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Could a dietetic led supported weight loss programme help people with cystic fibrosis who have excess weight?

Submission date
10/11/2025

Recruitment status
Recruiting

Registration date
25/11/2025

Overall study status
Ongoing

Last Edited
24/08/2026

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
In the UK, 11,000 people are living with cystic fibrosis (CF), a genetic condition that damages their lungs and digestive system. New medications help them improve their health and quality of life and will likely help them live longer. Before these new medications, people with CF often had low body weight and were advised by specialist dietitians to try and gain weight to a target that was linked to better lung health. Since taking these new medications, 4 in 10 people with CF have now significantly exceeded their target weight, which could harm their future health. People with CF are at higher risk of heart disease and cancers than the general population and these may also be linked to excess weight as they get older.As this is a new issue for people with CF, there has been no research on adapted programmes that could help them lose weight. There are concerns about whether weight loss (a) is safe for people with CF, (b) can fit within their complicated treatment plan and, (c) is possible as it is different to the long-held advice for a high-calorie diet. This study aims to test whether it is practical for people with CF to follow a weight loss programme.

Who can participate?
Adult patients living with CF who have excess weight.

What does the study involve?
Patients will receive one-to-one remote support from a specialist dietitian to help them eat less calories and lose weight over 12 weeks and then maintain this weight loss over the next 12 weeks. Individuals will be placed at random in 2 groups: the weight loss programme (20 patients) or routine dietitian care (10 patients). The research team will monitor participants' lung and overall health to ensure their safety. The research team will find out whether there are enough people who are willing to take part, lose weight and complete their follow up assessments. The research team will speak to participants to understand their experiences of the programme. The research team will discuss how participants felt about the study and gather feedback on anything they found easy or difficult to help make changes to the programme. The research team will also speak to clinicians to find out if they would use the programme in day-to-day practice. The research was designed with a group of 4 people living with CF who all wanted to

lose their excess weight. They felt they needed more guidance from their clinical teams to help them lose weight and welcomed this study. They suggested ways to make it easier for people to join the study, stick to the programme, and attend the follow-up assessments. They will continue to be involved in all stages of the research. They will help to interpret the results that will be published in research journals and will work with the CF Trust charity to communicate these to people with CF and health professionals.

What are the possible benefits and risks of participating?
By taking part, participants will help the researchers find out how to help people with CF in the future. Participants in the weight loss programme group may lose weight and this could bring benefits for their health. The standard care group, at the end of the study will be offered a one-off consultation focused on weight loss with a specialist CF dietitian to help them make an action plan if they still want support to reduce your weight. It is not expected that there will side effects from following the intervention but participants will be closely monitored.

Where is the study run from?
Nuffield Department of Primary Care and Health Services, University of Oxford (UK)

When is the study starting and how long is it expected to run for?
January 2026 to January 2030.

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
EASE-CF study team, easecf@phc.ox.ac.uk

Contact information

Type(s)
Scientific, Public

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
334334

Central Portfolio Management System (CPMS)
58557

National Institute for Health and Care Research (NIHR)
304079

Study information

Scientific Title
Weight loss intervention with specialist dietitian behavioural support for people with cystic fibrosis who have excess weight: the EASE-CF randomised controlled feasibility trial.

Acronym
EASE-CF

Study objectives
To assess the feasibility of progression to a definitive randomised controlled trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/11/2025, South Central - Oxford B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8032, 0207 104 8243; oxfordb.rec@hra.nhs.uk), ref: 25/SC/0323

Primary study design
Interventional

Allocation

Randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Parallel

Purpose
Health services research, Supportive care

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity and other hyperalimentation, Metabolic disorders

Interventions
This is a randomised controlled trial to assess the feasibility of progression to a definitive trial that would assess whether the weight loss intervention programme can help people living with cystic fibrosis reduce their excess weight.

The study aims to recruit 30 participants from Cystic Fibrosis centres in NHS Hospitals across England. Participants are expected to be involved in the study for a period of 24 weeks. Study assessments will be conducted at baseline, 4 weeks, 12 weeks and 24 weeks. All study assessments will conducted remotely with the equipment required to perform the measurements provided free of charge and delivered to their home. At baseline and 24 weeks they will be asked to fill in questionnaires remotely (online)and take part in video and audio-recorded video interviews about their experience in the trial and taking part in the intervention. They will be asked to provide consent to be reapproached 6 months after the end of the trial to participate in a follow up interview.

Eligible participants will be randomised into the intervention group (20 participants) or usual care (10 participants) stratified by presence of CF-related diabetes (yes/no) and age over or under or equal to 40 years. Randomisation can be performed following the baseline assessment once all baseline data including blood sample results have been received.
The unique randomisation codes will be generated using a central computer software (Sealed Envelope) which can be accessed by a member of the study team at sites via a secure login.

Once the screening assessment has been completed, if the participant meets the eligibility criteria and is keen to proceed with the study, the participant should be randomised. Queries on eligibility must be resolved before randomisation and participants who do not meet all the eligibility criteria must not be randomised. A member of the local study team will enter the participant details to the randomisation system (initials, participant ID and research site code, confirmation of eligibility, confirmation of completion of baseline assessments, date of informed consent, and stratification factors).

