Participant Information Sheet

The LightBAR Study

An intensive medical weight loss programme versus weight loss surgery

Version 2.0 30th August 2024

We'd like to invite you to take part in our research study. Before you decide, 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 talk about it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask the LightBAR research team.

The LightBAR study:

For people who are very overweight there are two possible options to support weight loss - surgery or non-surgical weight loss treatments. We don't know which is better. The LightBAR study will test whether the weight loss treatments or surgery are better at improving health and reducing the chances of a heart attack or stroke, or developing conditions like diabetes. It will also test which treatment is better at helping people lose weight and the effects of each treatment on quality of life.

The non-surgical weight loss treatment is a two-year programme that includes a weight loss diet and support from a health coach from Liva Healthcare, who provide health coaches to the NHS. It includes eating special weight loss soups, shakes and meals instead of a normal diet for the first 12 weeks, and then switching to eating healthily and slowly increasing the amount of physical activity that you are doing. Your health coach will help you make these changes in a way that works for you. A doctor may also prescribe weight loss medication, which uses the body's natural hormone system to suppress appetite, making it easier to stick to your goals.

The surgical treatment involves an operation that alters part of your gut to restrict the amount of food you are able to comfortably eat and so encourages people to eat less than previously.

How the study will work:

The study lasts two years. If you say 'yes' to taking part and are suitable for the study, you will be placed into one of two groups to either receive the non-surgical weight loss treatment or to receive weight loss (Bariatric) surgery.

Before you begin the study, you will need to lose 5% of your body weight (about 5-8kg or about a stone for most people) within 12 weeks (3 months).

Once you have lost 5% of your starting weight, we will sort you randomly into a treatment group. Neither you, your doctor nor the research team can decide which group you will go into. It is important that you are willing to be in either group and receive either of the two treatments.

We will ask to take measurements from you four times over two years. These will take place at the beginning, and then after 8 months, 1 year and 2 years after you start. After that, we will use your NHS records to follow your health over the next 18 years.

If you are interested in this study, please read the rest of this leaflet.

Why have I been invited?

We have invited you to take part because:

- You are over 18 years old but under 60 years old and are on the waiting list for NHS weight management services.
- You have a health condition that might be partly caused by being overweight, such as type 2 diabetes, high blood pressure, sleep apnoea, arthritis in your knees or hips or infertility as a female.

The University of Oxford do not have access to your personal or health information records. We can only invite people to take part because we work with NHS Trusts throughout the UK.

Unfortunately, you would not be able to take part in this research study if you have any of the following:

- Had weight loss surgery in the past.
- Have used any weight loss medication in the last three months, or medication for diabetes called a GLP-1 agonist.
- Have any conditions that mean you cannot safely use weight loss medications
- Conditions that can affect the use of total diet replacement foods i.e. using insulin; or conditions that require strict diets .
- You are pregnant or planning to become pregnant in the next two years, or you are currently breast feeding.
- You do not lose 5% of your starting weight within the first 12 weeks of the study before you are assigned to your treatment group.
- Another member of your household has already enrolled on the study.

This list above is not complete and we would go through everything with you before you start to make sure this study is right for you.

Do I have to take part?

No, you do not have to take part if you do not want to. Choosing not to take part will not affect any care your clinician team or your GP is currently giving to you. You will be able to stay on your current NHS waitlist and also access any weight loss options within your area: https://www.nhs.uk/better-health/lose-weight/

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

If you decide to take part, you must be willing to:

- Have weight loss surgery *OR* follow the intensive weight loss treatment.
- Attend four clinic appointments with a research nurse at a local clinical facility.
- Lose 5% of your body weight (about 5-8kg or about a stone for most people) in the first 12 weeks (3 months) before you are allocated to a treatment group.

