Participant Information Sheet

Aged 12+ years and adults

A Comprehensive Approach to Relief of Digestive Symptoms in Cystic Fibrosis (CARDS-CF research study): Testing CF Tummy Tracker, a Patient Reported Outcome Measure, by the recording of tummy symptoms using a smartphone app

For more information about the study, as well as to view the information contained in this information sheet electronically please visit our website at cftummytracker.org or use the QR code. **Once you have read the information below and have decided you wish to take part, instructions on how to download the app and register for the study can be found at the end of this information sheet.**

We are inviting you to take part in 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. Please contact the research team using the email addresses at the end of this information sheet. Take time to decide whether or not you agree to take part. This research is being carried out by Nottingham University Hospitals NHS Trust and the University of Nottingham, UK.

1. Why are we doing this study?

Tummy symptoms such as bloating, pain and sickness are common for people with cystic fibrosis (CF). These symptoms can be embarrassing, have an effect on body image and interfere with a person's quality of life. Two in every three people will miss either school or work because of tummy symptoms. We want to better understand how these symptoms disrupt or impact on the daily life of people with CF.

We have brought evidence together from previous studies as well as finding out the experiences of people living with CF through a patient survey, focus group and interviews to developing a scoring system called CF Tummy Tracker which is a 'patient reported outcome measure' (PROM). This PROM will allow people with CF to record their tummy symptoms and the daily impact of these. This study is to make sure the PROM measurement we have developed is suitable to be able to do this. This can then be used in the future by researchers to better assess tummy symptoms in CF and the impact that they have on daily life.

2. Who can take part?

We are asking people living with CF age 12 years and over to record their tummy symptoms daily for 2 weeks using a smartphone app. As we are asking you to score your own experiences, people younger than 12 years may struggle to do this without help from a parent or guardian so are not eligible to take part in this study.

3. Do you have to take part?

No, it's up to you if decide to take part. For young people 12-15 years of age, please talk to a parent/ guardian first. You will need to get their permission to take part. If you later decide to withdraw from the study, this will not affect the care you receive from your CF team. We will still keep the data recorded before you withdrew from the study and use the data as part of the final study analysis.

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

Once you have read the study information and decide to take part, you will be asked to tick the electronic consent on the smartphone app confirming that you understand what is involved. If you are under 16 years of age you must have the permission of your parent or guardian in order to take part. If you have any questions or would like to speak to the research team you can email us or request a call back using the contact details provided at the end of this information sheet.

The app will display 10 questions asking about different aspects of tummy symptoms you may have experienced and the impact of these on your daily life over the last 24 hours. We need you to record this daily. These will be submitted through the app to the research team. You will also be asked to complete another tummy symptom questionnaire (CFAbd-Score) on the first and last day on the study. An electronic version of this will be on the app for you. You may be familiar with the CFAbd-score from attending CF clinic.

The first time you use the app, you will also be asked some information about yourself such as your age and gender, what medications you take, your CF centre, tummy complications related to your CF and if you have had a transplant. You will also be asked if you have taken part in the earlier stages of CF Tummy Tracker development through CARDS-CF. You will remain anonymous and won't be able to be identified from the answers you give. However, to ensure you remain anonymous, please make sure to not include any personal identifiable information (such as name or date of birth) in any of the free text question boxes in the app.

The contact details you give in order to sign up to the app may be used by the research team to send you a thank you e-voucher, let you know about future work relating to the study or receive the study results. These will be separated from your app responses before we analyse the results so that your answers remain confidential. It may also be used by the study team or app provider uMotif to contact you during the study period, for example if you are not filling in the app everyday to encourage you and see if there are any technical problems we can help you with. You will also be asked questions about the scoring system in the app as well on day 7 and day 14, such as how easy the questions were to understand and whether you have any thoughts on how to improve it.

5. What are the possible benefits?

There are no direct benefits from completing CF Tummy Tracker but the results may help those with CF in the future. As a thank you for taking part the first 100 people to complete the study will receive a £10 e-voucher via the email used to sign up to the app.

6. What are the disadvantages?

You will be asked questions about your own tummy symptoms which some people can find uncomfortable or embarrassing. If you experience this we would recommend you speak to your usual CF care team about this. There is also additional support available online through the CF Trust (UK) or CF Foundation (USA). Links to support information are also available through the app.

CF Trust: https://www.cysticfibrosis.org.uk/the-work-we-do/support-available)

CF Foundation: https://www.cff.org/support

Unfortunately, we are not able to give individual health advice through the app so if you notice worsening tummy symptoms you will also need to contact your usual CF care team directly.

