[INSERT SITE LOGO]

Participant Information Sheet

A randomised study of nutritional management in patients with Amyotrophic Lateral Sclerosis.

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. Please take time to read the following information carefully and discuss it with others if you wish. 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>

What is the purpose of this study?

The purpose of this study is to test a support package (the 'OptiCALS' intervention) designed to increase energy available to people living with amyotrophic lateral sclerosis (ALS), also known as motor neurone disease.

Little is currently known regarding how food intake affects ALS and there is a lack of guidance for patients and healthcare professionals on weight and nutrition in ALS. Evidence from some small studies suggests that increasing the available energy for nerve cells may make them more resistant to the degenerative process in ALS. This may lead to a slowing down of ALS progression, improving physical function and quality of life for people living with ALS. However, to work out whether this is true, we need to conduct a large randomised controlled trial, where two thirds of participants will get the OptiCALS intervention and one third continue with treatment as usual.

What is the nutritional support package?

The OptiCALS intervention has been designed by a team of MND specialists to help people with ALS receive a tailored, high-energy diet at the most appropriate time, in the most effective manner. The OptiCALS nutritional intervention package is available via an online portal which

includes videos, dietary information, advice and interactive tools designed to assist people with ALS to optimise their nutrition. This will be provided alongside support from a healthcare professional.

Randomisation: In order to conduct a fair test, trial participants will be randomly allocated (like tossing a coin) by a computer to one of the two treatment arms:

1) Standard care, or
2) Standard care with additional active nutritional management using the OptiCALS intervention.

One third of people will be allocated into Group 1, two-thirds into Group 2 and you will be told which group you have been allocated to.

Why have I been invited?

You have been invited to participate in this study as a patient with ALS at [site name]. We would like to involve up to 304 patients in this study across 20 sites in the UK.

What would my participation involve?

Once consented and baseline measures have been collected, you will then be randomly allocated to a treatment arm. Visits will be arranged at a time convenient to you and may take place at your home or remotely, such as via video call, depending on local guidelines and staffing capacity. If you are asked to attend clinic for a visit, this will aim to be at the same time as one of your usual appointments. As well as [site name] staff, University of Sheffield staff will meet with you remotely as part of your visits – this may involve separate appointments. [Site name] and University of Sheffield staff will contact you to organise visits.

University of Sheffield staff will also contact you to organise the delivery of study equipment (to collect study measures) to you at the outset. Your contact details will be shared with a postal / courier company to facilitate the scheduled delivery, and to arrange collection at the end of your involvement. Further deliveries / collections may also be required to replace equipment, e.g. in the event of a faulty device.

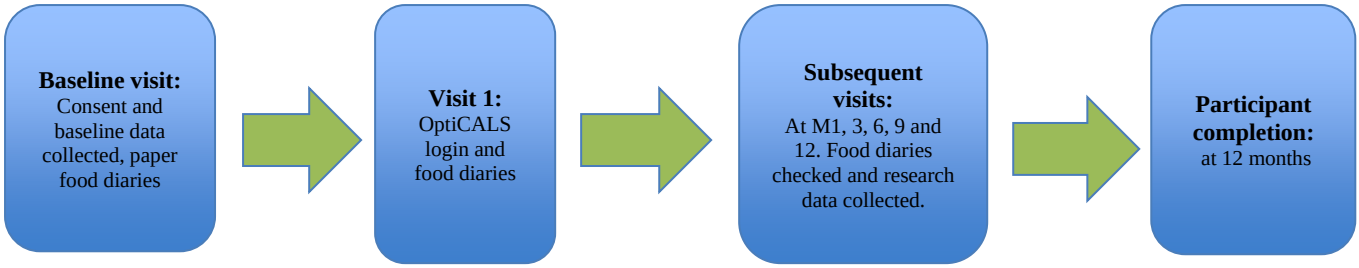
Your participation would last 12 months in total but you can withdraw your consent to participate at any time throughout the study.

<u>Standard care group:</u>

A study visit will be arranged within 1 week of joining the trial. This visit will last approximately 1 hour. During this visit you will be set up with an account on the OptiCALS website and shown how to record food diaries. You will be asked to log your food intake for a minimum of 3 days (2 weekdays and one weekend day) prior to each study visit. Wherever possible, subsequent study visits, during months 1, 3, 6, 9 and 12, will be arranged to coincide with your standard MND clinic visits. These visits will last approximately an hour. During these visits your food diaries will be checked and research data will be collected as follows:

Your **height** will have been measured during your baseline visit. Your **weight** will be measured at each visit using weighing scales, and a measurement of your **arm circumference** will be taken. You will be asked to complete a set of **questionnaires**, which will take around 30 minutes in total. Your **lung function** will be measured using a simple test called spirometry, which requires you to blow into a tube. A **blood test** will also be taken at each visit in order to determine certain measures, such as kidney function. You may experience some discomfort during the blood test.

If it is necessary for study visits to take place remotely, we will ask that you take some measurements, such as weight, at home. If this is required, we will provide you with the necessary equipment and training. If neither a face to face or remote appointment is possible, you may be asked to complete the questionnaires online or return them by post.

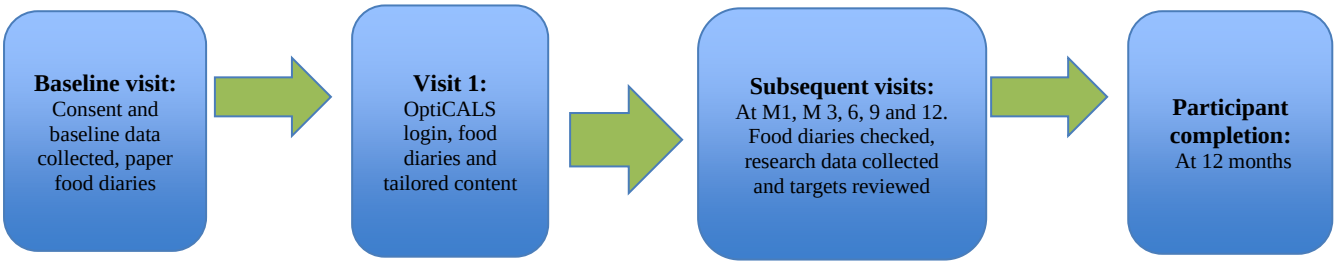


<u>Standard care with OptiCALS intervention:</u>
If you are allocated to the intervention group, you will undergo the same procedures as the standard care group, above. Additionally, you will be given access to the OptiCALS intervention. Your first visit will take around two hours (this may be split), instead of the one hour planned for those in the control group. During this visit the reasoning for the intervention will also be explained to you and, working with the interventionist, you will set a daily calorie target. You will be asked to use OptiCALS at home over a period of 12 months, accessing the materials provided and regularly logging your food intake for a minimum of 3 days (2 week days and one weekend day) prior to each study visit.

During the visits at months 1, 3, 6, 9 and 12 (either in person or remotely, taking into consideration local guidelines), your use of the website materials and targets will be reviewed, and research data will be collected. As OptiCALS is accessible via a website, the research team will be able to see how you have interacted with the support package over the 12 months, e.g. mouse clicks on pages on the website. You will receive a follow up call one month after each visit to review your calorie intake.

Some people will also be invited to participate in optional one-to-one interviews with a researcher – one during the first 3 months and again during the final 6 months so that we can find out more about their experiences of OptiCALS. The interviews will last approximately one hour each and would be completed in person at your home or the local MND care centre, or

remotely, such as over the phone, depending on local guidance and your preference. The interviews would be audio recorded. People who agree to take part and are selected for an interview will be contacted by a researcher at the University of Sheffield who will check whether they still would like to participate and to arrange their first interview.



Data collected	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
Questionnaires	(x4)	(x3)	(x5)	(x4)	(x5)	(x4)
Measure of lung function	x	x	x	x	x	x
Measure arm circumference*	x	x	x	x	x	x
Measure calf circumference	x	x	x	x	x	x
Measure triceps skin fold*	x	x	x	x	x	x
Weight	x	x	x	x	x	x
Height	x					
Blood test* (to monitor safety and understand how other factors may influence ALS) reporting on blood sugar, fats, liver function, kidney function, thyroid function, lactate, neurofilament	x	x	x	x	x	x
Food/drink intake		x	x	x	x	x
Overall survival		x	x	x	x	x

*These will not be collected if you are having a remote visit

What are the possible benefits and disadvantages of taking part?

This study aims to improve nutritional management and health outcomes for people with ALS. By taking part in this study, you will be directly helping us to do this. We also hope that you will find taking part interesting. There are no major disadvantages, other than the time taken to attend study visits and the optional interview.

We understand that you may need to take a break from or leave the interview at any time. We also appreciate that talking about your experiences can be uncomfortable, and we will take the interview at a pace to suit you. Should you become distressed/tired at any point during the interview, the recording/interview will be stopped and only continued with your consent.

Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. You may wish to discuss this information with family, friends, or a healthcare professional before making your decision. You are free to end your participation at any time during the trial by informing a member of the research team. In such circumstances, we will ask you if we can continue to collect routine clinical data from your MND centre for the remainder of the time you would have been involved in the trial, and any data collected up to withdrawal will be used for the analysis, unless specified otherwise. Whether or not you decide to take part, this will not affect the quality of standard care you receive. If you do decide to participate, you will be given this information sheet to keep and a copy of the signed consent form.

You will be given at least 24 hours to decide whether to take part after receiving this information sheet.

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. Contact details are provided at the end of this information sheet.

Alternatively, you can contact the Chief Investigator of the study, Professor Christopher McDermott:
Professor Christopher McDermott
Sheffield Institute for Translational Neuroscience
385a Glossop Road
Sheffield
S10 2HQ
Email: c.j.mcdermott@sheffield.ac.uk

If you remain unhappy and wish to complain formally, you can do this by contacting the local NHS Patient Services Team or Patient Advice and Liaison Service (PALs):
Address: <insert address>; Telephone: <insert phone number>; Email: <insert email>

Expenses and payments
You will not receive any payment for taking part. Travel reimbursement is not expected due to all face-to-face visits occurring in line with standard care clinical visits where possible. However, we will reimburse you for any reasonable travel expenses incurred as part of the study. This includes any additional visits outside of your standard of care and any parking costs incurred for the extended length of stay, due to the additional research procedures. Please note that these expenses would only apply to visits attended in clinic.

Who is organising and funding the study?
This research is funded by a National Institute for Health (NIHR) Programme Grant for Applied Research (PGfAR) and organised by Sheffield Teaching Hospitals NHS Foundation Trust.

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 [insert details here] Research Ethics Committee. 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 the OptiCALS Programme Manager using the contact details listed below.

Timescale
The research started in November 2020 and will continue until October 2026. However, the wider research programme, of which this stage forms part, continues until March 2027, with many of the publications from the research following after this point.

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 OptiCALS Programme Manager, using the details below:

Elaine Scott or Gemma Hackney
Tel 0114 2225158

Study Team Email: opticals@sheffield.ac.uk

What information will be recorded and how will this be used?

<u>OptiCALS website</u>
In setting up an account for you on the website, we will have to store your name and email address. This will also be shared with the myfood24 system where your food diaries will be completed. We will need to keep a record of various pieces of information on the website,

such as your date of birth, height, weight and activity questionnaire details, to enable it to be used effectively. To help see how people use OptiCALS, we will be tracking your use of the website, i.e. what pages you visit and for how long.

The food diary entries submitted on myfood24 will be recorded by their system, and then securely transferred to the OptiCALS website, where this information will also be stored. As such, there will be copies of this information on both systems. All information and data transfers will be encrypted.

For those in the intervention group, further details to help support you to use OptiCALS effectively, will also be stored on the website.

For more details on how your data is stored in myfood24, you can find the privacy policy linked at the bottom of the myfood24 webpage (https://myfood24.org) or email any queries to enquiries@myfood24.org.

The information stored on the website will be accessible to members of the research team. If you are allocated to receive the OptiCALS intervention then you will be given the opportunity to continue using the website (and myfood24) after your participation has finished, until the end of the study. If you choose to continue using the website then your data will continue to be collected as it was during the trial and may be used as part of future analysis.

Similarly, regardless of whether you receive the intervention or standard care, if you continue to use either OptiCALS or myfood24 after your involvement has finished, but before your account is deactivated, this data will be collected as it was during the trial and may be used as part of future analysis.

Interviews / recorded visits

For those people who are in the OptiCALS intervention group who are invited to take part in an interview or to have their study visits recorded, with your permission, these will be audio-recorded using encrypted electronic equipment or may, if taking place remotely, be video recorded using services under contract to the University of Sheffield. Interview recordings will only be available to members of the study team and the support staff within the University of Sheffield and will only be used to allow for the preparation of transcripts. Whilst these transcripts are being prepared, the recordings will be stored in a secure University of Sheffield server. Recorded study visits will also be used to assess that the intervention is being delivered as intended. These recordings will be stored in a secure University of Sheffield server and only members of the study team will have access.

Study data

As part of your involvement in the study, various pieces of study data about you will be produced, such as completed questionnaires. This information will be documented on paper

and also on our study database, hosted within the University of Sheffield. Paper records will be stored at the Clinical Trials Research Unit at the University of Sheffield, and / or [site name], depending on who is undertaking your visits.

