



**UNIVERSITY
OF WARWICK**



Follow Up Participant Information Leaflet

The Awake Prone Study:

A research study to find out if awake prone positioning is better than standard care for patients with respiratory failure

- We are inviting you to carry on taking part in a study called Awake Prone.
- You do not have to continue to take part if you do not want to. If you decide to continue to take part, you can change your mind at any time by telling the healthcare professionals looking after you. This will not affect any other care that you receive.
- You have recently been unwell and required a moderate or high amount of oxygen. At the time, the healthcare professionals looking after you felt that you were too unwell to make decisions about taking part in the study, so the study was discussed with your relative/friend or an independent doctor. As you are now getting better, it is now possible to discuss the study with you.
- The usual position for patients in hospital is to sit up in bed. The study is aiming to find out if lying on your front (awake prone positioning) or standard care (sitting up in bed) reduces the chance that someone will go on a ventilator. The group that you were in was decided randomly.
- You are now in the follow-up stage of the study. This means that we will no longer be asking you to lie in a certain position. However, we would like to continue to collect information about you to see how well you recover.
- In this study we will use information from you, your GP, your medical records and some national healthcare databases. We will only use information that we need for the study. We will let very few people know your name or contact details, and only if they really need it for this study.
- Everyone involved in this study will keep your data safe and secure. We will also follow all appropriate privacy rules. At the end of the study, we will save some of the data for future research or in case we need to check it. We will make sure no one can work out who you are from any reports we write.

Please read this information leaflet which provides an overview of the study, to help you decide if you wish to continue to take part. One of the hospital research team will go through this with you and answer any questions you have. Please talk to others about the study if you wish and please feel free to ask any questions.

Why am I being asked to take part in this research?

You have been in hospital with a condition called respiratory failure. This means you need extra oxygen to keep the oxygen levels in your blood at a safe level. There are several reasons why people have this condition. One of the most common reasons is a chest infection.

Your doctors will have given treatment for whatever condition was causing your respiratory failure. Despite this treatment, we know that some patients with respiratory failure will unfortunately get worse and may need to go on a ventilator (breathing machine) in an intensive care unit. Going on a ventilator can be lifesaving but comes with important risks and can have long-term effects on your health. Doctors and nurses try and avoid patients going on ventilators whenever it is safe to do so.



Picture of patient lying on their tummy in a hospital bed

Normally, when patients are in hospital and need oxygen for respiratory failure, they sit upright in bed. During the COVID-19 pandemic, we found that when patients with COVID-19 lay on their tummy (awake prone positioning), it reduced the chance of them needing to go on a ventilator.

Doctors and other healthcare professionals do not currently know whether awake prone positioning helps in patients with respiratory failure not due to COVID-19.

To find out if awake prone positioning is better, patients like you were invited to take part in this study. Some patients will try and lie on their tummy for at least 8 hours a day and some patients will continue to receive standard care. We will then compare how well each group recovers to see which treatment works best.

Do I have to take part?

No.

It is entirely up to you to decide. If you do not want to take part that's OK. Your decision will not affect the quality of care you receive.

What will I need to do if I take part?

You were previously assigned by chance to one of two groups: awake prone positioning or standard care (sitting up in bed). You, the research team, or the medical care team did not get to choose which group you were in. This was decided by a computer at random. This type of study is called a randomised controlled study and provides the best way for researchers and healthcare professionals to know if a treatment works.

You are now in the follow up stage of the study. This means that you will no longer be asked to lie in a certain position. However, we would like to continue to collect information about you to see how well you recover. If you are happy to carry on taking part, we will ask you to sign a consent form. We will give you a copy of your signed consent form and this information leaflet to keep.

We are collecting information about everyone in both groups to see how well and how quickly they recover. We will also record whether you needed to go on a ventilator. The information that we collect will include your age, sex, ethnicity and your medical information.

