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VOCAL FUNCTION EXERCISES FOR NORMAL VOICE:
THE EFFECTS OF MAXIMALLY SUSTAINED PHONATION

THESIS

A thesis submitted in partial fulfillment of the
requirements for the degree of Master of Science in Communication Sciences and
Disorders in the
College of Health Sciences
at the University of Kentucky

By

Mariah Elaine Morton

Lexington, Kentucky

Director: Dr. Joseph Stemple, Professor of Communication Sciences and Disorders

Lexington, Kentucky

2019

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ABSTRACT OF THESIS

VOCAL FUNCTION EXERCISES FOR NORMAL VOICE: THE EFFECTS OF MAXIMALLY SUSTAINED PHONATION

Vocal Function Exercises (VFEs) is a well-known treatment program that consists of four exercises, in which the first and fourth tasks require maximally sustained phonation. However, the active ingredients responsible for treatment efficacy are still unknown. The primary purpose of this investigation was to explore the effects of maximally sustained phonation on the VFE outcome measure of maximum phonation time (MPT) in individuals between the ages of 18-40 with normal voice. Participants were randomized into three experimental groups that completed VFEs for six weeks. The baseline group sustained tasks one and four for as long as was achieved at the baseline session; The three-week group sustained the exercises for as long as possible the first three weeks, then to their three-week MPT average for the remaining three weeks of the program; The standard group maximally sustained phonation for all six weeks. Results indicated significant improvement in percent to MPT goal attainment in the standard group and three-week group. The baseline group did not result in significant change. Including maximally sustained phonation throughout the course of VFEs is essential to producing substantial improvements in voice production, in terms of percent to MPT goal.

KEYWORDS: Vocal Function Exercises, maximally sustained phonation, tasks, maximum phonation time, active ingredients, normal voice

Mariah Elaine Morton

04/16/2019

VOCAL FUNCTION EXERCISES FOR NORMAL VOICE:
THE EFFECTS OF MAXIMALLY SUSTAINED PHONATION

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CHAPTER 1. INTRODUCTION

While therapeutic inputs and behavioral outputs are observable in many treatment programs, the active ingredients responsible for treatment efficacy are often opaque or simply unknown (Van Stan, Roy, Awan, Stemple & Hillman, 2015). Many evidence-based voice therapy programs are based on principles of exercise physiology and motor learning, however it is unclear which active ingredients (observable, measurable attributes of treatment selected/delivered by the clinician) are responsible for effecting change in the treatment target. In the field of rehabilitation sciences this phenomenon is often referred to as the “black box” (Whyte, 2014).

The well-known treatment program, Vocal Function Exercises (VFEs) is an example of this phenomenon, in which 29 outcomes studies have demonstrated that the standard VFE protocol improves the normal (Stemple, Lee, D’Amico, & Pickup 1994; Ellis & Beltyukova 2011), pathological (Roy, Merrill, Thibeault, Parsa, Gray & Smith 2004; Roy, Simon, Corbin-Lewis, & Stemple 2001; Texiera & Behlau 2014; Gillivan-Murphy, Drinnan, O’Dwyer, Ridha & Carding 2006; Ziegler, Gillespie, & Abbott 2010; Pedrosa, Pontes, Pontes, Behlau, & Peccin 2016; Kapsner-Smith, Hunter, Kirkham, Cox & Titze 2015; Patel, Pickering, Stemple & Donohue 2012; Sharma, De, Martin, & Pracy 2009; Gorman, Weinrich, Lee & Stemple, 2008; Kaneko, Hirano, Tateya, Kishimoto, Hiwatashi, Fujiu-Kurachi, & Ito, 2005; Tanner, Sauder, Thibeault, Dromey, & Smith, 2010; Sauder, Roy, Tanner, Houtz, & Smith 2010; Berg, Hapner, Klein, & Johns, 2008; Ziegler, Abbott, Johns, Klein, & Hapner 2014) and well-trained voice (Sabol, Lee, & Stemple 1995; Guzman, Angulo, Munoz, & Mayerhoff 2013), yet the reasons why it is efficacious have not been fully realized. VFEs are a holistic, physiologic training

approach to voice therapy purported to strengthen and rebalance the laryngeal musculature and restore coordination among the three subsystems of voice production: respiration, phonation and resonance, which are all interdependent and interconnected. The standard VFE protocol as outlined by Stemple, Lee, D'Amico, & Pickup (1994), consists of four exercises, in which the first and fourth tasks (the warm up and low impact adductory power exercises) require the client to maximally sustain phonation. However, we are unsure whether sustained phonation is necessary to improve voice, in terms of maximum phonation time.

To date we do know the VFE program has three active ingredients, one of which is compliance monitoring of home practice (Ellis et al., 2011). The second is dosage, the number of times a client is to complete each exercise daily (Bane, Brown, Angadi, Andreatta, & Stemple, 2018) and the third is vocal tract posture for completing the exercises 2-4 (Bane, Angadi, Dressler, Andreatta & Stemple, 2017). Knowing these three essential components is necessary, and it is important that this line of research continues identifying the other active ingredients within the VFE program. Knowledge of the essential components will inform speech-language pathologists of the degrees of freedom they have within the VFE program to modify the therapy to meet the needs and preferences of a patient while still maintaining the efficacy of the treatment (Whyte, 2014).

