**Dr Hayley Scott**
**Immune Health Research Program**
Level 2 West Wing, HMRI Building
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T: 02 4042 0113
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## Participant Information and Consent Form

# ***The Individualised Diet and Exercise Intervention for Optimising Asthma Control and Lung Function (IDEAL) Study***

### Invitation

You are invited to take part in a research study investigating a 16-week personalised diet and physical activity program to manage asthma symptoms. This study is being carried out at the Hunter Medical Research Institute (HMRI) by Dr Hayley Scott, Prof Lisa Wood, Dr Sarah Valkenborghs, Prof Anne Dixon, Prof Jay Horvat, Dr Natasha Weaver, A/Prof Serene Yoong, Dr Bronwyn Berthon, Dr Evan Williams, Dr Alexandra Brown, Meagan Morrissey, Prof Peter Wark, Prof Emad El-Omar, Prof Christine Jenkins, A/Prof Christopher Grainge, A/Prof Katie Wynne, Dr John Brannan and Tamara Blickisdorf from The University of Newcastle, Hunter Medical Research Institute, The University of Vermont, Deakin University, University of New South Wales, George Institute for Global Health and John Hunter Hospital.

Before you decide whether or not you wish to take part in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. A member of the research team will also explain the study to you. If you do not understand any of the information or have any worries, please ask us.

### 1. What is the purpose of this study?

This study will test the first tailored weight management approach for people with asthma. This will include personalised diet and physical activity advice. We will look at how this program effects asthma symptoms, inflammation in the blood and lungs, and bacteria in the gut and nose. We will also measure how well the program works, whether participants like the program, and the cost of the program.

## 2. Why have I been invited to participate in this study?

This study may be suitable for you if:

- You are aged 18 years or older with a doctor's diagnosis of asthma;
- Are usually using your asthma medication two (2) times per week or more;
- Have current asthma symptoms; and
- Have a body mass index (BMI) equal to or greater than 27kg/$m^2$ and/or a waist circumference equal to or greater than 88cm (women) or 102cm (men)

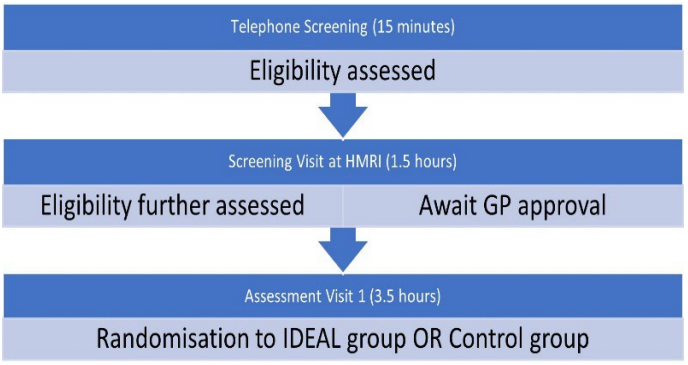
## 3. What if I don't want to take part in this study, or if I want to withdraw later?

Taking part in this study is your choice. It is up to you whether or not you take part in the study. If you decide not to take part, it will not affect the care you receive, now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. You may withdraw from the study at any time without having to give a reason. If you decide to withdraw from the study, you may choose to withdraw all data relating to you and have any samples taken destroyed. An exception to this is if you experience a side effect or reaction because of the study. This data needs to be kept for regulatory reporting. The researchers may withdraw someone if it is in their best interest, or for another appropriate reason. If this happens, the researchers will explain why and advise you about any follow-up procedures or alternative arrangements as appropriate.

**This study is <u>not</u> suitable for you if you:**

- Are a current smoker;
- Are pregnant or breastfeeding;
- Have a serious medical condition (e.g., unstable angina, unstable metabolic disease (e.g., unstable diabetes), stroke, renal (kidney) failure, hepatic (liver) failure, heart failure, HIV, or terminal illness;
- Have had unstable weight (±5% change in the last three months);
- Currently have a severe orthopaedic problem or a medical issue that would compromise your ability to undertake physical activity or dietary modification, including previous bariatric surgery; or
- Are taking insulin (oral diabetes medications and non-insulin injections are OK).

**4. What does this study involve?**




Telephone Screening

We will need to check that the study is suitable for you. To do this, we will ask you some questions about your medications and medical history.

Screening Visit

If you agree to take part in this study, you will be asked to attend a screening visit. This visit will be conducted at the Clinical Trial Facility on Level 4 of HMRI. At this visit you will be asked to sign the Participant Consent Form. During this visit we will:

- Measure your height, weight and blood pressure;
- Complete some questionnaires;
- Collect a blood sample; and
- Complete some breathing tests (see below for more information).

We may look at your medical record to find information about your asthma and other health conditions. We would like to access and record the visits and lung function results in your medical record. This will involve our staff accessing your medical record and recording the results of your visit in your patient notes. We may invite you back for an additional screening visit if we need to do another breathing test.

If this study is suitable, we will organise a convenient time for you to begin the study.

Visit 1

If you are eligible and choose to participate, we will first collect some baseline data. After this visit, you will also be randomly assigned (like a coin toss) to one of two groups:

i. **Group 1 – The 'IDEAL' Intervention Group:** 16 weeks of personalised dietary advice with a dietitian, and an individualised physical activity plan with a physiotherapist or exercise physiologist. Visits will be performed at baseline, 4 months, and 12 months.

ii. **Group 2 – The 'IDEAL' Control Group:** Usual diet and physical activity for 12 months. Visits at baseline (Week 0), 4 months, and 12 months. After the 12-month visit, this group will receive a 90-minute diet and physical activity counselling session and a Fitbit.

**5. How many visits and how long will each visit take?**

The total number of visits you will attend depends on the group you are assigned to (see tables below). Those in the intervention group will attend HMRI a total of nine (9) times, while those in the control group will attend HMRI a total of five (5) times. The screening visit will take approximately 1.5 hours. Visit 1-3 will take approximately 3.5 hours. If you are assigned to the intervention group, each diet and physical activity session (Visit A-E) will take approximately 1.5 hours. If this study is suitable for you, we will send a letter to your general practitioner (GP) with information explaining the study. Your blood test results and a clearance form must be signed off by your GP, as well as a physician involved in the research study. This will clear you to participate in the program. If this study is not suitable for you, with your permission we will advise your GP of your test results and will forward the information to your GP for follow up.

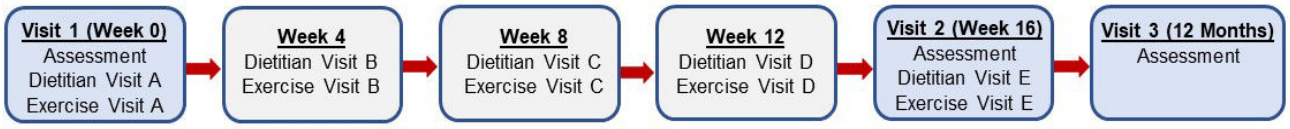
**Study Program Schedules**

**(i) Group 1 – The 'IDEAL' Intervention Group Visit Schedule**

This group will be asked to attend HMRI a total of nine (9) times. over 12 months (see table below). This includes the screening visit, 7 visits during the 16-week intervention period (2 assessment visits, 5 diet and physical activity sessions), and a follow up visit at 12 months. Visits 1-3 will be completed on separate days to the diet and physical activity sessions. The diet sessions will be completed with a dietitian. These sessions will be personalised and will include a review of your food diary along with nutrition counselling. The physical activity sessions will be completed with a physiotherapist or exercise physiologist. These sessions will include a review of your current exercise levels and a personalised exercise prescription. You will engage in physical activity during these sessions, which may include using hand held weights and/or a resistance band, or performing sit to standing movements.

