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STUDY PROTOCOL

REVISED Development of a Cystic Fibrosis Weight Management Programme: protocol for a co-design study

[version 2; peer review: 3 approved]

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Abstract

Background

Since the recent introduction of highly effective modulator therapies (HEMT), adults with cystic fibrosis (CF) have experienced significant health improvements. However, HEMTs can also lead to weight gain, and over 30% of adults living with CF, are now overweight or obese. The English National Health Service digital Weight Management Programme (NHS digital WMP) is offered to adults with obesity to support weight loss. This programme may not meet the complex health needs of people living with CF and may not address the established diet and physical activity behaviours that may contribute to weight gain in this population. Methods This paper outlines the steps to co-develop a CF-specific weight management programme (CF WMP), designed to be delivered alongside an NHS digital WMP. The CF-specific programme will be developed in collaboration with people with CF who have overweight or obesity (PwCF$^{ow/ob}$) and professional stakeholders, using the three phases of the Person Based Approach (PBA); planning, co-designing and optimising. Planning Mixed-methods research with PwCF$^{ow/ob}$ and CF health care professionals will identify the barriers and facilitators to healthy eating and physical activity experienced by PwCF$^{ow/ob}$. This will inform the guiding

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principles to underpin the co-design of the CF WMP and how it will address the dietary and physical activity behavioural needs of PwCF $^{ow/ob}$ to ensure it is engaging, acceptable and motivating. Co-design: a series of participatory workshops with PwCF$^{ow/ob}$ and key stakeholders will use guiding principles to specify design objectives and corresponding intervention features. Optimising: think aloud interviews with PwCF$^{ow/ob}$ will gather feedback on the CF WMP, to iteratively refine the programme.

Discussion

The resulting CF WMP will extend the usability of an NHS digital WMP to adults with CF, to better ensure it meets their needs, which have changed since the introduction of HEMT.

Plain English Summary

Cystic Fibrosis (CF) is a condition people are born with. It causes lung issues, digestive problems, and a shorter life expectancy. Historically people with CF struggled to gain weight and followed high-calorie diets to improve health and survival. Since the introduction of highly effective modulator therapies (HEMT) such as Kaftrio®, Kalydeco®, and Symkevi®, many have experienced overweight or obesity. They now require support to manage their weight management and prevent the development of health conditions such as heart disease, diabetes, and cancer.

A CF-specific weight management programme will be co-designed with people living with CF and healthcare professionals to support people with CF and overweight or obesity to adopt healthier diets and become more active. It will be designed to be delivered alongside an existing NHS digital weight management programme.

It will be developed using the Person-Based Approach (PBA) to ensure it is practical, engaging and relevant to people with CF.

20–30 people living with CF and overweight or obesity will record what they eat and wear a device to monitor their physical activity. They will 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 patients to eat a healthy diet and be more active. These results will be used to decide on the content of the CF specific weight management programme.

People living with CF, health care professionals and weight management experts will then work together to design the programme.

Feedback from people with CF, will guide programme refinements before it is tested.

People with CF will co-design the programme, shape its development

and help share the results with the CF and healthcare professional communities.

Keywords
co-design, person-based approach, behaviour change wheel, cystic fibrosis, NHS digital weight management program

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REVISED **Amendments from Version 1**

Across the revised manuscript, several amendments were made to address reviewers' comments and enhance the clarity and contextual grounding of the study.

First, the introduction was expanded to provide a more comprehensive account of the demographic, lifestyle, and clinical factors that may influence weight gain and weight management behaviours in adults with cystic fibrosis (CF). This includes a clearer articulation of how age, sex, socioeconomic status, pancreatic status, disease severity, and long standing CF specific dietary practices may contribute to overweight and obesity. In line with Reviewer 1's feedback, the introduction now also explicitly acknowledges digital exclusion as a potential limitation of digital intervention delivery, while situating this within the broader shift toward remote CF care and NHS digital policy priorities.

Second, the manuscript now provides clearer information on data management, organisation, and governance. A dedicated statement has been added to the Data Availability section, outlining where study materials including protocols, interview guides, and co design documentation and future data sets will be stored and accessed. Further clarification has been provided on how integrated qualitative and quantitative findings from the planning stage will be summarised and presented to the co design team.

Finally, in response to Reviewer 2, the introduction has been strengthened to justify the use of the NHS Digital Weight Management Programme (WMP) alongside a CF specific programme. The revised text explains why adults with CF and overweight may benefit from structured digital weight management support even at lower BMI thresholds, given elevated risks of cardiovascular disease and cystic fibrosis related diabetes. This clarification reinforces the clinical relevance and safety rationale underpinning the intervention design.

Any further responses from the reviewers can be found at the end of the article

Introduction

Cystic fibrosis (CF) is the most common life limiting genetic disease in the UK. It is caused by mutations of the cystic fibrosis trans membrane regulator (CFTR) gene, leading to deficiency or dysfunction of epithelial chloride channels and the production of abnormally thick mucus at the cell surface.[1] This defect predominantly affects the respiratory and gastrointestinal systems leading to frequent respiratory exacerbations and respiratory failure, exocrine pancreatic insufficiency, and gastrointestinal manifestations including liver disease. Other co-morbidities include cystic fibrosis related diabetes (CFD), sub-fertility in women, infertility in men, and osteoporosis.[2]

As a consequence of these clinical manifestations, patients historically had high nutritional requirements, and experienced difficulty achieving a healthy weight. Nutritional management recommended a high fat, high energy diet with pancreatic replacement enzyme therapy (PERT) to minimise malabsorption and maldigestion, prevent malnutrition and promote weight gain.[3] This nutritional management approach aimed to achieve BMI targets of 22kg/m^2 for women and 23kg/m^2 for men, as these are associated with better lung function and improved life expectancy.[4] Following the introduction of highly effective modulator therapies (HEMT), treatments that correct CFTR protein dysfunction, patients have experienced significant health improvements, including improved lung function and weight gain[5–7]). Over 84 % of people living with CF in the UK are receiving HEMT.[8] However, these treatments are associated with an increased prevalence of overweight and obesity. Over 30% of adults with CF are now living with overweight or obesity in the UK. This prevalence has also been observed internationally.[8–11]

The aetiology of weight gain is unclear, although several factors such as a reduction in the frequency of respiratory infections and resting energy expenditure, decreased gut inflammation, and increased fat intake and absorption have been suggested.[12,13] Lifestyle and demograohic factors such as older age, pancreatic status, disease severity and sex are also likely to play a role, as well as diet and physical activity behaviours formed as a consequence of CF management strategies. Specifically, adults with CF may continue to adhere to a high energy diet when no longer necessary, leading to the development of overweight or obesity.[14–17] In addition, levels of moderate-to-vigorous physical activity – which may contribute to maintaining a healthy weight - have been found to be lower in people with CF.[18,19]

HEMT are expected to increase the life expectancy of the CF population; in fact, median survival is now 66 years in the UK.[8] As more of the CF population survive into, and beyond middle age, overweight and obesity, and associated co-morbidities are expected to be more common.[20,21] Behaviour change interventions are now needed to support people living with CF and overweight/obesity to adjust to their new dietary needs with HEMT to support them to adopt healthy eating behaviours, and to become more physically active to manage their weight.

