Hospital Name:
Centre number:
Study number:

Participant Information Sheet

Title of project: RECOVERY-RS Respiratory Support: Respiratory Strategies in COVID-19; CPAP, High-flow, and standard care

You have been given this leaflet to read and consider because you were admitted to hospital with COVID-19 or suspected COVID-19 and need help to keep your oxygen levels high enough.

This information sheet explains the study and what it means for you. Your participation will help not only this pandemic but possible future pandemics as well. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish and please feel free to ask any questions.

Information about the research
The study is taking place in NHS hospitals (in England, Scotland, Wales, and Northern Ireland) or purpose built-hospitals with wards and critical care areas. It is aiming to recruit 4002 people who have COVID-19 or are suspected of having COVID-19.

The study compares three different treatments that help with breathing. These treatments are explained below:

A) **Continuous positive airway pressure (CPAP):** this treatment applies mild to high air pressure on a continuous basis through a tightly fitted face mask. It keeps the airways continuously open in people who are able to breathe normally on their own, but need help keeping their airway clear

B) **High flow nasal oxygen (HFNO):** this is a way of giving humidified (moistened) and warmed oxygen through tubes into the nose. The oxygen is delivered very quickly to help patients who have low oxygen levels and find breathing on their own difficult

C) **Standard care:** standard treatment will involve oxygen delivered via a normal face mask or tubes in the nose.

We want to find out which is best at keeping oxygen levels high enough and preventing a patient from needing more help with their breathing. All three treatments are in common use within the NHS.

Why have I been chosen for the study?
You were chosen for this study, because we identified you as having COVID-19 or suspected COVID-19 and you need help to keep your oxygen levels high enough. We would now like to ask you whether you would like to participate in the study.

Why do you need my consent?
We need you to consent to the clinical procedures explained in this information sheet and to gather, record and store some of your personal information, including data on your race and ethnicity, that will help us analyse how patients respond to the study and how well each treatment worked for them.

What happens next?
A member of the research team will contact you to discuss the study further.

A member of the research team will ask if you have had chance to read this information leaflet and will ask if you have any questions. They will discuss the study and information leaflet with you and do their best to answer any questions you may have.

If you do decide that you would like to take part in the study, the researcher will document your consent. You will be given a copy of this consent form, the researcher will keep a copy and a third copy will be placed in your medical notes.

Following your consent you will be recruited to the trial and will be randomly allocated to receive your treatment to either standard of care involving regular oxygen therapy, High Flow Nasal Oxygen (HFNO) or Continuous Positive Airway Pressure (CPAP). If you decide to take part, it will not be possible for you to choose which one of the 3 groups you are in. It is important that this is decided by a process of random selection. There is an equal chance of you being selected for any one of the 3 groups.

Following randomisation your treatment will then commence.

Do I have to take part?
You do not have to agree to take part. If you choose not to participate in the study, it will not affect the treatment or care that you receive in anyway.

You can withdraw from the study at any time and without giving a reason or affecting your rights. If you stop participating, we will not collect any more information about you. We will keep the information already collected prior to you withdrawing from the study.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the information we hold about you.

How will we use information about you? Will my taking part in this study be kept confidential?

To undertake this study the University of Warwick will use information from your medical records to try and find out which treatment works best.

Hospital staff and University of Warwick staff will collect information from your medical records, GP records, other NHS data sources, and the Intensive Care National Audit and Research Centre for this research study in accordance with the University of Warwick's instructions. We will only use information that we really need to for this research study.

We will use your name, date of birth, NHS number or CHI number and contact details (postcode), to contact you about the research study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. NHS hospital staff will pass these details to the University of Warwick using secure methods. Study data will be held securely and will only be accessible to authorised staff.

The University of Warwick and the hospitals taking part in the study will keep information about you for a minimum of 10 years after the study has finished so that we can check the results.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you later decide to withdraw from this study, we will keep the information that has already been collected. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Individuals from the University of Warwick and regulatory organisations may look at your medical and research records in order to check the accuracy of the research study.
The people who analyse the information will not be able to identify you.

If you agree to take part in this study, information we collect may be shared with other research teams for future projects and, as per the advice from the Secretary of State for Health and Social Care, your confidential patient information will be shared with organisations for COVID-19 purposes. (The Secretary of State's for Health and Social Care (England) advice is not applicable to data from Northern Ireland patients).

