

# Could supported weight loss reduce womb cancer surgery complications?

<b>Submission date</b> 25/10/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/10/2023	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/08/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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**  
Dr Dimitrios Koutoukidis

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
324534

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

## **Study type(s)**

Quality of life, Treatment

## **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(s)**

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  $\geq 5\%$  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.

### **Key secondary outcome(s)**

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

## **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  $\geq 28 \text{ kg/m}^2$  (or BMI  $\geq 25 \text{ kg/m}^2$  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  $\geq 28$  kg/m<sup>2</sup> (or BMI  $\geq 25$  kg/m<sup>2</sup> 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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Female

### **Key exclusion criteria**

Current exclusion criteria as of 30/12/2024:

or patients:

1.  $\geq 10\%$  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.  $\geq 10\%$  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**

United Kingdom

England

**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****Organisation**

University of Oxford

**ROR**<https://ror.org/052gg0110>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Academy

# Results and Publications

## 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?
<a href="#">Protocol file</a>	version 2.0	25/07/2023	27/10/2023	No	No
<a href="#">Protocol file</a>	version 5.0	09/10/2024	30/12/2024	No	No
<a href="#">Protocol file</a>	version 6.0	17/03/2025	08/08/2025	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	23/10/2023	27/10/2023	No	No
<a href="#">Statistical Analysis Plan</a>	SAP supplement version 1.0	08/04/2025	20/08/2025	No	No
<a href="#">Statistical Analysis Plan</a>	SAP supplement version 2.0	19/08/2025	20/08/2025	No	No