Currently, there are no weight management interventions that meet the specific needs of people with CF who are overweight/obese. Despite an increasing clinical need, published evidence on the dietary intake, physical activity and

their perspectives of weight management of this population remains scarce to inform intervention development.[22–24] Digitally delivered weight management interventions would align with the infection control needs of people living with CF, and the hybrid care model now delivered by many regional adult CF centres.[25]

In the non-CF population, the English NHS digital Weight Management Programme (NHS digital WMP), a 12-week diet and physical activity behaviour change intervention. It is commissioned for adults with obesity and increased risk of cardiovascular disease.[26] This programme has demonstrated effectiveness, with 31% of completers achieving clinically meaningful weight loss of 5% or more.[27] Increased survival associated with HEMT, and the presence of risk factors such as diabetes,chronic inflammation and chronic kidney disease may place people living with CF and overweight or obesity at increased risk of cardiovascular disease.[28] Therefore, although those living with overweight do not meet the NHS digital WMP referral criteria, the programme is appropriate to support management of both overweight and obesity in people living with CF. Digital delivery may introduce potential limitations related to digital exclusion, however, an increasing proportion of CF care is now delivered remotely, and digital models align with the emerging model of CF care and NHS policy plans.[29] However, this programme has not been trialled in the CF population, and may not meet their complex dietary, physical and psychological needs.

In this paper, we describe the co-development of a CF-specific weight management programme (CF WMP) for people living with CF and overweight/obesity (PwCF$^{ow/ob}$). The CF WMP will be co-designed with people living with CF and professional stakeholders. It will be designed to be delivered alongside the existing NHS digital WMP (MoreLife ®), with the intention of providing additional content and support necessary to meet the complex needs of people living with CF.

Protocol

Intervention development framework

A co-design approach will be used to develop a CF specific weight management programme. Co-design is an inclusive approach where individuals with lived experience of CF, stakeholders with clinical practice experience, and behaviour change researchers collaborate to make shared design decisions. It emphasizes a partnership approach to power-sharing, mutual respect for diverse perspectives and knowledge, with the aim of enhancing the relevance, quality and impact of the co-designed product.[30] This collaborative approach involves a range of stakeholders, particularly individuals representing the intervention target population. It is more likely to produce a programme that will be effective at supporting behaviour change and positively impact the health of the target population.[30,31]

The Person Based Approach (PBA) is a co-design methodology, which has been used successfully to develop digital interventions in a range of clinical populations.[32–36] The PBA guides intervention development from an in-depth understanding of the lived experiences, perspectives, and behavioural needs of the target population. It involves iterative qualitative research and patient and public involvement with the target population, including usability testing to inform the co-development process. This informs the formulation of guiding principles to underpin how these behavioural needs will be addressed by the intervention in a way that is acceptable, engaging, relevant and motivating. This is especially critical when designing digital interventions, which are mostly accessed independently, making user acceptability, engagement and usability essential.

Following the PBA, the CF WMP will be developed in 3 stages: planning the programme (stage 1), co-designing the programme (stage 2), and optimising the programme (stage 3)[32] (Figure 1). Below, we outline the co-design protocol and briefly describe how each stage of the PBA will be applied to develop the CF WMP programme. This intention is to provide an overview of the co-design process, following which, the methods for each of the studies conducted within the 3 stages of the PBA, will be described in more depth.

Co-design protocol: application of the PBA to develop a CF WMP

The first stage (planning), will involve undertaking primary mixed-methods research with both PwCF$^{ow/ob}$ and CF health care professionals (HCPs) to identify barriers and facilitators to the desired behaviours (i.e. diet and physical activity). For PwCF$^{ow/ob}$, gaining an in-depth insight into their evolving needs and preferences, and the specific behavioural challenges they encounter regarding their diet and physical activity, will be critical to designing an acceptable, engaging, relevant, and motivating intervention for them. Obtaining insights from HCPs in the planning stage will also ensure that the CF WMP is designed to be feasible to deliver in clinical practice and within the CF model of care (regional specialist centres).

Development of Guiding Principles: data from stage 1 will be used to formulate the "guiding principles" for the intervention, which underpin the co-design process. The guiding principles define how the intervention will address key behavioural issues (identified during stage 1), that are crucial to engagement with the intervention, specify intervention design objectives that may improve engagement, and outline key intervention features (intervention

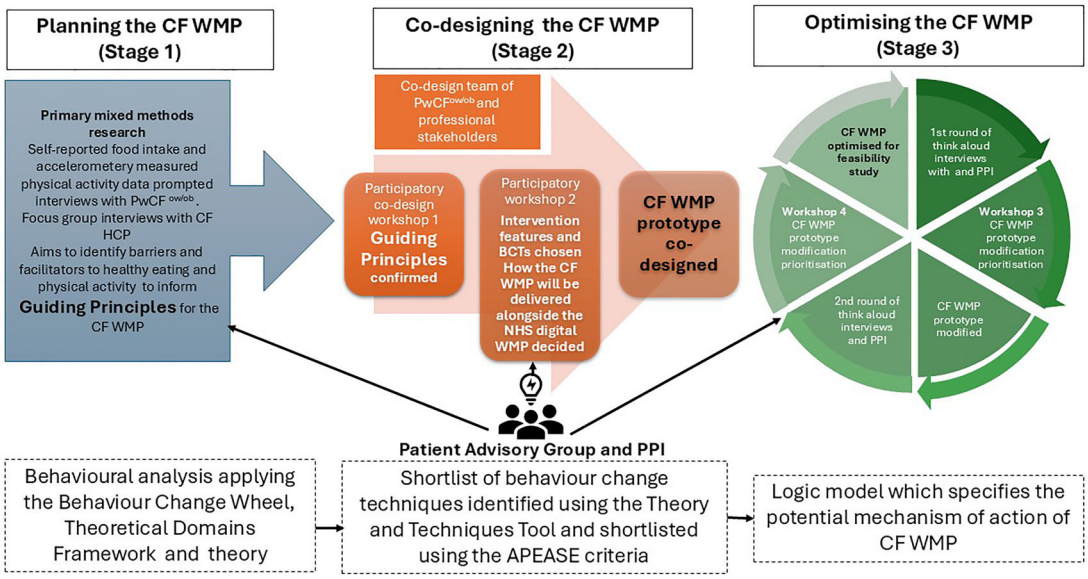


Figure 1. The 3 stages of the co-development of the CF Weight Management Programme (CF WMP).

components) that meet the design objectives. These guiding principles will be iteratively refined throughout the development process, from the findings of ongoing qualitative research and patient and public involvement (PPI) with the target population, to ensure that the intervention continues to meet their specific needs in a way that is acceptable, engaging, relevant and motivating.

