UNIVERSITY OF BIRMINGHAM

NIHR | National Institute for Health Research

Participant Information Sheet (PIS) – Part 1

Study Title:
Cystic Fibrosis Health Care Professional (CF HCP) Experiences and Perceptions of Managing Overweight and Obesity in Adults with Cystic Fibrosis treated with Cystic Fibrosis Transmembrane Conductance Regulator Therapy

We would like to invite you to take part in an online focus group as part of a research project.

Before you decide whether to take part or not, you need to understand why the research is being done and what it would involve for you. Taking part in research 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 patients with CF have experienced weight gain and many have become overweight/obese.

CF HCP's have observed a change in the health and nutritional status of their patients with CF and have modified their clinical practice to include advice about how to manage weight for those who are overweight.

There is a limited amount of published evidence exploring CF HCP's experience of managing adults with CF who are overweight/obese in their clinical practice, and/or how patients are best supported to make changes to their established diet and physical activity behaviours.

What is the purpose of the study?

The aim of this study is to explore CF HCPs experience of providing weight management advice to adults with CF who are overweight/obese and treated with CFTR modulator therapies. It also aims to identify what has been helpful and any challenges experienced when supporting this patient population to change their diet and physical activity behaviours.

The results of this research study will inform the development of a CF specific weight management programme. This programme will be co-designed with patients with CF, CF HCPs, and behaviour change and weight management experts.

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.

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

We are inviting dietitians, physiotherapists, clinical nurse specialists and doctors who have experience of working with adults with CF who are overweight/obese treated with CFTR modulator therapy to take part in this research.

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 the focus group, any information collected about you will be securely destroyed.

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

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

- **Complete an online eligibility screening questionnaire and consent form**
- **Complete a participant demographic information form with your name, contact details, healthcare discipline, which CF Centre you work in and your gender (only your health care discipline and gender will be reported in any study publications)**
- **Attend 1 online focus group interview with other CF HCP's who are from the same HCP discipline**

You will be required to take part in one online focus group interview with other CF HCP's. There will be between 4 and 8 CF HCPs in the group. The interview is expected to last between 60-90 minutes. A video-conferencing platform (Zoom©) will be used to deliver the session. You will need to be somewhere private with access to a computer to take part in the focus group interview. The session will be video recorded and you will be required to have your camera on so you are visible to the group.

Two days before the date of your scheduled focus group interview you will receive a link with a password to access the virtual meeting room where the focus group interview will take place and a copy of the focus group 'ground rules' for information.

The facilitators (Joanne Barrett and Professor Annie Topping) will then welcome the group and ask them a series of questions to stimulate discussion between participants about their experience of managing patients with CF who are overweight/obese.

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

Taking part in this research should not incur any expenses and you will not be paid to take 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 own experiences and views. You may feel uncomfortable discussing your experiences with other CF HCP and being video recorded.

We will ask you and others in the group not to talk to people outside the group about what was said during the discussion. However, we need you to be aware that we cannot stop or prevent participants who were in the group from sharing information that should be confidential.

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

It will help the researcher understand how CF HCPs support patients with CF to manage their weight and the approaches they use in their clinical practice. Understanding the current experience CF HCPs when supporting patients to manage their weight will help to identify what needs to be included in the design of a specific CF weight management programme.

Will my part in this study be kept confidential?

Yes. All information which is collected about you during the research will be kept strictly confidential and will be pseudonymised. You will only be identified as a number and pseudonym in the study, your name or any other identifiable information will not be used.

The recordings and written transcriptions of your 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. Joanne Barrett, the chief investigator for the study will be responsible for ensuring that data remains secure and anonymous.

We will follow ethical and legal practice and all information about you will be handled in confidence.

The University of Birmingham is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and Joanne will act as the data controller for this study. This means that she is responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, before the focus group interview we will destroy the information

about you that we have already obtained. During and after the focus group interview we will still use this information. If we must safeguard your rights, we will use the minimum personally-identifiable information possible.

The University of Birmingham will keep your name and contact details confidential. The research team at the University of Birmingham will use this information as needed, to contact you about the research study to oversee the quality of the study. Certain individuals from regulatory organisations may look at the research records to check the accuracy of the research study. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

The University of Birmingham will keep identifiable information about you from this study for ten years after the study has finished.

What to do if you are interested in participating?

If you would like to take part, please complete the eligibility screening questionnaire, consent from and demographic information using this link. Alternatively contact Joanne by email and she will send you a copy of these forms by email or post (jbb902@student.bham.ac.uk).

Once, Joanne has received your consent from she will contact you to arrange a date and time for you to take part in a focus group.

What if I have any questions about this research?

General information about participating in research can be obtained from the following website INVOLVE (www.invo.org.uk).

If you have any concerns or questions about any aspect of this research, please contact the Joanne Barrett, Specialist Cystic Fibrosis Dietitian, Doctoral Fellow, and Chief Investigator by email jbb902@student.bham.ac.uk .

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 Need Reference adding .

Thank you taking the time to read this information

Participant Information Sheet (PIS) – Part 2

Information about how we will protect your data and adhere to the Data Protection Act 2018 and UK General Data Protection Regulations (2018)

Study Title:

Cystic Fibrosis Health Care Professional (CF HCP) Experiences and Perceptions of Managing Overweight and Obesity in Adults with Cystic Fibrosis treated with Cystic Fibrosis Transmembrane Conductance Regulator Therapy

Will my data be protected?

In order to carry out the research project described above, we will need to collect information about you, and some of this information will be your personal data. Under data protection law, we have to provide you with very specific information about what we do with your data and about your rights. We have set out below the key information you need to know about how we will use your personal data.

The University of Birmingham's web page 'Data Protection - How the University Uses Your Data' sets out much of this information, including how to ask any questions you may have about how your personal data is used, exercise any of your rights or complain about the way your data is being handled. The rest of the key information you need to know about how we used your personal data is set out below.

Who is the Data Controller?

The University of Birmingham, Edgbaston, Birmingham B15 2TT is the data controller for the personal data that we process in relation to you.

What data are we processing and for what purpose will we use it?

We will collect and process your personal data to conduct the research project, as explained in this Participant Information Sheet.

What is our legal basis for processing your data?

The legal justification we have under data protection law for processing your personal data is that it is necessary to do so for our research, which is a task we carry out in the public interest.

Who will my personal data be shared with?

Sometimes, external organisations assist us with processing your information, for example, an electronic online survey platform provider. For this research study we will be using the

JSIC online electronic survey platform. These organisations act on our behalf in accordance with our instructions and do not process your data for any purpose over and above what we have asked them to do. We make sure we have appropriate contracts in place with them to protect and safeguard your data. If your personal data are transferred outside the European Union (for example, if one of our partners is based outside the EU or we use a cloud-based app with servers based outside the EU), we make sure that appropriate safeguards are in place to ensure the confidentiality and security of your personal data.

How long will my personal data be kept?
Your data will be retained for 10 years after the publication of the research outcomes.

Are changes made to this webpage?
This privacy notice is effective from 04/12/23 and is reviewed when necessary. Any changes will be published here.