



## **Participant Information Sheet (PIS)**

### **Study Title: The Co-Design of a Cystic Fibrosis (CF) Weight Management Programme. The More Life with CF Co-Design Study**

We invite you to inform the design of a weight management program for people living with cystic fibrosis by taking part in an interview.

Before you decide whether to take part or not in this research, you need to understand why the co-design work is being done and what it would involve for you. Taking part is voluntary, it is up to you to decide. Please take time to read the following information carefully and discuss it with others if you wish. Contact us if there is anything that is not clear or if you would like more information.

### **Why are we doing this research?**

Since the introduction of Cystic Fibrosis Transmembrane Conductance Regulator Therapies (CFTR), many people with CF have experienced weight gain and are seeking support to help them adjust their eating and physical activity habits to manage their weight.

National Health Service (NHS) digital weight management programmes (weight management programmes delivered online) do not meet the specific needs of people with CF. However, these existing NHS digital weight management programmes could be made suitable for people with CF by developing an additional CF-specific programme to be delivered alongside them.

### **What is the purpose of the study?**

The aim of this study is to design a CF-specific weight management programme (CF WMP) to be delivered alongside an existing NHS digital weight management intervention. The NHS digital weight management programme we will be developing the CF WMP to be delivered alongside will be the MoreLife® programme. MoreLife® are one of the companies that are funded by the NHS to provide online weight management services through the NHS digital weight management programme.

A group of people living with CF, CF Health Care Professionals, people who have expertise in techniques that facilitate behaviour change and Health Care Professionals with experience of delivering online weight management programmes have been working together to co-design the programme.

We are seeking feedback on the design of the programme from people living with CF to inform the design of the programme as it is developed. This feedback will be gathered during 'think aloud' interviews. The feedback received will inform the ongoing development of the programme.

### **Who is conducting this research?**

This research study is being conducted by Joanne Barrett, CF Dietitian and National Institute for Health and Social Care Research (NIHR) Doctoral Fellow at University of Birmingham. Joanne is being supervised in this research by Professor Annie Topping and Dr Sally Fenton from University of Birmingham. Joanne has been awarded funding from the NIHR to conduct this research as part of her doctoral fellowship. They will also be a member of the co-design group.

### **Why have I been invited to take part in this research?**

We are inviting people living with cystic fibrosis to take part.

### **Do I have to take part?**

It is up to you to decide if you would like to take part in the study.

If you agree to take part, we will then ask you to complete a consent form to confirm that you have agreed to take part.

### **If I decide to take part, can I change my mind at any time?**

You are free to withdraw without giving a reason. If you withdraw before taking part in an interview any information collected about you will be securely destroyed. If you withdraw after the interview but before your interview data has been analysed and collated, any data and information about you will be securely destroyed.

Once your interview data has been analysed, collated and used to inform the programme design, it will not be possible for you to withdraw your data and information about you.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

### **What happens if I lose capacity?**

If you lose capacity before taking part in a think-aloud interview, your data will be securely destroyed

If you lose capacity after taking part in a think aloud interview, any information collected will be securely destroyed unless the study data set has already been collated and analysed as it may not be possible to remove your data.**If I decide to take part, what will I be required to do?**

- Complete an eligibility screening form if you are eligible you will be asked to complete a consent form. If you are not eligible you will be thanked for your interest in participating in the research.

- Complete a participant demographic information form with your name, contact details, the CF centre you attend, your gender and age group, dates when you are available to attend for an interview (only your age and gender will be reported in any study publications) and whether you would prefer an online or an in-person interview.
- Participate in a 'think aloud' interview either in person at your CF centre which will be audio recorded, or via a video which will be audio- video recorded, , which should take between 30-60 minutes.

### **Will I be paid any expenses if I take part in this research?**

You will be reimbursed for your time for taking part in the interview and any additional reading or preparatory work you are asked to undertake. You will be reimbursed at the payment rates recommended by the National Institute for Health and Care Research, at a rate of £25 per hour.

