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A study of exercise compared to health promotion in 35 -45 year old men with elevated cardiovascular risk

Submission date
24/05/2012

Recruitment status
No longer recruiting

Registration date
06/07/2012

Overall study status
Completed

Last Edited
06/07/2012

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
If cardiovascular risk factors are identified early, cardiovascular disease can be prevented. Exercise has positive effects on many cardiovascular risk factors, and it can significantly reduce the components of metabolic syndrome. The main challenge with exercise, is how to motivate the patients to change and increase their exercise habits. Our aim is to modify the exercise habits of men in early middle age.

Who can participate?
Men aged 35 to 45 years with a high cardiovascular risk (with at least two risk factors). We plan to recruit 300 participants in a two year period.

What does the study involve?
We aim to modify the exercise habits of men in early middle age. The men will be allocated to either health promotion led by a public health nurse, or group exercise with health promotion led by a general practitioner. We predict that the treatments will have a beneficial effect on cardiovascular risk level and physical activity of the men, which are the main outcomes of the study. We will examine the effect of the two treatments on the individual risk factors of metabolic syndrome (e.g. weight, waist circumference, blood cholesterol level) and on the physical activity factors. The results of this study will help to plan the treatments used in future to reduce cardiovascular mortality.

What are the possible benefits and risks of participating?
The possibility to start physical training in a socially convenient surrounding with same-aged men having similar type of health problems. Main risk is that present intervention may not be strong enough to induce health benefits.

Where is the study run from?
The study will be run in Vantaa city, Finland by University of Helsinki and health authorities of Vantaa city.

When is study starting and how long is it expected to run for?
The study will start on 01 August 2012 and it will end 2015.

Who is funding the study?
Vantaa City, University of Helsinki and Yrjö Jahnssons Foundation.

Who is the main contact?
Timo Kauppila
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Study website
http://www.vantaa.fi/mies40

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NCT5099201109

Study information

Scientific Title
An exercise intervention compared to a health promotion intervention in 35 - 45 year old men with elevated cardiovascular risk: a randomized controlled trial

Acronym
EFFEXINCARR40

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)
Hospital District of Helsinki and Uusimaa (HUS) Ethics Committee, 31 October 2011, ref: 213/13 /03/00/11

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
http://www.vantaa.fi/mies40 [Available in Finnish, English, Russia 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: A health promotion intervention of 1 hour by a physician, followed an exercise course of 12 sessions in a group of men.
2. Control group: Health promotion intervention by a nurse practitioner for 1 hour. 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
Other

Phase
Not Applicable

Primary outcome measure

1. Cardiovascular risk assessed as FINNrisk 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. Body composition 0, 3 and 12 months
4. Use of health services

Overall study start date
01/08/2012

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Age 35 45 years
2. At least two cardiovascular risk factors of the following:
2.1. BMI 27.0 - 34.0 Kg/m²
2.2. Waist circumference > 94 cm
3. Fasting glucose < 6.1 mmHg/l
4.Total plasma cholesterol >4 mmHg/l
5. LDL-cholesterol > 3.0 mmHg/l
6. Triglycerides >2.0 mmHg/l
7. Blood pressure > 140/90 mmHg
8. Currently engaged with:
8.1. Smoking
8.2. Cholesterol-lowering medication
8.3. Blood pressure-lowering medication

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
300

Key exclusion criteria
1. BMI over 34 (or any other physical barrier that prevents participation in the exercise intervention)

2. Active exerciser (exercises 3 times a week or more)
3. Carrier of an immediate health problem requiring treatment or a severe risk factor; for example, recently diagnosed or uncontrolled type I diabetes, or a symptomatic coronary artery disease.

Date of first enrolment
01/08/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Finland

Study participating centre
Finnish Medical Network
Helsinki
Finland
00710

Sponsor information

Organisation
Finnish Medical Network (Finland)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.fimnet.fi/

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