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

Submission date
07/12/2020

Recruitment status
Recruiting

Registration date
11/12/2020

Overall study status
Ongoing

Last Edited
04/06/2025

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

Study website
https://www.sheffield.ac.uk/scharr/sections/dts/ctru/highcals

Contact information

Type(s)
Public

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Type(s)
Public

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Ms Gemma Hackney

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
275949

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
See study outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
01/04/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 259; UK Sample Size: 259

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
England

Scotland

United Kingdom

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

Study participating centre
King's College Hospital
King's College Hospital NHS Foundation Trust
Denmark Hill

London
United Kingdom
SE5 9RS

Study participating centre
Leicestershire and Rutland Hospice (LOROS)
Groby Road
Leicester Road
Leicester
United Kingdom
LE3 9QE

Study participating centre
The Walton Centre NHS Foundation Trust
Lower Lane
Liverpool
United Kingdom
L9 7LJ

Study participating centre
Salford Royal Infirmary
Salford Royal NHS Foundation Trust
Stott lane
Salford
United Kingdom
M6 8HD

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

Study participating centre
Derriford Hospital
University Hospitals Plymouth NHS Trust
Derriford Road
Crownhill
Plymouth

United Kingdom
PL6 8DH

Study participating centre
Royal Preston Hospital
Lancashire Teaching Hospitals NHS Foundation Trust
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 9HT

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

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

Study participating centre
NHS Tayside
Kings Cross
Clepington Road
Dundee
United Kingdom
DD3 8EA

Study participating centre
Dorothy House Hospice Care
Winsley

Bradford-on-avon
United Kingdom
BA15 2LE

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

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

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

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details
Northern General Hospital
Herries Road
Sheffield
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S5 7AU
+44 (0)114 215 9426
alessia.dunn@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2027

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?
Participant information sheet	version v3.0	15/10/2020	11/12/2020	No	Yes
HRA research summary			28/06/2023	No	No
Participant information sheet	version 5.0	30/04/2024	04/06/2024	No	Yes
Protocol article		27/05/2025	04/06/2025	Yes	No