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Physical activity and sedentary behaviour after bariatric surgery

Submission date
22/03/2021

Recruitment status
No longer recruiting

Registration date
23/03/2021

Overall study status
Completed

Last Edited
14/03/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The number of people who are considered to have overweight or obesity is increasing worldwide, which is the case in the UK too where two thirds of the population have a BMI equal to or more than 25 kg/m² (overweight), and about one third have a BMI greater than or equal to 30 kg/m² (obese). Obesity is associated with a number of serious health conditions such as heart disease, type 2 diabetes and obstructive sleep apnoea and is associated with an increased risk of some cancers and susceptibility to serious illness from COVID-19. The current most effective way to treat obesity is bariatric surgery, which can cause significant weight loss in a short period of time and can also improve other conditions such as diabetes. There is evidence that patients who increase their activity after surgery have better outcomes than those who do not. They tend to lose more weight, maintain this weight loss and have other improvements including health-related quality of life. Unfortunately, many patients do not increase their levels of activity after surgery and some become less active. As bariatric surgery is often the last resort for treating obesity, and so it is important that patients are supported to optimise their outcomes as much as possible. However, doctors are not entirely sure of how best to do this. This research is a feasibility study, a 'trial run' of a larger study to see if the proposed programme could be tested to see if it helps people who have had surgery to change their levels of activity and sedentary behaviour. The programme is based on published evidence and from primary research with patients, clinicians and commissioners, which asked these three key stakeholders what they thought the programme should include and what would help patients to become more active and less sedentary after surgery.

Who can participate?
People aged over 18 who have had bariatric surgery (excluding gastric bands or balloons) in the previous 5 years

What does the study involve?
The study involves four site visits to Aintree, Liverpool University Hospital; two before the programme stars and two afterwards. The programme is an online group behaviour change intervention with and for people who have had bariatric surgery within the previous 5 years which aims to help participants to increase their levels of physical activity and reduce their sedentary behaviour.

What are the possible benefits and risks of participating?
It is anticipated that this study is of low risk to participants. However, it is possible that they might develop injuries as a result of them increasing their levels of activity particularly if this is done quickly or they have a history of low physical activity. It is possible that participants might develop Delayed Onset Muscle Soreness [DOMS], which is stiffness and/or pain felt in muscles for hours or days after unaccustomed PA. Participants might also have a soft tissue injury (sprain or strain), this will likely be due to increasing levels of physical activity too quickly or unaccustomed physical activity. These risks have been anticipated and participants will be taught how to safely increase their levels of physical activity, what DOMS is and how to manage it. It is possible that patients taking anti-hypertensive medication may experience dizziness or light-headedness if they improve their cardiovascular status which is a known outcome of improved fitness. Participants should alert the research team to this and should consult their GP for this to be reviewed. Fitbit activity trackers will be provided free to participants as part of this intervention. They have an optional heart rate monitoring function which uses flashing light emitted by a sensor placed next to the skin (on the back of the watch) to calculate heart rate. Participants who are sensitive to flashing lights will be advised not to look at this and advised that they will be provided with an alternative that does not have this function. The strap on the Fitbit may also cause localised skin irritation, and so participants will be given the following Fitbit recommendations:" (1) keep it clean; (2) keep it dry; (3) don't wear it too tight, and (4) give your wrist a rest by removing the band for an hour after extended wear".

Where is the study run from?
Liverpool University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2017 to November 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
288505

Central Portfolio Management System (CPMS)
48374

Study information

Scientific Title
A prospective feasibility trial to facilitate increases in physical activity and reduce sedentary behaviour in patients after bariatric surgery

Acronym
PARIS

Study objectives
The primary aim of this study is to determine if this intervention could be evaluated in a future substantive study.

The primary objective of this study is to determine if this intervention could be evaluated in a larger study to assess efficacy. In particular, it seeks to answer the following uncertainties:
1. To ascertain recruitment and retention for the intervention and study overall
2. To investigate engagement and fidelity to the intervention, and acceptability of the intervention
3. To identify potential difficulties with study outcome measures – questionnaire completion, accelerometer wear and dual-energy x-ray absorptiometry (DEXA) scan undertaken

4. To use outcome data to calculate the necessary sample size for a future study to assess the efficacy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/12/2020, North West – Haydock Research Ethics Committee (3rd Floor - Barlow House, 4 Minshull Street, Manchester HRA Centre, M1 3DZ, UK; +44 (0)207 104 8012; haydock.rec@hra.nhs.uk), REC ref: 20/NW/0472

Primary study design
Interventional

Study design
Non-randomized; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Study type(s)
Treatment

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

Interventions
The purpose of this study is to do a 'trial run' of a study, which will support people who have had bariatric surgery to become more physically active and less sedentary. This 'trial run' is necessary because it will allow the research team to make changes and improvements for a future larger study.

For this study the researchers want to recruit 12-24 participants. The overall study time from agreeing to take part to the very end is expected to be between 20 and 28 weeks.

Eligible participants will have had bariatric (also known as weight loss) surgery within the previous 8 weeks to 5 years. Potential participants will be asked to attend the Clinical Sciences Building at Liverpool University Hospitals NHS Foundation Trust (Aintree site) to check that they are eligible for the study and discuss any questions they might have. If they decide that they would like to participate they will be able to start there and then and this will be the first of four visits to the site.

