

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

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

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## 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/m<sup>2</sup>
  - 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/m<sup>2</sup>
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

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**Sponsor information****Organisation**

University of Helsinki (Finland)

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**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?
<a href="#">Protocol article</a>	protocol	11/02/2013		Yes	No
<a href="#">Results article</a>	results	01/12/2014		Yes	No