ISRCTN91278516 https://doi.org/10.1186/ISRCTN91278516

The exercise and gut bacteria study

Submission date	Recruitment status	[ ] Prospectively registered
02/11/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/11/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/09/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity is a growing problem worldwide. In the UK alone, around 62% of the population are condifered to be overweight or obese. Obesity is associated with a number of health problems including type 2 diabetes mellitus, a condition where the sufferer has 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). The causes of obesity are complex, with unhealthy diets and low exercise levels considered to be the main driving forces. Recently, the composition of bacteria that live in the gut (gut microbiome) is being increasingly accepted as a major component in the bodily processes behind obesity. The composition of the gut microbiome can quickly change in response to changes, such as a change of diet. There is also evidence to show that physical activity can lead to changes in the gut microbiome, but there is little research looking into this. The aim of this study is to find out whether an exercise programme can change the composition of the gut microbiota (proportion of different bacteria that live in the gut) in obese men.

Who can participate?
Obese men aged between 25 and 50 years.

What does the study involve?
Participants attend a study visit where they have some measurements taken, including height, weight, blood samples. They are also given a specialist kit to take home with which to collect a small stool sample so that gut bacteria can be examined. Participants also perform an exercise test to assess fitness. All participants then complete an eight week supervised, standard exercise programme. This involves three sessions per week at the Leicester Diabetes Centre gym of exercise tailored to each participant's ability and fitness level. Exercise sessions progress to a point where participant can exercise comfortably for 50 minutes per session. After the final gym visit, participants are asked to return to the Leicester Diabetes Centre to have the same measures taken that were carried out at the first visit. They then return eight weeks later to see if there have been any lasting changes.

What are the possible benefits and risks of participating?
The participants will benefit by receiving a personalised exercise programme from a trained specialist, and will have free gym access three times a week for eight weeks. They will gain knowledge about their current fitness levels and receive information about the levels of sugar

and fat in your blood. The participants will also add to evidence-based exercise research that may improve the treatment for people in the future. During any physical activity there is always an increased risk of a heart event or injury. For those without any underlying heart disease, the risks to health are very low. Before participants start the exercise programme they will be assessed by a qualified clinical team member. There will be a member of the exercise research team developing and supervising the programmes. A fully qualified member of the research team will carry out all the blood tests so any pain should be kept to a minimum. However some people experience minor discomfort and slight bruising from blood tests.

Where is the study run from?
Leicester Diabetes Centre (UK)

When is the study starting and how long is it expected to run for?
August 2014 to July 2017

Who is funding the study?
Novo Nordisk UK Research Foundation (UK)

Who is the main contact?
1. Dr Tom Yates (scientific)
ty20@leicester.ac.uk
2. Ms Tatiana Plekhanova (public)
Tp150@le.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Tom Yates

Contact details
Leicester Diabetes Centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW
+44 116 258 4312
ty20@leicester.ac.uk

Type(s)
Public

Contact name
Ms Tatiana Plekhanova

Contact details
Leicester Diabetes Centre
Leicester General Hospital

Gwendolen Road
Leicester
United Kingdom
LE5 4PW
+44 116 258 8571
Tp150@le.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20121

Study information

Scientific Title
Determining the effect of exercise on the gut microbiota of obese men: A pilot study

Acronym
TEAM GB

Study objectives
The aim of this pilot study is to determine whether
exercise alters the gut microbiota of obese men.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands – Coventry & Warwickshire, 27/08/2015, ref: 15/WM/0244

Study design
Non-randomised; Interventional; Design type: Treatment, Prevention, Physical

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Obesity

Interventions
The participants will need to visit the Leicester Diabetes Centre for three study visits (pre-, post- and maintenance), and attend the gym within the centre three times a week, for eight weeks.

Pre-intervention visit. During the first study visit the participants will have their measurements such as height, weight, non-fasting bloods taken and will be assessed as safe to exercise. They will also be given a physical activity monitor to wear on their wrist to measure their physical activity levels for the duration of the study.

