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Participant Information Sheet

REC Ref No: 20/SW/0180

A questionnaire to identify predictive symptoms and risk factors for hydrogen and methane breath testing outcomes

Chief Investigator: Dr Anthony Hobson

We would like to invite you to take part in our research study. Before you decide, you need to understand why the research is being done and what it would involve for you**.** One of our team will go through the information sheet with you and answer any questions you have. This should take about 10 minutes. Talk to others about the study if you wish. If you are taking part in any other study, you may not take part in this study.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part.

Part 1

Why have I been invited?

You have been invited to participate in this study because you have been referred for a lactulose or glucose hydrogen and methane breath test (HMBT) at The Functional Gut Clinic. The study intends to investigate if there are any predictive symptoms.

How many people will take part?

This study has been designed to enrol at least 1040 patients to complete the study.

What is the purpose of the study?

Lactulose HMBT and Glucose HMBT are simple non-invasive tests to assess whether imbalances in gut bacteria may be contributing to troublesome tummy symptoms. These imbalances in gut bacteria include small intestinal bacterial overgrowth (SIBO) and excessive methane production.

Recently there has been a lot of work to done by experts in the field, to ensure that performance and interpretation of these tests are standardised, to help improve the

clinical utility of these investigations. Although there is a lot of information currently available demonstrating the risk factors and symptoms associated with these conditions, there is a lack of data demonstrating the factors that might lead to a positive test according to these new parameters. This study aims to collect data on symptoms and medical history, in patients referred for lactulose and glucose HMBT in order further improve the effectiveness of this test in the future.

Do I have to take part?
No, the decision to participate is completely voluntary. If you wish to proceed, you will be required to sign a consent form to show you have agreed to take part, a copy of which you can keep. You are still free to withdraw at any time and without giving a reason. A decision not to take part or to withdraw will not affect the standard of care you might receive in the future from the doctors or the clinic. If you want to stop being in the study, tell the study staff.

What does the study involve?
The study involves you to answer a questionnaire about your symptoms and medical history, that will be sent to you with your postal breath test kit and should be completed along the breath test they have been referred for. You will be assigned a unique study ID which will keep all of your personal data anonymous during the study. This means the results from your hydrogen and methane breath test and questionnaire results will only be linked by a unique ID and your personal data associated with the breath test will never be used in any part of the study.

<u>Enrolment into the study</u>

You will have been approached to take part after being referred for a glucose or lactulose HMBT with The Functional Gut Clinic. Once you have reviewed the patient information for at least 24 hours, you may contact the study team if you have any questions on 0161 302 7777 or sam.treadway@thefunctionalgutclinic.com. If you would like to take part in the study, you should complete the consent form that will be sent to you and following this the study questionnaire will sent to you to complete.

What are the possible benefits of taking part?
There are no direct benefits from partaking in the study, however, information we get from this study may help us to better utilise hydrogen and methane breath testing in the future.

What happens when the research study stops?
The results you and others provide will be analysed and published. You are welcome to see the final report of this research.

What if there is a problem?
Any complaint about the way you have been dealt with during the study, will be addressed. Detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. We will follow all ethical and legal guidelines and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?
Withdrawal from this study will not affect how you are treated in the future by The Functional Gut Clinic.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to Sam Treadway who will do his best to answer your questions (0161 302 7777). If you are unhappy with any aspect of the study and wish to complain formally, you can do this through The Functional Gut Clinics complaints process, and Amanda Barlow, registered manager will be happy to help (0161 302 7777).

What are the costs of taking part?

There will be no costs to you for participating in this study. Ask the study staff if you have any questions.

Will my taking part in this study by kept confidential?
If you join the study, some parts of your medical records (if there are any) and the data collected for the study will be looked at by authorised persons from the study team at The Functional Gut Clinic. They may also be looked at by representatives of regulatory authorities and by authorised people 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. All information collected will be securely stored in a locked filing cabinet or password protected computer systems at The Functional Gut Clinic and participants will only be identified by a unique ID number.

What will happen to the results of the research study?
Results will not be available until the study has been completed and analysed. We intend to publish the results, but no individual will be identified in any such publication. You are welcome to have access to the results and any subsequent publication when any of these are available.

Who is organising and funding the research?

The Functional Gut Clinic.

Who has reviewed this study?
All scientific research involving patients is looked at by an independent group of people called a Research Ethics Committee to protect your interests including safety, rights, wellbeing and dignity.

Further information and contact details
If you require any further information about the study, please feel free to contact Sam Treadway (0161 302 7777) who is co-ordinating this study.

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