Participant Information Sheet/Consent Form

John Hunter Hospital and Hunter Medical Research Institute

Title	Minimising Oral Corticosteroid Use in Asthma using Treatable Traits (TTOCS).
Short Title	TTOCS Study
Project Sponsor	The University of Newcastle
Coordinating Principal Investigator/ Principal Investigator	Professor Vanessa McDonald
Site Principal Investigator(s)	Professor Peter Gibson
Location	John Hunter Hospital and Hunter Medical Research Institute

Invitation

You are invited to take part in a research study. This study is looking at whether a personalised approach to asthma called 'Treatable Traits' reduces the need to take corticosteroid tablets. The approach involves an assessment to identify clinical issues that affect asthma and a personalised treatment plan to address these issues. This research is taking place at two locations in Australia (Newcastle and Perth). You will have your visits at the site most convenient for you.

Key information:

- Around 300 people will take part in this study.
- The study goes for 1 year.
- Every person in the study has a comprehensive assessment with the research team and receives active asthma treatment.
- A participant summary will be given to you at the end of the study.
- Across the year, there are a maximum of 7 in-person appointments.
- Visits will be completed at John Hunter Hospital and the Hunter Medical Research Institute.
- Additionally, there are a maximum of 6 phone calls with a researcher.

Before you decide whether to take part, you must understand why the research is being carried out. You must also know what it will involve.

Please take the time to read this information and discuss it with others if you wish. **Please feel welcome to contact us at any time to ask any questions you have.** You are welcome to contact Peter Gibson or any of the research team directly. Amber Smith, Study Coordinator will be the easiest person to connect with. Phone: (02) **4042 0134** or **Amber.Smith@newcastle.edu.au**

1. What is the purpose of this study?

Corticosteroid tablets, such as prednisone, are a powerful and lifesaving treatment for people with asthma. They are very good at treating asthma attacks and a small number of people need to take them every day. Unfortunately, they have negative side effects, especially when taken often and in large amounts.

We have developed a new personalised approach to treat asthma. We call this 'Treatable Traits'. In earlier research, we showed that this reduced the number of asthma attacks people had.

This study will find out whether the treatable traits approach will reduce the need for corticosteroid tablets in asthma.

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

This study is suitable for you if you have asthma, are aged 18 years or older and have taken corticosteroid tablets in the past 24 months.

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

This study is not suitable for you if you cannot speak, read, or understand English. The study is also not suitable if you are pregnant or have a significant life-limiting illness or cancer.

4. What does this study involve?

If you agree to take part in this study, you will be asked to sign the Participant Consent Form.

You will be allocated to one of two care groups. All participants will receive active asthma care. Your allocation to either group will be random (like tossing a coin).

Details about the asthma treatments.

Group 1

If you are allocated to ***group one*** you will receive an assessment and we will recommend management as per current asthma management recommendations (the Global Initiative for Asthma -GINA). A summary of your asthma control, corticosteroid use, lung function and exacerbation history will be provided to your GP. This summary will also include the asthma guideline recommendations. We will provide you with educational information to help you manage your asthma.

Group 2

If you are allocated to ***group two,*** you will also receive an assessment. A treatment plan will then be developed based on the results of this assessment. That is, based on the 'traits' identified. The treatment plan will be delivered by a multi-disciplinary team in the ambulatory care clinics of the Department of Respiratory and Sleep Medicine at John Hunter Hospital and the Hunter Medical Research Institute. Treatments may include education, smoking cessation counselling (if smoking) speech therapy (if vocal cord dysfunction is present) and breathing training. You will be given asthma medication depending on the results of your blood and breathing tests. This may be different to your normal asthma medication. Referral to an ear nose and throat specialist may be provided. Importantly you will only receive the treatment if it is needed based on your own individual assessment. An example treatment plan is shown in the table below.

