

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

Submission date 07/12/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/12/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/12/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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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, month 1, 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 $\geq 35\text{kg/m}^2$
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 Hospital

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

Morrison Hospital
Heol Maes Eglwys
Cwmrhydyceirw

Swansea
Wales
SA6 6NL

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

Study participating centre
Hounslow and Richmond Community Healthcare NHS Trust
Thames House
180-194 High Street
Teddington
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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
Study website	Study website	11/11/2025	11/11/2025	No	Yes