Gut Research Advancing a Mechanistic and Personalised Understanding of Symptoms in Cystic Fibrosis (GRAMPUS-CF) Strategic Research Centre

"In App" Participant Information Sheet for Group A

Virtual recruitment (for participation through a smart phone app)

For participants 12 years and over and adults

IRAS ID: 321418

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 telephone numbers 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 the University of Nottingham,Leeds Teaching Hospitals Trust and Belfast Health and Social Care Trust in the UK. The data and research findings will be used by PhD students as part of their degree.

What is the purpose of the study?

We want to find out more about the type of gut symptoms people with cystic fibrosis (CF) experience and what causes them. In this research we will study symptoms and diet, using questionnaires. You can complete these questionnaires on this mobile phone app. The app also lets you record your tummy symptoms every day on CF Tummy Tracker.

Who can take part?

We are inviting people with CF aged 12 years and over to take part. Your participation will be helpful whether or not you have trouble with gut symptoms and whether or not you are taking one of the new CFTR modulator drugs. Children and young people aged 12-15 years, should only take part with consent from their parent or guardian. The app is not designed for people younger than 12 years. If you are under 12 please do not use the app. If you attend the Children and Young Person's CF Centre in Nottingham or Leeds, you may still be able to take part through your CF Centre.

Do I have to take part?

No, it's up to you if you 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.

What will I have to do if I decide to take part?

Once you have read the study information and if you 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 12-15 years of age, you must have the permission of your parent or guardian. If you have any questions or would like to speak to the research team you can request a call back using the contact details provided at the end of this information sheet.

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 app development. You will remain anonymous and won't be identifiable from the answers you give. To ensure you remain anonymous, please do 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 app will then ask you to complete a series of questions and questionnaires: seven GRAMPUS-CF questions, a general gastrointestinal symptom measures (GSRS), a general measure of constipation (PAC-SYM) and a dietary questionnaire (Intake24.org). The app will then display 10 questions asking about different tummy symptoms you may have experienced and the impact of these on your daily life over the last 24 hours. This is called CF Tummy Tracker. The questions are presented on a flower pattern the "motif" and you answer by swiping along each petal. We would like you to record this every day for 7 days. After 7 days,

we will ask you to fill in the questionnaires again. We would like you to repeat this process at 6 and 12 months. We will send you a reminder to do this via the app. The information you provide will be submitted to the research team via the app.

Your contact details will be separated from your app responses before we analyse the results so that your answers remain confidential. Your contact information may be used to let you know about the progress of the GRAMPUS-CF research. The study team or app provider (uMotif) may also contact you during the study period, for example to encourage you to fill in the CF Tummy Tracker each day for 7 days and see if there are any technical problems we can help you with.

Some UK patients (in Nottingham, Leeds or Belfast) may want to be part of group B (blood and poo samples) and group C (MRI scan). If you would like to know more about these parts of the study please tick the appropriate box in the consent screen and indicate that you are happy for us to use your email to contact you about this. Recruitment to groups B and C is limited. Once we reach these numbers will stop recruitment and even if you are willing, we may not be able to take further samples.

What are the disadvantages?

We do not foresee any significant disadvantages. We will keep any information we collect about you confidential. The tests we do will not be used to guide your clinical care. 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.

What are the possible benefits?

We cannot guarantee that the study can help you directly. We hope that you will find it interesting and that, at the end of the study, we will be able to understand gut symptoms in CF better.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw from the study, we will not collect any more data from you. The data we have collected so far cannot be erased.

Will my taking part in this study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you and your medical records during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database by the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Prof Smyth) is the Data Custodian (manages access to the data). The Data Processor for this study is uMotif. This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible. You can find out more about how we use your information and to read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Information about you which leaves our research site will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth. Your contact information will be kept by the University of Nottingham for 4 years after the study ends so that can contact you about our findings and possible follow-up studies (unless you say you don't want to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. If we share your data in this way it will be anonymised (so that you cannot be identified).

The dietary questionnaire which you will complete Intake24.org will not hold any of your personal data. Your personal information will not be sent to other third-parties.

What happens after the research study?

Your participation will end after 12 months. After this time you will still be able to view the answers you recorded on the app, but will not be able to record any more tummy symptoms on it.

We will share our findings on the GRAMPUS-CF website and through social media. We will present our work at CF conferences to share with other researchers and clinical teams and publish our findings in scientific journals. Some of our team are studying for a PhD degree and some of this work may be in their PhD thesis. None of this published information will allow individual research participants to be identified.

Who is organising and funding this study?

The study sponsor is the University of Nottingham. GRAMPUS-CF is funded by the UK CF Trust.

Who has reviewed this study?

All research in healthcare is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This project has been reviewed and given a favourable opinion by the Cambridge South NHS Research Ethics Committee.

What if there is a problem?

If you have any concern about any aspect of the study, you can speak to a member of the research team. Please find their contact details in the 'further information and contact details' section. If you remain unhappy and wish to complain formally, you can do this by contacting Patient Advice and Liaison (PALS). PALS contact details are also in 'further information and contact details' section.

How do I get started?

If after reading this information you have decided to take part, please complete all the boxes on the next screen and click on the "I consent" button. You will then be taken to the questionnaire screens. Thank you!

Further information and contact details

Cystic Fibrosis Nottingham Team

- Darren Sills, Research Dietitian (0115 823 0612)
- Professor Alan Smyth (0115 823 0612)

Cystic Fibrosis Leeds Adults Team

- Dr. Hisham Saumtally, Medical Research Fellow (0113 243 3144, Extension 69106)
- Professor Daniel Peckham (0113 206 5282)

Cystic Fibrosis Leeds Childrens Team

- Jacqueline Lowdon, Dietitian (0113 39 22479)

Cystic Fibrosis Belfast Team

- Professor Damian Downey 02890329241

Study email: grampuscf@nottingham.ac.uk

Study website: https://www.grampus-cf.org/

If you remain unhappy and wish to complain formally, you can do this by contacting Patient Advice and Liaison

Nottingham University Hospitals Trust

- telephone 0800 183 0204
- or email: PALS@nuh.nhs.uk

Leeds Teaching Hospitals Trust

- telephone 0113 2066261,
- textphone: 07468753025 (if you are deaf or speech impaired)
- or email: patientexperience.leedsth@nhs.net

Belfast Health and Social Care Trust

- **By email complaints@belfasttrust.hscni.net**
- **By completing our online form**

Consent page on app

Once you have read the information on the previous screens, if you would like to take part please read and tick if you agree to the following statements below. If you are 12-15 years of age, you must have read and discussed this information with a parent/ guardian and get their permission to take part. You cannot use the app if you are aged 11 or under.

- I confirm that I have read and understand the Group A Participant Information.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.
- I understand that relevant sections of my data collected during the study, may be looked at by authorised individuals from the University of Nottingham, from the research team, from regulatory authorities where it is relevant to taking part in this research. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.
- I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.
- I would like more information about group B (blood and poo samples) and group C (MRI scan) – UK participants only.
- I agree for my email to be used by the research team to contact me about the study.
- I agree to take part in this study.