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Could supported weight loss reduce womb cancer surgery complications?

Submission date
25/10/2023

Recruitment status
No longer recruiting

Registration date
27/10/2023

Overall study status
Ongoing

Last Edited
08/08/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
In the UK 10,000 women each year are diagnosed with womb cancer. Surgery to remove the cancer is the best treatment. However, it has a risk of complications, which is higher for people with overweight/obesity. Patients experiencing complications recover more slowly, stay in hospital longer, and need more care. This isn't good for patients or the NHS.

Physical fitness and well-controlled blood sugar are linked with fewer complications from surgery. For people with overweight, weight loss improves both of these factors, so it may reduce complications. One reliable way to lose a meaningful amount of weight in the short period before surgery (3-4 weeks) is through a low-calorie diet programme: eating only special nutritious soups and shakes. With weekly support from a dietitian, most people succeed. Typically, people lose 5% of their weight within 20 days. The NHS uses a version of this programme to treat type 2 diabetes.

This study aims to start to find out if this treatment is in the best interests of patients physical and mental health.

Who can participate?
Patients with overweight awaiting womb cancer surgery.

What does the study involve?
Half the participants will be randomly allocated to continue with their usual care and half will be offered the weight loss programme. We will see whether enough patients are willing to take part, lose weight, and return for follow-up visits. We will monitor complications for 30 days after surgery and any reduction in muscle mass as a result of the weight loss. We will interview patients about their experience.

What are the possible benefits and risks of participating?
By taking part, participants will help the researchers find out if this treatment might help people with womb cancer in the future. For participants in the normal care group, there are no direct benefits. Participants in the supported weight loss group may lose weight and this could reduce complications after surgery. Most people who follow the low-calorie diet do not experience side

effects from it. The most common side effect is constipation and side effects are typically only mild and temporary.

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

When is the study starting and how long is it expected to run for?
September 2023 to February 2028

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

Who is the main contact?
Dr Dimitrios Koutoukidis, dimitrios.koutoukidis@phc.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324534

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56138, NIHR302549, IRAS 324534

Study information

Scientific Title

Pre-operative intentional weight loss to support post-operative recovery in patients with overweight and endometrial cancer: the ENDO-CARE feasibility randomised controlled trial

Acronym
ENDO-CARE

Study objectives
To assess whether progression to a definitive randomised control trial is justified

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/08/2023, Oxford B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8230; oxfordb.rec@hra.nhs.uk), ref: 23/SC/0223

Study design
Interventional randomized controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Quality of life, Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Womb cancer

Interventions
Following the screening visit, participants will be randomised 1:1 to the supported weight loss group or standard care.

Supported weight loss (intervention)
Participants will be asked to eat only formula products, such as soups and shakes until before their surgery. These products contain all the vitamins and minerals essential for good health, plenty of protein and fibre to help them feel full, but far fewer calories than most people usually eat. On average, we anticipate that they will follow the diet for 3-4 weeks. They will get remote (phone/video) support by a dietitian weekly to support them adhere to the diet.

Standard care (control)
Participants in the standard of care group will follow their standard pre-habilitation pathway in line with their local hospital policy.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment rate measured using the number of sites open, the total n participants recruited, and the number of participants recruited per site as documented in the study notes per month at screening.
2. Engagement rate measured using the mean proportion of phone calls answered per participant documented in the study notes throughout the intervention.
3. Adherence rate measured using the proportion of intervention participants with ≥5% weight loss documented in the study notes from baseline to the day of surgery.
4. Retention rate measured using the proportion of participants documented in the study notes as attending their final follow-up (30 days post-operatively)
5. Safety profile measured using related adverse events and expected related and unexpected related serious adverse events documented in the study notes throughout the study.

Secondary outcome measures
Current secondary outcome measures as of 30/12/2024:
Morbidity will be assessed from patient records at discharge and 30 days postoperatively using the Clavien-Dindo classification as follows:
1. Any morbidity
2. Morbidity by grade (II, IIIa, IIIb, IVa, IVb)

Oncological outcomes will be assessed from patient records using:
3. Survival (grade V) assessed at 3 years
4. Fitness to receive planned adjuvant therapy assessed at 30 days post postoperatively
5. Recurrence assessed at 3 years
6. New primary/secondary cancer assessed at 3 years

Operative outcomes will be assessed from patient records using:
7. Intraoperative blood loss assessed at discharge
8. Operative time assessed at discharge
9. Conversion to open surgery assessed at discharge
10. Surgical site infection assessed at discharge and 30- days post-operatively
11. Time in the intensive care unit and high-dependency unit assessed at discharge and 30- days post-operatively.
12. Re-operation rates assessed at 30 days post-operatively and 3 years
13. Re-admission rates assessed 30 days post-operatively and 3 years

Hospital stay will be assessed from patient records at discharge and 30 days postoperatively using:
16. Length of hospital stay (fitness to discharge) assessed at discharge.
17. Days alive and out of hospital assessed 30 days post-operatively.

