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**PARTICIPANT INFORMATION SHEET**

# Study Title: Glucose Monitoring in OSA (GLUCOMOSA) Study

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 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 study?

We want to understand if obstructive sleep apnoea (OSA) worsens sugar levels. We know that OSA is common in those with either type 2 diabetes mellitus (T2DM) or slightly raised glucose levels (sometimes called "pre-diabetes"). We want to see what effect briefly stopping effective CPAP has on sugar levels in participants with OSA and either T2DM not requiring insulin treatment or "pre-diabetes".

## Why have I been invited?

We are looking for participants who have known OSA, who have been using continuous positive airway pressure (CPAP) treatment for at least 3 months. Participants do not have to have known diabetes or "pre-diabetes"; we will test for these conditions as part of the study.

## Do I have to take part?

No, it is entirely up to you to decide if you wish to join this study. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. Neither declining to enrol nor withdrawing from the study at any point in time will in any way influence the clinical care you receive.

It is important to consider that if you decide to take part you will stop receiving effective CPAP, for a total of up to 11 nights.

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

As the first step, if you wish to consider participating, we will arrange a visit to meet with the research team face-to-face. This will give the opportunity to answer any questions you might have and make sure you understand the study. If you agree to participate, we will then ask you to

complete a consent form with the researcher. The study then consists of two parts, *Part 1* and *Part 2 (see Figure 1)*.

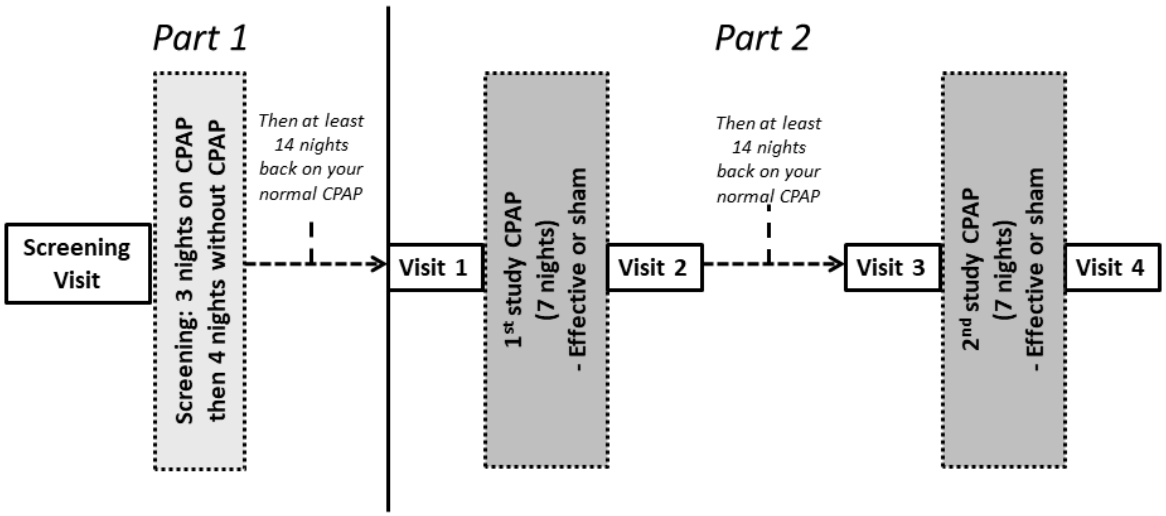


*Figure 1: Diagram of schedule of visits for the GLUCOMOSA study*

***Part 1 – Consent and Screening***

Part 1 involves one extra visit to hospital outside of any normal care you receive, lasting approximately one hour. If we are unable to offer you a hospital visits we can sometimes arrange for this visit to occur in your own home. If you consent, we will then continue to screening at the same visit. We ask you to bring your CPAP machine to this visit for us to download usage data from it. We will run through some questions, ask you to complete a questionnaire about your sleep, take a blood test to check your blood sugar levels and provide you with a pulse oximeter for you to use at home during screening. These tests are checks to make sure you are able to continue to participate.

Following this visit we ask you to use the pulse oximeter provided whilst you sleep. This is a small device that looks like a wristwatch with a soft probe attached to your finger. It records your oxygen levels and heart rate whilst you sleep. We ask you to use this for three nights whilst using your CPAP as normal to check that CPAP is fully treating your OSA. We then will ask you to use the pulse oximeter for four nights without your normal CPAP to check that your OSA comes back when you stop CPAP. We will give you separate written instructions on how to use the pulse oximeter.

Once you have finished using the oximeter we ask you to return the equipment to us in a prepaid addressed envelope that we will have provided.