The system will allocate the participant, and the researcher will be informed of the allocation. The researcher will then inform the participant of their allocation. There will be no maximum duration between completion of the screening assessment and randomisation. Allocation concealment is achieved as randomisation occurs after the baseline visit, the randomisation algorithm is unmodifiable and concealed from investigators and the local research teams, and the local research teams have no access to the total number of participants randomised to each group.

The recruiting site will receive notification of a new participant/randomisation via a message from Sealed Envelope. Following randomisation, the research team will send a letter to the participant's GP informing them about trial participation and group allocation.

Structured weight loss programme (intervention)
The intervention is a structured weight loss programme with behavioural support from a specialist cystic fibrosis dietitian.

Participants will be supported to reduce their energy intake to approximately 1200kcal per day with three main eating occasions. Participants will be asked to replace one of their meals with a formula product (shake/porridge/bar provided 7 days a week) which will provide 200kcal/day that conforms to the total diet replacement regulatory guidance regarding its composition, and a second meal with a ready prepared portioned meal that will provide approximately 500kcal and 30-40g protein(this will be provided for 6 days a week). The participant will select the third meal using guidance on portion size and meal ideas provided during the initial consultation with a specialist cystic fibrosis dietitian. On Sundays where they do not receive the ready prepared portioned meal they will select 2 of their own meals on this day but continue with the formula product.

Participants will be advised to drink energy-free fluids (e.g., water, coffee, tea, diet soft drinks) and avoid energy dense drinks (e.g., alcohol, milkshakes, sugar-sweetened beverages) during the programme.

Standard care (control)
Participants will follow the local standard care pathway attending their routine 3 monthly cystic fibrosis appointments where they will see a dietitian as part of their multidisciplinary care. The dietitian may provide advice and support regarding weight management and behavioural changes. To incentivise trial participation, control group participants will be offered a one-off 30 min weight loss consultation at the end of the trial with a specialist CF dietitian.

The study will also involve video and audio-recorded interviews with clinical and research staff about their experience of the trial.

Feasibility of progression to a definitive randomised controlled trial will be judged based on five primary outcome measures.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate per month, assessed using the number of sites open, the total number participants recruited, and the number of participants recruited per site measured using data documented in the study notes at one time point
2. Engagement rate, assessed using the mean proportion of participants who attended 6 or

more sessions during the 24 weeks (25% of sessions) and at least one of the last 3 sessions measured using data documented in the study notes at one time point at the end of the study
3. Adherence rate, assessed using the proportion of intervention participants with ≥5% weight loss at 12 weeks measured using data documented in the study notes at one time point
4. Retention rate, assessed using the proportion of randomised participants completing a 24 week follow up visit measured using data documented in the study notes at one time point
5. Safety profile assessed using related adverse events and expected related and unexpected related serious adverse events measured using data documented in the study notes at one time point

Key secondary outcome(s)
1. Body weight and body composition (weight, fat free mass, and fat mass) measured using scales at home at baseline, 4 , 12 and 24 weeks

2. Health-related quality of life (HRQoL) measured using the EuroQol health questionnaire (EQ-5D-5L) and AWESCORE (CF-specific quality of life score) at baseline and 24 weeks

3. Lung function (forced expiratory volume predicted (FEV1%) and forced vital capacity predicted (FVC %)) measured using home spirometry at baseline, 4 , 12 and 24 weeks

4. Fitness measured using the Sit to Stand Test by observed home measurement at baseline, 4 , 12 and 24 weeks

5. Respiratory exacerbation rate measured using data collected on respiratory exacerbations recorded as adverse events at study duration

6. Blood pressure measured using home blood pressure reading at baseline and 24 weeks

7. Glycaemic control – HbA1c measured using home blood test kit at baseline and 24 weeks

8. Blood lipid profile (Total cholesterol, HDL, LDL, and triglyceride levels) measured using home blood test kit at baseline and 24 weeks using home assessment

9. Adverse events measured using data collected on respiratory exacerbations recorded as adverse events at study duration

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Completion date
01/01/2030

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Established diagnosis of cystic fibrosis, including those who have previously received a lung or liver transplant
3. Forced expiratory volume (FEV1) > = 25% predicted
4. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the trial
5. Able to communicate in English or has a relative/friend/carer acting as interpreter

6. Aged 18 years or above
7. BMI >= 27 kg/m2 (or BMI >= 25 kg/m2 for people of Black, Asian, or minority ethnic origin)

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
0

Key exclusion criteria
1. Female participant who is pregnant, lactating or planning pregnancy during the course of the trial
2. >= 10% self-reported weight loss in the 6 months before the screening visit
3. Documented decompensated liver disease
4. Documented stage 4-5 kidney disease
5. Actively using enteral feeding
6. Currently taking part in other interventional clinical trials, unless agreed in advance by all trial teams (participation in observational studies is allowed)
7. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial

Date of first enrolment
26/01/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

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

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
England
ST4 6QG

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 will be stored in a non-publicly available repository (to be determined following publication of results).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/07/2026	28/07/2026	Yes	No
Protocol file	version 3.0	11/12/2025	26/03/2026	No	No
Statistical Analysis Plan	version 1.0	02/07/2026	24/08/2026	No	No