Austin Health

Buckinghamshire Hospitals NHS
NHS Trust

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

A prospective, randomised controlled trial of Continuous Positive Airway Pressure (CPAP) treatment for obstructive sleep apnoea after acute quadriplegia: the COSAQ trial

Chief Investigator Name: Dr Allison Graham
Associate Investigators: Professor Paul Kennedy

You are invited to take part in a research project looking at the effect of Continuous Positive Airway Pressure (CPAP) on Obstructive Sleep Apnoea (OSA) in acute quadriplegia. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions that you may have
You may discuss this study with your friends, relatives or your local doctor if you wish. Ask questions about anything that you don't understand or want to know more about.

What is the purpose of this study?

The purpose of this study is to examine the effect of CPAP therapy for OSA on thinking (especially memory, learning and concentration), quality of life, autonomic problems and breathing in people with acute quadriplegia. Autonomic problems include excessive sweating, a heart rate which is too fast or slow and periods of high blood pressure

Our research group have previously found that people with quadriplegia are more likely to have trouble with breathing overnight. We have found that up to 80% of people with quadriplegia have Obstructive Sleep Apnoea (OSA) at some time in the first year after injury. OSA is a condition where the muscles in your throat relax too much while you are asleep, causing the throat to close. This closure then leads to a drop in oxygen levels in the blood and disruption to sleep as your body partially wakes to clear the obstruction. Untreated OSA may also lead to a lack of refreshing sleep, sleepiness during the day and difficulties with memory, learning and concentration. The usual treatment for OSA is nasal CPAP (Continuous Positive Airway Pressure) worn overnight. This involves the use of a nasal mask connected to a machine that supplies enough pressure to keep the throat open while you are asleep. Information on these devices, including images, are included at the end of this information sheet.
While this treatment is known to be well tolerated in able-bodied people, our experience and that of others, is that this treatment poses specific challenges for people with quadriplegia. We therefore propose to test the use of CPAP in those with both quadriplegia and OSA to see how well it is tolerated.

Why have I been invited?

You have been invited to participate in this study because you have had a spinal cord injury (quadriplegia). Other people with quadrilplegia have been invited to take part.

Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are free to withdraw from

the project at any stage without giving a reason. Your decision to take part or not to take part, or to take part and then withdraw, will not affect the care you receive from this hospital. If you decide to leave the project, the researchers would like to keep the personal and health information about you that have been collected.
If you decide to participate in this study, you will be asked to sign the attached consent form before any study related procedures are undertaken. A witness for the consent process may be a relative, friend or patient representative who you have chosen to be present during the consent process. This person will have no involvement with the research.

Will I get paid for participation in this research project?

You will not be paid for your participation in this project. However, all participants who feel that they benefit from use of the CPAP will be free to keep the CPAP machine used in the study at no personal cost to themselves and its maintenance will be negotiated with the Primary Care Trust.

What does participation in this research project involve?

We will monitor your sleep and breathing during your inpatient stay at the National Spinal Injuries Centre, Stoke Mandeville Hospital. These will be tested as soon as you are considered to be medically stable by your treating team and again three months after injury.

At the first visit, we will arrange to do a sleep study. During the sleep study you will have non-invasive, surface electrodes placed on your body which allow collection of data describing your sleep, breathing and movements.

The following morning, we will look at the results from the sleep study to determine the number of times that you have interruptions to your breathing while asleep. If the sleep study shows that you have fewer than ten interruptions to your breathing per hour, you do not need to participate any further in this study.

If your sleep study shows that you had more than ten interruptions per hour, we will come to the ward in the early afternoon, you will be asked to give answers to questionnaires that ask about your mood, sleep, breathing and daily routine. You will then be asked to do some tests which look at your memory, learning and concentration. It will take between one and a half to two hours in the afternoon to complete all of the tests.

Then we will ask you to trial the use of CPAP overnight. For the following three nights you will be given CPAP to use while asleep. We will assist you as much as possible to use the CPAP. We will fit a mask and headgear and demonstrate how the machine works to you, your family and any other people that you wish. You will be asked to wear it as much as possible whilst in bed to sleep, especially overnight. A member of the research team will be there at night to help with the application of the mask and to troubleshoot any difficulties, and nursing staff will monitor you through the night. Your use of the machine will be monitored by the device and we will review that with you each morning.

If you are able to tolerate the mask for at least four hours on one of these first three nights, you will be randomised (like the tossing of a coin) to either stop or to continue with nightly CPAP for three months. If you are unable to use the mask and machine for at least four hours over one of these initial three nights, your participation in the study will cease.

If you continue in the study, a member of the research team will contact you at least weekly to record any difficulties you may have had, to rate your sleepiness and to download data

from the CPAP (if you are using it). Every month you will also be asked to perform some breathing tests to measure your lung capacity and the strength of your breathing muscles. These tests are not invasive.

At the final visit (three months), the breathing tests, the questionnaires, memory, learning and concentration tests and the overnight sleep study will be repeated. We will also invite you to participate in an interview to further investigate what you thought was good and bad about using CPAP.

Participation in this project is voluntary and your care will not be compromised should you choose not to be involved. The usual care of people with a spinal cord injury does not involve the routine screening for disordered breathing during sleep nor treatment with CPAP as this has not yet been shown to be effective. However, if you, your family or the clinicians treating you suspect that you have a sleep disorder or are at risk of developing one, you will be fully investigated and treated as appropriate. This is the current hospital standard of care and will not be affected by this study.

