Local Trust Logo

Taking part in the DENIM trial: what to expect?

Your clinic is helping with a health study

- Your clinic is part of a group helping to test new ways to care for people
- Some clinics will try something new, while others will keep doing what they usually do
- Your clinic will keep doing what it usually does

What this means for you

- Your care stays the same
- You'll see the same doctors and nurses
- You'll get the same medicines and treatments as usual

How you're helping

- If you agree to take part, your information might be used in the study, but your name will be kept private
- This helps doctors learn if new treatments work better

Good things about taking part

- It's safe - you get the same care you always have
- You're helping to make healthcare better for everyone

What you need to do

- Just come to your usual appointments
- Your care team will ask you some extra questions

Important to know

- It's your choice to take part
- If you don't want your information used, just tell your doctor
- Your care will be the same whether you take part or not

Questions?

Ask your doctor or nurse - they're happy to help!

On this page we will explain the important things about what we are asking you to help us with. After this we have written a lot more detail which you might want to read now or keep and read later.

What is this study?

This study is looking at improving how we help people with MND using breathing machines. We are inviting you to take part in this study because you may have recently been referred to start using a breathing machine (also known as non-invasive ventilation, or NIV).

This is really important because if people don't take part in research we don't know if treatments are working well for them.

Why do you need my help?

Your hospital has already decided to take part in this study, we just need you to say yes too if you are interested. You don't need to decide now! If you decide it's not for you, then you can carry on with your normal care.

What does it involve?

We'd like to:

- Check you are ok to help us with our study.
- Sign a form or ask someone else to sign it to say you are happy to take part.
- Take some basic information about you.
- Find out how our team can get in touch with you at a suitable time and in a language of your choice.
- Ask you to fill in some questionnaires about you, your family, your MND and treatment. This will take about 10-20 minutes and could be done by phone, video call, face to face visit or email, depending on what you would like.
- Ask you to fill in some different questionnaires in 3 months' time.
- Ask you to wear a small monitor on your finger for one night.
- Ask your permission to have your breathing machine set up so we can receive data from it.

How we can help you to take part

- We can arrange an interpreter.
- You can ask a family member or carer to help you during this.
- There are no right or wrong answers to the questionnaires.
- You don't have to read or write anything if you don't want to.
- We will not tell anyone outside the research team your name.
- You won't be paid but it won't cost you any money.
- You don't have to take part and can change your mind.

If you think you might be interested in taking part, please tell your healthcare team and we will do the rest.

If you would like this information translated into another language let us know.

Usual Care Participant Information Sheet

DENIM trial: Delivering Effective Non-Invasive ventilation in Motor neuron disease

We would like to invite you to take part in a research study. Before you decide if you would like to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to family, friends, or health professionals about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Who to contact?

If you have any questions about the study, please contact:

INSERT LOCAL CONTACT DETAILS

Contents

What is NIV?

Motor neuron disease (MND) causes breathing problems which can be helped by using Non-Invasive Ventilation (NIV). NIV is delivered using a portable ventilator and a mask. Although NIV can help people live longer and feel better, many people with MND still struggle to use NIV and don't get these benefits.

Your healthcare team will explain more about NIV, what the benefits might be to you and what might be the downsides to help you decide whether to start it. They will be able to answer your questions about this. You can also find out more about NIV on this website www.mybreathing.mymnd.org.uk

Why have I been invited to take part in this study?

You have been invited because you have recently been referred to start NIV treatment for MND and your local care team are participating in the DENIM research. If you decide to start NIV, you will then be asked whether you want to take part in this research. This leaflet talks about the option to take part in research when you start using NIV.

What is the purpose of this study?

This study will test a new approach to supporting people to use NIV. The study will compare the current NHS service, against the new approach. The new approach gives extra training to healthcare professionals and more frequent monitoring and support for patients. We want to see which service helps people use NIV more in the first 12 weeks. We don't know if this new NIV approach is the same, worse or better than the current NHS services.

Do I have to take part in this study?

It is up to you to firstly to decide whether to try NIV. If you do decide to try NIV then we will ask you if you want to take part in this study. You do not have to take part; it is up to you to decide.

We will describe the study in this information sheet, which you can keep. If you do agree to take part, you are free to withdraw at any time, without giving a reason. Your decision to take part will not affect the standard of care you receive, and you can continue to use NIV as normal.

If you decide not to take part, with your permission, you may be contacted at a later date by the study researchers, who want to better understand why people don't want to take part in research.

What will happen if I agree to take part?

Before you decide to take part, you may be asked some questions to confirm your suitability for the trial. You will also be given the opportunity to ask any questions you may have.

