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HighCALS Study - A programme to develop and test an online resource which aims to help people with Amyotrophic Lateral Sclerosis achieve a high calorie diet

Submission date
19/02/2020

Recruitment status
No longer recruiting

Registration date
27/02/2020

Overall study status
Completed

Last Edited
22/02/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Amyotrophic lateral sclerosis (ALS), also known as motor neuron disease (MND), is a devastating neurodegenerative disorder. People with ALS (pwALS) experience a progressive weakness of limb muscles, as well as loss of speech, chewing and swallowing, and eventually succumb to the consequences of respiratory failure due to respiratory muscle weakness. There is no cure for ALS. Malnutrition and weight loss are well recognised poor prognostic factors in ALS. In pwALS with weight loss of 5% or more there is a two-fold increase in risk of death, compared to those who have lost less than 5% of their usual weight at diagnosis. Current guidelines are not evidence-based and do not include any guidance on nutritional management. Surveys indicate a lack of knowledge in healthcare professions regarding the nutritional management of ALS. The poor evidence base explains the poor nutritional outcomes observed. There is a need to confirm the potential of a high calorie diet to influence the disease course in ALS. This study will aim to understand the barriers and enablers of high calorie nutritional interventions in pwALS and develop a nutritional support package targeting these areas.

Who can participate?
Adults over 18 years, with a 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 neurone disease. Carers and healthcare professionals associated with these patients will also take part.

What does the study involve?
This study will involve two phases – in phase 1, we will undertake interviews with people with ALS and their carers, and focus groups with ALS healthcare professionals, to find out about their views on what promotes or prevents best nutritional practice in ALS. Interviews will be undertaken at patient home, care setting or other agreed location. In phase 2, we will use the information gathered in phase 1, alongside that from others parts of our programme, including surveys and reviews of the literature, to help us develop and test a nutritional support package

for people with ALS. We will interview patients, carers and healthcare professionals to get their opinions on what we have developed, and as we further refine this, they will be given the package to test for themselves.

What are the possible benefits and risks of participating?
There are no major disadvantages, other than the time taken to do the interview. Participants may need to take a break or leave the interview at any time. Discussing the participants experience of ALS may be distressing for them, the research team will signpost participants to appropriate organisations for support if needed. We hope participants will find the process beneficial as an opportunity to reflect on their experiences in relation to nutritional management.

Where is the study run from?
1. Sheffield institute for translational neuroscience (UK)
2. Preston MND Care Centre, Royal Preston Hospital (UK)
3. South Tees Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2019 to September 2020

Who is funding the study?
National Institute of Health Research through their Programme Grants for Applied Research (PGfAR) (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
250732

Protocol serial number
CPMS 39652, IRAS 250732

Study information

Scientific Title
HighCALS intervention development: A qualitative study to develop, refine and assess the acceptability of a complex intervention to increase nutritional intake in people with Amyotrophic Lateral Sclerosis

Acronym
HighCALS

Study objectives
The proposed research described in this protocol forms part of wider programme of work (HighCALS) that seeks to develop and evaluate an intervention to help people living with ALS to achieve a high calorie diet through nutrition behaviours such food fortification and the use of oral nutritional supplements. In line with Medical Research Council guidance on development of complex interventions, the researchers are using a person centred approach to intervention

development. In this protocol, the researchers describe a series of qualitative studies to increase our understanding of the barriers to, and enablers of, nutritional behaviours and interventions to achieve a high calorie diet in ALS from the perspectives of patients, carers and healthcare professionals (Phase 1). On the basis of this information (as well as from systematic reviews) the researchers will develop materials (e.g., advice, tips, guidelines) to be delivered via an online portal that will be used as part of the HighCALS intervention. These materials will then be tested for acceptability and usability through further qualitative studies with patients, carers and healthcare professionals (Phase 2).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/10/2018, North West - Greater Manchester East Research Ethics Committee (Health Research Authority, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, HRA.Queries@nhs.net, 020 797 22545), ref: 18/NW/0638

Study design
Qualitative

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Amyotrophic lateral sclerosis (ALS)

Interventions
This study will involve two phases – in phase 1, we will undertake interviews with people with ALS and their carers, and focus groups with ALS healthcare professionals, to find out about their views on what promotes or prevents best nutritional practice in ALS. Interviews will be undertaken at patient home, care setting or other agreed location. In phase 2, we will use the information gathered in phase 1, alongside that from others parts of our programme, including surveys and reviews of the literature, to help us develop and test a nutritional support package for people with ALS. We will interview patients, carers and healthcare professionals to get their opinions on what we have developed, and as we further refine this, they will be given the package to test for themselves. The nutriotional support package will involve materials (accessible via the online portal and in paper format, if required) designed to help participants meet their calorie requirements, delivered in the form of a personalised strategy. Materials will be informed by behaviour change techniques - for example, information highlighting the link around weight loss and poor outcomes.

Eligible participants will be approached and consented into the study. Participants will attend a study visit, in which they will be introduced to the nutritional support package and how it works. They will then test the package at home over a period of 4 weeks. As the package is accessible via a website, the research team will be able to see how they have interacted with the support package over the 4 weeks, e.g. mouse clicks on certain pages of the website. After 4 weeks, participants will be invited to take part in a face to face interview with a member of the research team. This will last up to an hour and take place either in the participant's home or care setting.

The interview will involve discussing their experience of using the support package. This will mark the end of their participation in the study.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome is to develop materials and strategies, including an online portal, for MDT members and pwALS/carers as part of the HighCALS intervention. To achieve this we will first understand the barriers to, and the enablers of, high calorie nutritional interventions in pwALS from the perspectives of healthcare professionals, patients, and carers via interviews and focus groups. This will generate a list of behavioural targets to address in the HighCALS intervention. User testing will be carried out on the final iteration of the HighCALS intervention using semi-structured interviews with pwALS, their carers and healthcare professionals. As an intervention development study, we will conduct multiple iterative cycles whereby we will gather feedback from a small sample of participants, and use this to refine and update the intervention, before repeating the process with another small sample of participants.

Key secondary outcome(s))
A secondary outcome is to develop a training session for staff to deliver the HighCALS intervention to participants randomised to the intervention group for the future randomised controlled trial.

Completion date
30/09/2020

Eligibility

Key inclusion criteria
Patient inclusion criteria:
1. Aged 18 years or older
2. Capacity to give informed consent
3. 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 neurone disease
4. Clinician judgement has indicated suitability of patient to take part
5. Can understand written / verbal English

Carer inclusion criteria:
6. People are eligible to take part in this study where they are the main (or one of the main) informal carers for the patient, and can understand written / verbal English

HCP inclusion criteria:
7. Healthcare professionals who provide nutritional support to pwALS, including medics, specialist nurses, dietitians, speech and language therapists, physiotherapists, occupational therapists, healthcare assistants and so on
8. Can understand written / verbal English

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
153

Key exclusion criteria
Patient exclusion criteria:
1. Co-morbidity that would affect survival or metabolic state (e.g., unstable thyroid disease or diabetes mellitus).
2. BMI ≥ 35kg/m²

Date of first enrolment
18/11/2019

Date of final enrolment
31/08/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Institute for Translational Neuroscience
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Study participating centre

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Study participating centre
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Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research through their Programme Grants for Applied Research (PGfAR)

Funder Name
National Institute for Health Research

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
The datasets generated during and/or analysed during the current study are not expected to be made available as it is not a clinical trial.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes