Healthy Heart - Effect van een leefstijl interventie programma voor patiënten met een verhoogd risico op hart- en vaatziekten in de huisartsenpraktijk

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26762

Source
Nationaal Trial Register

Brief title
Healthy Heart

Health condition

Cardiovascular disease, prevention, lifestyle intervention

Sponsors and support

Primary sponsor: Leiden University Medical Center
Primary Care Group The Hague (ELZHA)
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Primary outcome is the difference in mean proportion of achievement of individual lifestyle goals between the control group (all patients during usual preventive care) and the intervention group (all patients during combined usual preventive care and group-based intervention).

Secondary outcome

As secondary outcomes we will evaluate change of lifestyle (composite of: stopping smoking, reducing alcohol intake, improving diet, reducing overweight, increasing physical activity) and compliance to (Dutch) lifestyle guidelines. Furthermore, we aim to identify the most effective components of the program and effective components of implementation of the program in primary care. Other secondary outcomes include quality of life, self-efficacy, cost-effectiveness of the integrated lifestyle program and treatment effects on blood pressure and cholesterol levels. For these secondary outcome measures we will assess differences between primary care practices in high- and low socioeconomic areas and between participants with western and non-western ethnicity.

Lastly, we want to assess food security status to assess the degree of food security. Further, we want to assess associations between risk factors for cardiovascular diseases and food security status, and the association between setting individual lifestyle goals and food security status.

Study description

Background summary

In the Healthy Heart project we evaluate two prevention strategies (individual usual care and a group-based lifestyle program) in a real-life primary care setting. Usual preventive care consists of one to four individual consultations during one year with a primary care nurse, specialized in cardiovascular care and trained for lifestyle education. During the intervention period patients proceed, based on shared-decision-making, with usual preventive care or follow the integrated group-based lifestyle program. Patients who choose to follow the group-based lifestyle program, attend seven to ten group sessions during 4 to 6 months in groups of 10 persons. During the group sessions, all aspects of lifestyle change (smoking, alcohol intake, diet, overweight, physical activity) are discussed by a lifestyle coach.

Study objective

Cardiovascular disease (CVD) is among the most frequent chronic diseases in the Netherlands. So, prevention is of high importance and primary care could play an important role. The cornerstone of CVD prevention is lifestyle change. However, knowledge on effectiveness and implementation of lifestyle intervention programmes in primary care is scarce. This project adds valuable knowledge of effect and successful implementation of integrated lifestyle intervention in primary care. Furthermore, food security status will be

assessed which is an important risk factor for CVD.

Study design

Patients will be included during consultation with the general practitioner or primary care nurse. Using questionnaires at baseline and 3, 6, 12 and 24 months after inclusion, we will assess achievement of individual lifestyle goals and change of lifestyle. Furthermore, all eligible patients will be asked to complete a questionnaire about barriers and facilitators to participation in this project. Routine care data will be used to compare blood pressure and cholesterol levels between patient groups.

Intervention

In this project we evaluate two prevention strategies (individual usual care and a group-based lifestyle program) in a real-life primary care setting, using a stepped-wedge observational cohort design. During the control period patients will be offered usual preventive care only. Usual preventive care consists of one to four individual consultations during one year with a primary care nurse, specialized in cardiovascular care and trained for lifestyle education. During the intervention period patients proceed, based on shared-decision-making, with usual preventive care or follow the integrated group-based lifestyle program. Patients who choose to follow the group-based lifestyle program, attend seven to ten group sessions during 4 to 6 months in groups of 10 persons. During the group sessions, all aspects of lifestyle change (smoking, alcohol intake, diet, overweight, physical activity) are discussed by a lifestyle coach.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Patients must be registered at primary care practices connected to Primary Care Group The Hague (ELZHA; Eerstelijns Zorggroep Haaglanden).

- Patients must be identified as high risk patients, which corresponds to a 10-year cardiovascular risk of >10% according to Dutch guidelines.

For the selection of high risk patients the following ICPC codes will be used, namely hypertension uncomplicated (K86), hypertension complicated (K87) and lipid disorder (T93). In addition, the following ATC codes will be used, namely cardiac therapy (C01), antihypertensive drugs (CO2), diuretic drugs (CO3), peripheral vasodilators (C04), vasoprotective drugs (G05), beta blocking agents (C07), calcium channel blockers (C08), agents acting on the renin-angiotensin system (C09) and lipid modifying agents (G10).

- Patients must be capable of giving informed consent (IC).

Primary care practices connected to ELZHA are eligible to participate in this study if data on blood pressure, fasting serum lipid profile and smoking status are accessible through patient records in at least 70% of their high risk population.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Patients who have an ICPC coded diagnosis of cardiovascular disease will be excluded.

For the exclusion of CVD patients the following ICPC codes will be used, namely ischemic heart disease with angina pectoris (K74), acute myocardial infarction (K75), ischemic heart disease without angina pectoris (K76), transient cerebral ischemia (K89), cerebral infarction (K90.03), intermittent claudication (K92.01) and aortic aneurysm (K99.01).

- Patients who have an ICPC coded diagnoses of diabetes mellitus (T90) will be excluded.

- Patients living in nursing homes will be excluded.

- Patients with dementia will be excluded.

- Patients with major comorbidity, for example patients who are terminally ill, will be excluded, based on judgment of the general practitioner.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2017
Enrollment:	1600
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-02-2018
Application type:	First submission

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
NTR-new	NL6834
NTR-old	NTR7071
Other	NL60795.058.17 ABR-form CCMO : P17.079 METC Leiden University Medical Center

Study results