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

Gepubliceerd: 07-07-2009 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22727

Bron
NTR

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

Aandoening

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

Ondersteuning

Primaire sponsor: Department of Public and Occupational Health, EMGO+ Institute for Health and Care Research, VU University Medical Center, Amsterdam, The Netherlands
Overige ondersteuning: the Netherlands Organisation for Health Research and Development (ZonMw 50-50110-96-489).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

LDL cholesterol.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Dpt. of Public and Occupational Health
Van der Boechorststraat 7
Karen Broekhuizen
Room G030
[default]
The Netherlands
+ 31 (0) 20 4449685

Wetenschappelijk

Dpt. of Public and Occupational Health
Van der Boechorststraat 7
Karen Broekhuizen
Room G030

[default]
The Netherlands
+ 31 (0) 20 4449685

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-02-2009
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-07-2009
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	NL1789
NTR-old	NTR1899
Ander register	ZonMw : 50-50110-96-489
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A