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Managing weight in obese patients before heart surgery to see if this improves the effects of surgery

Submission date
23/04/2021

Recruitment status
Stopped

Registration date
06/05/2021

Overall study status
Stopped

Last Edited
23/05/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Managing weight in obese patients before heart surgery to see if this improves the effects of surgery. The main outcomes of the trial are how often patients attend the weight management sessions and whether they lose any weight. We will also use behavioural analyses to understand how to explain the rationale for the trial to participants so that they feel confident that trusting this decision to chance is sensible.

Who can participate?
Adult patients (over 17 years) referred for cardiovascular surgery, who have obesity and willingness and ability to commit to up to 12 weekly sessions of the weight loss programme or to commit to maintaining a stable weight.

What does the study involve?
Patients who are suitable will provide their consent to take part in the trial and will be randomly allocated in a 1:1 ratio to:
Weight Management (Intervention): up to 12 weeks of a weight management programme.
Weight Stability (Control): Advised to maintain current diet and a stable weight.

What are the possible benefits and risks of participating?
There is no strong evidence for losing weight or not before your operation to help improve your recovery. This uncertainty is why currently some people are advised to lose weight, whilst others are not. This means that whichever group you are in, you will be experiencing what is already the standard of care offered, and the risks and benefits of taking part in this trial are therefore the same as if you did not take part.

Where is the study run from?
University of Leicester (UK)

When is the study starting and how long is it expected to run for?
June 2018 to May 2025

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Hardeep Aujla (Research Manager), ha200@le.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
201185

Central Portfolio Management System (CPMS)
48053

Protocol serial number
Grant Codes: PG/20/10/34886

Study information

Scientific Title
Pre-operative weight management to improve outcomes of cardiac surgery in adults with obesity (SLIM-CARD): a multicentre feasibility RCT

Acronym
SLIM-CARD (V1.0)

Study objectives
A weight management programme will achieve satisfactory levels of adherence, acceptability of randomisation to this weight management programme, and clinically important weight loss while the control group participants stay the same weight

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/02/2021, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44(0)207 1048008; preston.rec@hra.nhs.uk), ref: 21/EM/0015

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pre-operative weight management to improve outcomes of cardiac surgery in adults with obesity

Interventions
MONTHS 1 - 4 (approx.)
ALL SITES
BEHAVIOURAL STUDY 1:
This will involve interviewing patients and healthcare professionals about their thoughts around cardiac surgery and recruitment into a trial involving weight management so that a 'recruitment script' can be developed.

Patients:
Patients will be posted a PIL ahead of their initial clinic. This will be bundled with their clinic appointment letter. When they arrive at the clinic, after their consultation with the cardiac surgeon, they will meet a research nurse who will discuss the PIL, and ask if the patient wishes to consent. If yes, then the research nurse will obtain written consent and the patients contact details on a 'Contact Slip'; sharing these with the behavioural researcher who will call the patient at a convenient time (but within 24-48 hours of the clinic appointment) and conduct the interview over the telephone and audio record it. The 'Contact Slip' will be destroyed when it is no longer needed so as not to retain personal information unnecessarily.
HCPs:
The process will be the same as above with the local research nurse providing the PIL to HCPs and obtaining consent at least 24 hours later.

