Assessing the impact of vaping on lung function
PARTICIPANT INFORMATION SHEET

Investigators: Dr Kelly Burrowes, Dr Vinod Suresh, Professor Merryn Tawhai, Professor Chris Bullen

Researcher introduction
Dr Burrowes is a Senior Research Fellow at the Auckland Bioengineering Institute. Dr Burrowes has a passion for understanding lung function in health and disease. Dr Suresh is a bio/chemical engineer with expertise in cell culture systems and mathematical modelling. In this study, he is interested in the link between any changes seen in cells and in the lung as a whole organ. Professor Tawhai is renowned for her world-leading research on developing mathematical models of the lung. In this project, we will be aiming to create computer models of the lung to understand what we see in the images obtained through this study. Professor Bullen is a physician and researcher based at the School of Population Health. His primary area of research is in tobacco control. He has a decade of research experience in electronic cigarettes, in terms of their effectiveness for smoking cessation.

Invitation
You are invited to take part in a Magnetic Resonance Imaging (MRI) scan and Pulmonary Function Testing (PFTs) to assist with our understanding of the impact of the use of electronic cigarettes on lung function. In order to decide whether you wish to volunteer, it is important that you read and understand enough about the risks and benefits to enable you to make an informed decision. Detailed information about this study is provided on these sheets and you will have the opportunity to discuss any questions you have with the Investigators and/or the MRI staff.

Participation
If you have decided to participate, you will be asked to complete and sign a safety checklist and a consent form. Participation is completely voluntary, and you may refuse to participate or withdraw your consent at any time without giving a reason. You will also be able to withdraw any data, without giving reason, any time after participation in the study. You will be given a copy of this Participant Information Sheet to keep as a record.

Why are we doing this study?
Electronic-cigarettes have only been available for about 10 years and the impact of using these devices on lung function is not yet known. In this study, we aim to measure regional function – meaning how lung function changes within the lung - (using MRI) and global function – meaning a measure of how the lung is functioning as a whole - (using PFTs) in healthy vaping volunteers to see if we can observe any differences pre- and immediately post-vaping. With MRI, we aim to measure regional airflow, blood flow and tissue density within your lungs. The PFT measurements - which will include standard measures of lung function as well as a measurement technique called Impulse Oscillometry (IOS) - will provide a measure of how well your lungs are working overall.

Selection of participants
We are inviting healthy volunteers, with no known/prior respiratory conditions who currently use e-cigarettes/vapes. Since Magnetic Resonance Imaging is associated with a strong magnetic field, some people may not be eligible to volunteer because of the presence of the following:
- Pacemakers / defibrillators
- metal clips in the brain (aneurysm clips)
- metal fragments in or near the eyes

At the Centre for Advanced MRI, all participants will first be checked for these and any other reasons a scan should not be performed.

**Procedures**

To participate in this study, you will be required to participate in the following three tasks:

1. **Attend an MRI session (~60 minutes) at Auckland City Hospital:**

2. **Attend an appointment at Greenlane Clinical Centre to have your pulmonary function tested (~45 minutes):**

3. **Complete an online questionnaire so that we can obtain some additional information about you.**

1. **The MRI session**

You will be inside the MRI scanner for approximately 45 minutes — in total this appointment will be ~60 minutes. You will be asked to complete the safety checklist then change into a gown and remove all items of jewellery. You will be asked to lie on a bed, and lightweight equipment will be placed on top of or around the region being scanned. As the scanner is very noisy while scanning, (sounds like someone drilling the road) you will be given ear plugs and headphones to wear, and an emergency buzzer to hold. The bed is then slid into the scanner (the MRI scanner consists of a tunnel slightly shorter than a person). It is important to remain as still as possible during the procedure to ensure the resulting images are movement free.

At all times you will be in voice contact with the MRI technologist and you will have an emergency button which you can press to be immediately slid out of the scanner. The scanning process is **painless, free from X-ray exposure and no needles** are involved.

**MRI Scans to measure blood flow in the lungs:** Leads will be attached to stickers on your chest or back to monitor your heart rate. You will then be asked to hold your breath for approximately 10-15 seconds while images are taken of your lungs.

