

**Participant Information Sheet**

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| **Study title:** | Altering the cough response after stroke |
| **Locality:** | Christchurch, New Zealand | **Ethics committee ref.:** | 21/NTB/100 |
| **Lead investigator:** | Phoebe Macrae | **Contact phone number:**  | +64 (0)3 369 2385 |

Thank you for expressing your interest in this research study. My name is Keri and I am assisting the lead investigator with this study. I am from the United Kingdom and worked as a speech and language therapist for nearly five years before coming to study at the University of Canterbury. Phoebe is a qualified speech and language therapist, and a senior lecturer at the University of Canterbury.

You are invited to take part in a study exploring whether we can alter the cough response following a stroke. You have received this information sheet as you have expressed an interest in finding out more about the study. Please take your time to read through the information provided and make sure you have read and understood all the pages. You are encouraged to ask questions to clarify any aspects that you do not fully understand.

## Background to the study:

The purpose of the study is to explore how effective airway stimulation is at altering the cough response of people who have had a stroke. Another aim is to confirm that breathing patterns remain unchanged after the airway stimulation. A stroke can affect a person’s ability to cough due to injury to parts of the brain that control coughing. It can mean that a person does not cough when food, drink or saliva go down the wrong way. This means that people with impaired cough after stroke can be at greater risk of choking and/or getting lung infections (pneumonia).

The airway stimulation treatment being used in this study has been shown to be safe in people who have not had a stroke, so the next step is to trial it with people who have had a stroke.

## Participants:

We are looking for participants who:

* are over the age of 18
* have had a stroke
* have been discharged from hospital
* are able to attend the research laboratory
* are able to cough voluntarily

**Location:**

The study will take place at the University of Canterbury Rose Centre for Stroke Recovery and Research. This is located in St George’s Medical Centre in Merivale.

## What participation in the study will involve:

The study will take place over a three-week period. If eligible, you will be required to attend for a total of 12 sessions. Please see the table below.

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| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Mon | Tues | Weds | Thurs | Fri | S | S |
| Week 1 | **Session 1 (screening)** |  |  |  | **Session 2**Cough test |  |  |
| Week 2 | **Session 3**Treatment | **Session 4**Treatment  | **Session 5**Treatment  | **Session 6**Treatment  | **Session 7**Treatment |  |  |
| Week 3 | **Session 8**Treatment | **Session 9**Treatment | **Session 10**Treatment | **Session 11**Treatment | **Session 12**Treatment |  |  |

Each part of the study requires different amounts of time from participants.

* **Week 1** comprises of two sessions. Session 1 is a screening session, this is to ensure you meet the criteria for the study. This session will take up to one hour.Session 2 consists of a cough test and will take up to 40 minutes.
* **Weeks 2 and 3** (sessions 3-12) require participants to attend the Rose Centre for daily sessions (excluding weekends) for a two-week period. Six of the sessions will take up to one hour, and four of the sessions will take up to one hour and 30 minutes (total 12 hours).

Prior to attending the research centre, you will receive a phone call to answer any questions you may have and ensure you meet the criteria for the study. This will include some questions about your medical history and the medications you take. If you are eligible and happy to take part in this study, a date and time for you to attend the research centre will be arranged.

***Session 1: Consent and screening session***

To see if you are eligible to participate in this study, you will complete a screening session. During this session, two measures will be carried out. One of your cough response and another of your lung function. We need your consent to carry out these tests. The results of these tests will tell us if you are able to continue with the study.

We would also like to collect further information about you and your health, as it relates to the study. We will ask you for this information, or with your consent, we will contact your GP after the session. The information we would like to collect is:

* Your age
* Your assigned sex at birth (male / female)
* Your ethnicity
* The type of stroke you had
* The location of the stroke in your brain
* The date of your stroke
* Whether you’ve had a previous stroke or brain injury
* Your current medications
* The result(s) from any previous cough testing that has been completed

This session is summarised into three steps below:

1. The research team will explain the study, talk through the consent form and answer any questions you, your family, whānau, or friends may have. If you are happy to participate, you will sign the consent form. You need to sign the consent form before beginning the study. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep for your records.
2. You will complete a lung function test. This is called spirometry. This test will see how much air you can blow out of your lungs as fast as you can. If there are any concerns with your lung function, you will be unable to participate further in the study. If there are no concerns with your lung function, you will be eligible to continue with the study.