Anthropometry will be assessed by measuring in-person at baseline, on admission, and 30 days postoperatively using:

18. Weight
19. Fat-free mass

Fitness will be assessed by measuring in-person at baseline and 30 days postoperatively using:
20. Time for sit-to-stand test

Health-related quality of life will be self-reported at baseline, 4 days preoperatively, and 30 days postoperatively using:
21. EQ-5D-5L
22. HADS

Endometrial cancer specific health-related quality of life will be self-reported at 30 days postoperatively using:
23. EORTC-QLQ-EN24

Costs and resource use will be assessed from trial records and by self-report using:
24. Intervention costs assessed at the end of intervention.
25. Healthcare resource use questionnaire assessed at baseline, and 30 days post-operatively.
26. QALYs assessed at baseline, and 30 days post-operatively.

27. Adverse events will be self-reported throughout the study

Process outcome measures:

Experience of the intervention will be assessed using:
1. Analysis of qualitative interviews with intervention participants conducted halfway from starting intervention to surgery.
2. Feedback pre-operatively self-reported using a feedback questionnaire at 4 days preoperatively.
3. Feedback post-operatively self-reported using a feedback questionnaire 30 days post-operatively.

Experience of the trial will be assessed using:
4. Feedback post- operatively self-reported using a feedback questionnaire 30 days post-operatively.
5. Interviews with staff conducted throughout the trial.

6. Interviews with next of kin/friends/carers

Control group contamination will be assessed using:
7. Feedback post- operatively self-reported using a feedback questionnaire 30 days post-operatively.

Fidelity of delivery will be assessed using:
8. Observation of consultations throughout the intervention

Barriers to trial enrolment will be assessed using:
9. Reasons for declining participation assessed from patient records at screening

Exploratory (sub-study) – Manchester NHS Foundation Trust only :

Skeletal and lean muscle mass will be assessed at baseline and 2 days preoperatively using:
1. Appendicular skeletal muscle
2. Whole-body lean mass
3. Relative lean mass (%)

Fat mass will be assessed at baseline and 2 days 2 days preoperatively using:
4. Whole body fat mass

Cardiorespiratory fitness will be assessed at baseline and 2 days preoperatively using:
5. V02 peak
6. First ventilatory threshold
7. Distance walked during 6-minute walk test

Bone mineral density will be assessed at baseline and 2 days preoperatively using:
8. Bone density at the (total hip, femoral neck, lumbar spine, whole body)

Previous secondary outcome measures:
Morbidity will be assessed from patient records at discharge and 30 days postoperatively using the Clavien-Dindo classification as follows:
1. Any morbidity
2. Morbidity by grade (II, IIIa, IIIb, IVa, IVb)

Oncological outcomes will be assessed from patient records using:
3. Survival (grade V) assessed at 3 years
4. Fitness to receive planned adjuvant therapy assessed at 30 days post postoperatively
5. Recurrence assessed at 3 years
6. New primary/secondary cancer assessed at 3 years

Operative outcomes will be assessed from patient records using:
7. Intraoperative blood loss assessed at discharge
8. Operative time assessed at discharge
9. Conversion to open surgery assessed at discharge
10. Surgical site infection assessed at discharge and 30- days post-operatively
11. Time in the intensive care unit and high-dependency unit assessed at discharge and 30- days post-operatively.
12. Re-operation rates assessed at 30 days post-operatively and 3 years
13. Re-admission rates assessed 30 days post-operatively and 3 years

Hospital stay will be assessed from patient records at discharge and 30 days postoperatively using:
16. Length of hospital stay (fitness to discharge) assessed at discharge.
17. Days alive and out of hospital assessed 30-days post-operatively.

Anthropometry will be assessed by measuring in-person at baseline, on admission, and 30 days postoperatively using:
18. Weight
19. Fat-free mass

Fitness will be assessed by measuring in-person at baseline and 30 days postoperatively using:
20. Time for sit-to-stand test

Health-related quality of life will be self-reported at baseline, 4 days preoperatively, and 30 days postoperatively using:
21. EQ-5D-5L
22. HADS

Endometrial cancer specific health-related quality of life will be self-reported at 30 days postoperatively using:
23. EORTC-QLQ-EN24

Costs and resource use will be assessed from trial records and by self-report using:
24. Intervention costs assessed at the end of intervention.
25. Healthcare resource use questionnaire assessed at baseline, and 30 days post-operatively.
26. QALYs assessed at baseline, and 30 days post-operatively.