Such individualization may lead to greater generalization of the program into the patient's daily activities. Also, identification of active ingredients may allow clinicians to meaningfully define rehabilitation interventions so that they may be replicated with high

treatment fidelity as well as systematically trained and communicated to clinicians and patients alike.

Therefore, the present investigation is the fourth study to continue this series of research by exploring the importance of maximally sustained phonation as an active ingredient by manipulating tasks one and four of the VFE program. Sustained phonation is being investigated because attainment of an MPT goal is often used as a discharge criterion for voice therapy.

MPT is an important element of VFEs because based on principles of exercise physiology applied to the laryngeal musculature, it has been suggested that increased duration of sustained phonation may be critical to training fatigue resistance/management. In addition, sustained phonation may promote endurance capabilities that cannot be developed in the absence of such training (Sandage & Hoch, 2017). However, duration of sustained tones may affect a multitude of treatment-related factors, including time spent during home practice, dosage and adherence. Therefore, if clinicians can improve the efficiency of this therapy, it may assist with increasing adherence and decreasing attrition. This is vital because it has been proposed that a treatment protocol may be more critical than the specific therapy program due to dropout being a major issue within voice therapy (Verdolini-Marston, Burke, Lessak, Glaze & Caldwell, 1995).

1.1 Statement of the Problem

Clinicians routinely modify evidence-based treatment programs to meet the needs of individual patients. However, it is unclear whether these clinical choices undermine, preserve, or enhance treatment efficacy. As stated previously, the importance of

maximally sustained phonation within the VFE protocol has yet to be systematically examined. It is unclear whether MPT is necessary or if shorter practices of sustained phonation result in the same outcome after six weeks of intervention. Therefore, this is the fourth study in a series of research designed to systematically dismantle Vocal Function Exercises and identify its active ingredients to improve the efficiency of the protocol and to inform clinical choices.

1.2 Purpose of the Study

The purpose of this study was to determine the effect of maximally sustained phonation on the primary outcome measure of MPT in a group of healthy volunteers, by manipulating the required lengths of tasks one and four of the protocol. Since vocal wellness exists on a continuum that includes the disordered, normal, and well-trained voice, individuals are always capable of improving their vocal quality (Stemple, 2005). Therefore the intervention of focus here, VFEs, while aimed primarily at improving the disordered voice, may be equally effective in enhancing those perceived to have normal voice (Stemple, 2005).

Three experimental groups completed VFEs for six weeks, with practice twice daily. Each group varied in the duration for which they sustained VFE tasks one and four. The baseline group (BG) sustained only to their baseline maximum phonation time, which was obtained at the initial session. The three-week group (3G) sustained VFE tasks one and four for as long as possible for the first three weeks and then sustained these tasks to their three-week MPT average for the remainder of the intervention. The standard group (SG) sustained each exercise for as long as possible, as outlined by Stemple et al. (1994). By systematically changing a single element of the VFE protocol, maximally

sustained phonation, the primary purpose of this study was to investigate whether maximally sustained phonation over the course of six weeks resulted in greater MPT improvement.

1.3 Chapter Summary

Chapter one served to introduce the concept and importance of active treatment ingredients, specifically the ingredient of maximally sustained phonation, as it relates to Vocal Function Exercises. Chapter two will serve to review the relevant literature.

CHAPTER 2. LITERATURE REVIEW

Previous research has demonstrated that VFEs are efficacious in improving voice in a wide range of patient populations in all five domains of voice assessment (acoustic, aerodynamic, auditory-perceptual, self-assessment and stroboscopic imaging). As stated previously, a recent line of research has begun dismantling the VFE program to identify its active ingredients. This study specifically aims to determine whether a fourth component of the VFE protocol, maximally sustained phonation, is an active ingredient in the treatment program. To date, the sustained phonation aspects of VFEs have not been systematically studied.

2.1 Standard Vocal Function Exercise Protocol

Below is a description of the four exercises initially outlined by Stemple et al., (1994) and later elaborated upon by Stemple (2005):

1. Warm-up exercise: The client sustains the vowel /i/ *for as long as possible*.
Females and adolescent boys on the musical note (F) above middle (C). Adult males on the musical note (F) below middle (C). Placement of tone should be extremely forward focused and nasal in quality.
2. Stretching exercise: The client glides from their most comfortable low note to their most comfortable high note on the word, “knoll”. Placement of tone should be extremely forward focused with an open pharynx and sympathetic lip vibration. The client should continue to stretch despite phonatory breaks, with the ultimate goal of eliminating all voice breaks.

3. Contracting exercise: The client glides from their most comfortable high note to their most comfortable low note on the word, “knoll”. Placement of the tone should remain extremely forward focused, with an open pharynx and sympathetic lip vibration. The client is instructed to avoid growling at the low note, and the ultimate goal is to eliminate all voice breaks.
4. Low-impact adductory power exercise: The client sustains the musical notes C-D-E-F-G *for as long as possible* on the sound /o/ of the word “knoll”. The /o/ should be produced with an open pharynx and sympathetic lip vibration. Females and adolescent boys begin on middle (C) and adult males begin an octave below middle (C).

