IRAS Number: 351656

PARTICIPANT INFORMATION SHEET

CORE Study: Clinical Observations and Research on Engagement in Weight Management Services

Summary of the Study

In this research study, we will collect information from you and your medical team. We will only use the information that is needed for the study.

Only a small number of people will have access to your name or contact details, and only if it is absolutely necessary for the research.

Everyone involved in the study will keep your information safe, secure, and private. We will follow all data protection and confidentiality rules.

Some of your data will be saved at the end of the study so we can look at the results and answer future research questions.

When we share the findings, we will write them in a way that means no one will be able to tell who you are.

This information pack tells you more about the study.

CORE Study: Clinical Observations and Research on Engagement in Weight Management Services

We would like to invite you to take part in our research study. Before you decide if this is right for you, it is important that you understand why the research is being done and what taking part will involve. Please take your 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 details, please ask us.*

What is the CORE Study?
The CORE Study is a national research project starting in 2025. It aims to find out if a new app, called PeopleWith, can help us collect important information about:

- Who attends to specialist weight management clinics
- What treatments are offered in these clinics
- How well these treatments work.

If the study, is successful, the app could be adopted by the NHS to help improve care for patients attending these clinics

What is the purpose of the Study?
In the UK, obesity care is organised into four levels:

- Tier 1: Focuses on prevention through public health programmes, such as encouraging healthy eating and exercise.
- Tier 2: Community-based services, such as Weight Watchers or the Counterweight Programme, are for people with a BMI between 28–35 who don't have complicated medical issues.
- Tier 3: Specialist clinics offer treatments for people with more complex needs—those with a BMI over 35 (or 30 if they have diabetes) or other medical conditions. These services may offer medication, low-energy liquid diets, and support before and after weight-loss surgery.
- Tier 4: Focuses on bariatric (weight-loss) surgery, usually provided in hospitals.

While there is good data on Tier 1 prevention programmes and who attends Tier 4 services and has weight-loss surgery, we know very little about what happens in Tier 3 clinics. Only 4 out of the 42 Tier 3 NHS clinics currently share information. This makes it hard to understand:

- Who is using these clinics
- How referrals are managed
- What treatments are offered
- How well these treatments are working

This lack of data makes it difficult to ensure fair access to these services and to improve care.

Previous attempts to collect data from these specialist weight management services have failed, often because staff in busy clinics don't have the time to enter the information themselves. In this study, we are testing a new app called *PeopleWith* to see if it can help collect important data directly from patients. people attending specialist weight management clinics.

To show it works, we need:

- 50 % of Tier 3 weight management services to start using the app, and
- Have at least 60% of patients at those clinics share their information through it.

This study will help us understand if the app can track who uses these clinics and how effective the treatments are. If the app works, the NHS could use it across all weight management services to gather the data needed to improve services and outcomes for everyone.

What will I have to do if I decide to take part in this study?

If you decide to take part and feel all your questions about the study have been answered, the first step will be to download the *PeopleWith* app. We will provide instructions to help you do this. Before using the app, you will be asked to sign a consent form, which can be done electronically or on paper if you prefer. A copy of the consent form is shown at the end of this information sheet.

After signing the consent form, you will asked to use the app to enter some personal and medical information, as well as answer questions about your general health and quality of life.. If you develop new medical problems or start new medications during the study, we would ask you to update these details in the app. Every six months, you will be asked to update the health and quality-of-life questions. You will be asked to continue using the app for as long as you attend the Tier 3 weight management clinic.

You will be asked to enter the following information into the app:

- **Personal Details**: Age, sex, first three letters of your postcode, ethnicity, marital status, job, and employment status.
- **Weight History**: Weight at key life stages (e.g., birth and leaving school), when weight issues began, highest and lowest adult weight, and weight changes in the past five years.
- **Previous Weight Loss Attempts**: What methods you have tried before and how well they worked.
- **Medical Conditions**: A list of your conditions and when they started.
- **Medication**: Dosages, frequency, and when you started taking them.
- **Patient-Reported Outcomes**: Quality of life (using EQ5D) and well-being (using BodyQ).

During your clinic visits, your treatment details will be added to the app's secure online system by your healthcare team or research staff. This information will sync with your app and include:

- **Treatments**: Any care or interventions you received.

- **Measurements**: Your weight, height, BMI, and blood pressure.
- **Diabetes Information**: Your HbA1c level, if relevant.

If you are unsure about any of your medical history or medication, the study team may check your NHS records using our existing clinical systems, which are updated with your GP records. This is something we do routinely in clinical practice.

This study only collects information that is already part of your routine care. You will not be asked to attend extra appointments and your clinic visits will take the usual amount of time.

