (T2), anxiety levels significantly decreased in the low-risk groups after receiving their results (see *Figure 2E*). Anxiety levels in the SCORE high-risk group remained unchanged upon receiving their results, while in contrast, anxiety increased in the high CAC group after getting their results. The high CAC group experienced significantly more anxiety at result (T4) than the SCORE high-risk group [$b = 2.14$, SE = 0.64, $t(5988) = 3.34$, $P = 0.003$] or their low CAC counterparts [$b = 3.26$, SE = 0.60, $t(5477) = 5.47$, $P < 0.001$] after adjustment for multiple comparisons. These statistically significant differences in anxiety of the CAC high group compared to the other groups or to before screening did not reach the clinically meaningful difference cut-off score (>4).

Effects of demographic covariates on health-related quality of life

Generally, female sex, lower education level, immigration background, longer smoking duration, larger waist circumference, reduced physical activity, and higher number of medication types and chronic diseases were statistically significantly related to lower quality of life in the studied asymptomatic population (data not shown).

A family history of CVD and younger age were significantly related to increased anxiety. A higher BMI was related to lower physical health, but also to higher mental health, lower anxiety, and overall health (EQ-5D).

Discussion

To make an informed decision about implementing CT screening for its improved predictive ability to estimate cardiovascular risk in a high-risk

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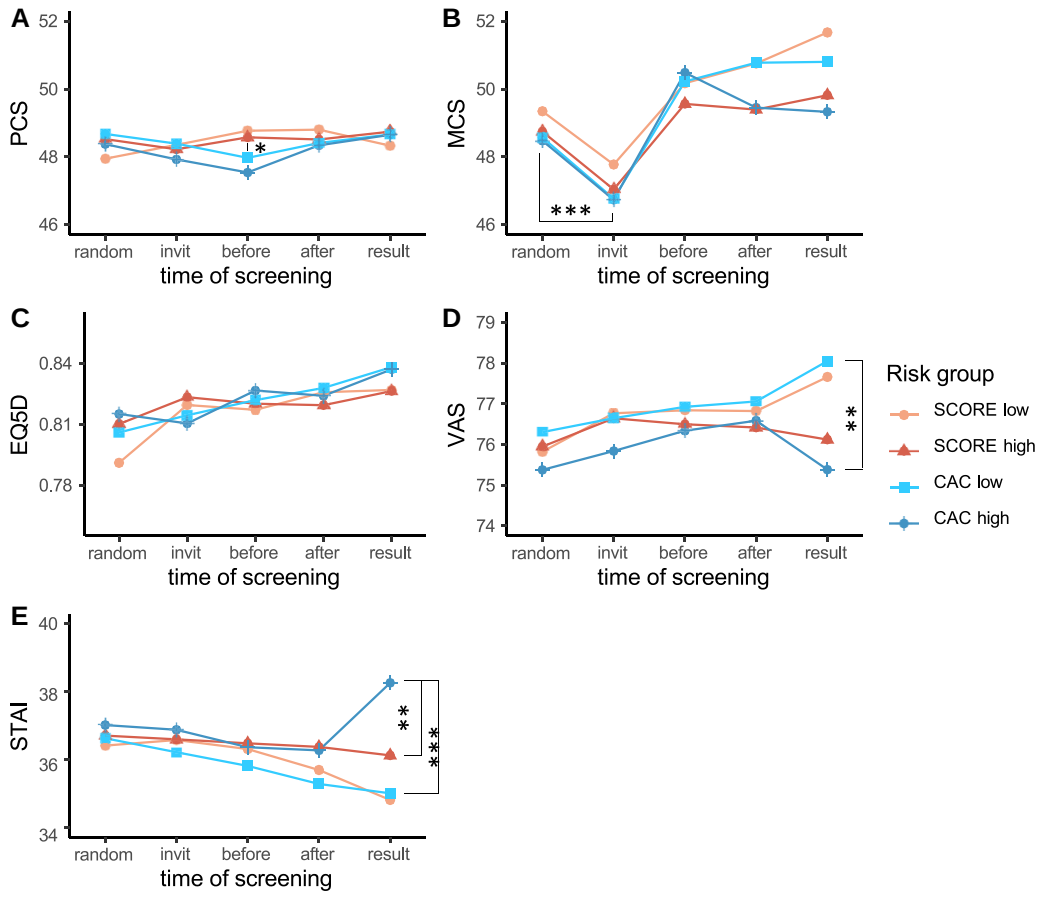

