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Participant Information and Consent Form

Understanding Breathlessness in Asthma

Invitation

You are invited to participate in a research study that aims to understand breathlessness in asthma. This study is being conducted by Professor Vanessa McDonald, Professor Peter Gibson, Dr. Vanessa Clark, Dr. Sarah Hiles and Dr. Anne Vertigan of the John Hunter Hospital and the University of Newcastle, and Professor Janelle Yorke at the University of Manchester.

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?'

Breathlessness is one of the most common and troubling symptoms that people with asthma report. Breathlessness may have many causes, such as reduced lung function, an abnormal breathing pattern, vocal cord dysfunction, obesity, or anxiety. Little research has been done to understand the different causes of breathlessness in asthma or people's experiences of breathlessness.

This study will use different methods to characterise breathlessness. By doing these assessments we will better understand how breathlessness impacts people with asthma, how breathlessness differs according to how severe your asthma is, and what the multiple causes of breathlessness are.

We will also gain a better understanding of the experience of people living with breathlessness that is caused by a condition known as vocal cord dysfunction. This condition is known to cause breathlessness and frequently overlaps with asthma.

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

This study is suitable for you if you have asthma and are aged 18 years or older.

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

This study is not suitable for you if you are under the age of 18 years, or cannot speak, read or hear 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 participate in this study, you will be asked to sign the Participant Consent Form.

The study involves three components: 1. A characterisation study, 2. An optional interview, and 3. An optional art-based activity.

Characterisation study

All potential participants are invited to participate in the **Characterisation Study.** This involves two consecutive visits 2-4 weeks apart in which you will undergo a series of tests and measurements.

These visits will be conducted at Hunter Medical Research Institute. Each visit will take no longer than 2.5 hours to complete.

We will ask you to complete some questionnaires. These will be spread over the two visits and you will be able to take some questionnaires home to complete and return on your next visit. These questionnaires are designed to gain information about your:

- General health or quality of life (visit 1 , visit 2 and in the take-home pack)
- Medical history and the medications you take (visit 1)
- Asthma symptoms (including attacks of your asthma in the past year, asthma control) (visit 1)
- Overall well-being and mental health (including symptoms of anxiety, depression and resilience) (visit 2)
- The amount of time you are active and inactive (visit 1)
- Problems you experience related to your breathing (including questions about breathlessness, vocal cord dysfunction, sleep quality, cough and mucus) (visit 1, visit 2 and in the take-home pack).

The majority of the questionnaires will be self-administered, meaning you will complete them yourself. For the other questionnaires the research officer will complete the questionnaire with you. For the questionnaires you can complete yourself, you can take them home and return them on your second visit. It will take you around 30 minutes to complete the questionnaires at home. If you need assistance, a research officer will be available to talk to over the phone.

We will also ask you to undergo some tests and assessments. These include:

Breathing Tests

Hypertonic saline challenge and spirometry: We will do some breathing tests, which involve you breathing into some tubing, which will allow us to assess how well your lungs work. You will then be asked to breathe in a mist of salty water delivered by a machine. You

will be asked to do this for periods of 30 seconds, 1 minute, 2 minutes, 4 minutes, 4 minutes and 4 minutes. The breathing test (spirometry) will be done at the end of each period. The test will be stopped at your request or if you experience increased symptoms. You will be given a reliever medication if you develop any problems with your breathing. The test can cause coughing and wheezing and a temporary fall in your lung capacity. These effects are usually quickly and completely reversed by reliever medication. We will closely monitor your symptoms and breathing throughout the study.

Respiratory inductive plethysmography: We will ask that you wear a band around your chest and abdomen to measure the timing and pattern of your breath while you are resting. The band remains on your chest and abdomen for the duration of the test, which is 10 minutes.

Body Plethysmography: This is used to calculate how big your lungs are. This test will involve sitting inside a glass cabinet and taking small quick breaths followed by very big breaths. The test will take about 7 minutes.