At your first appointment we will talk to you more about the study, and you can ask any questions you may have. You will also see a surgeon, who will talk to you about weight loss surgery and see whether you are able to be given surgery. We would like to video or audio-record this discussion to help us improve the way we communicate with people, but we'll ask if you are willing to do this beforehand.

We will then ask you to come back for your first clinic appointment.

If you decide ***not to take any further part*** in the study, we would like to ask:

- If you are willing to discuss your experiences of this recruitment discussion with a researcher so we can learn how to improve the way we discuss treatments and research.

If you join the study we will, at each of the four clinic visits:

- Take your weight, waist and height measurements.
- Record any significant health problems and medications you are taking.
- Take your blood pressure.
- Take a blood sample.
- Collect a urine sample.
- Look at your physical fitness by using a short walking test and measuring the how many times you can sit down and then stand up in 30 seconds.
- Attach a small monitor to your leg that tracks your sleep and physical activity. We will ask you to wear this for one week. You can do normal activities including showering or swimming whilst wearing the monitor.
- Have a body scan called a DEXA scan, sometimes called a bone scan. This will only be at the first and last appointments (at 2 years).

We will also ask you to:

- Complete some questionnaires about how you think and feel, your work and how much you use health services. We will send you these via email.

- Provide a stool sample (we will give you a pack that will have everything you need, including instructions about how to collect the sample and on posting it back).
- At the final appointment at 2 years, we will also ask you to wear a glucose monitor on your arm for a week and keep a simple diary whilst you're wearing it and post them back to us. You will be able to do your normal activities while wearing this monitor.

After the first clinic appointment, we will ask you to lose at least 5% of your starting weight and give you some advice about how to achieve this. If you lose this weight within 12 weeks, you will be entered into the study and randomly selected for a treatment group.

If you are allocated to the non-surgical weight loss treatment group:

We will refer you to a health coach at Liva Healthcare, who will help you through the treatment programme over the next two years.

For the first 12 weeks, we will ask you to eat soups, shakes, and pre-prepared meals instead of what you normally eat. These special weight loss foods have all the nutrients you need, and are designed to help you feel full. But because they give you only 800-1000 calories per day, they will help you to lose weight quickly. After this, your health coach will help you to reintroduce healthy foods, and help you find ways to slowly increase the amount of physical activity you do. Your health coach will talk to you about weight loss medication, this is medication that controls your natural appetite system to make you feel less hungry, to make reaching your weight loss goals easier. If you want to use the medication, a doctor will prescribe it for you. We expect this programme will help you to lose 20% of your initial body weight. Your health coach will stay in touch with you for 2 years to help you continue to manage your weight.

We may record the conversations you have with the health coach to help us understand more about your experience of losing weight and how the support we provide could be improved. These recordings will be kept confidential, and only the researchers will know you have taken part.

