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A study testing a weight management programme for adults with cystic fibrosis

Submission date
17/11/2026

Recruitment status
Not yet recruiting

Registration date
19/11/2026

Overall study status
Ongoing

Last Edited
19/11/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] 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 life-limiting genetic condition that affects the lungs and digestive system. People with CF were encouraged to eat a high-calorie diet because gaining weight was difficult and being well nourished helps them stay healthier. New treatments have now improved their health, but some adults with CF are becoming overweight or obese and they now require support to manage their weight.
This study will test whether it is feasible to deliver a CF-specific digital weight management programme (MoreLife® CF) alongside an NHS digital weight management programme (MoreLife®). We want to understand whether the study design and the MoreLife® CF programme can be delivered in CF services, whether it is more acceptable, useful and interesting to people with CF than the NHS MoreLife® only, and whether a future larger trial would be possible.

Who can participate?
Patients aged 18 years and over with CF who are overweight or obese

What does the study involve?
Participants will be allocated by chance into two groups: one group will receive MoreLife® CF and the other will receive the NHS MoreLife® only. The study will last 16 weeks. Before and after taking part in the programmes, participants will have their height, weight, waist, body composition and handgrip strength measured. They will complete some questionnaires about their wellbeing, knowledge and approach to behaviour change. They will also record what they eat, and wear an activity monitor. At the end of the study, participants and the dietitians who delivered the programmes will be invited to interviews to share their views on taking part and how acceptable and engaging they found the study procedures and the MoreLife® CF programme.

What are the possible benefits and risks of participating?
Taking part in this study may help adults with CF learn new ways to manage their diet, weight and physical activity. It will also provide them with access to useful educational resources about healthy eating and physical activity suitable for adults with CF. Participation in the study will also help researchers improve future weight management support for adults with cystic fibrosis.

Taking part will require time and commitment, and some people may find discussing their experiences or completing study activities emotionally challenging. The programme aims to support healthy weight loss, but any concerns about weight loss, physical and mental health, or wellbeing will be monitored by the participants CF team. Adults with CF who are pregnant are not eligible to participate. Continued participation will be reviewed if they become pregnant during the study.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
March 2027 to March 2028

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

Who is the main contact?
Joanne Barrett, joanne.barrett2@nhs.net

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Central Portfolio Management System (CPMS)
74330

National Institute for Health and Care Research (NIHR)
302884

Study information

Scientific Title

A randomised feasibility study to test a cystic fibrosis specific weight management programme alongside an NHS digital weight management programme (MoreLife®-CF) compared to delivering an NHS digital weight management programme only (MoreLife®) in adults with cystic fibrosis (the MoreLife®-CF feasibility study)

Study objectives
1. To assess the feasibility of the study procedures
2. To assess the feasibility of intervention delivery within adult CF centre care
3. To assess participant engagement with the study procedures
4. To assess participant engagement with MoreLife®-CF intervention
5. To assess participants' and CF healthcare professionals' (HCPs') perceived acceptability of the study procedures
6. To assess participants' and CF HCPs' perceived acceptability of MoreLife®-CF

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cystic fibrosis (CF)

Interventions
This is a non-blinded randomised mixed-methods feasibility study.

Following informed consent, participants will undertake four study visits. At visit 1 pre-intervention data will be collected, at visit 2 participants will be randomised to the intervention or control arm, at visit 3 post-intervention data will be collected, and at visit 4 post-intervention and control study interviews will be conducted.

Study Visit 1 - baseline data collection (week 0, pre-intervention):
Visit 1 will take place at the recruiting NHS study location and the following data will be collected:

Demographic and clinical data:
Data recorded from participants medical notes; participants; age, sex, ethnicity, CF genotype and microbiology, comorbidities, lung function (actual and % predicted Fev1 best within previous 6 months and postcode), household income and employment/education status.

Anthropometric and handgrip data:
Participants will have their weight, height, waist circumference, handgrip strength and body composition measured.

Dietary intake and physical activity data:
1. Food diary: participants will be asked to record their food intake for 7 consecutive days using the MyFood24® smartphone application or paper food diary.
2. Physical activity monitoring: participants will be provided with a wrist worn accelerometer monitor to wear for 7 consecutive days (at the same time of completing the food diary). Participants will be advised to wear the monitor for as many hours as they can each day, ideally for at least 10 hours per day. They can also wear it when they are asleep.

