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 join a co-design group that will work together in a series of online participatory workshops to develop a weight management program for people living with cystic fibrosis.

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. Health Care Professional's working with people living with cystic fibrosis have also experienced the impact this change has had on their clinical practice.

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 co-design a CF-specific weight management programme (CF WMP) to be delivered alongside an existing NHS digital weight management programme. 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 with 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 will work together to co-design 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 health care professionals working with people who have cystic fibrosis, people living with cystic fibrosis, behaviour change experts and health care professionals who have experience of delivering weight management programmes to join the co-design group.

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 a workshop, any information collected about you will be securely destroyed.

It will not be possible for you to withdraw your data during or after the workshops due to the nature of the group discussion and video recording.

What happens if I lose capacity?

If you lose capacity before any data is collected, you will be withdrawn from the study and your data will not be used, any information collected about you will be securely destroyed .

If you lose capacity during or after the workshops, we will stop collecting any further data. However, due to the nature of group discussion and video recording,data may still be used in the analysis.

If I decide to take part, what will I be required to do?

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

•Complete a participant demographic information form with your name, contact details, which CF Centre you work at, your gender and age group, and dates when you

are available to attend workshops (only your health care discipline and gender will be reported in any study publications)

•Provide a short video or written biography about yourself to introduce yourself to other participants in the co-design group. This will be sent out with the preworkshop information

•Participate in a series of online workshops with people living with CF, other CF Health Care Professionals, a behaviour change expert, and a health care professional who has experience of delivering weight management programmes.

You will be required to participate in between 2 and 4 online workshops. Each workshop is expected to last between 60-120 minutes. A video-conferencing platform (Zoom© or MS Teams©) will be used to deliver the workshop. You will need to be somewhere private with access to a computer , phone or tablet and internet to take part. Before the workshop you will receive a link with a password to access the virtual meeting room where workshop will take place. The workshop will be audio or video recorded, and you will be required to have your camera on.

Prior to each workshop, you may be sent information to read, to prepare you for the workshop.

Each workshop will be facilitated by Joanne Barrett, Sally Fenton and Lead Research Partners who are living with CF. At each workshop the co-design group will be presented with some information to discuss as a group and work together to decide what the CF specific programme should contain and how it should be delivered. For example, the techniques that should be included to help people change their behaviour, called behaviour change techniques e.g. monitoring physical activity, setting goals, writing an action plan for change and educational resources etc. You will also be asked to prioritise modifications to the programme prototype, following feedback from people living with CF.

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

We do not envisage that you will occur any expenses through taking part in this research. You will not receive any payment for taking part in this research.

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 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 hospital trust occupational health service or CF Centre psychology service.

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

It will help the researcher develop a programme that is relevant to the needs of 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

-profession and CF centre where you currently work.

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. Only the authorised researchers involved in this study will have access to identifiable data. All audio-visual recordings will be securely deleted following transcription, within a maximum period of four weeks from the date of recording.

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
- by asking one of the research team
- by sending an email to 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) or phone (07867143787).

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 your details and dates you are available to take part in workshops.

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). If you have any concerns or questions about any aspect of this study, please contact Joanne Barrett, Specialist Cystic Fibrosis Dietitian, Doctoral Fellow, and Chief Investigator by email 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 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 .

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