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Weight management before surgery

Submission date
30/09/2026

Recruitment status
Recruiting

Registration date
02/10/2026

Overall study status
Ongoing

Last Edited
02/10/2026

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
About one-third of people on NHS surgical waiting lists live with obesity. Living with obesity prior to surgery may increase the risk of surgical complications, such as wound infections, heart problems, and longer hospital stays. Although effective weight management programmes exist, they are not routinely offered to patients while they wait for surgery.
The PRE Weight Loss (PRE-WEL) study aims to find out whether it is practical and acceptable to offer free weight management programmes to patients preparing for surgery. The study will also measure weight changes, hospital stay length, surgical complications, quality of life, and healthcare resource use to help design a future larger-scale trial.

Who can participate?
Patients aged 18 years or older with Body Mass Index (BMI) 30 kg/m² or higher, who are referred for hip or knee joint replacement, laparoscopic cholecystectomy (gallbladder removal), hysterectomy, or coronary artery bypass graft and/or valve surgery (between 1 and 6 months before their scheduled operation date)

What does the study involve?
Participants will be randomly placed into one of two groups:
1. The weight management group are offered a choice of free weight management programmes) to access for 1 to 6 months before surgery.
2. The booklet group are given an NHS weight management information booklet.
Participants will complete short questionnaires and send a photograph of their weight reading from home scales at the start, shortly before surgery, and 90 days after surgery. Surgical details and post-surgery recovery information will also be collected from hospital and GP records. Participants can optionally choose to take part in interviews or keep voice/paper diaries sharing their experiences.

What are the possible benefits and risks of participating?
Participants receive free access to a structured weight loss programme or booklet, which may help them lose weight before surgery. All participants contribute to research aimed at improving pre-operative NHS care. Participants receive a £20 voucher each time for completing follow-up assessments or qualitative sub-studies.
The overall risk is low and no higher than standard NHS care. Weight management programmes are non-invasive.

Where is the study run from?
The study is managed by Loughborough University (Centre for Lifestyle Medicine and Behaviour) in partnership with the Leicester Clinical Trials Unit (LCTU) (UK)

When is the study starting and how long is it expected to run for?
November 2026 to August 2029

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

Who is the main contact?
Dr Claire D. Madigan, prewel@mailbox.lboro.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
371974

Central Portfolio Management System (CPMS)
74081

National Institute for Health and Care Research (NIHR)
303187

Study information

Scientific Title
A randomised controlled trial to examine the feasibility of a weight management programme prior to surgery with embedded qualitative study

Acronym
PreWel

Study objectives
The primary objective is to examine the feasibility and acceptability of referring participants and the participation in a weight management programme to improve post-operative outcomes.

The trial also aims to assess:
1. Weight change from start of programme to pre-surgery and from the start of programme to post-surgery
2. Unexpected, serious adverse events during the weight management programme and post-surgery (up to 90 days)

To see if we can collect data for a future trial:
1. Complications from surgery
2. Health care resource use
3. Health-related quality of life

To examine the processes involved for the feasibility trial and allow refinement for a future trial we will:
1. Examine engagement with weight management
2. Examine heterogeneity between surgical operations
3. Examine contamination with the comparator group
4. Describe who takes part in the trial to assess equality, diversity and inclusion
5. Examine methods to collect postoperative data

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/09/2026, London - Bromley Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; bromley.rec@hra.nhs.uk), ref: 26/LO/0622

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hip/knee joint replacement, laparoscopic cholecystectomy, hysterectomy, or coronary artery bypass graft/valve surgery

Interventions
Participants will be randomised stratified by surgical speciality (hip/knee joint replacement, laparoscopic cholecystectomy, hysterectomy or coronary artery bypass graft and/ or valve surgery) using random block sizes. Participants will be randomly assigned (1:1) to either:
1. Intervention arm: free referral to a weight management programme of their choice for up to 6 months before surgery.
2. Control arm: delivery of a NHS weight management booklet.

