

UK NAVA Easy Read Patient Information Sheet

Neurally Adjusted Ventilatory Assist (NAVA) in the adult critical care unit: The UK NAVA Trial

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You have been given this leaflet because you were in hospital with breathing issues and needed to be put on a breathing machine (called a ventilator).



Whilst you were ill, you were enrolled into a trial called UK NAVA as you couldn't make this decision yourself.

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1. What is UK NAVA and what does it involve?

Patients who have sick lungs sometimes need help from a breathing machine called a ventilator.



NAVA stands for Neurally Adjusted Ventilatory Assist, and is a type of technology which allows doctors to see how well the ventilator is working for each patient. NAVA technology can tell doctors how much a patient is trying to breathe on their own, and set the ventilator settings to work best with them, depending on how their body responds.

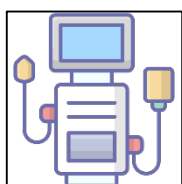


We think this might help patients get better quicker and spend less time on a ventilator, but we need to do a trial to find out.

In the trial, half of the patients have ventilation with NAVA, and half have ventilation without (as usual in critical care units). Each patient is randomly allocated to one of the groups by a computer programme. You were very sick and needed treatment as soon as possible, so we couldn't talk to you about the trial. Where possible, we asked a family member, friend or independent doctor if they thought you would be happy to join the trial.



2. What happens now?



You were assigned (randomly, by a computer programme) to one of two groups.

1. **NAVA:** The ventilator is used alongside NAVA technology to help doctors see how you are responding to the ventilator.

2. **Usual care:** The ventilator is set as usual by the critical care team.

There will be no other changes to care delivered by the critical care team for patients in either group.



The trial treatment stopped when you no longer needed to be on the ventilator. To see how well you're recovering, we would like to send you a questionnaire at 2 and 6 months after your ventilation. These will take 5-10 minutes to complete. If needed, someone can complete them for you. To thank you for your time, we will send you a £10 gift token with each questionnaire. We will share your name, email address, and phone number with a third-party company in order to send you the questionnaires by text message, email or post. We may also get in touch by text, email or telephone if we have any queries about your questionnaire or if we have any updates related to the trial.

If you do not want to complete the questionnaires, this won't affect your care in any way. We also plan to collect information about your recovery from hospital records and national databases. If you do not want us to do this, please tell us. We would normally keep and use all the information already collected about you. If you say yes today, you can change your mind at any time, without giving us a reason.



To help us know how to best use NAVA in the future, we will need to collect the two questionnaires, your personal details (name/address/date of birth/NHS number) and information about your recovery.

The University of Warwick is collecting all the information from the trial, and we will keep it safe and private. With the exception of using your personal data to send out the questionnaires (via a company called Twilio), personal data won't be shared with anyone else. When the trial is finished, the university and the hospital that treated you will keep the information for 5 years and then delete anything that links the information to you. Only staff members who are working on this trial and need to see it will be able to access your personally-identifiable data.



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 are taking part in other studies within CoReCCT, you will not need to complete questionnaires for each study – you will only be asked to complete each questionnaire once.

3. What if something goes wrong?

Doctors don't know whether using NAVA is always better, and this is why we're doing a trial to find out. We can't promise there will be any benefit to taking part, however we hope that this research will help patients in the future who need help with their breathing on critical care units. The risk of harm of taking part in this trial isn't thought to be any higher than the usual care you would get, because NAVA is already used in the NHS. Because the trial involves completing questionnaires, there's a risk you may find some questions about your recovery upsetting to answer. Our trained research staff can talk to you about any feelings you may have, and there are contact details listed further down if you need to get in touch with someone.



If you have any concern about any element of this trial, you can contact the researchers at your hospital: **[insert PI contact details]**

You can also seek advice from: **[insert local Patient Advice and Liaison Service details or relevant local contact]**

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 trial:

Head of Research
Governance Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Tel: 02476 575733
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.

The University of Warwick is the trial Sponsor and data controller. This means that they are responsible for looking after your information.

To find out more about how your data is being used in this trial, please see the CoReCCT Data Information Leaflet.

4. Who has reviewed this research?

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. This committee is there to protect your interests. This trial has been reviewed and been approved by **Wales** REC 2.

5. Further information

For more information, please contact the NAVA Trial Manager at Warwick University:

Email: NAVA@warwick.ac.uk

An online version of this information sheet can be accessed by scanning the below QR code or via: <https://warwick.ac.uk/nava/public>



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

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