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Participant Information Statement and Consent Form

Investigating the Effect of Gut Metabolites on Inflammatory Responses in COPD: The BEYOND Study

Invitation

We invite you to take part in our research study. We are looking at how compounds produced by bacteria in the gut affect immune function in adults with and without Chronic Obstructive Pulmonary Disease (COPD). The gut holds bacteria that produce compounds which affect the body's natural defence against illness. Professor Lisa Wood, Dr Hayley Scott, Dr Evan Williams, Dr Bronwyn Berthon, Professor Peter Wark, Professor Chris Grainge and Ms Laura Dowling from the Hunter Medical Research Institute (HMRI) and The University of Newcastle are conducting this study. This study forms part of Laura Dowling's PhD, studied at The University of Newcastle.

The purpose of this sheet is for you to learn why we are doing the research and what it involves. This is important for you to know before you decide if you would like to take part in this study. Please take time to read this sheet and talk about it with others if you wish.

What is the purpose of this study?

Changing bacteria in the gut can improve lung health. At this point in time, we do not have enough information to do clinical trials, so as a first step, we would like to do test tube research to measure how the immune cells of people with and without COPD respond to different gut compounds.

Why am I invited to take part in this study?

You may be suitable for this study if you are 18 years or older and have COPD.

Are there any reasons why this study may not be for me?

This study is not for you if you:

- Currently smoke;
- Are pregnant or breastfeeding;
- Have a terminal illness or cancer; or
- Take certain medicines.

What does the study involve?

Telephone screen

To confirm if the study is right for you, we will ask you some questions over the phone. These questions will be about any illness you may have, the medicines you take, and whether you smoke.
If we find this study is right for you, and you would like to take part, we will arrange for you to visit HMRI.
If you agree to take part in this study, we will ask you to:

- Sign the Participant Consent Form
- Attend a visit at the HMRI (details to follow).

Study Visit
The study visit will take about 1.5 hours.

First, we will measure your height, weight, and blood pressure. Then we will do breathing tests, collect a blood and sputum sample, and fill out surveys. Each test is outlined below.

- **Breathing Tests:** This is a routine breathing test with no known danger. You may feel breathless or dizzy, but this only lasts for a few seconds.
  You will be asked to breathe through a mouthpiece while wearing a nose clip. You will be asked to take in as big a breath as possible. You will then blast the air out as fast as you can until your lungs are completely empty and then take another deep breath in again. You will do these three times or more to make sure the results are accurate.
- **Sputum (Phlegm) Test:** We would like to collect a sputum sample, which you can cough and spit into a jar. We use this to look at the immune cells in your lungs.
- **Blood Test:** We would like to collect a blood sample (about 3 tablespoons or 54mL). Before you attend the study visit, we ask that you do not eat or drink anything other than water for 12 hours. We will collect your blood from your arm. After we collect your blood, we will offer you a snack.
- **Blood Pressure and Oxygen Levels:** We will measure your blood pressure using a blood pressure machine. We will measure your oxygen levels using a machine which wraps around your finger.
- **Surveys:** We will ask you about any illness you may have, your diet, if you smoke, and about any medicine you take. It will take between 20-30 minutes to fill out these questions.

We may invite you back for a second study visit, a minimum of 4 weeks later. This visit will have the same tests and surveys as Visit 1, outlined above.

What if I don't want to take part in this study, or if I want to withdraw later?

Taking part in this study is your choice. If you decide not to join the study, it will not affect your care.
If you decide to withdraw from the study, you can choose to have your details or samples destroyed. An exception to this is if you have a side effect or reaction because of the study, where the data needs to be retained for regulatory reporting. If you wish to withdraw from the study once it has started, you can do so at any time.

Are there gains or dangers to me taking part in this study?

You will be provided with a $20 gift voucher to cover the cost of travel associated with taking part in this study. You will also receive the nutritional summary of your dietary intake survey.

By taking part, you will help us understand how compounds produced by bacteria in the gut affect the body's defence against illness. We can send the details we collect about your health to your doctor. All car parking for the study will be free of charge.
All medical tests involve some risk. You may bleed or bruise at the blood collection site. You may also feel dizzy or faint. Please tell the research team if you feel dizzy or faint when you have blood collected.

What happens if I become sick or injured during this study?

You should get in touch with the Study Coordinator as soon as possible. They will help you to get medical treatment.

How will you protect my details?

Any details we collect about you in the study will remain private. We will only give out your details if you agree, or except if needed by law. We will keep your details secure at HMRI. Only the staff named below may view your details.

What happens with my samples?

By agreeing to take part in this study, you also agree for us to collect, store and test your samples. We will test and store your samples for further testing in the HMRI Respiratory Research Laboratory.

We will remove your identity from your samples stored within a secure freezer. This means a code will replace your personal information. If you agree, we may use your coded samples for future research that relate to this research project. You have the right to have your samples destroyed at any time by getting in touch with Professor Lisa Wood using the contact details provided below.

What happens with the results?

We can give you a summary of the results at the end of the study. Please be aware that the study may take over a year to finish.
We plan to talk about and report the results of this study. In any report, your details remain private. We will share the results from this study with other research and medical staff. We may share the results on social and other media, or at events for research, medical staff, and the public.

If you are taking part in another study at HMRI, both studies may need the same details from you. You can approve us to share your details from our study. This may limit the need for you to have further testing.

What should I do if I want to talk about this study further before I decide?

If you would like to know more, please get in touch with the Study Coordinator below. We will talk about the study with you and answer any questions.

Professor Lisa Wood
Head of School, Biomedical Sciences and Pharmacy

Dr Hayley Scott
Postdoctoral Researcher
Immune Health Research Program,
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Dr Evan Williams
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Dr Bronwyn Berthon
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Miss Laura Dowling
Study Coordinator and PhD Candidate
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Professor Christopher Grainge
Senior Respiratory Physician and HMRI Affiliate Researcher
Asthma and Breathing Research Program
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Lot 1 Kookaburra Circuit,
New Lambton Heights NSW 2305
E: christopher.grainge@health.nsw.gov.au

Who should I get in touch with if I am concerned about this study?

Hunter New England (HNE) Human Research Ethics Committee have approved this study, reference number 2023/ETH00314.

Please report any concerns you have about this study with one of the research staff listed above. Or if you would like to speak someone outside of the study, please get in touch with the HNE Research Office and quote 2023/ETH00314.

HNE Research Office:

Hunter New England Local Health District, Level 3 POD, HMRI
Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305.
Telephone: 02 4921 4140. Email: HNELHD-ResearchOffice@health.nsw.gov.au

Thank you for taking the time to read about this study.

If you wish to take part in this study, please sign the attached consent form.

This information sheet is for you to keep.

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Participant Consent Form

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I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the participant information statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to:

- ☐ Completing the tests and questionnaires involved in the study
- ☐ The study coordinator contacting my respiratory specialist or GP to access historical lung function results and confirm my COPD diagnosis
- ☐ A copy of my results being sent to my General Practitioner
- ☐ A copy of my dietary intake report emailed or posted to me. My email address is: _____
- ☐ A copy of the study results emailed or posted to me.
- ☐ Allowing other studies that I am enrolled in within the Hunter Medical Research Institute to access data that is duplicate to the data collected in this study
- ☐ Having my blood/sputum samples stored for use in future research. If I decline to have samples stored, I am still able to participate in the study

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

Name _____

Signature _____ **Date** _____

I have informed the above person about this research and am sure that they understand both the content of the Information Statement and the additional information I have provided.

_____

Investigator/Delegate Name (printed) Signature Date