What are the possible side-effects or risks?

There is a risk that performing some of the tests may distress you, either physically or emotionally. The breathing tests require a maximal effort, but there have been no reports of injury with these simple tests and sufficient rest will be provided between trials to ensure that you do not become tired. The questionnaires do not have any correct answers, however sometimes people may feel uncomfortable answering some questions that are asked. If you do not wish to answer these questions, you do not have to. All of the tests will be performed by fully trained staff. There may be additional risks that the researchers do not expect or do not know about. Tell a member of the research team immediately about any new or unusual symptoms that you get.

Some people find using the CPAP nasal masks uncomfortable. If you find you are unable to tolerate the equipment, you are free to withdraw from the study and this will not affect your usual standard of care.

What are the possible benefits?

You may or may not receive any direct benefit from participating in this research. All participants who feel that they benefit from use of the CPAP will be free to keep the equipment at no personal cost to themselves. If equipment breaks or is faulty, this is usually repaired or replaced by the manufacturing company

What happens when the research study stops?

At the end of the study you will receive a copy of your results and these will be explained to you by one of the researchers. If the study identifies any sleep disordered breathing, you can be referred to a Sleep Physician for ongoing evaluation and treatment if you desire. If you would like to keep the CPAP equipment after the study ends, you are free to keep the equipment at no personal cost to yourself.

Confidentiality

All information obtained from the National Spinal Injuries Centre during this study, including hospital records, personal data and research data will be kept confidential in locked cabinets within locked offices of the NSIC and in password protected electronic databases that can

only be accessed by study personnel.

This study will be performed at the National Spinal Injuries Centre, Stoke Mandeville, Princess Royal Spinal Injuries Unit, Sheffield, and in a number of spinal units across Australia and the world. Your study information will have personally identifying information, such as name, date of birth, etc removed before it is collated into the study database. The combined, re-identifiable (coded) information may be transmitted within the study group interstate and overseas for analyses and review, however only the study team at the Austin Institute for Breathing and Sleep (IBAS), Australia will be able to access your identified data.

In any study reports, or if the results are published, your identity will remain confidential. Members of the Buckinghamshire Hospitals Research Ethics Committee may ask to look at your results, but no other people will be authorized to access them. Information about your participation in this research project may be recorded in your health records. You can request to have access to the information collected and held about you during the study. Once the study is complete and the final study report is released, we will be able to supply you with an outline of the study results. Your records associated with your participation in this project will be kept under safe storage in locked archive facilities for 7 years after completion of the study then shredded or incinerated.

What will happen to the results of this research project?

Your information in this study will be anonymous and you will not be identified in the results of this research. You will receive a copy of your individual results and also information on the findings from the research.
The results of this study will be published in peer reviewed journals.

Who is organising and funding this research?

This is a multi-national research project that will involve collaboration with other hospitals and research centres located interstate and overseas. This project has been funded by the Victorian Neurotrauma Initiative (VNI) and the collaborating centres will be reimbursed for the costs associated with participating in the trial according to a pre-agreed funding schedule. You may request to be informed of this schedule.

Who has reviewed this study?

This project will be carried out according to the guidelines set out by the Department of Health which were to protect the interests of people who agree to participate in human research studies. The ethical aspects of this research project have been approved by the West MIdlands Research Ethics Committee.

Contact for further information:

If you would like more information, or if you have any problems, concerns or questions about the research project, please contact:

Dr Alison Graham	**Telephone Number: 01296 315851**
Prof Paul Kennedy	**Telephone Number: 01296 315823**

If you wish to contact someone, independent of the study, about ethical issues or your rights, or to make a complaint you may contact Dr Rowena Warwick, research clinical lead for Buckinghamshire Hospitals, on 01296 316917.

Thank-you for considering participation.

Example image for CPAP device

The Autoset Spirit II self-adjusting sleep apnoea system is indicated for the treatment of obstructive sleep apnoea (OSA) in adult patients. The S8 Autoset Spirit II self adjusting sleep apnoea system has two treatment modes: Autoset and fixed pressure CPAP. The system is intended for both home and hospital use

Example image for humidifier

The ResMed heated humidifier provides heated humidification to relieve symptoms of dryness and congestion with CPAP therapy.

Example image for mask

CPAP therapy is traditionally provided through a nasal mask that seals around the nose.
A nasal mask seals around the entire nose and is held in place with straps, or headgear. This is a good device for first-time CPAP users.

Consent Form to Participate in Research

Project Title: A prospective, randomised trial of Continuous Positive Airway Pressure (CPAP) treatment for obstructive sleep apnoea after acute quadriplegia; the COSAQ trial
Project Number:

Principal Investigator: Dr Allison Graham

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Institute for Breathing and Sleep concerning my disease and treatment that is needed for this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that this involves risks as listed on page 3 of this Information Sheet.

I understand that the researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

I understand that I can withdraw or be withdrawn by the principal investigator from this research project at any time and that this will not change my relationship with my doctor.

I freely agree to participate in this research project as described.

I understand that I will be given a signed copy of this document to keep.

Participant's name (printed) ……

Signature……Date …….

Name of witness to participant's signature or to participant's verbal consent (printed)

……

Signature……Date……

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed) ……

Signature…… Date

** A senior member of the research team must provide the explanation and provision of information concerning the research project.*
Note: All parties signing the consent section must date their own signature.