Title of Research Study: Cardiovascular Conditioning in the Treatment of Vocal Fatigue
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Organization of Principal Investigator: East Tennessee State University

INFORMED CONSENT

This Informed Consent will explain about being a participant in a research study. It is important that you read this material carefully and then decide if you wish to voluntarily participate.

Summary

The purpose of this research study is to identify the most efficient and effective treatment for relieving vocal fatigue or tiredness of voice with voice use. Taking part in this research is voluntary. Participants in this study will be asked to complete:

- A preliminary examination at Voice Physiology Lab
- A baseline testing session consisting of reading two passages for around 5-7 minutes per passage while wearing a mask.
- 8 treatment sessions of either voice therapy or aerobic conditioning. Treatment sessions will be conducted twice a week for 45-50 minutes each.
- A post-treatment baseline testing session consisting of reading two passages for around 5-7 minutes per passage while wearing a mask.

This will require 10 sessions lasting around 45-50 minutes each. There will be approximately 2 sessions per week. The total length of the study is about 6-weeks.

The greatest risks of this study include the possibility of mild discomfort while wearing a breathing mask during the first and last sessions of the study.

You will be paid $150 for your time in the study for completing the entire protocol. If you do not qualify for the study during the preliminary examination, no payment will be given. For each visit, a $15 compensation will be provided. Cash will be provided at the end of each session and you will be asked to sign a document indicating your receipt of the payment.

If you are interested in volunteering for this research study, please read the rest of this document.

A. Purpose:

The purpose of this research study is to identify the most efficient and effective treatment for relieving vocal fatigue or tiredness of voice with voice use. Specifically, the effects of behavioral voice therapy and aerobic conditioning on voice will be studied. Such data will help identify the most efficient and effective way to relieve vocal fatigue, one of the most common symptoms in individuals with voice disorders.

B. Duration:

The study will recruit 52 participants for this study in total. The study will require you to participate over a 6-week period, depending on scheduling and your availability. During this period, you will complete a screening at the Voice Physiology Lab (approx. 30-minutes), a baseline testing of your voice (45 minutes)- same day if you qualify for the preliminary screening,, undergo the treatment protocol of either voice therapy or aerobic conditioning for 2 sessions per week (each session lasting approx. 50-minutes) for 4 weeks, and a final post testing- week 6. In total, the study will be completed over a duration period of 6 weeks.

C. Procedures:

As part of this study, you will complete a preliminary evaluation at the Voice Physiology Lab to determine the vocal quality of your voice. During this visit, you will be asked to read 6 sentences, and will be asked to make the /i/ vowel sound at three different pitches with a soft volume. This will determine the vocal quality and if this screening procedure qualifies you for the study and you have consented to participate, you will be scheduled for an experimental procedure- baseline testing, the same day. Following the experimental procedure, you will be randomized to receive the treatment program.
Once you arrive at the scheduled appointment, further information including your height and weight will be collected to complete the baseline testing. During this testing, a mask will be placed around your nose and mouth and you will be asked to complete reading tasks at different loudness levels and will be provided periods of rest in between the reading tasks. This procedure will last around 45-50 minutes. Following this baseline testing, you will be randomly assigned to either the voice therapy or aerobic conditioning protocol. If you receive voice therapy, you will participate in voice exercises including using a forward voice with airflow and pace of the exercises will progress as treatment progresses. You will be provided an option to attend voice therapy in person at the Voice Physiology Lab or via telehealth using a ETSU zoom platform. If you receive aerobic conditioning, you will complete the PAR-Q to determine eligibility to complete the conditioning program. Following eligibility, you will participate in warm-up exercises and walking on a treadmill at a pace determined for your body needs and the pace will progress as the treatment progresses. During this cardiovascular treatment session, your blood pressure and heart rate will be monitored. If your blood pressure is abnormal, you will be given the results and you may be referred to see your physician.
For each treatment session, you will be required to come in 2 times a week for the next 4 weeks, and the timing will be scheduled at your convenience. If you choose to complete voice therapy via telehealth, we will have 2 sessions online per week. Following the treatment protocol, you will be asked to complete the baseline testing again (reading in to a mask). During this process of baseline

testing and the post testing, you will be asked to rate your perceived effort for speaking using the BORG scale, Rating of Fatigue Scale (ROF) and your voice quality using the VFI. All testing will be completed on ETSU campus.
Due to COVID-19, additional precautions will be taken during the study including (a) monitoring researcher and participant temperature for every visit, (b) answering COVID screening questions at every visit as outlined by ETSU's research committee guidelines, (c) researcher will wear mask and gloves at all times during the protocol, (d) sanitization and disinfection of the room between participants.
COVID related treatment modifications: If you test positive for COVID-19, please inform the PI at 423-439-4036 or nanjundeswar@etsu.edu. During the study protocol, if you are exposed to COVID-19, but have tested negative and are asymptomatic, we will follow the 10-day symptom free protocol. During this time, we will continue a home-based treatment protocol. If you are in the voice therapy group, we will continue therapy via telehealth using a ETSU zoom platform. If you are in the cardiovascular conditioning group, you will be given a home-based program. You will be asked to continue walking or biking and the duration of the walk for that week will be provided to you. You will be asked to monitor the pace of your exercise and the exertion levels during the exercise using the Borg scale. You will be asked to reduce the duration or pace of the exercise if you reach a number of 15 "hard" on the Borg scale.
During the protocol, there are instances where you can be removed from the study without your consent. These include a) an indication of poor vocal quality during the preliminary examination, b) a deterioration in your voice during the course of the study protocol, c) you miss two consecutive treatment sessions, and d) you test positive for COVID-19, symptomatic or asymptomatic.

