PROTOCOL

Factors that influence diet and physical activity behaviours of adults living with cystic fibrosis who are overweight and on Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapies; a mixed methods study (The More Life with CF Study)

The More Life with CF Study (phase 1)

Protocol version number and date

Protocol version number:	V2.1
Protocol version date:	14/03/25

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Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the CI agrees to adhere to the signed University of Birmingham's sponsorship CI declaration.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the project will be given; and that any discrepancies from the project as planned in this protocol will be explained.

Full project title:	Factors that influence diet and physical activity behaviours of adults living with cystic fibrosis and overweight on Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapies; a mixed methods study (The More Life with CF Study)
Protocol version number:	2.1
Protocol version date:	14/03/25

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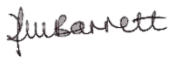
Date:	**14/03/25**
Signature:	

Sponsor statement

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

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Key contacts

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Sponsor	University of Birmingham

Project summary

Project Title	Factors that influence diet and physical activity behaviours of adults living with cystic fibrosis and overweight on Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapies; a mixed methods study (The More Life with CF Study)
Short Title	The More Life with CF Study
Project Design	Mixed Methods
Participants	Adults living with Cystic Fibrosis and Overweight on Cystic Fibrosis Transmembrane Conductance Regulator Modulator (CFTR) Therapies
Planned Recruitment Target	60
Planned Study Period	24 months
Research Aim	This study aims to assess the dietary intake and physical activity of adults living with cystic fibrosis and who are overweight and on Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapies (CFTR). Additionally, it will explore the key context of specific diet and physical activity behavioural issues, experience and perceptions of these in weight management of people living with CF and overweight on CFTR (PwCF+Ow+CFTR)

Funding and support in kind

Funder(s)	Financial and non-financial support given
University of Birmingham, Edgbaston Birmingham, B15 2TT	Sponsor, Supervisory Non-financial support
National Institute for Health and Care Research	Doctoral Fellowship Award funding and financial support

Role of sponsor and funder

University of Birmingham will be the sponsor for this study and will be responsible for the initiation and management of the study.

University of Birmingham will provide supervision for the chief investigator and contribute to the study design, data analysis and interpretation, manuscript writing and dissemination of results.

Roles & responsibilities of management committees/groups & individuals

This study is part of the first stage of a three-stage research project; the MoreLife with CF study which is funded by the NIHR Doctoral Fellowship award scheme. The Chief Investigator for this study, Joanne Barrett, will be supervised by Dr Sally Fenton, Professor Annie Topping, Professor Alice Turner, and Dr Helen White. Overarching supervision for the study will be provided by the MoreLife with CF Steering Group. Their role will be to; monitor study's progress, adherence to the protocol, ensure appropriate ethical and other approvals are obtained, agree proposals for substantial protocol amendments and provide advice to the investigators on all aspects of the study.

Patient & public involvement group

The MoreLife with CF Lead Partners; Mrs Jane Bull and Mrs Carly Beale, and Patient Advisory Group (MCFPAG) are involved in shared decision-making with the Chief Investigator and Supervisory Team. This includes: the study design and methods used, drafting, and editing participant information and online informed consent forms, the development of qualitative interview schedules, verifying qualitative themes, and emerging findings.

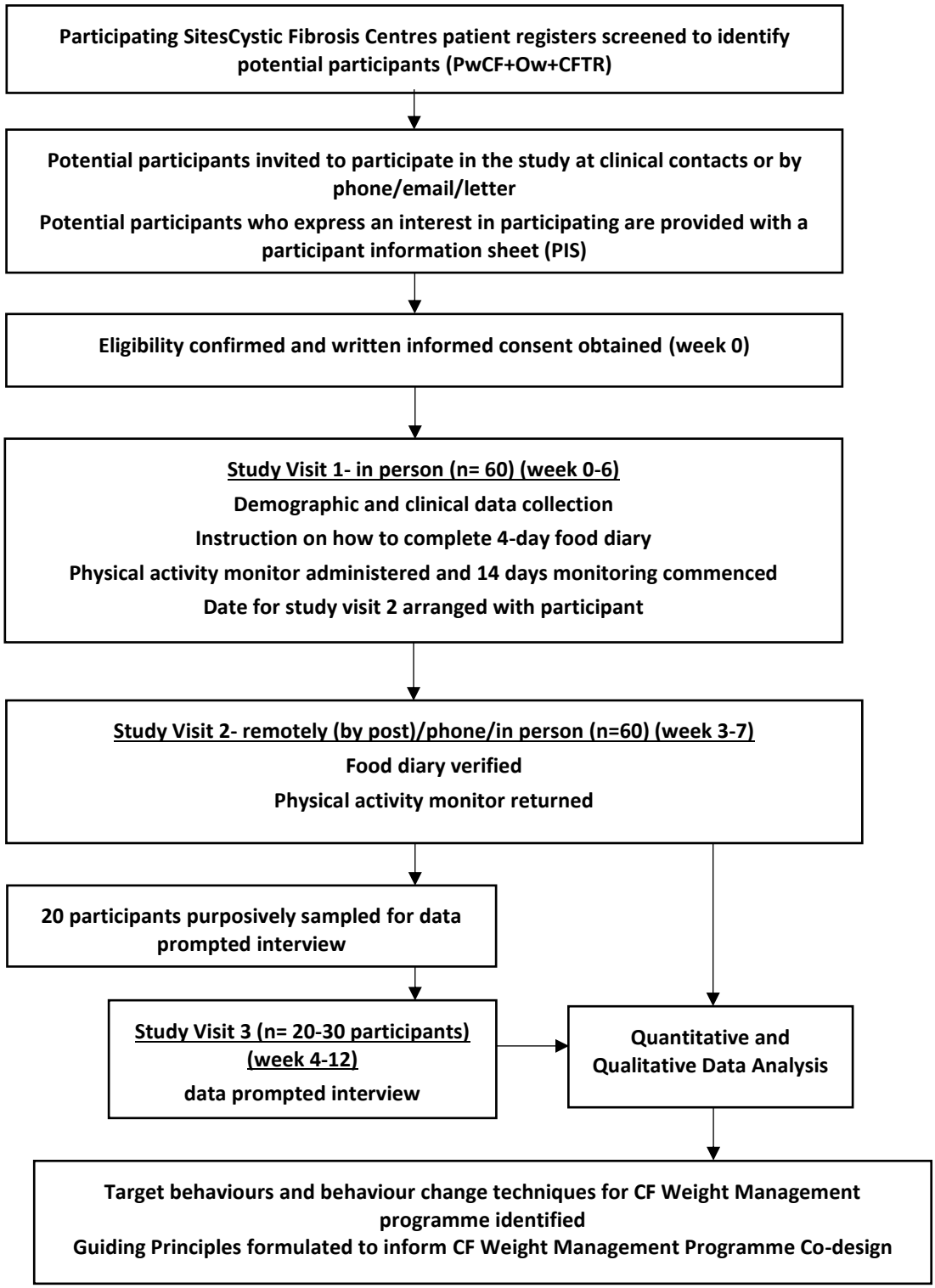
Protocol contributors

This protocol has been written by the Chief investigator Joanne Barrett in collaboration with Dr Sally Fenton University of Birmingham, Professor Annie Topping University of Birmingham, Professor Alice Turner University of Birmingham and University Hospitals Birmingham and Dr Helen White, Leeds Beckett University. The Chief Investigator is registered for a Doctor of Philosophy at the University of Birmingham and they will act as the study CI, and will lead in regards to the study design, data analysis and interpretation, manuscript writing and dissemination of results.