2.2 Standard VFEs for the Normal Voice

Stemple et al., (1994) conducted a study investigating VFE efficacy in improving normal voice. This study included 35 female participants randomized into one of three groups: experimental, control, or placebo. Each participant underwent a four-week intervention with the experimental group performing VFEs as described by the standard protocol. The placebo group engaged in a placebo exercise program. Results indicated that the experimental group demonstrated significant improvement in phonation volume, flow rate, maximum phonation time, and phonational frequency range. No significant changes in outcome measures were noted for the control or placebo groups.

There are various other studies that have examined the effect of VFEs in vocally normal patients and those studies will be addressed later in this chapter as we discuss research investigating the active ingredients within the standard VFE protocol.

2.3 Standard VFEs for Voice Disordered Teachers

The effect of VFEs has been researched among teachers as well because this is a population extremely susceptible to voice disorders. Roy, Merrill, Thibeault, Parsa, Gray & Smith (2004) found that the likelihood of having at least one occurrence of dysphonia during the lifespan is as high as 57.7% for educators as compared to only 28.8% for non-educators. Also, when compared to other professionals, teachers reported that they were more likely to miss work due to voice-related issues. Thus, VFEs have been trialed with voice disordered teachers and were demonstrated to be efficacious in this population.

Roy, Simon, Corbin-Lewis, & Stemple (2001) conducted a prospective, randomized control trial study with elementary and secondary teachers with self-reported voice problems. Participants were assigned to one of three groups: VFEs, vocal hygiene (VH) or a no-treatment control (NTC). The primary outcome measure was scores on the Voice Handicap Index (VHI). Teachers in the VFE group demonstrated significant improvement on the VHI as compared to no improvement in the VH group and regression in the NTC group. All subjects also completed a post-treatment questionnaire in which they were to rate the extent of their voice improvement and treatment compliance on a five-point scale, whereby one was “not at all” and five was “a lot”. Results of the questionnaire indicated the VFE group had greater vocal clarity and greater ease of speaking posttreatment when compared to the NTC and VH groups.

Texiera & Behlau (2014) conducted a similar study with 162 female Brazilian teachers with behavioral dysphonia. This single-blinded, controlled trial investigated the effectiveness of VFEs versus voice amplification after six weeks of intervention.

Participants were randomized into one of three groups: Control Group (CG), Voice Amplification Group (VAG) or Vocal Function Exercise Group (VFEG). Results indicated that only the VFEG showed statistically significant differences in auditory-perceptual evaluation with blinded and experienced speech-language pathologists using the Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V) to evaluate voice quality pre- and post- treatment. On laryngeal examination, all participants in the VFEG improved in either glottal closure or in glottal closure and lesion size. VFEG participants also demonstrated significant improvements across all acoustic parameters used in this study (noise to harmonics ratio, shimmer, jitter and fundamental frequency) compared to the VAG and CG. Lastly, the VFEG was the only group to demonstrate statistically significant improvements in all seven dimensions of the self-rated Voice Activity and Participation Profile (VAPP) completed pre- and post-intervention. The authors concluded that teachers with behavioral dysphonia benefitted more from voice therapy, such as VFEs, than from voice amplification, which is best used as a preventative measure.

A pre-post-controlled trial conducted by Gillivan-Murphy, Drinnan, O'Dwyer, Ridha & Carding (2006) included 20 female teachers randomized into one of two groups: treatment or no treatment. Three self-reported voice measures were administered at baseline and then after six weeks of combined VFEs and vocal hygiene. Although there were no significant improvements observed in the treatment group on the Voice Related Quality of Life (VRQoL) measure, there was significant improvement on the Voice Symptom Severity Scale (VoiSS) measure and an increase in knowledge and awareness

of hygienic vocal care post-treatment as analyzed using the A Voice Care Knowledge Visual Analogue Scale (VAS) in both groups.

Ziegler, Gillespie, & Abbott (2010) summed up the literature on VFEs as treatment for teachers with voice disorders, stating that VFEs in isolation have the greatest treatment value for school teachers when delivered in individual therapy sessions where both the clinician and client are well-trained. This conclusion was based on a comparison of positive VFE efficacy findings to a study by Pasa, Oates, & Dacakis (2007), which found that a vocal hygiene group of teachers with self-reported vocal abuse improved more on outcome measures of voice characteristics and voice knowledge than a VFE group. These findings have been largely attributed to (1) the use of a modified VFE protocol, in which participants produced musical tones not at specific pitches but at “high”, “comfortable” and “low” pitches and (2) delivery of VFEs in a group setting which greatly reduced exposure to clinician input (Ziegler et al., 2010). Thus, certain VFE protocol modifications may undermine treatment efficacy.

2.4 Standard VFEs for the Pathological Voice

In addition to teachers, VFEs are efficacious in improving the disordered voice in other populations. Pedrosa, Pontes, Pontes, Behlau, & Peccin (2016) conducted a randomized clinical trial. The objective was to evaluate and compare the effectiveness of the Comprehensive Voice Rehabilitation Program (CVRP) versus Vocal Function Exercises. CVRP is an exercise program originated from research carried out by the Larynx Institute of São Paulo (INLAR) in Brazil and the Centre for the Study of Voice (CEV). Eighty professional voice users were the subjects in this study which included

television and radio station personalities, lawyers and telemarketers. However, singing professionals or those with acute or organic dysphonia were excluded. Nevertheless, the 80 participants were randomized into one of two groups: CVRP and VFEs and were to complete their respective exercise programs for six weeks as well as an additional month after. Outcome measures were the following: 1) laryngeal imaging, in which blinded judges used a visual analog to rate the stroboscopic exams. Zero was normal and 100 was extremely abnormal, 2) self-assessment measures: VHI and VRQoL and 3) auditory perceptual evaluation conducted by blinded judges using a visual analog scale, in which zero was no vocal deviation and 100 was maximum deviation. These measures were collected pre-intervention, after the first six weeks and at the one month follow up. Results indicated the VFE and CVRP groups improved in all three outcome measures after six weeks as well as after the additional one month follow up. However, results of two out of the three outcome measures favored the VFE group. Participants that completed VFEs demonstrated greater reduction in VHI scores and greater increase in VRQoL scores after intervention. Furthermore, the VFE group numerically had greater reduction of scores in auditory perceptual evaluation.

