ISRCTN12337078 https://doi.org/10.1186/ISRCTN12337078

Ethnic differences in glucose regulation following interval training

Submission date
13/05/2015

Recruitment status
No longer recruiting

Registration date
20/05/2015

Overall study status
Completed

Last Edited
06/09/2019

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
The benefits of regular exercise and physical activity are well established, yet most people fail to do the minimum recommended amount. Many people say that they do not have time to fit in physical activity into their daily lives. High-intensity interval training (HIT) has been proposed as a time-saving form of exercise. HIT has been shown to improve fitness but the benefits to metabolic health e.g. blood glucose regulation (controlling the amount of glucose in the blood) are unclear. It is also uncertain whether people from different ethnic backgrounds respond in the same way to the same physical activity. This is important to establish if HIT is to be recommended to the general population as a therapeutic health tool for people at risk of or with diabetes. The primary aim of this study is to look at the effect of a single bout of high-intensity interval training compared to matched-work continuous exercise on the response of the body to blood glucose levels after a meal (post-meal glucose responses) in white European and South Asian patients at risk of type 2 diabetes. We also want to look at the effect of HIT on cardiovascular risk biomarkers and whether participants enjoy it.

Who can participate?
South Asian and white European adults aged between 50-75 whose blood glucose is higher than normal but not high enough to be diagnosed with type 2 diabetes.

What does the study involve?

Participants visit the centre four times, each visit separated by 1-week. The first visit will be a familiarisation visit lasting approximately 2-hours. They are then randomly allocated into one of three groups. Participants in all groups take part in all three of the following treatment sessions but in a different order. In the control condition participants remain seated for the whole day. The other two days are run exactly the same except that HIT or moderate-intensity continuous exercise is performed for approximately 30 minutes. During the treatment days at least every hour participants have a blood sample taken, blood pressure reading taken and are asked to fill out a questionnaire.

What are the possible benefits and risks of participating?
Participants will find out information about their risk of developing diabetes, daily blood glucose

levels, their fat and cholesterol levels, body fat percentage, current physical activity levels and overall fitness level using the latest technology. Individual feedback will be presented to each participant, explaining what the data means for them. They will find out how their health may benefit from physical activity and be introduced to a novel form of exercise that they might enjoy. The study itself may not be of direct benefit to the individual participant but it will contribute to ongoing work aimed at the prevention and management of type 2 diabetes. Participants will be provided with detailed, personalised education regarding physical activity and blood glucose control. They will also be invited to be contacted regarding future studies conducted at the Leicester Diabetes Centre, which may involve interventions that result in more long-term health benefits. There are risks associated with performing maximal exercise by those unaccustomed to exercise therefore medical history, resting and exercise ECG will be assessed by a specialist cardiac nurse.
There is mild pain and discomfort associated with blood sampling and cannulation, although this is minimal. All procedures will be performed by an experienced research nurse. The study required participants to wear activity and continuous glucose monitoring devices, which may cause some inconvenience. However, devices are small, minimally invasive and will be worn for the minimum period required for meaningful analysis. Making 4 trips including 3 full days to the Leicester Diabetes centre presents a time burden to participants. To minimise disruption to participant's routines individuals will be invited on days convenient to them, provided with meals and offered £50 on completion of the study.

Where is the study run from?
November 2014 to February 2016

When is the study starting and how long is it expected to run for?
Leicester Diabetes Centre, Leicester General Hospital (UK)

Who is funding the study?
Professor Melanie Davies' Senior Investigator Award and funds from the Leicester Diabetes Centre.

Who is the main contact?
1. Miss Charlotte Jelleyman (public)
2. Dr Tom Yates (scientific)

Contact information

Type(s)
Public

Contact name
Prof Tom Yates

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Davies_0521

Study information

Scientific Title
The effect of a single bout of high-intensity interval training on glucose responses in white European and South Asian patients at risk of type 2 diabetes

Acronym
GO for IT

Study objectives
The aim of this study is to investigate the effects of high-intensity interval training (HIT) on glycaemic control in white European and South Asian patients at risk of type 2 diabetes, and to compare these effects with matched-work continuous exercise and a non-exercising control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Leicester, 05/05/2015
2. University Hospitals of Leicester NHS Trust R&D, 17/08/2015, ref 167328/829251/14
3. Leicestershire, Northamptonshire and Rutland Research Ethics Committee, 26/05/2015, ref 15/EM/0259

Study design
Single-centre fully randomised three treatment crossover trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Individuals at risk of type 2 diabetes

Interventions
The experimental conditions are:
1. High-intensity interval training (HIT)
2. Continuous training (CT)
3. Control (CON)

