TREATMENT OF ACUTE COUGH in upper respiratory tract infection (TAC) including COVID-19 information

INFORMATION FOR PARTICIPANTS

Introduction:

You are invited to take part in a research study into treatment for cough following an upper respiratory tract infection, also known as the 'common cold'.

What is the research about?

Cough is an annoying symptom following the common cold and can persist for weeks or months in some individuals. This study aims to test whether early intervention for cough reduces symptoms and reduces the duration of cough. If you agree to participate in this study you will be randomly allocated to receive one of two treatments.

Where is the research being done?

The study is being conducted at the Hunter Medical Research Institute by Associate Professor Anne Vertigan (Service Manager, Speech Pathology, John Hunter Hospital); Professor Peter Gibson (Conjoint Professor, Senior Staff Specialist, Respiratory and Sleep Medicine, John Hunter Hospital); Professor Vanessa McDonald (Professor of Nursing, School of Nursing and Midwifery, University of Newcastle); Dr Alistair Cook (Asthma Fellow, Respiratory and Sleep Medicine, John Hunter Hospital) and Ms Sarah Kapela (Speech Pathologist, John Hunter Hospital).

Who can participate in the research?

Participating in this research is suitable for you if:

- Your cough has been present for between 3 and 6 weeks following an upper respiratory tract infection (common cold)
- You are not coughing up phlegm
- You are aged 18 years or older

This study will not be suitable for you if:

- You are coughing up blood
- You have cystic fibrosis, bronchiectasis, chronic bronchitis, chronic obstructive pulmonary disease or interstitial lung disease
- You are unable to attend study visits
- You are a current smoker
- You have significant breathing difficulties, especially at rest or at night
- You have a history of unexplained weight loss
- You have current or ongoing chest pain

- You currently have pneumonia

What Choice do you have?
Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. You can ask that any data collected concerning you also be withdrawn from the study. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with your treating doctors.

What would you be asked to do?
If you are interested in the study you will first be asked questions over the telephone to determine whether this study is suitable for you. This should take approximately 15 minutes. The researcher will explain the study and you can ask any questions you may have about the study. This telephone interview should take approximately 15 minutes. If you agree to participate in this study, you will be asked to attend 3 appointments with the researcher at HMRI. In addition, the researchers would like to have access to your medical record to obtain information relevant to this study.

Visit One The first appointment needs to occur between 3 and 6 weeks after the onset of your cough. This appointment will take 90 minutes. It will involve the following procedures: *Please note: Due to the current COVID-19 pandemic we will conduct the study via telehealth rather than face to face visits. As a result of this we will be unable to do the procedures marked below with an asterisk.

1. **Consent form.** Once all your questions about the study have been answered you can sign the participant consent form.
2. **Background information.** You will be asked questions about your background details. You will be asked about your current illness and symptoms, medical history and your current medications**.** These questions should take about 30 minutes to complete.
3. **Physical examination*.** We will measure your blood pressure, pulse rate, respiratory rate, height, weight and temperature. This should take about 5 minutes to complete.
4. **Questionnaires**. You will be asked to complete six questionnaires about your cough, throat, breathing and nasal symptoms. These questionnaires will take about 20 minutes to complete.
5. **Voice testing***. Voice testing will involve you reading a short paragraph aloud and saying some sounds. We will record your voice to assess your voice quality.
6. **Spirometry***. Spirometry is a common office test used to assess how well your lungs work by measuring how much air you breathe in and out. You will be asked to breathe in and then breathe out forcefully via a hand held device.
7. **Fractional exhaled nitric oxide (FeNO)*.** FeNO measures the level of nitric oxide in the air you slowly breathe out of your lungs. You will be asked to breathe into and then out of a hand held device for about 10 seconds.
8. **Treatment.** You will then be randomised to receive one of two treatments. Randomisation is like tossing a coin. It is necessary to help us determine whether the treatment is effective. Treatment will involve strategies to manage cold and cough symptoms. You will not be informed of which of the two treatments you have received. This is called 'blinding'. Blinding is used in medical research to accurately judge whether the treatment is effective.