**MRI Scans to measure air flow:** You will be fitted with a face mask and will be required to take 20 breaths of room air followed by 20 breaths of pure oxygen. This will be repeated 5 times ending with 20 breaths of pure oxygen (total 220 breaths). This will take approximately 20 minutes. You will be able to breathe normally during this procedure, although we will ‘train’ you to try to breath in between the scanner noises. The scanner noises (which is the sound of the picture being taken) lasts for ~1 second and will be spaced apart ~5 seconds to time with your breathing cycle. We will perform this ventilation measurement before and immediately after use your e-cigarette. Please bring along your e-cigarette and try to refrain from using your vape **for at least 4 hours prior to the MRI session** (or longer if possible).

2. **Pulmonary Function Testing**

These tests will be performed at Greenlane Clinical Centre according to standard clinical guidelines. This is a safe, painless testing procedure done routinely in respiratory medicine. More details can be provided on request.

3. **Online questionnaire**
If you decide to participate in our study, we will ask you to complete an online questionnaire. The main questions we will include are as follows:

- Have you previously been diagnosed with any respiratory illnesses?
- Are you currently or have you ever been a smoker? If so, please answer questions related to duration of use, current frequency of use and brand of cigarette used.
- Related to your e-cigarette use, please answer questions related to duration of use, current frequency of use, type and settings of EC used, type of e-liquid used (brand, flavour(s), nicotine strength).

This questionnaire is particularly useful for us in studying vaping, as there are currently many different devices and e-liquids available and these devices are used in different ways. We hope to understand more about usage in this study as well.

**Discomforts and Risks**

There are no known side effects or risks from MRI scanning or from the inhalation of oxygen for a short period. The scanner is **noisy** while scanning, and it is necessary to wear ear muffs during the scan. Some people can find the scanner makes them **feel warm or even hot**. Should you feel uncomfortably hot you should let the MRI technologist know via the communication system. Sometimes you can feel a **tickling sensation** or a **twitching feeling**. This can occur across the bridge of the nose, across the chest or back, and is quite harmless. People who are prone to **claustrophobia** can find lying in the MRI scanner difficult to tolerate, as the tunnel is quite narrow. If this should occur, the imaging will be discontinued. MRI staff trained in Basic Life Support will always be present during scanning and emergency provisions are in place in the very unlikely event of a medical emergency.

**Right to compensation**

If 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 won’t affect your cover.

**Benefits**

Your participation will greatly assist in optimising our measurement procedures and in increasing our understanding and knowledge on whether vaping changes how our lungs work. This is a really exciting study that has potential to educate many about what is happening inside our lungs. It will also give you the opportunity to experience a MRI scan and receive pulmonary function testing. A copy of your images can be made available to you on request in the form of a CDROM or via secure web transfer.

**Detection of Unexpected Abnormalities**

In the event that a condition which is assessed to be a clinical abnormality is detected through performing a scan on you, you will be informed of this and will be advised to consult your general practitioner. Because the images are not routinely reviewed by a radiologist we are unable to perform diagnostic scans for medical purposes of areas where you have known abnormalities.

You should be aware that once you have been informed that a clinical abnormality has been detected through performing a scan on you this could affect your ability to obtain insurance whether or not
you take the matter further. If a participant does not wish to be advised of such findings then it is our policy to exclude them from taking part.

Data Storage, Retention, Destruction and Future Research Use
The data collected within this study (MRI, PFTs and questionnaire information) will be stored indefinitely on appropriate University managed storage. It is possible that we may wish to use the data collected in this study for further analysis / studies in the future. Consent for future research use of the data is included in the consent for this study. If you do not want your results used in another study then you can indicate that now.

Any paper documents (i.e. consent forms) will be kept in a lockable filing cabinet in Dr Burrowes’ office. Paper-based information will be destroyed onsite using a paper shredder.

Confidentiality and Privacy
Strict confidentiality of your information will be observed. No individual will be identifiable in any report, presentation, publication, demonstration or teaching carried out as a result of this scan.

If you wish, a copy of the research findings will be made available to you via email.

Right to ask Questions
If you have any queries, please discuss them with Dr Burrowes, the co-Investigators or MRI staff.

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For any queries regarding ethical concerns you may contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 extn. 83711, E-mail: ro-ethics@auckland.ac.nz

Statement of Approval
Approved by the University of Auckland Human Participants Ethics Committee on 22nd November 2019 for three years. Reference Number 023695.