When we receive your pulse oximeter back in the post, we will be able to see if you are able to continue in the study. If these tests show that you are able to continue in the study, we will then invite you to continue on to the ***Part 2***. If they show you are not able to continue, you will not be able to participate in ***Part 2*** and you should carry on your treatments as normal.

***Part 2***

Part 2 includes four morning visits to hospital outside of your normal care, each lasting approximately 2-3 hours. If we are unable to offer you hospital visits, we can sometimes arrange for these visits to occur in your own home. We ask you not to eat for 8 hours before coming to each of these study visits so we can record your fasting blood sugar levels.

At each of these visits, we will perform an examination (height, weight and neck circumference, blood pressure and pulse), and ask you to complete a questionnaire about your sleep. More details about each visit are listed below:

***Visit 1***

At Visit 1 we will fit you with a continuous glucose monitor (*see figure 2*). The researcher will apply a small sensor patch with a tiny needle the width of a hair to your upper arm or abdomen. This should be less painful than a normal blood test. This will then be worn for 7 days until the next study visit. It is water resistant, meaning that you can take showers but not swim or bathe whilst wearing it. The patch senses sugar levels and connects to a transmitter that continuously sends this information to a receiver device.


*Figure 2: Dexcom G6 receiver paired with sensor patch with transmitter attached.*

We will collect your normal CPAP machine and tubing and issue you with a new study CPAP machine and tubing to use with your own CPAP mask. The study CPAP machine will either deliver effective CPAP treatment or be a sham CPAP device. There is a 50% chance that you will receive effective CPAP and a 50% chance you will receive sham CPAP at Visit 1. You will not be told which you have

been given. Sham CPAP delivers a low CPAP pressure with which your OSA will return. Effective CPAP will start at low pressures and increase once you have fallen asleep so you are not likely to know which treatment you have been given.

Following the first visit, we will ask you to use your study CPAP device (effective or sham) for the next seven nights. We will also give you a pulse oximeter and ask you to use this on each of these nights along with the study CPAP machine.

***Visit 2***

Visit 2 will be seven days after the first visit. We ask you to bring your study CPAP device and pulse oximeter with you. At the end of visit 2 we will return your normal CPAP machine and tubing to you. We will then ask you to start using your normal CPAP again every night and will invite you to return for Visit 3 at least 14 days after Visit 2.

***Visit 3***

This visit will be the same as Visit 1, except that you will be supplied with whichever study CPAP device you did not receive at Visit 1 (i.e. if you received sham CPAP at visit 1 you will receive effective CPAP at Visit 3).

***Visit 4***

This visit will be seven nights after Visit 3. We ask you to return your study CPAP machine and pulse oximeter at Visit 4. The end of Visit 4 is the end of the study and you will be given your own CPAP machine and tubing.

**What should I consider?**

Before deciding to take part, we encourage you to take some time to consider if you feel this would be the right thing for you. You will not be able to take part if you are taking regular insulin as a medication for diabetes or if you have diabetic eye disease undergoing specialist treatment. You will not be able to take part if you are a professional driver, have any other job where vigilance is critical, or have had a road traffic incident related to sleepiness previously. You are able to take part in this study if you are taking part in other research studies but may also wish to discuss participation in our study with those running the study you are already taking part in.

During the trial you should continue all of your normal medications and over-the-counter medicines. There are no specific requirements in relation to contraception but if you become pregnant or think you might be pregnant during the study, we would ask you to inform us as we would wish to discuss whether continuing in the study is the right thing for you.

**Are there any possible disadvantages or risks from taking part?**

Before taking part, you should consider any potential disadvantages of the study.

If you agree to this study, you will also agree to have five sets of blood tests. Blood tests can be slightly painful and can cause some bruising although they will be carried out be an experienced clinician.

You will be asked not to eat anything for 8 hours before each of the four morning study visits and this has a small chance of giving you a low blood sugar level which can make you feel unwell.

If you agree to take part in the study, you will also agree to wear a sensor patch for continuous glucose monitoring. The sensor patch consists of a needle smaller than the width of a hair attached to a sticky pad which is worn on the upper arm or abdomen for 7 days. Inserting this needle is slightly painful, but should be less painful than a blood test. The sensor is water resistant, meaning that you can get it wet but it should not be submerged in water (i.e. it is OK to shower whilst wearing this sensor but not to bathe or swim).

If you agree to take part in this study you will have to stop effective CPAP for up to a total of 11 days. Over 100 participants have previously stopped CPAP for two weeks in similar studies and there have been no serious health issues as a result. It is possible however that you may begin to feel sleepy in the daytime during the study. If you feel at all sleepy it is important to refrain from driving or operating heavy machinery, and please do let us know.

