New and more individualised population-based screening for cardiovascular disease; from a RCT including selfassessments, primary care and coronary artery calcification score to modelling risk-benefit

Reporting

Project Information

ROBINSCA

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Final Report Summary - ROBINSCA (New and more individualised population-based screening for cardiovascular disease; from a RCT including selfassessments, primary care and coronary artery calcification score to modelling risk-benefit)

Coronary Heart Disease (CHD) remains a major cause of morbidity and mortality worldwide. Despite all medical advances last decades, one major concern is that CHD is often asymptomatic until the presentation of a serious event as myocardial infarction (MI) leading to persisting disability and/or premature death. The rationale of screening is to halt or delay progression of the (subclinical) disease and thereby gain healthy life-years by offering treatment options at an earlier, yet undetected, and hopefully more efficacious stage.
The ROBINSCA trial was started to provide evidence on the potential effectiveness of screening for a high risk of developing cardiovascular diseases (CVD), as it is unknown whether such screening for subclinical disease improves outcomes enough to justify the associated adverse effects and costs.
About 390,000 men (aged 45-74 years) and women (aged 55-74 years) from the general population received an information packet (information brochure, risk questionnaire, waist circumference tape, informed consent form, invitation to participate). A total of 43,447 who completed the baseline questionnaire and fulfilled at least one of the inclusion criteria were included in the trial. Through the baseline questionnaire, general personal data was obtained like weight, waist circumference, country of birth, educational level and smoking status. Furthermore, general health was questioned (blood pressure, cholesterol, chronic diseases) as well as current medication use. Randomization (1:1:1) allocated the participants to either a control arm, intervention arm A where classical risk factor screening was performed, or intervention arm B where CT screening to quantify coronary artery calcium (CAC) was performed. These numbers are anticipated to have enough power to detect a possible meaningful effect in reducing morbidity and mortality related to coronary heart disease.

We achieved to screen 12,184 participants from intervention arm A by collecting blood for cholesterol measurements and by measuring blood pressure. From intervention arm B, 12,950 participants were screened by CT scanning for quantifying CAC. Within intervention arm A, 45.1% of the screened individuals is at low risk, 26.5% has a medium risk, and 28.4% is at high risk of developing cardiovascular disease. In intervention arm B, 76% is at low risk, 15.1% has a high risk, and 8.9% is at very high risk of developing cardiovascular disease. All screening results were communicated to both the participant and their general practitioner. Participants at high risk were advised to consult their general practitioner to start preventive measures according to the study treatment protocol.

Several questionnaires were sent to subsamples of participants before and after screening. One online questionnaire was designed to measure contamination bias, as this can affect the power of the trial. A sample of 700 participants was asked whether they underwent a screening different from their allocated screening by randomization. Results showed that there was almost no contamination seen in intervention arm A and in the control arm. For intervention arm B, the amount of contamination could not precisely be

determined but is likely to be low enough to maintain statistical power in the trial. Another online questionnaire questioned 600 participants about the impact of receiving the screening result at home. Participants with a screening result indicating a high risk for developing CVD in the future showed preventive-seeking behaviour by consulting their general practitioner for help in preventing CVD, especially participants who underwent CT-scanning. Also, almost all at risk participants stated that they comply with the preventive treatment prescribed by the general practitioner. Last, a subset of questionnaires was developed to measure the health-related quality of life and general anxiety. At several time points before and after screening, 4,967 participants were asked to complete five questionnaires. Results from the completed questionnaires are currently being analysed.

Combining data from the baseline questionnaire, screening results and sub-study questionnaires, a large database was created. Various associations can be investigated with this database. First, the prevalence and distribution of CAC and its predictors in this Dutch population were examined. Also, associations of body mass index and physical activity with CVD risk, either assessed in the classical way or with CT-screening, were investigated. Several other research topics have been identified, for example the association of baseline medication or smoking behaviour or diabetes mellitus or other comorbidities with CVD risk. These subjects are currently under investigation.

All participants will be followed for five years, and more. Then, CVD-related information will be obtained from general practitioners, hospitals and Statistics Netherlands. This information will provide insight in consults and/or hospitalizations related to CVD morbidity, referrals to cardiologists, CVD treatment prescriptions, or CVD-related mortality. At present, mean follow-up of individuals is about 4 years, so that it will take two more year for the final analyses (one year for completing the time frame of the follow-up and one year for all data linkages, data quality control, analyses, e.g.).

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