7. What happens after the research study?

Your participation will end after using the app daily for 2 weeks. After this time you will still be able to view the answers you recorded on the app, but will not be able to record anymore tummy symptoms on it. Your email address may be used in order to send you an e-voucher as a mark of thanks, to let you know about other research related to this study or to receive the study results.

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. 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 CF Tummy Tracker we are testing or any other aspects of the study, you should contact the researchers who will do their best to answer your questions. The researchers' 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. You can also contact the Patient Advice and Liaison Service (PALS), telephone 0800 183 0204.

9. Will me taking part 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. These will be kept strictly confidential at all times. The information will be secured electronically by uMotif (the data processors for this study), the University of Nottingham and Nottingham University Hospitals NHS Trust under the provisions of the General Data Protection Regulation 2018 and the Data protection Act 2018.

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 will be securely archived for a minimum of 5 years. This will be done by Nottingham University Hospitals NHS Trust. Arrangements for confidential destruction will then be made.

10. Use of personal data in research

The Data Processor for this study is uMotif and Nottingham University Hospitals NHS Trust is the data custodian and sponsor for the 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, for 5 years after the study has finished.

Your rights to access, change or move your 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 from the study, we will keep the information we have already obtained. We will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at;

- our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following web pages www.nuh.nhs.uk/gdpr
- https://www.nottingham.ac.uk/utilities/privacy.aspx

Nottingham University Hospitals NHS Trust may use your 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.

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. uMotif are responsible for app development and data processing within the app.

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).

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

Contact details

Study email: CFTummyTracker@nottingham.ac.uk

Study website: cftummytracker.org

13. How do I get started?

If after reading the information sheet above you have decided to take part, please follow the steps below to download the app onto your device. You will need at least iOS 2.12.2 or Android 4.01 software on your phone to do this.

Guide for iOS

Step 1: Identify and tap the App Store on the home screen of your iOS device

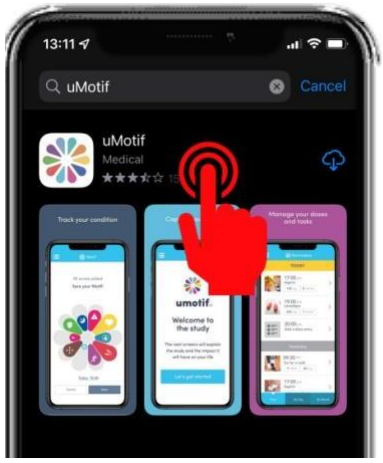
Step 2:

1. Identify and tap on the search bar to bring up the keyboard.

2. Search for “uMotif” in the App store.

3. Select the uMotif App.

4. Tap on “GET” and follow the on-screen instructions to complete the installation of the uMotif App. Once installation is complete, locate the uMotif App on your home screen and tap to open it.

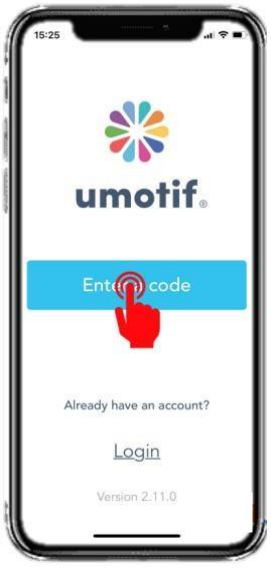


Step 3:

On opening the app, you will be taken to our home page where you are given the option to enter a code or login.

1. Click on Enter a code and then select the region you are in from the list
2. Enter the access code: CARDS
3. You are all set! Follow the instructions on the app to register and give consent for the study

Once you have completed the registration process, please use the “Login” button and enter your details to access the app during the rest of the study.



Guide for Android

Step 1: Go to the google play store and search for the uMotif app

Step 2.

1. Search for “uMotif” in the App store.
2. Select the uMotif App.
3. Click ‘Install’ to download the app onto your mobile device. Once downloaded you will be able to see the uMotif app on your device’s home screen

Step 3.

On opening the app, you will be taken to our home page where you are given the option to enter a code or login.

1. Click on “Enter a code” and then select the region you are in from the list
2. Enter the access code: CARDSCF
3. You are all set! Follo the instructions on the app to register and give consent for the study

Once you have completed the registration process, please use the “Login” button and enter your details to access the app during the rest of the study.