Breath hold time: We will ask you to hold your breath. We will then record the time it takes to feel discomfort or first sense difficulty. The researcher will monitor you during the test. You can let go of your breath hold at any time. While you are asked to hold your breath until it is no longer comfortable, there are no known risks associated with this test.

Hypocapnia: We will ask you to do normal breathing for 10 minutes while wearing a nasal tube that is attached to a device called a capnograph. The capnograph analyses the movement of air in and out of the lungs and monitors the concentration of carbon dioxide at the end of each breath.

Fraction of Exhaled Nitric Oxide (FeNO) Airway inflammation test: We will ask you to perform a FeNO test. When the airway is inflamed, the cells in the lungs produce higher than normal levels of nitric oxide. Measuring nitric oxide is a simple test where you breathe gently into and out of a small device via a mouthpiece. The test usually only requires one breath and is completed in less than a minute.

Blood Tests

We ask your permission to collect blood samples (about 2 teaspoons or 10mL). We will look for signs of inflammation. We will also store samples of your blood to analyse at a later time for other signs of inflammation and molecules. At all times your privacy will be maintained; your blood samples will be stored in a secure laboratory with an anonymous code before they can be analysed. We will store the codes and names in a secure locked file that can only be accessed by the research team.

Exercise Walk Test

We will ask you to walk for 6 minutes in a hallway and we will record how many laps of the track you can do. Before the test we will assess your pulse, blood pressure and pulse oximetry (measure of oxygen in your circulation by placing a sensor on your finger for approximately 1 minute). You will not be asked to do the walk test if you have a resting heart rate of more than 120 beats per minute or if your blood pressure is too high on the day of the visit. You should wear comfortable

clothing and shoes to your visits and use your usual walking aids. You will be asked to walk as far and as fast as you can within the 6 minutes. During the test you may experience breathlessness; if this happens you may slow down or rest at any time. If you take medication for angina, we will ask you to bring this medication with you to your visit.

Physical Activity

You may be asked to wear a physical activity monitor for a period of 14 days. These monitors are usually worn around the waist and they calculate how much activity you do throughout the day. We ask you to wear this throughout the day and while sleeping. You will need to remove the monitor while bathing or before water activities.

Body Composition

Bioelectrical impedance analysis (BIA) is a simple and safe measure of body composition. BIA is a common method used for estimating body fat and muscle mass. It involves standing on a device that is similar to a set of scales and holding some handles for 90 seconds. Your height and weight will also be recorded.

Laryngoscopy

The laryngoscopy test 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 Dr Anne Vertigan.

We may look at your medical record to find information about your asthma and other health conditions.

Interview

In addition to the clinical tests and questionnaires described above in the **Characterisation study**, we would also like to invite a smaller group of participants who we determine to have vocal cord dysfunction to participate in an interview. This interview will be like a conversation where the researcher will ask you a set of questions about your symptoms and your experience of them.

If you have evidence of vocal cord dysfunction based on your initial set of tests and you decide to participate in this aspect of the study, you will be asked to take part in a one-on-one interview with a researcher. In this interview, we would like to hear about your experiences of breathlessness and the impact it has on your day-to-day life. The interview will take up to 2 hours and will be audio-recorded. You may ask for the recording to be stopped and for any sections to be edited or deleted at any time during the interview. You can also edit a transcript of the interview, if you request it.

Art-based (Painting or drawing) Activity

We also invite some participants who have vocal cord dysfunction or who experience breathlessness from other causes to participate in an art-based activity. This will allow us to get more detail on your experience of breathlessness using a form of art expression. We will ask you to reflect on your experience of being breathless, and draw or paint what that experience means to you. You will be provided with the art supplies a canvas or paper of your choice. Please know that you do not have to be an artist. There are no right or wrong images. Any image you create is simply an expression of your feelings and thoughts. After you have completed this activity you will also be asked some questions about your image. This will allow you to provide some interpretation about what the image means to you. The interview will be audio-recorded. You can ask us to stop the recording or delete sections of the recording, or you can edit the transcript of the recording if you request it. This activity may take up to 3 hours. This activity will take place in a private room at the Hunter Medical Research Institute. At the end of the activity, we will keep the artwork you have created for our research and communication activities.