Intervention Type
Other

Primary outcome measure
Incremental glucose area under the curve: blood samples taken at -1h, 0h, 0.5h, 1h, 2h, 3h, 3.5h, 4h, 5h, 6h, 7h throughout each treatment day will be analysed for glucose concentration using a glucose oxidase method

Secondary outcome measures
1. Questionnaires: RPE, positive mood/affect, sleepiness, appetite
2. Blood markers: IL-6, CRP, insulin, leptin, ghrelin, acylated ghrelin, PYY3-36, GLP-1, Selenoprotein-P, LECT2, Follistatin, Fetuin-A, FGF21
3. Blood pressure

These measures will be taken at -1h, 0h, 1h, 1.5h, 2h, 3h, 3.5h, 4h, 5h, 6h, 7h

Overall study start date
01/11/2014

Completion date
30/09/2018

Eligibility

Key inclusion criteria

Current inclusion criteria as of 16/05/2016:
1. Has had 2 hour glucose between 7.8mmol.L-1 and 11.1mmol.L-1 after an oral glucose tolerance test (performed at the Leicester Diabetes Centre as part of another study within 12 months)
OR
Has HbA1c between 5.7% to 6.49% within the last 5 years
2. Is of south Asian (Indian, Bangladeshi, Pakistani) or white European (British, Irish or other European country) descent
3. Adults aged between 50 to 74 years inclusive (subject to females being post-menopausal defined as no menstruation in the last 12 months as reproductive hormones interact with appetite hormone responses)
4. Able to walk and use treadmill
5. BMI ≥27.5kg/m2 (WE) or ≥25kg/m2 (SA)
6. Weight stable (weight has not fluctuated more than ±5kg in the last 6 months)
7. Ability to communicate in and understand English to participate in the informed consent process

Previous inclusion criteria:
1. Has had 2 hour glucose between 7.8mmol.L-1 and 11.1mmol.L-1 after an oral glucose tolerance test (performed at the Leicester Diabetes Centre as part of another study within 12 months)
OR
Has HbA1c between 6%-6.49% at baseline or at their most recent blood test within the previous 12 months
2. Is of south Asian (Indian, Bangladeshi, Pakistani) or white European (British, Irish or other European country) descent
3. Adults aged between 50 to 74 years inclusive (subject to females being post-menopausal defined as no menstruation in the last 12 months as reproductive hormones interact with appetite hormone responses)
4. Able to walk and use treadmill
5. BMI ≥27.5kg/m2 (WE) or ≥25kg/m2 (SA)
6. Weight stable (weight has not fluctuated more than ±5kg in the last 6 months)
7. Ability to communicate in and understand English to participate in the informed consent process

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
24

Key exclusion criteria
Current exclusion criteria as of 16/05/2016:
1. Regular purposeful exercise (≥3 x 20 minute bouts of self-reported vigorous exercise performed per week)

2. Individuals who stand for extended periods of time (standing has been shown to improve glycaemic variability)
3. Mixed race (including individuals of mixed race would prevent determination of whether ethnicity is a modifying factor in the response to HIT)
4. Use of any glucose lowering medication
5. Dieters/restrained eaters (as assessed using the 3 factor eating QA)
6. Any contraindications to exercise such as abnormal resting ECG, breathlessness or dizziness on exertion, poor circulation, hypo- or hypertension
7. Significant renal or hepatic impairment defining parameters i.e. chronic kidney disease stage 3b, liver markers more than 3x greater than the normal range
8. Consent not given to contact GP with test results

Previous exclusion criteria:
1. Diagnosed type 2 diabetes
2. Regular purposeful exercise (≥3 x 20 minute bouts of self-reported vigorous exercise performed per week)
3. Individuals who stand for extended periods of time (standing has been shown to improve glycaemic variability)
4. Mixed race (including individuals of mixed race would prevent determination of whether ethnicity is a modifying factor in the response to HIT)
5. Use of any glucose lowering medication
6. Dieters/restrained eaters (as assessed using the 3 factor eating QA)
7. Any contraindications to exercise such as abnormal resting ECG, breathlessness or dizziness on exertion, poor circulation, hypo- or hypertension
8. Significant renal or hepatic impairment defining parameters i.e. chronic kidney disease stage 3b, liver markers more than 3x greater than the normal range
9. Consent not given to contact GP with test results

Date of first enrolment
02/05/2015

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Diabetes Centre
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Sponsor information

Organisation
University of Leicester (UK)

Sponsor details
College of Medicine
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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
Melanie Davies Senior Investigator Award

Funder Name
Leicester Diabetes Centre (UK)

Results and Publications

Publication and dissemination plan
The study will be written up and submitted to relevant academic journals. Overall and individual results will be sent to participants in lay language and as personalised plans.

2018 thesis in https://pdfs.semanticscholar.org/a5d2
/a69a9596c8599d8670c5285133950af5b89a.pdf

Intention to publish date

30/09/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No