A Comprehensive Approach To Relief Of Digestive Symptoms In Cystic Fibrosis (CARDS-CF): Interview

We are asking if you would like to join a research study

Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please take time to read this leaflet carefully, and talk to your parents/carers, other family members and friends about it if you wish. One of our team will go through it with you. This information sheet tells you why we are doing this study, what will happen if you take part and how the study will be done.

Please feel free to ask us if there is anything that is not clear. Please take time to decide whether or not you wish to take part.

Why are we doing this study?

Gut symptoms such as bloating, pain and sickness are common for people with Cystic Fibrosis (pwCF). PwCF previously told us that these symptoms can be embarrassing and interfere with their everyday life. Two in every three people will miss either school or work because of this. We want to better understand how these symptoms disrupt or impact on the daily life of pwCF.

To do this we are developing a scoring system called a “patient reported outcome measure” that will allow pwCF to record their gut symptoms. When it is finished, we will ask pwCF to test it by using it to record gut symptoms every day on a smartphone app. This patient reported outcome measure will be used in the future by researchers to better assess gut symptoms in Cystic Fibrosis (CF) and the impact that they have on daily life.

To help us create our scoring system, we are asking people with CF to take part in a patient interview to tell us their experiences and to help us decide what questions we need to include in our scoring system.

Why are we asking if you would join a research study?

You have been invited to take part in the study because you are 12 years or over and have CF. You are being invited to talk to us about your experiences and tell us your thoughts about questions we may include in our scoring system.

Do you have to take part?

No, you do not have to take part and we would only want you to take part if you want to. You are free to stop the interview at any time without giving a reason. If you decide to stop, this will not affect the care you receive. We will still keep the records from the interview we had with you and use them as part of the study. This information will be kept safe and confidential and we will describe what these means below.

What will the study involve?

- If you agree to take part, then we will ask you and your parent/carer to sign a consent form.
- We will interview you to talk to about some of your gut symptoms and ask your thoughts on the questions for our scoring system.

- The interview will last approximately 1 hour and will either be on the telephone, or on a video call over the internet. We will do whichever you feel most comfortable with.
- We will need to record your interview. This will be an audio recording if the interview is completed over the phone, or audio and video recording if the interview is done over the internet. This is so we can listen back to your answers later to help us with our research.

What are the possible benefits?

There are no direct benefits from taking part in the interview but the results may help pwCF in the future. To thank you for taking the time to do the interview, we will give you a £30 shopping voucher.

What are the disadvantages?

You may be asked to talk about some of your own experience of gut symptoms which some people can find uncomfortable or embarrassing. If you feel this way, please talk to the research team about this during or after your interview who can help you and also give you information about support available to you. We would also recommend you speak to your usual CF care team. Websites you may also find helpful for support or to talk to someone in addition to your CF care team are;

www.cysticfibrosis.org.uk/the-work-we-do/support-available

www.childline.org.uk

Will my taking part in the interview be kept confidential?

Yes, we will keep all your information strictly confidential. This means that we will not let anyone else other than the research see the answers you gave. Your data may also be seen by some authorised people to check that the study is being done correctly. All of us have a duty to keep you and your information safe and we will do our best to do this. This also means that we may need to break confidentiality in the interview if you tell us about something or someone which is causing you harm or hurting you or someone else. If we need to do this, we will talk to you about it first.

We will keep the information you gave safe on the University computer system which is password protected and limits who is able to access the information. We change our passwords regularly and we will change your name into a number code so that you cannot be recognised from it. We will keep this information, including the recording of the interview, for 5 years and then destroy it securely.

Who is doing the study?

The Nottingham University Hospitals NHS Trust and the University of Nottingham.

What if there is a problem?

If you have any concerns, you should ask to speak with the researchers who will do their best to answer your questions. The researcher’s contact details are given at the end of the information sheet. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. These details are available from the hospital or you can contact the Patient Advice and Liaison Service (PALS), telephone 0800 183 0204.

Thank you for taking the time to read this information sheet and to consider this study.

Contact details

Dr Rebecca Calthorpe: Rebecca.calthorpe@nottingham.ac.uk
Prof Kim Thomas: Kim.Thomas@nottingham.ac.uk
Prof Alan Smyth: tel 0115 82 30612: alan.smyth@nottingham.ac.uk