Why have I been invited to take part in the Study?
You have been invited to join this study because you attend a specialist Tier 3 weight management clinic in the UK. We are looking for 41,160 volunteers from around 50% of weight management services to take part and allow us to collect information about their experiences and care.

Do I have to take part in this Study?
- The answer is 'No'. Taking part is entirely voluntary.
- If you do decide to participate, but then change your mind at a later date, you can withdraw without giving a reason;

Answering 'No' or withdrawing at a later date will not affect your clinical care in any way.

What should you consider?
- If you have any other medical history, this would not exclude you from participating in this Study.
- Your medical care will not be altered in any way due to your participation in the Study.
- Agreeing to be involved in the Study will not prevent you from participating in any other additional research trials. Please just let your doctor know if you are participating in anything else.

Are there any possible disadvantages or risks from taking part?
There are no known risks or disadvantages to taking part in this Study.

What are the possible benefits of taking part?
While the study may not directly benefit you, it could:
- Help you track your health and symptoms using the app, which may support conversations with your doctor and help you understand what treatments have worked best for you.
- Give you access (via the app) to information about relevant clinical trials, such as studies of new weight-loss medications or surgery.
- Help your doctor better understand your health and tailor your care more effectively.

The information you provide will be combined with data from other patients and will help to:
- Improve our understanding of who is using Tier 3 weight management services

- Ensure care is fair and accessible for everyone, especially people with complex needs
- Identify where services are working well and highlight areas that could be improved

Will my General Practitioner/family doctor (GP) be informed of my participation?
As this Study does not affect your clinical care your GP will not be automatically notified of your participation in the Study. You can of course inform your GP if you wish.

What will happen to the information collected in the Study?

The information collected in this study is already part of your routine medical care, including details about your medical history, clinical exams, and treatments. A member of your clinic or research team will enter this data into the study system. You will be able to view your details as they are added.

The information you provide will be kept anonymous. Personal details such as your name, address, or hospital number will not be included in the study records. Only your hospital doctor will be able to link the study data to your hospital records. No one else, not even the study investigators or organizers, will be able to identify you.

Your anonymised data may be used to:
- Track how many clinics and patients are using the app
- Understand what treatments are provided and how well they work
- Describe the characteristics (like age, health conditions) of people using these services
- Explore whether access or outcomes differ based on ethnicity or income
- Help develop new research and improve NHS guidance

Because this study focuses on long-term outcomes, your data may be used even after you pass away.

The data collected will be used to:

- Show that enough clinics are using the app and collecting data from at least 60% of their patients.
- Show the outcomes of weight management clinics.
- Ensure that enough data is collected to fairly represent patients attending these clinics.
- Describe the characteristics (like age, gender, and health conditions) of people in the clinics.
- Examine changes in weight and well-being during treatment and how different treatments affect these outcomes.
- Investigate potential differences in access to Tier 3 clinics based on factors like ethnicity or socioeconomic status.
- Explore differences in treatment outcomes based on these same factors.

The data might also be used to:

- Conduct additional research or create new studies related to weight management.
- Update national clinical guidelines.
- Publish results in medical journals to benefit other patients and professionals.
- Help develop new treatments.

Because the study focuses on long-term outcomes, your data will remain stored even after you pass away. You can ask your hospital doctor or the study team about how your information is being used in various research projects.

How will we use information about you?

We will need to use some information from you and your medical records for this research project. This information will include your date of birth, ethnicity, your medical history, and answers to health questionnaires. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The study is sponsored by the Society for Endocrinology, who is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- doctors, scientists, government health departments, researchers from the pharmaceutical industry, or patient organisations

We will keep all information about you safe and secure by

- Only allowing authorised staff to enter or view your data
- Not sharing your information with anyone who does not have permission
- Making sure no data is transferred to anyone inside or outside the UK without strict safeguards in place

We may share or provide access to data about you outside the UK for research related purposes to answer the questions related to the data for this research.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- doctors, scientists, government health departments, researchers from the pharmaceutical industry, or patient organisations

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following

- the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

Once the study is finished, we will keep some of the data for at least five years so we can check the results if needed. After this time, the study data will then be fully anonymised and securely archived or destroyed.

In the future, approved researchers may be given access to the anonymised study data. These could include doctors, scientists, government health departments, researchers from the pharmaceutical industry, or patient organisations. However, no one will be able to identify you personally, as your data will only ever be linked to your unique study number, not your name

Will my taking part in the Study be kept confidential?
Yes, absolutely. Your information will be kept strictly confidential throughout the study. All data will be stored securely on a trusted platform called *PeopleWith*. Only authorised and trained members of the research or clinical team will be able to enter information into the system.

To protect your privacy, your personal details, such as your name, address, or hospital number, will not appear in the analysed study data. Instead, you will be given a unique study number, which means your data will be anonymised and no one outside your care team will be able to identify you.

