

Study Title: The Effects of Respiratory Training on Voice

NCT #: NCT04710862

Document Title: Protocol Summary

Document Date: May 25, 2025

Participants were recruited from local physicians, speech-language pathologists, communication disorder clinics, and ClinicalTrials.gov. Participants were included if ages 18 or older, were in good general health per self-report other than the voice disorder, with normal pulmonary function, reported problems with their voice that had been present for 2 months or longer, were non-smokers, had English as their primary language to avoid potential linguistically-based differences in acoustic measures of voice, showed adequate corrected or uncorrected vision to read basic graphs and print as determined with visual screening, showed no organic or neurologic vocal fold pathology per laryngology exam performed and assessed by a laryngologist, were not currently receiving voice therapy, did not report a bilateral severe or profound level of hearing loss, had a diagnosis of muscle tension dysphonia, showed acoustic dysphonia (Cepstral/Spectral Index of Dysphonia) that exceeded normative values for the participant's age and sex, showed one or more patterns of supraglottic activity and presence of normal/complete vocal fold closure patterns during laryngoscopy examination, and showed evidence of speech breathing abnormalities relative to normative values. Prior to scheduling the first visit, general information about the study was provided during a telephone screening to determine basic eligibility status, with a copy of the consent form emailed or mailed to them for review before the first appointment.

Assessments

In the initial assessment visit, informed consent was obtained and an initial voice questionnaire was completed. For all participants, speech breathing behavior and voice acoustic recordings were obtained during a variety of speaking tasks that were repeatedly administered to determine performance at baseline, after the training phase, and at long-term follow-up timepoints. The primary testing and training phases took place over an 8-week period that included two pre-training assessment sessions in week 1 (baseline assessments), six training sessions held 1xweek (weeks 2 through 7), and two post-training assessment sessions in week 8. Assessment visits were approximately 2 hours, and training sessions were approximately one hour.

Laryngoscopy evaluation was completed in week 1 if not recently performed and with recording obtainable through participant's consent. In addition to the acoustic and speech breathing measurement described below, questionnaires were completed at each assessment timepoint including the Voice Handicap Index-10 and quantification of self-reported speaking effort on a visual analog scale. Participants were provided compensation for their time spent during all assessment but not training visits.

Acoustic recordings were obtained with a digital recording system simultaneously with speech breathing recordings. The Computerized Speech Lab (Pentax Medical) was subsequently used for all analyses of the acoustic data. To record and display respiratory signals, the respiratory InductoTrace system (Ambulatory Monitoring Inc)

was used, which included placement of transducer bands around the rib cage and abdomen to record volume changes associated with inspiration and expiration. Procedures for speech breathing calibration and measurement were based on well-established methods used clinically and in research. Participants performed calibration tasks while lung volume was measured with a digital spirometer, noseclip and mouthpiece. Subsequent recordings of the change in volume for the rib cage and abdomen during speech productions were measured while the participant read a passage aloud, providing estimated lung volume levels without the use of the spirometer. Participants returned for long-term assessments at 3 and 6-months post-training. After all short-term sessions were completed (weeks 1-8), control (sham) condition participants were subsequently offered the experimental condition (described below).

Training

Participants with muscle tension dysphonia were randomly assigned to one of two conditions: 1) respiratory lung volume training (RLVT) and 2) a control training (CT) condition involving a sham training device. For the RLVT condition, after the initial assessment sessions, training session 1 addressed instruction and training on appropriate speech breathing behavior, the rationale for targeting increased lung volume initiation and termination levels, and the targeted movements of the rib cage and abdomen. Training sessions 2 through 6 directly trained higher lung volume level targets during speech. Specifically, higher levels of lung volume initiation and termination were targeted to capitalize on non-muscular forces contributing to speech production. Increased frequency of breaths and reduced words per breath group were also incorporated into speech training. Training for RLVT included real-time visual biofeedback of lung volume levels in graphic form, with signals displayed on a large screen monitor and target levels for lung volume initiation and termination superimposed on the graphic display. This visual biofeedback was used to enhance motor learning of new speech breathing patterns. A hierarchical progression of gradually increasing length and complexity of speech was followed throughout training to facilitate skill acquisition and transfer of skills, while also incorporating spontaneous speech throughout training. A videorecording of one training session was performed for each participant using a digital video camcorder and tripod. This was later rated by a research team member who did not perform the training to determine fidelity of the training to specified protocol goals and stimuli.

The CT condition provided respiratory-like “training” that was not expected to improve speech breathing, and has been used as a control (sham) respiratory condition in prior studies. Expiratory muscle strength training (EMST) is among the most frequently studied respiratory treatments in studies addressing vocal outcomes and has been studied in people with voice disorders. A commercially available device (EMST 150;

Aspire Products) was purchased in modified form as a sham-EMST device which removed the internal spring device that offers expiratory resistance. Multiple studies involving general respiratory training have effectively implemented this device with the spring removed as a sham respiratory condition that allows for participant blinding. In the CT condition, participants performed multiple sets of 5 exhalations each through the non-resistive device following a full inspiration, with intervening rest periods between each exhalation and longer rest periods between each set. Number of sessions and time per session were identical for the CT and RLVT conditions, including pre-training and post-training assessment visits.

A home practice program with homework tracking sheets was completed throughout all six training sessions for both the RLVT and CT conditions to facilitate carryover of training and equalize home practice time between the two conditions. Additional explanation and speech stimuli for a continued home practice program was provided at the post-training assessment sessions after RLVT. Participants were encouraged to continue structured home practice including tasks associated with daily activities of living at least three times a week through the 6-month time period elapsing between training completion and the final long-term follow-up session.