

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

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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,...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26762

Bron

Nationaal Trial Register

Verkorte titel

Healthy Heart

Aandoening

Cardiovascular disease, prevention, lifestyle intervention

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Primary Care Group The Hague (ELZHA)

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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 (C02), diuretic drugs (C03), 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-07-2017
Aantal proefpersonen: 1600
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 26-02-2018
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten