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# A randomised study of nutritional management in patients with amyotrophic lateral sclerosis

**Submission date**
07/12/2020

**Recruitment status**
No longer recruiting

**Registration date**
11/12/2020

**Overall study status**
Ongoing

**Last Edited**
30/12/2025

**Condition category**
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Amyotrophic lateral sclerosis, or ALS, is a progressive nervous system disease that affects nerve cells in the brain and spinal cord, causing loss of muscle control. ALS is often called Lou Gehrig's disease, after the baseball player who was diagnosed with it.
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 small studies suggests better nutrition helps people with ALS live for longer. In light of this, we have designed a web portal called OptiCALS that people with ALS can use. The OptiCALS intervention has been designed to help people with ALS receive the best diet at the most appropriate time, in the most effective manner. The intervention package includes a range of materials including videos, 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. We will test if using OptiCALS helps people with ALS live for longer than those who do not use OptiCALS.
The purpose of this study is to test a support package (the 'OptiCALS' intervention) designed to improve nutritional management for people living with amyotrophic lateral sclerosis (ALS), also known as motor neurone disease.

Who can participate?
Patients diagnosed with Amyotrophic Lateral Sclerosis/Motor neuron disease, within 2.5 years onset of first muscle weakness. Their carers can also participate in qualitative interviews.

What does the study involve?
Participants will be randomly assigned to the control group or the intervention group. The control group will continue to receive their usual care, and be restricted to only completing food diaries on the OptiCALS web portal. They will have subsequent study visits during months 1, 3, 6, 9 and 12 to review their food diaries. During these visits, the participant will have measurements and tests taken.
The intervention group will be shown OptiCALS during their first study visit. Participants will use OptiCALS for 12 months. They will be asked to complete three food diaries before each study visit during months 1, 3, 6, 9 and 12. These visits will be planned around clinic visits or will be planned separately. At each visit, the participant will have measurements and tests taken.
We will also interview 20 participants and their carers to discuss their thoughts on using

OptiCALS. Each interview will last an hour and take place in the participant's home or care setting. These interviews will take place 1-3 months after joining the study and then again at 6-12 months.

What are the possible benefits and risks of participating?
None

Where is the study run from?
1. Sponsor - Sheffield Teaching Hospitals NHS Foundation Trust (UK)
2. The University of Sheffield Clinical Trial Research Unit (day-to-day delegated management)

When is the study starting and how long is it expected to run for?
April 2020 to April 2027

Who is funding the study?
National Institute for Health (NIHR) Programme Grant for Applied Research (PGfAR) (UK)

Who is the main contact?
Elaine Scott, Gemma Hackney, OptiCALS@sheffield.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Ms Elaine Scott

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### Type(s)
Public

### Contact name
Ms Gemma Hackney

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
275949

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
CPMS 46436, IRAS 275949

# Study information

### Scientific Title
OptiCALS: a randomised controlled trial with parallel process evaluation and health economic analysis to evaluate a nutritional management intervention, OptiCALS, for patients with amyotrophic lateral sclerosis

### Acronym
OptiCALS

### Study objectives
A high-calorie diet that meets the estimated calorie requirement, factoring in ALS hypermetabolism and physical status, will improve functional outcomes, quality of life and survival in people with ALS

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 08/09/2020, North West - Greater Manchester East Research Ethics Committee (Health Research Authority, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 797 22545; HRA.Queries@nhs.net), ref: 20/NW/0334

### Study design
Interventional randomized controlled trial

### Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Nutritional management in motor neuron disease

## Interventions
Participants will be randomly assigned to the control group or the intervention group. The control group will continue to receive their usual care, and be restricted to only completing food diaries on the OptiCALS web portal. They will have subsequent study visits during months 1, 3, 6, 9 and 12 to review their food diaries. During these visits, the participant will have measurements and tests taken.

The intervention group will be shown OptiCALS during their first study visit. Participants will use OptiCALS for 12 months. They will be asked to complete three food diaries before each study visit during months 1, 3, 6, 9 and 12. These visits will be planned around clinic visits or will be planned separately. At each visit, the participant will have measurements and tests taken. They will also set targets regarding their food intake. If they are not meeting their targets, they will be given oral nutritional supplements, to help them meet their targets.

We will also interview 20 participants and their carers to discuss their thoughts on using OptiCALS. Each interview will last an hour and take place in the participant's home or care setting. These interviews will take place 1-3 months after joining the study and then again at 6-12 months.

## Intervention Type
Behavioural

## Primary outcome(s)
Daily functional abilities will be assessed using the The Amyotrophic Lateral Sclerosis Rating Scale (ALSFRSR), a validated rating scale. This will be assessed at baseline, month1, 3, 6, 9 and 12

## Key secondary outcome(s))
1.CAFS, calculated using survival and ALSFRSR scores, at baseline, month 1, 3, 6, 9 and 12
2. Quality of life via WHOQOL-BREF questionnaire at baseline, month 1, 3, 6, 9 and 12
3. Health status via EQ-5D-3L questionnaire at baseline, month 1, 3, 6, 9 and 12
4. Total calorie intake using food diaries at week 1, month 1, 3, 6, 9 and 12
5. Healthcare resource use questionnaire at baseline, month 3, 6, 9 and 12
6. Adverse events at month 1, 3, 6, 9 and 12
7. Slow vital capacity / FEV6 using spirometer at baseline, month 1, 3, 6, 9 and 12
8. Mid arm circumference at baseline, month 1, 3, 6, 9 and 12
9. Triceps skin fold thickness at baseline, month 1, 3, 6, 9 and 12
10. Calf circumference at baseline, month 1, 3, 6, 9 and 12
11. Weight measured at baseline, month 1, 3, 6, 9 and 12
12. Height measured at baseline, month 1, 3, 6, 9 and 12
13. Acceptability of intervention questionnaire at months 3 and 12
14. Overall survival at months 1, 3, 6, 9, 12 and last patient/last visit
15. Fasting lipids via blood sample at baseline, month 1,3,6,9 and 12
16. Albumin via blood sample at baseline, month 1,3,6,9 and 12
17. Lactate via blood sample at baseline, month 1,3,6,9 and 12
18. Renal function via blood sample at baseline, month 1,3,6,9 and 12

19. Creatinine via blood sample at baseline, month 1,3,6,9 and 12
20. C-reactive protein via blood sample at baseline, month 1,3,6,9 and 12
21. Neurofilament serum via blood sample at baseline, months 6 and 12
22. HbA1c via blood sample at baseline, month 1,3,6,9 and 12
23. Thyroid function via blood sample at baseline

### Completion date
01/04/2027

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 04/06/2024:
1. Age 18 years or older
2. Diagnosis of clinically definite, lab supported, clinically probable, or possible ALS by the Gold Coast criteria and additionally the PMA variant where appropriate investigation has excluded mimics of motor neuron disease
3. Within 2.5 years of onset of first muscle weakness
4. Stabilised on riluzole for 1 month or not on riluzole

Previous inclusion criteria:
1. Age 18 years or older
2. Diagnosis of clinically definite, lab supported, clinically probable, or possible ALS by the El-Escorial criteria and additionally the PMA variant where appropriate investigation has excluded mimics of motor neuron disease
3. Within 2 years of onset of first muscle weakness
4. Stabilised on riluzole for 1 month or not on riluzole

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
100 years

### Sex
All

### Total final enrolment
172

### Key exclusion criteria

1. Co-morbidity that would affect survival or metabolic state (e.g. unstable thyroid disease or unstable diabetes mellitus)
2. BMI >=35kg/m²
3. Lacking capacity to provide fully informed written consent, verbal consent (for those who cannot provide written consent), or consent via the use of a communication aid.
4. Previous participation in the HighCALS PGfAR research programme
5. Unable to understand written and spoken English
6. Using a gastrostomy tube for feeding (those using a gastrostomy tube for fluid or medication are not excluded)

### Date of first enrolment
15/01/2021

### Date of final enrolment
30/09/2025

## Locations

### Countries of recruitment
United Kingdom

England

Scotland

### Study participating centre
### Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
England
S5 7AU

### Study participating centre
### King's College Hospital
King's College Hospital NHS Foundation Trust
Denmark Hill
London
England
SE5 9RS

### Study participating centre
### Leicestershire and Rutland Hospice (LOROS)
Groby Road
Leicester Road

Leicester
England
LE3 9QE

**Study participating centre**
**The Walton Centre NHS Foundation Trust**
Lower Lane
Liverpool
England
L9 7LJ

**Study participating centre**
**Salford Royal Infirmary**
Salford Royal NHS Foundation Trust
Stott lane
Salford
England
M6 8HD

**Study participating centre**
**John Radcliffe Hopsital**
Oxford University Hospitals NHS Foundation Trust
Headley Way
Oxford
England
OX3 9DU

**Study participating centre**
**Derriford Hospital**
University Hospitals Plymouth NHS Trust
Derriford Road
Crownhill
Plymouth
England
PL6 8DH

**Study participating centre**
**Royal Preston Hospital**
Lancashire Teaching Hospitals NHS Foundation Trust
Sharoe Green Lane North
Fulwood

Preston
England
PR2 9HT

**Study participating centre**
**The James Cook University Hospital**
South Tees Hospitals NHS Foundation Trust
Marton Road
Middlesbrough
England
TS4 3BW

**Study participating centre**
**Royal Stoke University Hospital**
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
England
ST4 6QG

**Study participating centre**
**NHS Tayside**
Kings Cross
Clepington Road
Dundee
Scotland
DD3 8EA

**Study participating centre**
**Dorothy House Hospice Care**
Winsley
Bradford-on-avon
England
BA15 2LE

**Study participating centre**
**Morriston Hospital**
Heol Maes Eglwys
Cwmrhydyceirw

Swansea
Wales
SA6 6NL

**Study participating centre**
**University College London Hospitals NHS Foundation Trust**
250 Euston Road
London
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NW1 2PG

**Study participating centre**
**Hounslow and Richmond Community Healthcare NHS Trust**
Thames House
180-194 High Street
Teddington
England
TW11 8HU

# Sponsor information

**Organisation**
Sheffield Teaching Hospitals NHS Foundation Trust

**ROR**
https://ror.org/018hjpz25

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1016-20006

**Funder Name**
National Institute for Health Research (NIHR) (UK)

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
Data availability statement
Deidentified participant data and statistical code will be made available upon reasonable request. Requests should be made via email to ctru@sheffield.ac.uk, stating the data fields required and the purpose of the request (ideally with a protocol but, at a minimum, with a research plan). The data dictionary and statistical analysis plan can also be made available. Requests will be considered on a case-by-case basis and requestors will be asked to complete a data sharing agreement with the sponsor before data transfer.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 27/05/2025 | 04/06/2025 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Other publications | Process evaluation | 01/09/2025 | 01/09/2025 | Yes | No |
| Participant information sheet | version v3.0 | 15/10/2020 | 11/12/2020 | No | Yes |
| Participant information sheet | version 5.0 | 30/04/2024 | 04/06/2024 | No | Yes |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |