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Participant Information and Consent Form

Dietary fibre as a modulator of airway inflammation in asthma

Invitation

You are invited to participate in a research study examining if a soluble fibre and probiotic supplement can help to reduce inflammation in adults with asthma. This study is being conducted by Associate Professor Lisa Wood, Dr Katherine Baines, Dr Bronwyn Berthon and Professor Peter Gibson from the Hunter Medical Research Institute and The University of Newcastle and is part of a larger programme looking at diet and asthma. This study is being undertaken as part requirement for a PhD at the University of Newcastle by Rebecca Zapirain, under the supervision of Associate Professor Lisa Wood and Doctor Katherine Baines.

Before you decide whether or not you wish to participate 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.

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

We will examine whether a soluble fibre and probiotic supplement are effective in increasing markers in the blood that may help to reduce airway inflammation. Soluble fibre comes from plant based foods and absorbs water in the intestine like a sponge. Probiotics are a source of live bacteria which boost numbers of beneficial bacteria in the body. In the large bowel soluble fibre provides nourishment to, and is fermented by, healthy bacteria to produce anti-inflammatory compounds. We hope to gain further insight into how soluble fibre may be useful in adults with asthma.

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

This study may be suitable for you if you are aged 18+ years old.

This study is not suitable for you if you are: a current smoker, are unable or unwilling to limit your diet to 2 serves of fruits and vegetables per day and consume All Bran daily for the duration of the study, currently taking cholesterol lowering medication, pregnant or breastfeeding.

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

Participation in this study is voluntary. It is completely up to you whether or not you participate. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you decide to withdraw from the study, you have the option of withdrawing all data relating to you and have all samples that have been taken destroyed. An exception to this is in the case of an adverse event, or a serious adverse event, where the data needs to be retained for regulatory reporting. The researchers may withdraw a participant if it is considered in the

participant's best interest or it is appropriate to do so for another reason. If this happens, the researchers will explain why and advise you about any follow-up procedures or alternative arrangements as appropriate.

4. 'What does this study involve?'

If you agree to participate in this study you will be asked to sign the Participant Consent Form. We will also need to check that the study is suitable for you and to do this we will invite you to come into the clinic for a screening visit, which will take approximately 30 minutes. This visit will include:

- A brief medical history; current medications
- Measurement of your height, weight and blood pressure;
- Questionnaire on asthma exacerbations and dietary intake
- Spirometry and a saline challenge may be undertaken if there is no evidence of asthma diagnosis

If following the screening visit it is that that this study is not suitable for you, we will advise you of the results and, with your permission, will forward the information to your GP for follow up. If this study is suitable, we will organise a mutually convenient time for you to begin the study.

The study takes place over 9 weeks. Two weeks prior to the start of the study and for the duration of the study we would like you to change your diet to include no more than 2 serves of fruits and vegetables per day and consume ½ cup of All Bran each day. We would also like you to avoid some foods such as yoghurt and fibre supplements. A dietitian will give you advice on how to do this prior to starting the study.

Two weeks after you have started the study diet, you will attend the clinic at HMRI for your first study visit (visit 1). Each study visit will take approximately 1.5 hours.

The study involves three phases where you will be asked to take the study medication for 7 days for each phase, with assessment at HMRI before and after each phase. Between each phase of the study will be a 2 week period to allow for the effects of the study medication to be eliminated.

Study timeline:

Start Study Diet	Phase One	Break	Phase Two	Break	Phase Three
Week 1-2	Week 3	Week 4-5	Week 6	Week 7-8	Week 9

The study medication that you will receive for each phase of the study will include a combination of a single serve powder sachet that is mixed with liquid and taken twice daily and a capsule that is taken once daily. These will contain a soluble fibre powder and a placebo capsule, a soluble fibre powder and a probiotic capsule or a placebo powder and placebo capsule.

The placebo will look exactly the same as the soluble fibre and probiotic supplement, but does not contain any active ingredients. You will receive each of these supplement regimes and the placebo, to take for a period of 7 days each. The order that you receive them in will be randomly decided (like tossing a coin). This study is blinded, this means that you will not know which regime you are on at what time. At the end of the study we will look at which supplement regime you took in each phase of the study then compare the results to work out whether the supplements made a difference.

Please note that you will be supplied with the study medication required for this study. You will also be supplied with a study diary, to indicate each day whether you have taken the medication, and to record any unusual symptoms or additional medications used during the study period. This will take about 1 minute of your time each day.

Prior to coming into the clinic, you will need to fast for 12 hours before each visit, and withhold your asthma medications for 6-24 hours, depending on which medications you use. However, if you feel that your symptoms worsen during this time, you should use your normal medications, and then come to your visit at the HMRI clinic as planned. The longest you will be asked to fast is 12 hours. If you feel you will be unable to do this, please notify the study staff.

Visits 1-6 (for details on each test see below):

- Blood test
- Spirometry
- Saline Challenge
- Exhaled Nitric Oxide test
- Blood pressure
- Questionnaires
- Stool sample collection

5. 'What does each of the tests involve?'