Lung function testing (spirometry)

1. If eligible to continue, you will have a cough test. You will inhale a number of different mists of citric acid and saline. The concentrations of citric acid and saline used in this study are safe to inhale. Some of these mists may make you cough, others may not. You will be told to “cough if you need to” A range of different mists will be tested during each of these tests. We will repeat this test in the next session to make sure we have stable and accurate measures.

Cough threshold testing

***Session 2: Second cough test***

In this session you will have a cough test. This is the same test as you will have had in session one.

***Sessions 3-12: Airway stimulation sessions***

In these ten sessions, you will have lung function testing before and after receiving stimulation treatment. For four sessions, cough testing will also be completed at the start or end of the session.

The lung function testing (spirometry) will be a shorter test than the one you had in session 1 of the study and each attempt will take approximately three minutes. You will be asked to blow out as fast as you can for two seconds. This test will be repeated four times in each session. We are repeating the test throughout the treatment to monitor any changes in your lung function. In the unlikely event your lung function changes as a result of inhaling the mists, you may feel short of breath or wheezy, or you may not feel any symptoms. This is why we are monitoring your lung function with the use of spirometry. In the unlikely event that there was a change in your lung function test that indicated that your lungs were inflamed (bronchoconstricted) you would be treated with an inhaler by the researchers to reverse the inflammation, under the guidance of a respiratory physician. You will remain at the Rose Centre until all signs of inflammation are gone, and we have confirmed your lung function is back to normal. You would not be able to participate further in the study.

For the airway stimulation, you will inhale distilled water or saline through a mouthpiece. The researcher conducting the sessions will not know which mist you are inhaling, another member of the research team will prepare the solutions. You will not be told which mist you are inhaling. It is important you do not know which mist you are inhaling to allow us to show if the treatment is effective.

At the end of each stimulation session, you will be given the phone number of a respiratory physician. If you feel wheezy or short of breath in the 24 hours following the session, you are to call the respiratory physician to let them know. The use of inhalations of distilled water has been shown to be safe in participants with no history of asthma. We are excluding anyone who has a history of asthma or respiratory disease, as this group are known to be at increased risk of lung inflammation (bronchoconstriction).

## Costs:

* There are no costs to take part in this study.

**Reimbursement and refreshments:**

* You will be given a $10 MTA voucher *each session* to cover your travel expenses (total reimbursement of $120 over the duration of the study i.e. twelve sessions).
* Refreshments will be available for you and any accompanying persons after each session.

## The possible benefits of this study:

## There are no direct benefits for you as an individual for participating in this study.

* Your cough sensitivity may be altered, but we do not know whether this will be of any benefit to you.

## Findings from this study will guide further research into the cough response and may benefit others in the future.

## The possible risks of this study:

* You may experience some dizziness in completing spirometry, if this happens you will be given some time to rest and provided with the instructions and/or a further demonstration as required.
* You may have an unpleasant taste in the mouth as a result of inhaling the mists, but this usually resolves within an hour of finishing the cough test.
* Your throat may feel irritated as citric acid and distilled water act as irritants on the airways. This usually resolves within an hour of finishing the test.
* While the risk is very small, you may experience lung inflammation and you may or may not notice any symptoms. Lung function testing (spirometry) will allow us to review your lung function to ensure we do not miss this if it happens. In the unlikely event that inflammation does occur, you will be treated with an inhaler to reverse the inflammation, under the guidance of a respiratory physician.

## Your rights:

* Participation in the study is voluntary (your choice).
* You are free to decline to participate and if you do not want to take part, you do not have to give a reason.
* You can withdraw from the study at any time.
* You have the right to access information that is collected about you as part of the study.

