THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Dr Hayley Scott
Immune Health Research Program
Hunter Medical Research Institute
Lot 1 Kookaburra Circuit
New Lambton Heights NSW 2305
Ph: 02 4040 0113
Email: Hayley.Scott@newcastle.edu.au

Participant Information and Consent Form

Fruits and Vegetables for Chronic Obstructive Pulmonary Disease (COPD): A Cross-Sectional, Observational Study

Document Version 1 – 3/11/2024

Invitation

You are invited to take part in a research study looking at fruits and vegetables and how they may affect lung health. This study is being carried out at the Hunter Medical Research Institute (HMRI) by Prof Lisa Wood, Dr Hayley Scott and Rhiannon Stent from The University of Newcastle, Hunter Medical Research Institute, and is being completed as part of the PhD studies of Rhiannon Stent.

This information sheet is designed to help you understand why we are conducting this research and what it involves, so you can make an informed decision about participating.

Please take the time to read this sheet carefully, and feel free to discuss it with others if you wish.

What is the purpose of this study?

This study is looking at dietary intake of fruits and vegetables, as well as other foods and nutrients, in people with chronic obstructive pulmonary disease (COPD) and people without COPD. This will help us assess fruit and vegetable intake to see if there is a connection between fruit and vegetable intake and symptoms of COPD.

Why have I been invited to participate in this study?

This study may be suitable for you if you:

- Are 40 years or older and have been diagnosed COPD, chronic bronchitis or emphysema
- Are 40 years or older and have no respiratory diagnosis
- Currently taking medication for COPD (Puffer or inhaler)

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Dr Hayley Scott
Immune Health Research Program
Hunter Medical Research Institute
Lot 1 Kookaburra Circuit
New Lambton Heights NSW 2305
Ph: 02 4040 0113
Email: Hayley.Scott@newcastle.edu.au

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

This study is not for you if you:

- COPD is not your primary (main) respiratory diagnosis
- Are pregnant or breastfeeding.
- Are younger than 40 years old.

What does this study involve?

If this study is suitable, and you would like to take part, you will be invited to complete some online questionnaires. We will ask you to complete online questionnaires related to your medical history, medications, COPD symptoms (if you have COPD), quality of life, diet, physical activity, sleep and anxiety and depression. The questionnaires can be self-completed on your own device, at a time and place that suits you, there's no need to attend a clinic or research site. They can be completed in one sitting or over multiple sessions. Depending on your responses, it may take between 30 and 60 minutes to complete the questionnaires.

If you agree to take part in this study, we will ask you to:

- Sign the Participant Consent Form
- Complete the study questionnaires

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 wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. If you choose to withdraw, you may also request that all data related to you be removed.

Are there benefits or risks to me in taking part in this study?

We hope that participating in this study will be a positive experience for you. The study includes online questionnaires, which will take about 30-60 minutes of your time to complete. By participating in this study, you will help us to understand more about the possible health benefits of fruits and vegetables for people living with COPD, however you may not directly benefit from taking part. After completing the study, you will be provided with a $20 gift voucher for your time spent participating in

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Dr Hayley Scott
Immune Health Research Program
Hunter Medical Research Institute
Lot 1 Kookaburra Circuit
New Lambton Heights NSW 2305
Ph: 02 4040 0113
Email: Hayley.Scott@newcastle.edu.au

this study. You can also receive a summary of the results of your dietary intake survey if you would like this sent to you.

While we don't anticipate any significant risks from taking part, some questions may cause discomfort, particularly those related to mental health or diet. If you experience any distress or anxiety while completing the questionnaires, contact details for support services such as as Lifeline (13 11 14) are provided for you to access at any time. If you're concerned about your fruit and vegetable intake, you can visit the Dietitians Australia website to find an accredited practising dietitian near you (www.dietitiansaustralia.org.au/find-an-apd). If you're worried about your respiratory health, we recommend discussing your concerns with your GP or regular healthcare provider.

How will my confidentiality be protected?

Any identifiable information that is collected about you for this study will remain confidential and will be disclosed only with your permission, or except as required by law. The online survey software is REDCap, which is a secure online data management tool hosted by Hunter Medical Research Institute. REDCap can only be accessed by registered users and is password protected. Once data collection closes, the data will be downloaded and stored in the University of Newcastle's online cloud network (OneDrive) in a password protected file. Access to the data will only be available to the research team, who have been listed below.

No personal information will be collected as part of the research questionnaire. Personal information required for the purposes of gift card supply will be collected in a separate, secure survey that links out from the main questionnaire. This personal information will be stored securely within REDCap, accessible only to the research team, and will be stored separately from research responses to maintain participant anonymity.

Data will be retained securely for at least 5 years from the research project's completion. Information will be managed and stored in accordance with the University's Research Data and Materials

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Dr Hayley Scott
Immune Health Research Program
Hunter Medical Research Institute
Lot 1 Kookaburra Circuit
New Lambton Heights NSW 2305
Ph: 02 4040 0113
Email: Hayley.Scott@newcastle.edu.au

Management Guideline, or any successor guideline as applicable by University of Newcastle policy provisions.

What happens with the results?

At the end of the study, if you would like a copy of the study results a summary of the results will be sent to you via email or a letter will be sent to you in the mail as per your preference indicated in the online survey. Please note that the study may take one to two years to complete.

You will be able to access a summary of your nutrition data from the Food Frequency Questionnaire (FFQ); however, no other individual questionnaire responses or scores will be provided.

The research will contribute to the PhD thesis of Rhiannon Stent, which is being completed at the University of Newcastle. We plan to publish the results of the study and present the findings at scientific conferences. In any publication or presentation, your details will remain private and presented in a way that you cannot be identified. We may also use the stored data in future research that is closely related to this research project, if you give your consent for this to occur.

Costs

Participation in this study will not cost you anything. After completing the study, you will be sent a $20 electronic gift card via email as a thank you for your time.

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

If you'd like to know more at any stage, please feel free to contact Rhiannon Stent or any of the other Investigators listed below. We will be happy to discuss the study with you and answer any questions.

Dr Hayley Scott Lecturer in Nutritional Biochemistry Immune Health Research Program, Level 2, Hunter Medical Research Institute Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305	Professor Lisa Wood Pro Vice Chancellor College of Health, Medicine and Wellbeing MS605 Medical Sciences Building	Miss Rhiannon Stent PhD student, Study dietitian Immune Health Research Program, Level 2, Hunter Medical Research Institute Lot 1 Kookaburra Circuit,

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Dr Hayley Scott
Immune Health Research Program
Hunter Medical Research Institute
Lot 1 Kookaburra Circuit
New Lambton Heights NSW 2305
Ph: 02 4040 0113
Email: Hayley.Scott@newcastle.edu.au

T: 02 4042 0113 E: Hayley.Scott@newcastle.edu.au	University Drive Callaghan, NSW 2308 Australia T: 02 49217485 E: lisa.wood@newcastle.edu.au	New Lambton Heights NSW 2305 T: 02 4042 0978 E: Rhiannon.Stent@uon.edu.au

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2025-0139.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher or, if an independent person is preferred, to the Human Research Ethics Officer, Research Services, NIER Precinct, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

Thank you for taking the time to consider this study.

If you wish to take part in it, please click the link to sign the consent form.