Data will be collected at baseline, 1 week pre-surgery, and 90 days post-surgery via electronic questionnaires and participant-submitted weight photographs.

Optional embedded qualitative sub-studies (interviews and WhatsApp "think aloud" voice notes) will gather real-time data on participant experiences. Progression to a full-scale trial will be guided by definitive traffic-light criteria tracking recruitment and retention rates.

Intervention Type
Behavioural

Primary outcome(s)
1. The feasibility and acceptability of referral and participation in a weight management programme before surgery, measured using the number of participants randomised after a 12-month recruitment period; engagement with the intervention; retention rate: the number of participants at follow-up (pre-surgery and 90-days post-surgery) as a proportion of participants randomised; embedded think aloud study and qualitative interviews with participants will examine the acceptability of referral and participation in weight management programmes

Key secondary outcome(s)
1. Change in weight measured in kg from baseline to pre-surgery and baseline to 90 days post-surgery
2. Number of serious adverse events occurring prior to surgery as a proportion of participants randomised

3. Number of serious adverse events occurring during surgery and up to 90-days post-surgery as a proportion of participants randomised
4. The proportion of participants with no specified complications related to surgery, hospitalization or mortality from date of surgery up to 90 days post-surgery
5. The proportion of participants that are readmitted to hospital, have a re-operation or mortality within 90 days post-surgery
6. Length of stay (LOS), defined as the time in days between admission for surgery and discharge from surgery
7. Surgery duration, measured in minutes as recorded in hospital notes
8. The number of participants with complete data as a proportion of participants randomised when quality of life is measured using EQ-5D-5L at baseline, pre-surgery and 90-days post-surgery
9. Engagement data collected from the weight management programmes
10. The length of access to the weight management programme, defined as the time between first attendance and their surgery
11. Heterogeneity between surgical operations measured using the means (SD) and proportions by surgical operation of the weight change data and the postoperative complications
12. Whether weight management interventions are delivered as planned and patient's experiences of the intervention, measured using qualitative interviews and think aloud sub-study during the weight management programme
13. Comparator group contamination measured using:
13.1. Proportion of participants randomised to the comparator arm whose weight pre-operatively remains within 2 kg of baseline weight
13.2. Proportion of the comparator that actively managed their weight pre-operatively, defined as answering yes to the question about actively managing their weight and answered yes to options other than "I have been following the plan"
14. Number and proportion (of randomised) participants by age, sex, ethnicity, index of multiple deprivation, comorbidities, malnutrition status (as measured using PS-SGA short form) and long-term health condition
15. The number of participants with data collected from hospital records, GP data and patient-reported data as a proportion of participants randomised, reported separately for each method

Completion date
01/08/2029

Eligibility

Key inclusion criteria
1. Aged >=18 years
2. Referred for hip/knee replacement, laparoscopic cholecystectomy, hysterectomy or coronary artery bypass graft and/ or valve surgery
3. Body mass index (BMI) >=30 kg/m2

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Greater than 6 months to operation date or less than one month before operation date
2. Urgent/emergency or surgery listed outside of the inclusion criteria
3. Currently/recently enrolled in a weight management programme or lost >3 kg of weight in the last 3 months
4. Women known to be pregnant of breastfeeding
5. History of eating disorders within the last 10 years
6. Any other significant disease or disorder which, in the opinion of the investigator or healthcare team, may put the participant at risk because of participation in the trial (e.g., serious mental health concerns)

Date of first enrolment
01/11/2026

Date of final enrolment
01/01/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Loughborough University
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Study participating centre
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Study participating centre
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Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
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LE1 5WW

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
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Mindelsohn Way
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B15 2GW

Study participating centre
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Royal Derby Hospital
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Derby

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Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
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England
TS4 3BW

Sponsor information

Organisation
Loughborough University

ROR
https://ror.org/04vg4w365

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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