

Exercise intensity and diabetes type 2

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Registration date 01/10/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/10/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). It is medically proven that an active lifestyle can help to prevent and improve serious health conditions, including T2DM. Along with medication and a healthy diet, regular exercise is considered to be an important part of treating T2DM. It has been found that exercising makes it easier to control blood sugar as the muscles use up excess glucose without affecting the insulin levels in the body. Exercise is also greatly beneficial for the heart and lungs, as when we exercise, our bodies are able to take in more oxygen (maximal oxygen consumption, MOC). The aim of this study is to find out whether high-intensity exercise or moderate-intensity exercise is more beneficial to good general health in diabetics.

Who can participate?

Adults between 20 and 70 years of age with type 2 diabetes and healthy adults of the same age.

What does the study involve?

Participants with and without diabetes are randomly allocated into one of two groups. Those in the first group perform high-intensity aerobic interval training (HAIT) three times a week for 12 weeks, and those in the second group perform moderate intensity continuous training (MIT) three times a week for 12 weeks. The maximum amount of oxygen the body can use during exercise and general blood sugar levels are measured at the start of the study, after the 12 week exercise programme, 6 months, one year and two years.

What are the possible benefits and risks of participating?

Probable benefits of participating include lower blood sugar levels and improved cardiovascular capacity (how strong the heart is). Possible risks include the general risks associated with hard physical testing and training, such as the risk of injury.

Where is the study run from?

Telemark University College (Norway)

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

January 2011 to June 2018

Who is funding the study?
Telemark University College (Norway)

Who is the main contact?
Miss Eva Maria Støa

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2010/3016

Study information

Scientific Title
Effects after 12 weeks of high intensity aerobic exercise versus moderate aerobic exercise among adults with diabetes type 2

Study objectives
Physiological and motivational:
1. High-intensity aerobic interval training (HAIT) is more effective than moderate intensity continuous training (MIT) to improve maximal oxygen consumption
2. There are no differences in effects on HbA1c after HAIT compared to MIT
3. HAIT will lead to similar motivational effects compared to MIT

Genetic:
The importance of genetic variables to optimal exercise adaptations.

Sociological:

How do sociocultural and socioeconomic factors and physical activity during childhood influence physical activity level in adulthood among individuals with type 2 diabetes?

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Regional Committee for Medical and Health Research Ethics in Southern Norway, 26/09/2014, ref: 2010/3016-16
2. Institutional review board at Telemark University College

Study design

Single-center non-randomised interventional study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes Mellitus type 2

Interventions

Adults diagnosed with type 2 diabetes and non-clinical controls without type 2 diagnosis will be allocated to a high-intensity aerobic interval training group (HAIT) or to a moderate intensity continuous training group (MIT). Both groups will perform supervised and guided outdoor group exercise three times per week for 12 weeks. After the intervention, the participants will be followed for 2 years, and maximal oxygen uptake, HbA1c, body composition, fat oxidation rate, blood lipids and blood pressure, as well as motivational factors will be measured at baseline, 12 weeks, 6 months, 12 months and 24 months.

The study also includes observational methods. The prevalence of genetic variants related to type 2 diabetes and training adaptations will be identified from blood samples and compared to a healthy population. Also, socioeconomic status- and physical activity level during childhood will be identified using questionnaire and interview.

Intervention Type

Primary outcome measure

1. Maximal oxygen uptake is measured at baseline, 3 months, 6 months, 12 months and 24 months using ergo spirometry measurement
2. Glycated haemoglobin (HbA1c) is measured at baseline, 3 months, 6 months, 12 months and 24 months from a blood sample

Secondary outcome measures

1. Fat oxidation rate is measured at baseline, 3 months, 6 months, 12 months and 24 months using indirect calorimetry
2. Body composition is measured at baseline, 3 months, 6 months, 12 months and 24 months using body fat caliper
3. Blood lipids is measured at baseline, 3 months, 6 months, 12 months and 24 months from a blood sample
4. Motivational effects is measured at baseline, 3 months and 24 months using the behavioural regulation in exercise questionnaire (BREQ), the Beck Depression Inventory (BDI) score, Subjective Vitality Scale (SVS)
5. Prevalence of genetic variables related to type 2 diabetes and training adaptations is determined from a single blood sample taken at 24 months
6. Socio-economical background and physical activity level during childhood is determined at 24 months using a questionnaire and interview

Overall study start date

01/01/2011

Completion date

01/06/2018

Eligibility

Key inclusion criteria

1. Diagnosed with type 2 diabetes
2. Aged between 20 and 70 years
3. Capability to perform exercise in an outdoor environment.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

50

Key exclusion criteria

1. One or more contradictions to intensive physical activity or testing according to the ACSM guidelines
2. Performing less than 70% of exercise sessions

3. Sickness in the last week before pre-testing
4. Sickness for two consecutive weeks the last month prior to testing
5. Making extensive changes in diet
6. Change of medications related to their diabetes diagnosis during the 12 weeks of intervention
7. Sickness for more than one week during the 12 week intervention period

Date of first enrolment

01/04/2011

Date of final enrolment

01/01/2012

Locations

Countries of recruitment

Norway

Study participating centre

Telemark University College

Hallvard Eikas plass

Bø

Norway

3800

Sponsor information

Organisation

Telemark University College

Sponsor details

Hallvard Eikas plass

Bø in Telemark

Norway

3800

Sponsor type

University/education

ROR

<https://ror.org/05ecg5h20>

Funder(s)

Funder type

University/education

Funder Name

Telemark University College

Results and Publications

Publication and dissemination plan

The first two manuscript from this study is planned to be accepted for publication in 2016 (motivational data and physiological data). The focus in the next two manuscripts and planned publication is to be confirmed at a later date.

Intention to publish date

01/02/2016

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request