The visit schedule for the IDEAL group is as follows:

| | |
|---|---|
| **Pre-Week 0** | • Screening Visit (approx. 1.5 hours), Optional: Additional Screening Visit B (45min) |
| **Week 0** | • Visit 1 (approx. 3.5 hours) |
| | • Visit A: Diet / Physical Activity Session (approx. 1.5 hours) |
| **Week 4** | • Visit B: Diet / Physical Activity Session (approx. 1.5 hours) |
| **Week 8** | • Visit C: Diet / Physical Activity Session (approx. 1.5 hours) |
| **Week 12** | • Visit D: Diet / Physical Activity Session (approx. 1.5 hours) |
| **Week 16** | • Visit E: Diet / Physical Activity Session (approx. 1.5 hours) |
| | • Visit 2 (approx. 3.5 hours) |
| **12 Months** | • Visit 3 (approx. 3.5 hours) |




**(ii) Group 2 – 'IDEAL' Control Group Visit Schedule**

This group will be asked to attend HMRI for a total of five (5) times over 12 months (see table below). This includes the Screening Visit, 2 visits during the 16-week control period, and a follow up visit at 12 months. Following Visit 1, participants will be advised to continue with their usual dietary intake and physical activity levels. Participants will then attend Visit 2 at week 16 and Visit 3 at 12 months. Following Visit 3, participants will receive a 90-minute counselling session with the study dietitian and physiotherapist or exercise physiologist. In this session, participants will receive information about the Australian nutrition and physical activity guidelines. This session will be performed on a separate day to Visit 3 to reduce fatigue.

The visit schedule for the Control group is as follows:

| | |
|---|---|
| **Pre-Week 0** | • Screening Visit (approx. 1.5 hours), Optional: Additional Screening Visit B (45min) |
| **Week 0** | • Visit 1 (approx. 3.5 hours) |
| **Week 16** | • Visit 2 (approx. 3.5 hours) |
| **12 Months** | • Visit 3 (approx. 3.5 hours) |
| | • Diet / Physical Activity Session (approx. 1.5 hours) |


**6. What will I need to do to prepare for my visits?**

- *Withholding asthma and allergy medications*: Before your Screening Visit and Visits 1-3, you will need to withhold your asthma medications for certain amounts of time. The amount of time will depend on what medication you are taking. Study staff will advise how many hours each medication would need to be withheld for each visit. Medications to withhold include asthma inhalers for 8 hours to 3 days, and allergy medication (antihistamines) for 3 days. However, if you feel that your symptoms become significantly worse during this time, you should use your normal medications. We will still see you in the clinic as planned.

- *Wear clothing and shoes suitable for exercise* for all visits to HMRI, except the Screening Visit. You may also wish to bring along a towel and water bottle.

- Bring a *list of current medications and supplements* to the Screening Visit, including doses.

- *Twelve (12)-hour fasting* required for Visits 1, 2, and 3. Please drink plenty of water during this time.

Study staff will remind you of how you need to prepare for each visit.

**7. What procedures will be carried out at?**

All visits will be performed at the Clinical Trial Facility on Level 4 of HMRI. Below describes the tests to be done at each visit:

| Timepoint: | Screening Visit | Visit 1, 2, and 3 | |
|---|---|---|---|
| **Duration:** | 1.5 hours | 3.5 hours | |
| **Procedures:** | • Height, weight<br>• Blood pressure<br>• Breathing tests<br>• Blood test<br>• Questionnaires<br>• Mannitol challenge (only if required at additional Screening visit) | • Waist circumference<br>• Blood pressure<br>• Breathing tests<br>• Mannitol sputum induction<br>• Blood test<br>• Questionnaires | • Weighed food diary<br>• Nasal swab<br>• Fitness tests<br>• Hand grip strength<br>• Body composition scan<br>• Exercise tracking |

**i. Breathing tests:**

*Spirometry:* Your lung function will be measured by blowing into a machine. This machine measures the amount of air you can breathe out of your lungs. You will be asked to blow into the machine until your lungs are empty (about 6 seconds). This is a safe and routine breathing test. You may feel short of breath and/or dizzy, but this usually only lasts for a few seconds.

