VOICE THERAPY WITH A SEMI-OCCLUDED VOCAL TRACT:

FROM CURRENT CHALLENGES TO NEXT LEVEL EFFICACY STUDIES

Protocol and statistical analysis plan

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PROTOCOL

This study has been approved by the Ethics Committee of Ghent University Hospital (BC-09807).

Participants

Female students in the first year of study toward a bachelor degree in Logopaedic and Audiological Sciences at Ghent University (academic year 2021-2022), will be recruited for this study by convenience sampling. They will all provide written informed consent. Exclusion criteria are: an organic vocal fold pathology diagnosed by a specialized otorhinolaryngologist, smoking, pregnancy and hearing problems.

Design

A randomized controlled trial will be used. Participants will be assigned randomly to one of three experimental groups or a control group: (1) straw phonation (SP) in air, (2) SP in 2cm water, (3) SP in 5cm water or (4) /u/ phonation with similar soft onset and slightly pursed lips as in SP but without a straw (control group). An online random number generator will be used for this procedure.

Material and methods

Straw phonation material

Ecologic compostable wheat stirring straws with a diameter of 3mm and a length of 20cm will be selected for all experimental groups. SP in water will be performed in reusable cups, and the water depth (2cm or 5cm) will be set by drawing a line on the straw.

Preparatory phase

Before the experiment, in the second week of the academic year, all students will receive one group SP workshop of 20 min guided by an experienced voice therapist (I.M.). The aim of this session is to strive for a correct and comfortable SOVT production prior to the actual experiment. First, focus will be on an eutonic posture in sitting position and costo-abdominal breathing. Participants will be instructed to breath in through the nose and blow out through the mouth without phonation. Second, they will be asked to repeat this but now adding phonation on a [ɔ] vowel with soft onset [hhhɔɔɔ] during exhalation, at habitual comfortable pitch and loudness. Afterwards, both step one (without phonation) and step two (with phonation) will be repeated with the straw. Attention will be drawn to sensory feedback, forward focus, and avoidance of hyperfunction. At the preparatory phase, students will be unaware of their group assignment and will be specifically instructed to not practice the exercises at home.

Flexible strobovideolaryngoscopy and phonatory tasks

In the third and fourth week of the academic year, all students will undergo flexible SVL by a specialized otorhinolaryngologist (P.T. or F.D.) using an EndoFLEX Spectar laryngoscope (Xion Medical). The participants will be examined in seated position with the head upright and without administration of topical anesthesia. During the examination, they will be asked to phonate an [u] vowel at habitual pitch and loudness (baseline), followed by the specific SOVT exercise of their group assignment. For the SOVT phonation, they will be instructed to produce an [u] vowel at habitual pitch and loudness with soft onset and slightly pursed lips through the stirring straw (either in air, 2cm water or 5cm water) or without a straw (control group). The [u] vowel will be selected for all phonatory tasks (baseline and SOVT, both in the experimental group and the control group) so that potential differences are more certainly attributable to SP and not to differences in vowel production. The same voice therapist (I.M.) will guide them through these phonatory tasks, together with a master's student (K.P.) for practical support.

Visual-perceptual ratings

After data collection, all video samples will be evaluated randomly and blindly by an otorhinolaryngology resident (C.D.V.) and a speech-language pathologist specialized in voice (I.K.). Evaluations will be standardized by use of the Voice-Vibratory Assessment with Laryngeal Imaging (VALI) rating form for stroboscopy (Poburka et al., 2017). In advance, a half hour training session will be provided in which each parameter will be clarified with the definition, a high-quality graphic, and two video examples.

After the training, the assessors will first independently evaluate each video sample on a self-paced basis, after which a consensus evaluation will be reached. Ten percent of the samples will be randomly repeated to assess intrarater reliability. The video samples will be presented without audio to prevent bias of the participant's voice quality on the judges' ratings.

The parameters to be evaluated are glottal closure (complete, anterior gap, posterior gap, hourglass, spindle gap, irregular, or incomplete), amplitude (magnitude of lateral movement of the vocal folds, in %), mucosal wave (magnitude of lateral movement of the mucous membrane in %), vertical level (on-plane, off-plane left lower, or off-plane right lower), nonvibratory portion (adynamic segments of tissue that appear stiff, in %), anteroposterior (AP) and mediolateral (ML) supraglottic activity (constriction of the supraglottic structures, rated $0 - 5$ with the aid of concentric circles), free edge contour (normal, convex, concave, irregular, or rough), phase closure (open phase predominates, nearly equal, or closed phase predominates), phase symmetry (the degree of symmetry between the left and the right vocal folds in terms of opening and closing, in %), and regularity (consistency of averaged stroboscopic cycles, in %) (Poburka et al., 2017).

STATISTICAL ANALYSIS PLAN

The data will be analyzed statistically by SPSS version 28 (SPSS Corporation, Chicago, IL, USA) at $\alpha = 0.05$.

To determine the interrater reliability of the visual-perceptual ratings, a two-way mixed, consistency, average-measures intraclass correlation coefficient (ICC) will be calculated for the continuous variables, and a Cohen's kappa (K) will be used for the nominal variables (Hallgren, 2012; Koo & Li, 2016). Intrarater reliability will be determined using a two-way mixed, absolute agreement, single-measures ICC for the continuous variables, and a Cohen's K will be used for the nominal variables (Hallgren, 2012; Koo & Li, 2016).

Linear mixed model analyses will be used to compare the groups over phonatory condition (habitual [u] phonation vs SOVT phonation) on each continuous variable using the restricted maximum likelihood estimation and scaled identity covariance structure. Group, Phonatory Condition and Phonatory Condition * Group interaction will be determined as fixed factors. A random intercept for subjects will be included. Model assumptions will be checked by inspecting whether residuals were distributed normally. Within-group effects of Phonatory Condition will be determined by posthoc pairwise comparisons. Marginal homogeneity tests will be used to compare nominal variables between habitual /u/ phonation and SOVT phonation within groups.