Video link

Could supported weight loss reduce womb cancer surgery complications?

What is the purpose of this research?

- We are trying to find ways to reduce complications from surgery for womb cancer and help people recover faster.
- For people carrying excess weight, losing even a few pounds ***could*** reduce complications after surgery, because it improves physical fitness and blood sugar levels.
- This research will find out how practical it is to lose weight after a womb cancer diagnosis and while waiting for surgery.
- This will help us to plan future research to see whether losing weight is of benefit to a larger number of patients.

Why have I been invited?

- Because you may need surgery for cancer in your womb.
- Participation is voluntary. The decision to take part in this research will not affect the care you receive.

What will I have to do?

- You will need to agree to be put at random into 1 of the 2 groups:

A. Standard care group	B. Supported weight loss group
You will carry on with your care as usual – nothing about your care will change.	You will eat only nutritious soups and shakes until your surgery. A specialist will support you over the phone.

Regardless of the group you are in, you will also need to

- ✅ attend the hospital twice for 1-2 hours: once before you start the research and once about 30 days after your surgery. You will have some simple measurements taken, such as your weight, and fill in brief a questionnaire.
- ✅ fill in brief a questionnaire once at home.
- ✅ tell us about how you found the diet in an audio-recorded phone interview (group B only).

What if I am in the supported weight loss group?

- Most people quickly adjust to the diet after the first few days and follow it well. Your specialist will support you every step of the way.
- We chose to use this diet because people who follow it usually lose more weight than if they follow diets based on eating less of regular food.

- You will be asked to eat only tasty and nutritious soups and shakes until your surgery.
  - ✅ These products contain all the essential vitamins and minerals, and plenty of protein and fibre but are low in calories.
  - ✅ They are free of gluten, nuts, sesame, and shellfish, suitable for Halal, Hindu, or Kosher diets, and used by the NHS in other medical conditions.
- You can choose from a variety of flavours.
- We will provide you with these products for *free*.

- You will have weekly consultations with a specialist (a dietitian) who will support you over the phone or through video calls.

Other points to consider

- By taking part, you will help us find out if this treatment might help people with womb cancer in the future.
- Group B: Most people do not experience side effects from the diet, but you may experience some, such as constipation. Most side effects are only mild and go away when you stop the diet.
- We will offer you vouchers up to £30 for your travel expenses for each of the two journeys to the hospital.

What if I want to stop taking part?

- You are free to leave the research at any point.

Patients who have had womb cancer thought this research was a good idea and have helped design it.

Confidentiality

- All your data will be kept strictly confidential.

Our contact details

- Local research team: [local phone number] [local email]

Watch the video explaining the study on qrplanet.com/endocare

Detailed Participant Information Sheet

Could supported weight loss reduce womb cancer surgery complications?

We would like to invite you to take part in our research. Before you decide if you would like to take part, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. *If there is anything that is not clear, or if you would like more information, please ask us.*

What is the purpose of the research?

Surgery is used to treat womb cancer, but it carries a risk of complications. This risk is significantly higher for people carrying excess weight. Patients experiencing complications recover more slowly, have to stay in hospital longer, and may need more care.

We are trying to find ways to reduce these complications and help people recover faster after surgery. Physical fitness and well-controlled blood sugar are linked with fewer complications after surgery. For people carrying excess weight, weight loss improves both fitness and blood sugar, so it could reduce complications.

This research will find out how practical it is to lose weight after a womb cancer diagnosis and while waiting for surgery. This will help us to see, in future research, whether losing weight is of benefit to a larger number of patients.

Why have I been invited?

- Because you may need surgery for cancer in your womb. If you do not have surgery, then this research will not be suitable for you.
- You may read the information now and decide about taking part in the research later. We aim to include 72 individuals awaiting womb cancer surgery.

Do I have to take part?

No. Taking part is entirely up to you. You are free to leave the research at any point if you later change your mind. The decision to do so will not affect the care you receive.

What will happen to me if I decide to take part?

1. Screening visit at the hospital (~2 hours)

- We will discuss the research study with you.
- We will check that the research is suitable for you.
- You will agree (i.e., give informed consent) to take part.
- We will ask you a few questions about yourself.
- We will ask you about your current medication.
- We will measure your weight and height.
- You will sit and stand from a chair 5 times.