Behavioural analysis: during stage 1, a behavioural analysis will also be undertaken, with the aim of specifying intervention content to address the barriers and facilitators to diet and physical activity.[37,38] First, the barriers and facilitators to eating a healthy diet and being physically active will be a mapped to the capability, opportunity and motivation domains of the Behaviour Change Wheel (BCW). The BCW will be used to specify intervention functions that can target the specific barriers and/or facilitators, and then second, to identify possible Behaviour Change Techniques (BCTs) that meet the intervention functions (i.e. that could act as intervention features). In parallel, the barriers, facilitators and COM-B domains will be mapped onto the Theoretical Domains Framework, and the TTaT tool will be used to link BCTs to their mechanism of action. , i.e. to specify the active ingredients of the intervention.

The second stage (co-design) will draw on the data and information gathered during stage 1, to develop the CF WMP prototype. This will be achieved through a series of participatory co-design workshops. Workshops will comprise PwCF$^{ow/ob}$, CF and weight management HCPs, and professionals with experience of developing and delivering NHS digital WMPs. The aim of these workshops will be for the co-design team to (1) confirm and refine the guiding principles, and (2) decide which intervention functions/features and BCTs should be included in the CF WMP, that are likely to be acceptable, engaging, relevant, and motivating to PwCF$^{ow/ob}$.

To guide these decisions, potential intervention functions and BCTs will be appraised and shortlisted using the APEASE criteria (affordability, practicability, effectiveness and cost-effectiveness, acceptability, side-effects/safety and equity) for consideration and inclusion in the CF WMP by the co-design team. A preliminary logic model will be constructed to begin to outline the potential mechanisms of action of the intervention.

In the final stage (optimisation), the co-design team will iteratively refine the CF WMP prototype using think-aloud interviews. The think-aloud interview technique enables feedback on a prototype to be rapidly obtained capturing participants immediate thoughts and reactions as they are observed interacting with a prototype.[39] To optimise the CF WMP, think-aloud interviews will be conducted with PwCF$^{ow/ob}$, to gather their views and opinions of the intervention features and BCTs (focussed on acceptability, engagement, motivation and useability), and inform modification decisions. Participant views and opinions will be tabulated in a "table of changes" and coded according to PBA guidance (e.g. regarding importance, ease of change), to direct and prioritise modifications. The CF WMP prototype (and logic model) will then be iteratively modified through during 2 cycles of think aloud interviews and PPI activities followed by a modification workshop with the co-design team.

Patient and Public Involvement (PPI)

PPI will be integrated throughout the research process, and in the activities employed to co-develop the CF WMP. The PPI plan for this research has been guided by the NIHR INVOLVE National Standards for Public Involvement and developed in collaboration with people living with CF.[40] Prior to obtaining research funding, the views and opinions from the CF community on this research were gathered during online focus groups, face-to-face and telephone interviews. PwCF viewed this research as important to the many who had experienced significant weight gain on HEMT and they welcomed specific weight management support tailored for PwCF. Additionally, consultation with CF HCPs supported this research as a high priority for their clinical practice.[41]

Since securing research funding, two lead research partners representing PwCF$^{ow/ob}$, have been recruited to work with the study team, to develop and refine the research ideas, lead on the delivery of PPI activities, and facilitate co-design activities (e.g. workshops). These lead research partners will also contribute to the dissemination of the research findings to the CF community.

A patient advisory group has also been established, comprising people living with CF who have experienced overweight or obesity. The advisory group will inform the development of study documents, research protocols (including outcome measures), plain English summaries, and co-design activities. They will be used to check the qualitative findings that inform the CF WMP co-design process and provide their views and opinions on the CF WMP prototype as it is developed.

In addition to working with the patient advisory group, PPI activities will also be undertaken with the wider CF community via charity involvement activities and through contact with people receiving care at adult CF centres. This will aim to gather the views and opinions from a diverse range of PwCF$^{ow/ob}$, and those who may have barriers to participating in a patient advisory group.

Methods

Stage 1: Planning

Data-prompted interviews will be conducted with PwCF$^{ow/ob}$, to understand the barriers and facilitators to eating a healthy diet and being physically active. Focus groups with CF HCPs will also be conducted to explore their experiences of delivering diet and physical activity behaviour change to this patient group.

Sampling and recruitment: A purposive sampling technique will be employed to recruit 20–30 PwCF$^{ow/ob}$ to maximise variation in terms of age, sex, disease severity and socioeconomic status from adult CF centres in Birmingham, Nottingham, and Sheffield. To be eligible to participate, individuals must have a confirmed diagnosis of CF with genotype, be clinically stable (no respiratory exacerbation within previous 28 days), 18 years of age or over, BMI >25kg/m^2, and be prescribed HEMT. Those with conditions that may affect usual diet and physical activity behaviours including the diagnosis of an eating disorder, pregnancy,currently undergoing screening for diabetes during study recruitment and participation period (potential participants with a confirmed diagnosis of CF diabetes will be eligible), prescribed an increased dose of glucocortocid (above usual maintainence dose) recieving treatment for acute constipation, distal ileal obstruction syndrome or receiving IV antibiotic therapy for a respiratory exacerbation will not be eligible to participate.

For focus groups, up to 24 CF HCP will be purposively sampled via professional specialist interest groups and social media advertisements. To be eligible to participate, CF HCP must be working as a registered dietitian, physiotherapist, clinical nurse specialist, psychologist or physician at an adult CF centre in the UK.

Interviews with PwCF$^{ow/ob}$: Using a sequential exploratory mixed methods design, data-prompted interviews will be undertaken with PwCF$^{ow/ob}$. Participants will be provided with a wrist-worn accelerometer to wear for 14 days (Actigraph wGT3X-BT[42]), and an app-based food diary to complete for 4 consecutive days (MyFood24 ®[43]). Data from the accelerometer and food diary will be analysed to quantify habitual physical activity and dietary behaviours and summarised into a visual format. These visual summaries will be used as a prompt to guide narratives during a qualitative semi-structured interview. Interviews will explore participants experiences of weight management, contextual influences on dietary choices and physical activity behaviours, and perceptions of diet and physical activity. Their experiences of managing pancreatic enzyme replacement therapy, CF diabetes, supplementary nutritional support and gastrointestinal symptoms will be explored if raised by participants during the interview. They will also be asked to discuss the content and features they would like included in a CF WMP. Lastly, their experience of the data collection techniques used will be explored in preparation for design of a future feasibility study to test the CF WMP. Participants will be interviewed, at their usual CF Centre, in their home or by video-conferencing platform (Zoom® or MS Teams®) and will be audio/audio-video recorded.

