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The effect of exercise on impaired glucose regulation in middle-aged men

Submission date
22/02/2012

Recruitment status
No longer recruiting

Registration date
21/03/2012

Overall study status
Completed

Last Edited
10/09/2014

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes can cause serious illnesses that are difficult and expensive to treat. Commitment to a healthier lifestyle is known to prevent the development of type 2 diabetes. However, the separate effect of exercise on the development of type 2 diabetes has not been demonstrated previously. Our goal is to investigate the effect of two different exercise programs on the sugar and fat metabolism and general health of men at an increased risk of developing type 2 diabetes. In addition, we will investigate the possible influence of the intensity and amount of physical activity, muscle cell distribution and genetic background, on the response to exercise.

Who can participate?
Men aged 40-65 years old with prediabetes.

What does the study involve?
You will be asked to give blood samples, which are used to test the levels of different natural elements in your blood, including blood sugar, fat, hormones and insulin. In addition, you will be asked to give a blood sample which is used to identify genes and mutations associated with exercise response. You will also be asked to drink a small amount of sweet liquid, similar to a soft drink, between blood samplings, which is used to test your responsiveness to sugar. To control the accuracy of the blood samples they are taken in fasting conditions. Therefore, you are asked to fast for 12 hours before providing the blood samples. Blood samples are taken from your upper arm with a small needle, similar to the ones used in the health services. To test the effect of exercise on your muscle and fat tissue, small samples will be taken from each tissue by a medical doctor under a local anaesthetic. Participation in these tests is optional, as for all other tests described here. Before the test, you are asked to give informed consent in addition to the one that is asked before the study.
You will also be asked to participate in different tests to examine your body composition, blood pressure, elasticity of the arteries, and fitness level. Fitness tests include strenuous cycling with an ergometer under the supervision of a medical doctor; in addition, they may include jumping, walking, and strength measurements. These tests are relatively easy to complete. Different questionnaires will be given to you to complete, and we will request that you keep a diet diary. All participants will then be randomly divided into three groups: the Nordic walking group, the

power-type resistance training group, and the control group . If you are allocated to the Nordic walking group or power-type resistance training group, you are asked to exercise for 12 weeks, three times a week for 60 minutes. In both exercise groups, you are first introduced to the exercises before the intensity is increased. All exercise is performed under the supervision of exercise specialists and involves standard exercise equipment. You will be asked to participate in energy expenditure measurements when exercising. Energy expenditure is measured with a device that records acceleration and temperature during exercise. Measurements are taken at baseline, 3, 6, and 12 months. In the control group, you are only asked to maintain your current lifestyle.

What are possible benefits and risks of participating?
You will be participating in many health-related measurements, which will give you a comprehensive picture of your current health and your risk of developing type 2 diabetes. In addition, you will receive information regarding exercise and diet. If you are allocated to the control group, you will be given printed versions of both exercise programs after the intervention. The possible risks are minor. You may feel some discomfort after the blood tests, and you can expect some discomfort or pain in the region where the tissue sample has been taken. The risk of injury during the fitness test and exercise intervention is similar to taking regular physical exercise. Your personal information is coded with an identification number, and this will be used to store and handle your data.

Where is the study run from?
This study is run in two universities of applied sciences: Turku University of Applied Sciences, which is the lead centre, and Arcada.

When is the study starting and how long it is expected to run for?
The study ran from November 2007 to December 2009.

Who is funding the study?
The Finnish Ministry of Education and Turku University of Applied Sciences (Finland).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of NOrdic WAlking STrength and power-type resistance Exercise Program on impaired glucose regulation in middle-aged men with prediabetes (NOWASTEP)

Acronym
NOWASTEP

Study objectives
Evaluate the effect of endurance and power-type resistance training interventions on glucose and fat metabolism, blood coagulation and cytokines in middle-aged men with prediabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Hospital District of Helsinki and Uusimaa, 30/10/2007, ref: 135/EO/2007

Study design
Multicentre randomised controlled three-arm study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Overweight or obese with impaired glucose regulation

Interventions

Intervention - 12 weeks
Participants were advised not to change their habitual diet or their other lifestyle habits during the intervention. If they had been physically active during their leisure time, they were asked to continue these habits. The aim of the intervention program was to be an additional, not compensatory program and the time for that should be taken from the inactive leisure time.

The control group, which had no supervised exercise during the intervention period, was advised, however, about the health benefits of exercise during the first test day.

Both intervention groups (Nordic walking program or resistance training program) trained three times per week for 60 minutes per session during 12 weeks according to special exercise programs in which both the exercise intensity and load were increased so that the strain of the subjects was progressively increased after every four weeks of training. Training sessions were supervised at least by two physical education instructors.

Follow-up 12 months
The participants were given training programs (Nordic walking program or resistance training program), which they can comply with the follow-up period. They were advised to continue their training either in a regular exercise program, or to do physically strenuous exercise two to three times a week. The control group was asked to start a 12-week Nordic walking or resistance training program, and to exercise thereafter two to three times a week. All participants received feedback on their diet immediately after the end of the intervention. Participants were offered the option to call dieticians, if they wanted more specific nutritional guidelines.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Impaired glucose tolerance from plasma blood samples with WHO criteria, measured at baseline and follow-up at 12, 26, and 52 weeks

Secondary outcome measures

1. Glucose, adiponectin, leptin, tumor necrosis factor (TNF)-α, interleukin (IL)-6, gamma glutamyltransferase (gamma-GT), total cholesterol, high density lipoprotein (HDL) cholesterol, low density lipopotein (LDL) cholesterol, triacylglycerols, and uric acid from the blood plasma samples
2. Insulin, Chemerin and RPB-4 from blood serum samples
3. Glycated haemoglobin (HbA1c) and serum high-sensitive C-reactive protein (CRP) with routine standardized methods
4. Blood pressure with standard procedures using automated device
5. Waist circumference, midway between spinailiaca superior and the lowest rib margin
6. Total body fat mass, fat-free mass, fat percentage by bioelectrical bioimpedance to the nearest 0.1 kg
7. Maximum oxygen uptake with direct maximal continuous incremental cycle ergometry until exhaustion or subjective maximum, measured at 0 and 3 months.

8. Maximum oxygen uptake, UKK fitness index, walking speed with a 2-km UKK walk test
9. Standing vertical jump height and counter-movement vertical jump height, with contact mat
10. Grip strength with dynamometry

Data will be collected at baseline and follow-up at 12, 26 and 52 weeks

Overall study start date
19/11/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Male
2. 40-65 year old
3. Have a body mass index >25.1 34.9 kg/m2
4. Obtain >12 points on the Finnish diabetes risk test
5. Have a plasma glucose 5.66.9 mmol/l and/or 2 hour plasma glucose 7.811 mmol/l
6. Have no other metabolic diseases
7. Passed medical examination

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
150

Key exclusion criteria
1. Previously detected impaired fasting glucose or impaired glucose regulation and engaging in prescribed diet or exercise program
2. Engaged in regular and physically very vigorous activities
3. Use a medication affecting glucose balance

Date of first enrolment
19/11/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment

Finland

Study participating centre
Turku University of Applied Sciences
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Sponsor information

Organisation
Turku University of Applied Sciences (Finland)

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Sponsor type
University/education

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ROR
https://ror.org/04s0yt949

Funder(s)

Funder type
Government

Funder Name
The Finnish Ministry of Education (Finland), ref: 100/627/2007

Funder Name
Turku University of Applied Sciences (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