Questionnaires:
Participants complete seven questionnaires:
1. Patient Health Questionnaire 9 (PHQ-9) and Generalized Anxiety Disorder 7 (GAD-7)
2. CF-specific Alfred Wellness Score (AWESCORE)
3. Digital health literacy e-Heals
4. Healthy Eating and Weight Self-Efficacy Scale (HEWSE)
5. A study-specific healthy eating and physical activity knowledge questionnaire
6. A study-specific Theory of Planned Behaviour questionnaire to assess the five core TPB constructs: attitudes towards the behaviour, subjective norms, perceived behavioural control, behavioural intentions, and self-reported behaviour for both healthy eating and physical activity.

Visit 2 – Randomisation, commencement of intervention (week 2):
Randomisation:
Participants will be randomised to the intervention MoreLife®-CF (the CF-specific weight management intervention + the NHS digital weight management intervention MoreLife®) or the control arm (the NHS digital weight management intervention MoreLife®). Both of these programmes will last for 12 weeks.

Intervention arm (MoreLife®-CF):
The intervention (MoreLife®-CF) will comprise a one-on-one consultation with their CF dietitian at the start of the intervention to set personalised goals, an action plan and adjustment plan. These will be reviewed at one-to-one follow-up visits during weeks 4, 8 and 12 of the intervention.

Following the first one-to-one consultation they will be provided with access to the MoreLife®-CF platform and the NHS digital weight management programme MoreLife® via the MoreYou app.

A weekly text message will be sent to each participant during the 12-week intervention from their CF dietitian, and they will be invited to attend online group/peer support sessions.

Control arm (MoreLife®):
Participants will be invited to a one-to-one consultation with a CF dietitian at week 0 of the intervention. Following the first one-to-one consultation they will be provided with access to the NHS digital weight management programme (MoreLife®) via the MoreYou app.

Visit 3 - post intervention data collection (week 13):
All measures undertaken during visit 1 will be repeated at the end of the intervention at the participants recruiting location.

Visit 4 - participant post-intervention interview for intervention and control arm participants (weeks 15):
Online or in person semi-structured interviews will be conducted with both intervention and control participants by the CI and will explore participant's experiences of taking part in the study, including their views on study procedures and methods of data collection, reasons for completion/non-completion of the programme, acceptability and engagement with the MoreLife®-CF intervention, and how it can be improved (intervention participants only).

CF dietitian focus group interviews:
All CF dietitians who have delivered the intervention will be invited to participate in a online focus group to explore their views on methods of study delivery, reasons for completion/non-completion of the programmes by participants, the feasibility of delivering MoreLife® in adult CF centre care and acceptability and engagement with the intervention (MoreLife®-CF) and NHS digital weight management intervention (MoreLife®) by participants. They will also be asked to provide feedback on how MoreLife®-CF could be improved.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility of study procedures:
1.1. Proportion of eligible participants who were recruited and successfully randomised. In those who declined participation, reasons for declining (captured via a decliner questionnaire)
1.2. Proportion of participants who completed the study/did not complete the study and reasons for withdrawal from the study
1.3. Proportion of participants who had demographic, clinical and anthropometric measurements and recorded and questionnaires administered at baseline and follow up

2. Feasibility of intervention delivery:
2.1. Proportion of participants who received intervention components (e.g., were able to access the MoreLife®-CF platform and MoreYou app, one-to-one sessions with CF dietitian, weekly text messages sent out by NHS locations, invitation to online peer group sessions, additional ad hoc support provided by CF dietitian if requested)
2.2. Proportion of intervention components delivered as planned by dietitian at recruiting NHS locations

3. Engagement with the study procedures
3.1. Proportion of patients who attended study visits
3.2. Proportion of participants who adhered to study procedures; completed a food diary (>3 days), completed physical activity monitoring (>4 days >10 hours/day), completed questionnaires and attended for interview

4. Engagement with the intervention (MoreLife®-CF):
4.1. Proportion of participants who completed the programme and did not complete the programme
4.2. Proportion of participants who engaged with the MoreLife®-CF platform and MoreLife® MoreYou app; frequency and number of logins, time spent on platform pages, number of and type of information downloads, activities completed, e.g., smart goals, action planning
4.3. Proportion of participants who self-monitor weight, diet, and physical activity
4.4. Proportion of participants who attended one-to-one CF dietitian consultations
4.5. Proportion of participants who attended online peer group sessions