Key words

Cystic Fibrosis, Overweight, Dietary Intake, Accelerometery, Data Prompted Interviews

Project flow chart



Protocol

1. Background

Cystic fibrosis (CF) is the most common life limiting genetic disease in the UK, affecting around 10,000 people(1). It is a complex multisystem disorder caused by dysfunction of the cystic fibrosis transmembrane conductance regulator (CFTR) protein (2). This leads to a defect in epithelial chloride channels at the cell surface and abnormally thick mucus that effects the lungs, digestive system, and other organs. People with CF experience frequent respiratory exacerbations and respiratory failure, pancreatic insufficiency, CF related diabetes (CFRD), liver disease and osteoporosis (3).

Over the last 30 years, advances in treatments have improved health and life expectancy of people living with CF. Median predicted survival is currently 56.1 years(1). In 2012, a new treatment targeting the underlying cause of cystic fibrosis, by correcting CFTR protein dysfunction - CFTR modulator therapy (CFTR) became available(4). This was followed in 2020 with a more effective therapy, elexacaftor/tezacaftor/ivacaftor (ETI (Kaftrio®)(5). This highly effective triple CFTR modulator therapy is significantly improving the health and life expectancy of most people with CF(6). People living with CF are experiencing a reduction in the frequency of respiratory infections, improved lung function and weight gain (7, 8).

Prior to the introduction of CFTR therapy, the nutritional management of CF focused on the prevention of malnutrition and weight gain with a high calorie, high fat diet, pancreatic enzyme therapy to minimise malabsorption due to pancreatic insufficiency, in combination with regular physical activity (PA). Patients were advised to achieve a Body Mass Index (BMI) of 22-23kg/m^2 and undertake 150 minutes per week of moderately vigorous physical activity as this was associated with better lung function (9, 10). Whilst this approach was successful at improving their health and life expectancy, the prevalence of being overweight and obesity increased, with up to 30% of the adult CF population observed to be overweight or obese with lower levels of physical activity than healthy peers (11-16). This prevalence has further increased since the introduction of ETI (17-20). Median BMI of UK adults with CF aged 48 years and over now exceeds 25kg/m^2 in (1).

As more of the CF adult population, treated with CFTR modulator therapy, survive into and beyond middle age, overweight and obesity, and associated co-morbidities are expected to be more common (21). There is limited knowledge about the diet and physical activity behaviour of adults with CF treated with CFTR modulator therapy. It is important to characterise these behaviours, understand what influences them and the barriers and facilitators to having a healthy diet and being physically active. This will help understand how people with CF can be supported to adopt to healthy lifestyle to manage their weight, optimise their health, and reduce their risk of developing obesity and associated co-morbidities.

2. Rationale

This study aims to assess the dietary intake and physical activity of people living with cystic fibrosis and who are overweight and are prescribed CFTR modulator therapy (PwCF+Ow+CFTR). It aims to understand their experiences and perceptions of diet, physical activity, and weight management. The findings from this study will inform the co-design of a person-centred CF specific weight management programme. This programme will be co-designed with people living with CF and who are overweight/obese, CF Health Care Professionals (CF HCP), and behaviour change and obesity experts in collaboration with the Chief Investigator and supervisory team.

Overweight and obesity (Body Mass Index (BMI) > 25kg/m^2), low levels of physical activity and increased amounts of sedentary behaviour are associated with an increased risk of developing non-communicable diseases such as hypertension, cardiovascular disease, diabetes, and cancer in the non-CF population(22, 23). CFTR modulator therapy combined with continuation of a high calorie diet and low levels of physical activity are contributing to more adults with CF becoming overweight or obese. As more people living with CF survive into middle and older age, their risk of developing non-communicable diseases is expected to increase (21). Furthermore, people with CF have lower fat-free mass than age matched controls (24-26), a higher BMI and central and visceral adiposity which are associated with dyslipidaemia, insulin resistance, higher fasting blood glucose levels and chronic inflammation (27-29). This suggests people living with cystic fibrosis and who are overweight are likely to have a similar or increased cardiometabolic risk in comparison to general population(30-32).

In contrast to the non-CF population, people living with CF have been advised to eat a high fat, high calorie diet to gain weight gain since childhood. Healthy lifestyle promotion messaging has not previously been relevant to them. Prior to CFTR modulator therapy, high calorie food choices were perceived as an important strategy for maintaining their health(33). This is reflected in the dietary intakes of adults with CF which have been found to be higher in calories and of lower quality than healthy peers (28, 34).

The aetiology of weight gain with CFTR modulator therapy is still not fully understood. Patients on CFTR modulator therapy have been found to gain weight despite a reduction in calories consumed(35), whilst evidence from singular CFTR therapies (Ivakaftor) suggest weight gain may be due to increased fat intake, improved fat absorption and a reduction in energy requirements(36).

Physical activity is beneficial to the health of people with CF; it is associated with a slower rate of decline in lung function, improved aerobic capacity, reduced hospital admissions, improved quality of life and less fatigue (37-41). Furthermore, exercise can benefit; bone density, body composition, lipid profiles and blood glucose levels of people with CF(42-47). Despite these benefits, most patients with CF are physically inactive, spend long periods of the day sitting (57, 58) and engage in less moderately vigorous physical activity than healthy age matched controls(15, 16, 48).

There is limited published evidence on dietary intake and device-measured physical activity of adults living with CF and who are overweight and are being treated with CFTR modulator therapies. Additionally, their experiences and perceptions of diet, physical activity, and weight management, to our knowledge has not been explored in an adult CF population treated with CFTR modulator therapy. This research will aim to meet this knowledge gap and identify the diet and physical activity behaviours and contextual factors that are contributing to being overweight in people living with CF.

Patient and public involvement activities with patients living with CF and CF HCP have supported this work as an important research topic and an unmet need for people with CF and a high priority for CF HCP to underpin their clinical practice.

3. Theoretical framework

This study will take a pragmatic mixed methods approach to investigate the diet and physical activity behaviours, behavioural influences, experiences and perceptions of diet, physical activity, and weight management of adults living with CF and who are overweight and being treated with CFTR modulator therapy (PwCF+Ow+CFTR)(49, 50). A mixed method approach is suitable for researching this complex issue. This approach using quantitative and qualitative methods has the advantage of drawing on the strengths of each method. An exploratory sequential design will be used, with priority given to the qualitative data; quantitative data collection (food and nutrient intake and physical activity) followed by qualitative data collection (data prompted interviews) used to further understand and explore the contextual factors related to diet and physical activity behaviours(51).

The qualitative phase of this study will take a realist inductive qualitative approach to explore PwCF+Ow+CFTR experiences and perceptions of these issues. This position and a qualitative approach are appropriate for exploring experiences and understanding the reality of PwCF+Ow+CFTR experience of diet, physical activity, and weight management (52). Realism supports the idea that the real world exists independent to an individual's perspective, but that social and physical context influence their beliefs and perspectives(53). It is recognised that the researchers background as an experienced female CF HCP (dietitian), who may also know and be known to participants in her professional capacity may have an influence on interpretation of the results hence the importance of the More Life with CF Patient Advisory Group (MLCFPAG) and supervisors (AT and SF) to contribute to peer debriefing.

The Behaviour Change Wheel (BCW) (54) will be used to map qualitative themes and sub themes to identify and understand the barriers and facilitators to diet and physical activity, key influences on these behaviours and effective behaviour change techniques. The BCW is a theoretical model derived from a synthesis of 19 behaviour change theories. It incorporates the COM-B behaviour change model that proposes there are three components to any behaviour (B): Capability (C), Opportunity (O) and Motivation (M). To perform or change a particular behaviour, there must be the physical and psychological capability to do so, there must be social and physical opportunity for the behaviour and motivation to perform the behaviour.

The integrated findings from this study and a previous study that has identified the barriers and facilitators to CF Health Care Professionals experience in supporting patients with diet and physical activity behaviour

change (55), will be used to inform the development of a specific CF weight management programme using the Person Based Approach (PBA)(56). The PBA uses key contextual behavioural issues identified from mixed methods research, behaviour change theory, and the perspectives of users, to guide design and development of an intervention.

Guiding Principles, a unique component of the PBA, will be formulated. These outline the key context-specific behavioural issues and how the intervention should address these issues with design features that are likely to be attractive, engaging, enjoyable and persuasive the target population. Using these Guiding Principles and the results of these studies, the co-design team will work together to design the programme.

Relevant health behaviour theories will be examined to explain the psychological mechanism of action of the behaviours and a preliminary logic model will be constructed.

We intend to complete co-design workshops in order to help develop and design this intervention. The co-design workshops will be completed as a separate phase of work.

4. Research question/aims

This study aims to assess the dietary intake and physical activity of adults living with cystic fibrosis and who are overweight and on Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapies

(PwCF+Ow+CFTR). Additionally, it will explore key context of specific diet and physical activity behavioural issues, experience, and perceptions of these in weight management of people with PwCF+Ow+CFTR.

4.1. Objectives

In adults living with cystic fibrosis and who are overweight on Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapies (PwCF+Ow+CFTR);

i. To characterise food intake and estimate nutritional intake from self-reported food diaries
ii. To characterise physical activity patterns and assess physical activity level using accelerometery
iii. To explore the diet, physical activity and weight management experiences and perceptions of PwCF+Ow+CFTR
iv. Use the BCW to undertake an inductive analysis to identify the barriers and facilitators of achieving a healthy diet and being physical active and map themes and subthemes to the COM-B model
v. To identify target behaviours for the CF weight management programme
vi. To select evidence-based behaviour change techniques (BCT's) and intervention features for the CF weight programme
vii. Formulate Guiding Principles for the CF weight management programme
viii. Apply relevant health behaviour theories to understand the mechanism of action of the behaviour and construct a preliminary logic model

4.2. Outcomes

i. Identification of the key context specific diet and physical activity behavioural issues experienced by PwCF+Ow+CFTR

ii. Identification of the perceived barriers and facilitators to diet and physical activity mapped to COM-B domains

iii. Identification of target behaviours for the CF specific weight management programme

iv. Identification of evidenced based behaviour change techniques (BCT's) and key features to address diet and physical activity issues identified

v. Guiding Principles formulated to inform how the CF weight management programme should address the key context specific diet and physical activity issues.

vi. Preliminary logic model constructed to begin to understand the mechanism of action of the behaviour

5. Design and methods of data collection and data analysis

This is a sequential exploratory mixed methods study.

5.1.1. Study Visit 1- Base Line Data Collection, Food Diary, and Physical Activity Monitoring (week 0-4)

Following written informed consent to the study, visit 1 will take place in a clinic room in the West Midlands Adult Cystic Fibrosis Centre, University Hospital Birmingham, Heartlands Hospital (WMACFC),Sheffield Adult Cystic Fibrosis Centre, Northern General Hospital, Sheffield (SACFC) North West Midlands Cystic Fibrosis Centre Royal, Stoke University Hospital NHS Trust (NWMCFC) and Wolfson Cystic Fibrosis Centre, Nottingham University Hospital NHS Trust (WCFC).

Each participant will be assigned a study number between 01 - 60 in order of recruitment. Participants and their data will be identified by their study number. A record of study numbers and each participant, name and date of birth will be recorded on the participant identifier log which will kept separate to the site file or saved on a password protected computer server at the recruitment site; University Hospitals Birmingham,Northern General Hospital Sheffield, Royal Stoke University Hospital Nottingham University Hospital NHS Trust and University of Birmingham server.

Demographic and Clinical Data Collection

Demographic and clinical data will be extracted from the electronic medical notes of the participant and recorded in the case report form (CRF see appendix). The CRF will be completed on paper and a copy stored in the site file in a locked office in NHS premises. The CRF data will be transferred to the electronic CRF spreadsheet and this will be saved on an NHS password protected computer server. This will include;

Age, sex, ethnicity, CF genotype and microbiology, prescribed medications including CFTR modulator and dose and start date, co-morbidities, lung function (actual and % predicted Fev1 best within previous 6 months).

Participants will be asked to provide information on their household income and employment/education status. They will be given the option to decline disclosure of their household income and employment/education status.

Anthropometric measurements

The participant will have their weight (in kg) and height (in m) measured following local standard operating procedures (see appendix). Using these values, BMI (kg/m^2) will be calculated and recorded in the CRF.

Body Composition

The participants body composition will be measured following the device measurement protocol. This non-invasive, indirect method measures body composition from resistance (impedance) to the flow of a low-level electrical current passed through the body(57). Fat free mass, fat mass and fat free mass index will be recorded in the CRF.

Assessment of Dietary Intake

The MyFood24®(58) smart phone application will be used to record and analyse participants' food and nutrient intake. Participants will be asked to record their food intake over 4 days including a weekend day using the smart phone application. Four days of self-reported food intake data (including a weekend day) will provide an adequate amount of data to capture participant day to day variation, estimate true mean nutrient intakes, and minimise recording burden (59, 60). This aligns with the methods used by the National Diet and Nutrition Survey (61). MyFood24® meets Best Practice Guidelines for dietary assessment in health research tools, has been validated against dietitian interview-led 24 hour recalls and urinary and plasma biomarkers(62, 63). Food diary applications have been shown to be preferable to participants than conventional methods and

may reduce the potential bias arising from an interview approach (64-66). However, they require access to a mobile phone, the internet and a degree of technological literacy and numeracy. Whilst most people living with cystic fibrosis use mobile phones as part of their daily lives, the option to record dietary intake using a paper food diary will be provided to enable participation from those who do not have access to a mobile phone or are not digitally literate. Alternatively, participants who do not have a smart phone can use a paper food diary (see appendix). Paper food diary data will be entered into the Myfood24 platform by the Chief Investigator after study visit 2.

