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The More Life with CF co-design study

Submission date
23/11/2025

Recruitment status
No longer recruiting

Registration date
09/02/2026

Overall study status
Ongoing

Last Edited
10/03/2026

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Cystic fibrosis (CF) is a condition that some people are born with. It causes lung issues, digestive problems and a shorter life expectancy. Because it was hard to gain weight, people living with CF were advised to eat a high-calorie diet. This diet helped people living with CF to become well-nourished and live longer. More recently, some people have now become overweight or obese. This is because new treatments called highly effective modulator therapies (HEMT), e.g. Kaftrio®, Kalydeco®, Symkevi®, which are helping to treat CF, have reduced the need for a high-calorie diet. As a result, people living with CF who are overweight or obese need to have a diet that is lower in calories and be more active. This will help them to manage their weight and prevent the development of other health problems such as heart disease, diabetes and cancer. This study aims to co-design, with people living with CF and CF health care professionals, a CF-specific weight management programme (CF WMP) to support people living with CF and overweight or obesity to eat a healthy diet and become active. The programme will be designed to support people living with CF to adjust to their new diet and activity needs that have resulted from improved health with HEMT. It will be co-designed to be delivered alongside an existing NHS digital weight management programme.

Who can participate?
People living with CF and overweight or obesity, CF Health Care Professionals and weight management professional stakeholders.

What does the study involve?
The Person-Based Approach (PBA) will be used to develop the programme. This approach focuses on developing programmes that are easy to use, helpful and interesting to the people they are designed for, by working with them throughout the design process.
Planning the Programme- a group of 20-30 people living with CF and overweight/obesity on HEMT will be asked to record what they eat, and their activity will be measured using an activity monitor. They will then be interviewed about what influences how they eat and how active they are. CF health care professionals will also be interviewed about their experience of advising people living with CF to eat fewer calories and become more active. The results from these studies will be used to choose what additional content the CF-specific weight management programme needs to provide that is not provided by the NHS digital weight management programme and meet the specific needs of people living with CF and overweight/obesity.
Co-designing the Programme- a group of people living with CF, CF health care professionals and

weight loss experts will work together to design the CF-specific weight management programme. The results of the planning stage and known methods that can help people change their diet and physical activity habits will be shared with the group. The group will decide on what should be included to make the programme easy to use, helpful to people living with CF and overweight/obesity.
Refining the Programme- people living with CF will be asked to provide feedback on the programme. The co-design group will use this feedback to make changes to the programme before it is tested in a future study.

What are the possible benefits and risks of participating?
The possible benefits of taking part in this study are contributing to research that will help design a diet and physical activity programme tailored for people with CF to support weight management.

There are no anticipated risks beyond the potential discomfort of being video recorded during interviews and discussions, which may cause discomfort or possible emotional distress when reflecting on diet, activity, or health behaviours. If this occurs, access to psychological support will be provided.

Where is the study run from?
The study will be conducted at the University of Birmingham and the University Hospitals Birmingham NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
December 2025 to July 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR) under its HEE/NIHR Doctoral Fellowship scheme, UK.

Who is the main contact?
Joanne Barrett, Specialist Cystic Fibrosis Dietitian and NIHR Doctoral Fellow, joanne.barrett2@nhs.net

Contact information

Type(s)
Public, Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
355378

Central Portfolio Management System (CPMS)
68086

National Institute for Health and Care Research (NIHR)
301286

Protocol serial number
RG_25-019

Study information

Scientific Title
The co-design of a cystic fibrosis weight management programme to be delivered alongside an existing NHS digital weight management programme (MoreLife®)

Acronym
ML-CF

Study objectives
This study aims to co-design a CF-specific weight management programme (CF WMP) to be delivered alongside an existing NHS digital weight management programme (MoreLife®).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 12/09/2025, Yorkshire and Humber - Bradford and Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 1048083; bradfordleeds.rec@hrs.nhs.uk), ref: 25/YH/0189

2. Approved 25/07/2024, Northern Ireland Research Ethics Committee (Business Services Organisation Unit 4, Lissue Industrial Estate, West Rathdown Walk, Moira Road, Lisburn, BT28 2RF, United Kingdom; +44 (0)28 9536 1400; info.orecni@hscni.net), ref: 24/NI/0098

