The effect of individually tailored lifestyle counselling on the cardiovascular disease risk of people with Familial Hypercholesterolemia (FH).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22727

Source
NTR

Brief title
PRO-FIT: promoting a healthy lifestyle in people with FH through an individually tailored lifestyle intervention.

Health condition

Familial hypercholesterolemia (FH) is an autosomal dominant disorder of the lipoprotein metabolism. Due to a defect of the low density lipoprotein (LDL) receptor gene, plasma concentrations of LDL cholesterol (LDL-C) are elevated. In the Netherlands, approximately one in 300 people is affected with the heterozygous type of FH. A national cascade screening project to detect people with FH was introduced in 2003 by the Ministry of Health, Welfare, and Sports. The project is run by the Foundation for Tracing Hereditary Hypercholesterolemia (StOEH) and through this project, some tens of thousands of people in the Netherlands have already been and are made aware that they have FH. Elevated serum LDL-C in general and therefore also FH is associated with an elevated risk of premature cardiovascular disease (CVD)(4), which is the disease with the highest burden in disability adjusted life years (DALYs) in the Netherlands. If not diagnosed and treated, the cumulative risk of developing coronary artery disease (CAD) by age of 60 is over 60% for men, and over 30% for women. This elevated risk does not appear to make people with FH more anxious. However, they seem to underestimate their CVD risk and perceive it similar to those who were clinically diagnosed with FH, but in whom no mutation was found.

Keywords (ENG):
Familial Hypercholesterolemia
Lifestyle
Cardiovascular disease risk

Keywords (DUTCH):
Familiaire Hypercholesterolemie
Leefstijl
Cardiovasculair ziekterisico

Sponsors and support

Primary sponsor: Department of Public and Occupational Health, EMGO+ Institute for Health and Care Research, VU University Medical Center, Amsterdam, The Netherlands
Source(s) of monetary or material Support: the Netherlands Organisation for Health Research and Development (ZonMw 50-50110-96-489).

Intervention

Outcome measures

Primary outcome

LDL cholesterol.

Secondary outcome

1. Other biological cardiovascular risk indicators (glucose, blood pressure, body mass index (BMI), waist circumference, triglycerides, LDL cholesterol, total cholesterol (TC), HDL cholesterol and TC/HDL ratio);

2. Healthy lifestyle behaviour (with regard to smoking, physical activity, nutritional pattern and compliance to statin therapy) and psychological correlates and determinants of healthy lifestyle (knowledge, attitude, risk perception, social influence, self-efficacy, cues to action, intention and autonomy).

Study description

Background summary

Because of a high cardiovascular disease (CVD) risk in people with FH, prevention of cardiovascular disease in people with FH is important for health gain and cost reduction. This randomised controlled trial (RCT) focuses on CVD risk reduction through promoting a healthy

lifestyle among people with Familial Hypercholesterolemia (FH). This project is designed as a RCT in which individuals with FH will be assigned randomly to a control or intervention group. In the intervention group (n=200), participants receive a personalized intervention which is a combination of web-based computer tailored lifestyle advice and personal counselling by a lifestyle coach. The control group (n=200) will not receive this intervention. The participants will be followed for 12 months after randomisation. Primary outcomes are biological indicators of the CVD risk, such as: systolic blood pressure, glucose, BMI, waist circumference and lipids (triglycerides, total, LDL and HDL cholesterol). Secondary outcomes are: healthy lifestyle behaviour (with regard to smoking, physical activity, nutritional pattern and compliance to statin therapy) and psychological correlates and determinants of healthy lifestyle (knowledge, attitude, risk perception, social influence, self-efficacy, cues to action, intention and autonomy). Additionally, a throughout process-evaluation plan will be followed to assess and monitor intervention implementation during the trial. Results of the PRO-FIT project will provide information about individuals with FH managing their own health and about how they adopt and maintain a healthier lifestyle. Our experiences will be indicative about the suitability and benefits of this personalized multi-channel-approach for future interventions in other high-risk groups.

Study objective

Because of a high cardiovascular disease (CVD) risk in people with FH, prevention of cardiovascular disease in people with FH is important for health gain and cost reduction. This randomised controlled trial (RCT) focuses on CVD risk reduction through promoting a healthy lifestyle among people with Familial Hypercholesterolemia (FH).

Study design

LDL cholesterol and other biological cardiovascular risk indicators;
Timepoints: 0-12 months;
Measures: chronologically, Cholestech LDX analyzer (Cholestech, Hayward, USA), fully automated blood pressure monitor, portable height measure, calibrated weight scales, measuring tape.

Secondary outcomes:

Healthy lifestyle behaviour (smoking): timepoints 0-12 months;
Measure: self-reported measure, asking participants if they are a current smoker, an ex-smoker, or a never smoker, how many years they smoke(d) and how many cigarettes/shag they smoke(d) a day.

Healthy lifestyle behaviour (physical activity): Timepoints: 0-12 months;
Measure: Short QUestionnaire to ASsess Health-enhancing physical activity (SQUASH).

Healthy lifestyle behaviour (saturated fat intake, fruit and vegetables intake): Timepoints: 0-12 months;
Measure: the short Dutch questionnaire on total and saturated fat intake and on fruit and vegetable intake.

Healthy lifestyle behaviour (compliance to statin therapy): Timepoints: 0-12 months;
Measure: the five-item Medication Adherence Report Scale (MARS-5) and pharmacy records are used to study the persistence of medication use (period from first prescription to discontinuation) and refill compliance (percentage of prescribed medication that was actually obtained at the pharmacy).

Knowledge, attitude, social influence, self-efficacy, cues to action, intention and autonomy.
Timepoints: 0-12 months;
Measure: self-administered questionnaire.

Risk perception. Time points: 0-3-12 months.
Measures: Questions on risk perception were developed from literature and partly based on the brief Illness Perception Questionnaire (IPQ), the revised IPQ (IPQ-R) and questionnaire of Claassen, 2009.

Intervention

A personalised health counselling intervention which is a combination of computer tailored web-based counselling, face-to-face counselling and telephone booster sessions. Counseling will be done according to Motivational Interviewing techniques and will focus on nutritional pattern, physical activity, smoking behaviour and adherence to medication.

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Eligibility criteria

Inclusion criteria

1. FH is diagnosed by standard StOEH procedures;

2. Aged 18-65 years old;

3. Sufficiently fluent in Dutch;

4. Given informed consent;

5. Able to be moderately physically active.

Exclusion criteria

None.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-02-2009
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-07-2009
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	NL1789
NTR-old	NTR1899
Other	ZonMw : 50-50110-96-489
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A