5. '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. If you decide not to participate, it will not affect any treatment you receive now or in the future. 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 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, or a serious adverse event, where the information 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 without having to give a reason.

6. How Many Visits?

We will ask you to attend two assessment visits of up to 2.5 hours each for the characterisation study. If you choose to participate in the interview or art study, this will involve additional visits on different days.

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

The study is supported through Professor Vanessa McDonald's research programme.

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

All medical procedures involve some risk. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of 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, which will be provided for you. You may also possibly feel light-headed or dizzy. Please let the researcher know when you experience any of these difficulties.

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

The Walk Test may make you breathless, in which case you will be given time to rest and recover.

The laryngoscopy is routinely used in clinical practice and is considered a very low risk test, however 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 over the next 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 for you 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 and 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 as a result of this study, you should contact the study doctor or nurse as soon as possible, who will assist you in arranging appropriate medical treatment.

10. 'Will I benefit from the study?'

You may not personally benefit from being in this study. Involvement in the study is purely voluntary and you may withdraw at any time.

11. 'How will my confidentiality be protected?'

Only the researchers named below and other 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 in connection with 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 that will be held securely in the Hunter Medical Research Institute. In any publication, information will be provided in such a way that you cannot be identified. For example, all quotes obtained from the qualitative interviews or artworks produced will be de-identified and a pseudonym provided. If your artwork is shown in public, the following information may also be displayed:

- title of artwork;
- the materials used in the artwork;
- the year the work was made;
- aspects of your qualitative description.

12. 'What happens with the results?'

Your participation in the study will benefit our understanding of respiratory disease management. All information about your condition will be available to be sent to your general practitioner at your request. A participant summary of the results will be available to you at the completion of the study.

We plan to discuss and publish the results of the study. Results of the study including the artworks will be presented to researchers and clinicians via seminars at local university and health service meetings, presentations at national and international conferences, and publication in peer reviewed journal articles. It will also be shared on social media and other media/events for researchers, clinicians and the public, which may include patients with severe asthma and their families. Artworks may be used in public health campaigns to raise awareness of the impact of severe asthma and comorbidity on patients' lives.

The University of Newcastle and Professor Vanessa McDonald (as the Principal Investigator) will be the copyright owner of all artworks produced and have the right to:

- reproduce or copy your de-identified artwork;
- publish your de-identified artwork in a book, magazine, newspaper or journal article; and
- communicate your de-identified artwork, for example, put your artwork on the internet.

However, if at any time you withdraw your consent, your artwork will have no further reproduction.

For all participants in the study we would like to access and record the visits, lung function and laryngoscopy 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 give us permission, we would also like to store unused blood samples for future research studies for up to 15 years.

If you are enrolled in another study within the Priority Research Centre for Healthy Lungs 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. '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 and any queries you may have with you. If you would like to know more at any stage, please do not hesitate to contact him/her or any of the other investigators on the numbers listed.

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Dr. Anne Vertigan
Conjoint Associate Professor
Speech Pathologist
John Hunter Hospital
Locked Bag 1, HRMC NSW 2310
Tel: (02) 4921 3726

13. '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. 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@health.nsw.gov.au

The Manager is the person nominated to receive complaints from research participants. You will need to quote reference number 2019/ETH12515.

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.

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Understanding Breathlessness in Asthma
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.
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 lung function results in my file.

Yes No

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

Yes No

If eligible, I consent to completing the art-based (drawing or painting) component of the study

Yes No

I consent to allowing other studies that I am enrolled in within the Priority Research Centre for Healthy Lungs to access data that is duplicate to the data collected in this study:

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**

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Understanding Breathlessness in Asthma

Consent Form – Researcher 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.

I consent to-

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2) Completing questionnaires to obtain research data
3) A copy of my results being sent to my General Practitioner
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Investigator/Delegate Name (printed)	**Signature**	**Date**