After leaving hospital, we will also ask you to complete a questionnaire about your recovery at 2 and 6 month timepoints. They will each take you 5-10 minutes to complete. If needed, someone can complete them on your behalf. We may send you the questionnaires via text, email or post, or collect your answers to the questionnaire via telephone. We may share your name, email address, and phone number with a third-party company in order to send you the questionnaires by text message, email. We will also get in touch by text message, email or telephone if we have any queries about your questionnaire or if we have any updates related to the study.

Please take what time you need to decide whether or not to take part. You may wish to talk to family members.

The University of Warwick is currently leading several studies looking at how we treat patients with respiratory failure. This group of studies is called the 'Confederation of Respiratory Critical Care Trials' or 'CoReCCT'. If you need to go on a ventilator, we may approach you or your family about other research studies within the CoReCCT family of studies that you might be able to take part in. You do not have to take part in any of these other studies.

What are the benefits of taking part?

As this is a research study, you may or may not benefit from taking part. However, the findings of the research will help us to continually improve the treatments and care provided to patients with a similar condition now and in the future.

There is no payment for taking part in this research study. However, to thank you for your time in completing the follow up questionnaire at 2 months and 6 months, we will give you a small monetary gift voucher alongside each questionnaire. If you are taking part in other studies within the CoReCCT family, you will not need to complete questionnaires for each study. You will only be asked to complete the questionnaires once and will receive one voucher with each questionnaire.

What are the disadvantages or risks of taking part?

We know that some people will find lying on their tummies uncomfortable. You may have experienced this if you were in the awake prone positioning group.

At this time, there are no important disadvantages or risks to taking part.

What happens if something goes wrong?

The University of Warwick will provide indemnity for this study. It is very unlikely that anything will go wrong as a result of taking part in this study however, if you are harmed due to someone's negligence, you may have grounds for legal action which you may have to pay for. NHS bodies may also be liable if you are harmed as a result of negligence whilst taking part in a clinical trial. Non-negligent harm by NHS staff is not covered by the NHS indemnity scheme, and therefore compensation may not be paid in these circumstances

Who should I contact if I wish to make a complaint?

If you have any concern about any part of this study, you can contact the researchers at your hospital: <insert PI contact details>.

You can also seek independent advice from <insert local Patient Advice and Liaison Service and contact number or relevant local contact> or follow the NHS complaints procedure in your country.

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:

Head of Research Governance, Research & Impact Services
University House, University of Warwick
Coventry, CV4 8UW
Email: researchgovernance@warwick.ac.uk
Telephone: 02476 575733

What if I change my mind?

You can change your mind about taking part at any time just by telling the healthcare team looking after you. Even if you decide that you no longer wish to complete the follow up questionnaires, we would still like to continue to collect information about you from healthcare records. This is important to make sure the study results are valid.

Will my taking part in this study be kept confidential?

In this research study, we will use information from you, your GP, your medical records, and healthcare databases such as NHS England. We will only use information that we need for the research study.

We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

For more details on how your data will be used and kept safe, please take a look at the data information by visiting www.warwick.ac.uk/awakeprone or scanning the QR code at the end of this leaflet. Alternatively, please ask a member of staff to print a copy for you.

Who is organising and funding the research?

This study is being sponsored and carried out by the University of Warwick, in partnership with NHS hospitals across the United Kingdom. The study is being coordinated by Warwick Clinical Trials Unit. The study is funded by the National Institute for Health Research, Health Technology Assessment (NIHR154796).

Who has reviewed this study?

People with personal experience of having respiratory failure and other members of the public have helped design and set up this study.

Research in the NHS that involves patients is reviewed by an independent group of people called a Research Ethics Committee (REC). This committee is there to protect your interests. This study has been reviewed and been approved by Wales REC 2.

Contact for further information:

If you have any questions about the study, either now or in the future, you may contact your local hospital research team at [<local research contact details>](#)

Alternatively, please contact the Awake Prone study manager at the University of Warwick:

Email: awakeprone@warwick.ac.uk

An online version of both this information leaflet and the data information leaflet can be found on the study website www.warwick.ac.uk/awakeprone, or by scanning the QR code below:



Thank you for taking the time to read this information and for considering to continue taking part in this study.

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