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 have been admitted to hospital with COVID-19 or suspected COVID-19 and needed help to keep your oxygen levels high enough.

At that time, we enrolled you in a trial which is running across England, Scotland, Wales, and Northern Ireland. We are testing three different ways (CPAP, HFNO, or standard care) to treat people with low oxygen levels with COVID-19. 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.

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.

Due to the urgency of your condition, we did not have time to discuss your involvement in the study with you at that time. You were randomly selected to receive your treatment to either standard of care involving regular oxygen therapy, High Flow Nasal Oxygen (HFNO) or Continuous Positive Airway Pressure (CPAP). We are now asking for your consent to gather, record and store some of your personal information that will help us analyse how patients respond to the study and how well each treatment worked for them.

A member of the hospital study team will go through this information with you. We have also produced a more detailed information leaflet which you are welcome to read either online (https://warwick.ac.uk/fac/sci/med/research/ctu/trials/critical/recovery-rs/patients/) or you can ask staff for a copy to keep and take home with you. This describes the treatments and provides detailed information about how we will use your information. You are welcome to ask questions.

Do I have to take part?
You do not have to agree to take part. If you choose not to participate in the study any further, it will not affect the treatment or care that you receive in anyway. If you decide to participate today, you can change your mind (withdraw) at any time and without giving a reason or affecting your rights.

If you decide not to take part, now or later, we will not collect any more information about you. We will keep the information already collected before you withdrew from the study. This is because we need to manage your records in specific ways for the research to be reliable. This also means that we won't be able to let you see or change the information we hold about you. If you agree to take part in this study, information we collect may be shared with other research teams for future projects.

What happens next?
A member of the research team will discuss the study further with you. They will answer any questions you have. There is no rush to make a decision. Once you have decided, you just need to tell the researcher what your decision is.

What are the possible benefits and risks of taking part?
At this time, you will have already started to receive your study treatment, and it may already have finished. If 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.

Who is organising the study?
The study is organised by a group of clinicians and scientists led by Professor Gavin Perkins (University of Warwick) and Professor Danny McAuley (Queen's University Belfast).

Who has reviewed this study?
This study has been reviewed and given a favourable opinion by an independent NHS Research Ethics Committee London - Brighton & Sussex Research Ethics Committee and the Health Research Authority.

How will we use information about you? Will my taking part in this study be kept confidential?
The University of Warwick will act as the information controller for this study, and is responsible for looking after your information and using it properly. To undertake this study we will be using information from your hospital medical records, GP records, other NHS data sources, and the Intensive Care National Audit and Research Centre. Data on race and ethnicity will be collected. Hospital staff and University of Warwick staff will collect information from your medical records 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 some identifiable information (e.g. name, date of birth) 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. Only people at the University with specific roles (e.g. audit data collection, linking your data with other NHS data) will be able to access your identifiable information.

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.

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. 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 and will not be able to find out your name, NHS number or contact details.

Information may also be used for future research, subject to your consent at the outset of this research project. 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. As per the advice from the Secretary of State for Health and Social Care, your confidential patient information has been 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.)

What happens if I have any questions, concerns or complaints about the study or if something goes wrong?
Please refer to the detailed information leaflet – how to access this is detailed above.

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