A contract for providing licensing and access for participants to use the MYFood24 app is in place between Dietary Assessment Ltd (MyFood24) and University of Birmingham.

Food Diary Instruction and App Registration

i. The CI or PI will complete a participant profile within the MyFood24 online platform (name, email address, date of birth and sex) and send the participant an invitation link to download and register the app by email. The participant will be asked to;

I. download the MyFood24 app from the Google Play or Apple App Store
II. to register with the MyFood24 Dietary Assessment Ltd and link their account to the research study account to enable them to share their food diary data
III. to log in to the app using their registration details (email address and password they have chosen)

ii. Participants will be asked to record all food and drinks consumed for 4 days including a weekend day and advised to;

I. record details of foods and beverages consumed at the time of consumption
II. estimate portion sizes as accurately as possible using common unit sizes (e.g., cups of drinks, slices of bread), and use the pictorial guide incorporated into MyFood24
III. how to search for food items, how to choose the most appropriate item that matches the food/drink eaten, how to record homemade meals made from several ingredients and how to use the bar code scanner to search for packaged foods. This Face-to-face training will be supported with MyFood24 instructional videos and information sheets which the participant will also be able to refer to (see appendix).
IV. the purpose of the research and the importance of recording their 'usual' food intake will be explained to the participants to minimise reporting bias. Participants will be advised that they will not be judged on their diet, and they should avoid making dietary changes during the recording period.
V. participants will also be able to contact the CI for additional app support by phone or email.
VI. A date will be agreed with the participant when they will commence recording their food intake. Participants will receive a reminder notification from MyFood24 to complete a food diary for each day. Participants completing a paper diary will receive a text message reminder from CI during the monitoring period in week 1 and 2. MyFood24 dietary target notifications will be turned off to minimise this influencing their food intake e.g., modifying it in response. The participant will be provided with information on how to use the app and links to 'YouTube' videos in their study information booklet (see appendix).
VII. At the end of their participation in the study the participants will be advised to delete the MyFood24 app.

Physical Activity Monitoring

Accelerometery will be used to measure physical activity over 14 days. Physical activity is defined as any bodily movement produced by skeletal muscles resulting in energy expenditure (67). Sedentary behaviour is defined as sitting, reclining, or lying postures, excluding sleep, with energy expenditure of ≤1.5 metabolic equivalents (METs)(68). Accelerometers are electronic devices capable of continuously recording changes (accelerations) in

movement. Triaxial accelerometers measure movement in three axes (directions); X (left to right), Y (forward and backward), and Z (up and down). Data can be analysed to provide an estimate of time spent in different frequencies, intensities, and durations of physical activity. Seven days wear (≥10 waking hours/day) is usually considered a sufficient time to gather data on habitual physical activity patterns (69). Longer wear periods are recommended where adult populations may demonstrate higher variability in levels of physical activity week to week (70). In this study, the measurement time frame will therefore be 14 days of continuous wear (including overnight), to ensure habitual levels of physical activity are reliably captured. Overnight wear also helps to increase compliance, and provides important data on sleep (quantity, efficiency), which is important to understand when investigating physical activity (69).

Participants will be provided with an ActiGraph wGT3X-BT monitor (Actigraph, Pensacola, Florida, USA), either in person at visit 1 or by post from the Chief Investigator following this visit. They will be instructed to wear this on their non dominant wrist for 14 days. The participant will be advised to wear the monitor for at least 10 hours a day up to 24 hours per day. They will be advised that the monitor is not waterproof and they should not wear it whilst swimming, taking a bath or a shower. A date, time and location for study visit 2 will be arranged with the participant (2 weeks' time from study visit 1).The participants GP will be informed of their participation in the study by letter.

5.1.2 Study Visit 2- Verification of Food Diary and Return of Physical Activity Monitor (week 3-7)

Study visit 2 will take place in a mutually convenient time; face to face in a private clinic room at WMACFC, SACFC, NWMCFC, WCFC or in the participants home, alternatively remotely by phone or via a videoconferencing platform using a MS Teams/Zoom© University of Birmingham account via the University of Birmingham secure server. If via videoconferencing participants will be sent an invitation link to the virtual meeting room by email. The link will have a passcode which will only be available to the participant. The option of interviewing via video has been included to facilitate interviews with participants located a considerable distance from their CF centre and throughout the UK. Video interviews will also give more flexibility for interview date and time for those participants who are not available during normal working hours.

If Visit 2 takes place at the participants home, the CI will adhere to University of Birmingham Health and Safety Guidance on Home Visits . The visit will be risk assessed.

i. Food diary Verification

JB will view participants food diary data via the MyFood24 web-based platform and check with the participant that that the correct food type has been entered, portion sizes are accurate and probe if any food items have not been recorded using a checklist (see appendix) and pictorial portion size food Atlas(71). Incorrect or absent entries will be amended by CI in agreement with the participant.

ii. **Physical Activity Monitor**

The physical activity monitor will be returned by the participant. If study visit 2 takes place virtually, they will be asked to either; 1) return the physical activity monitor by post in a pre-paid envelope to the CI/PI at WMACFC/SACFC/NWMCFC/WCFC, 2) JB will arrange to collect from the participants home, or 3) a member of the CF Team will arrange to collect the monitor from the participants home during a scheduled clinical home visit (adhering to university home visit or local lone worker policies). Once the physical activity monitor has been returned by the participant, they will be sent a £10 retail voucher. All participants who take part in the study will be invited to join the co-design team for the next phase of the study by letter which will be sent with the retail voucher.

The participants physical activity data recorded on the ActiGraph wGT3X-BT (Actigraph, Pensacola, Florida), USA) will be downloaded via the Actilife software (using Actilife® software (version 6.2)(72) on a University Hospitals Birmingham password protected computer as soon as possible once the device being returned, not exceeding 2 weeks after being received by the Chief Investigator. Once the data has been downloaded the participant data will be deleted from the device. The device will then be cleaned using disinfectant wipes. Data is linked by participant ID only.

Each participants food diary, eating pattern and physical activity data will be summarised in a visual format to use as a data prompt to stimulate discussion during the semi-structured interviews. A copy of the food diary and physical activity summaries will be entered in the paper and electronic CRF. These will be saved on a University of Birmingham password protected server (see Data Management Plan)

5.1.3 Study Visit 3- data prompted interview (week 4-12)

Semi-structured data-prompted interviews will be used to explore participant experiences and perceptions of diet, physical activity behaviours, and weight management. Using personalised data as a prompt during the interview, can aid an individual's recall of events and decision making and be a more accurate method of retrospective qualitative data collection (73).Semi structured interviews are a qualitative research method that gathers data on personal experiences and views on an issue. An interview structure of open-ended questions, with follow up questions and probes are used to facilitate more in-depth exploration.