*Forced Oscillation Technique (FOT):* You will be asked to breathe in and out normally into a machine. The machine will vibrate slightly while you are breathing. This test measures the mechanics of your lungs. This test is generally well tolerated, is comfortable and quick to perform.

*Fractional Exhaled Nitric Oxide (FeNO):* This test involves slowly breathing out into a machine, and measures inflammation in your lungs. This test is generally well tolerated, is comfortable and quick to perform.

**ii. Mannitol Challenge OR Sputum Induction:** You may be asked to complete a mannitol challenge at the screening visit. You will also be asked to complete a Mannitol Sputum Induction at Visits 1-3. These are breathing tests where we will ask you to breathe in a small amount of powdered sugar, called Mannitol. For both tests, Mannitol powder is breathed in via a dispenser in increasing doses, up to a maximum of 9 doses. A breathing test will be done at the end of each dose. Throughout the test, you will also be asked to cough up a sample of sputum (phlegm). This is a

routine test, which allows us to look at the amount and type of inflammation in your lungs. This is measured by counting types of cells in the sputum sample. These tests will be stopped at your request or if you develop any problems with your breathing. If you have any problems with your breathing, you will be given a reliever medication (Ventolin). We will closely monitor your symptoms and breathing throughout the test.

Some asthma and allergy medications may need to be withheld for certain amounts of time before the Mannitol tests. We will discuss suitability of this with you and give you more information about the withholding times, if applicable.

Instead of doing either test, we may instead ask you to cough up a sample of sputum (phlegm).

**iii. Blood Test:** Approximately 60mL (4 tablespoons) of blood will be taken from a vein in your forearm. This will be used to measure:

- Metabolic markers (e.g., blood sugar levels, cholesterol)
- Inflammatory markers
- Immune function
- Full blood count; and
- Sex hormone levels.

Screening bloods will confirm you are safe to enter the study by checking blood sugar control (HbA1c), and liver and kidney function.

**iv. Body Composition:** Your weight and waist circumference will be measured. Your height will be measured at your screening visit. We will also measure your body composition. This is a routine procedure that involves the use of a flatbed scanner that you lay flat on, which produces very low levels of radiation. The effective dose from this study is approximately 1-2μSv (equal to <5% of the radiation dose from a standard chest X-ray). As part of everyday living, everyone is exposed to naturally occurring background radiation (~5-8 μSv/day). This scan delivers a low dose, where no harmful effects of radiation have been demonstrated and the risk is negligible. This test is not painful and takes about 10 minutes to complete.

**v. Blood Pressure and Oxygen:** An automatic blood pressure monitor will be used to measure your blood pressure. A machine which clips onto your finger will be used to measure your blood oxygen levels. These tests are quick to run and are painless.

**vi. Physical fitness tests:** We will get you to carry out a 6-minute walk test and 30-second sit-to-stand test to assess your fitness level.

**vii. Handgrip strength:** You will be asked to squeeze a device known as a hand grip dynamometer as hard as you can. The best of three (3) attempts will be used to assess your hand grip strength.

**viii. Questionnaires:** At Visits 1-3, you will be asked to complete questionnaires related to your medical history, medications, asthma symptoms, quality of life, diet, physical activity, and anxiety and depression. There will be an additional questionnaire for women only asking about your menstrual history. These questionnaires will take approximately 30 minutes to complete. Between Visit 1 and Visit 2 you will be asked to complete a short weekly questionnaire sent via email. This questionnaire will be reduced to monthly between Visit 2 and Visit 3. The questionnaires involve answering some simple questions to check if you have had an asthma flare up, to monitor your asthma symptoms, and how much you have been needing your inhalers. This check should take less than 5 minutes to complete. Before each assessment visit, you will also be asked to complete a 4-day weighed food diary. You will be provided with kitchen scales, and measuring cups and spoons, to complete this diary.