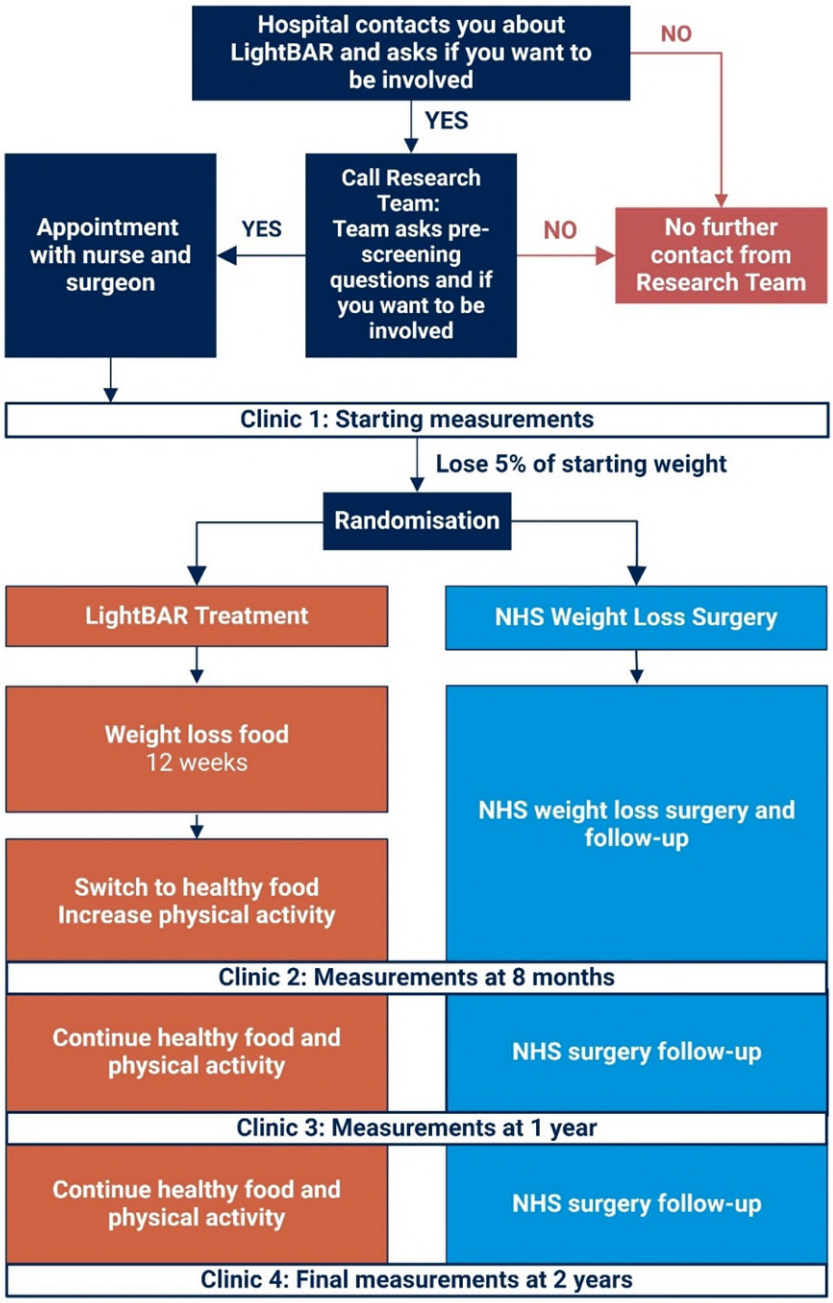
We may ask you to consider talking to one of our researchers from the University of Oxford about your thoughts and feelings about the treatment you have had, and the effects, if any, on your life. We may also like to find out how your weight loss has affected your family. To do this we may ask to interview you and members of your family and/or household during the course of the 2 years. If approached, it is up to you whether you agree to talk to the researcher.

If you or a member of your household are willing to do this, an experienced researcher will speak with you on the phone for about 45 minutes. These discussions will be confidential.

If you are allocated to the weight loss surgery group:

You will be referred to receive obesity surgery within 12 weeks. During preparation for surgery you will see various health professionals to talk you through what to expect and check you are ready for surgery. After your surgery you will need to attend hospital clinics regularly, about every few months for a year, but each hospital is slightly different and your hospital will be able to tell you exactly how often. After this you will be referred to your GP for a yearly check-up.

The following image gives a brief outline of your involvement in the study over the 2 years:



Created with BioRender.com

What are the possible benefits of taking part?

Whichever treatment group you are in:

- You will be helped to lose weight, which could be good for your wellbeing and reduce your risk of health problems such as diabetes, heart problems and stroke in the future.
- Have regular blood tests and health assessments that will be like an enhanced health screening check.
- Have the opportunity to talk to researchers about this study and help us improve how we conduct research and provide care for NHS patients.
- You will be helping research to find out how best to help us improve quality of care for people living with obesity in the future.

Are there any possible disadvantages or risks from taking part?