Visits 2 and 3: Visits 2 and 3 will take approximately 45 minutes each. Visit 2 will occur four weeks after your initial visit and visit three will occur 8 weeks after your initial visit. The purpose of the follow-up visits is to determine if your cough and throat symptoms have persisted or resolved. Visits 2 and 3 can occur at the Hunter Medical Research Institute or via telephone or video-teleconference from your home or workplace. The follow-up visits will involve the following procedures.

1. **Progress and symptoms**. We will ask you about changes to your cough since the previous visit, other illnesses and current medications. These questions will take approximately 5 minutes.
2. **Questionnaires.** You will be asked to complete six questionnaires about your symptoms. These questionnaires will take approximately 20 minutes to complete.
3. **Voice Testing*.** Voice testing will involve you reading a short passage aloud and saying some sounds. We will record your voice to assess voice quality.
4. **Feedback about treatment**. We will ask you about your opinion of the treatment and what you found useful.

What are the risks and benefits of participating?

Risks:

All medical procedures - whether for diagnosis or treatment, routine or experimental involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown and unforeseeable.

While suppressing a dry irritated cough is not harmful there would be a risk if your cough becomes productive or originates from your chest. For this reason we will monitor you to ensure that this study remains suitable for you. If you present with possible lower airway signs at any point during the study you will be referred for medical review.

Risks of performing spirometry are dizziness, fainting and cough. We will always perform spirometry with you in a seated position to optimise your safety.

Benefits:

While we intend that this research study furthers medical knowledge and may improve treatment of cough in the future, it may not be of direct benefit to you. It is possible that we will teach you to control your cough symptoms however we do not know what the long term benefits of this will be.

Will the study cost you anything?

Participation in this study will not cost you anything, nor will you be paid. Parking will be available at the Hunter Medical Research Institute free of charge.

How will your privacy be protected?

All the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it. The study results may be presented at a conference or in a scientific publication, but no personal identifying details would be

provided. With your permission we can notify your GP that you have participated in the study.

All your personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002. All your data will be recorded with a unique anonymous identification code.

Data will be kept for 7 years and all researchers involved with the study will comply with the requirements of the Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Further Information
When you have read this information, the researchers Sarah Kapela or A/Prof Anne Vertigan will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact them on 49213700.

You may be contacted in the future with an invitation to participate in other studies related to chronic cough. At the completion of your participation in this study you will be given the option not to be contacted if you do not wish for this to occur.

This information statement is for you to keep. Thank you for considering this invitation.

Signatures

Associate Professor Anne Vertigan
Service Manager, Speech Pathology
John Hunter, Belmont Hospital & Mental Health

Ms Sarah Kapela
Speech Pathologist
John Hunter Hospital

Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2020/ETH0050.

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, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit New Lambton NSW 2305, telephone (02) 49214950, email HNELHD-HREC@health.nsw.gov.au

CONSENT FORM for PARTICIPANT (STUDY ID No. _____)
Title: TREATMENT OF ACUTE COUGH in upper respiratory tract infection (TAC)

Please initial box

☐ I have read and understand that the study will be conducted as described in the Participant Information Statement, a copy of which I have retained.

☐ I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

☐ I understand that my participation in this study will allow the researchers to have access to my medical record, and I agree to this.

☐ I agree to participate in this study and understand that I can withdraw at any time without providing a reason.

☐ I agree for data in this study to be used in other studies by the same research team.

☐ I understand that my personal information will remain confidential to the researchers.

☐ I have had the opportunity to have questions answered to my satisfaction.

☐ I would like my GP to be notified of my participation in the study.

☐ I would like to receive a summary of the study results via email once the data is published and I understand this will not contain my personal results or any identifiable information.
Email address: _____

Name of participant: _____

Signature of participant: _____

Date of consent: _____