For further information, please refer to the University of Warwick Research Privacy Notice which is available here:

https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice (you may request a copy of this document from the research team) or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

You can also find out more about how we use your information here: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/ (you may request a copy of this document from the research team).

What would taking part involve?
You will receive the treatment to help your breathing, determined by the study. We will also collect data about your continued treatment and recovery. We will record what treatment you receive and follow you up for 30 days or until you are discharged from hospital, whichever is later. This will help us work out which treatment works better for people with COVID-19 and stops them needing more help with their breathing.

Once the trial treatment ends, there will be no further impact on you, if you are still in hospital you will continue to receive care and treatment as normal.

What are the possible benefits and risks of taking part?
Whilst standard care improves oxygen delivery, the anticipated benefit of both high-flow nasal oxygen and CPAP is that they improve the delivery of oxygen to your lungs further. This may help you feel better and less breathless. It may also help to avoid the need to place you under a general anaesthetic and put you on a ventilator.

Some people do not like the feeling of both high-flow nasal oxygen and CPAP. For example, they may make people feel claustrophobic. CPAP may also make you feel sick, may cause you to vomit, and may cause some pressure sores around your nose and mouth. If you do experience them, the treatment can be stopped.

If you are allocated to receive oxygen via a standard mask or slowly in to your nose, this will be unlikely to cause any problems except dryness of the mouth/ nose or feelings of claustrophobia.

Once you have completed your treatment, there are no significant personal direct benefits or risks associated with you continuing to participating in this research. However, the information we collect from you will help decide what is the best way to treat other patients in the future.

What if something goes wrong?
It is extremely unlikely that something will go wrong as a result of you taking part in the study as the treatments given through the study are currently all used within the NHS to

treat patients with breathing difficulties. The study is comparing which works best. The hospitals treating you will follow their normal clinical practice for giving each treatment.

However, if you feel that you have been harmed during your treatment due to someone's negligence, then you may have grounds for a legal action against the relevant NHS organisation, but you may have to pay your legal costs.

What will happen to the results of this study?
This study will take around 2 years to complete. Interim results will be shared as soon as available with other healthcare professionals and we will publish the results of the study in medical journals. When any information from the study is published it will not contain personal information, and it will not be possible to identify you.

We will ensure the results of the study are shared widely. If you would like a copy of the published results, please contact the study team (contact details below).

Who is organising and funding this study?
The study is organised by a group of doctors and scientists led by Professor Gavin Perkins at the University of Warwick and Professor Danny McAuley at Queen's University Belfast.

The costs of the study are being met by the NHS and the National Institute for Health Research.

How have patients and the public been involved in this study?
Patient and public representatives have helped us ensure that patient views remain central to how the research is designed and conducted. Patients and public representatives will continue to work closely with us as part of the research team to help inform how the trial is conducted as well as how it will be analysed and shared with others.

Who has reviewed this study?
All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study was reviewed and given a favourable opinion by the London - Brighton & Sussex Research Ethics Committee. The Study has also been reviewed by the Health Research Authority (HRA) and National Institute for Healthcare Research (NIHR).

What if relevant new information becomes available?
If new or relevant information becomes available that suggests one or more of the study treatments is causing harm or is ineffective then this treatment will be stopped. Your care team will ensure you continue to receive the best available care. The study may continue with the two remaining treatment options.

What happens if I have any questions, concerns or complaints about the study?

If you have any questions or concerns about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

If you are unhappy about any aspect of your treatment and wish to complain, you can do this through the NHS Complaints Procedure. You can contact the hospitals Patient Advice Liaison Service (PALS) or the hospitals Patient Advice and Support Service (PASS) or local Clinical Commissioning Group. For more information on the NHS complaints procedure or to find your local contact go to: http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/ (you may request a copy of this document from the research team).

If you remain unhappy and wish to complain formally, you can do this by contacting the person below, who is a senior University of Warwick official and is independent of this study:

Deputy Director/ Head of Research Governance Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Tel: 024 76 522746
Email: researchgovernance@warwick.ac.uk

This study is covered by the NHS and University of Warwick's insurance and indemnity cover. Any complaint about the way you have been dealt with during the study or any possible harm you may have suffered will be addressed.

In the event that you have been harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Warwick or the relevant NHS organisation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who do I contact for more information about the study?

If you have any questions please speak to your hospital medical team. Further information about the study will also be available on the study website (https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/).

Thank you for reading this information leaflet