D. Alternative Procedures/Treatments:

The alternative procedures/treatments available to you if you elect not to participate in this study is the same behavioral voice therapy for your voice problem that is offered as part of this study protocol.

E. Possible Risks/Discomforts:

The possible risks and/or discomforts of your involvement include having a mask around the nose and mouth during the gas exchange protocol. However, the mask will not prevent normal breathing function. Additionally, if assigned to the aerobic conditioning protocol, there is a possible risk of physical discomfort during the completion of the exercises. However, you will be allowed to set your own pace and the intensity of the exercises will be gradually increased to reduce any risk of physical discomfort. Additionally, your heart rate and blood pressure will be monitored periodically at rest times and ratings of perceived exertion will be obtained to ensure comfort levels with the physical exercise. If your blood pressure is abnormal, you will be informed of the results and may be advised to see your physician. There is also a potential risk of loss of confidentiality from

participating in this study. However, your confidentiality will be protected by providing services in a closed room and storing your data in a de-identified form using key codes.

F. Possible Benefits:

There is a direct benefit to participants with voice problems. The treatment that the participants receive during this period can aid in the alleviation of their voice symptoms. Also, teachers/college instructors are a large percent of the workforce and are at increased risk of voice disorders, such as vocal fatigue. Data from this study will benefit the teachers/college instructors in the society by determining appropriate treatment protocols for those that experience a voice problem, specifically, vocal fatigue.

G. Compensation for Research Injury: If you have an injury while you are in this study, you should call the Principal Investigator immediately. East Tennessee State University (ETSU) will pay the cost of emergency first aid for any injury that may happen as a result of you being in this study. ETSU makes no commitment to pay for any other medical treatment. Claims against ETSU or any of its agents or employees may be submitted to the Tennessee Claims Commission. These claims will be settled to the extent allowable as provided under TCA Section 9-8-307. For more information about claims contact ETSU Office of University Counsel.

H. Financial Costs:

There are no financial costs to you.

I. Compensation in the Form of Payments to Participant:

You will be paid $150 for your time in the study for completing the entire protocol. If you do not qualify for the study during the preliminary examination, no payment will be given. For each visit, a $15 compensation will be provided. Cash will be provided at the end of each session and you will be asked to sign a document indicating your receipt of the payment. Based on ETSU's policy, a payment of over $100 for a study in a calendar year requires you to provide your SSN, name and home address.

J. Voluntary Participation:

Your participation in this study is completely voluntary. You may decide to withdraw from the study at any time. Your decision to withdraw from the study will not have any effect on your current or future relationship with ETSU and your care to treatment. You may withdraw by calling Chaya Nanjundeswaran at 423-439-4036.

If there are any findings in the interim that can be revealed to you, we will provide you with such information and findings at the time of your decision to withdraw. If

such findings change your mind, you can continue to participate in the study.

In addition, if there might be adverse consequences including deterioration of your voice during the experimental protocol or time commitments (e.g., missing more than 2 consecutive treatment sessions), you will be removed from the study. Prior to such removal, you will be informed of the reason for your removal. If you decide to withdraw due to time commitments, please inform Chaya Nanjundeswaran at 423-439-4036 or nanjundeswar@etsu.edu.

K. Contact for Questions: If you have any questions, problems, or research-related medical problems at any time, you may call PI Chaya Nanjundeswaran at 423-439-4036 or nanjundeswar@etsu.edu. You may also call the Chairperson of the ETSU Institutional Review Board at 423.439.6054 for any questions you may have about your rights as a research participant. If you have any questions or concerns about the research and want to talk to someone independent of the research team or you can't reach the study staff, you may call an IRB Coordinator at 423.439.6055 or 423.439.6002.

L. Confidentiality: We will make every effort to keep your study records confidential. The results of this study may be published and/or presented at meetings. You will not be named as a participant. Although your rights and privacy will be maintained, both the research records and signed consent form that identify you may be looked at by others that have the legal right to see that information. This may include the ETSU IRB overseeing this research, other individuals at the University with the responsibility for ensuring we follow the rules related to this research, the federal Office of Human Research Protections (OHRP) that protects participants like you, NIH, and the Principal Investigator and research team. Your records will be kept completely confidential according to current legal requirements. They will not be revealed unless required by law, or as described in this form.

M. Certificate of confidentiality: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH, which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

By signing below, I confirm that I have read and understand this Informed Consent Document and that I had the opportunity to have them explained to me verbally. You will be given a signed copy of this informed consent document. I confirm that I have had the opportunity to ask questions and that all my questions have been answered. By signing below, I confirm that I freely and voluntarily choose to take part in this research study.

_____ _____

Signature of Participant Date

_____ _____

Printed Name of Participant Date

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of Witness Date