**ix. Accelerometer:** Before Visit 1, 2, and 3 you will be asked to wear a physical activity tracking device on your wrist for 7 days. This is a slimline watch that records your physical activity and sedentary time.

**x. Stool sample:** We will ask you to collect a stool (poo) sample, which may be done at the study visit, or at home before you come in for your visit. We will provide you with a collection kit and instructions for collection, storage and return of the sample. This will be used to measure your gut bacteria.

**xi. Nasal swab:** We will collect a nasal swab from you during your visits. We will insert a cotton swab 1-1.5cm into your nostril and rotate gently to collect the sample. If you prefer, you can do your nose swab yourself. This will be used to measure any bacteria in your nose.

**xii. IDEAL Program extra requirements**: If you are randomised to the IDEAL Program, you will be asked to wear a Fitbit (slimline physical activity monitor worn on your wrist) which would be

provided to you. You will also be sent small deliveries of fruits, vegetables, nuts and oils every three (3) weeks for the duration of the program.

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

Your participation in this study will benefit our understanding of asthma, but you may or may not benefit personally. All information about your condition will be available to you.

Side effects of having blood collected may include bleeding or bruising at the injection site and possible dizziness and/or fainting. Please advise the research team if you normally feel dizzy or faint when you have blood collected. The sputum test can cause temporary coughing, some minor chest discomfort and wheezing in some people. This is brief and responds quickly to Ventolin.

If you take diabetes medication, there is a risk of changes in blood sugar levels that may require review of your medication dose. Our study endocrinologist (A/Prof Katie Wynne, Department of Endocrinology and Diabetes at John Hunter Hospital) has been consulted to reduce this risk. If you have diabetes mellitus that requires medication, your blood sugar diaries will be monitored during each counselling session. Blood sugar control (HbA1c) will also be measured at Visits 1-3. Your GP will need to give safety clearance to enter the study and will assist in monitoring blood sugar levels. If blood sugar levels show changes beyond safety parameters, a GP review will be required.

**9. What happens if I suffer injury or complications as a result of the study?**

If you suffer any injuries or complications resulting from this study, you should contact the study coordinator as soon as possible. They will assist you in arranging appropriate medical treatment.

**10. How will my confidentiality be protected?**

Only the researchers named above and clinical staff involved in your care will know whether or not you are participating in this study. 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. Only the researchers named below will have access to your details and results, which will be held securely in the Immune Health Research Program, HMRI.

**11. What happens with my blood, sputum, stool, and nasal swab samples?**

By consenting to take part in this study, you also consent to the collection, storage and use of the blood, sputum, stool and nasal swab samples. Blood, sputum and nasal swab samples will be tested in the HMRI Respiratory Research Laboratory. Some of your blood sample will be sent to Pathology

North and Pathology East for testing. Stool samples will be sent to the University of New South Wales for analysis. Testing of metabolites in blood samples will be conducted by the Australian National Phenome Centre.

Stored samples will be de-identified and kept in freezers at -80°C in a restricted-access laboratory. This means that any identifying information will be replaced with a code so that you will not be identifiable. If you give us permission, we would like to store unused samples for at least 15 years. The de-identified samples may be used for future research that is closely related to this research project, if you give your consent for this to occur. During and after the study, you retain the right to have your samples destroyed at any time by contacting the Chief Investigator.

**12. What happens with the results?**

Your participation in the study will help us learn more about asthma management. All information about your condition will be available to be sent to your general practitioner at your request. A summary of the results of the study will also be sent to you in an email, or a letter will be posted to you, at the completion of the study; however, you should be aware that the study may take several years to complete.