Semi-structured data prompted interviews will be conducted with 20 - 30 participants. Interview participants will be selected to maximise variation and has been suggested as sufficient when there is a specific research question(74). Following initial analysis of 20 interviews, if new issues emerge after these interviews, further sampling will be employed for additional participants to take part in data prompted interviews to reach data saturation

Interview Procedure

A mutually convenient date, time and preferred location for interview will be arranged with them; in a private clinic room at WMACFC/SACFC/NWMCFC/WCFC, in the participant's home or by video using a University of Birmingham Zoom© or Microsoft Teams© video conferencing platform account.

If Visit 3 takes place at the participants home, the CI will adhere to University of Birmingham Guidance on Out of Hours Activities and Lone Working.The visit will be risk assessed.

JB will verify ongoing agreement to participate and the participant will have the opportunity to ask any questions. The interview will commence and audio recording will be started using an encrypted voice recorder. If the interview is being conducted by video using the Zoom© video conferencing platform, the interview will only be audio recorded using the platform recording function and the platform transcription facility will be used to record speech to text. If the interview is being conducted by video using Microsoft Teams© video conferencing platform, the interview will be audio and video recorded using the platform recording function and the platform transcription facility will be used to record speech to text A visual summary of the participants food and physical activity data will be used as a prompt with a series of open questions, framed around the study objectives to stimulate the participant to talk about their experiences, perceptions, views, and opinions (see appendix for interview schedule). Probes and follow up questions will be used to explore the topics/views and elicit more detail from the participant. Interviews are estimated to take up to approximately 60 minutes. At the end of the interview the CI will summarise to verify what has been said and thank the participant for attending.

The audio file will be uploaded to Microsoft Word 365 and transcribed using the automated transcription function by Joanne Barrett. Microsoft Word 365 will be accessed through the University of Birmingham secure server. The transcription will be saved on a University of Birmingham server as soon as possible not exceeding 4 weeks and then deleted from the encrypted voice recorder. Transcriptions from the audio recordings will be downloaded from the University of Birmingham Zoom© or Microsoft Teams© video conferencing platform account and saved on a University of Birmingham server as soon as possible not exceeding 4 weeks and then deleted from the platform.

Following initial analysis of the first 20 interviews, the quality of data and depth of themes generated (saturation) will determine if more participant interviews are required.

Interview Questions

The interview guide has been developed from the COM-B model, knowledge gaps identified in the literature, and the background and experience of the research team; Specialist CF Dietitian Joanne Barett – Chief Investigator (CI), qualitative research expert and nurse (Professor Annie Topping), and Associate Professor of lifestyle behaviour change (Dr Sally Fenton) and the MLCFPAG. It aims to stimulate a narrative and exploration of the participant's experience and perceptions of their diet and physical activity behaviours, influences on

these behaviours, and their experience of weight management since CFTR modulator therapy (see appendix for interview schedule).

The interview schedule was revised in response to feedback from the MoreLife with CF Patient Advisory Group and Lead Partners.

Post Interview

At the end of the interview, the Microsoft Word transcription and voice recording will be saved on a password protected server at the University of Birmingham (Data Management Plan) and deleted from the encrypted voice recorder.

CI will record field notes of personal assumptions, responses, and thoughts in a reflexive diary. Any minor amendments to structure, ordering of topics, or rephrasing of questions that may be required to enhance clarity will be identified and discussed with AT and SF. In line with the inductive approach, interview questions will then be modified if necessary to include emergent issues may be required for the next interview.

5.1.4 Data Analysis

The quantitative and qualitative data will be analysed separately and integrated;

Descriptive statistics will be performed on all quantitative outcomes using SPSS vs 27 (75)

Quantitative Data Analysis

The self-reported food intake diary will be analysed using myfood24® nutritional analysis software(76).The food diary and nutrient intake data will be generated from MyFood24®(see appendix) in a Comma Separated Values (CVS) output file and saved on a University of Birmingham password protected server (see Data Management Plan (DMP)). Participants who complete less than 3 days food records will be excluded from the dietary data analysis, as it is unlikely to be a true representation of their habitual food intake and will not be approached for interview

Daily mean nutrient intakes will be calculated for each participant, across the number of days completed food diary data. For macronutrients and free sugars, both total and total food energy-adjusted values (per 1000kcal) will be reported employing Atwater factors(77). Fibre will be quantified using the Association of Official Analytical Chemists (AOAC) method. Nutrient intake data will be compared to Dietary Reference Values for food and Nutrients in the UK(78), Scientific Advisory Committee on Nutrition Recommendations(79-81), European Cystic Fibrosis Nutrition Guidelines(82) ;

In addition, percentage distribution of nutrients (energy, fat, carbohydrate, total sugar, protein, fibre, calcium) per meal (breakfast, lunch, evening dinner, snacks, drinks) will be summarised and the top 5 foods that contribute to intake of energy, fat, carbohydrate, total sugar, protein, fibre, and calcium will be tabulated.

Physical Activity Data

Participants accelerometery data will be downloaded,analysed and stored using Actilife® software (version 6.2)(72). This software will be accessed via and the data will be stored on a University of Birmingham password protected computer server. Once the data has been downloaded the participant data will be cleared from the device. The physical activity data will be summarised and exported as a pdf file and saved on a University Hospitals Birmingham password protected computer server A summary of this data will be entered into the participant Case Report Form. Non-wear time will be determined by Actilife® software. Participants with < 10 hours valid wear time per day, for <4 days, will be excluded from the analysis. The amount of valid wear time will be used as a co-variate in any statistical analysis, to account for variability between participants.

Accelerometer cut-points will be used to compute average total daily sedentary time (SED), light-intensity physical activity (LPA), and moderate-to-vigorous-intensity physical activity (MVPA) (83-86).

Qualitative Data Analysis

The audio-recording and transcription will be imported into NVivo 12(87). NVivo 12 will be used to organise, and chart the focus group interview data.

The framework approach will be used to analyse the data(52, 88). This method has been chosen as it is a systematic process for organising, reducing, and interpreting qualitative data. It guides a process of thematic analysis with the development of an analytic framework and charting matrix from the coding and categorising of interview data to aid the comparison across the data set so that relationships, and patterns can be developed into key themes. An advantage of this method is the inclusion of participant accounts in the matrix ensure that individual descriptions and interpretations are not lost in the analysis.