2. Randomisation

- You will be placed at random with a 50:50 chance in one of the two groups. This will allow us to compare the two groups fairly.

A. Standard care group

You will carry on with your care as usual – nothing about your care will change.

B. Supported weight loss group

You will eat only tasty and nutritious shakes and soups until your surgery. A specialist will support you over the phone.

Phone interview (~45 minutes)

- To tell us how you found the diet.

3. A couple of days before surgery (online / home ~10 minutes)

- We will ask you a few questions about yourself.

4. On admission (~2 minutes)

- We will measure your weight.

5. Visit at the hospital 30 days after the operation (~1 hour)

- We will check how your surgery went.
- We will measure your weight.
- We will ask you a few questions about yourself.
- You will sit and stand from a chair 5 times.

records for 3 years to check your ongoing health.

What will happen if I get allocated to the standard care group?

You will continue with the care you receive at your hospital as standard.

What will happen if I get allocated to the supported weight loss group?

You will have phone or video consultations with a dietitian weekly. They will support you to follow the diet and keep you motivated.

You will start the diet as soon as possible after you get allocated to the group and finish it the day before your surgery. This will be about 3-4 weeks, or longer depending on the date of your surgery.

Every day, you will eat only 4 nutritious products. You can choose from a variety of soups and shakes for each meal.

These products contain

- ✅ all the vitamins and minerals essential for good health
- ✅ plenty of protein and fibre to help you feel full
- ✅ far fewer calories (~800 calories/day) than usual (~2,000 calories/day).

They are

- ✅ gluten-free
- ✅ free of nuts, sesame, egg, celery, mustard, and shellfish
- ✅ suitable for Halal, Hindu, or Kosher diets
- ✅ already used by the NHS in other medical conditions.

- We will provide you with these products <u>for free</u>.
- We will advise you to drink plenty of fluids (e.g., water, tea, coffee, and diet soft drinks) but not high-calorie drinks (e.g., alcohol).
- Many people who start the programme find that it takes a few days to adjust to the diet. After that, most find it easier to follow the diet.

What will happen after surgery?

Regardless of which group you are in, you will receive the standard post-operative care from your local hospital.

What should I consider?

We would expect you to

- ✅ attend all appointments and complete all measurements
- ✅ follow the diet to the best of your ability, if you are in the diet group.

You will **<u>not</u>** be able to take part if you

- ❌ have lost more than 10% of your body weight in the last 6 months

- ✗ have been told that you have serious problems with your heart or kidneys
- ✗ have type 1 diabetes
- ✗ are currently using insulin AND have ever had diabetic ketoacidosis
- ✗ take warfarin (a type of blood thinning medication)
- ✗ have an allergy to soy or
- ✗ have previously had weight loss (bariatric) surgery

For patients with type 2 diabetes and/or hypertension

The diet can improve your blood glucose and blood pressure without the need for medication. If you are in the supported weight loss group and take medication for type 2 diabetes or hypertension (raised blood pressure), the study doctor *may or may not* advise you to reduce or stop these when you start the diet. If necessary, we will provide you with blood glucose and blood pressure monitors.

Other research studies

If you would like to take part (or are already participating) in other research studies while being in this research study, you will be able to do so in most cases. The researcher will advise you on this.

After surgery

As getting back to driving can take anything between 2 and 6 weeks after your surgery, you may want to consider your travel arrangements (such as having someone drive you) for your visit at 30 days after the surgery.

Are there any possible disadvantages or risks from taking part?

Standard care group: There are no risks from taking part.

Supported weight loss group: Most people do not experience side effects from the low-calorie diet. About 1 in 5 people will experience at least one side effect due to the diet. A few people have constipation but we will give you a fibre supplement to help prevent this. Less common side effects include fatigue, headache, dizziness, dry mouth, abdominal pain, bad breath, diarrhoea, hair loss, dry skin, mood changes, and feeling cold. Most of these side effects do not pose a health risk, are mild, and temporary. Your dietitian will monitor these and advise you on how to manage them.

What are the possible benefits of taking part?

If you are in the standard care group, there are no direct benefits to you. Standard care groups are important for research as they help us to accurately estimate the effects of the treatment. Everyone who takes part in this research will help us find out if this treatment might help people with womb cancer in the future.

Most people who follow the low-calorie diet lose a significant amount of weight, but how much weight you will lose will depend on how closely you will follow the advice you receive. This *could* reduce complications after surgery.

Will I be reimbursed for taking part?

To cover your travel expenses, you will receive two [Amazon] vouchers, one for attending the baseline visit and one for attending the follow-up visit. Each voucher will be either £15 or £30 depending on how far you have travelled.

Will my General Practitioner (GP) be informed of my participation?

Yes. We will inform both your GP and your hospital specialist doctor of your participation and any medication changes we may recommend.

What will happen if I don't want to carry on with the research?

You are free to leave the research at any time without giving a reason. We will give you the opportunity to tell us the reason for withdrawing if you would like to. Your future NHS care will not be affected. You could choose to stop the diet but continue with the research assessments and visits.

If you don’t carry on with this research, we will delete your identifiable information, but will use the data collected up to the point that you stopped. You also have the option to tell us to collect no further data after your withdrawal. Unless you explicitly state otherwise, we will continue to access your medical records and any relevant hospital data that is recorded as part of routine care; e.g., ultrasound, blood results, disease data etc.

What will happen to the results of this research?

The results of this research will be published in scientific journals and presented at academic conferences. We will send you a summary of the results. De-identified data will be part of the presentations and publications and this may include quotations from your interview. You will not be identifiable in any presentation or publication.

The results of this research will help us see if another bigger research study is worthwhile to test whether this diet can reduce complications from surgery.

Will my taking part in the research be kept confidential?

Yes. Any information that is collected about you during the course of the research will be kept strictly confidential. We will use code numbers to avoid identification of participants with their names. All data will be stored securely on password-protected databases and drives at the University of Oxford. Only the research team will be able to access the information. All your research data (e.g., questionnaire data) will be de-identified at the earliest practical opportunity. Responsible members of the University of Oxford and the relevant NHS Trusts may be given access to data for monitoring and/or audit of the research study to ensure that the research is complying with applicable regulations.

What will happen to my data?

UK data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom is the sponsor for this research study, and the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records in order to undertake this research study and will use the minimum personally-identifiable information possible.

Data transfers: Your phone interviews will be audio-recorded and sent to a professional transcription company for transcription. Following transcription, the company will delete their copies of your data. If you are in the supported weight loss group, we will securely share your name and contact details with the company providing the shakes and the courier company, so that you can receive the shakes by post if needed. You will be contacted by these companies [Habitual and DHL] for the purposes of the study but will not be contacted directly for marketing purposes. They will delete this information at the end of the research study. In all cases, appropriate contracts and procedures will be in place to ensure all data is kept confidential.

Local NHS Trust: The local NHS Trust will use your name, NHS number, home address, and contact details, to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study as per the local Trust policy.

Retention of identifiable data: We will keep identifiable information about you securely at the University of Oxford until the end of the study. We will delete your contact details at the earliest possible opportunity. Copies of the audio-recording files will be deleted at completion of the relevant analysis.

Retention of research data: Following review to ensure participant anonymity is safeguarded, de-identified research data will be securely archived to a repository following publication of the results where they will be stored indefinitely. De-identified data obtained as part of this research study may be used in future research, here or abroad and may involve commercial organisations.

UK data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights. You can find out more about how we use your information by contacting endocare@nds.ox.ac.uk.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this research. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this research, you should contact Dr Dimitrios Koutoukidis on 01865

617767 or endocare@nds.ox.ac.uk or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865 616480, or the director of RGEA, email rgea.complaints@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research. If you wish to contact the PALS team, please contact <insert relevant NHS site phone number and email>.

How have patients and the public been involved in this research?

Patients with womb cancer, their relatives, and members of the public have helped to develop and design this research. They will continue to provide feedback and be involved in the research.

Who is organising and funding the research?

- Organised by: the Surgical Intervention Trials Unit, University of Oxford.
- Sponsored by: the University of Oxford.
- Funded by: the National Institute for Health and Care Research (NIHR).

Who has reviewed the research?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This research has been reviewed and given favourable opinion by the South Central – Oxford B Research Ethics Committee (Ref: 23/SC/0223).

Further information and contact details:

Please contact your local research team.

 [local phone number]  [local email]

Thank you for considering taking part in this research.