Participant Information Sheet: The LightWAY Study

An intensive medical weight loss programme versus individually tailored weight loss support

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We would 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 discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please contact the LightWAY research team.

The LightWAY study:

For people living with obesity, there are limited services available to help them lose weight for the long term. We now have new weight loss treatments available, and the LightWAY study will test whether a two-year programme that includes a weight loss diet and support from a health coach from Liva Healthcare, who provide health coaches for 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 LightWAY study will test if the new weight loss treatment is better at helping people lose weight, and if it can reduce their risk of a heart attack or stroke, improve fitness and generally improve quality of life more than current weight loss care available on the NHS. We will also look whether any benefits from the new weight loss treatment can be maintained for the long-term and whether the new treatment could be good value for money for the NHS.

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 new weight loss treatment or receive weight loss support available in your local area. We will sort you randomly, so neither you or your doctor or the research team can decide which group you will go into. To join the study, you need to be willing to accept being part of either group.

We will ask to take measurements from you four times over two years. This will take place at the beginning then about 8 months, 1 year and 2 years after you start. After that, we will use your NHS records to follow you 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
- Your medical records show your last recorded body mass index (BMI) was 35 kg/m^2 or over (if you are of a white ethnic group) or 32.5 kg/m^2 or over (if you are from any other ethnic group).
- Have one or more of these types of conditions: cardiovascular disease, type 2 diabetes, high blood pressure, liver problems, or sleep apnoea

If this still applies to you and you are willing to try to lose weight, you may be suitable for this study.

You can check your BMI using the NHS BMI Calculator: https://www.nhs.uk/live-well/healthy-weight/bmi-calculator/

The University of Oxford do not have any 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.

You can take as much time as you like to read everything within this information sheet. You can also ask the Research Study Team any questions you may have about the study.

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

- You are pregnant or planning to become pregnant in the next two years, or you are currently breast feeding.
- Have used any weight loss medication in the last three months, or medication for diabetes called a GLP-1 agonist.
- You have received weight loss surgery.
- You are currently being treated for cancer other than long-term oestrogen antagonist therapy after breast cancer or non-melanoma skin cancer.
- Have any conditions that mean you cannot safely use weight loss medications
- Have any conditions that can affect the use of total diet replacement foods like using insulin; or conditions that require strict diets.
- Use insulin
- Another member of your household has already enrolled on the study.

This list is not complete, and we would go through each point with you 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. If you are on a current NHS waitlist you will be able to stay on the list 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 will be invited to visit your GP surgery or a local hospital four times over two years.

At your first clinic visit we will go through this participant information sheet with you to make sure you are happy with all the information provided.

You will have the opportunity to ask further questions and make sure you wish to take part in this research study. Once you are happy and wish to proceed into the study, we will also go through a consent form with you and ask for this to be signed and dated.

For each clinic visit the research team will:

- Take your weight, waist, and height measurements.
- Record any medications you are currently taking.
- Take your blood pressure.
- Take a blood sample.
- Collect a urine sample.
- Look at your physical activity by using a short walking test and measuring the how many times you can sit down and 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 1 week. You can do normal activities including showering or swimming whilst wearing the monitor.

We will also ask you to:

- Attend a local facility near you to have a body scan called a DEXA scan, often called a bone scan. This will only be at the first and last appointments (at 2 years).
- Complete some questionnaires about how you think and feel, your work and how much you use health services. We will send you these questionnaires via an email link.

After taking the measurements to check you are suitable for the study at the first appointment, we will randomly sort you into one of the two treatment groups in the study.

If you are in the new 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 may talk to you about weight loss medication, which 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, and it is safe and suitable for you to take, 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 talk 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 talk to you and members of your family and/or household over the 2 years. If approached, it is up to you to whether you agree to talk to the researcher.