Similarly, Kapsner-Smith, Hunter, Kirkham, Cox & Titze (2015) completed a study aimed to provide evidence regarding the efficiency of phonation through a narrow flow-resistant tube (FRT) compared to oral semi-occlusion with VFEs. Twenty-five individuals with dysphonia were randomized into one of four groups: immediate FRT therapy, immediate VFE therapy, delayed FRT therapy and delayed VFE therapy. The two delayed groups served as the control groups that began therapy after six weeks. The

primary outcome measure was the VHI. Both treatment groups (FRT and VFE) showed significant reduction in VHI scores while the control groups showed no change.

In addition, VFEs have been shown to be efficacious in improving voice for a patient with a contact granuloma. A single-subject before-after prospective study was conducted with a 51-year-old male with unilateral contact granuloma who completed VFEs for six weeks (Patel, Pickering, Stemple & Donohue 2012). Multiple outcome measures were used. High-speed imaging (HSDI) measured several elements including voice onset, peak closing velocity and peak-to-average opening velocity. Acoustic measures included average fundamental frequency, pitch range and noise-to-harmonics ratio. Aerodynamic measures looked at expiratory volume, mean expiratory airflow, etc. Stroboscopic images were assessed for glottal closure and phase closure. Perceptual assessment was also completed using the CAPE-V by three blinded speech-language pathologists pre and post therapy. After VFEs, the subject had a reduced voice onset time, increased peak closing velocity and a decreased peak-to-average opening velocity. Acoustic measures demonstrated, the subject was within normal limits pre and post therapy, so there was not much change, except for in vocal intensity which increased by 26.7% after VFEs. In aerodynamic measures there was a 4.07% increase in respiratory volume and a decrease in mean expiratory airflow by 54.16%, which is appropriate in the case of this subject who had a significant pre-treatment glottal gap preventing closure due to the granuloma. This gap caused air leakage which improved post VFEs. Additionally, there was improved closure and a smaller posterior glottal gap, which is consistent with the aerodynamic findings. Lastly, the pre-intervention CAPE-V average score was 18/100, while the mean after Vocal Function Exercises was 0/100. Therefore, the

researchers concluded that these changes in phonatory physiology support the claim that voice therapy techniques such as VFEs are a viable treatment for contact granuloma.

Finally, in a single-subject case study, Sharma, De, Martin, & Pracy (2009) implemented VFEs post-operatively with a 26-year-old Marine after having suffered from a shrapnel injury to the right side of the neck causing a laryngeal fracture. The subject had displaced fragments of the right thyroid cartilage and a complete disruption of the anterior commissure. Although laryngeal injuries are uncommon, when they do occur, they result in high mortality rates. As a result of his injury, the Marine underwent a laryngofissure in which the fragments were repaired with miniplates. After surgery the patient underwent extensive speech and language therapy which involved completing VFEs. The author stated the Marine demonstrated great compliance with the therapy. After performing VFEs, his MPT more than doubled and overall vocal quality improved quickly. He was able to return to work just six months post-operatively.

The studies discussed in this section indicate there is evidence to suggest that VFEs are effective in both behavioral and functional voice disorders, either in isolation or following medical/surgical intervention

2.5 Standard VFEs for Presbylaryngeus

For individuals with presbylaryngeus (or aging larynx), there is ample research supporting VFE efficacy. In a pre- posttreatment study conducted by Gorman, Weinrich, Lee & Stemple (2008) they found that 19 male participants between the ages of 60-78 years old had continuous improvements in MPT across the 12 weeks of VFE intervention. Additionally, significant differences were noted before and after treatment

on aerodynamic measures related to glottal closure, including decreased glottic airflow and increased subglottic pressure following VFEs. It is important to note that the elderly men in this study never leveled off in MPT. They continually increased their phonation times. Such improvements in the aerodynamic measurements may not have occurred if the participants were asked to only sustain for a certain duration.

Similarly, a prospective study by Kaneko, Hirano, Tateya, Kishimoto, Hiwatashi, Fujiu-Kurachi, & Ito (2005) enrolled sixteen participants with vocal fold atrophy between the ages of 65-81 and administered VFEs. After six weeks of intervention, significant improvements were found on the Grade, Roughness, Breathiness, Asthenia, Strain (GRBAS) scale, MPT, jitter and the VHI -10 compared to a historical control group of similar age that showed no improvements.

