Intervention study investigating the effect of a dietary intervention geared towards improved adherence to the Dutch dietary guidelines on the 10-year risk for recurrent vascular events (SMART risk score) in patients with cardiovascular diseases compared with usual care.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON49536

Source
ToetsingOnline

Brief title
Dutch dietary guidelines for patients with cardiovascular diseases.

Condition

- Cardiac disorders, signs and symptoms NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Cardiovascular diseases

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van Volksgezondheid;Welzijn en Sport via nationaal preventieakkoord en regiodeal aan de Stichting Alliantie Voeding in de Zorg

Intervention

Keyword: cardiovasculair diseases, Dutch dietary guidelines, RCT, SMART risk score

Outcome measures

Primary outcome

The change in Smart Risk Score from baseline until 6 months will be the primary outcome of this study. The SMART Risk Score estimates the 10-year risk for recurrent vascular events in patients with manifest cardiovascular disease based on the following modifiable parameters: systolic blood pressure, creatinine, hsCRP and cholesterol.

Secondary outcome

Secondary study variables are the difference in biomedical cardiovascular outcomes, nutritional status, and mental and physical wellbeing between intervention and control group from baseline to 6 months.

Cardiovascular outcomes include systolic and diastolic blood pressure, biomarkers such as hba1c, cholesterol, triglycerides, eGFR, insulin and glucose and inflammation markers. In addition, we measure urine to be able to determine

salt and protein. Body weight and waist circumference are further outcomes of the study.

Nutritional status is measured by the DHD15 index, which requires participants to complete a habitual diet questionnaire. Furthermore, a number of biomarkers for nutrition are used.

Mental and physical fitness is measured with questionnaires about quality of life, self-efficacy, mental status, and physical activity. In addition, data on health care use is requested and hospitalization, development of comorbidities and mortality from the patient files will be assessed.

Study description

Background summary

In contrast with the wealth of data on the role of nutrition in prevention of disease, there is a sparsity of data on the effect of better adherence to dietary guidelines on secondary prevention of disease in patients with cardiovascular diseases.

Study objective

The aim of this study is to investigate the effect of a dietary intervention geared towards improved adherence to the Dutch dietary guidelines on the 10-year risk for recurrent vascular events (SMART risk score) in patients with cardiovascular diseases compared with usual care.

Study design

The study will be a 6-months randomized, controlled trial. Hereafter, participants will be followed-up for 6 months.

Intervention

The intervention group will receive personalized guidance from a dietician to improve adherence to the Dutch dietary guidelines, the control group will receive usual care.

Study burden and risks

Participants of the study will be asked to complete questionnaires, donate blood samples and collect 24hr urine samples. Participants in the intervention group will meet with a dietitian at least seven times, and will be stimulated to adjust their dietary intake towards better adherence with the dietary guidelines. The dietary advices that are given in this study are the Dutch Dietary Guidelines (Richtlijnen Goede Voeding), which means these advices are applicable to the whole Dutch society. These guidelines are based on years of scientific evidence and are generally regarded as safe advices, without direct risks for patients. Benefits for participants include probable improvements of cardiovascular risk factors which can lead to reduction of symptoms and improvement of quality of life. This research may be beneficial to group of cardiovascular patients, since the results will probably contribute to a dietary guideline for their disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Be categorised in the highest risk category of the guideline for cardiovascular risk management 2019 (Tjin-A-Ton, J., & Vrolijk, M., 2019). This includes patients with:
o Previously diagnosed cardiovascular disease, including acute coronary disease syndrome, angina, coronary revascularization, TIA or stroke, symptomatic aortic iliofemoral atherosclerosis, aortic aneurysm, intermittent claudication or peripheral revascularization.
- Aged 18 year or older.

Exclusion criteria

- Uses medication (e.g. metformine, sulfonylureumderivate, insulin or DPP4-inhibitors/GLP1-agonists) for treatment of diabetes
- a known hereditary form of cardiovascular diseases (e.g. Familial hypercholesterolaemia)
- chronic kidney disease in stage 4 or above (meaning an eGFR<30)
o In this case, patients should get dietary advise about their protein intake, which is not in line with the general advise in our study
- The patient has changes in one or more of the following medication in the past two weeks: lipid-lowering agents, blood pressure-lowering agents, glucose-lowering agents and antithrombotics
- The patient participates in another research study of which the outcomes may interfere with the current trial
- Not able to speak and understand the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-05-2021
Enrollment:	144
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-08-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-03-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL73021.091.20

Study results

Date completed: 07-12-2023

Results posted: 28-11-2024

Actual enrolment: 124

First publication
26-11-2024