Participant Information Sheet

For young people, 12-15 years

Nottingham University Hospitals NHS
NHS Trust

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

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 join our focus group to talk to us about their experiences and to help us decide what 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 Cystic Fibrosis. 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. It is up to you. We would only want you to take part if you want to. Even if you have decided to take part and at a later time decide you wish to stop, you are free to stop taking part at any time without giving a reason. If you decide to stop, this will not affect the care you receive but we will still keep the records from the group discussions we had with you and use them as part of the study.

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 then invite you to join a group a focus group with other pwCF to talk about some of your CF symptoms and ask your thoughts on what to include in our scoring system.

- The focus group will last approximately 2 hours and will be on a video call over the internet.
- We will need to audio and video record the discussions. 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 focus group but the results may help pwCF in the future. To thank you for taking the time to be a part of the focus group, 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 the focus group who can help you and also give you information about support available to you. We can do this as a separate “breakout room” to the rest of the focus group so that you can talk to us privately. 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 me taking part in the focus group be kept confidential?

Yes, we will keep all your information strictly confidential. This means that we will not let anyone else other than the researchers see the answers you gave. Your data may also be seen by some authorised people to check that the study is being done correctly. Even if you withdraw from the study, we will continue to keep this information safe and confidential. All of us have a duty to keep you and your information safe and we will do our best to do this. This means that we may need to break confidentiality in the focus group 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 want everyone who takes part in the focus group to feel it is a safe space to share their ideas and experiences to the study. Therefore, it is important that you keep what other participants share confidential and do not share this information outside of the focus group.

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 focus group, 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

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