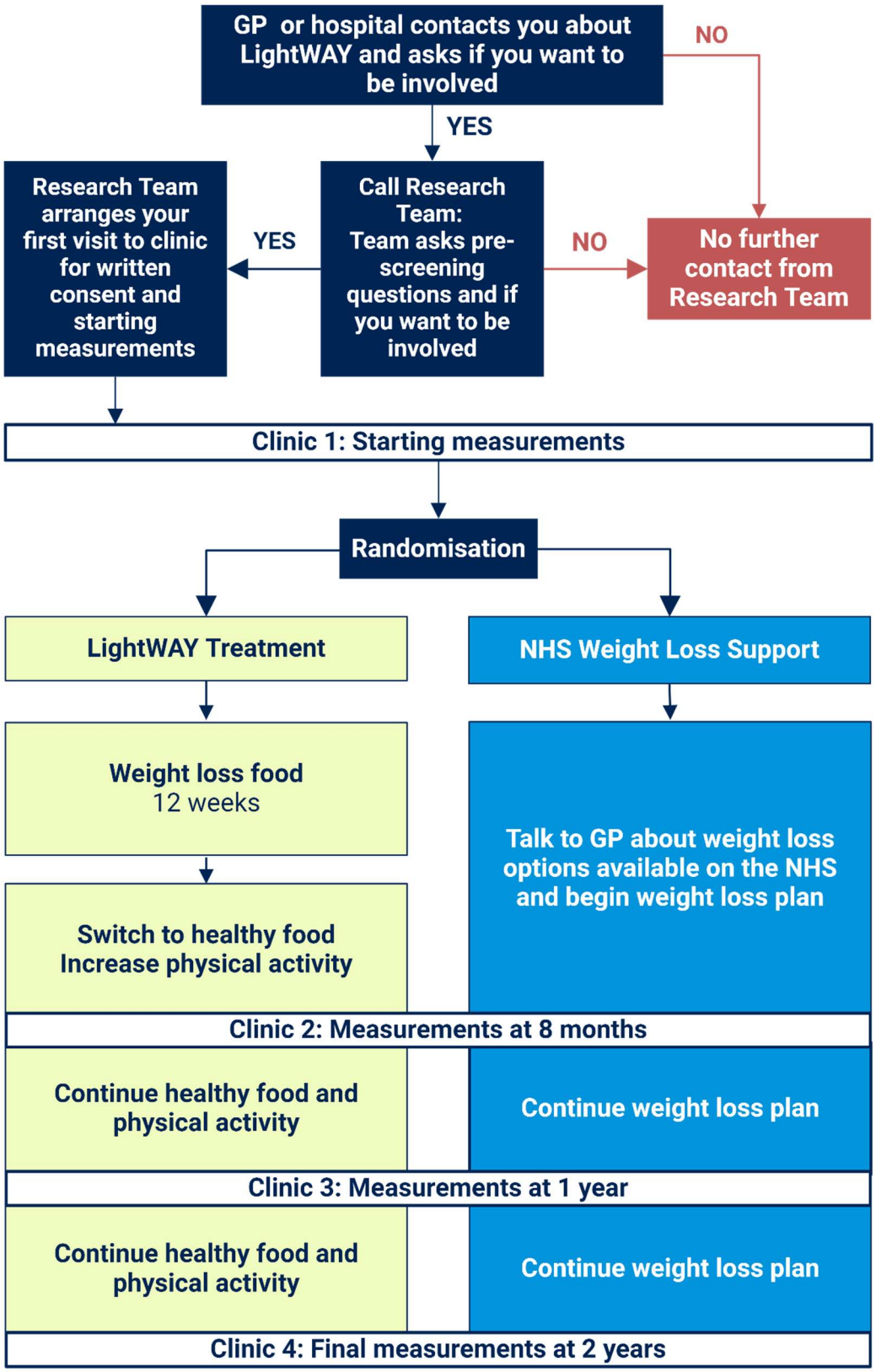
If you or a member of your household are willing to do this, an experienced researcher will speak with you on the phone for about 45 minutes. These discussions will be confidential.

If you are allocated to receive weight loss support available on the NHS:

You will talk to your local clinician about the NHS weight loss services that are available to you and they will refer you to an appropriate service. This can be different in different areas and may include specialist weight management services. We will also ask you to come to study visits at 8 months, 1 year and 2 years to take some measurements.

By being in this group you will be playing a vital part in helping us to improve NHS care, because this group will give us a standard to test our new treatment against.

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 and heart problems 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?

As a participant you must be willing to take part in dietary and behaviour changes which is intended to support weight loss and improve general health. 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.

If you are in the intensive weight loss group:

- 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 are safe to use for weight loss. Some people get side-effects including constipation, diarrhoea, and nausea, but these can be managed with changing the dose and your coach will support you to get the best out of the medication without side-effects.

Will my general practitioner/family doctor (GP) be informed of my participation?

Yes. Your GP may be the person that has invited you to this study. If your hospital has invited you to take part, we will let you 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 in taking part you will receive a £50 shopping voucher for attending each assessment visit at weeks 32 (approximately 8 months), 1 year and 2 years.

You will also get a £25 shopping 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 research team.

We will also be happy to pay the travel expenses you incur to travel to the DEXA scan.

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 names, date of birth, and/or NHS patient numbers where needed, for example to link to your NHS records or contact you. Information that can identify you will only be held by the research team securely for the purpose of the study. We use codes to avoid any identification 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, 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.

With your consent we would like to use 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 carried 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 or 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. 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 and audio recorded consultations and interviews:

If you are placed in the new 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. 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 help us know 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 new 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 LightWAY research team: 01865 617831

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 LightWAY 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 the reason for withdrawing. Your future medical care will not be affected.

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 (this is data without any name, just a unique ID code) that has been collected up until the time you asked to 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 want to manage their weight.

We plan to publish our findings in lots of different places including 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. By agreeing to be contacted 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?

The Copenhagen University Hospital – Amager and Hvidovre, Copenhagen is the sponsor of this study and has appropriate insurance in place in the very unlikely event that you suffer harm as a direct result of your participation in this study (including, for example through the study specific use of monitoring equipment we have leant you). The NHS indemnity operates in respect of the clinical treatment provided.

If you have any concerns in the UK, you can contact 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, you should 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 LightWAY 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.

WHAT TO DO NEXT:

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

Email: lightway@phc.ox.ac.uk or by telephone: 01865 617831

Thank you for considering taking part in the LightWAY study