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Health benefits of a novel exercise intervention in Type 2 diabetes

Submission date
18/11/2013

Recruitment status
No longer recruiting

Registration date
18/11/2013

Overall study status
Completed

Last Edited
11/08/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Although exercise is considered one of the three cornerstones of diabetes care programmes (together with diet and medication), the majority of individuals with type 2 diabetes do not achieve the minimum recommended levels of physical activity. One of the key barriers to exercise appears to be lack of time. We have recently shown that a novel exercise intervention requiring 80% less time than current physical activity recommendations is effective at improving insulin sensitivity in inactive men. This study compares the effectiveness of the interventions at improving blood sugar regulation, their effects on various other health measures (aerobic fitness, blood pressure, blood lipid profile), and views on the two exercise interventions (through measures of enjoyment and rating of perceived exertion).

Who can participate?
Men aged 40-60 who have been diagnosed with type 2 diabetes at least 6 months before entering the study

What does the study involve?
Participation involves following two 8-week supervised exercise interventions, spaced at least 6 weeks apart. Participants are randomly allocated to take part in either the new high-intensity interval training programme (cycling) or the currently recommended physical activity intervention (moderate intensity walking), then after a 6-week break the participants swap and take part in the other intervention. Before and after each intervention a range of health measurements will be taken to establish the effects of the interventions.

What are the possible benefits and risks of participating?
Positive results from this study will provide individuals with type 2 diabetes with an alternative means to manage their condition. There are no major risks involved with the study. However, blood samples will be taken and this may be associated with some discomfort or bruising. Only trained staff will perform this procedure and they will make every effort to minimise discomfort. Furthermore, the exercise sessions may be tiring, and as with all physical exercise there is a small inherent risk of physical injury. However, the exercise sessions are short and the risk of injury is low. Finally, there is a small risk of adverse cardiac events when performing high intensity exercise, but we will check for signs of undiagnosed heart disease before you start the exercise

programmes. All research staff involved in this study are first-aid trained, and our labs are equipped with a defibrillator as standard.

Where is the study run from?
University of Bath (UK)

When is the study starting and how long is it expected to run for?
January 2014 to June 2015

Who is funding the study?
Diabetes UK

Who is the main contact?
Dr Niels Vollaard
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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
15666

Study information

Scientific Title
A comparison of the effects of reduced-exertion high-intensity interval training and moderate /vigorous intensity walking on glycaemic control in Type 2 diabetes

Study objectives
Whether the high-intensity interval training programme will result in equivalent (or better) improvements in glycaemic control compared to current physical activity recommendations.

The primary aim of the proposed study is to profile the impact of the highly time-efficient REHIT exercise intervention on glycaemic control in individuals with Type 2 diabetes, in comparison to current physical activity recommendations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Frenchay, 05/12/2013, ref: 13/SW/0298

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
21 men with T2D will perform two 8-week exercise interventions in a counterbalanced crossover design, separated by =6 weeks. Before and three days after each 6-week intervention all participants will undergo a testing day to determine changes in glycaemic control and other health markers. Training-induced changes in health markers will be compared between the two interventions. One of the interventions will involve a time-efficient high-intensity interval training programme, whereas the control intervention will be based on current physical activity recommendations and involve moderate intensity walking.

REHIT training: the REHIT intervention will involve three 10-min exercise sessions per week, consisting of unloaded cycling interspersed with two cycle-sprints against a resistance equivalent to 5% of body weight as previously described by Metcalfe et al. (2012). Sprints will last 10 s in weeks 1 and 2, 15 s in weeks 3 and 4, and 20 s in weeks 5-8.

Walking intervention: the walking intervention will be based on guidelines provided by the American College of Sports Medicine and the American Diabetes Association, and involve five 30-min walking sessions per week, at an intensity corresponding to 40% of VO2max in weeks 1 and 2, 50% of VO2max in weeks 3 and 4, and 60% of VO2max in weeks 5-8.

Follow Up Length: 6 month(s)
Study Entry : Single Randomisation only

Intervention Type
Behavioural

Primary outcome measure
Glycaemic control; timepoint(s): pre and post both interventions

Secondary outcome measures
1. Aerobic fitness; timepoint(s): pre and post both interventions
2. Body composition; timepoint(s): pre and post both interventions

Overall study start date
01/01/2014

Completion date
01/06/2015

Eligibility

Key inclusion criteria
1. Men aged ≥40 years and ≤60 years
2. Diagnosed with Type 2 diabetes according to WHO criteria at least 6 months prior to entering the study: fasting plasma glucose ≥ 7.0 mmol/l (126 mg/dl) - OR 2-hour plasma glucose sample in a standard OGTT of ≥11.1 mmol/l (200 mg/dl)

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 21; UK Sample Size: 21; Description: We aim to recruit 21 men with type 2 diabetes.

Key exclusion criteria
1. Insulin therapy
2. Use of sulphonylureas
3. Use of more than two anti-diabetic drugs
4. Use of β-blockers

5. Use of inhaled steroids (e.g., for asthma)
6. Any cardiovascular condition with the exception of well-controlled uncomplicated hypertension treated with no more than two drugs (either an ACE, ARB, calcium channel blocker or diuretic)
7. Cerebrovascular disease including previous stroke or aneurysm
8. History of exercise-induced asthma
9. History of Type 1 diabetes mellitus or a history of ketoacidosis
10. History of other specific types of diabetes (e.g., genetic syndromes, secondary pancreatic diabetes, diabetes due to endocrinopathies, drug- or chemical-induced, and post-organ transplant)
11. Any prior history of malignancy with the exception of:
11.1. Basal cell carcinoma of the skin
11.2. Squamous cell carcinoma of the skin that has been recurrence-free for 5 years
11.3. Other malignancies (regardless of site) that have been recurrence-free for 5-10 years
12. BMI >35 kg/m2
13. Uncontrolled hypertension (systolic blood pressure >160 mmHg and/or diastolic blood pressure >90 mmHg after at least a 5-minute seated rest at the screening visit)
14. A clinically significant ECG abnormality at the screening visit which in the opinion of the investigators exposes the subject to risk by enrolling in the trial
15. Overt contraindications to exercise as determined with a normal resting ECG
16. Yes to any questions on a standard physical activity readiness questionnaire (PAR-Q)
17. Classification as highly physically active on the International Physical Activity Questionnaire (IPAQ)
18. Current participation in another research study
19. Inability to fully understand the verbal and written descriptions of the study in English, and the instructions provided during the study

Date of first enrolment
01/01/2014

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department for Health
Bath
United Kingdom
BA2 7AY

Sponsor information

Organisation
University of Bath (UK)

Sponsor details
The Avenue
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Sponsor type
University/education

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK) Grant Codes: ZR-X0342

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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	01/02/2017		Yes	No
HRA research summary			28/06/2023	No	No