ISRCTN90672085 https://doi.org/10.1186/ISRCTN90672085

Does high intensity intermittent exercise promote health and wellbeing in overweight and obese men?

Submission date
22/02/2017

Recruitment status
No longer recruiting

Registration date
22/02/2017

Overall study status
Completed

Last Edited
25/04/2017

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
In the UK, rates of metabolic diseases (conditions that involve problems with metabolism) are increasing, primarily due to rising levels of obesity. Being overweight or obese can lead to the development of type 2 diabetes mellitus (T2DM), as the cells of the body do not respond properly to the hormone insulin and so cannot easily absorb glucose (sugar) from the bloodstream. In addition, being overweight or obese can also greatly increase a person's risk of heart disease or stroke. High-intensity intermittent training (HIIT) is a type of exercise which alternates short periods of very intense exercise with less intense recovery periods. To date, little attention has been given to profiling the potential health benefits of HIIT or modified HIIT training within overweight and obese cohorts with particular focus on inflammation (the body's response to injury). The aim of this study is to find out whether six sessions of HIIT over two weeks can improve overweight or obese men's metabolic and inflammatory profiles.

Who can participate?
Overweight and obese men who are otherwise healthy who exercise less than twice per week.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in six sessions of HIIT exercise over a two-week period on Mondays, Wednesdays, and Fridays. Those in the second group complete only four sessions over the same period on Mondays and Fridays. In both groups, the training consists of ten lots of one minute bouts of very intensive exercise separated by one minute recovery periods of less intensive exercise. One week before the program starts and 72 hours after the last session, participants in both groups provide blood samples which are tested for blood sugar control and chemical indicators of inflammation.

What are the possible benefits and risks of participating?
Participants can benefit from improving their general health and fitness. There is a risk that taking part in the study exercises can cause mild discomfort in the form of exhaustion, heat,

sweat, muscular soreness and sometimes light headedness. More severe risks include risk of injury and at worst can lead to death. Every precaution will be taken via detailed screening to prevent all severe side effects.

Where is the study run from?
Loughborough University (UK)

When is the study starting and how long is it expected to run for?
January 2012 to May 2013

Who is funding the study?
Loughborough University (UK)

Who is the main contact?
Dr Benjamin Kelly
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GCT01

Study information

Scientific Title
An evaluation of low volume high-intensity intermittent training (HIIT) for health risk reduction in overweight and obese men

Study objectives

Six sessions of high intensity intermittent exercise over 2-weeks is sufficient to improve inflammatory and metabolic profile in overweight and obese adult males.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Loughborough University Ethical Advisory Sub-Committee for human biological or psychological and sociological investigations, 16/03/2012, ref: R12-P46

Study design
Single-centre randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Prevention

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
Obesity

Interventions
Participants are randomised to one of two groups using an online random number generator. Those in the first group (N=8) complete 6 sessions of HIIT exercise over a 2-week period where as group 2 (N=10) complete only 4 over the same period. Group 1 exercise sessions will be carried out on Mondays, Wednesdays, and Fridays. Group 2 sessions will be conducted on Mondays and Fridays.

Intervention:
The HIIT protocol utilised in this study was based on that devised by Little and colleagues [2011]. Using a Lode cycle ergometer, participants warm up at a resistance of 50 W for 3 minutes and during the last 10 sseconds participants are counted down before the wattage is elevated to a pre-determined resistance set to elicit 90% HRpeak. Resistance will be manipulated manually throughout to ensure pre-determined heart rate values are achieved. During the 60 s high intensity interval, participants are asked to maintain a cadence of 80-100 RPM. After 60 s of high intensity cycling participants are instructed to cycle for the next 60 s at a cadence of 70-80 RPM against a resistance of 50 W (active recovery). This is to be repeated a further 9 times followed immediately by a 2 minute cool down against a resistance of 50 W.

All participants are assessed at baseline, 1 week prior to intervention and again 72 hours after the final exercise bout. Follow up testing consists of blood pressure and body composition assessment, an oral glucose tolerance test and a test of maximal aerobic capacity. Time zero blood samples from the oral glucose tolerance test are used in order to analyse inflammatory profile.

Intervention Type
Other

Primary outcome measure
Fasting glucose is measured via an oral glucose tolerance test (OGTT) which will be performed one week prior to intervention and 72 hours immediately post the last exercise session in week two.

Secondary outcome measures
Inflammatory profile is assessed at baseline, 1 week prior to intervention and once again 72 hours post-the final exercise bout. Inflammatory profile is assessed by measuring:
1. Adiponectin, MCP-1 and CRP using commercial sandwich enzyme linked immunosorbent assays (ELISAs)
2. CRP and TNF-αvia using high sensitivity ELISAs (R & D systems, Minneapolis, MN, USA)
3. Plasma IL-6 and sIL-6R via 'in-house' ELISAs

Overall study start date
10/01/2012

Completion date
10/05/2013

Eligibility

Key inclusion criteria
1. BMI ≥ 27 kg·m-2
2. Reported taking part in any form of exercise less than 2 times per week
3. Otherwise healthy
4. Male

Participant type(s)
Other

Age group
Adult

Sex
Male

Target number of participants

A total of 16 participants are required for this trial. Based on data on repeated measures of the oral glucose tolerance test (OGTT) test protocol, it is calculated that with a power of 80% and alpha set at 0.05, 8 participants are required per group to detect the minimal clinically relevant difference between the two interventions

Key exclusion criteria
1. Smokers
2. Previously diagnosed with impaired fasting glucose or diabetes
3. BMI ≥ 40 kg.m-2

Date of first enrolment
20/04/2012

Date of final enrolment
30/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Loughborough University
Epinal Way
Loughborough
United Kingdom
LE11 3TU

Sponsor information

Organisation
Loughborough University

Sponsor details
Epinal Way
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LE11 3TU

Sponsor type
University/education

Website
http://www.lboro.ac.uk/?external

ROR
https://ror.org/04vg4w365

Funder(s)

Funder type
University/education

Funder Name
Loughborough University

Alternative Name(s)
Lboro

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed open access journal, with the intent to publish in the first half of 2017.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/04/2017		Yes	No