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

We are inviting the young person in your care to take part in a research study

Before you decide whether or not to agree for the young person in your care to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and family if you wish.

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you agree for the young person in your care to take part. You can have more time to think this over if you are unsure.

1. Why are we doing this study?

Gut symptoms such as bloating, pain and sickness are common for many people with Cystic Fibrosis (pwCF). PwCF previous told us that these symptoms can be embarrassing, have an effect on their body image and interfere with their quality of life. Two in every three people will miss either school or work because of gut symptoms, affect people from being able to exercise or being able to attend social events. We want to better understand how these symptoms disrupt or impact on the daily lives of pwCF.

We are developing a scoring system called a 'patient reported outcome measure' (PROM) that will allow people with CF 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 can 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.

2. Why has the young person you care for been asked to take part?

We are recruiting pwCF age 12 years and over to talk to us about their own experiences and tell us their thoughts about questions we may include in our scoring system.

3. Does the young person in your care have to take part?

No, it is up to you and the young person in your care whether to decide to take part. If you both agree for the young person to take part, they are also free to leave the study at any time without giving a reason. If you decide to withdraw the young person from the study, this will not affect the care they receive. Unless you object, we will still keep the records from their group discussions we had with them and use them as part of the study.

4. What will the young person have to do if they take part?

If you and the young person in your care decide they wish to take part, you will both be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. You will be given copies of this information sheet and the consent form to keep.

We will hold a focus group with the young person and other pwCF to talk about some of their gut symptoms and ask their thoughts on 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 focus group. This is so we can listen back to the responses later to help us understand the discussions and recognise any themes between participants. We will also transcribe the conversation in the focus group.

5. 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 the young person for taking the time to participate in the focus group, we will compensate them with a £30 shopping voucher.

6. What are the disadvantages?

The young person may be asked to talk about some of their own experience of gut symptoms which some people can find uncomfortable or embarrassing. If they experience this, please talk to your research team who will be able to signpost you to support services.

7. What happens after the research study?

The young person's participation ends after they have completed the focus group. The results of the discussions will be used to help determine a list of possible questions to be included as part of the patient reported outcome measurement we are developing. If you and the young person would like to be involved in further aspects of the study such as further interviews, reviewing these questions in a survey or trialling the scoring system on the app, details of these can be sent to you by the research team.

The results of the study will be available after it ends and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the participants involved in the study will be identified in any report or publication.

After the publication we will send you a plain English summary of the study findings. Should you wish to see the publication, please ask the study research team. We will hold an online event that you may be able to attend.

8. What if there is a problem?

If you or the young person you care for have any concerns about the focus group or any other aspects of the study, 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. Details can be obtained from the hospital or you can contact the Patient Advice and Liaison Service (PALS), telephone 0800 183 0204.

9. Will taking part in the focus group be kept confidential?

Yes, we will keep all the information and the consent form strictly confidential. This means that we will not let anyone else other than the research team see the answers the young person gave. Their responses will be audio and video recorded and transcribed after the discussions. The information will be secured electronically at the University of Nottingham under the provisions of the General Data Protection Regulation 2018 and the Data Protection Act 2018. The young person's name will not be passed on to anyone else outside the research team or the sponsor. The research study team also reserves the right to break confidentiality in the event of disclosure of harm during the interview, however where possible the study team will discuss this with you and the young person before doing this.

We want everyone who takes part in the focus group to feel it is a safe space to contribute their ideas and experiences to the study. Therefore, it is important that the young person keeps what other participants share confidential and does not share this information outside of the focus group.

The young person's research records will be available to the research team but may also need to be made available to people authorised by the NHS Trust, which is the organisation responsible for ensuring that the study is carried out correctly (research sponsor). By signing the consent form you agree to this access for the study and for any further research that may be conducted in relation to it, even if you withdraw the young person from the study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee. This is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to the research participant.

In line with Good Clinical Practice guidelines, at the end of the study, the data including the recording of the focus group, will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

10. Use of personal data in research

Nottingham University Hospitals NHS Trust is the sponsor and data custodian for this study. This means we are responsible for looking after your information and using it properly. Once the study is completed the sponsor will be responsible for storing information collected from the young person you care for, including the consent form and the recording of the focus group for 5 years after the study has finished.

Your rights to access, change or move the young person's information are limited, as we need to manage the information in specific ways in order for the research to be reliable and accurate. If you withdraw the young person from the study, we will keep the information we have already obtained. To safeguard the young person's rights we will use the minimum personally-identifiable information possible.

Nottingham University Hospitals NHS Trust may use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Nottingham University Hospitals NHS Trust and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in Nottingham University Hospitals NHS Trust who will have access to information that identifies you will be people who need to audit the data collection process.

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

- at www.hra.nhs.uk/information-about-patients/
- our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following link www.nuh.nhs.uk/gdpr
- by asking one of the research team
- by emailing the Data Protection Officer for NUH at dpo@nuh.nhs.uk,
- by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 83975)

11. Who is organising and funding the study?

The Nottingham University Hospitals NHS Trust act as a sponsor for the research. The National Institute for Health Research are funding the research.

12. Who has reviewed this study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion on the 1st February 2022 by HRA and Health and Care Research Wales (HCRW).

13. Further Information

You are encouraged to ask any questions you wish before, during or after the focus group. If you have any questions about the study please speak to the research team who will be able to provide you with up to date information about the study involved.

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

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