A case study conducted with a set of 79-year-old twins both with severe vocal fold bowing was completed to examine their individual responses to treatment. Despite surgical intervention that improved glottal closure, no consistent voice improvement was observed. However behavioral therapy, which included completing VFEs, resulted in increased mid-membranous and posterior laryngeal glottal closure post voice therapy as well as a decrease in overall severity based on the VHI, although intermittent dysphonia remained in both cases (Tanner, Sauder, Thibeault, Dromey, & Smith, 2010).

Another pre and post treatment study conducted by Sauder, Roy, Tanner, Houtz, & Smith (2010) included nine elderly patients diagnosed with presbylaryngeus (2 female, 7 male). There was no comparison group, however the participants underwent a six-week course of Vocal Function Exercises. Pre and post intervention comparisons were analyzed using self-ratings of the Voice Handicap Index, phonatory effort level, auditory-

perceptual assessment, acoustic analysis and laryngeal imaging. The results demonstrated significant reductions on VHI scores, phonatory effort levels, and voice disorder severity following Vocal Function Exercises. In addition, blinded listeners rated the posttreatment voices of all nine participants as significantly less breathy and strained.

In 2008, Berg, Hapner, Klein, & Johns conducted a pre-post study and found improvement in VRQoL scores in individuals with age-related dysphonia after four sessions of voice intervention over the course of five months. The therapy group received vocal hygiene, resonant voice, and VFEs and was compared to a control group. Average improvement on the VRQoL was 19 points for the experimental group and one point for the control group.

Similar results were found in 2014 by Ziegler, Abbott, Johns, Klein, & Hapner in VRQoL improvement. This prospective, randomized, controlled trial included sixteen elderly participants with presbyphonia randomized into one of three groups: VFE, PHoRTE, or a no-treatment control group. Results showed improved scores on the VRQoL for the VFE and PHoRTE groups as compared to no improvement in the control group. In addition, numerically the VFE group demonstrated slightly greater adherence to home practice, while the PHoRTE group demonstrated greater perceived treatment satisfaction over VFEs.

Nonetheless, VFEs have been shown to improve voice as measured by several objective vocal assessments for the aging voice.

2.6 Standard VFEs for the Well-Trained Voice

Additional studies have investigated the effects of VFEs on singers and other populations who have already undergone professional vocal training. Sabol, Lee, & Stemple (1995) studied the effects of VFEs on voice production for a group of 20 graduate-level vocal majors with similar vocal training. Participants were assigned either to the experimental (VFE) group or control group and practiced regularly for four weeks. The VFE group displayed significant improvements in aerodynamic measures of flow rate, phonation volume, and maximum phonation time, while the control group failed to improve significantly.

Guzman, Angulo, Munoz, & Mayerhoff (2013) investigated the effect of VFEs on voice quality in conjunction with vocal warm-ups in pop singers. The experimental group completed a single VFE session, and the control group completed traditional singing warm-ups. The singers were recorded pre- and post- vocal exercises using a read-aloud task at habitual intensity and singing “Happy Birthday” in a comfortable musical key. Then, using a long-term average spectrum (LTAS), acoustical analyses of the sets of recordings were completed using the LTAS protocol for both groups. The measures gathered from LTAS included energy level differences between F_1 and F_0 , the alpha ratio which provides information on spectral declination, and the singing power ratio. Upon comparison, the experimental group demonstrated statistically significant improvements in energy level difference and singing power ratio following VFEs, which were results not observed in the control group. The authors concluded that VFEs were advantageous as a vocal warm-up for singers.

2.7 Modified VFE Protocol

Previous studies examining VFEs have modified the VFE protocol by deviating from the prescribed exercise regimen. However, these modifications were not always made purposefully or with the intent of determining their effect on treatment efficacy.

Ellis & Beltyukova (2011) conducted a comparison study examining the effects of monitored versus unmonitored compliance in adult women with normal voice who performed VFEs over four weeks. The study found that both groups increased MPT and improved maximum phonational frequency (MPFR). However, the group monitored for compliance via audio recording improved significantly more than the unmonitored group.

A second element of the VFE protocol which has been modified is the semi-occluded vocal tract (SOVT) posture. There are currently three studies that have investigated the importance of this element in the standard VFE protocol. The first appears in a case study by Radhakrishnan & Scheidt (2012), in which the patient was unable to achieve the SOVT posture required and was also unable to match pitch for the final low-impact adductory power exercise. Thus, the vocal tract posture, pitch glides and final power tasks were all modified. Despite such modifications, the results indicated improvements in several measures including VHI score, MPT, CAPE-V, perturbation measures and pitch range. However, because Radhakrishnan & Scheidt (2012) made multiple modifications, it is unclear which potential active ingredient(s) was/were responsible for the study's outcomes.

Another study that modified the recommended semi-occluded vocal tract posture was single-blinded, randomized controlled trial conducted by Nguyen & Kenny (2009). Forty Vietnamese school teachers, previously diagnosed with muscle tension dysphonia

(MTD), were randomly assigned to one of two groups. The full exercise (FE) group followed the traditional VFE protocol of practicing the four exercises two times each, twice daily. The partial exercise (PE) group completed only the first exercise of the VFE standard protocol two times each, twice daily. Furthermore, the standard SOVT posture was modified by using Vietnamese vowels (as opposed to English vowels) as a means of tailoring VFEs to speakers of tonal languages, which alters the shape of the vocal tract. The outcome measures were acoustic measures (frequency, amplitude perturbation, harmonics to noise ratio, mean fundamental frequency) and perceptual data. After four weeks of treatment, the VFE group demonstrated significant changes in perturbation, noise to harmonics ratio and perceptual data as well as a wider pitch range. The PE group failed to demonstrate any of these improvements.

