A randomised controlled trial on the effects of an individual tailored lifestyle intervention to minimise the cardiovascular disease risk of individuals with Familial Hypercholesterolemia (FH)

Published: 27-08-2008
Last updated: 06-05-2024

The study aims at examining the effect of an individual tailored lifestyle intervention to reduce the cardiovascular disease risk in people with FH.Secundary, the study aims at promoting a healthy lifestyle (no smoking, proper nutritional pattern,...

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

Summary

ID

NL-OMON33700

Source
ToetsingOnline

Brief title
The PRO-FIT study

Condition

- Cardiac disorders, signs and symptoms NEC
- Metabolic and nutritional disorders congenital

Synonym
Type III hyperlipidemia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw-Preventie

Intervention

Keyword: Cardiovascular disease risk, Familial Hypercholesterolemia, Lifestyle

Outcome measures

Primary outcome

1. LDL cholesterol

Secondary outcome

2. Biological cardiovascular risk indicators: blood pressure, glucose, body mass index (BMI), waist circumference, triglycerides, LDL cholesterol, blood total cholesterol (TC), HDL cholesterol and TC/HDL ratio.

3. Lifestyle intentions and behaviours (non-smoking, > 30 minutes of daily physical activity, a prudent nutritional pattern, and compliance to FH-related medication);

4. Psychological correlates and determinants of a healthy lifestyle: motivational factors (attitude, self-efficacy, social influences) and awareness factors (knowledge, cues to action, risk perception)?;

Study description

Background summary

Cardiovascular disease (CVD) has the highest burden in disability adjusted life years (DALYs) in the Netherlands5. FH is characterized by an elevated risk of developing cardiovascular disease. Worldwide, no in-depth intervention is known on the promotion of a healthy lifestyle within this risk population. Until now, attention has mainly been focussed on the effectiveness of pharmaceutical

interventions instead of achieving a relevant lifestyle improvement4.
Given the high a priori CVD risk of people with FH and proven effects of lifestyle interventions in other high-risk groups the absolute risk reduction that can be gained is much larger than in the general population.

Study objective

The study aims at examining the effect of an individual tailored lifestyle intervention to reduce the cardiovascular disease risk in people with FH.
Secundary, the study aims at promoting a healthy lifestyle (no smoking, proper nutritional pattern, sufficient physical activity, adherence to medication) in people with FH.

Study design

The study is a randomised controlled trial. 400 people who are notificated of their positive FH-status, are randomly assigned to either the intervention (n=200) or control group (n=200).

Intervention

The intervention consists of counselling a health lifestyle which is a combination of web-based counselling, face-to-face counselling (1 session), brochures and telephone booster sessions (3 sessions). Face-to-face counselling will take place at the participant*s home. The control group will not receive this intervention.

Study burden and risks

The intervention (including all intervention components) will cost approximately 135 minutes, as calculated in section E2 of this form. We expect the participants, who are just notificated of their FH status, have a higher intrinsic motivation to change their lifestyle. Thereby, the type of behaviour to change is dependent on their personal situation (tailored counselling) and that*s why we expect the participants to be motivated to cooperate.

Measurements and questionnaires will also take time (approximately 130 minutes, see section E2 of this form) but do not pose a risk to the participants.
Benefits for the participants include gained knowledge about behavioural change with regard to the risk of premature CVD. Additionally, increased physical activity has a beneficial effect on psychological wellbeing.

Contacts

Public
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7
1081 BT Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7
1081 BT Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

People are included if*
-FH is diagnosed by standard StOEH procedures between january 2007 and march 2009
-aged 18-70 years old
-living in 150 km radius of Amsterdam
-sufficiently fluent in Dutch
-given informed consent
-being able to be moderately physically active

Exclusion criteria

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-01-2009
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-03-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL23932.029.08