Focus groups with CF HCPs: Semi structured focus groups will be delivered online to CF HCPs in groups of 4–6 participants, who work in the same professional discipline. Focus groups will be conducted via a video-conferencing platform (Zoom® or MS Teams®) and will be audio/audio-video recorded. One-to-one virtual interviews will also be conducted with CF HCP who are unable to attend a scheduled focus group interview.

Data analysis

Qualitative Data Analysis: An inductive thematic framework approach will be used to analyse the data. Specifically, to develop codes and categories into themes and subthemes which represent barriers and facilitators to eating a healthy diet and being physically active, experienced by PwCF$^{ow/ob}$.[44]

Quantitative and Qualitative Data Integration: food supplementary nutrition and nutrient intake (mean energy, macronutrient intakes, portions of fruit and vegetables, sugar intake and foods making a significant contribution to macronutrient intakes), physical activity data (mean percentage time spent in sedentary, light, moderately vigorous, vigorous activity levels and daily step count), comparison to healthy eating and physical activity guidelines and CF nutritional guidelines[45–47] and qualitative themes from CF HCP and PwCF$^{ow/ob}$ interviews) will be integrated using joint display analysis.[48,49] Joint display analysis is a technique used to visually integrate qualitative and quantitative data, enabling comparison of how themes are reflected in, or contrast with the findings of a quantitative data set. It will be used to explore perceptions of dietary intake and physical activity among PwCF$^{ow/ob}$ and to examine where these perceptions align with or diverge from their food intake and physical activity behaviours, and the perceptions of CF HCPs.

Development of Guiding Principles: barriers and facilitators identified in focus groups and interviews will be combined with a synthesis of existing evidence to formulate the "guiding principles" for the intervention. The guiding principles will; (1) identify the specific characteristics of PwCF$^{ow/ob}$, that are likely to affect engagement, (2) outline intervention design objectives that may improve engagement (which address the behavioural issues, barriers and facilitators identified in qualitative research), and (3) specify key intervention features (intervention components) that meet the design objectives.

Behavioural analysis: This will be done using the Behaviour Change Wheel – a structured framework and synthesis of 19 behaviour change models that can be used to map barriers and facilitators to sources of behaviours (capabilities, opportunities and motivations).[50] It specifies that three domains must be present for a **B** ehaviour (B) to occur: psychological and physical **C** apability to enact the behaviour (C), social and physical **O** pportunity for the behaviour to occur (O), and sufficient **M** otivation to do the behaviour (autonomous and reflective (M)). The barriers and facilitators to diet and physical activity of PwCF$^{ow/ob}$ will be mapped into each of these domains, to identify intervention functions and Behaviour Change Techniques (BCTs) for the CF WMP, that can target the specific barriers and/or facilitators.

Following this, COM-B domains will be mapped onto the Theoretical Domains framework (TDF), to understand the underlying psychological constructs that may be influencing Capabilities, Opportunities and Motivations of PwCF$^{ow/ob}$ in regard to diet and physical activity behaviours. The TDF is a synthesis of 33 behaviour change theories and evidenced-based constructs grouped into 14 domains that include beliefs about capabilities and consequences, emotions, behavioural regulation and decision-making processes.[38] This will provide the theoretical grounding for the intervention[32,33] – i.e. the intervention functions and BCTs will be directly linked to theoretical constructs, to specify the active ingredients of the intervention. The Medical Research Council framework for complex interventions,[30,51] outlines the importance of developing theory-informed interventions. The Theory and Techniques Tool (TaTT)[52] will also be used alongside the TDF, to identify relevant BCTs that map onto the theoretical constructs underpinning the intervention.

Patient Advisory Group Collaboration and Patient and Public involvement

Findings from interviews with PwCF$^{ow/ob}$ and CF HCP focus groups will be shared and discussed with the patient advisory group to check qualitative themes. PPI activities will also be conducted to gather views and opinions on the challenges of eating a healthy diet and being physically active from the wider CF community. Their opinions will be integrated with the qualitative themes and subthemes from interviews with PwCF$^{ow/ob}$ and CF HCP.

Outcomes

Key outcomes of the planning stage are:

1. Key context specific barriers and facilitators to eating a healthy diet and being physically active experienced by PwCF$^{ow/ob}$

2. Development of the guiding principles – described in a table; (1) key design objectives that may improve engagement and (2) key intervention features that meet the design objectives (i.e. to overcome barriers to diet and physical activity behaviour change)

3. Behavioural analysis - intervention functions and potential BCTs for the CF WMP identified and mapped to theoretical constructs

Stage 2: Co-design

A co-design team of key stakeholders will be established. The co-design team will undertake a series of participatory co-design workshops to develop the CF WMP prototype, informed by the outcomes of stage 1 (planning).

Sampling and recruitment: a purposive sampling technique will be used to recruit 12 participants to the co-design team (PwCF$^{ow/ob}$ and HCPs and professionals involved in the area of CF care and weight management). An equal number of people living with CF and professional stakeholders will be recruited to achieve an equitable balance of power for collaborative working and shared decision-making by the team.[53] Co-design team members who are PwCF$^{ow/ob}$, will be recruited via adult CF centres and CF Charity patient communication e.g. newsletters, websites. Other team members will be recruited via professional groups and social media advertisements.

Participatory co-design workshops: a summary of the integrated qualitative and quantitative findings from the planning stage will be presented to the co-design team. Using these integrated findings, the co-design team will work together to design the CF WMP prototype during 2 participatory workshops (Table 1). The aim of these workshops will be for the co-design team to confirm and refine the guiding principles and decide which intervention features and BCTs should be included in the CF WMP. CF specific safety considerations such as preventing unintended loss of lean muscle mass, monitoring of gastrointestinal symptoms and meeting vitamin and mineral requirement will inform the co-design work to ensure clinical appropriateness. The workshops will be delivered online using a video conferencing platform (Zoom® or MS Teams®), to enable participation from team members located throughout the UK, and to remove the risk of cross-infection among PwCF.

Patients Advisory Group Collaboration and Patient and Public involvement

Views and opinions on the guiding principles and how the CF WMP should be delivered alongside the NHS digital WMP will be gathered from the patient advisory group and people with CF during PPI activities. Their opinions will be presented to the co-design team to inform their co-design work.

Outcomes

1. Confirmation of guiding principles

2. Draft intervention prototype, including confirmation of:

    - intervention functions

    - intervention features, BCTs, and theoretical underpinning

    - delivery format, communication style, and details regarding how the CF WMP should be delivered alongside the NHS digital weight management programme.