A third study that modified the recommended SOVT posture did so systematically (Bane, Brown, Angadi, Andreatta, & Stemple, 2018). Three experimental groups completed VFEs using varying degrees of vocal tract occlusion. The first group used the traditional SOVT posture with the greatest semi-occlusion. The second group used a modified /o/ posture which resulted in partial occlusion; the third group used a modified /a/ posture without significant occlusion. Only the traditional SOVT group resulted in significant improvement in MPT. These results imply that the SOVT posture is essential to VFE treatment efficacy, though the /o/ group also demonstrated near-significant improvement and therefore may be a viable alternative for individuals who are unable to achieve semi-occlusion.

In addition to compliance monitoring and vocal tract posture, another ingredient of the VFE protocol has been modified and researched. Bane, Angadi, Dressler,

Andreatta & Stemple (2017) systematically investigated the effects of home practice VFE dosage on MPT in healthy volunteers. Participants were randomized into one of three experimental groups and completed a six-week VFE protocol with practice twice daily. The low dosage group (LD) performed each exercise once, the traditional dosage (TD) group twice (as traditionally prescribed) and the high dosage (HD) group completed each exercises four times. The HD group demonstrated greatest improvement in MPT, while the LD group failed to significantly improve. Although participants in the HD significantly improved MPT, the authors concluded that increased dosage may compromise compliance, since HD increased participant withdrawal to 50%. Therefore, the traditional group approach appeared to be the best option clinically. A high percentage of individuals in the TD group met 80% of their VFE MPT goal (33%) and demonstrated improvement maintenance post-intervention similar to the high dose group.

Systematic dismantling of the VFE protocol allows active ingredients essential to treatment efficacy to be identified while minimizing the risk of confounding influences. Overall, studies that have modified the VFE protocol have demonstrated that VFEs can be modified to a certain extent while preserving treatment efficacy, though not every study has demonstrated the same degree of methodological rigor.

2.8 Exercise Duration

The importance of duration has not been thoroughly investigated in the area of voice therapy. The term “duration” is often described as the dosage of a given treatment program within a span of time (e.g. six weeks, 10 sessions, 50 minutes). Menezes, Ubrig-Zancanella, Cunha, Cordeiro, Nemr, & Tsuji (2010) conducted a study examining the

relationship between tongue trill performance duration at one given time and vocal changes in dysphonic women. Twenty-seven women with vocal nodules were assigned to the experimental group (EG) and were given tongue trill exercises to complete. Ten women were placed in the control group (CG) and given finger tapping placebo exercises to complete. The voices were recorded before and after experimental and placebo exercises at one minute (m1), three minutes (m3), five minutes (m5) and seven minutes (m7) of performance. The voice material used for the acoustic and auditory perceptual analysis consisted of the sustained emission of the /æ/ vowel sound, at comfortable intensity and frequency, chosen by the subjects themselves and performed as naturally as possible. Recordings were randomized and analyzed using the Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V) by blinded judges (speech-language pathologists). Additionally, after hearing paired recordings (A and B) one from the experimental group and one from the control group the blinded judges were to write down if the voices were the same or to select the better voice. If the judges did indeed find one voice to be better based on their clinical judgement, subsequently the judge was asked to point out which reason(s) led them to make their choice according to the features contained on the CAPE-V. Acoustic analysis used the following parameters: fundamental frequency, jitter, shimmer, glottal-to-noise excitation (GNE), irregularity, and noise. According to the CAPE-V results, the experimental exercise (tongue trills) caused significant changes in seven out of nine of the assessed parameters. At m1, there was a loudness increase and at m3, there was a pitch increase. However, at m5, the voice was presented with a better overall voice quality, less roughness, and less breathiness. When comparing the voice recordings there was little difference between the groups at

m1 and m3. Yet at m5, positive responses prevailed 60% of the time in the experimental group. While the control group was considered better 70% of the time at m7. Lastly, the only distinguishing acoustic parameter was fundamental frequency when comparing the experimental group and control group.

Overall, the authors found statistically significant vocal improvement at m5 of tongue trill exercises. However, m7 tongue trill duration was found to interfere with vocal performance, resulting in increased vocal tension and a decline in overall voice quality. The authors concluded that increased duration is not necessarily better, particularly if technique is compromised.

Although this study examined the effects of sustained phonation with tongue trills, a commonly used semi-occluded vocal tract exercise in voice therapy, it is unclear whether there was repetition of the task to continue for several minutes, which means duration was investigated slightly differently than in the present study. Additionally, the authors did not address the cumulative effects of endurance and sustained duration as it relates to improved voice over time.

In summary, there are very few studies addressing the effects of duration of specific tasks in voice treatment. Research has not thoroughly defined “duration” as this current study does by systematically investigating maximally sustained phonation in Vocal Function Exercises to determine if this element is essential to improve voice production. Most of the knowledge about sustained phonation is borrowed from principles of exercise physiology, applied to limb musculature and has not been systematically investigated in the area of voice therapy. However, the following preliminary conclusions can be drawn.