### **What are the possible disadvantages and risks of taking part?**

There are no anticipated disadvantages, side effects, or risks of taking part in this study. You will be asked about your opinions and views on the design. You may feel uncomfortable discussing your views and being audio or video recorded. If you require any support as a result of becoming distressed during participation, you will be provided with support by the facilitators and also advised to seek support from your CF Centre psychology service or your GP.

### **What are the potential benefits of taking part in this research?**

If you agree to participate in this study, we will invite you to take part in a think-aloud interview. A think-aloud interview is a type of interview where you will be asked to say out loud any thoughts that come to mind as you work through the weight management programme and programme resources .

Your interview will help us to gather your feedback on the programme content, format, resources and structure. It will also help us to find out if there are any problems with using it (e.g. unclear instructions), any features or resources that you find confusing or dislike, so that these can be changed.

This will help the researcher develop a programme that is relevant, engaging and usable to people with cystic fibrosis and deliverable by Health Care Professionals working in CF.

### **Will my part in this study be kept confidential?**

We will need to use information from you for this research project. This information will include your ;

name

-contact details

-age group

- gender
- the CF centre you currently receive your CF care.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Birmingham is the sponsor of this research. The University of Birmingham is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- The research team at the University of Birmingham to oversee the quality of the study.
- Regulatory organisations to check the accuracy of the research study.

We will keep all information about you safe and secure by:

- All information which is collected about you during the interview will be kept strictly confidential and will be pseudonymised. You will only be identified as a number and pseudonym, your name or any other identifiable information will not be used.
- The recordings and written transcriptions of the interviews will be stored securely on a password protected server at the University of Birmingham. All audio-visual recordings will be securely deleted following transcription, within a maximum period of four weeks from the date of recording. Only the authorised researchers involved in this study will have access to identifiable data. Joanne Barrett, the chief investigator for the study will be responsible for ensuring that data remains secure and anonymous.

### **International transfers**

Your data will not be shared outside the UK.

### **How will we use this information about you after the study ends?**

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 of years. The study data will then be fully anonymised and securely archived or destroyed.

### **What are your choices about how your information is used?**

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have

- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information:

- our leaflet [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by asking one of the research team
- by sending an email to [dataprotection@contacts.bham.ac.uk](mailto:dataprotection@contacts.bham.ac.uk)

### **What to do if you are interested in participating?**

If you would like to take part, please contact Joanne by email ([joanne.barrett2@nhs.net](mailto:joanne.barrett2@nhs.net)) or phone ( 07867143787 ) or speak to Joanne in person.

Once, Joanne has checked that you are eligible to take part she will ask you to complete and return a consent form. Once your consent is received Joanne will contact you by phone or email and ask you to complete a form with you details and dates you are available to take part in an interview.

### **What if I have any questions about this research?**

General information about participating in research can be obtained from the following website INVOLVE ([www.involve.org.uk](http://www.involve.org.uk)).

If you have any concerns or questions about any aspect of this study, please contact the Joanne Barrett, Specialist Cystic Fibrosis Dietitian, Doctoral Fellow, and Chief Investigator by email [joanne.barrett2@nhs.net](mailto:joanne.barrett2@nhs.net) .

### **Who is funding this research?**

This research is being conducted as part of a Doctoral Fellowship funded by the National Institute for Health and Care Research (NIHR).

### **Who has reviewed this research?**

This research has been reviewed and given a favourable opinion by the University of Birmingham Research Ethics Committee.

The study is sponsored and insured by the University of Birmingham and is being completed as part of a doctoral qualification.

### **What if something goes wrong ?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you have any concerns or questions about any aspect of this study, please contact the Joanne Barrett, Specialist Cystic Fibrosis Dietitian, Doctoral Fellow, and Chief Investigator by email [joanne.barrett2@nhs.net](mailto:joanne.barrett2@nhs.net) or phone 07867 143787.

If you remain unhappy and wish to complain formally, you can do this by contacting the University of Birmingham. Details can be obtained from [researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk).

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.

**Thank you taking the time to read this information**