The following process of the framework approach will be used to analyse the data;

i. Transcription

Following each interview, JB will check the transcription for errors by listening back to the audio-recording and reading the transcripts simultaneously. Corrections will be made to ensure an accurate verbatim transcription for analysis.

ii. Familiarisation with the interview

JB will listen back/view to the audio recording and read and re-read the transcript to familiarise with the data thoroughly. Initial analytical thoughts on the key study objectives, relevant issues that emerge and impressions will be noted.

iii. Independent Coding

JB will independently code data from the first 5 interviews. The transcription will be read line by line and coded by applying a descriptive label to a section of text that is significant or relevant to summarise and described what has been said by each participant.

iv. Develop analytical framework and then discuss to form a consensus of a set of codes to apply to future transcripts

JB will discuss their independent coding with AT and agree on a set of codes. Codes that are conceptually related will be grouped together into clearly defined categories. This coding index will form the analytical framework which JB will then be applied to subsequent transcripts.

v. Applying the analytical framework

The analytical framework will be used to code and categorise subsequent interview transcripts. Any new codes which emerge from the subsequent interviews will be discussed by JB with AT to reach a consensus and the framework will be updated to incorporate new codes.

vi. Charting the data into the framework

Once all the data has been organised into categories and codes using the analytical framework, a matrix will be constructed; one spreadsheet for each category and a column for each code within that category. Codes from each transcript will be summarised and charted into the Matrix. Illustrative participant quotations will also be charted into the matrix. JB will chart the data and this will be reviewed by AT. Any differences of opinion will be discussed and the charting will be revised considering agreed changes.

vii. Interpreting the data

Influenced by the key study objectives, JB will interpret he data by using the matrix to compare across categories and codes, between and within individual participant data to identify any connections or patterns. Codes and categories will be mapped to the COM-B framework and developed into themes and subthemes. Themes and subthemes will be further developed in discussion with AT.

viii. Validation of Themes and Subthemes

The MLCFPAG and study steering group committee will be provided with the opportunity to review the pseudonymised research findings(89). This feedback will be discussed with AT and the themes and subthemes will be refined in response to feedback received.

Quantitative and Qualitative Data Integration

The quantitative (descriptive statistical summary of nutrient, food intake, and physical activity data) and qualitative results (themes and subthemes) will be integrated using joint display analysis (90, 91). The data sets will be illustrated together to enable them to be compared and explored to identify and understand contextual factors that influence diet and physical activity behaviours, how perceptions compare to quantitative data.

Relevant health behaviour theories will be examined to explain the psychological mechanism of action of the behaviours and a preliminary logic model will be constructed.

The results will be used to formulate guiding principles for CF weight management programme.

6. Project setting

This study will recruit participants from 4 sites; West Midlands Adult CF Centre, University Hospitals Birmingham, Heartlands Hospital (WMACFC) and Sheffield Adult CF Centre, Northern General Hospital, Sheffield (SACFC), North West Midlands Cystic Fibrosis Centre, Royal Stoke University Hospital NHS Trust(NWMCFC) and Wolfson Cystic Fibrosis Centre, Nottingham University Hospital NHS Trust (WCFC)

Study visits will take place at the WMACFC/SACFC/NWMCFC/WCFC, the participants home or virtually via a video-conferencing platform using a University of Birmingham Zoom© or MS Teams© accessed via the university's secure server.

7. Participant recruitment

7.1. Eligibility criteria

Inclusion Criteria

- Registered at WMACFCSACFC,WMCFC or WCFC
- Confirmed diagnosis of CF with genotype
- Clinically stable (no respiratory exacerbation within previous) 28 days
- >18 years
- BMI >25kg/m^2
- Prescribed CFTR modulator therapy
- Able to give informed consent

Exclusion Criteria

- Pregnant
- Diagnosis of an eating disorder
- Currently a hospital inpatient
- Currently being screened for CFRD using flash glucose monitoring
- Currently receiving treatment for DIOS or acute constipation
- Currently receiving oral or IV antibiotics for respiratory exacerbation
- Currenlty prescribed an increased dose of glucocortocid (above usual maintainence dose)

7.2. Sampling

7.2.1. Size of sample

The sample size will be a minimum of 30 with maximum of 60. (1). As this is a purposive sample, a sample size has not been calculated. This sample size of 30-60 has been considered sufficient to characterise the target population, their diet and physical activity behaviours and to achieve data saturation.

Twenty participants will be selected to take part in a semi-structured data prompted interview. Interview participants will be selected to maximise variation and has been suggested as sufficient when there is a specific research question (74). Following initial analysis of 20 interviews, if new issues emerge after these interviews, further sampling will be employed for additional participants to take part in data prompted interviews to reach data saturation.

Sampling technique

Potential participants will be identified from the database of patients registered at the West Midlands Adult CF Centre,Sheffield Adult CF Centre, North West Midlands Cystic Fibrosis Centre,Stoke and Wolfson Cystic Fibrosis Centre, Nottingham. by the clinical team. Eligibility screening of potential participants at West Midlands Adult Cystic Fibrosis Centre will be undertaken by the Chief Investigator, Joanne Barrett who is also a member of the clinical team. Eligibility screening of potential participants at Sheffield Adult CF Centre, North West Midlands Cystic Fibrosis Centre, Stoke and Wolfson Cystic Fibrosis Centre, Nottingham will be undertaken by the sites Principal Investigators who are a members of the clinical teams. Patient medical records will be reviewed and patients with "opt out" of research on their medical records will not be invited to take part. If an individual meets all the inclusion criteria and none of the exclusion criteria they will be invited to participate in the study by a member of the clinical team by phone, and during hospital inpatient admissions or outpatient appointments (video-call and face-to-face).

7.3. Recruitment

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place and any required agreements are in place.

7.3.1. Sample identification

The Chief or Principal Investigator (and member of the participants clinical team), member of the participants CF Team will invite eligible participants to take part in the study during outpatient appointments, hospital admissions and home visits. Eligible participants will also be contacted directed by phone, email, or letter outside of any clinical appointments. This is a group of patients who due to improved health, and receiving treatment at a regional centre alternate between face to face and virtual outpatient appointments. Therefore, recruitment contacts may be undertaken by phone, video, or face to face contact.

The study will be advertised in WMACFC/SACFC/NWMCFC/WCFC newsletters, posters, and flyers at the CF centres, published on the centre websites, www.heartlandscf.org and social media.

7.3.2. Consent

Potential participants who express an interest in taking part in the study will be provided with a participant information sheet (PIS). If this discussion takes place by phone or video call the patient will be emailed a copy using the email address registered with their hospital contact details from a secure NHS email account. Alternatively, they can request a copy by post.

At these contacts, the research study details will be explained to the patient; what participation involves, how it will be beneficial to the treatment of cystic fibrosis, any potential risks of the study, and the right to withdraw from the study at any time. They will have the opportunity to ask questions.

Potential participants will have time to consider if they would like to take part in the research and will receive a follow up phone call a minimum of 7 days after the first recruitment contact from the chief investigator. Alternatively, they may receive a follow up contact at their next outpatient appointment at the CF centre. There is no minimum timeframe between receiving information about the study and giving informed consent defined by the World Medical Association Declaration of Helsinki (92), Good Clinical Practice Guidelines (93) and the UK Policy Framework for Health and Social Care (94). If willing, individuals can provide informed consent on the same day they receive the invitation and PIS.