Figure 2 Changes in health-related quality of life and anxiety scores of the risk result groups during the screening process. The changes in estimated marginal means in health-related quality of life (measured by EQ-5D and SF-12) and anxiety (measured by STAI-6) over time are shown for both screening groups (coronary artery calcium and Systematic COronary Risk Evaluation). The two screening groups are further split up according to the risk result participants received. *Note*: It is important to keep in mind that the *y*-axes do not start at 0 when interpreting the graphs. This is done for better visibility of a possible meaningful clinical difference. Higher scores represent higher health-related quality of life, except for STAI (anxiety). *$P < 0.05$; **$P < 0.01$; ***$P < 0.001$. All the presented statistically significant differences did not reach the clinically minimal important difference. Part A: PCS, physical component summary of SF-12 = Short Form 12 (generic HRQoL); Part B: MCS, mental component summary of the SF-12; Part C: EQ-5D, EuroQoL 5 dimensions 3 levels; Part D: VAS, Visual Analogue Scale; Part E: STAI-6, Spielberger State-Trait Anxiety Inventory 6.

Table 3 Distribution of screening results (estimated cardiovascular disease risk category) within both screening groups

Screening result: CVD risk	Frequency (%)
SCORE	
>10%	562 (45)
10–20%	321 (26)
≥20%	351 (29)
CAC	
<100	1093 (75)
100–399	226 (15)
≥400	134 (9)

Those with a screening result of SCORE ≥10% or CAC ≥100 were advised to consult their GP for preventive treatment.

population, the impact on HRQoL should be considered. Ideally, as screening targets a large asymptomatic and healthy population, effects of CT screening on HRQoL should be minimal and not clinically relevant. In line with this, we did not find any clinically important differences in CT scan vs. traditional risk assessment on HRQoL and anxiety. Health-related quality of life outcomes were comparable between the two screening groups at all time points, and neither screening modality had a detrimental effect on distress levels. Overall, distress even decreased during the screening process. This replicates earlier studies that have found a decline in distress post-screening compared to pre-screening.[14,15]

The CT screening group reported statistically significant lower physical health shortly before screening than the SCORE group, possibly due to some additional uncertainty with the screening process and health preoccupation before screening. The CT screening group also experienced statistically higher anxiety after having received the results, which was due to the increase anxiety of participants with abnormal CAC score. These statistically significant differences did not represent clinically relevant differences, implying no harmful impact of CT screening.

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Population-based screening provides an opportunity to promote behaviour change among a wide audience.[33] Both screening groups reported their lowest mental health at the time of invitation, likely due to being confronted with the idea of being screened and the potential high CVD risk. While distress is statistically significant and increased at this stage, the screening population did not experience a surge in anxiety at a clinically relevant level. In line with previous findings of an inverted U-shaped relationship of distress and engaging in health behaviours,[11] the invitation period could be utilized as a teachable moment to address cardiovascular risk factors such as smoking, drinking, and physical inactivity. These behaviour changes are also relevant for other major non-communicable diseases like cancer, chronic obstructive pulmonary disease, and diabetes.

While no significant differences were observed using the SF-12 or EQ-5D index score as measures, the CAC high group had lower scores on the EQ-5D VAS than those with a low CVD risk. A previous study investigating the correspondence between EQ-5D index and VAS score found that distress was an additional determinant of the VAS score,[34] potentially explaining why the VAS score was more sensitive to changes in psychological distress in our study compared to the EQ-5D index.

An increased CVD risk as measured by CAC may be associated with some psychological distress, although not clinically elevated, as seen in previous pre-post studies.[18,19] Studies that have not found an effect of an abnormal result on HRQoL or distress have assessed HRQoL only several months after screening.[16,17] However, one study by Jørgensen *et al.*[15] found that worry measured one hour after screening was not increased compared to before screening invitation. In our study, we observed increased distress several days after receiving the results, which suggests that distress may increase after some time for reflection, allowing participants to process the implications of their heightened CVD risk. Similar to other impactful healthcare experiences such as doctor visits or disease diagnosis, receiving an abnormal result can serve as a teachable moment by providing personalized feedback on the harms of unhealthy behaviours.[35]

Other studies have indeed demonstrated positive effects of high CAC scores on various health behaviours, including medicine intake, further consultations and testing, dietary changes, and physical activity.[18,36–38] Conveying the message about the importance of lifestyle changes in preventing CVD at the optimal moment, such as several days after receiving the results, may enhance the positive effects, particularly for those with increased CAC.