We plan to discuss/publish the results of the study. In any publication, information will be provided in such a way that you cannot be identified. We may also use the stored data in future trials, for which ethical approval will be sought beforehand. Samples collected in this study will be stored securely and may be used in further research, only if you agree and the research has been approved by the Hunter New England Human Research Ethics Committee. For all participants in the study, we would like to access and record the visits and lung function results in your medical records. This will involve our staff accessing your medical record and recording the results of your visit in your patient notes.

If you are enrolled in another study within the Immune Health Research Program and both studies need the same data/information from you, you can give us permission to share the data collected during our study with these other researchers to reduce the need for you to have further testing.

**13. Costs**

Participation in this study will not cost you anything. Parking will not cost you anything and a parking space will be reserved for you prior to each visit. Your general practitioner (GP) may ask you to see

them before they give their approval for you to participate in the study. Your GP may charge you for this appointment.

### 14. How is this trial being paid for?

This study is funded by a research grant from the Medical Research Future Fund (MRFF).

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

When you have read this information, one of the named researchers will discuss it and any questions you may have with you. If you would like to know more at any stage, please do not hesitate to contact any of the investigators on the numbers listed below.

| | | |
|---|---|---|
| Dr Hayley Scott<br>Chief Investigator<br>Lecturer in Nutritional Biochemistry<br>Immune Health Research Program<br>Level 2, HMRI Building<br>Lot 1 Kookaburra Circuit,<br>New Lambton Heights NSW 2305<br>T: 02 4042 0113<br>hayley.scott@newcastle.edu.au | Catherine Delahunty<br>Study Coordinator<br>Immune Health Research Program<br>Level 2, HMRI Building<br>Lot 1 Kookaburra Circuit,<br>New Lambton Heights NSW 2305<br>T: 02 40420135<br>catherine.delahunty@newcastle.edu.au | Tamara Blickisdorf<br>PhD Student, Study Dietitian<br>Immune Health Research Program<br>Level 2, HMRI Building<br>Lot 1 Kookaburra Circuit,<br>New Lambton Heights NSW 2305<br>T: 02 4055 0983<br>tamara.blickisdorf@uon.edu.au |

### 16. Who should I contact if I have concerns about the conduct of this study?

This research has been **approved** by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2023/ETH00833. The conduct of this research has been authorised by the Hunter New England Local Health District to be conducted at the John Hunter Hospital site. 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, please contact the HNE Research Office, Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305. Telephone: 0249214140. Email: HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number: 2023/ETH00833.

**Thank you for taking the time to consider this study.**
**If you wish to take part in it, please sign the attached consent form.**
**This information sheet is for you to keep.**

Health
Hunter New England
Local Health District

HMRI
Hunter Medical Research Institute

**Dr Hayley Scott**
**Immune Health Research Program**
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Fax: 02 4042 0046

**PARTICIPANT COPY**
**Participant Consent Form**

***The Individualised Diet and Exercise Intervention for Optimising Asthma Control and Lung Function (IDEAL) study***

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 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 involved in the study.
- ☐ Completing questionnaires to obtain research data.
- ☐ A copy of my results being sent to my General Practitioner.
- ☐ A copy of the study results being emailed or posted to me. My email address is:

  _____
- ☐ Allowing research personnel access to my medical record and to record attendance and results in my file
- ☐ Allowing other studies that I am enrolled in within HMRI to access data that is duplicate to the data collected in this study.
- ☐ Having my blood/sputum/stool/nasal swab samples stored for use in future research. I understand my samples will be retained for a minimum of 15 years. 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

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Health
Hunter New England
Local Health District

HMRI
Hunter Medical Research Institute

**Dr Hayley Scott**
**Immune Health Research Program**
Level 2 West Wing, HMRI Building
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**STUDY COPY**
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**Name** _____

**Signature** _____ **Date** _____

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_____

Investigator/Delegate Name (printed) Signature Date