Participant information sheet

Enhancing the efficacy of non-invasive ventilation (NIV) for patients with motor neurone disease (MND): exploring the services that provide and deliver NIV to people with MND.

We are a team of researchers from the University of Sheffield and Sheffield Teaching Hospitals NHS Trust. We would like to invite you to take part in a research study. Before you decide if you would like to take part in this study, it is important that you understand the aim of the study and what it would involve. This information sheet will describe what the aim of the study is and what it will involve if you decide to take part. If you are interested in taking part, please read the following information. If after reading this information sheet you have any questions, please contact a member of the research team using the contact details at the bottom of this page.

Study summary

This survey will contribute to the second work package of a wider project which aims to identify the best ways of providing NIV services to people with MND. This project is funded by the National Institute for Health Research and is supported by the Motor Neurone Disease Association. The wider project will use these findings to develop resources to help improve the way in which NIV is delivered in order to ensure that patients gain the most benefit from NIV.

The aim of this survey is to explore the role and clinical practices of healthcare professionals (HCPs) in NIV services and the community team in delivering NIV to patients with MND. The results of this survey will help inform the development of the resources in the following work packages of the wider study.

Why am I being invited?

We are inviting HCPs in NIV services and community HCPs who are involved in providing respiratory care/NIV to patients with MND.

What will the study involve?

If you would like to take part in the study, you will be asked to complete a questionnaire exploring your role and experience in delivering NIV to patients with MND. The questionnaire will be in the form of an online questionnaire and the link will be sent to you via email. We expect the survey to take approximately 15-35 minutes. The survey will be available to complete until Tuesday 26th March 2019 so you are able to take some time to think about whether you would like to take part.

Do I have to take part?

No, taking part in this study is voluntary and you can withdraw your participation at any time before you complete the survey. However, you will not be able to withdraw from

the survey after it has been submitted. You are welcome to ask the researchers if you have any questions before deciding to take part.

What are the benefits and disadvantages of taking part?

We cannot promise that this study will benefit you. However, the survey will give you the opportunity to share your experiences of delivering NIV to people with MND. We hope to use the results from the survey to develop resources to help improve clinical practice to ensure that patients get the best service possible. This can have potential positive implications for patient survival and quality of life. We are also offering the chance to be entered into a prize draw. We have two £50 prizes on offer. If you decide to take part, you will be given the chance to enter the raffle at the end of the survey.

We expect there to be minimal risks/burdens involved in taking part in the study. One of the disadvantages to taking part in the survey is the time it will take to complete. However, you do not have to answer all of the questions and you do not have to complete the survey in one sitting. You can leave the survey and your responses will be saved so you can pick up where you left off later. However, your responses will not be stored on the database unless you submit the survey. The only other disadvantage we can think of is that sensitive topics may be triggered by the questions. This is because we are asking questions about your experiences of delivering NIV along the entire care pathway. However, you are not required to answer all of the questions. If you do not wish to answer a particular question then you can leave it blank and move on to the next one.

How will you use my information and will it be kept confidential?

Sheffield Teaching Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom but will not have access to personal identifiable information. The University of Sheffield will be using information from you in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly.

The University of Sheffield will collect information from you for this research study in accordance with our instructions. You will be asked to indicate whether you would like to provide your contact details for future contact. Contact will only be made if you indicate that you are happy to be contacted by the research team if we identify an area of good practice (e.g. trust guidelines, pamphlets etc.) which we would like to find out more about or if the research team would like to clarify any of your responses. We will also contact you if you state that you wish to find out more about the wider project or if you would be interested in answering some questions about your experience delivering cough assist. If you choose to provide your contact details for future contact, the University of Sheffield will keep your name and contact details confidential and will not pass this information to Sheffield Teaching Hospitals NHS Foundation Trust. The University of Sheffield will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded

for your care, and to oversee the quality of the study. The University of Sheffield will keep identifiable information about you for up to 2 years after the study has finished.

Your right to access, change or move information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

All of the information that we will collect will be kept confidential. Only members of the research team will have access to the information. All research data will be stored in a folder on the University's secure Medical School M: drive. Data will only be accessed on the University of Sheffield computers which are password protected. Your responses may be used in reports of the research. However, your responses will be anonymised in reports using simple coding such as by profession (e.g. HCP 1, 2, 3 etc.). Therefore, no individual or place of work will be identifiable in any publication.

Any information you enter will be stored and processed using services provided by Qualtrics. These services have been the subject of independent assessment to ensure compliance with applicable data security standards. Further information can be found on the Qualtrics website (https://www.qualtrics.com/security-statement/). Data will only be stored on the survey system for 1 month following the deadline for completing the survey.

Anonymous data will be retained for 5 years after the final publication is complete. When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you such as insurance.

Certain individuals from Sheffield Teaching Hospitals NHS Foundation Trust and regulatory organisations may look at your research records to check the accuracy of the research study. Sheffield Teaching Hospitals NHS Foundation Trust will only receive information without any identifying information.

If any issues are identified by the research team, these will be reported to the chief investigator and co-investigators. If judged to be a serious risk to patient safety and we are able to identify the site, we will report the information to the senior clinician in charge of the unit but we will not identify the person who said it to maintain their anonymity.

What happens if I have a complaint?

Any complaints should be addressed to the chief investigator of the study, Dr Esther Hobson in the first instance:

Dr Esther Hobson
Sheffield Institute for Translational Neuroscience (SITraN)
University of Sheffield
385a Glossop Road
Sheffield
S10 2HQ

Email: e.hobson@sheffield.ac.uk
Telephone: 0114 222 2230

If complaints cannot be resolved, then you can contact the sponsor of the study:

Clinical Research & Innovation Office
Sheffield Teaching Hospitals NHS Foundation Trust
D49, D Floor
Royal Hallamshire Hospital
Glossop Road
Sheffield
S10 2JF

Telephone: 0114 226 5938

Who is organising and funding the study?

This research is funded by a National Institute for Health Research (NIHR) Programme Grant for Research for Patient Benefit (RfPB) and organised by the University of Sheffield.

Who has reviewed the study?

The study has received approval from the Health Research Authority, part of the Department of Health in the United Kingdom.

Timescale

This stage of the research is planned to take place for 6 weeks starting in January 2019.

Further information:

Please ask the research team:

Research assistant: Lucy Musson

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