

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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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)

ROR

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

Funder(s)

Funder type

University/education

Funder Name

University of Helsinki (Finland)

Results and Publications

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?
Results article	results	01/12/2014		Yes	No
Protocol article	protocol	11/02/2013		Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes