



Could supported weight loss reduce bowel cancer surgery complications?



What is the purpose of this research? (See page 3 for details)

- Physical fitness and well-controlled blood sugar are linked with fewer complications after surgery.
- For people carrying excess weight, losing weight improves both of the above, so it **could** reduce complications after surgery.
- This research will try to find out how practical it is to lose weight after a bowel 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? (page 3)

- Because you may need surgery for cancer in your bowel. If you do not have surgery, this research will not be suitable for you.
- You may read the information now and decide about taking part later.

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What will I have to do? (pages 4-5)

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

A. Normal care group

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

B. Supported weight loss group

You will eat only nutritious shakes and soups until 2 days before your surgery. A specialist will support you over the phone.



- You will also need to
 - ✓ come to the hospital twice for 1-2 hours: one time before you start the research and one time about 30 days after your surgery. You will have some simple measurements taken, such as your weight, and fill in brief questionnaires.
 - ✓ fill in brief questionnaires once at home.
 - ✓ tell us about how you found the trial and the diet in one or two audio-recorded phone interviews.



What if I am in the supported weight loss group? (page 5)

- Supported by a specialist, most people have been able to follow the diet.
- We chose to use this diet because, on average, people who follow it lose more weight than people following diets based on eating less of regular food.



- You will be asked to eat only nutritious soups and shakes until 2 days before your surgery. 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 than most people usually eat.They are
 - ✓ gluten-free and free of nuts, sesame, and shellfish.
 - ✓ suitable for Halal, Hindu, or Kosher diet
 - ✓ already 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 (pages 6-7)

- By taking part, you will help us find out if this treatment might help people with bowel cancer in the future.
- Supported weight loss: Most people do not experience side effects from the low-calorie diet. You may experience side effects, such as constipation, but most side effects are only mild and go away when you stop the diet. We will check these regularly.
- 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? (page 8)

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



Confidentiality (page 8-9)

- All your data will be kept strictly confidential.



Our contact details (page 9)

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



Detailed Participant Information Sheet

Could supported weight loss reduce bowel 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 to remove bowel cancer is a very effective treatment. However, the risk of complications from surgery is high. Patients experiencing complications recover more slowly, have to stay in hospital longer, and 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 from surgery. For people carrying excess weight, weight loss improves both fitness and blood sugar, so it may reduce complications.

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

Why have I been invited?

- Because you may need surgery for cancer in your bowel. 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 have capacity for only 72 individuals awaiting bowel 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

- A computer will decide at random which one of the two groups you will be in. Your chance to be in either group is 50-50.

Phone interview (~15 minutes, optional)

- To tell us how you found the process so far.

A. Normal care group

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

B. Supported weight loss group

You will eat only nutritious shakes and soups until 2 days before 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.

After this, we will continue having access to your hospital medical records for 3 years to check your ongoing health.

We will also audio-record the conversations you have with the research team before you decide whether you want to take part in the research for training and quality purposes (e.g., to see how well the research is explained to you). Recordings are optional. If you don't want to be audio-recorded, you can still take part in this research.

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

You will continue with the care you receive at your hospital as standard. Nothing about your care will change.

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



You will have phone (or video) consultations with a dedicated dietitian weekly. They will support you in following the diet.



You will start the diet as soon as possible after you get allocated to the group and finish it 2 days before your surgery. On average, this period will be about 3 weeks. However, it may be longer depending upon the time of your surgery. In the unlikely event that your surgery is scheduled in 7 weeks' time or more, you will stop the diet when you lose at least 15% of your weight.



Every day, you will eat only 4 nutritious products. You can choose from a variety of soups and shakes. You can mix and match them in any combination you like.

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, 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 for free.
 - We will advise you to drink plenty of fluids (e.g., water, tea, coffee, and diet soft drinks) but not calorie-dense 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 about 2 days before surgery and after surgery? (**both groups**)

Regardless of the group you are allocated:

- For the 2 days before your surgery, the local hospital where you are having your surgery will advise you on what diet to follow. This may include laxative bowel preparation medication or carbohydrate-rich supplements.
- Your local hospital may also give you diet advice after your surgery.

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 **not** 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
- ✗ have been told that you have serious problems with your kidneys
- ✗ have type 1 diabetes
- ✗ take warfarin (a type of blood thinning medication)
- ✗ follow a fully vegan diet, have lactose intolerance, or have an allergy to soy
- ✗ have previously had weight loss (bariatric) surgery or
- ✗ are planning to get pregnant, are pregnant, or breastfeeding.



For patients with type 2 diabetes and/or hypertension

The low-calorie 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 a blood glucose and a blood pressure monitor, so that you can monitor these at home.



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.

Are there any possible disadvantages or risks from taking part?

Normal 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 one in five people will experience at least one side effect due to the diet. A few people develop constipation but we will give you a fibre supplement to take 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 risk to your health, 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 normal care group, there are no direct benefits to you. Normal 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 bowel 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 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 a scientific journal and presented at academic conferences. We will send you a summary of the results. Anonymised data will be part of the presentations and publications. 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 and improve outcomes for people with bowel cancer.

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 and 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 conversations with the research team and 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. 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 to allow for the long-term follow-up through medical records to occur and so that you can receive a summary of the results. 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, anonymised research data will be securely archived to a repository following publication of the results where they will be stored indefinitely. Anonymised 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 care@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 care@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 bowel cancer, their relatives, and members of the public helped 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 Nuffield Department of Primary Care Health Sciences at the 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: 22/SC/0465).

Further information and contact details:

Please contact your local research team.



[\[local phone number\]](#)



[\[local email\]](#)

Thank you for considering taking part.