DENIM
Delivering Effective Non-Invasive ventilation in Motor neuron disease

University of Sheffield | School of Medicine & Population Health

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

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 is trying a new way to help people

What this means for you

- You'll see the same doctors and nurses
- You'll get the same medicines and treatments as usual
- You may have more phone calls with your care team

How you're helping

- If you agree to take part, your information will 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 if you wish.

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 information 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.

Intervention 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 you wish to take part.

Who to contact?

If you have any questions about the study, please contact:
INSERT LOCAL CONTACT DETAILS

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What is Non-Invasive Ventilation (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.

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 try 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 care team are taking part in the DENIM research. If you decide to try NIV you will then be asked whether you want to take part in this study. 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 setting up NIV. This study will test whether giving extra training for healthcare professionals and more frequent monitoring and support for patients can help more people to use NIV better in the first 12 weeks. It might also reduce the number of times people need to come to hospital. The study will compare this new approach to the current NHS service.

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.

Who else is taking part?

The healthcare professionals who support your care are also participating in the study. They have received some additional training and will be being observed and interviewed about their experience of changing the way they deliver care. With your consent, family, friends or

carers may also be invited to take part in some interviews about their experience of supporting NIV.

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.

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 at your NIV initiation appointment 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.

After we have your consent, we will ask you some questions about your symptoms and quality of life. Your care team will set up your ventilator and show you how to use it.

As part of the new approach, your care team will receive extra training on setting up and supporting NIV. When you start NIV, your care team will do some assessments to identify anything that might make NIV harder for you. They will talk to you about your treatment goals. They will then set up your ventilator and show you how to use it.

Your care team will set up your NIV machine, so it uses the mobile internet to send information to your care team and the research team. Once you are using NIV at home, your care team will use telemonitoring to check your ventilator data frequently during the first 12 weeks. They will contact you at set times (at least four times in the first two weeks, then at least four further times, in the next 12 weeks after starting NIV), and whenever they notice any issues that need adjusting. They will find out the best way to contact you which might include telephone, text, email or video. They can also contact your carer if you prefer. They can provide advice and support and make changes to your ventilator settings remotely. They will also explain how to contact them if you have any concerns.

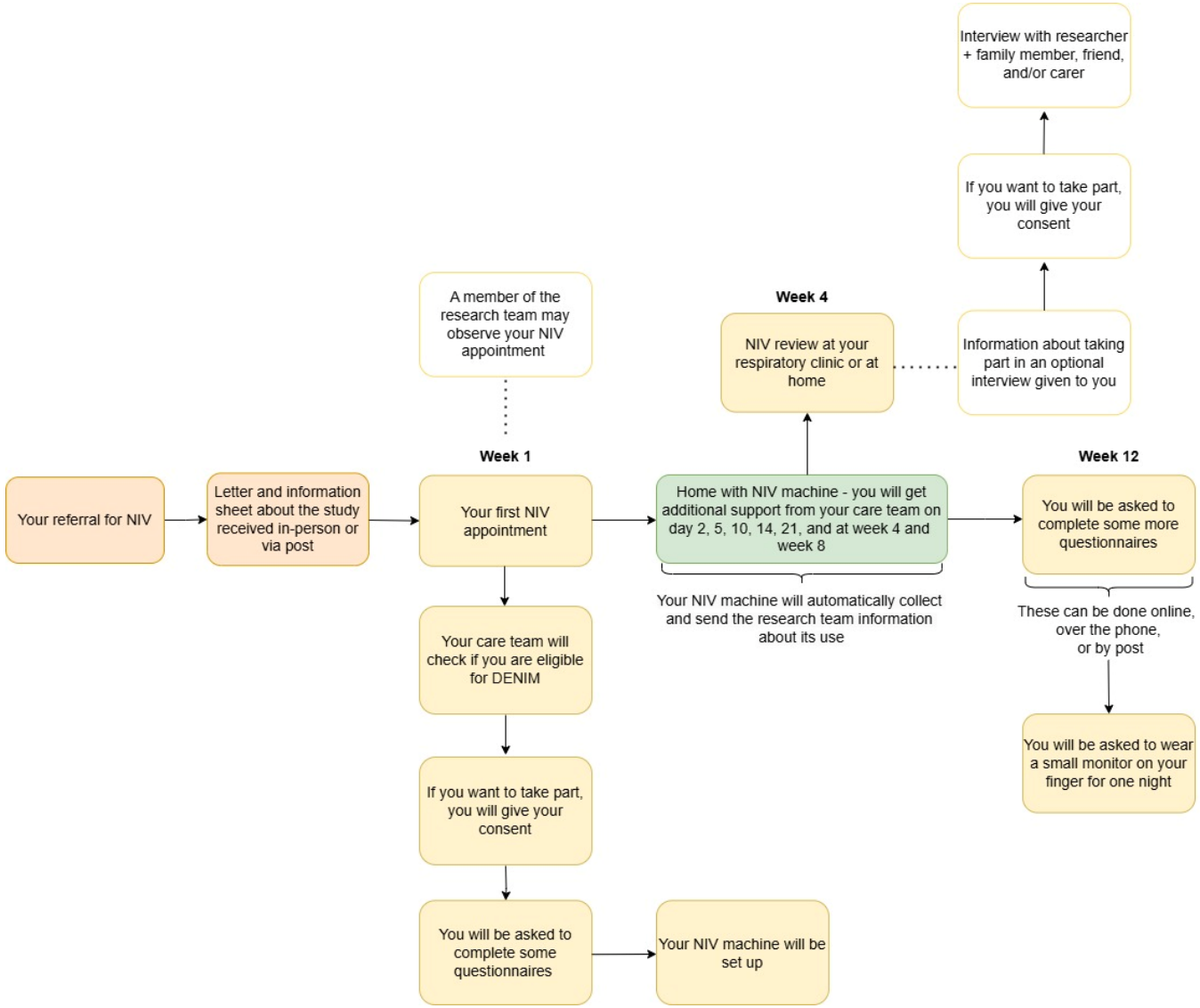
For the study, we will access pseudonymous data (this is where your data will be given a code, instead of using your name) from your NIV machine to measure how many hours per day you use NIV and how your NIV machine is working.

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. These can be completed at home via post, telephone 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.

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



Optional interviews and observations

We may invite you to take part in an interview about your experience with NIV. We may also ask if a researcher can observe some of your consultations with your ventilation team. This is to help us understand if the new intensive NIV service works and how it could be best rolled out across NHS hospitals. Observations and interviews are all optional and you can indicate this on the consent form.

What are the possible disadvantages and risks of taking part?

The main difference with this new approach is that you will have more contact with your care team during the first 12 weeks of starting NIV. This is unlikely to be a burden as patients tell us they value regular contact, advice and support from their care team when starting NIV. There are no expected additional risks from taking part.

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?

There are no guaranteed benefits to participating in this research. The extra monitoring and support from your care team may help you to adjust to and use NIV. However, we don't know this for certain, which is why we are doing this study. By taking part, you will be helping us determine the best way to support people with MND to use NIV effectively. This will inform the treatment of future patients.

What happens when the research study stops?

Your MND care team will continue your care and NIV treatment. The level of telemonitoring and frequency of contact may change back to your site's standard approach.

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 care team or the research team. You do not have to give a reason. We will keep your 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,
- Device 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 of using your personal details. Sheffield Teaching Hospitals is the Sponsor of this research and is responsible for looking after your information along with the University of Sheffield, who will both act as 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. 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: denimtrial@sheffield.ac.uk