ONS provider

Your details including address, date of birth and NHS number may be shared with an approved third party oral nutritional supplement (ONS) provider, for the purpose of allowing home delivery of ONS during the trial (facilitated by a postal / courier company). This information will not be retained once your participation in the study is over.

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 5 years after the end of the project which is planned for March 2027. After the project has ended, this information will be archived in line with the policies of the Clinical Trials Research Unit at the University of Sheffield, who are responsible for coordinating the OptiCALS research programme.

Your data will be pseudonymised wherever possible, using a unique study ID for each participant rather than personal details. The key will be restricted to relevant members of the research team only.

Your blood samples will be destroyed at the end of the research, or where appropriate, stored for future research purposes, in accordance with the Human Tissue Authority's Code of Practice.

What will happen if I decide I no longer want to take part?

You can withdraw from the study at any time; you do not have to give a reason and this will not impact on the medical care you receive during or after the study. Any data collected from you up until the point of withdrawal will be retained and used in the study results. If you do decide that you no longer want to take part, please let your doctor or nurse know. We will keep any information collected up until the point that you stop taking part.

Will my taking part in the study be kept confidential?

All information that is collected about you during the course of this study will be kept strictly confidential and will be held securely in line with the Data Protection Act.

A copy of your signed consent form, which also contains your name, will be emailed or posted to Sheffield CTRU for monitoring and auditing purposes. If you agree to receive information about the trial, including being informed of the results at the end, you will be asked whether you prefer to receive this information by post or email. These contact details will only be accessible by your local research team, and the central study management team at Sheffield Clinical Trials Unit. If you do not wish to receive this information, your contact details will not be shared with anyone outside of your local research team and select members of the

Sheffield CTRU. We will not use your name in any publications that result from this research. With your permission, however, we may use anonymised quotes.

We should point out that if you raise something during the interview discussion that gives rise to a potential safeguarding concern. In such situations the research team is obliged to report this in line with the policies at [site name].

If you wish to make a report of a concern or incident relating to potential exploitation, abuse or harm resulting from your involvement in this project, please contact the project's Designated Safeguarding Contact, through your local PALS team (please see details earlier in this information sheet). If the concern or incident relates to the Designated Safeguarding Contact, or if you feel a report you have made to this Contact has not been handled in a satisfactory way, please contact the Sponsor safeguarding team at Sheffield Teaching Hospitals NHS Foundation Trust at sth.safeguardingadults@nhs.net and/or the University of Sheffield's Research Ethics & Integrity Manager (Lindsay Unwin; l.v.unwin@sheffield.ac.uk).

We will also inform your GP, with your permission, that you are taking part in the study.

Use of my data

Sheffield Teaching Hospitals NHS Foundation Trust (STH) is the sponsor for this study based in the United Kingdom and will act as the data controller for this study. The day to day running of the study is delegated to The University of Sheffield (UoS). Together Sheffield Teaching Hospitals NHS Foundation Trust and The University of Sheffield will be using information from you and your medical records to undertake 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 5 years after the study has finished.

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

You can find out more about how we use your information here: https://www.sheffieldclinicalresearch.org/for-patients-public/how-is-your-information-handled-in-research/ or by contacting the study team (Tel: 0114 222 0820 or Email: opticals@sheffield.ac.uk).

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 / The

Sponsor's Data Protection Officer is Michael Maginnis and you can contact them by phone (0114 2265153) or email (sth.infogov@nhs.net).

[Site name] will collect information from you and your medical records for this research study in accordance with instructions from The University of Sheffield.

[Where the Sponsor is also a site]

The research team and [site name] will use your name and contact details to contact you about the research study, and to oversee the quality of the study. Individuals from Sheffield Teaching Hospitals NHS Foundation Trust, the University of Sheffield and regulatory organisations may look at your research records to check the accuracy of the research study. The [site name] will pass these details to the University of Sheffield, with your consent, 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. [Site name] will keep identifiable information about you from this study for 5 years after the study has finished.

OR

[For all other participating sites]

[Site name] will keep your name and contact details confidential and will not pass this information to Sheffield Teaching Hospitals NHS Foundation Trust and regulatory organisations, although they will share them with the research team at the University of Sheffield with your consent. The research team and [site name] 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. Certain individuals from Sheffield Teaching Hospitals NHS Foundation Trust, the University of Sheffield and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people at 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. [Site name] will keep identifiable information about you from this study for 5 years after the study has finished.