Everyone will be required to make changes to what they eat. We do not expect this to put your health at risk, but changing your diet might mean you experience constipation. We will give you advice on how to prevent and /or treat this and treatment will be provided if required.

You might feel some discomfort from the needle for the blood sample, but this will not last.

If you take part in this study you will have a DEXA scan. DEXA scans are a special type of X-ray scan and are used routinely by the NHS. All of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body to tell us about the strength of your bones and the amount of fat and other tissues in your body. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very tiny chance of this happening to you. The radiation the DEXA scan exposes you to is about the same amount of radiation as you would get on a flight from the UK to southern Spain.

The physical fitness tests may feel tiring and make you feel short of breath. We will stop the tests if they cause you too much discomfort or if the nurse feels that they are not safe for you to do.

We will ask you to wear a physical activity monitor for a week, which will be attached to your thigh using a medical patch. This can be removed if you have a reaction to the patch.

Some of the questionnaires we will ask you to complete ask questions about your health, including your mental health. Some people might find answering some of the questionnaires distressing. If you do, we would ask you to tell someone at your

appointment or contact the research team, and they can talk you through any concerns, and speak to other healthcare professionals if needed.

Possible Risks of Non-Surgical Weight Loss:

- Losing weight usually means that people's blood pressure and blood glucose levels decrease, so if you are using medication for blood pressure or diabetes, you may be asked to reduce or stop these medications. If you are taking these medications, we will ask you to monitor your blood glucose and blood pressure so you can tell your doctor or nurse if these are out of safe limits and your medication may need to be reviewed.
- Any weight loss medications you are prescribed as part of this study, are already licensed in the UK and have been approved as safe to use for weight loss.

Possible Risks of Weight Loss Surgery:

Weight loss surgery is standard practice within the NHS, and the risks from the surgery is low. However, all surgery has some risks. Your surgeon will talk to you about the risks of surgery and the best surgery for you. Your hospital will invite you to a clinic where they will make sure that you are fit and ready for surgery. This visit is on top of other visits you will go to for the study.

The pre-operative check can take up to a full afternoon.

Below is a chart that summarises the possible risks of the surgery you might be offered. You can ask any questions about your surgery at any time.

Weight Loss Surgery - Possible Complications and Side Effects		
Risks of Both surgeries	**Additional risk of Gastric Bypass**	**Additional risk of Sleeve Gastrectomy**
• Anaesthetic risk • Blood clots • Bleeding • Infection • Feeling sick or being sick • Mineral & vitamin deficiencies • Stomach ulcers • If you eat a big meal, you may feel faint and have stomach pains afterwards • Changes in your sense of taste • Increased risk of osteoporosis and breaking bones	• Internal hernia • It might be harder to absorb medication	• If you keep eating big meals you could put the weight back on

• Leak of surgical joints in your gut which could mean you need another operation • Developing small-fibre neuropathy		

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

Yes. We will let your GP know that you are in the study and which of the treatment groups you are in. Your GP will get the results of blood tests you have, and they might make an appointment with you if they need to speak to you about your results. We may also write to your GP if we discover something that could affect your health. Taking part in the study will not affect the healthcare you receive from your GP for anything else.

Will I be reimbursed for taking part?

Yes. To thank you for your time, we will give you a £50 shopping voucher for attending the study visits at 8 months, 1 year and 2 years appointment.

We will also give you a £25 voucher for any additional discussions that you have with us.

These shopping vouchers will be for Amazon, however, if you would prefer something else, please speak to a member of the trial team.

If you have to travel to a separate DEXA scan, we will be happy to pay the travel expenses you incur.

Will my taking part in the study be kept confidential?

Yes. Any information that is collected about you during the course of the study will be kept strictly confidential. All study records and samples (e.g. blood and urine) will be identified by a code instead of your name. We will only use your name, date of birth, and/or NHS number where necessary, for example to link to your NHS records or contact you. Information that could be used to identify you will be kept securely by the research team for the purpose of the study. We use codes to avoid identifying you with your name and any publications from the study will have no identification about you at all.