In a prior analysis of the ROBINSCA trial by Denissen *et al.*,[39] individuals with high CAC levels engaged in more prevention-seeking behaviour compared to individuals with an increased CVD risk in the SCORE group. Consistent with these findings, the high-risk CAC group experienced increased anxiety in our study after receiving the result, while the SCORE high-risk group showed no significant changes in anxiety. Taken together, the results suggest additional impact of receiving a result in the CT vs. the SCORE group on anxiety and thereby ultimately on behaviour.

However, the high-risk participants received a uniform message to consult their GP for lifestyle changes and preventive medication, irrespective of the screening arm. Future research should explore whether the impact on HRQoL is stronger when the communication about the results includes CT images visualizing the calcification and provides personalized risk feedback using easily understandable graphical representations.[40]

We replicated findings of Søgaard *et al.*[12] and Johnson *et al.*[17] that receiving a result indicating a low CVD risk (e.g. a CAC score between 0 and 100 or SCORE of below 10%) was related to a significant decrease in distress. A result indicating a low risk can be seen as a rightful reassurance for individuals, especially a CAC score of 0. However, careful communication when informing the results is warranted, to ensure that participants with a low risk (continue to) engage in healthy lifestyle choices to retain their low CVD risk.

To the authors' knowledge, this is the first trial comparing HRQoL and anxiety levels between cardiovascular screening modalities in a large, randomized sample across time. This information is crucial for cost-effectiveness analyses and policy-making decisions regarding cardiovascular screening implementation. Several limitations of the studies have to be considered, such as the use of self-reports that may be susceptible to social desirability and recall biases. We aimed to mitigate such inaccuracies with narrow reporting time windows. Next, self-selection might have occurred in that healthier individuals with more health literacy might have a higher response rate. In line with this notion, we found that longitudinal dropout, e.g. not completing all the HRQoL questionnaires, was related to lower education, sedentary lifestyle, non-Western immigration background, more types of medication used, and smoking status.

According to the guidelines of that time, the study is based on the SCORE, while in the meantime the SCORE2 was released with a change in calculation methodology. Compared to the SCORE model, the SCORE 2 predictions result in a higher proportion of high-risk participants eventually being classified into a high-risk category and requiring medication. This could also influence HRQoL measures.

Lastly, the study population is limited to the Netherlands, and the results may not be generalizable to the more diverse global population due to specific lifestyle factors. The study was however conducted in three different Dutch regions, with different sociographic compositions with varied levels of urbanization, socioeconomic status, and education level.

While this study focuses on short-term HRQoL outcomes and teachable moments during the screening process, long-term differences in HRQoL between screening modalities and risk results have yet to be investigated.

Conclusions

Before implementing imaging techniques such as cardiac CT scans for screening, it is important to consider factors beyond prognostic value and mortality benefits, including the psychological impact on participants. Our findings, which do not indicate a negative clinical impact on HRQoL in the CT screening group, support the favourable benefit-to-harm ratio of CT screening compared to traditional risk assessment in a high-risk population. Further trial data and cost-effectiveness analyses are needed to fully understand the added value of CT screening in comparison to traditional risk assessments and usual care.

Invitation to screening and receiving a high CVD risk result, as indicated by CAC measurements, present opportunities for teachable moments where participants are more likely to respond to behaviour change interventions.

Lead author biography

Dana Moldovanu is a PhD candidate at the Department of Public Health and practising psychologist at Erasmus Medical Centre in Rotterdam, the Netherlands. She studies the impact of population-based screening programmes on health-related quality of life, as well as how to motivate screening participants to adopt healthier lifestyle behaviours.

Data availability

The data underlying this article cannot be shared publicly due to protecting the privacy of individuals that participated in the study. The data will be shared on reasonable request to the corresponding author.

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Supplementary material

Supplementary material is available at *European Heart Journal Open* online.

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