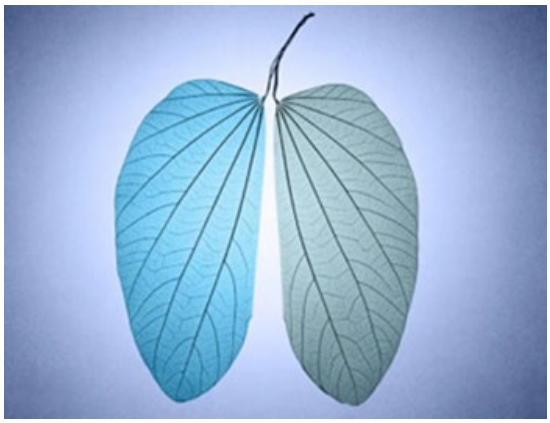
Motor Neurone Disease Association logo**IRAS Project ID:** 318973



INTERVIEWS

Information Sheet: Family (including friends)

Final version 1: 18th October 2022

Researchers:

Eleanor Wilson (Chief Investigator)

Nicola Turner (Senior Research Fellow)

Understanding living with tracheostomy ventilation for Motor Neurone Disease (MND) and the implications for quality of life

We are researchers from the School of Health Sciences at the University of Nottingham, and we would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. **Please ask us if there is anything that is not clear.**

What is the purpose of the study?

The purpose of the study is to understand what it is like to live with tracheostomy ventilation to manage the respiratory symptoms of MND. We want to understand:

- what it is like for patients with MND living with trachy ventilation, whether this has been planned or placed in an emergency
- what are the benefits and challenges for patients and their families (including close friends)
- how decisions about having trachy ventilation were made, what ongoing decisions there might be and how these might be best supported
- the range and roles of health and care professionals involved in the care of someone using trachy ventilation

Why have I been invited?

You have been invited to take part because you have experience of supporting a family member or friend to use trachy ventilation for the respiratory symptoms of MND. We are inviting 10 people like you to take part in this study, alongside 10 patients and 20 health and care professionals. Another part of the study involves more in-depth case studies, following families for up to six months.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still **free to withdraw at any time** and without giving a reason. This would not affect your rights.

What happens if I take part?

If you decide to take part in the study, you will be asked to speak to the researcher in **an interview that will be tailored to suit you**. This can take place over the phone, a video chat or via email exchanges. This is an informal discussion and can be done as one interview (lasting up to 1 hour), or several shorter conversations. When the interviews take place and for how long is very flexible and will be arranged entirely at your convenience.

The interview will be **about your experience** of your family member using trachy ventilation. Before starting the interview, you will be asked how you would like it to be recorded (video or audio) and **whether a video, audio or written version** of your interview can be used in the study. If you do not want your interview to be recorded, you can still take part in the study. The researcher will take written notes instead.

How will my interview be used?

The results of the study will be used to help improve knowledge and understanding of what is like to live with trachy ventilation for MND. This may help patients, families and health and care professionals in the future. The information you give us will be used to prepare a **report** for the MND Association, which has funded the study. The results of the research will be made available more widely through professional and academic journal **publications and conference presentations**. We may use direct quotes from your interview in reports and publications, but we will not include any personal details that may make it possible to identify you. All participants will be sent a summary of the findings and recommendations at the end of the study if they would like to receive this.

We may also wish to use the information you give us to develop new resources for staff training and public education. We will always discuss with you how we would like to use your data and we will ask you to give your consent. This would be in addition to the consent you give to take part in the study. Your data will not be used anywhere without your explicit consent, and it will never be used for advertising or purely commercial purposes.

What are the possible benefits of taking part?

We cannot promise the study will help you directly but the information we collect may help other patients, families and health and care professionals to understand the experience of living with trachy ventilation. This may help **to improve the care and support provided in future**. We hope that the research findings might contribute to the National Institute for Health and Care Excellence (NICE) guidance on the treatment and care of people with MND.

We hope participants find involvement in the study an interesting experience. Some people find it helpful to have the opportunity to reflect on and talk about their experiences.

What are the possible disadvantages and risks of taking part?

We understand that talking about issues relating to the illness of someone you care about may be difficult and upsetting. We ask you to consider very carefully how you would feel about sharing this experience with a researcher. It is important that you understand what is involved and have the opportunity to discuss this fully with the researcher and others you may choose to talk to before you decide to take part.

It is possible that you may feel upset at times during the interview. However, you will never be under any pressure to answer questions or talk about topics that you prefer not to discuss. **You can stop the interview, take a break, or withdraw from the study, at any time.**

Expenses and payments

Participants will not be paid to take part in the study. If you need to pay a carer extra time to provide care for your relative with MND so that you can take part in the study, you will be able to claim the cost of any additional care.

Will my taking part be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. If you join the study, information collected from you will be kept strictly confidential, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data

Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Eleanor Wilson) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information and read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx or contact: Data Protection Officer, Legal services, A5, Trent Building, University of Nottingham, NG7 2RD, 0115 748 7179.

The information collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Information about you that leaves the University of Nottingham will have your name and address removed and a unique code will be used so that you cannot be recognised from it. By giving your consent you agree to the above.

Your contact information will be kept by the University of Nottingham for 3 to 6 months after the end of the study so that we are able to contact you about the findings (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your information will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal information.

In accordance with University of Nottingham, the Government and our funders' policies we may share our research data with researchers in other universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information, we will seek your consent for this and ensure it is secure. You will

be made aware if the information is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Your confidentiality will only be broken if the researcher becomes aware of actions or situations resulting in serious risk of harm to yourself or others. In these circumstances, the researcher will discuss this with you and consider the need to raise the matter with a senior manager.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

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 given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS) on 0800 183 0204 or email PALS@nuh.nhs

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the Motor Neurone Disease Association (MNDA).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the XXXX

What do I have to do?

Please let one of the research team know if you are interested in taking part in the study or would like to discuss this further. Our contact details are:

Contact details

Dr Nicola Turner

Senior Research Fellow

0115 8230537

nicola.turner@nottingham.ac.uk

I am an experienced researcher in palliative and end of life care with an interest in care at home for people who have serious, advanced illness. I have worked on several studies that aim to understand individual experiences of treatment and care in the context of the family, community and wider social settings

Dr Eleanor Wilson

Chief Investigator

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I have been a researcher in palliative and end of life care for a number of years and have a particular interest in neurological conditions. My background is in anthropology so for this study I am working with experienced clinicians with expertise in MND, palliative care, respiratory disease, and home ventilation.