

**School of Healthcare Studies**

**Participant Information Sheet**

**Study Title: Cystic Fibrosis and the gut: what adults would tell their younger selves**

Study ID No.: 218231Name of Centre: SJUH

We would like to invite you to take part in the above research study. Before you decide whether or not you wish to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information and discuss it with others if you wish.

**What is the purpose of this study?**

We would like to explore how you make sense of how CF affects your gut. The purpose of the study is to gain an understanding of your experiences and how you have developed your knowledge and understanding. We would like you to share your insights to answer the question: ‘what would you tell your younger self about the CF gut?’. These insights will then be used in the development of an intervention for children with CF, which will aim to develop confidence and skills to self-manage gut involvement.

**Who is doing the study and when?**

Laurie Cave will be doing the study. She is a children’s CF Dietitian who is conducting the study as part of a masters in research at the University of Leeds. Her supervisor is Associate Professor, Dr Linda Milnes, School of Healthcare, University of Leeds. The study will run from March to July 2017.

**Why have I been asked to participate?**

You have been asked to take part in this study because you were diagnosed with CF in childhood, are now aged 20-30 years old and you use pancreatic enzyme replacement therapy (Creon). This is because the study is about your experience of living with CF since childhood and how your understanding of diet and Creon has changed over time. We expect that between 8 and 10 patients will take part in the study.

**What will be involved if I take part in this study?**

You will have one face-to-face interview with Laurie Cave. This will last up to one hour and will take place at a time to suit you, in the second week of a two-week admission to the ward between May and July 2017. We would like you to talk about your experiences and what these experiences mean for you. For example, perhaps there was something or someone that particularly helped you make sense of how CF affects your gut? or what to eat or how to take Creon? The interview will be audio-recorded so that it can be written out, with all personal information removed, and looked at in detail to answer the study question.

**What are the possible benefits of taking part?**

Whilst there are no immediate benefits for those taking part, the insights and explanations shared could make a significant contribution to the development of an intervention for children with CF.

**What are the possible disadvantages and risks of taking part?**

The interview will take up to one hour of your time.

As the interview is about your experiences, though unlikely, it is possible that you may become upset during the interview. If this happens you will be asked if you would like to end the interview and if you wish to discuss any issues raised with your nurse or a psychologist within the team.

**Do I have to take part?**

No, taking part is entirely voluntary – it is up to you to decide whether or not to take part. The dietitians will describe the study. If you are interested, they will give you a copy of this information sheet and go through it with you. If you agree to take part, you will be asked to sign two copies of a consent form before the start of the interview and will be given one of the signed consent forms to keep.

**Can I withdraw from the study at any time?**

Yes, you can withdraw from the study at any time, without giving a reason. This will not affect the care you receive in any way. If you wish, all data obtained from you that we are able to identify as yours, will be withdrawn. Data that has already been anonymised and is no longer identifiable as yours, will not be able to be removed. If this is the case, the data will be used for purposes for which you had already given consent.

**Will the information I give be kept confidential?**

All information given by you will be kept confidential, in accordance with the University of Leeds Data Protection, Anonymisation and Sharing Research Data Protocol which incorporates the Data Protection Act 1998. Please note if you were to disclose abuse, potential harm to others or malpractice among health professionals, this would need to be followed up by Laurie Cave discussing it with her supervisor in the first instance.

Personal data in the form of paper consent forms and email or postal addresses (for those wishing to receive a summary of the results), will be stored securely at the University of Leeds and will only be accessed by those carrying out the study. They will be disposed of securely within 3 months of the study’s completion.

Laurie Cave will write out (transcribe) the recorded interviews, anonymise them and use another name for you and anyone else mentioned in the interview. Audio-recordings will be securely erased as soon as they are transcribed. During the study, the anonymised interview transcripts will be stored securely in a password-protected dedicated folder on a University of Leeds computer and will only be accessed by those carrying out the study. When the study is completed, the anonymised interview transcripts will be archived at the University of Leeds Research Data Repository (Research Data Leeds) for a minimum of 10 years, so that they may be looked at and possibly used again.

**What will happen to the results of the study?**

The results of the study will be available after it finishes. They will be written up as a dissertation and may be published in a healthcare journal or presented at a scientific conference. The data, including any direct quotations from those taking part, will be anonymous and no patient involved in the study will be identified in any report or publication. The results will also be fed back through the patient newsletter and again will remain anonymous. If you wish, you can receive a summary by email or post.

**Who is sponsoring this study?**

The University of Leeds.

**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 interests. This study has been reviewed and given a favourable opinion by the South West - Exeter Research Ethics Committee on 07/04/17, ethics reference 17/SW/0042.

If you would like more information or have any questions about this study, please contact: Laurie Cave, MSc student at the University of Leeds on 07816 259 160. If you have any concerns or wish to make a complaint about the study, please contact Dr Linda Milnes, Associate Professor at the School of Healthcare, University of Leeds on 0113 343 1342.

**Thank you for taking the time to read this information sheet**

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