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High Intensity Exercise Training in Type 2 Diabetes

Submission date
18/12/2012

Recruitment status
No longer recruiting

Registration date
23/01/2013

Overall study status
Completed

Last Edited
15/03/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Recent information suggests that exercise may help people with type 2 diabetes improve their glucose control by increasing the ability of the body to burn fat, and increasing the sensitivity of the body to food. We aim to show the effect of exercise on sensitivity of the body to food, levels of fat in the liver and abdomen, and heart function.

Who can participate?
Men and Women aged between 30-70 years with Type 2 Diabetes, have a body mass index (BMI) between 25-35kg/m2 and who currently take part in no regular exercise.

What does the study involve?
You will be assigned to one of two groups. The first group will do three exercise sessions per week over 12 weeks. Each exercise session will involve you using a stationary cycle and resistance band, and will last about 40 minutes. A member of the research team will come with you on your first session to familiarise you with doing the exercises safely and after that an ipod with exercise tracks will guide you through the remaining sessions. Exercise will be held at a local gym which you choose and your gym membership will be paid for during the study. To maintain your weight throughout the study you will be given high calorie food supplements if your weight goes down by more than 1%. The second group will not do the exercise sessions or be required to undertake any exercise over the 12 weeks. If you are placed in this group, at the end of the study you will be given the opportunity to receive the exercise training, though this is not compulsory. Both groups will attend the Newcastle Magnetic Resonance Centre at the Newcastle General Hospital, or the Royal Victoria Infirmary on 5-9 occasions over 3 months. These visits include fasting blood tests, exercise tests, magnetic resonance scans and body composition measurements. You will wear a small device on your upper arm for 7 consecutive days before the 12 weeks and at the end to measure physical activity levels.

What are the possible benefits and risks of participating?
Being more physically active may be beneficial to the level of fat in your liver and if sustained after the study, may help in preventing other complications such as heart disease. You will have supervised exercise sessions which will teach you about your body, show you how to exercise correctly and help you become more physically fit. This study involves exercise so there are no

side effects. Disadvantages of the study could be the time given up to participate and some people can experience claustrophobia (fear of confined spaces) in the magnetic resonance scan but if this happens we immediately stop the scan.

Where is the study run from?
The Institute of Cellular Medicine, Newcastle University.

When is the study starting and how long is it expected to run for?
The study started in September 2012 and aims to finish in September 2013.

Who is funding the study?
National Institute for Health Research Biomedical Research Centre for Ageing and Age Related Diseases.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Prof Michael Trenell

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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 exercise on metabolism and liver lipid in people with non-alcoholic fatty liver disease (NAFLD)

Acronym
T2DHIT

Study objectives
The original hypothesis was that exercise would decrease liver fat independent of weight loss. Due to the clinically meaningful observations that were found during this study, those with more advanced glucose control problems were included to allow us to make comments about the impact of glucose control upon liver fat and cardiac function. It was hypothesized that exercise would improve glucose control, decrease liver fat and improve cardiac function in those with Type 2 Diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
All the procedures involved in this trial have been in accordance with institutional ethical standards and the Helsinki declaration. The original study received a favorable opinion from the Newcastle and North Tyneside 1 Research and Ethics Committee on the 07/10/2008. The Newcastle upon Tyne Hospitals Trust gave approval for the research to be conducted within the trust on 31/10/2008. The amended study was given approval by the Newcastle and North Tyneside 1 Research and Ethics Committee on the 17/04/2012 and the Newcastle upon Tyne Hospitals Trust on the 04/07/2012.

Study design
Single-site open-label randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Type 2 Diabetes

Interventions
The exercise group will be given a high intensity exercise prescription for 3 sessions per week for 12 weeks. Each session will include 40 minutes of mainly cycling exercise in which intensity will

be individually tailored and monitored using the rate of perceived exertion scale. Exercise sessions will be conducted at the participant's local gym following familiarisation by a member of the research team.

The control group will their clinical care without any additional advice. They will be offered Exercise Counselling and Supervision similar to the treatment group at the end of their evaluation.

Intervention Type
Behavioural

Primary outcome measure
Glucose control (HbA1c)

Secondary outcome measures
1. Liver fat
2. Abdominal fat
3. Cardiac function
4. Resting and exercise metabolism (lipid oxidation)
5. Cytokine production
6. Insulin sensitivity
7. Physical Activity

Overall study start date
01/09/2012

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Aged between 30-70 years old
2. Diagnosed with Type 2 Diabetes which is metformin or diet controlled
3. BMI 25-35 kg/m2
4. Take part in no regular exercise

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
28

Key exclusion criteria

1. The absolute and relative contraindications to exercise testing as stated by the American Heart Association (Fletcher et al., 2001)
2. Taking insulin/Sulfonylurea/ TZD/ Beta-blockers
3. Contraindications for MRI scanning
4. Heart or kidney disease
5. Undergoing dietary change

Date of first enrolment
01/09/2012

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Univeristy
Newcastle Upon Tyne
United Kingdom
NE3 5JB

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Joint Research Office
Level 6, Leazes Wing
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Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (UK) - Biomedical Research Centre for Ageing and Age Related Diseases

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?
Results article	results	01/12/2015		Yes	No
Results article	results	01/01/2016		Yes	No
Results article	results	01/01/2019	15/03/2019	Yes	No