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35-45 year old men at elevated cardiovascular risk: Effects of Health Promotion interventions on periodontal health (EHP)

Submission date
03/01/2011

Recruitment status
No longer recruiting

Registration date
28/07/2011

Overall study status
Completed

Last Edited
20/04/2017

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Periodontal inflammation (gum disease) is a very common condition where the gums become swollen, sore or infected. Cardiovascular (heart) disease (CVD) has several risk factors such as male gender, high blood pressure, high blood cholesterol, obesity, lack of physical activity and smoking. One suggested additional risk factor is infection. Periodontitis infection may be linked to CVD. Patients with periodontitis have increased levels of CRP and fibrinogen. Periodontal treatment has shown to reduce CRP levels. Severe forms of periodontitis can result in systematic inflammation (affecting the whole body) with high blood levels of CRP. Studies have found that CRP levels can be used to predict the risk of heart disease. The aims of these studies are to assess the effects of health promotion interventions on gum health, and to study the effects of periodontal treatment on general health and heart disease risk.

Who can participate?
Men aged 35 to 45 with two or more CVD risk factors (overweight, regular smoking, high blood fat/cholesterol, high blood sugar, high blood pressure)

What does the study involve?
This is a series of two studies. In the first study, participants are randomly allocated to three groups. The first group attends a health information session about heart disease and diabetes with a nurse. The second group receives both health information from nurses and a group exercise course of 12 sessions. The third group receives the exercise course after the 1-year follow-up. Participants undergo periodontal examinations carried out by dental hygienists and receive instructions on oral hygiene. They are followed up after 12 months to assess their exercise activity and heart disease risk. In the second study, participants found to have poor gum health are selected and randomly allocated to one of two groups. Plaque samples are taken at the start of the study and at follow-up. Participants in one group receive a deep cleaning under the gums carried out by a dentist, have a periodontal examination carried out by a dental hygienist, and provide blood samples. Participants in the other group are treated 3 months later. Heart disease risk factors and periodontal health are assessed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Helsinki (Finland)

When is the study starting and how long is it expected to run for?
June 2009 to June 2011

Who is funding the study?
University of Helsinki (Finland)

Who is the main contact?
Dr Helena Liira

Study website
http://www.kirkkonummi.fi/mies40

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Association of periodontal infection with cardiovascular risks

Acronym
EHP

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 dental periodontal health 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
Cohort study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
http://www.kirkkonummi.fi/mies40. Patient information sheets will be available in Finnish and Swedish

Health condition(s) or problem(s) studied
Men's general health and dental periodontal health

Interventions
Participants will be randomised into one of three groups:
1. First a health promotion intervention of 1h by a nurse practitioner, followed by an exercise course of 12 sessions in a group of men
2. Health promotion intervention by a nurse practitioner of 1h. Cardiovascular and diabetes risks are assessed and the consultation focuses on perceived risk behaviour
3. 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
Exercise activity and general health indicators and periodontal health indicators

Secondary outcome measures
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 then 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
University of Helsinki
Kirkkonummi
Finland
02400

Sponsor information

Organisation
Universty of Helsinki (Finland)

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Sponsor type
University/education

Website
http://www.helsinki.fi/university/

ROR
https://ror.org/040af2s02

Funder(s)

Funder type

University/education

Funder Name
Helsingin Yliopisto

Alternative Name(s)
University of Helsinki, Helsingfors Universitet, Universitas Helsingiensis, HY, UH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
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