You will also stay in control of your information. The *PeopleWith* app allows you to manage your data and decide how it is shared. The app follows strict data protection rules, including the UK's General Data Protection Regulation (GDPR).

Before you join the study, your doctor or a member of their team will explain everything clearly. This can be done during a regular clinic visit, or remotely by phone or video call. If you choose to take part, you'll be asked to give your consent, and a copy of your signed consent form will be stored safely at your clinic for future reference or auditing if needed.

In short, your personal information will be handled with great care and kept safe at all times.

Will I be reimbursed for taking part?
No payments are made to patients to take part in the Study. All questions and samples taken will be part of your routine care.

What will happen to the tests I have at the appointment?
Routine blood tests or scans taken during your clinic visit will continue as normal. The results of these tests or scans will be handled and reported per the standard of care outlined at your hospital. The results of these samples will be uploaded to the Study as part of the clinical data collected. The test results will be stored and disposed of per normal local hospital policy.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- You choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- **If** you agree to take part in this study, you will have the option to take part in future research using your data saved from this study and stored securely in Society for Endocrinology.

Where can you find out more about how your information is used?

If you would like to know more about how your information is used in this study, including how it may be transferred outside the UK, you can:

- Ask a member of your research team
- Contact the study sponsor's Data Protection Officer by emailing: research@endocrinology.org
- Visit the Health Research Authority website: www.hra.nhs.uk/patientdataandresearch

What will happen to the results of this Study?
The information collected will help us understand whether the app can effectively gather data from specialist weight management services. It will also give a clearer picture of who attends these clinics, what treatments they receive, and how well those treatments work.

The study will also look at whether access to services or treatment outcomes vary based on factors such as ethnicity or income. The results may be used to support further research, improve NHS guidelines, and help develop new treatments.

The findings will be shared with you, other patients, healthcare professionals, researchers, and policymakers. They will also be published in medical journals, presented at conferences, and made

available on public websites such as the Society for Endocrinology, where you will be able to access them.

What if we find something unexpected?
If we find anything of concern in your data when we do the analysis, your local doctors will be informed so they can discuss it with you.

What do if I have a complaint?
If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this Study, you should contact <name of investigator><contact details (phone number & email). There are no special compensation arrangements.

If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical study as a result of negligence on the part of a member of the Study team this liability cover would apply. Non-negligent harm is not covered by the Society for Endocrinology's scheme. If you experience harm due to the design of the study then this would be covered by Society for Endocrinology.

You will also be able to contact the [Local sites to delete as appropriate] Patient Advice and Liaison Service (PALS) [Insert local PALS information] or PASS (Patient Advice and Support Service Scotland) in the first instance (Insert local PASS information).

How have patients and the public been involved in this study?
The Obesity Health Alliance and South East London Patient Support Group have been involved in in designing this study and reviewing the documents.

Who is organising and funding the study?
This Study is being organised by the Steering Group and the Society for Endocrinology. Novo Nordisk, Boehringer Ingelheim and, Rhythm Pharma have provided funding for the Study but they have not been involved in the design of the Study nor are will they be involved in the collection of the data or analysis of it. These companies will be not be be able to access the data unless they apply through the Steering Group and are approved.

Who has reviewed the Study?
All research that involves NHS patients or staff, information from NHS medical records or uses NHS buildings must be approved by an NHS Research Ethics Committee before it goes ahead.

Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision. This study has been reviewed and given favourable opinion by the Wales REC Committee

If you decide to participate in this study you will be given a copy of the patient information sheet and the signed consent form to keep.

How do I take part?
If you would like to take part in our study please contact your local study team at the health service mentioned on the information website.

Alternatively, you can download the app using the process shown on the information website and consent to join the study through the PeopleWith App.

Thank you for reading this information.

IRAS Number: 351656

CONSENT FORM

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If you agree, please initial box

1. ☐ I confirm that I have read the information sheet dated 28 April 2025 (version 1.2) for this Study.
2. ☐ I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
3. ☐ I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected
4. ☐ I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor, from regulatory authorities [and from the NHS Trust(s)], where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
5. ☐ I approve of the information to be stored on the study portal and shared with approved researchers
6. ☐ I agree to take part in this study
7. ☐ I agree to download the free app from *PeopleWith* to input my own data when appropriate
8. ☐ Optional: I agree to be contacted about future research or research questions (please do not tick if do not want to be contacted)

Name of Participant
Date
Signature

_____ _____ _____

Name of Person taking Consent
Date
Signature

_____ _____ _____

Please keep one copy of this sheet in case records and hand one copy to the person who has signed this form or held electronically if the consent has been completed through the application.