3. Preliminary logic model, which specifies the potential mechanisms of action of the intervention.

Stage 3. Optimisation

To optimise the CF WMP, the co-design team will iteratively refine the CF WMP prototype through a series of think-aloud interviews and co-design workshops.

Table 1. Co-design workshop activities.

Stage 2 Co-designing the CF WMP				
Co-design Workshop	**Delivery Method**	**Resources/information provided/ activities**	**Aims and objectives**	**Workshop Outcome**
Pre-workshop 1	Pre-workshop information will be emailed/posted to all co-design team members 2 weeks prior to the first workshop.	Video or written biographies from all team members Short videos and written information that give an overview of what co-design is, an outline the PBA and how these approaches will be used to develop the CF WMP in lay terms. Explain the role of the co-design team and the decisions they will be asked to make. Outline of NHS digital WMP content, structure delivery format and features	Team member introductions Co-design team familiarised with the co-design process and specific elements and process of the PBA. Team members understand the role of the co-design team and the type of decisions they will be asked to make. Familiarised with the NHS digital WMP structure delivery format and features	
Workshop 1	Online facilitated participatory workshop	Team members introductions and ice-breaker activity *'Guiding Principles Table'* presented to the team by the facilitator populated with - guiding principles for the CF WMP - a summary of diet and physical activity behaviours of PwCF $^{ow/ob}$ the CF WMP - key design objectives required to meet their specific needs -present an overview of the NHS digital WMP and how it does not meet needs of PwCF $^{ow/ob}$	Build team relationships and facilitate open discussion and effective group decision making processes Understand the key diet and physical activity behaviours of PwCF $^{ow/ob}$ and how these needs will need to be addressed by the CF WMP (as they are not met by the NHS digital weight management programme – MoreLife®) Reach consensus on key features that the CF WMP should have to be engaging, enjoyable, relevant and motivating to PwCF $^{ow/ob}$ Confirm and refine guiding principles and update guiding principles statement Discuss initial ideas on how the CF WMP should be delivered alongside the NHS digital weight management programme	guiding principles formulated Preliminary ideas on how the CF WMP should be delivered alongside the NHS digital WMP generated

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Table 1. *Continued*

Stage 2 Co-designing the CF WMP				
Co-design Workshop	**Delivery Method**	**Resources/information provided/ activities**	**Aims and objectives**	**Workshop Outcome**
Pre-workshop 2	Pre-workshop information will be emailed/posted to all co-design team members prior to the second workshop.	Information explaining what intervention functions and BCTs are in lay terms.	Understand what intervention function and BCTs are and how these can influence diet and physical activity behaviours	
Workshop 2	Online facilitated participatory workshop	*'Intervention Planning Table'* presented to the team by the facilitator populated with. -barriers and facilitators to eating a healthy diet and being physically active experienced by PwCF $^{ow/ob}$ - the intervention functions required by the CF WMP to address these barriers and facilitators that have been identified from the behavioural analysis - the shortlist of appraised BCTs Present initial ideas from workshop 1 on how the CF WMP should be delivered alongside the NHS digital weight management programme Guiding principles for the CF WMP presented	Understand the barriers and facilitators to eating a healthy diet and being physically active experienced by PwCF $^{ow/ob}$ and the intervention functions and BCTs that will be required to be delivered by the CF WMP to address these Co-design team to decide how the CF WMP should be delivered alongside the NHS digital weight management programme Co-design team review the guiding principles statement and update as required	BCTs and intervention features selected for the CF WMP How the CF WMP will be delivered alongside the NHS WMP decided guiding principle statement updated
CF WMP prototype designed				
CF WMP prototype reviewed by PwCF $^{ow/ob}$ during Think Aloud Interviews and PPI activities				
Stage 3 Optimising the CF WMP				
Workshop 3	Online facilitated participatory workshop	*'Table of changes'* presented to team populated with views and opinions of PwCF $^{ow/ob}$ guiding principles presented	Understand the views and opinions of PwCF $^{ow/ob}$ on CF WMP prototype Team prioritise modifications to the CF WMP prototype using the MoSCoW criteria Co-design team review the guiding principles statement and update as required	CF WMP prototype modifications decisions made guiding principle statement updated

Table 1. *Continued*

Stage 2 Co-designing the CF WMP				
Co-design Workshop	**Delivery Method**	**Resources/information provided/ activities**	**Aims and objectives**	**Workshop Outcome**
CF WMP prototype modified				
CF WMP prototype reviewed by PwCFow/ob Think Aloud Interviews and PPI activities				
Workshop 4	Online facilitated participatory workshop	Summary of previous modifications made to CF WMP presented to the team *'Table of changes'* presented to team populated with views and opinions of PwCF $^{ow/ob}$ guiding principles presented	Familiarise co-design team with modification decisions made in previous workshop Understand the views and opinions of PwCF $^{ow/ob}$ on CF WMP prototype Team prioritise modifications to the CF WMP prototype using the MoSCoW criteria Co-design team review the guiding principles statement and update as required	CF WMP prototype modifications decisions made guiding principles refined
Further modifications to optimise the CF WMP ready for a future feasibility study				

Sampling and recruitment: a purposive sampling technique will be used to recruit 16 PwCF$^{ow/ob}$ for think-aloud interviews. Participants will be recruited via adult CF centres and CF community communication e.g. newsletters, websites. Eligible participants will be 18 years or over and have lived experience of CF and overweight/obesity.

Think-loud interviews; think-aloud interviews will be conducted with 6–8 PwCF$^{ow/ob}$, using the CF WMP prototype. The aim will be to identify any acceptability, engagement, motivational and usability issues with the intervention features, BCTs and delivery format. Participants will be asked to say out loud any thoughts or reactions they have in response to interacting with the CF WMP. Probes and follow up questions will be used to explore their experience of using the programme and suggestions on how it could be modified to improve acceptability and engagement. Interviews will be conducted in person or online via a video conferencing platform (Zoom © or MS Teams ©) and will be audio or video recorded.

Prototype Modification: participant views and opinions gathered from think-aloud interviews and PPI activities, will be tabulated in a "table of changes". Possible modifications will be outlined and coded as; important for behaviour change, consistent with guiding principles, easy to modify within resources available, supported by PPI opinions or the literature, a frequently occurring theme, or no change to be made.

The co-design team will be presented with this "table of changes" during an online workshop, The co-design team will discuss this feedback and prioritise CF WMP modifications using the MoSCoW criteria[54]; **Must have** –essential for the programme to be effective, **Should have** –may directly or indirectly influence programme effectiveness. **Could have** –a useful change if resources allow, **Would like**- not necessary for effectiveness, but may enhance acceptability, engagement, enjoyment, usability, feasibility, if resources allow. A rationale as to why this decision was made will also be documented. Any differences of opinion within the team will be resolved using a triangulation matrix to reach a consensus. The modifications prioritised by the co-design team will then be made to the CF WMP prototype.