- **Blood Test** - At each visit approximately 20mL (1 tablespoon) of blood will be taken from a vein in your forearm after a 12 hour overnight fast, to measure your levels of inflammation and gene expression.
- **Spirometry**- Your lung function will be measured by blowing into a spirometer, a machine that measures the amount of air expelled from your lungs. You will be asked to blow into the spirometer until your lungs are empty (approximately 6 seconds).
- **Saline Challenge** - You will be asked to inhale a mist of salty water delivered by a nebuliser. You will be asked to do this for 30 seconds, 1 minute, 2 minutes, and three lots of 4 minutes. A breathing test will be done at the end of each period. This is a routine lung test. During the test we will ask you to cough to produce a sample of sputum, which we will measure for inflammation. The test will be stopped at your request or if your breathing test worsens and you will be given ventolin if you develop any problems with your breathing. Ventolin is a medication that immediately relieves constriction of the airways and is inhaled by mouth through a spacer device.
- **Exhaled nitric oxide –** (eNO) You will be asked to do a breathing test to measure the inflammation in your airways. This is a simple test and you will be asked to breathe in and then out using a mouthpiece.
- **Blood Pressure**– Your blood pressure will be measured using an automatic blood pressure monitor.
- **Questionnaires** – During your visit you will be asked to complete questionnaires related to your quality of life, diet, medication use and gastrointestinal symptoms. These questionnaires will take between 5-15 minutes to complete.
- **Stool sample collection** – We will provide you with a stool collection kit to collect a stool sample before each visit, which you will freeze until you come in for your visit.

6. 'Are there risks to me in taking part in this study?'

- The 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 saline challenge test can cause difficulty breathing, coughing, some discomfort in your chest and wheezing. This is brief and responds promptly to reliever medication such as Ventolin.
- If you are pregnant, intending to become pregnant or breastfeeding, you cannot participate in this study. If at any time you think you may have become pregnant, it is important to let the researchers know immediately.
- The supplements used in this trial are available over the counter and we are asking you to take them in doses within the ranges approved by the Therapeutic Goods Administration. When soluble fibre supplements are taken the most common side effect is mild flatulence. Less common side effects can include gastrointestinal pain or discomfort, diarrhoea, nausea, and stomach pressure with a sensation of fullness. In some people use of the probiotic supplement may cause cramps or pain in the stomach area, constipation, diarrhoea, mucus in the stool, bloated stomach area, and discomfort in the upper stomach area or flatulence. However these symptoms are generally mild and will disappear when you stop taking the supplement. It is important to notify the study staff if and when any of these symptoms occur, straight away.

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

If you suffer any injuries or complications as a result of this study you should contact the study coordinator as soon as possible, who will assist you in arranging appropriate medical treatment.

8. 'How will my confidentiality be protected?'

Only the study investigators will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. You will be notified by letter if this occurs. Only the study investigators will have access to your details and results that will be held securely at the Hunter Medical Research Institute.

9. 'What happens with the results?'

Your results including breathing tests will be available to be sent to your general practitioner, at the end of the study at your request. The results of the study will also be available to you at the completion of the study; however you should be aware that the study may take over a year 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. For all participants in the study we would like to access and record the visits in your medical records. This will involve our staff accessing your medical record and recording the results of your visit in your patient notes. 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 Human Research Ethics Committee.

10. Costs

Participation in this study will not cost you anything nor will you be paid. Parking will not cost you anything and a parking space will be reserved for you prior to each visit. The capsules required as part of this study will be provided to you at no cost. We will also provide you with a light snack at the end of each visit because you will have been fasting.

11. '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 queries you may have with you. If you would like to know more at any stage, please do not hesitate to contact her or any of the other investigators on the numbers listed.

A/Prof Lisa Wood
Associate Professor in Nutritional Biochemistry
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HMRI, Lot 1 Kookaburra Circuit
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Dr Katherine Baines
Postdoctoral Research Fellow
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Dr Bronwyn Berthon
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Professor Peter Gibson
Senior Staff Specialist and Conjoint Professor
School of Medicine & Public Health, University of Newcastle
HMRI, Lot 1 Kookaburra Circuit
New Lambton Heights NSW 2305
Tel: 02 4042 0143

12. 'Who should I contact if I have concerns about the conduct of this study?'
This study has been approved by the Hunter New England Human Research Ethics Committee, reference number 15/03/18/3.03 If you have concerns or complaints about the conduct of this study you should contact:

Dr Nicole Gerrand, PhD
Manager, Research Ethics and Governance
Hunter New England Local Health Network
Locked Bag 1, NEW LAMBTON, NSW. 2305
Tel: (02) 4921 4950
Fax: (02) 4921 4818
Email: Nicole.Gerrand@hnehealth.nsw.gov.au

The Manager is the person nominated to receive complaints from research participants. You will need to quote reference number 15/03/18/3.03.

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.

A/Prof Lisa Wood
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Participant Consent Form (Participant Copy)

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

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

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

I consent to-

1) Completing the tests involved in the study
2) Completing questionnaires to obtain research data
3) A copy of my results being sent to my General Practitioner
4) Allowing research personnel access to my medical record and to record attendance and results in my medical record

I consent to secure storage of samples collected in this study to be used in future research, subject to approval by the Hunter New England Human Research Ethics Committee.
YES ☐ NO ☐

I understand that my personal information will be maintained in confidence by 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)

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Participant Consent Form (Researcher Copy)

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Signature _____ **Date** _____

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Investigator/Delegate Name (printed)