Clinical Problem	Treatment	Health Care Professional
Smoking	Smoking cessation counselling and/or medication.	Nurse and Doctor
Not using inhaler/s correctly	Education and training for optimal inhaler technique.	Nurse
No written asthma action plan	Provide Written Asthma Action Plan.	Doctor
Inflammation in the lungs	Step 1. Review of medication. Step 2. Commence approved targeted therapy e.g., mepolizumab.	Doctor
Vocal Cord Dysfunction	Education and training.	Speech Pathologist

Study Visits: Questionnaires and Measurements

All participants will complete the same questionnaires and assessments. These will be performed when you enter the study, at the end of the treatment period (24 weeks), and again at 52 weeks. The visits will take no longer than 2.5 hours to complete. The visits include the following:

Clinical Measures

- Vital signs- we will measure your blood pressure, heart rate, temperature, and respiratory rate.
- Breathing tests to assess how well your lungs work. This involves blowing out hard and fast into a mouthpiece and device. We will also measure inflammation in the lungs. The test usually only requires one breath and is completed in less than a minute.
- Blood tests to look at inflammation in the body. We will collect about 2 teaspoons or 10ml of blood at each visit.
- Based on your symptoms we may recommend performing a laryngoscopy. A laryngoscopy involves passing a small flexible tube with a camera through your nostril into the back of your throat to view your vocal cords. Local anaesthetic is sprayed into your nostril prior to inserting the tube. This procedure takes between 2 and 5 minutes and will be performed by a qualified Speech Pathologist.

Questionnaires

We will ask you to complete some questionnaires. These questionnaires are designed to gain information about your:

- Demographics, general health, and quality of life.
- Medical history and medications.
- Asthma symptoms.
- Asthma-related healthcare use.
- Adherence to asthma medications.
- Vocal cord dysfunction symptoms.
- Rhinosinusitis symptoms.

Participant Diary

You will be given a participant diary at the first visit. We will ask you to bring this to every visit for review. This diary is for you to keep track of any symptoms you experience, medications you take and any GP or hospital visits during the study.

Telephone Follow-up

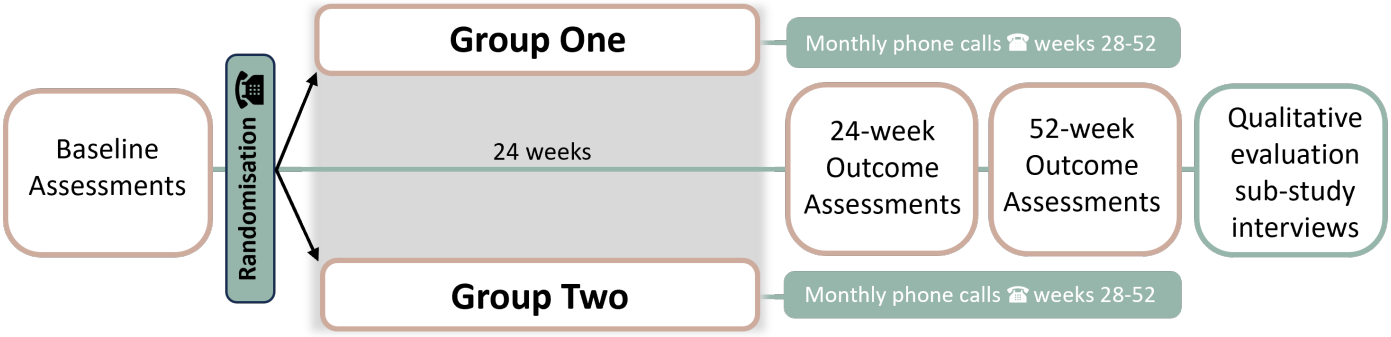
Every month after the end of the treatment period, we will phone you for about 15 minutes to ask questions about your health. This will be 6 phone calls in total. We will be especially interested in whether you have had any attacks of your asthma that required extra medication or visits to a doctor or hospital.

Group two will also need to attend up to 4 visits over the 24-week treatment period. The visits will depend on the treatment plan.

Interview

We will invite some people from group two to take part in a post-treatment interview. This will be either face-to face or online (i.e., via a video call). This interview will be like a conversation. The researcher will ask you about your thoughts on the treatment you received. The interviews will be audio recorded for accuracy. You may ask for the recording to be stopped at any time during the interview or for sections to be edited or deleted. You may also review and edit a transcript of the interview.