If they decide they would like to participate in the study, a mutually convenient time will be arranged with the participant to obtain written informed consent At this contact, participants will again be provided with the opportunity to ask questions about the research, what will be required during their participation, any possible risks that could occur and how they can withdraw at any time without giving a reason. It will be explained that if they decide to withdraw before their data analysis has been completed any information collected about them will be securely destroyed. If they withdraw after the study data set has been collated and analysed, it may not be possible to withdraw their data. Study visit 1 will take place after informed consent has been obtained. It is likely that this will occur on the same day following informed consent to minimise participant visits. This adheres to guidance on consent from the Health Research Authority (95).

If the participant is selected for interview, the Chief Investigator will be provided will the participants the contact details by the Principal Investigator to arrange a suitable date, time, and location for interview to take place. Consent for this access will be explicitly gained prior to any interaction between the Chief Investigator and the participant through discussion with the local PI and the participant, and will be recorded on the study consent form and in the case report form.

Original paper copies of all consent forms will be kept in the study site file, the participant will be given a photocopy and a scanned copy will be uploaded to the patient's electronic medical record saved in the electronic site master file on a password protected server at the University of Birmingham (see DMP).

Confirmation of consent and ongoing participation will be verified at the start of each study contact and they will have another opportunity to ask questions.

8. Storage and analysis of human tissue

Not applicable to this study

9. Safety reporting

We do not envisage any safety reporting will be required for this study as participants will not be exposed to the potential for any adverse events recording food intake, having body composition measured or monitoring physical activity, or taking part in an interview. University of Birmingham QMS procedures will be followed.

10. Ethical and regulatory considerations

10.1. Assessment and management of risk

The potential risk of this study is that participants may find it difficult recording their food intake and physical activity, and discussing their experiences. Additionally, they may feel self-conscious wearing the physical activity monitor on their wrist. Maintaining nutritional status to improve health and life expectancy has been a constant burden for many people living with CF. The recent introduction of CFTR modulator therapy has caused a significant change in their health and many have gained a significant amount of weight. Some people have struggled with this change and it has had a negative impact on their mental health. Participation in this study may signal a transition to them living with and managing CF differently.

Only trained clinical NHS staff will measure participant's weight and body composition at the NHS sites.

All participants will be provided with the contact details of the Chief Investigator (JB) and their CF Team to contact for support if they experience any distress or anxiety whilst recording their food intake or physical activity. If during the data prompted interview, they become distressed discussing their experiences, the Chief Investigator (JB) will stop the interview. The interview will be recommenced when the participant indicates they are ready, or terminated if the participant does not wish to continue. If the interview is terminated, the participant will be asked if they wish to continue to take part in the study. If they chose to continue to participate a new interview date will be arranged. If they decide not to continue to take part in the study, a debrief will take place and their participation will end.

Any participants who disclose any psychological distress to the CI, PI, or member of the CF Team, at any time during the study, the participant will be offered referral to psychological services at their CF Centre. Alternatively, if preferred they will be provided with information on how to access these services.

If the Chief Investigator (JB) identifies or suspects significantly harmful eating or physical activity behaviours or disclosure of these at interview, the researcher will inform the participant of their safe guarding concerns and advise them that it is their duty of care to inform their CF Consultant. They will also be offered referral to CF Centre psychology services. If the participant discloses any financial difficulties, they will be sign posted to contact their social work team.

10.2. Research ethics committee (REC) and other regulatory review & reports

Before the start of the study, HRA approval and a favourable opinion will be sought from a REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

The University of Birmingham will be sponsor for the study.

All study documentation will be supplied for review. Recruitment will only commence once all essential and required ethical and governance approvals have been granted and permission to proceed confirmed.

The CI will notify the NHS REC and sponsor of the end of the study. It is the CI's responsibility to produce the annual and final reports as required and notify the NHS REC and sponsor of the end of the study. An end of study form will be submitted to the NHS REC and sponsor within 90 days of when study is declared ended. Within one year after the end of the study, the CI will submit a final report with the results, including any publications/abstracts, to the NHS REC and sponsor.

If the study is ended prematurely, the CI will notify the NHS REC and sponsor, including the reasons for the premature termination.

All correspondence with the NHS REC will be retained in the electronic Study Master File on a password protected computer server at University of Birmingham and the Investigator Site File at University Hospitals Birmingham,Sheffield Teaching Hospitals (Northern General),, Royal Stoke University Hospital NHS Trust and Nottingham University Hospital NHS Trust . The investigator site file will be stored in a locked filing cabinet in a locked office at WMACFC/SACFC/NWMCFC/WCFC. Additionally, a paper copy of the Trial Master File will be located in a locked filing cabinet and office at University Hospitals Birmingham.

10.2.1. Regulatory review & compliance

The CI will be responsible for ensuring that participants will not be enrolled into the study, until all required approvals are in place.

10.2.2. Amendments

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

The CI will discuss proposed amendments with members of the research team. Amendments must be agreed by all members of the research team. The CI will submit all proposed amendments to the sponsor to decide whether an amendment is substantial or non-substantial for the purposes of submission to the NHS REC. Any amendments will not be implemented until all required approvals are received. Any required amendments to the NHS REC application or the supporting documents will be submitted to the NHS REC with a valid notice of amendment. Substantial amendments that require review by NHS REC will not be implemented until the REC grants a favourable opinion for the study amendment and mechanisms are in place to implement these.

Once amendment approval is issued the protocol will be updated. A copy of the updated protocol will be recorded in the protocol version log (with updated date of update and version number) will be saved in the electronic Study Master File at University of Birmingham and the Investigator Site File at University Hospitals Birmingham Sheffield Teaching Hospitals (Northern General),Royal Stoke University Hospital NHS Trust and Wolfson Nottingham University Hospital NHS Trust .

10.3. Peer review

The study design and proposal will be internally reviewed and agreed by the Chief Investigators supervisory team at University of Birmingham, and research and development governance office before initiation.

Further peer review has been undertaken as part of the application process for the NIHR Doctoral fellowship Award Scheme which is funding this research.

Peer review will be undertaken on submission of this protocol for publication in a peer-reviewed journal.

10.4. Patient & public involvement

The MoreLife with CF Patient Advisory Group was established for this research (MLCFPAG) and there are Lead Partners for this research; Mrs Jane Bull and Mrs Carly Beale. A series of online meetings were conducted by the Chief Investigator (JB) with the MLCFPAG to gather feedback on the study design and methods, interview schedule, trial of food diary app and all patient facing documents. Open feedback and questions were invited at the sessions and the group was also able to provide feedback using an anonymous online Jamboard®. Additionally, online anonymous surveys were conducted to gather feedback from the WMACFC population. The key points from feedback were as follows;

- 4 days food diary records and 14 days physical activity monitoring was acceptable
- The MyFood24 food diary smart phone app has been chosen for participants to record food intake as it was preferred to an alternative app.
- The terminology that is acceptable to be used in the protocol should be 'overweight'
- The terminology that should be used in participant information and study adverts should be unwanted weight gain (most popular) followed by high BMI, gene modulator weight, excess weight
- Participants should be sign posted to social work if financial difficulties become apparent during interviews
- The interview schedule had the following amendments in response to feedback – to start with exploring experience of CFTR modulator therapy and weight and to include questions about diet and physical activity when people are well/unwell.
- The Participant Information Sheet had the following amendments; to include an explanation on why participants would be asked to about household income and educational status and to change the order of point 9 and 10, to include a short explanation of what the study is about at the start of the PIS.
- An incentive should be offered to participants for taking part in the research – a £10 Amazon voucher

10.5. Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

Any protocol deviation will be documented and filed in the investigator Site Files and a scanned electronic copy stored in the Master File at University of Birmingham. It will be reported to the CI and sponsor immediately.