If you agree to take part in this study, you will have to give up some of your time. You will commit to one screening visit lasting 1 hour and four study visits lasting 2-3 hours each. You will have to get used to new devices including continuous glucose monitoring, new study CPAP machines, and a wrist watch to measure oxygen levels (pulse oximeter). Please do get in touch with us if you have any problems with these devices using the contact details provided below.

**What are the possible benefits of taking part?**

Taking part in this study may show that you have undiagnosed diabetes mellitus or “pre-diabetes”. In this case we will discuss this with you fully and inform your GP.

**Will my General Practitioner/family doctor (GP) be informed of my participation?**

As a key person and gate keeper in coordinating your NHS healthcare, it is important that your GP is aware of your participation in this study. We will specifically ask your written consent to send out a letter to your GP explaining your participation in this study if you agree to enter.

**Will my taking part in the study be kept confidential?**

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be identified to anyone outside your research team. Your study data (apart from the consent form which will have your identifiable details) will be kept coded with a study number and only members of the research team will be able to identify you from that number. Your identifiable data will be kept securely within the Oxford University Hospitals NHS Foundation

Trust. If you consent to long-term storage of samples, a copy of your consent form will be kept securely within the Oxford Respiratory Trials Unit for as long as these samples are stored. Any electronic records will be kept secure on password-protected NHS computers and will only be accessible to the relevant research team members. The study data will be kept for 5 years after the study has finished (but any identifiable data will be destroyed within 12 months after the study has finished).

Responsible members of the University of Oxford and the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

**Will I be reimbursed for taking part?**

You will be able to claim reasonable travel expenses for any hospital visits additional to standard care on production of receipts, or a mileage allowance provided as appropriate. You will be able to claim up to £10 for a meal at each of the four study hospital visits, but not the screening visit, on production of receipts. You can discuss this with the research team if you require any additional details.

**What will happen to the samples I give?**

Blood samples will be taken at the screening visit and during the four study visits. These will be sent to the laboratory for analysis and, if you consent to have your samples stored long term, they will be coded with your trial number stored securely to be used in future ethically approved research.

**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.' The University of Oxford is 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 study and will use the minimum personally-identifiable information possible.

The Oxford University Hospitals NHS Foundation 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 for 6-12 months after the study has finished. After the study has finished the research team will archive copies of the consent forms and any other study records for 5 years. If you agree to log term storage of your blood samples, a copy of your consent form will be kept for as long as your sample is kept.

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 Dr Chris Turnbull at christopher.turnbull@ouh.nhs.uk

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

You can withdraw from the study at any time but we will use the data and results of samples collected up to your withdrawal. If you decide to withdraw you can request that any samples stored, but not yet analysed, are destroyed. Your withdrawal from the study will have no impact on your normal clinical care.

**What will happen to the results of this study?**

The results of this study will be submitted for publication in a medical journal with all study data anonymised. The study results may also be presented at conferences.

**What if we find something unexpected?**

If any of the study assessments produce findings of clinical significance for you, we will discuss it with you as further clinical verification and/or referral to your GP may be needed.

**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 study.

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 study, you should contact Dr Chris Turnbull, email: christopher.turnbull@ouh.nhs.uk Tel: 07816655475

or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@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 study.

If you wish to contact the PALS team please contact them on 01865 235855 or at PALS@ouh.nhs.uk

**How have patients and the public been involved in this study?**

This research has been directly informed from recognising the priorities of patients and a patient has helped to design this study. We surveyed patients with OSA from the membership of the Sleep Apnoea Trust Association, a patient led OSA support group. We received 585 responses to our

survey of their membership. 97% of respondents either agreed that "research to help understand if OSA causes or worsens diabetes is important" and 64% agreed with the statement "consider stopping CPAP for 10-14 days for a research study to enable better understanding of the effects of OSA".

You can find further information about taking part in research at:

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
- www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

**Who is organising and funding the study?**

This study is sponsored by the University of Oxford. It is funded by the NIHR Oxford Biomedical Research Centre and the Oxford Radcliffe Hospitals Charitable Funds. The equipment for continuous glucose monitoring has been provided by Dexcom.

**Who has reviewed the study?**

All research in the NHS 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 _____Research Ethics Committee.

**Further information and contact details:**

For any further information on the study please do not hesitate to contact the study team. The contact details are:

Dr Chris Turnbull (christopher.turnbull@ouh.nhs.uk Tel: 07816655475)

*Thank you for considering taking part.*