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Measuring tongue force

Information Sheet for participants

Kia ora,

You are invited to participate in a research study on swallowing. This study is being conducted by Donald Derrick and Phoebe Macrae from the University of Canterbury | Te Whare Wānanga o Waitaha (UC). It is being conducted at the Rose Center Clinics (St George's Medical Centre, Level One, Leinster Chambers, 249 Papanui Road, Merivale).

What is the purpose of this research?
This research aims to determine soft and hard tongue pressure at the bony ridge just behind your top front teeth amongst people who do not have any swallowing disorders to test a new computer method for analyzing ultrasound images. We are comparing ultrasound video recordings to tongue pressure bulb recordings for use in future medical imaging.

Why have you received this invitation?
You are invited to participate in this research because you contacted us, are 18 or older, and let us know you do not have any swallowing disorders.

Your participation is voluntary (your choice). If you decide not to participate, there are no consequences. Your decision will not affect your relationship with me, the University of Canterbury or any member of the research team.

What is involved in participating?
If you choose to take part in this research, you will be asked to follow this procedure:

You will confirm understanding of information sheet and sign the consent form.

We will record your age and biological sex, and whether you have a swallowing disorder in a short questionnaire.

For all recordings, we will record ultrasound and bulb during soft tongue pressure for 3-5 seconds.

We will help you place ultrasound probe on head stabilizer unit on your head.

You will take a pressure bulb in the mouth and hold it at the bony ridge just behind your top front teeth.

Then you will perform 3 soft tongue presses with a short break between, take a longer 1 minute break, and

then perform 3 hard tongue presses.

You will take the pressure bulb out of your mouth, take the probe holder off, walk around and come back while we swap in a new, clean pressure bulb.

We will repeat this process 5 more times, alternating the soft vs. hard tongue presses.

You will then remove the probe holder and final pressure bulb.

Are there any potential benefits from taking part in this research?

We do not expect any direct benefits to you personally from participating in this experiment. However, the information gathered will potentially benefit people who develop swallowing disorders as our long-term goal is to reduce or eliminate the need for fluoroscopic (x-ray) videos of barium swallowing in the process of identifying and treating swallowing disorders.

One of the researchers, Donald Derrick, invented the ultrasound post-processing technique used in this study, it is the subject of patent filings, and he could benefit if it leads to clinical tools in future. He has declared this conflict of interest to the University of Canterbury Human Research Ethics Committee. To keep the research transparent, the de-identified data and analysis methods will be made publicly available so that other researchers can independently check the results.

At the conclusion of the study, we will provide you with a $30 Prezzee card. You will get this inducement even if you withdraw from the study.

Are there any potential risks involved in this research?

1) The use of a pressure bulb is a non-invasive device widely used in clinical and research settings. Measurement involves the participant pressing the tongue against a small, air-filled disposable plastic bulb held between the tongue and the hard palate; the device records the resulting air pressure. Nothing is ingested during measurement. A single-patient, disposable bulb will be used for each of 6 rounds to eliminate contamination risk, and the device will be handled per manufacturer infection-control guidance. Bulb placement will be demonstrated and participants can reposition or withdraw at any time if they experience a gag sensation or discomfort. Consistent with established research practice, the bulb is in place only during tongue presses.
Physical risks from the pressure bulb are minimal. Possible effects are a brief gag sensation, extra saliva, and mild, short-lived tongue or jaw tiredness after the hard presses. Participants set their own 'hard' press level and are not asked to go beyond what feels comfortable. Each press lasts only 3–5 seconds, and the bulb sits in the mouth only during presses. Anyone who feels a gag sensation, pain or discomfort can pause, reposition the bulb, or stop at any time with no consequence.

2) Diagnostic B-mode ultrasound is non-invasive and uses no ionizing radiation. It is among the safest imaging modalities in routine clinical and research use. The only physical interaction is a handheld transducer with water-based coupling gel placed on the skin under the chin, and a probe stabilizer (a lightweight headset that holds the ultrasound probe steady under your chin) worn on the head. Scanning will be performed by Donald Derrick, or by a PhD student once they have joined the research team and been trained, using minimal transducer pressure sufficient for image capture. Standard hypoallergenic, water-based ultrasound gel will be used; participants will be asked about known gel or skin sensitivities beforehand, and any residual gel will be wiped off at the end. The transducer will be cleaned between participants per standard infection-control procedure.

3) The task has 6 rounds of 3 soft and 3 hard presses (36 presses in total), each lasting 3–5 seconds. There is a short rest between presses and a 1-minute rest between the soft and hard sets. Between rounds, participants take off the bulb and headset and walk around. Total pressing time is a few minutes of a roughly 40-minute session. The head stabilizer may feel snug, so it is removed between rounds and adjusted for comfort. Participants may ask for extra breaks at any time, and the researcher will watch for signs of tiredness and offer a rest.

What if you change your mind during or after the study?
You are free to withdraw at any time. To do this, please let me know either during the study or after you have finished. We will remove any information you have provided up to that point from the data set if it is still possible. Your data will not be placed in the public archive until at least 2 weeks after your session, so you can always withdraw it during that time. However, once your recordings and data have been placed in the public archive, they can no longer be withdrawn or deleted.

What will happen to the information you provide?

All data will be confidential. To ensure your identity is not known to anyone outside the research team, we will keep your signed consent form in files separate from your observation results. Your identity will not be shared with anyone outside the research team. Note that other researchers may be added to this project, including a potential as yet unidentified PhD student.

Your ultrasound recordings, bulb pressure data, and associated age and biological sex will be stored publicly on the University of Canterbury Data Repository (Figshare) for use by other researchers and clinicians. This image sharing is one of the primary goals of this research as it provides a foundation for future research on swallowing disorders. However, and as you will be able to see during the experiment itself, unlike videos of a face, ultrasound videos of the tongue do not record any externally identifiable information.

To provide you with the $30 Prezzee card, the person recording your data must keep a register of your participation for 7 years in case IRD (Inland Revenue) wish to audit the University. The register will need to include your name and email address; but an email address alone is acceptable to maximise confidentiality. The register will not be linked to any other aspect of this study – you cannot be identified through it.

We will store all study data in password-protected files on the University of Canterbury computer network or in lockable cabinets in lockable offices.

Donald Derrick will be responsible for making sure that only members of the research team use your data for the purposes mentioned in this information sheet.

Will the results of the study be published?
Results may be published in peer-reviewed, academic journals. Results will also be presented during conferences or seminars to wider professional and academic communities. You will not be identifiable in any publication. A summary of results will be sent to all participants who request a copy of these.

Who can you contact if you have any questions or concerns?
If you have any questions about the research, please contact: Donald Derrick (donald.derrick@canterbury.ac.nz), or Phoebe Macrae (phoebe.macrae@canterbury.ac.nz).

This study has been reviewed and approved by the University of Canterbury Human Research Ethics Committee (HREC). If you have concerns or complaints about this research, please contact the Chair of the

HREC at human-ethics@canterbury.ac.nz).

What happens next?
If you would like to take part, please contact us to book a session. You may sign the consent form and return it by email beforehand to Donald Derrick (donald.derrick@canterbury.ac.nz) or Phoebe Macrae (phoebe.macrae@canterbury.ac.nz), or sign it at the start of your session. No data will be collected until we have your signed consent form.