selective prevention of cardiovascular disease witH panElmAnagement and integrated LifeSTYlE inTervention in primARy care (HEALThY HEARt)

Published: 12-06-2017
Last updated: 13-04-2024

The primary goals of this project are to 1) evaluate the effectiveness, 2) identify effective elements and 3) find successful implementation factors of an integrated group-based lifestyle intervention programme in primary care.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON45708

Source
ToetsingOnline

Brief title
Healthy Heart

Condition

- Cardiac disorders, signs and symptoms NEC
- Vascular disorders NEC

Synonym
Cardiovascular diseases

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cardiovascular disease, Lifestyle intervention, Prevention, Primary care

Outcome measures

Primary outcome

The primary outcome is change of lifestyle (composite of: stopping smoking, reducing alcohol intake, improving diet, reducing overweight, increasing physical activity).

Secondary outcome

As secondary outcomes we aim to identify the most effective components of the program and effective components of implementation of the program in primary care. 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.

Study description

Background summary

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.

Study objective

The primary goals of this project are to 1) evaluate the effectiveness, 2) identify effective elements and 3) find successful implementation factors of an integrated group-based lifestyle intervention programme in primary care.

Study design

Using a stepped-wedge design we will assess effectiveness. The implementation will be evaluated with mixed-methods design. High risk patients (n=1600) are identified and followed with a panelmanagement method.

Intervention

In this project we evaluate two prevention strategies (individual and group-based) in a real-life primary care setting. Based on shared-decision-making patients proceed with usual preventive care or follow the integrated group-based lifestyle program.

Study burden and risks

High risk patients are invited for a consultation in their primary care practice and are offered the integrated group-based intervention. Based on shared-decision-making patients proceed with usual preventive care or follow the integrated group-based lifestyle program. Usual preventive care consists of one to four consultations during one year with a primary care nurse, specialized in cardiovascular care and trained for lifestyle education. 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. Using questionnaires at baseline and at the end of the intervention (usual preventive care or the integrated group-based lifestyle program), we will asses 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.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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 ELZHA.
- 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 (C05), beta blocking agents (C07), calcium channel blockers (C08), agents acting on the renin-angiotensin system (C09) and lipid modifying agents (C10).
- 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
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

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

Ethics review

Approved WMO

Date:	12-06-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	12-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL60795.058.17