The image below shows the study timeline.



Services Australia Consented Data Release

We will assess the cost-effectiveness of the study in reducing the use of corticosteroid tablets. To do this we would like to collect information from Services Australia regarding your use of health care services and medications.

If you consent to the collection of this information from Services Australia, you will be asked to sign a separate consent form (see the *Services Australia Participant Information Document and Participant Consent Form).* If you decide to decline consent to this, you can still take part in the study.

Services Australia is not involved in this research other than to provide the information that you have consented to the release of, should you decide to participate in this study. Services Australia has confirmed that this research and any associated documents have received approval from a Human Research Ethics Committee (HREC) that is registered with and operates within guidelines set out by the National Health and Medical Research Council (NHMRC).

Services Australia data will be stored on servers, or hosted through cloud computing providers, physically located within Australian borders.

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

You get to decide whether you take part in this project. You can say yes or no.

Your decision won't affect your relationship with your doctor or the hospital. If you don't take part, it will not affect any treatment you receive now or in the future.

You can change your mind at any time.

If you do take part, you can stop at any time. If you want to stop, please tell someone in the study team. You do not have to tell us the reason. This can be done by completing the *Form for Withdrawal of Participation* at the end of this document. You can also withdraw verbally over the phone.

If you wish to withdraw your consent to the collection of your Services Australia data, you will need to complete the *Services Australia Withdrawal of Consent Form*.

Once you stop taking part, you have the option of withdrawing all information relating to you and have any blood samples that have been taken destroyed. An exception to this is in the case of an adverse event, where the information needs to be retained for regulatory reporting.

6. 'How is this study being paid for?'

The study is supported by a Medical Research Future Fund Preventative and Public Health Research Initiative Chronic Respiratory Conditions Grant.

7. Will taking part in this study cost me anything?

All tests and medical care required as part of the research will be provided to you free of charge. Parking will be free of charge. You will also receive medications such as nicotine replacement therapy, nasal corticosteroids, and saline nasal wash free of cost if indicated.

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

All medical procedures involve some risk. There may also be risks associated with this study that are currently unknown or unforeseeable. Despite all reasonable precautions, you might develop medical complications from participating in this study. For example:

The breathing tests can cause coughing, some minor chest discomfort and wheezing. This is brief and quickly responds to reliever medication. This will be provided for you. You may also feel light-headed or dizzy. Please let the researcher know if you experience any of these symptoms.

The side effects of having blood collected may include bleeding or bruising at the injection site. Dizziness and/or fainting is also possible. Please tell the research team if you normally feel dizzy or faint when you have blood collected.

The laryngoscopy is often used in clinical practice and is considered a very low risk test. However, it may cause mild and brief irritation of the nose. The test will be stopped if you feel uncomfortable. There are no lasting side effects to this test and the local anesthetic spray wears off within 30 minutes.

It is not our aim to ask questions that might be upsetting, stressful or uncomfortable. However, it is possible that these feelings may come up as you talk about your experiences. You are free to not answer any questions or withdraw from the study at any point. If the interview raises any issues for you, please let the researcher know. We will organise appropriate support for you.

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

If you suffer any injuries or complications because of this study, please contact the study team as soon as possible. We will assist you in arranging medical treatment as needed.

10. Will I benefit from the study?

This study may help guide the management of asthma and improve asthma recommendations. The information we get from this study may therefore help us to treat a patient's asthma better in the future.

11. How will my confidentiality be protected?

Only the researchers and clinical staff involved in your care will know whether you are taking part in this study. Any identifiable information that is collected about you in connection with this study will remain confidential. Identifiable information will be disclosed only with your permission, or except as required by law. Only authorised staff will have access to your details and results, which will be held securely at the study site. Study results, including direct quotes from the interviews, will be presented at conferences and in publications. These will not be identifiable. For example, all quotes will be de-identified.

12. What happens with the results?

Your participation in the study will benefit our understanding of asthma management. A participant summary of the results will be available to you at the end of the study. A summary of results will also be sent to your GP.

We would like to access your hospital medical record and make notes about your visits. This will make your results available to other clinicians who you may see at the hospital.