In this stage of the study your hospital has been asked to carry on starting and supporting NIV in the usual way. At some point in the future, they will switch to giving extra support to

people starting NIV. As you are starting NIV now you will carry on receiving this usual care whether you decide to take part in the study or not.

It is really important that people take part in the study even if it doesn't change their treatment. This is to make sure we learn about what happens with your NIV treatment. Without people to compare the new approach to, we won't know which is better.

In a 'cluster randomised trial' such as this one, instead of individual patients being randomly assigned to different groups, entire sites (like hospitals or clinics) are randomly assigned. When a site is in the "control arm," it means:

- Your NIV care stays the same
- You will see the same respiratory team
- You will receive the same medicines and treatments as usual

Remember, being in the control group is just as important as being in the treatment group for the success of the research. Control arms are important to research because they allow us to compare whether our new intervention is more effective than usual care.

If you decide to take part, you will be asked to complete a consent form. This form confirms you are happy to take part in the DENIM trial. We will also ask for your consent for the University of Sheffield to keep a record of your contact details for the purpose of sending you any additional equipment and questionnaires necessary for the study. You will provide consent when you start NIV or shortly after. If you provide consent over the telephone or by videoconference, we will make and store an audio recording of the conversation for auditing purposes. We will also ask if you would like to nominate a personal consultee. This is someone who knows you well. If we are concerned that you might struggle to tell us your view on whether you're happy to keep taking part, we will ask the consultee to give us advice on this. They will complete some paperwork to confirm this.

Only after we have your consent, we will ask you some questions about your symptoms and quality of life and ask you and someone who knows you well to complete some short questionnaires. You can have help with the questionnaires from a carer or a staff member. We are happy to help you use your communication device if you prefer. Your care team will follow their usual procedures, set up your ventilator and show you how to use it.

What will taking part involve?

- Complete some short questionnaires when you start NIV taking 10 minutes.
- Complete some short questionnaires at home after 12 weeks either by phone, post or videocall.
- Wear an oxygen monitor on one finger for one night whilst you are at home after 12 weeks.
- Have your NIV machine set up so it sends information from the NIV machine about how you use it, to be collected by the research team.

- Return any equipment we have given you by post or courier in a prepaid envelope (we will arrange for equipment to be collected from your home/preferred location).

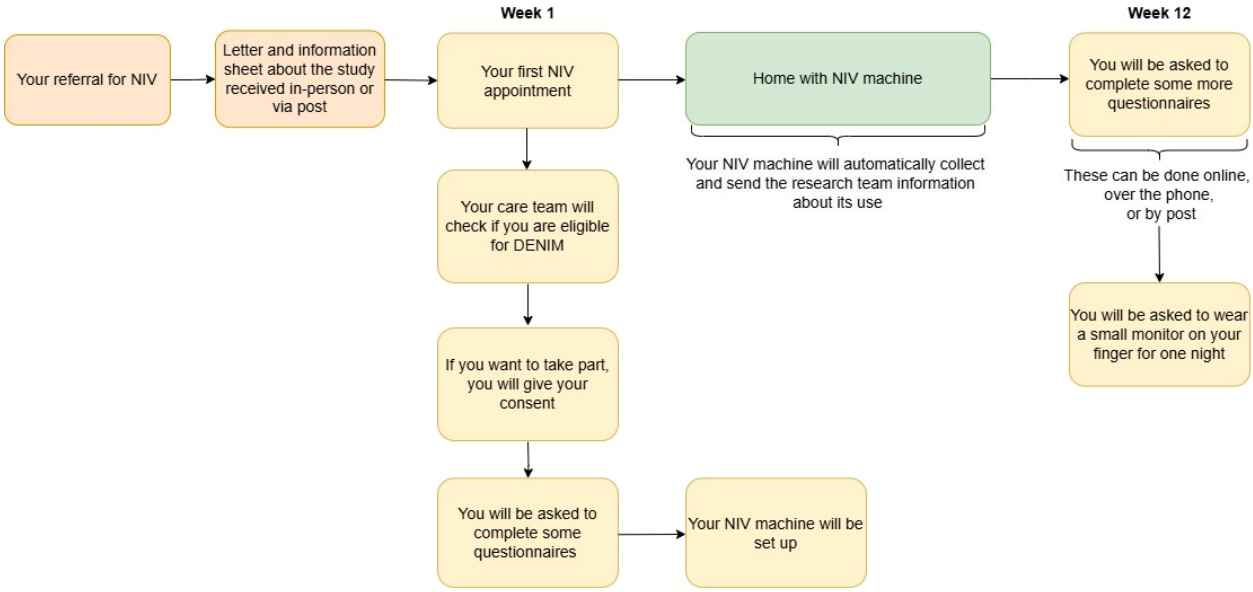
For the study, the research team will receive 'pseudonymised' (this is where your data will be given a code, instead of using your name) data from your NIV machine, for the first 12 weeks of your treatment. This is to measure how many hours per day you use NIV. We will not share this information with your healthcare team.