The modified CF WMP prototype will then be user tested again, in a second round of think-aloud interviews with a further 6–8 PwCF$^{ow/ob}$ and adjunct PPI activities. The above modification prioritisation process will be repeated during a final co-design workshop. Any remaining modifications that have been identified as being high priority will be made and further think-aloud interviews and refinements conducted where required. After which it will be considered optimised and ready for testing in a subsequent feasibility study. In parallel to modifications, the logic model will be updated to reflect the proposed mechanisms of actions of the intervention.

Patient Advisory Group Collaboration and Patient and Public involvement

Views and opinions on the CF WMP prototype will also be gathered from the patient advisory group during online meetings, and with members of the wider CF community to inform discussions regarding possible modifications.

Outcomes

1. The optimised CF WMP ready to be tested in a feasibility study

2. A logic model which specifies the potential mechanisms of action of the intervention.

Discussion

Since the introduction of HEMT, the prevalence of overweight and obesity has increased in the adult CF population. PwCF$^{ow/ob}$ now need diet and physical activity behaviour change interventions to support them to manage their weight. Although effective NHS digital weight management interventions are available, they may not meet the complex health needs of people living with CF.[27] These complex health needs include person-centred support for pancreatic insufficiency and gastrointestinal issues, CF diabetes and low bone mineral density. Furthermore, existing programmes do not address the pre-HEMT experience of people with CF, particularly the traditional 'legacy' dietary needs, severe disease and limited life expectancy that have shaped diet and physical activity behaviours. These experiences present additional challenges to weight management for individuals who are adjusting to improved health and extended life expectancy.

This study aims to co-design with PwCF$^{ow/ob}$ and professional stakeholders, a theory informed diet and physical activity behaviour change intervention to support people living with CF and overweight/obesity to manage their weight. To our knowledge this will be the first CF-specific weight management programme to be developed for PwCF$^{ow/ob}$.It will be designed to be delivered alongside an existing NHS digital WMP (Morelife®) to extend the usability to people living with CF by meeting their specific and changed dietary needs that have emerged since the advent of HEMT.

Ethical approval
Ethical approval for the planning stage has been granted by the NHS Research Ethics Committee Northern Ireland (24/NI/0098). Ethical approval for the co-design stage and optimisation stage has been granted by Bradford Leeds Research (Yorkshire & The Humber) Research Ethics Committee ((25/YH/0189)) and Health Research Authority.

Sponsorship
These studies are sponsored by the University of Birmingham, Edgbaston, Birmingham, B15 2TT, UK.

Dissemination
Findings from the study will be disseminated via scientific meetings, publications in open access peer-reviewed journals and Researchfish® (https://researchfish.com/). Plain English summaries of the study findings produced by the patient advisory group and Lead Partners will disseminate to the CF community in newsletters, social media posts and websites publications (www.heartlandscf.org).

Data availability
No data are associated with this article.

The protocols, interview guides, co-design workshop documentation and future data sets for this study can be accessed at the University of Birmingham eData repository https://doi.org/10.25500/edata.bham.00001503.

Reporting guidelines
Intervention Taxonomy (ITAX) will be used to describe and report the features, content and delivery methods of CF WMP. Patient and public involvement will be reported in published findings from this research using GRIPP2 reporting guidelines.

Acknowledgements
The authors acknowledge the support of the National Institute for Health and Care Research (NIHR) Research Delivery Network (RDN) for facilitating study set-up, recruitment, and delivery. The authors also would like to thank the National Institute for Health and Care Research (NIHR) for funding this project, and the adult CF centres and future research participants, Mrs Lorna Allen and the Cystic Fibrosis Trust Involvement Group, the More Life with CF Patient Advisory Group and Lead Partners Mrs Jane Bull and Mrs Carly Beale who have and will be contributing to this study. Additionally, our gratitude extends to the members of the study steering committee chaired by Dr Martin Wildman and our collaborators Professor Paul Gately and Dr A B Sirin-Ayva from MoreLife®.

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Open Peer Review

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Version 2

Reviewer Report 26 February 2026

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✔ **Ammar Ahmed**
University of Minnesota School of Medicine, Minneapolis, Minnesota, USA

I have no further comments to make

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Adult cystic fibrosis care, obesity and weight management in CF, cystic fibrosis related diabetes, and metabolic effects of CFTR modulator therapies

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 16 February 2026

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✔ **Kimberly McBennett**
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In this report, Joanne Barrett and colleagues describe a comprehensive, evidence-based protocol to co-create a cystic fibrosis specific weight management programme to complement the NHS

digital WMP.

The authors have appropriately recognized that the forces driving weight gain, overweight and obesity in people with cystic fibrosis are different from those of people without cystic fibrosis. As a result, an effective intervention to reverse these medical conditions will be unique for this population.

For many years, health care providers in cystic fibrosis clinics have defined "healthy food" differently for people with CF, emphasizing a high fat, high calorie diet. As a result, many people with cystic fibrosis have seen this type of food as an important part of their medical regimen, as it served them well before the development of highly effective modulators. For a myriad of reasons described by the authors, this high energy diet may no longer be supporting the health of people with cystic fibrosis. Changing one's daily food choices is difficult for most of the population, and presents an even greater challenge to those living with cystic fibrosis.

The protocol described by the authors creates an opportunity for people living with cystic fibrosis to co-create a weight management programme that addresses the unique needs of those living with cystic fibrosis.

The authors describe a three step approach to planning, co-designing, and optimising the weight management programme. In each stage of the process, authors allow the voices of people with cystic fibrosis, and the health care providers caring for them, to be heard.

In summary, the guiding principles for intervention will be derived through a series of focus groups. Evidence-based models of change including the Behaviour Change Wheel and Behaviour Change Techniques, the Theoretical Domains Framework, and the TTaT tool will be used to inform the co-design group. A series of co-design workshops will be used to develop the CF WMP prototype. Lastly, the co-design team will use think-aloud interviews and workshops to optimise the program before implementation.

This protocol looks promising due to the inclusion of multiple stake holder groups, and the clear delineation of each step of the process.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I am an internal medicine specialist with over 20 years of experience treating adults with cystic fibrosis. I have published reviews about how the challenges facing those living with cystic fibrosis have changed over the years, and I have spoken at the North American Cystic Fibrosis Conference about the increasing incidence of overweight and obesity in people with cystic fibrosis.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 29 January 2026

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Summary :
This protocol describes the development of a cystic fibrosis (CF) specific weight management programme intended to be delivered alongside the NHS Digital Weight Management Programme. The authors propose a structured, theory informed co design methodology using the Person Based Approach and Behaviour Change Wheel across three phases: planning, co design, and optimisation. The stated aim is to ensure that the resulting intervention is acceptable, relevant, and feasible for adults with CF who are overweight or obese in the era of highly effective modulator therapy. The rationale is timely and clinically important, given the changing nutritional and metabolic profile of the adult CF population.

