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PARTICIPANT INFORMATION SHEET

EASY-OSA Study

Evaluating an ambulatory monitoring system in obstructive sleep apnoea: a proof-of-concept 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.

Key Facts

- Home sleep studies are used to detect problems with breathing during sleep
- Home sleep studies detect changes in breathing by wearing wires and sensors overnight
- Home sleep studies can be cumbersome and take time to interpret
- Ambulatory monitoring systems made up of a patch attached the chest, a wristwatch device and a tablet which connect wirelessly to measure vital signs such breathing
- Ambulatory monitoring systems show changes in vital signs in people admitted to hospital but have not been used to assess breathing pattern during sleep

What is the purpose of the study?

We aim to see if an ambulatory monitoring system can detect breathing changes overnight using a chest-worn patch and a wristwatch device measuring oxygen levels. We will do this by comparing breathing changes recorded by an ambulatory monitoring system to a standard home sleep study.

Why have I been invited?

You are being invited because you are due to have a home sleep study. This study will involve approximately 10 patients who are having a home sleep test.

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.

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

As the first step, if you wish to consider taking part we will arrange a visit to meet with the research team face-to-face on the same day as your clinical appointment to collect equipment for your home sleep study. This will give you the opportunity to ask 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.

After completing the consent form, the researcher will ask you some questions about your health and medications, along with recording your height, weight and neck size. You will be provided with equipment, fitted with a chest worn patch, and instructions for how to use the equipment at home. We will fit you with a chest-worn patch (VitalPatch, VitalConnect, USA) which is a small lightweight patch which is roughly the size of a bowtie, provide you with a pulse oximeter which is a wristwatch size device to be worn every night during sleep (Nonin WristOx2 BLE OEM, Nonin Medical Inc., USA). You will also be supplied with a computer tablet to use during the study. You will be given instruction in how to use all of the equipment.

The ambulatory monitoring system patch is attached by strong adhesive to make sure it stays securely in place during the study. It is comfortable to wear, and it is water-resistant. This means that you can shower whilst wearing the patch. **Swimming or taking a bath is not possible whilst wearing the patch as it is not completely waterproof.**

We ask you to start using the ambulatory monitoring system on the same night that you are carrying out your home sleep study provided by the clinical team.

The research team will then see you for a second visit on the day of your appointment to return your home sleep study equipment (usually the next day). At this second visit we will check that the ambulatory system is working well and ask some questions about the comfort of each device.

We ask you to continue using the ambulatory system at home overnight whilst you sleep for the next 4-6 nights. We will then arrange for you to return for a third research visit. At this visit we will ask you return the ambulatory monitoring system. We will also ask you some questions about how comfortable and easy to use the equipment was. After this research appointment you will have completed your participation in the study, and you will not need any more appointments for the study.

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. The ambulatory monitoring system is attached using a medical hydrocolloid adhesive. You should not take part if you are allergic to hydrocolloid adhesives. Please feel free to ask the research team if you have any questions about allergies. You can 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.

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 take part in this study, you will have to give up some of your time. You will commit to three research visits, each lasting approximately 30-45 minutes. You will need to use the ambulatory monitoring system to record your sleep in addition to your clinical home sleep test, and for a further 4-6 nights without the home sleep test. We will give you full instructions in how to use all of the equipment. The ambulatory monitoring system is attached using a medical adhesive. This can rarely cause rash causing redness of the skin, which might be slightly painful. If this does happen to you whilst taking part, please do let us know as soon as possible.

What are the possible benefits of taking part?

We do not know what this study will show, and we are carrying out the study to see if we can detect changes in breathing overnight using an ambulatory monitoring system. Answering this question would not directly benefit you now but might benefit patients in the future.

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

We are not routinely informing GPs of participation in this study. If you would like to, please feel free to discuss participation with your GP and to share this information sheet with them.

Will my taking part in the study be kept confidential?

Your taking part will be kept confidential as far as possible. Study records will be identified only by a code. We will only use names, date of birth, and NHS numbers where this is necessary contact you. Information that can identify you will only be held securely by the Oxford University Hospitals NHS Foundation Trust and the University of Oxford for the purposes of the study.

Responsible members of the University of Oxford, regulatory authorities and 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?

There is no reimbursement for participation in this study. We will reimburse travel expenses for the third visit as this is an extra visit outside of your normal clinical care. If reimbursed for travel expenses, we will need your bank details and we will handle this data as outlined below.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), 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 sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you from your medical records for this research project. We will share your information related to this research project with the following types of organisations; regulatory authorities.

This information will include your name, hospital medical record number, date of birth and NHS number. 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.

We will keep all information about you safe and secure by:

- Securing research data on an access restricted database (REDCap) hosted on a secure backed-up server
- Pseudo-anonymising data held on the research database by a unique study number without identifying information such as initials, date of birth, or hospital medical record number
- Storing paper consent forms in a locked secured filing cabinet

International Transfers

Your personal data will not be shared outside the UK.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.
We will keep your study data for the minimum period of time required by the University of Oxford. Data will be kept for five years after the completion of the study.

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 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.

You can find out more about how we use your information, , by:

- asking one of the research team christopher.turnbull@ndm.ox.ac.uk
- calling us on 01865225789
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: How we use your personal data for research purposes | Compliance.

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: Patient data and research leaflet - Health Research Authority.

Your bank details will be stored for 7 years in accordance with University of Oxford financial policy.

We will keep any other identifiable information about you for (name, address, telephone number, email address) after the study has finished.
We may use your anonymised data from this project in future research, including potentially developing algorithms to detect OSA.

The ambulatory monitoring system will store data on computer tablet, and this will be transferred to the University of Oxford's secure AMS cloud when connected to the internet. Data with be pseudo-anonymised and only identifiable by a unique study identifier.

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
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.

A copy of the consent form from this study will be kept in your medical records for as long as those records are retained.

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 collected up to your withdrawal. 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 with all study data anonymised. We would like to reassure you that you will not be identifiable when the results at presented. If you agree, we will send you a summary of the results at the end of the study.

What if we find something unexpected?

In the unlikely event that 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?

If you have a concern about any aspect of this study, please speak with the research team. They will do their best to answer your questions.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

NHS indemnity operates in respect of the clinical treatment 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, contact Dr Chris Turnbull (christopher.turnbull@ndm.ox.ac.uk, 07816 655475) or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk

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

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

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

Service users helped develop the research topic and what research questions should be asked and will continue to be involved in the study.

Who is organising and funding the study?

This study is Sponsored by the University of Oxford and the Chief Investigator who is organising the study is Dr Chris Turnbull. The study is funded by the NIHR Oxford Biomedical Research Council and the Oxford Sleep Research Fund 0189. The Nuffield Department of medicine are supporting salaries for staff involved in this study.

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 a favourable opinion by <TBC> Research Ethics Committee.

Participation in future research:

If you consent to be contacted for participation in future ethically-approved research that you may be eligible for, we will keep your contact details securely in a register which is password-protected in computers in the Nuffield Department of Medicine, separately from this study. Access to this register will only be given to members of this research team, who will approach you – if appropriate – in relation to this.

Please note that agreeing to be contacted does not oblige you to take part in future research, and you can be removed from this register at any time you wish.

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@ndm.ox.ac.uk, Tel: 07816655475)

Thank you for considering taking part.