

Exercise intervention as compared to health promotion intervention in 35-45 year old men at elevated cardiovascular risk

Submission date 16/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/05/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.kirkkonummi.fi/mies40>

Contact information

Type(s)

Scientific

Contact name

Dr Helena Liira

Contact details

Kuninkaantie 4
Kirkkonummi
Finland
02400
+358 (0)50 5771351
helena.liira@helsinki.fi

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NCTXXX

Study information

Scientific Title

Exercise intervention as compared to health promotion intervention in 35-45 year old men at elevated cardiovascular risk: a randomised controlled trial

Acronym

EIHP

Study objectives

Exercise is an effective method to control the cardiovascular risk in men. The challenge is to change the exercise habits of men. In this study we aim to modify the exercise habits by a exercise intervention in a group and by a health promotion intervention by a nurse. We hypothesize that the interventions have effect on the cardiovascular risk level of the men.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The coordinating ethics committee at Helsinki University Hospital, 08/06/2009, ref: 4/13/03/00/09

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

More information may be found at <http://www.kirkkonummi.fi/mies40>. Patient information sheets will be available in Finnish and Swedish

Health condition(s) or problem(s) studied

Men at elevated cardiovascular risk (at least two risk factors, please see above)

Interventions

Participants will be randomised into one of two groups:

1. Exercise intervention: First a health promotion intervention of 1 h by a nurse practitioner,

followed an exercise course of 12 sessions in a group of men.

2. Control group: Health promotion intervention by a nurse practitioner of 1 h. Cardiovascular and diabetes risks are assessed and the consultation focuses on perceived risk behaviour. The control group will receive the exercise intervention after one year.

All groups are followed up after 12 months.

Intervention Type

Behavioural

Primary outcome measure

1. Cardiovascular risk assessed as Framingham risk based on lab analysis of HDL, LDL-Cholesterol, relative risk (RR) and smoking habits measured at 0, 3 and 12 months
2. Exercise habits surveyed as exercise sessions per week at 0, 3, 6, and 12 months

Secondary outcome measures

1. Walking test, standardised UKK-walking test performed at 0, 3 and 12 months
2. Subjective well-being and health are measured on a continuous visual analogue scale (VAS) of 100mm at 0, 3, 6 and 12 months
3. Use of health services

Overall study start date

06/06/2009

Completion date

06/06/2011

Eligibility

Key inclusion criteria

1. Male
2. Age 35 - 45 years
3. At least two cardiovascular risk factors of the following
 - 3.1. BMI 27.0 - 34.0 kg/m²
 - 3.2. Waist circumference > 94 cm
 - 3.3. Fasting glucose < 6,1 mmHg/l
 - 3.4. Total plasma cholesterol >4 mmHg/l
 - 3.5. LDL-cholesterol > 3,0 mmHg/l
 - 3.6. Triglycerides >2,0 mmHg/l
 - 3.7. Blood pressure < 140/90 mm Hg
 - 3.8. Currently engaging in/taking all of the following:
 - 3.8.1. Smoking
 - 3.8.2. Cholesterol-lowering medication
 - 3.8.3. Blood pressure-lowering medication

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

300

Key exclusion criteria

1. Exercise more than 3 times per week
2. BMI >34 kg/m²
3. Chronic conditions (alcoholism, unstable heart problem, severe mental problems)

Date of first enrolment

06/06/2009

Date of final enrolment

06/06/2011

Locations**Countries of recruitment**

Finland

Study participating centre

Kuninkaantie 4

Kirkkonummi

Finland

02400

Sponsor information**Organisation**

University of Helsinki (Finland)

Sponsor details

c/o Helena Liira

Kuninkaantie 4

02400 Kirkkonummi

Kirkkonummi

Finland

02400

+358 (0)50 577 1351

helena.liira@helsinki.fi

Sponsor type

University/education

ROR

<https://ror.org/040af2s02>

Funder(s)

Funder type

University/education

Funder Name

University of Helsinki (Finland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/02/2013		Yes	No
Results article	results	01/12/2014		Yes	No