Responsible members of the University of Oxford, Copenhagen University Hospital – Amager and Hvidovre (the study sponsor) and the relevant NHS trusts may be given access to some data for monitoring, and/or to audit the study to ensure the study is complying with the appropriate regulations.

What will happen to the samples I give in this study?

Some of your blood and urine samples will be sent straight to a laboratory for analysis and then destroyed as soon as they have been tested.

We will store the rest of your samples (blood, faeces, urine, DNA) in a sample storage facility called a biobank at the University of Bristol. This is so that we can continue to use them to help answer our research questions about obesity and health. These samples will be destroyed after we have finished testing them, but this could be a long time in the future.

We will store some of your samples as a source of genetic material (DNA and RNA). The study of DNA, RNA, and genes is referred to as genetic research. Our genes play an important role in defining many characteristics about individuals. We all have a slightly different set of genes in our bodies. Genetic studies can help us look at these differences and understand varying characteristics. Providing these samples is part of the study.

The samples will be stored with unique ID numbers and any identifying information such as your name and date of birth will be removed from your samples. Therefore, the laboratory storing the samples and any researchers that analyse the samples will not be able to link the samples to you. We will not be able to let you know the results of any future genetic testing that is carrier out on these samples. The information linking your unique sample ID to your study data will be kept confidential and password-protected, and only specific members of the research team will be able to access it.

Health research often involves information being shared between researchers who work in the NHS, universities, other research institutions or in biotechnology or pharmaceutical companies. This maybe in the UK or overseas. If your samples are shared with other researchers, they will only be used in research that has ethical approval, and only anonymised information will be shared. We may ask for a fee from researchers to help cover the costs of running the biobank where your samples are stored. The samples that you donate will not be sold for profit.

What if we find something unexpected?

Some tests of measurements that we take might indicate increased risk for some health problems that can be treated if you know about them. We will inform you and/or your doctor if this is the case. We will not tell you the results of tests that have no implications for you and your health.

What will happen to my data?

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.' Copenhagen University Hospital – Amager and Hvidovre, Denmark is the Sponsor for

this study. It is a joint data controller with the University of Oxford, and both institutions are responsible for looking after your information and using it properly. We will be using information from you, your medical records, NHS digital and other central NHS registries in order to do this study and will use the minimum personally identifiable information possible. We will store any research documents with your personal information, such as consent forms, securely at the University of Oxford and Copenhagen University Hospital – Amager and Hvidovre for up to 20 years.

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form and your details separate from one another and any research data.

We will keep any other identifiable information about you, including your NHS number, for up to 20 years to allow us to link your records to related health records in the future. We will also keep your contact details for at least 6 months after the study has finished so that we can let you know the results of the study and if you agree to be contacted about future research studies, we will also need your details for this reason.

The Copenhagen Trials Unit based at Copenhagen University, Denmark will be responsible for the data management for this study. All data will be held securely on an electronic data system, it will go through regular monitoring and will comply with strict security and data protection.

Your GP practice and/or the local research team will use your name and contact details to get in touch with you to arrange appointments.

Half of the participants in this study are based in Denmark and the research team includes researchers at the University of Copenhagen, Copenhagen University Hospital and Southern Denmark University. We will combine data from the study in the UK with data collected from the Danish participants. This will include looking at how well the trial has worked, whether we have seen a benefit to participants and whether the treatment would be value for money.

Video or audio recorded consultations and interviews:
If you are placed in the non-surgical weight loss treatment group, we may ask to interview you and close members of your household. This is to find out how a weight loss journey can affect family life and we may ask to audio record the interviews. We may also video or audio record some of your consultations with your health coach to help us investigate effective communication by health coaches. These recordings will help us improve how the study is run and what we could do to improve your experience in this study.