27. Adverse events will be self-reported throughout the study

Process outcome measures:

Experience of the intervention will be assessed using:
1. Analysis of qualitative interviews with intervention participants conducted halfway from starting intervention to surgery.
2. Feedback pre-operatively self-reported using a feedback questionnaire at 4 days preoperatively.
3. Feedback post-operatively self-reported using a feedback questionnaire 30 days post-operatively.

Experience of the trial will be assessed using:
4. Feedback post- operatively self-reported using a feedback questionnaire 30 days post-operatively.
5. Interviews with staff conducted throughout the trial.

Control group contamination will be assessed using:
6. Feedback post- operatively self-reported using a feedback questionnaire 30 days post-operatively.

Fidelity of delivery will be assessed using:
7. Observation of consultations throughout the intervention

Barriers to trial enrolment will be assessed using:
8. Reasons for declining participation assessed from patient records at screening

Overall study start date
01/11/2023

Completion date
29/02/2028

Eligibility

Key inclusion criteria

Current inclusion criteria as of 30/12/2024:
For patients:
1. Participant is willing and able to give informed consent for participation in the study.
2. Able to communicate in English or has a relative/friend/carer acting as interpreter.
3. Aged 18 years or above.
4. BMI >= 28 kg/m² (or BMI >= 25 kg/m² for people of Black, Asian, or minority ethnic origin).
5. Planned for curative elective surgery for endometrial cancer.
6. Performance status 0-2.

For staff:
1. Any research or clinical staff involved in the study and recruitment process

For next of kin/friends/carers:
1. Next of kin, friend or carer of a trial participant who has been randomised to the supported weight loss group.
2. Participant is willing and able to give informed consent for participation in the study
3. Able to communicate in English
4. Aged 18 years or above.

Previous inclusion criteria:
For patients:
1. Participant is willing and able to give informed consent for participation in the study.
2. Able to communicate in English or has a relative/friend/carer acting as interpreter.
3. Aged 18 years or above.
4. BMI >= 28 kg/m² (or BMI >= 25 kg/m² for people of Black, Asian, or minority ethnic origin).
5. Planned for curative elective surgery for endometrial cancer.
6. Performance status 0-2.

For staff:
1. Any research or clinical staff involved in the study and recruitment process

Participant type(s)
Patient, Health professional, Other

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 72; UK Sample Size: 72

Key exclusion criteria
Current exclusion criteria as of 30/12/2024:
or patients:
1. > = 10% self-reported weight loss in the 6 months before the screening visit
2. < 20 days from the screening visit until surgery.

3. Having allergy to soy.
4. Documented stage 4-5 kidney disease.
5. Documented severe heart failure (defined as New York Heart Association grade 3 or 4).
6. Previous bariatric surgery.
7. Type 1 diabetes.
8. Currently on insulin with a previous episode of diabetes ketoacidosis.
9. Currently on warfarin.
10. Pregnancy, breastfeeding, or planning pregnancy during the course of the trial.
11. Any other significant disease or disorder which, in the opinion of the Investigator or healthcare professional, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial.
12. Currently taking part in other interventional clinical trials unless agreed in advance by all trial teams (participation in observational studies is allowed).

Additional exclusion criteria for sub-study in Manchester:
1. Weight >155 kg.
2. Inability to cycle

For staff:
1. No exclusions

For next of kin/friend/carers:
1. No exclusions

Previous exclusion criteria:
For patients:
1. > = 10% self-reported weight loss in the 6 months before the screening visit
2. < 20 days from the screening visit until surgery.
3. Having allergy to soy.
4. Documented stage 4-5 kidney disease.
5. Documented severe heart failure (defined as New York Heart Association grade 3 or 4).
6. Previous bariatric surgery.
7. Type 1 diabetes.
8. Currently on insulin with a previous episode of diabetes ketoacidosis.
9. Currently on warfarin.
10. Pregnancy, breastfeeding, or planning pregnancy during the course of the trial.
11. Any other significant disease or disorder which, in the opinion of the Investigator or healthcare professional, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial.
12. Currently taking part in other interventional clinical trials unless agreed in advance by all trial teams (participation in observational studies is allowed).

For staff:
1. No exclusions

Date of first enrolment
06/11/2023

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Liverpool Women's NHS Foundation Trust
Liverpool Womens Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

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

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Manchester University NHS Foundation Trust
St Marys Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Somerset NHS Foundation Trust
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Somerset NHS Foundation Trust
Yeovil Hospital
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre

Imperial College Healthcare NHS Trust
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Sponsor information

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University of Oxford

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United Kingdom
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rgea.sponsor@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Results and Publications

Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication

Intention to publish date
28/02/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (to be determined following the publication of results).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	25/07/2023	27/10/2023	No	No
Statistical Analysis Plan	version 1.0	23/10/2023	27/10/2023	No	No
Protocol file	version 5.0	09/10/2024	30/12/2024	No	No
Protocol file	version 6.0	17/03/2025	08/08/2025	No	No