10.6. Data protection and confidentiality

All investigators and study site staff will comply with the with Caldicott Principles and requirements of the Data Protection Act 2018 and UK GDPR Policy with regards to the collection, storage, processing, and disclosure of personal information and will uphold the act's core principles(96, 97). Study data transferred between University Hospitals Birmingham,Sheffield Teaching Hospitals, Centre, Royal Stoke University Hospital NHS Trust, Nottingham University Hospital NHS Trust and University of Birmingham will take place in accordance with secure NHS and University of Birmingham transfer policies.

Participant name, email address, date of birth, sex and food intake data logged in the MyFood24 app will be stored by Dietary Assessment Ltd (MyFood24). This data will only be accessible by the Chief Investigator Joanne Barrett via a password protected login, the participant via their personal password protected login and

Dietary Assessment Ltd as data processor. At the end of the study, and for any participants who are withdrawn or request to be withdrawn, the Chief Investigator Joanne Barrett, will delete all participant data from the MyFood24 platform. This will automatically be deleted from any MyFood24 cloud storage. In any event, it will be deleted from the myfood24 system after a maximum of six years from the end of the study.

No data will be stored outside of the UK.

Participant screening log, identifier log ,enrolment log, signed informed consent forms, participant invitation letter/email and GP letters will be stored in the investigator site files at University Hospitals Birmingham, Sheffield Teaching Hospitals (Northern General), Royal Stoke University Hospital NHS Trustand Nottingham University Hospital NHS Trust .

Pseudonymised participant Case Report Forms and paper food diaries will be stored in the investigator site files at University Hospitals Birmingham and Sheffield Teaching Hospitals (Northern General), Royal Stoke University Hospital NHS Trust, and Nottingham University Hospital NHS Trust .and electronically on a password protected server (research data storage) at University of Birmingham (see DMP).

Pseudononymised participant physical activity data will be stored on a password protected secure server at University of Birmingham(research data storage) (see DMP).

Pseudonymised participant food intake data will be stored on the MyFood24 (Dietary assessment Ltd) secure server and electronically in the master site file on a password protected server (research data storage) at University of Birmingham (see DMP).

Pseudonymised participant interview transcripts and complete study data set excel spreadsheet will be stored on a password protected server (research data storage) at University of Birmingham (see DMP).

Once the transcriptions of the audio and video recordings have been transferred to a password protected University of Birmingham server and transcriptions have been checked for accuracy and pseudonymised, the interview audio and video recordings will be securely deleted.Only the pseudonymised transcriptions will be stored electronically in a file on a password protected server at University of Birmingham (see DMP).

Dr Sally Fenton, will be the data custodian.

Data will be stored as outlined in the Data Management Plan (DMP).

All study documents and data will be stored for 10 years after the end of study.

10.7. Indemnity

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.

10.8. End of study and archiving

The completion of the last scheduled study visit of the 60th participant will be considered the end of study.

Study documentation and data will be archived for at least 10 years after completion of the study in University of Birmingham Research Data Archive.

The Sponsor will advise of the archiving requirements as part of the site closure process if required.

10.9. Access to the final dataset

The following individuals will have access to full dataset:

Joanne Barrett Specialist Cystic Fibrosis Dietitian and NIHR Doctoral Fellow (Chief Investigator)

Annie Topping Professor of Nursing

Alice Turner Respiratory Consultant and Professor of Respiratory Medicine

Sally Fenton Associate Professor of Lifestyle Behaviour Change

Additionally other Health Care Professional or Academics individuals who may join the research team during the study. They will be supervised by the CI or CI's supervision team and will receive relevant research governance and data protection training.

11. Dissemination policy

11.1. Dissemination policy

The data will be owned by the, University of Birmingham and National Institute for Health and Care Research.

On completion of the project, the data will be analysed and a final report prepared. The full study report will be stored on a password protected university computer file.

After the final report has been prepared. Study participants will be provided with a summary of the findings by post. Research findings will be disseminated to relevant patient user groups through newsletters, website posts, social media, and public presentations.

The findings will be submitted to an international Cystic Fibrosis Conference and peer reviewed journal. The National Institute for Health and Care Research will be acknowledged in reports and publications as the funder of this research.

11.2. Authorship eligibility guidelines and any intended use of professional writers

The following people with have authorship on the final study report;

Joanne Barrett Specialist Cystic Fibrosis Dietitian and NIHR Doctoral Fellow Chief Investigator

Sally Fenton Associate Professor in Lifestyle Behaviour Change, University of Birmingham

Annie Topping Professor of Nursing, University of Birmingham

Alice Turner Respiratory Consultant and Professor of Respiratory Medicine, University of Birmingham

Helen White, Associate Lecturer, Leeds Beckett University

Joanna Whitehouse, Cystic Fibrosis Consultant, West Midlands Adult Cystic Fibrosis Centre

Ailsa Milne, Cystic Fibrosis Dietitian, Sheffield Adult CF Centre, Sheffield Teaching Hospitals

Martin Wildman, Cystic Fibrosis Consultant, Sheffield Adult CF Centre, Sheffield Teaching Hospitals

Hannah King, Cystic Fibrosis Dietitian, Wolfson Cystic Fibrosis Centre, Nottingham University Hospital NHS Trust (WCFC).

Darren Sills, Cystic Fibrosis Dietitian, Wolfson Cystic Fibrosis Centre, Nottingham University Hospital NHS Trust (WCFC)

Heather Seabridge, Cystic Fibrosis Dietitian, North West Midlands Cystic Fibrosis Centre, Royal Stoke University Hospital NHS Trust (NWMCFC)

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13. Appendices

13.1. Appendix 2 – schedule of procedures

Procedures	Screening	Baseline	Visit Number
Eligibility Screening	x		
Informed Consent		x	
Demographic and clinical data collection		x	1
Instruction on food intake diary recording and physical activity monitor		x	1
Commence physical activity and food intake monitoring		x	1
Verification of food diary and return of physical activity monitor			2
Data prompted interview			3

13.2. Appendix 3 -amendment history

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment
1	07/10/24	2.0	substantial	Additional sites and option to post physical activity monitor added
2	08/04/25	2.1	substantial	Addition of interviews by video and Darren Sils as PI at Nottingham site