MONTHS 5 - 6 (approx.)
GLENFIELD GENERAL HOSPITAL ONLY
BEHAVIOURAL STUDY 2 & MAIN TRIAL:
This will test the 'recruitment script'; research nurses will use it during the initial discussion with participants and this will be audio recorded and qualitatively analysed. The Clinical Trial will also commence, with patients being randomised to a weight management programme (Slimming World) or weight stability. The local research nurse will complete a referral form for the patient with their trial ID and they take this home with them. The patient then calls the Slimming World number on the form, provides their trial ID to redeem the free sessions, and books onto an available and convenient session.
Patients:
The above procedures in Behavioural Study 1 will be followed, except that the initial discussion with a researcher will be audio recorded with verbal consent. Subsequently written consent will be sought to keep this if the participant wishes to participate in the trial. If not, and the patient is not happy for the recording to be kept, it will be deleted. Participants will otherwise have their baseline data collected immediately after written consent. Shortly thereafter, likely 1 day later, they will be telephoned by the behavioural researcher who will conduct an audio recorded interview. 2-4 weeks after the baseline visit, a researcher will telephone the patient for another audio recorded discussion concerning randomisation adherence and adverse event monitoring. One day pre-surgery, when the participant is admitted, the research team will collect the next set of data which includes body weight and a second EQ-5D questionnaire which is administered in-person. Adverse events will also be monitored here.
On the day of the surgery, operative details will be recorded. Four days after the surgery, data on organ injury, infection or any other adverse events will be collected from the medical records. Six weeks after the surgery, participants will be invited to attend a routine follow-up clinic. The research team will meet with the participant to collect data on healthcare resource use since their operation, and monitor adverse events. If this cannot be done in person for any reason, the participant will be telephoned to discuss the information required. Three months after the surgery, a final telephone call will be made to collect the last set of data which includes a final EQ-5D questionnaire, healthcare resource use since their last follow-up, and monitoring any adverse events.
HCPs:
The above procedures in Behavioural Study 1 will be followed, except that HCPs will be initially provided with a Consent Form along with the PIL by the local research nurse. If they wish to participate, they will sign the Consent Form and post this back to the researcher who will then countersign and conduct the audio recorded interview over the telephone.

MONTHS 9 - 21
ALL SITES

BEHAVIOURAL STUDY 3 & MAIN TRIAL:
Continues as above, except there is no recruitment of HCPs, and the interview of patients one day after baseline by the behavioural researcher is omitted.
The initial discussion around the trial and consent is still audio recorded and qualitatively analysed to explore communication of equipoise and any issues hindering recruitment. The 'recruitment script' is still used.
Patients are randomised as above and attend Slimming World sessions if allocated to this arm.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes:
1. Number of participants randomised to the intervention arm attending ≥75% sessions measured using case report forms at 1-day pre-op
2. Number of participants randomised to the control arm whose weight at surgery remains within 1.5kg of their baseline weight (measured as below point 3) at 1-day pre-op

Efficacy outcome:
3. Weight (kg) baseline and 1-day pre-op measured using weighing scales

Key secondary outcome(s)
1. Recruitment rate, attrition rate, data completeness at end of study measured using case report forms
2. A composite endpoint of ischaemic organ injury: low cardiac output, acute kidney, brain or gut injury at day 5 post op measured using clinical observation and blood tests
3. A composite endpoint of infection: surgical site infection, lower respiratory tract infection, urinary tract infection, sepsis at day 5 post op measured using clinical observation and blood tests
4. Adverse events, including mortality, collected from randomisation to 3 months post-surgery at day 5 post op, 6 weeks and 3 months using case report forms
5. Quality of life measured at baseline, 1-day pre-operation and 3 months using the EQ-5D-5L
6. Resource use up to 3 months post-surgery estimated from a bespoke questionnaire at 5 post op, 6 weeks and 3 months

Completion date
11/03/2025

Eligibility

Key inclusion criteria
1. Adult patients (>17 years) referred for cardiovascular surgery.
2. Patients who have obesity; defined as BMI≥30 for patients of White-European ethnicity and as BMI≥27.5 for all other ethnic groups.
3. Willingness and ability to commit to up to 12 weekly sessions of the intervention or to commit to weight stability.
4. Behavioural Study 1: Willingness to be interviewed within 24-48 hours of the clinic appointment and have the interview audio recorded.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
17 Years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Patients undergoing urgent or emergency surgery.
2. Patients who are participating in another interventional trial.
3. Patients who are currently/ recently (<3m) enrolled in a weight management programme.

Date of first enrolment
01/01/2022

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Royal Papworth Hospital NHS Foundation Trust
Papworth Road
Cambridge Biomedical Campus
Cambridge

United Kingdom
CB2 0AY

Study participating centre
The James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Derriford Hospital
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Victoria Hospital
Blackpool Teaching Hospitals NHS Foundation Trust
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Bristol Royal Infirmary
University Hospitals Bristol and Weston NHS Foudnation Trust
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Liverpool Heart And Chest Hospital NHS Foundation Trust
Thomas Drive
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version V2.0	03/02/2021	06/05/2021	No	No