5. Acceptability of the study procedures:
5.1. Participants' views of the acceptability of the randomisation, the number of study visits and the format of these visits, e.g., in person/virtual, anthropometric measurements, food intake monitoring, physical activity monitoring, and questionnaires administered
5.2. CF dietitians' views of the acceptability of the randomisation process, the number of study visits and the format of these visits, e.g., in person/virtual, anthropometric measurements, food intake monitoring, physical activity monitoring devices and questionnaires, intervention training

6. Acceptability of the intervention (MoreLife®-CF):
6.1. Participants' views and opinions on the acceptability of the MoreLife®-CF platform, resources, and activities
6.2. Participants' views and opinions of CF dietitian support (one-to-one consultations, text message check ins, ad hoc support and online group sessions)
6.3. CF dietitians' views and opinions on the acceptability of delivery and the relevance of MoreLife®-CF in adult CF centre care

Timepoint(s): 12 weeks post commencement of intervention

Key secondary outcome(s)

Measured at weeks 0 and 15:
1. Dietary intake in relation to personalised goals measured by total energy (calorie intake), macronutrient intake as a percentage of energy (protein, fat and carbohydrate), free sugar intake as a percentage of energy, fibre as measured in grams per day and fruit and vegetable intake as measured in portions per day
2. Physical activity measured in relation to personalised goals as measured as time spent sedentary, light, moderate and vigorous activity intensities
3. Weight (kg) and body mass index (kg/m2)
4. Handgrip strength measured in kg
5. Waist circumference measured in cm
6. Body composition measured by percentage fat mass, percentage fat-free mass and fat-free mass index
7. Perceived capabilities, opportunities and motivations
8. Questionnaire scores:
8.1. Depression and anxiety measured using the Patient Health Questionnaire 9 (PHQ-9) and the Generalized Anxiety Disorder 7 (GAD-7) questionnaire
8.2. CF-specific wellness measured using the Alfred Wellness Score (AWESCORE)

8.3. Digital health literacy measured using the Electronic Health Literacy Scale (eHEALS)
8.4. Healthy eating and weight self-efficacy measured using the Healthy Eating and Weight Self-Efficacy (HEWSE) Scale
8.5. Theory of Planned Behaviours constructs attitudes towards the diet and physical activity behaviours, subjective norms (injunctive and descriptive norms), perceived behavioural control, behavioural intentions, and self-reported behaviour for both healthy eating and physical activity

Completion date
31/03/2028

Eligibility

Key inclusion criteria
1. Registered at recruiting site
2. Confirmed diagnosis of CF with genotype
3. Clinically stable (no respiratory exacerbation within previous) 28 days
4. Aged >18 years
5. Body mass index (BMI) >25 kg/m2
6. Prescribed or self-funded GIP-1, GIP dual receptor agonist medications for weight loss or diabetes management, e.g., tirzepatide,semaglutide
7. Digital smartphone and web access
8. Able to give informed consent

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. Pregnant
2. Diagnosis of an eating disorder
3. Currently a hospital inpatient
4. Currently being screened for cystic fibrosis–related diabetes (CFRD) using flash glucose monitoring at time of recruitment
5. Currently receiving treatment for distal intestinal obstruction syndrome (DIOS) or acute constipation at time of recruitment
6. Currently receiving oral or IV antibiotics for respiratory exacerbation at time of recruitment

7. Currently prescribed an increased dose of glucocorticoid (above usual maintenance dose) at time of recruitment

Date of first enrolment
01/03/2027

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
West Midlands Adult Cystic Fibrosis Centre, University Hospitals Birmingham NHS Foundation Trust
Heartlands Hospitals
Bordesley Green East
Birmingham
England
B9 5SS

Study participating centre
Sheffield Adult CF Centre, Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre
Wolfson Cystic Fibrosis Centre, Nottingham University Hospitals NHS Trust
Nottingham City Hospital
St Francis Way
Nottingham
England
NG5 1PF

Study participating centre

Newcastle Adult Cystic Fibrosis Centre, Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
NE1 4LP

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

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 available upon request

IPD sharing plan summary

Available on request