Overall assessment:
This is a well conceived and methodologically sound intervention development protocol. The rationale is clearly articulated, the objectives are appropriate for this stage of research, and the use of iterative co design with people living with CF and CF health care professionals is a major strength. The protocol aligns well with established guidance on the development of complex digital behaviour change interventions and appropriately focuses on acceptability, engagement, and feasibility prior to formal testing [4,5,6].
The comments below are intended to strengthen clarity, reproducibility, and real world implementation, rather than to suggest substantive redesign.
Major points requiring clarification
Alignment with NHS Digital Weight Management Programme eligibility
The protocol states that the CF specific programme will be delivered alongside the NHS Digital Weight Management Programme. However, eligibility for the planning stage includes individuals with BMI greater than 25 kg/m^2. In routine NHS practice, access to the NHS Digital Weight Management Programme is primarily structured around obesity based eligibility criteria. As

written, it is unclear how individuals who are overweight but not obese would interface with the NHS programme during later implementation phases [1].
Clarifying whether the broader BMI range is intentionally used at the development stage to capture early post modulator weight gain, and how eligibility alignment will be handled in future feasibility or implementation studies, would strengthen translational clarity.

Handling of cystic fibrosis related diabetes

Cystic fibrosis related diabetes is highly prevalent in the adult CF population and is directly relevant to dietary modification, physical activity, and weight management. The exclusion criterion referring to participants “undergoing screening for diabetes” is ambiguous and may be interpreted inconsistently across sites. It is also unclear whether individuals with established cystic fibrosis related diabetes are intended to be included [2].
Clarifying this criterion and explicitly stating how cystic fibrosis related diabetes status will be considered in interviews, analysis, and future programme content would strengthen clinical relevance and reproducibility. Acknowledging glycaemic safety considerations within the CF specific context would be appropriate [3].

CF specific safety framing for weight management

Although this is an intervention development study rather than an outcomes trial, weight management in CF requires careful clinical framing due to the historical emphasis on preventing undernutrition and preserving lean mass. Contemporary guidance highlights the need to adapt nutritional care in the modulator era while avoiding unintended harm [3].
Including a short statement outlining how CF specific safety considerations will inform the co design process would improve clinical clarity. Examples include avoiding unintended loss of lean mass, monitoring gastrointestinal tolerance, and maintaining appropriate micronutrient intake.
Minor clarifications that would enhance replicability
The dietary assessment strategy is appropriate, but it would be helpful to briefly state how CF specific factors such as pancreatic enzyme replacement therapy use, oral nutritional supplements, or enteral feeding will be captured or contextualised during dietary analysis and interviews. These factors may materially influence interpretation of dietary intake and perceived behavioural barriers [3].
A short acknowledgement of heterogeneity within the CF population, such as differences in age, disease severity, or socioeconomic context, and how this will be considered during purposive sampling or interpretation of themes, would further strengthen the qualitative methodology.
Aspects not assessed
As this is a protocol paper, I was not able to assess the content of the CF specific weight management programme itself, nor the detailed interview guides, workshop materials, or prototype content referenced in supplementary materials or external repositories. Evaluation of these elements will be important in subsequent publications reporting the outcomes of the co design and optimisation phases.
Conclusion and recommendation
This is a high quality and timely protocol addressing an important and emerging clinical need in adult cystic fibrosis care. The rationale and overall study design are strong. Addressing the targeted clarifications outlined above, particularly regarding alignment with NHS Digital Weight Management Programme eligibility, handling of cystic fibrosis related diabetes, and explicit CF specific safety framing, will further strengthen the scientific and implementation credibility of the work.

Recommendation: To be approved with reservations.

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Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Adult cystic fibrosis care, obesity and weight management in CF, cystic fibrosis related diabetes, and metabolic effects of CFTR modulator therapies

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 04 Feb 2026

Joanne Barrett

Thank you for your detailed and thoughtful review. We appreciate your favourable assessment of the study rationale, methodological approach, and the contribution this work makes to an emerging area of clinical need in adult cystic fibrosis (CF) care. We have carefully considered all points raised and have revised the manuscript to strengthen clarity, reproducibility, and clinical relevance. Please note that there may be a delay in uploading documents outlined below to the edata repository, but this has been request.

1. Alignment with NHS Digital Weight Management Programme eligibility
We agree that clarification was needed regarding the rationale for using an NHS digital weight management programme which is usually only available for people living with obesity. We have expanded the introduction section to explain the justification for using this programme; adults with CF have may be at increased risk of cardiovascular disease and a high prevalence of cystic fibrosis related diabetes (CFRD), even at lower BMI categories. These clinical risk factors justify developing a CF specific weight management programme to be delivered alongside an NHS digital weight management programme for people living with CF who may not meet standard eligibility criteria but may benefit from multi component digital weight management programme, with any safety concerns being minimal.
'In the non-CF population, the English NHS digital Weight Management Programme (NHS digital WMP), a 12-week diet and physical activity behaviour change intervention. It is commissioned for adults with obesity and increased risk of cardiovascular disease (25). This programme has demonstrated effectiveness, with 31 % of completers achieving clinically meaningful weight loss of 5% or more(26). Increased survival associated with HEMT, and the presence of risk factors such as diabetes ,chronic inflammation and chronic kidney disease may place people living with CF and overweight or obesity at increased risk of cardiovascular disease(27). Therefore, although those living with overweight do not meet the NHS digital WMP referral criteria, the programme is appropriate to support management of both overweight and obesity in people living with CF. Digital delivery may introduce potential limitations related to digital exclusion, however, an increasing proportion of CF care is now delivered remotely, and digital models align with the emerging model of CF and NHS care (ref). However, this programme has not been trialled in the CF population, and may not meet their complex dietary, physical and psychological needs.'

The broader BMI threshold (>25 kg/m^2) at the development stage is intentional, reflecting early post-modulator weight gain and the need to capture a wide range of emerging weight-related concerns in adults with CF. As there are no specific BMI categories for CF, but evidence now suggested that body composition is increasingly important in assessing nutritional status as lean body mass is more strongly associated with lung function than BMI. The eligibility study criteria for a future feasibility study of this intervention will need to consider clinical status as well as BMI thresholds that are appropriate for weight management interventions in CF. We agree with the reviewer that it may not be appropriate for some people living with CF and overweight to participate in a weight management programme, this will be part of the safety management of any future feasibility study.
2. Handling of cystic fibrosis–related diabetes
We appreciate the need for clearer wording regarding diabetes related eligibility. The exclusion criterion has been revised to specify that individuals undergoing active screening for diabetes are excluded to avoid confounding during periods of clinical uncertainty. Adults with established CFRD are eligible to participate.
'Those with conditions that may affect usual diet and physical activity behaviours including the diagnosis of an eating disorder, pregnancy, currently undergoing screening for diabetes during study recruitment and participation period (potential participants with a confirmed diagnosis of CF diabetes will be eligible) , prescribed an increased dose of glucocorticoid (above usual maintenance dose) receiving treatment for acute constipation, distal ileal obstruction syndrome or receiving IV antibiotic therapy for a respiratory exacerbation will not be eligible to participate'.