1. There is literature to support that frequent, short periods of exercise are not as effective as less frequent, longer sustained phonation tasks (Sandage & Hoch, 2017; Menezes et al., 2010). However according to the Menezes et al., 2010 article, longer duration is beneficial only to a certain point. Nonetheless, voice production does change over time, meaning sustained phonation times could affect voice production.
2. Maximally sustained phonation has not been systematically differentiated or studied in depth.

Thus, the purpose of this study is to systematically investigate the effect of maximally sustained tones on the VFE outcome measure of maximum phonation time in healthy volunteers who complete six weeks of VFEs.

2.9 Research Hypotheses

1. The standard group will demonstrate the greatest improvements in MPT. This hypothesis is based on the Sandage & Hoch (2017) discussion of the benefit of longer duration in training to increase vocal endurance when improving vocal output.
2. The baseline group will not demonstrate significant improvement toward MPT goal over the six-week period. This hypothesis is based on the Sandage & Hoch (2017) rationale that shorter task duration fails to vocally train the voice as longer durations would. In addition, this hypothesis is based on Menezes et al., (2010) failure to find statistically significant improvements in voice quality at the shortest duration participants sustained the lip trill task. In a regimen that

investigated the efficacy of various durations of performance, it is reasonable to apply these conclusions in hypothesizing about this study.

2.10 Chapter Summary

Chapter two served to review pertinent literature regarding VFE efficacy, VFE modifications, treatment fidelity, and duration of phonation tasks. Chapter three will present the methods used to address the following research question: What is the effect of maximally sustained phonation on the VFE outcome measure of MPT in healthy volunteers who complete six weeks of VFEs?

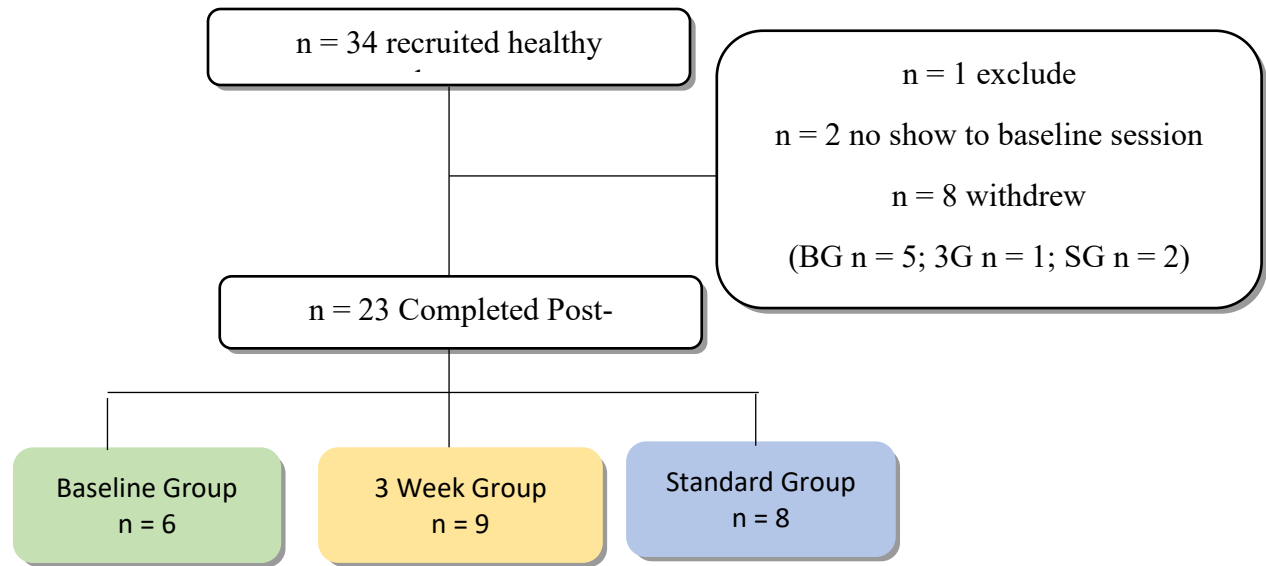
CHAPTER 3. METHODOLOGY

All recruitment, intervention and data collection procedures were approved by the Institutional Review Board (IRB) at the University of Kentucky (UK).

3.1 Participants

A total of 34 participants with normal voice were recruited from the University of Kentucky and greater Lexington Community (Appendix A). Participants met the following criteria: ages 18-40 years, non-smokers for the past five years, hearing within functional limits allowing for completion of the consent process and participation in the experimental protocol and normal scores on the CAPE-V and VRQoL. Exclusion criteria consisted of the following: a history of uncontrolled asthma, a year or more of professional vocal training, the presence of vocal fold pathology identified by rigid endoscopic laryngeal examination and/or previous experience with VFEs. Thirty-one participants successfully completed the baseline assessment protocol. One participant was unable to tolerate the laryngeal examination due to heightened gag reflex and was disqualified from the study. Within three weeks, eight participants withdrew. A total of 23 individuals completed the study.

