

Information Sheet

Name of project:

A survey of the nutritional management of people with Motor Neurone Disease in UK Health Services

Name of lead researchers:

Dr Vanessa Halliday, Senior Lecturer, University of Sheffield

Professor Christopher McDermott, Professor of Translational Neurology, University of Sheffield

We would like to invite you to take part in our research study, coordinated by a team at the University of Sheffield. Before you decide if you would like to take part, it is important that you understand why this research is being done and what it would involve for you. We would like to encourage you to read this information sheet in your own time and consider whether you would like to participate in the study. Thank you for reading this.

What is the purpose of this project?

This survey is part of the first work package in a programme of research to develop and test a complex intervention (HighCALs) to achieve a high calorie diet for people living with amyotrophic lateral sclerosis (ALS), also known as motor neurone disease (MND). The aim of this National Institute for Health Research funded programme is to ensure people with MND receive the best diet at the most appropriate time, in the most cost-effective manner.

The specific aim of this study is to investigate the role of healthcare professionals in the nutritional management of people with MND. We would also like to understand what their experiences and opinions are in relation to this aspect of care. The information gathered will inform the development of the HighCALs intervention that will be tested in a future project.

Why have I been invited?

You have been invited to participate in this study as a healthcare professional who may have a role in, or personal experience of, the nutritional needs and management of people with MND.

The survey is open to **any** healthcare professionals who feel able to comment on this topic, including for example, doctors, nurses, dietitians, speech and language therapists, occupational therapists, physiotherapists and care coordinators.

What would my participation involve?

If you decide to take part in the study, you will be asked to complete an online survey consisting of mostly multiple choice questions about your involvement with people with MND. Most of the questions will focus on the nutritional needs and management of this group of patients. The survey is expected to take approximately 15 to 20 minutes. If you are a dietitian you will be asked

a number of additional questions specifically about the nutritional assessment and treatment of patients with MND. We anticipate that these questions will take an additional 10 to 15 minutes to complete.

As part of the survey, you will also be given the opportunity to provide your email address so that the research team can contact you for further information about your response to a specific question in the survey around commissioning of services. Your email address will be collected and stored separately from your survey responses.

Please note that 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/>).

Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. You are free to end your participation at any time before you complete the survey, without needing to give any reason. However, you will not be able to withdraw from the survey after you submit it.

What will happen to the information collected about and from me during the project?

Your personal and study data will be retained for a period of 7 years after the end of the project, following this it will be destroyed. After the project has ended, this information will be stored within the Clinical Trials Research Unit at the University of Sheffield, who are responsible for coordinating the HighCALs research programme. Electronic data will be stored in an access restricted folder in the University's Shared Networked Filestore.

What are the possible benefits and disadvantages of taking part?

We hope that you will find the process beneficial as an opportunity to share your experiences in relation to the nutritional management of people with MND. There are no major disadvantages, other than the time taken to participate. Upon completion of the survey you will have the choice to be entered into a prize draw to win £200 in vouchers. If you wish to take part in the prize draw you will be asked for your email address. This will be collected and stored separately from your survey responses, and will only be kept for as long as is needed to manage the draw.

What if there is a problem?

Any problem should be addressed to the Chief Investigator of the study, Professor Christopher McDermott in the first instance:

Professor Christopher McDermott
Sheffield Institute for Translational Neuroscience
385a Glossop Road
Sheffield
S10 2HQ

If you have any concerns about the conduct of this research, please feel free to contact:

Professor John Brazier
Dean of School of Health and Related Research
Regent Court
30 Regent Street
Sheffield
S1 4DA
Telephone: 0114 2220726
Email: j.e.brazier@sheffield.ac.uk

Will my taking part in the study be kept confidential?

The outcomes of this research may be published externally in a journal, on a website or via a conference presentation. Any details that have the potential to personally identify an individual or organisation will be removed in any work published as a result of this research.

Information you provide about your role and organisation in completing the survey may identify you, but this information will not be shared outside of the research team.

Use of my data

In order to collect and use your personal information as part of this research project, we must have a basis in law to do so. The basis that we are using is that the research is 'a task in the public interest'.

The University of Sheffield is the sponsor for this study based in the United Kingdom. We 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 we are responsible for looking after your information and using it properly. The University of Sheffield will keep identifiable information about you for 7 years after the study has finished, following this it will be destroyed.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order 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 by contacting the HighCALs Programme Manager.

The research team will use your contact details to contact you about the research study, and to oversee the quality of the study. Individuals from the University of Sheffield and regulatory organisations may look at your research records to check the accuracy of the research study. The research team will pass these details to the University of Sheffield along with the information collected from you. The only people in the University of Sheffield who will have access to information that identifies you will be members of the research team or those auditing the data collection process.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer is Anne Cutler and you can contact her at dataprotection@sheffield.ac.uk.

Who is organising and funding the study?

This research is funded by a National Institutes for Health (NIHR) Programme Grant for Applied Research (PGfAR) and organised by the University of Sheffield.

Who has reviewed this project?

The study has been reviewed and approved by an independent NIHR scientific panel, the Health Research Authority (HRA) and the Research Ethics Committee at the School of Health and Related Research, University of Sheffield. If there is any aspect of the project, or your participation that you would like to discuss further, or feel you may need support with, please do not hesitate to get in touch with using the contact details listed below.

Timescale

This stage of the research is planned to take place between September and November 2018.

Further information

We would be very happy to keep you informed about how the project progresses and the conclusions that are reached – you can contact us using the details below.

For further information about the research study, please contact the HighCALs Programme Manager, using the details below:

Daniel Beever

Telephone: 0114 2220820

Email: high.cals@sheffield.ac.uk

Webpage: <https://www.sheffield.ac.uk/scharr/highcals>