The exercise intervention will be a supervised eight week exercise programme that is designed to meet the recommendations for physical activity i.e. three sixty minute sessions to ensure a minimum 150 minutes per week of moderate exercise. The programme will be based on aerobic exercise; walking and/or jogging exercise will be encouraged on the treadmill to promote weight bearing exercise and increased gut transit time. All exercise sessions will be specific to the individual's ability and progressions made accordingly. At participant's first exercise visit they will be requested to provide a stool sample using the collection kit provided at the pre-intervention visit.

Post-intervention visit. After eight weeks of the exercise intervention participants will return for a repeat of the pre-intervention visit. Participants will provide a further stool sample at this visit.

Maintenance visit. Participants will be asked to return four weeks after the Post-intervention visit to investigate whether any potential changes in gut microbiota remain one month after the intervention is complete. At this visit all measurements taken at the Pre-intervention visit will be carried out, a final stool sample will be procured.

Intervention Type
Other

Primary outcome measure
Ratio between bacteroidetes and firmicutes is measured using established qPCR assays on faecal samples collected at baseline and 8 weeks.

Secondary outcome measures
1. Relationship between gut microbiota and inflammation is investigated by measuring inflammatory markers such as CRP, TNF-α and IL-6 on non-fasting blood samples collected at baseline and 8 weeks
2. Concentration of short chain fatty acids in faecal samples is measured using established qPCR assays at baseline and 8 weeks
3. Association between the gut microbiota and physical fitness on appetite hormones is determined by measuring GLP-1, PYY and ghrelin on fasting blood samples collected at baseline and 8 weeks

Overall study start date

01/08/2014

Completion date
22/07/2017

Eligibility

Key inclusion criteria
1. Caucasian Males
2. Aged 25-50 years inclusive
3. BMI 30-40kg/m2 inclusive
4. HbA1c less than 6.5%
5. Completion of an eligibility stress test and approval from an in house clinician according to our standard operating procedures
6. Able to speak and understand English

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 19; UK Sample Size: 19

Key exclusion criteria
1. Unable to understand and speak English
2. Unable to provide written informed consent
3. Diagnosed with type 1 or 2 diabetes
4. Diagnosed with crohn’s disease, celiac disease or irritable bowel syndrome
5. Highly active individuals or individuals meeting current physical activity guidelines (self-report ≥2.5 hours per week)
Participants should not report exercising two or more times per week for 20minutes or longer ove

6. Patients with orthopaedic limitations, motor neurone disease, stage II hypertension (systolic BP>

BP>100mmHg), cardiovascular disease (coronary artery disease, cardiomyopathy, heart failure, cor

cardiac dysrhythmias, endocarditis, myocarditis, valvular heart disease, cerebrovascular disease, pe

disease, congenital heart disease and rheumatic heart disease), pulmonary disease (inflammatory l

obstructive lung disease, chronic obstructive pulmonary disease, emphysema, cystic fibrosis, respir

infections, pleural cavity disease, pulmonary vascular disease) renal disease or chair bound
7. Current smokers
8. Are currently on a calorie restricted/weight loss diet
9. Have changed their dietary habits in the past three months

10. Individuals who have used antibiotics or pre/probitoics in the past three months
11. Weight limit (due to operating scales): maximum 200kgs

Date of first enrolment
22/07/2015

Date of final enrolment
12/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Diabetes Centre
Gwendolen road
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University of Leicester

Sponsor details
Academic Department
Leicester General Hospital
Leicester
England
United Kingdom
LE5 4PW
+44 116 258 4867
uolsponsor@leicester.ac.uk

Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Research organisation

Funder Name
Novo Nordisk UK Research Foundation

Alternative Name(s)
The Novo Nordisk UK Research Foundation, ovo Nordisk Research Foundation UK, NNUKRF

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
Planned dissemination of the results of the study in peer reviewed scientific journals, internal reports, conference presentation, publication on web-site and submit to regulatory authorities.

Intention to publish date
22/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository (University of Leicester computer system).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	21/06/2016	30/11/2016	No	Yes
HRA research summary			28/06/2023	No	No