UNIVERSITY OF MINNESOTA
Driven to Discover℠
School of Kinesiology

Effect of Short-term Laryngeal Vibration on Voice Quality

Consent Form

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What is this research and why is it being done?
You are being invited to participate in a procedure that will examine how your voice responds to vibration of your voice box (larynx). The study is conducted by researchers in the Human Sensorimotor Control Laboratory in the School of Kinesiology at the University of Minnesota. The purpose of this study is to examine the effect of such laryngeal vibration on speech in order to develop possible future treatments for voice disorders in the future. You will wear a wearable device around your neck, and a small vibratory motor embedded in the device will be in contact with your skin above your larynx (the Adam's apple in males). When the vibrator is turned on you will feel a small tingling sensation. You will be asked to speak a series of test sentences while the vibrator is either turned on or off. You are being invited to participate because you either have no known history of neurological or musculoskeletal impairment that affects speech motor function, or have been diagnosed with an impairment that affects your speech function.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

How long will the research last?
We expect that you will be in this research study for one session that last up to 5 hours.

Will being in this study help me in any way?
This is an exploratory study. At this point, there are no known data on the longer-term effects of

laryngeal vibration for improving symptoms of voice disorders. Thus, you may have no direct benefits by participating in this study.

What happens if I do not want to be in this research?
There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

What happens if I say "Yes, I want to be in this research"?
If you agree to participate, we will:

- Ask relevant questions regarding your health history including the possible occurrence of neurological or musculoskeletal impairment and regular medication intake.
- Ask you to wear a device around your neck. There are two non-invasive low voltage, light-weight surface vibrators embedded in the device. Vibrators will be placed on the neck, specifically to the two sides adjacent to your larynx or voice box. The tasks comprise vocalization of a few vowels, before, during and after receiving laryngeal vibration via surface vibrators.
- Place electroencephalography (EEG) electrodes over your scalp with a water-based conductive gel.
- Place two EOG electrodes around your left eye to record your eye movement.
- Record your EEG and EOG signals simultaneous with the performance of the vocalization tasks (on/off vibration).
- Record your voice during the vocalization task for further acoustic analysis.
- Fill out a usability questionnaire at the end of the study. The questionnaire is about the wearable collar and will ask for your comments regarding its features and usability.
- The entire procedure will take place in a single visit that will last a maximum of four hours, and EEG and EOG recordings will last a maximum of three hours.

Where is the study location?
The experiment will take place in the Multi Sensory Perception Laboratory which is located in Room S39 of Elliot Hall at the University of Minnesota. Lab website address is: http://msp.psych.umn.edu/

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

What are the risks of being in this study?

Vibration Risks
The risks in this study are minimal other than the possibility of skin redness over the skin or feelings mimicking numbness over the neck area during trials. These discomforts, if any occurs, usually disappear within minutes after vibration is removed. Please note you may opt to take a break or stop/withdraw at any time during the study if you feel you are experiencing any discomfort or become fatigued.

EEG Risks
There is no particular risk associated with the EEG recording; however, you may opt to take a break or stop/withdraw at any time if you feel you are experiencing any discomfort.

EOG Risks
There is no particular risk associated with the EOG recording; however, you may opt to take a break or stop/withdraw at any time if you feel you are experiencing any discomfort.

Wearable Device Risks
This risk of using the collar with respect to irritation/rubbing is minimal. Because the textile is chosen from biocompatible material and the collar is not moving during the testing, there is minimal risk associated with it. In addition, because the electronics do not have any contact with the tissue and are enclosed in a housing, the risk of the electronics being affected by moisture/sweat is minimal.

Research Related Injury & Compensation
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study researchers know right away.

Confidentiality: What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the Institutional Review Board (IRB) of the university and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. Your health information created or received for the purposes of this study is protected under the Health Insurance Portability and Accountability Act of 1996 (known as HIPAA). Refer to the attached HIPAA authorization for details concerning the use of this information. The collected personal health information is limited and will only be used in de-identified form during analysis and in any possible scientific publications. All personal information will be stored in a secured location. All data measured will be deidentified and stored separately on a University of Minnesota computer, which is password protected. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

You may choose to provide your authorization to release and use identifiable information about you, your specific condition and the treatment you received (together referred to as your "Protected Health Information" or PHI) to prepare and publish education and training materials, case reports, videos, presentations, professional/medical publications, professional and staff communications, newspaper or other form of articles, broadcast stories, television newscasts, newsletters, advertising, brochures, websites, social or other media communications, marketing and fundraising materials and/or promotional materials (together referred to as "Media Materials"). Should you choose to do so, you will be asked to sign a separate "Media and Publication Authorization form."

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Benefits

There is no direct benefit to participating in this study. At this point, there is no known data on the benefits of laryngeal vibration on the effectiveness of laryngeal vibration on improving symptoms of voice disorders.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you. As a participant in this study you will be compensated $100 for each in-laboratory assessment. You may receive parking reimbursement if necessary.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study

team contact information and “Whom do I contact if I have questions, concerns or feedback about my experience?” of this form for HRPP contact information.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you $100 for your time and effort. Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio or video record me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team.
_____	_____	The investigator may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity.
_____		The investigator may contact me in the future to see whether I am interested in participating in other research studies by Dr. Jürgen Konczak.

Persons to Contact
This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

For questions about research appointments, the research study, research results, or other concerns, please contact:

Dr. Jürgen Konczak
Human Sensorimotor Control Laboratory
400 Cooke Hall
1900 University Ave. SE
Minneapolis, MN 55455
(612) 624-4370

You will be given a signed copy of this form to keep for your records.

Statement of Consent:
I have read the above information. I have asked questions and received appropriate answers. I consent to participate in this study.

_____	_____
Participant's Printed Name	Participant's Signature
_____	_____
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent

Date: _____