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 whether or not 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 wish 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 previously 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 and affects people being able to exercise or attend social events. We want to better understand how these symptoms disrupt or impact on daily life.

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 take part in a patient interview to talk to us about their experiences and to help us decide what questions we need to include in our scoring system.

2. Why have you been asked to take part?

We are recruiting pwCF age 12 and over. This is because you are being invited to talk to us about your own experiences and tell us your thoughts about questions we may include in our scoring system.

3. 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.

4. What will you have to do if you take part?

If you decide to take part you will 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 interview you and talk to about some of your gut symptoms and ask your thoughts on questions we may include in 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 and can arrange to do this at a time that is most convenient for you.

We will need to record your interview and this is so we can listen back to your answers later to help us understand your answers and help us recognise any themes between the answers you and other participants gave. 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. We will also transcribe the conversation in the interview.

5. 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 participate in the interview, we will compensate you with a £30 shopping voucher.

6. 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 experience this, please talk to your research team who will be able to signpost you to support services for this.

7. What happens after the research study?

Your participation ends after you have completed your interview. Your answers will be used to help decide on a list of possible questions to be included as part of our patient reported outcome measure we are developing. If you would like to be involved in further aspects of the study such as reviewing these questions in a survey or trialling the scoring system in 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 also hold an online event that you may attend.

8. What if there is a problem?

If you have any concerns about the interviews 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 me taking part in the interview be kept confidential?

Yes, we will keep all the information you give and the consent form strictly confidential. This means that we will not let anyone else other than the researchers see the answers you gave. Your responses will be audio and video recorded (where applicable) and transcribed after the interview. These will be kept strictly confidential at all times. 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. Your 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 before doing this.

Your 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 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 you as a research participant.

In line with Good Clinical Practice guidelines, at the end of the study, your data, including the recording of the interview, 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 you, including your consent form and recording of the interview for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum amount of 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 1st February 2022 by HRA and Health and Care Research Wales (HCRW).

The study has also been reviewed and approved by the Research & Innovation department of Nottingham University Hospitals NHS Trust.

13.Further Information

You are encouraged to ask any questions you wish before, during or after your interview. If you have any questions about the study please speak to your 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.

Contact details

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