Of the four visits, two will be before the programme starts and two will be afterwards. As mentioned above, at the first visit, participants will be asked to sign a consent form and provide some information about themselves including what type of operation they had and when they had it. They will also be asked to complete two questionnaires which ask about their physical activity and sedentary behaviour and their perception of their health status. They will also be asked to wear an activity monitor for one week which they will return a week later.

At the second visit a week later they will return the activity monitor and have a DEXA scan. Participants will also be given a Fitbit and handbook that will be used during the programme, both of which they are free to keep after the programme has finished.

The programme will start shortly after visit two, this will be six weekly group sessions, held via Zoom with J JAMES [PI] and other participants who have also had surgery. These meetings will last 1 hour to 1.5 hours. The aim of these sessions is to help participants to become more active and less sedentary. In each of these sessions topics related to physical activity and sedentary behaviour will be discussed, such as what these are, what happens when people are more active and less sedentary and the different strategies that can be useful when trying to change these. After the programme has finished, participants will be asked to attend two further site visits. The first one will be immediately after the programme where they will be asked to repeat the questionnaires and wear the activity monitor for 1 week. Six weeks after this participants will be asked to complete another batch of questionnaires (which will have been given to them at their previous appointment to avoid them having to come to the research site) and wear the activity monitor for another week. After wearing the activity monitor for one week, participants will be asked to visit the site for a final time, to return their activity monitor and have a repeat DEXA scan.

Some participants will be asked to participate in a one-to-one interview with the researcher to discuss the programme, so that changes can be made for the future. This will be done either via telephone or using Zoom.

All of the meetings and interviews will be audio recorded on an external recorder and transcribed (typed up) after which the recordings will be deleted. Recording the meetings will allow the research team to check that the sessions went as originally planned or if there needs to be any changes to the programme.

All of the visits will require participants to attend the Clinical Sciences Building, which is the research centre on the hospital site and is a non-clinical area. The centre is COVID secure; there is a one-way system in operation; participants will be asked to use alcohol gel and wear a face mask at all times whist in this building (unless exempt). If it appropriate for them to have a DEXA scan this will take place in one of the outpatient departments of the main hospital. Participants will be provided with masks and access to handwashing and alcohol gel to sanitise their hands. They will be escorted to the scan to make sure that they don't get lost on their way. This should help to reduce the amount of time that they are on the hospital site. The hospital's policies and procedures with regard to COVID-19 will be followed at all times. J JAMES will see the participants at each visit. Research nurses will not be used in this study. This will reduce the number of in-person contacts that participants have.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate and retention to the intervention and study, measured using records of how many patients received the information sheet, how many subsequently consented and the attendance of those who had baseline assessments completed will be kept (PARIS recruitment log) at recruitment, consent, baseline, each weekly session, post-intervention and follow up
2. Attendance recorded via the attendance log at each weekly session
3. Participant engagement, acceptability of the intervention and receipt (fidelity) assessed with semi-structured interviews within 8 weeks of the final follow up measures
4. Intervention fidelity assessed with facilitator self-assessment tool at the end of every intervention session for one group of participants in the intervention
5. Rate of completion of outcome measures and accelerometer wear time assessed by reviewing questionnaires and accelerometer data at baseline, post-intervention and follow up

6. Sample size for a future study calculated by analysing the accelerometer data collected at baseline, post-intervention and follow up. The analysis will be conducted after follow up

Key secondary outcome(s)
1. Self-reported levels of physical activity measured using the International Physical Activity Questionnaire - Long Form (IPAQ-LF) and objectively using a wrist-worn accelerometer (ActiGraph GT9X Link) at pre-intervention, post-intervention and follow up
2. Self-reported health status assessed using the SF-36 (RAND 36-Item Health Survey 1.0) at pre-intervention, post-intervention and follow up
3. Body composition assessed using DEXA scan at pre-intervention and follow up

Completion date
01/11/2021

Eligibility

Key inclusion criteria
1. Anyone who has had bariatric surgery within the previous 5 years
2. Age over 18 years
3. Written and informed consent must be obtained from participants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
18

Key exclusion criteria
1. Gastric band or gastric balloon
2. The presence of a medical condition that could (in the opinion of the PI) comprise the participant's safety - including poorly controlled diabetes, or an acute or severe cardiac history requiring medical review (i.e. recent MI, heart failure). The CI will be available to discuss participants when there is uncertainty regarding their suitability for this study
3. Bariatric surgery within the previous 8 weeks
4. Any congenital cardiac condition (likely to affect younger participants)
5. Unable to converse in English
6. Weight in excess of 204 kg (maximum safe working load of DEXA scanner)

Date of first enrolment
15/03/2021

Date of final enrolment
02/08/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Liverpool University Hospital
Liverpool University Hospitals NHS Foundation Trust
Prescot Street
Liverpool
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L7 8XP

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: ICA-CDRF-2017-03-008

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to this being a feasibility study.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/12/2021	30/12/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other unpublished results	Patient flow, baseline characteristics, adverse events		03/02/2023	No	No
Other unpublished results	Outcome measures		14/03/2023	No	No