3. CF-specific safety considerations in weight management
In response to your recommendation, we have added a dedicated statement describing how CF specific safety principles will guide the co-design process to ensure clinical appropriateness. This includes explicit consideration of preventing unintended loss of lean muscle mass, monitoring gastrointestinal symptoms and pancreatic enzyme adequacy, and ensuring adequate intake of vitamins and minerals.
'The aim of these workshops will be for the co-design team to confirm and refine the guiding principles and decide which intervention features and BCTs should be included in the CF WMP. CF specific safety considerations such as preventing unintended loss of lean muscle mass, monitoring of gastrointestinal symptoms and meeting vitamin and mineral requirement will inform the co-design work to ensure clinical appropriateness.'
4. CF-specific contextual factors
We have expanded the qualitative interview description to clarify that data on pancreatic enzyme replacement therapy, diabetes, oral nutritional supplement use, and enteral feeding will explored if raised by participants during the semi-structured interview.
'*Interviews will explore participants experiences of weight management, contextual influences on dietary choices and physical activity behaviours, and perceptions of diet and physical activity. Their experiences of managing pancreatic enzyme replacement therapy, CF diabetes, supplementary nutritional support and gastrointestinal symptoms will be explored if raised by participants during the interview.'*
5. Purposive sampling and heterogeneity within the CF population
We have strengthened the sampling description by adding a statement that purposive sampling will maximise variation in age, sex, disease severity, and socioeconomic status to ensure that the co-design process captures the diversity of experiences and needs within the adult CF population.
'Sampling and recruitment: A purposive sampling technique will be employed to recruit 20-30 $PwCF^{ow/ob}$ to maximise variation in terms of age, sex, disease severity and socioeconomic status from adult CF centres in Birmingham, Nottingham, and Sheffield.'
6. Availability of interview guides and supplementary materials
We have now deposited the interview guides in the Birmingham eData repository and added a statement in the manuscript confirming their availability.

Competing Interests: I have no competing interests

Reviewer Report 27 January 2026

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This article describes the protocol for the co-development of a CF specific weight-management programme for adults living with CF and overweight or obesity. A co-design method grounded in the Person-Based Approach and behavioural change theory was outlined by the authors. It is proposed that this programme will be delivered alongside the NHS Digital Weight Management Programme (MoreLife®). Evidence for such a programme is addressed well and outlines the emerging clinical need due to increasing prevalence of overweight and obesity in people with CF arising from wide use of CFTR modulator therapies.

The protocol is detailed and methodologically sound, clearly detailing the three stages of the programme development (planning, co-design, optimisation) with patient and public involvement embedded throughout, alongside mixed-methods research and iterative refinement. As highlighted this is one of the first weight management programmes designed to meet the specific needs of people with CF.

The rationale for this study clearly described and well supported with current, relevant literature. The need for a CF-specific digital programme is justified well considering infection control requirements and hybrid models of care.

The use of the Person-Based Approach, co-design methodology, and established behaviour change frameworks is appropriate and justified well. The staged approach to developing the intervention is logical and transparent.

The inclusion and exclusion criteria are clearly described and justified. Appropriate sampling strategies for both people with CF and healthcare professional are relevant and outlined well. Weight management and digital engagement can be impacted by age, socioeconomic status, disease severity or sex it may be worth clarifying if consideration will be given to any of these factors.

The use of wrist-worn accelerometers, app-based food diaries, qualitative interviews, focus groups, and think-aloud usability testing is appropriate and closely aligned with the aims of the study.

While the approach to data analysis is clearly described, it is less clear how the datasets will be organised, presented and made accessible for use during the co-design process and afterwards. The protocol should therefore address data management and governance.

Overall, the study is well-designed and addresses a significant gap in the care of adults with CF.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Nutritional management of people with cystic fibrosis, qualitative research, complex intervention development.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 04 Feb 2026

Joanne Barrett

Response to Reviewer 1
Thank you for your thorough and constructive review of our manuscript. We appreciate your favourable assessment of the study rationale, methodological approach, and the contribution this work makes to an emerging area of clinical need. We have carefully considered your suggestions and have revised the manuscript accordingly. Please note that there may be a delay in uploading documents outlined below to the edata repository, but this has been request.

1. Consideration of lifestyle and demographic factors
We agree that factors such as age, socioeconomic status, sex, and disease severity may influence weight management behaviours and engagement with digital interventions. To address this, we have expanded the introduction to acknowledge the potential influence of these demographic and lifestyle characteristics on overweight and obesity.
'The aetiology of weight gain is unclear, although several factors such as a reduction in the frequency of respiratory infections and resting energy expenditure, decreased gut inflammation, and increased fat intake and absorption have been suggested (12, 13). Lifestyle and demographic factors such as older age, pancreatic status, disease severity and sex are also likely to play a role, as well as diet and physical activity behaviours formed as a consequence of CF management strategies(11, 14, 15) Specifically, adults with CF may continue to adhere to a high energy diet when no longer necessary, leading to the development of overweight or obesity (16) In addition, levels of moderate-to-vigorous physical activity – which may contribute to maintaining a healthy weight - have been found to be lower in people with CF(17, 18). '
Digital exclusion as a potential limitation has been acknowledged also in the introduction.
'Digital delivery may introduce potential limitations related to digital exclusion; however, an increasing proportion of CF care is now delivered remotely, and digital models align with the emerging model of CF care and NHS policy plans (28). However, this programme has not been trialled in the CF population, and may not meet their complex dietary, physical and psychological needs.'

2. Clarification of data management, organisation, and governance
Thank you for highlighting the need for greater clarity regarding data handling. We have

now added a dedicated statement within the 'data availability' section outlining how datasets generated during the study will be organised and stored. To support the co-design process we have further outlined how a summary of the integrated qualitative and quantitative findings from the planning stage will be presented to the co-design team. We hope this will enhance transparency and support study reproducibility.

'Data Availability

No data are associated with this article. The protocols, interview guides, future co-design workshop documentation and future data sets for this study can be accessed at the University of Birmingham eData repository https://doi.org/10.25500/edata.bham.00001503'

Competing Interests: I have no competing interests