ISRCTN17240262 https://doi.org/10.1186/ISRCTN17240262

Effect of a 12 week supervised exercise programme 12–24 months after weight-loss surgery on physical function and physical activity maintenance: the Motion Study

Submission date
20/01/2015

Recruitment status
No longer recruiting

Registration date
06/02/2015

Overall study status
Completed

Last Edited
08/08/2017

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Worldwide, increasing numbers of people are becoming morbidly obese (extremely overweight). Obese people are more likely to have health problems such as type 2 diabetes (a disease in which the pancreas does not produce enough of the hormone insulin or the individual's cells do not react to the insulin), heart disease, non-alcoholic fatty liver disease (a build-up of fat in the cells of the liver), problems with sleep and some cancers than are people with a healthy weight. Obesity can also reduce how long people live. Bariatric surgery (weight loss surgery) is a successful way for obese people to lose weight. After surgery, some people might regain weight and not everyone regains the same amount of weight after surgery. Increasing exercise and physical activity (e.g., walking, house work and playing with children or grandchildren) after bariatric surgery can improve weight loss and make daily activities easier. The aim in this study is to improve movement and physical wellbeing while preventing weight regain after surgery.

Who can participate?
People with a BMI of at least 30 kg/m2 (≥28 kg/m2 for South Asian individuals)

What does the study involve?
Patients will be randomly assigned to one of two groups. Patients in the exercise group will be offered a 12-week structured and supervised hospital gym-based exercise programme at a time when they often start putting weight back on after weight loss surgery. Individuals in the control group will have 12 weeks of no structured exercise. Both groups will have advice sessions, will be offered an exercise programme of their choice and will be given a diet information sheet. Patients will have a follow-up assessment at 6 months.

What are the possible benefits and risks of participating?
The possible benefits are physical wellbeing and prevention of weight gain. Risks were not provided at the time of registration.

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

When is the study starting and how long is it expected to run for?
From February 2014 to July 2015

Who is funding the study?
Leicester Loughborough Diet, Lifestyle and Physical Activity Biomedical Research Unit (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
120659

Study information

Scientific Title
Effect of a 12 week supervised exercise programme 12–24 months after bariatric surgery for obesity on physical function and physical activity maintenance: a randomised controlled trial

Study objectives

1. To examine the effect of a 12 week exercise intervention on physical fitness (aerobic and musculoskeletal) and body composition in patients 12–24 months after bariatric surgery
2. To examine the combined effect of a 12 week structured and supervised exercise intervention in addition to physical activity advice on physical fitness and activity maintenance at 24 weeks

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service West Midlands - Edgbaston, 10/12/2013, reference 13/WM /0445

Study design
Interventional single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Obesity

Interventions
Patients will be randomly assigned to one of two groups:
1. Exercise group: moderate intensity exercise combining aerobic and resistance exercise
1.1 Pre-intervention (baseline) assessment
1.2. 12 week hospital-based moderate intensity exercise intervention (3 x 60 minute sessions per week)
1.3. Ongoing behavioural counselling incorporated into sessions (through ongoing client–trainer interaction)
1.4. Post-intervention assessment (at about 12 weeks)
1.5. Patient-specific advice session (30–60 minutes) to discuss relevant topics (e.g., physical activity maintenance, overcoming barriers and goal setting); patients will be offered an optional exercise programme of their choice (e.g., home based, walking outside, gym or swimming); and they will be given a diet information sheet
1.6. 6 month follow-up assessment
2. Control group
2.1. Pre-intervention (baseline) assessment
2.2. 12 weeks of no structured exercise

2.3. Post-intervention assessment (at about 12 weeks)
2.4. Patient-specific advice session (60 minutes) to discuss relevant topics (e.g., physical activity maintenance, overcoming barriers and goal setting); patients will be offered an exercise programme of their choice (e.g., home based, gym or swimming); and they will be given a diet information sheet
2.5. 6 month follow-up assessment

Intervention Type
Behavioural

Primary outcome measure
Incremental shuttle walk test (metres): will be measured at baseline, 3 months and 6 months

Secondary outcome measures
1. Grip strength (kg), measured with a analogue hand grip dynamometer
2. Seat to stand test (seconds), using a 5 x seat to stand protocol
3. Body composition: measured using Tanita bioelectrical impedance scales (BC-418-MA)
4. Height (cm), measured by a SECA stadiometer
5. Weight (kg), measured by Tanita bioelectrical impedance scales (BC-418-MA)
6. Waist and hip circumference (cm), measured with a SECA tape measure
7. Physical activity, measured by Actigraph GT3X+ accelerometer
8. Self-reported physical activity, measured with the Short form International Physical Activity Questionnaire (IPAQ)
9. Blood pressure (mmHg), measured with an automated Intelle sense blood pressure machine (arm cuff)
10. Resting heart rate (beats per minute), measured with a finger pulse oximeter
11. Oxygen saturation (%), measured with a finger pulse oximeter
12. Dietary intake, measured with a 24-hour food recall
13. Self-efficacy, measured using the self-efficacy to regulate physical activity (SERPA) questionnaire
14. Anxiety and depression measured with the Hospital Anxiety and Depression Scale (HADS)
15. Medications and doses: obtained from medical notes
18. Cholesterol, measured with venous blood specimens
19. High-density lipoprotein, measured with venous blood specimens
20. Low-density lipoprotein, measured with venous blood specimens
21. Triglycerides, measured with venous blood specimens
22. Non-fasting glycated haemoglobin, measured with venous blood specimens
All these outcomes will be measured at baseline, 3 months and 6 months.

Overall study start date
26/02/2014

Completion date
01/07/2015

Eligibility

Key inclusion criteria
1. Age 18–60 years old
2. Had bariatric surgery in past 12–24 months
3. Body-mass index (BMI) of at least 30 kg/m2 (≥28 kg/m2 for South Asian people)

4. Completion of a stress test and approval from an in-house clinician in accordance with our standard operating procedure and document

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
52

Key exclusion criteria
1. Highly active individuals or individuals meeting current physical activity guidelines (self-report of ≥2·5 hours per week)
2. Unstable diabetes
3. Orthopaedic limitations
4. Motor neurone disease
5. Stage II hypertension (systolic blood pressure >60 mmHg and/or diastolic blood pressure >100 mmHg)
6. Cardiovascular disease: coronary artery disease, cardiomyopathy, heart failure, cor pulmonale, cardiac dysrhythmias, endocarditis, myocarditis, valvular heart disease, cerebrovascular disease, peripheral arterial disease, congenital heart disease and rheumatic heart disease
7. Pulmonary disease: inflammatory lung disease, obstructive lung disease, chronic obstructive pulmonary disease, emphysema, cystic fibrosis, respiratory tract infections, pleural cavity disease and pulmonary vascular disease
8. Renal disease
9. Chair bound
10. Weight limit of 200 kg or greater

Date of first enrolment
26/02/2014

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Diabetes Centre
Leicester General Hospital
Gwendolen Road
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Sponsor information

Organisation
University of Leicester

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
University/education

Funder Name
Leicester Loughborough Diet, Lifestyle and Physical Activity Biomedical Research Unit (UK)

Results and Publications

Publication and dissemination plan

The study results will be published in peer-reviewed journals. Publishing dates are likely to be November 2015 to March 2016.

Intention to publish date
30/11/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2017		Yes	No
HRA research summary			28/06/2023	No	No