The recordings will be transcribed by a University of Oxford approved transcriber with a contract in place which makes sure they keep the contents of the recording confidential. Your name will be removed from the transcriptions and will be replaced with a unique identifier code number.

Recordings with names removed and anonymised transcripts will be stored on secure drives at the University of Oxford for up to 20 years, and they may be used in future ethically approved research.

Any recordings used in publications, teaching or training will be subject to further pseudonymisation including distorting of voices and images, and removal of further identifying information, such as location, date, time. This means you will not be identified in recordings used in teaching and presentations

Health coach:

If you are assigned to the non-surgical treatment programme, we will pass your information onto a third-party provider who runs the service and employs the health coaches. This company provides other NHS programmes and is subject to all NHS data protection rules. They have a contract in place with the University of Oxford and will not be allowed to use your data for any activities other than those they are contracted to deliver and will not be allowed to use your information for any marketing or advertising reasons.

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 the LightBAR research team: 01865 617847

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

It is up to you whether or not you take part in the LightBAR study. If you decide you do not want to continue taking part in this study, you can withdraw at any time without giving a reason.

If you would like to, you can tell us why you want to withdraw from the study. This will not affect any healthcare you are given in the future.

If you decide to withdraw, there are three options you can choose from:

1. Withdraw from treatment: stop the weight loss treatment, but still come to the study visits.
2. Withdraw from treatment and study visits: Stop the weight loss treatment and do not come to the study visits, but allow us to collect data from your medical records.
3. Withdraw from the study completely: Stop the treatment, don’t come to study visits, and do not give us permission to use your medical records.

We will ask you what you would like to do.

If you do decide to withdraw from the study, we will use the pseudonymised data (without any name, just a unique ID code) that has been collected up until the time you withdraw from the study including any recorded interviews. We would use this pseudonymised data (meaning we cannot directly identify you) after your withdrawal from the study to help with the research results.

What will happen to the results of this study?

We will use what we learn in this study to help us and the NHS to improve future treatment for people who struggle with their weight.

We plan to publish our findings in academic journals, present them at conferences or to healthcare professionals. We will also put a summary of our findings on a website for members of the public to read about and send you a summary of the results. **You will not be identified in any report or publication** from this study.

Participation in future research:

We may wish to get in touch with you to see how you are getting on in the future, or we may have other studies that you might be interested in. If you agree, we may contact you to ask if you would like to take part in another study. Agreeing to be contacted by us does not mean you would have to agree to be involved in future research, and you can be removed from this register at any time if you wish.

If you agree to your details being held and to be contacted regarding future research, we will keep a copy of your consent form securely. We will keep the consent form and your details separate from each other and any other research data.

What if there is a problem?

Copenhagen University Hospital – Amager and Hvidovre, 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 study. NHS indemnity operates in respect of the clinical treatment provided.

The sponsor is being represented in the UK by the James Bristow, Head of Information Compliance and Data Protection Officer at the University of Oxford, email: data.protection@admin.ox.ac.uk

If you wish to complain about any aspect of the way that you have been approached or treated, or how your information is handled during the course of this study, contact Prof. Susan Jebb: 01865 617826 or email: susan.jebb@phc.ox.ac.uk

The Patient Liaison Advisory Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please email: PALS@ouh.nhs.uk or visit their website: http://www.ouh.nhs.uk/patient-guide/pals.aspx

Who is organising and funding the study?

The LightBAR study is funded as part of the Lighthouse Consortium on Obesity Management (LightCOM), a collaborative scientific initiative between researchers in Denmark and the UK.

Who has reviewed the study?

All research in the UK is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by South Central – Oxford B NHS Research Ethics Committee.

Further information and contact details:

If you would like to be find out more about the LightBAR study, or to be involved, please contact the LightBAR research team at:

Email: lightbar@phc.ox.ac.uk or by telephone: 01865 617847

Thank you for considering taking part in the LightBAR study