**If you have any questions, or would like to participate in the study:**

Please contact Keri by phone or by email.

Phone: 03 369 2385

Email: keri.darrock@pg.canterbury.ac.nz.

**Questions you may have:**

**Can I talk about the study with other people?**

You are encouraged to do this. Before you decide, you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers.

## What happens to the data after the study?

* Nothing that could identify you will be stored with your results. All hard copy data will be kept in a locked filing cabinet at the University of Canterbury Rose Centre or stored on a password protected computer. The only people who will have access to the data are the researchers and supervisors. Data will be kept for 10 years following which it will be destroyed.
* Results from this study may be published in a peer-reviewed journal, presented at conferences or reported in other publications, but your identity will not be made public.
* Please use the consent form to indicate if you would like to receive a summary of the results. Please be aware that there may be a delay between data collection and completing the final report.

**What if I change my mind?**

* If you do want to take part now, but change your mind later, you can pull out of the study at any time.
* You may ask for your data to be returned to you or destroyed at any time up to the point when analysis of the data begins.

**What if something goes wrong?**

In the unlikely event that you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

## Who do I contact for more information or if I have concerns?

If you would like to participate in the study, or if you have any questions, concerns or complaints about the study at any stage, you can contact:

The lead investigator for this study:

Name: Dr Phoebe Macrae

Phone: 03 369 2385

Email: phoebe.macrae@canterbury.ac.nz

The assistant investigator for this study:

Name: Keri Darrock

Phone: 03 369 2385

Email: keri.darrock@pg.canterbury.ac.nz

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz

Website: <https://www.advocacy.org.nz/>

For information about Māori and Pasifika community health support and services please contact:

Name: Hector Matthews, Executive Director, Maori and Pacific Health, Canterbury DHB

 Phone: 03 364 4169

 Email: hector.matthews@cdhb.health.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz



**Participant Consent Form**

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| **Locality:** | Christchurch, New Zealand | **Ethics committee ref.:** | 21/NTB/100 |
| **Lead investigator:** | Phoebe Macrae | **Contact phone number:**  | +64 (0)3 369 2385 |

**Please tick to indicate you consent to the following**

|  |  |  |
| --- | --- | --- |
| I meet the requirements for this study (as outlined on the participation information sheet) and understand that testing in the first session will determine if I am able to continue with the study. | □ |  |
| I have been given sufficient time to consider whether or not to participate in this study.  | □ |  |
| I have had the opportunity to discuss my participation in this study with other people, such as family, whānau, friends, or healthcare providers. | □ |  |
| I have had the information sheet explained to me by the researcher and have been given a copy of this consent form and information sheet. | □ |  |
| I have had the opportunity to ask questions, and I am satisfied with the answers I have been given. |  |  |
| I understand what is required of me, and my responsibilities as a study participant, if I agree to take part in the research. | □ |  |
| I understand that participation is voluntary (my choice) and I may withdraw at any time without penalty.  | □ |  |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes □ | No □ |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | □ |  |
| I consent to the research team contacting my GP for information about my health and stroke as it relates to participation in this study (as outlined on the participation information sheet). | □ |  |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. | □ |  |
| I consent to my GP being informed (by written letter) if my lung function results are outside the normal range.  | Yes □ | No □ |
| I understand that all data collected for the study will be kept in locked and secure facilities and/or in password protected electronic form and will be destroyed after ten years. | □ |  |
| I know who to contact if I have any questions about the study. | □ |  |
| I wish to receive a summary of the results from the study. | Yes □ | No □ |
|  |  |  |

**Declaration by participant:**

I …………………………………………. hereby consent to take part in this study.

|  |  |
| --- | --- |
| Signature: | Date: |
| GP name:GP practice: | Phone: |
| Participant’s email and/or postal address (if you wish to receive a summary of results): |  |
| I would like to be contacted with information about any future research relating to coughing. | Yes □ No □ |  |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: |
| Signature: | Date: |