We will also ask you to complete some questionnaires about your breathing symptoms and quality of life at the start of the study and at 12 weeks. You can take as long as you need to complete them and this can be done at home on the telephone, or via post or online. We will also ask you to wear an oxygen monitor on your finger whilst you sleep at home for one night which will be delivered in the post and collected.

You will not need to make extra visits to the hospital.

We might place a small device on the back of your NIV machine to send us information automatically via mobile internet. If so, we will ask you to send this back at the end of the study using a prepaid envelope or prepaid courier.

Please see flowchart below for an outline of the study timeline:



What are the possible disadvantages and risks of taking part?

The study involves very little time and effort. The main additional activity is completing the study questionnaires and measuring your oxygen once overnight. There are no expected additional risks from taking part in this study.
You will not have to pay any extra costs such as postage or internet access.

We estimate that the average cost of using NIV is less than 6p per day or £25 per year. We don't expect the extra costs of the electricity required by device fitted to the modem to cost more than 5p for the whole time you are in the study. You do not have to use the internet or do anything with the internet device to take part in the study.

What are the possible benefits of taking part?

You will receive the normal treatment and care from your hospital team whether you choose to take part in the study or not. We do not know yet if the new NIV approach being tested will be better than normal care. By taking part, you will be helping us work out the best way to support people with MND to use NIV. This will help us improve the treatment of future MND patients. Later in the study the staff at your service will get extra training about NIV.

What happens when the research study stops?

Your care team will continue your care and NIV treatment. After the study your care team may introduce new ways of working to support NIV use.

What will happen if I do not want to carry on with the study?

You can withdraw from the study at any time, by telling your clinical team or the research nurse. You do not have to give any reason. We will keep your pseudonymised study data collected up to that point. If you decided to withdraw, this will not affect your ongoing care.

How will we use information about you?

We will need to use information from you, from your medical records, your MND care team, and your NIV machine for this research project. This information will include your:

- Name,
- Contact details,
- Ventilator serial number,
- NHS number,
- Date of birth.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Sheffield Teaching Hospitals is the Sponsor of this research and is responsible for looking after your information along with The University of Sheffield, who both act as a joint data controller. We will keep all information about you safe and secure by:

- Linking all of the data collected about you to a 'pseudonymised' identification number (a code number)
- Only providing people who need to contact you (i.e. the people treating you) with your personal information

International transfers

Your data will not be shared outside the UK.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- our leaflet (Patient data and research leaflet - Health Research Authority)
- by asking one of the research team
- by sending an email to STH.InfoGov@nhs.net, or
- by ringing us on 0114 2265153.

What will happen with the results of the research study?

The results will be published in scientific journals and presented at conferences. A summary will also be available on the study website www.denim-mnd.co.uk and information will be placed on social media and advertised through charities such as the Motor Neuron Disease Association. You will not be identifiable in any publication.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details

are at the end of this information sheet. If you wish to seek advice or reassurance about your own health, then contact your GP. If you experience harm or injury as a result of any study activities, you may be eligible to receive compensation.

If you remain unhappy and wish to complain formally, you can do this by contacting the local NHS Patient Services Team:

Address: <insert address>

Telephone: <insert phone number>

Email: <insert email>

Who is organising and funding the research?

The project is being carried out by a team of researchers from the Sheffield Centre for Health and Related Research (SCHARR) at The University of Sheffield and Sheffield Teaching Hospital NHS Foundation Trust. This study is funded by the National Institute for Health Research Health and Social Care Delivery Research, reference NIHR158715.

Who has ethically reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Yorkshire & The Humber - Leeds East Research Ethics Committee (REC reference 25/YH/0019).

Thank you for taking to time to read this information sheet, we hope that it has been helpful in enabling you to decide if you would like to take part in the DENIM trial. This information sheet is for you to keep.

For further information or if you have any questions, please find the research team's contact details below:

Local Contact Details:

[Add local NHS Trust details]

Central Office Contact Details:

Denim Trial Manager
Barber House

387 Glossop Rd

Broomhall

Sheffield

S10 2HQ

Tel: [insert number]
Email: Email: denimtrial@sheffield.ac.uk