Primary study design
Observational

Secondary study design
Qualitative co-design study

Study type(s)
Other

Health condition(s) or problem(s) studied
Adults with cystic fibrosis who are living with overweight or obesity

Interventions
This study aims to co-design, with people living with CF and CF health care professionals - a CF-specific weight management programme (CF WMP) to support people living with CF and overweight or obesity to eat a healthy diet and become more physically active. The programme will be designed to support people living with CF adjust to their new diet and activity needs that have resulted from improved health with Highly Effective Modulator Therapies (HEMT). It will be co-designed to be delivered alongside an existing NHS digital weight management programme.

Co-development process:
The Person-Based Approach (PBA) will be used to develop the programme. This approach focuses on developing programmes that are easy to use, helpful and interesting to the people they are designed for, by working with them throughout the design process.

Planning the programme:
A group of 20-30 people living with CF and overweight/obesity on HEMT will be asked to record what they eat, and their activity will be measured using an activity monitor. They will then be interviewed about what influences how they eat and how active they are. CF health care professionals will also be interviewed about their experience of advising people living with CF to eat fewer calories and become more active. The results from these studies will be used to choose what additional content the CF-specific weight management programme needs to provide that is not provided by the NHS digital weight management programme and meet the specific needs of people living with CF and overweight/obesity.

Co-designing the programme:
A group of people living with CF, CF health care professionals and weight loss experts will work together to design the CF-specific weight management programme. The results of the planning stage and known methods that can help people to change their diet and physical activity habits will be shared with the group. The group will decide on what should be included to make the programme easy to use, helpful to people with living with CF and overweight/obesity.

Refining the programme:
People living with CF will be asked to provide feedback on the programme. The co-design group will use this feedback to make changes to the programme before it is tested.

Intervention Type
Behavioural

Primary outcome(s)
CF-specific weight management programme is co-designed, ready to test in a subsequent feasibility study, measured by the production of a CF weight management prototype at the end of the optimisation stage (stage 3)

Key secondary outcome(s)
1. Key context-specific barriers and facilitators to eating a healthy diet and being physically active experienced by people living with CF and overweight or obesity as qualitative themes and subthemes mapped to COM-B domains during the planning stage (stage 1)
2. Key design objectives that may improve engagement and key intervention features that meet

the design objectives (i.e. to overcome barriers to diet and physical activity behaviour change) summarised into a guiding principle statement during the co-design stage (stage 2)
3. Intervention functions and potential BCTs for the CF WMP identified during co-design work with people living with CF and professional stakeholders in stage 2 and mapped to theoretical constructs

Completion date
01/07/2027

Eligibility

Key inclusion criteria
1. A person with lived experience of CF and overweight or obesity (eligible for participation in co-design workshops and think aloud interviews)
2. A registered Clinical Nurse Specialist, Physiotherapist, Dietitian, Psychologist, or Physician working at a UK adult CF centre or registered Clinical Nurse Specialist, Physiotherapist, Dietitian, Psychologist, or Physician working in adult weight management services(eligible for participation in co-design workshops only)
3. Able to access Zoom© or MS Teams© video conferencing platform (if a co-design group participant)
4. Able to be locate themselves in a private room to take part in the workshops (if a co-design group participant)
5. Over 18 years of age
6. Able to provide informed consent

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Not a registered Clinical Nurse Specialist, Physiotherapist, Dietitian, Psychologist, or Physician working at a UK adult CF centre
2. Not a registered Clinical Nurse Specialist, Physiotherapist, Dietitian, Psychologist, or Physician

working in adult weight management services
3. Not a person living with CF and overweight or obesity

Date of first enrolment
15/01/2026

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Birmingham Heartlands Hospital
Bordesley Green
Birmingham
England
B9 5SS

Study participating centre
The University of Birmingham
School of Sport, Exercise and Rehabilitation Sciences, Edgbaston
Birmingham
England
B15 2TT

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Not defined

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 and analysed during the study will be stored in a publicly available repository https://edata.bham.ac.uk/

IPD sharing plan summary
Stored in publicly available repository