To make sure our study results are shared widely de-identified group data will be presented in scientific journals and at research conferences. We will also share the results via social/other media and at events for researchers, clinicians, and the public. This may include other people with asthma and their families. If you participant in the one-on-one interview de-identified direct quotes may be included in publications.

13. How will my records be stored?

Recordings and transcriptions from the study interviews be stored on secure network drives. Once the transcripts are received the interview recordings will be destroyed (within 6 months).

All other study related records will be retained for 15 years. Paper documents will be securely stored in a locked file cabinet, and access restricted to delegated personnel. Electronic data will be stored on password-protected computers on secure network drives. Only approved users can access this data. All data is physically located within Australian borders. After the 15-year period, paper records will be shredded, and any electronic data files will be deleted.

If you give us permission, we would also like to store unused blood samples for future research studies. These will be stored for up to 15 years.

If you are enrolled in another study within the Asthma and Breathing Research Program, you can give us permission to share the data collected during this study with these other researchers. This can help to reduce the need for you to have further testing.

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

When you have read this information, one of the researchers will discuss it with you. They will answer any questions you may have. If you would like to know more at any stage, please contact any of the researchers listed below.

Chief Principal Investigator	Professor Vanessa McDonald	Phone	(02) 4042 0146
Site Investigator	Professor Peter Gibson	Phone	(02) 4042 0143
Study Coordinator	Amber Smith	Phone	(02) 4042 0134

15. Complaints about this research

Ethics:
This research has been **approved** by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference **2023/ETH00612**

Governance:
The conduct of this research has been **authorised** by Hunter New England Local Health District at the John Hunter Hospital /Hunter Medical Research Institute site.

Complaints about this research:
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: 02 4921 4140. Email: HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number: **2023/ETH00612**.

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.

Professor Peter Gibson
Hunter Medical Research Institute
The University of Newcastle
Lot 1, Kookaburra Cct,
New Lambton Heights NSW 2305.
Ph:(02) 40420143 *Fax:* (02) 40420046

Minimising Oral Corticosteroid Use in Asthma using Treatable Traits (TTOCS)

Consent Form – Participant Copy.

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. If I take part in a post-treatment interview, I understand that de-identified or anonymised quotes will be used in publications and presentations.

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 usual General Practitioner.
4) Allowing research personnel access to my medical record and to record attendance and lung function results in my file.

Yes No

If eligible, I consent to completing the interview component of the study:

Yes No

I consent to allowing other studies that I am enrolled in within the Asthma and Breathing Research Program to access data that is duplicate to the data collected in this study:

Yes No

I consent to being contacted in the future or about participating in other studies:

Yes No

I consent to the storage of my blood samples for future research:

Yes No

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:

Minimising Oral Corticosteroid Use in Asthma using Treatable Traits (TTOCS)

Consent Form – Researcher Copy.

Professor Peter Gibson
Hunter Medical Research Institute
The University of Newcastle
Lot 1, Kookaburra Cct,
New Lambton Heights NSW 2305.
*Ph: (*02) 40420143 *Fax:* (02) 40420046

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. If I take part in a post-treatment interview, I understand that de-identified or anonymised quotes will be used in publications and presentations.

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 usual General Practitioner.
4) Allowing research personnel access to my medical record and to record attendance and lung function results in my file.

Yes No

If eligible, I consent to completing the interview component of the study:

Yes No

I consent to allowing other studies that I am enrolled in within the Asthma and Breathing Research Program to access data that is duplicate to the data collected in this study:

Yes No

I consent to being contacted in the future or about participating in other studies:

Yes No

I consent to the storage of my blood samples for future research:

Yes No

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:

Form for Withdrawal of Participation

(Complete only if you want to withdraw from the study after enrolling)

I wish to **WITHDRAW** my consent to participate in the TTOCS study.

Name _____

Signature _____ Date _____

For WITHDRAWAL of Participation in the TTOCS study this page should be forwarded to:

Study Coordinator	Amber Smith
Email	Amber.Smith@newcastle.edu.au
Phone	(02) 4042 01 34
Postal Address	Lot 1, Kookaburra Cct, New Lambton Heights NSW 2305.