Figure 3.1: Consort Diagram



3.2 Training Research Assistants

Six research assistants were trained prior to study initiation. Each research assistant was provided relevant literature and didactic materials to review prior to the training session. Using the provided materials and literature, the research assistants were to familiarize themselves with the standard VFE protocol. Four of the six research assistants had conducted research in the UK Laryngeal and Speech Dynamics Laboratory prior, which involved teaching and using VFEs. Therefore, they had previous experience with the experimental design and with VFEs. The formal instruction included extensive face-to-face training with speech-language pathologists coupled with mock sessions completed with each research assistant while the other RAs observed. After each mock session a debrief was conducted with all the RAs present to shape/correct their VFE technique as well as to shape/correct the way they would train participants in proper technique

3.3 Baseline Data Collection

During the baseline session, a first-year graduate student reviewed in detail the consent forms approved by the UK IRB (Appendix B) with each participant. Once consent was obtained, all participants were briefly educated on vocally traumatic behaviors and on the importance of maintaining good vocal hygiene. Supplementary written information related to these topics was provided (Appendix C). All participants verbally agreed to abstain from vocally traumatic behaviors for the duration of the study, however once verbal consent was established, there were no standard means of monitoring or tracking these behaviors.

Baseline measures were obtained prior to intervention. A self-assessment, the Voice Related Quality of Life (VRQoL), was administered to ensure each participant began with what they perceived as normal voice and were not experiencing any vocal discomfort. (Appendix D). Each participant then participated in a laryngeal examination performed with a rigid endoscope to confirm normal appearance of the vocal folds. Laryngeal examinations were completed by a licensed and certified speech-language pathologist specializing in voice disorders and blinded to group assignment. The Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V) was also completed by a licensed and certified speech-language pathologist blinded to group assignment (Appendix E). Both the laryngeal imaging and CAPE-V were also completed to ensure eligibility for the study. Once this was established, Maximum Airflow Volume (MAV) was obtained to calculate the participants' physiologic maximum phonation time (MPT). MAV is an individual's maximal exhalation after maximal inhalation and was collected using a KayPentax Phonatory Aerodynamic System (PAS). Each participant exhaled all

possible air into a handheld mask after maximum inhalation. Once maximum airflow volume was determined, individual physiological MPT goals were calculated by first converting MAV from liters to milliliters and then dividing by an airflow rate of 80 mL/s (e.g. MPT goal = $4000/80 = 50$ seconds). 80mL/s is thought to be an efficient airflow rate through the glottis (Hirano, 1981). MAV was obtained twice for each participant to guarantee accurate measurements. All data were recorded on the study checklist (Appendix F).

3.4 Group Assignment

After inclusion criteria were verified and baseline measures were obtained, participants were randomized into one of three groups based on the assigned phonation times of VFE tasks one and four: Standard Group (SG), 3-Week Group (3G), or Baseline Group (BG). The Standard Group sustained exercises one and four for as long as possible for six weeks. The 3-Week Group sustained exercises one and four for as long as possible for three weeks, then the average MPT for the first three weeks was calculated and participants sustained exercises one and four to the calculated average MPT for the remaining three weeks. The Baseline Group sustained exercises one and four for as long as was achieved at the baseline session for all six weeks.

3.5 Baseline Training Session

Trained research assistants taught participants VFEs as outlined by Stemple et al. (1994). Once proper technique was established, MPT baseline measurements were recorded on a Participant Data Sheet (Appendix G). The research assistants then

informed participants of the assigned duration to sustain exercises one and four for home practice based upon group assignment. It is important to note that there was no manipulation to tasks two and three of the protocol. Each group was to complete an ascending and descending glide on their most comfortable low- and high-pitched notes with a SOVT posture. For the baseline group, the phonation time for exercises one and four were written on the practice record sheet as a reminder (Appendix H) and participants were instructed not to sustain phonation for any longer than the time provided. All other participants were given the standard home practice record sheet (Appendix I) during the baseline session. The 3-Week Group was given the same home practice sheet as the Baseline group at the mid-point of the study once 3-week average MPT had been calculated for the first and fourth tasks. Their average MPT from the first three weeks was written on the practice record sheet to remind participants they were only to sustain to this calculated value for the remaining three weeks of the protocol.

In addition, during the baseline session, participants were asked to set two alarms in their cell phone (morning and evening/afternoon) to facilitate twice daily completion of the exercises as outlined by the standard VFE protocol. Participants were then provided a VFE recording via text to their cell phones that provided verbal instructions and pitches. Research assistants also encouraged all subjects with a smart phone to download a free piano application to assist with pitch matching. However, participants were encouraged to use the VFE recording to ensure proper technique was achieved. Ultimately, all 23 participants that completed the study had downloaded a piano application on their smart phones. Lastly, before exiting the session, each participant was provided a Participant Confidence Rating Scale to rate his/her confidence in their VFE

technique (Appendix J). This linear scale included the numbers one through five accompanied by verb equivalences for either end of the spectrum. One was considered “Not confident at all” and five was equivalent to “Very Confident”. If a participant rated themselves a one or two on the scale, the research assistants were trained to spend some additional time answering questions and working on technique before concluding the baseline session.

Table 3.1: Exercise Protocol by Group

Exercise	Baseline Group	3-Week Group	Standard Group
1. Warm up exercise Nasalized /i/	Baseline Phonation Time	First 3 weeks: Maximum Phonation Last 3 weeks: Average 3-week phonation time	Maximum Phonation Time
2. Stretching exercise Ascending Glide	Forward focus with lip buzz (SOVT)	Forward focus with lip buzz (SOVT)	Forward focus with lip buzz (SOVT)
3. Contracting Exercise Descending Glide	Forward focus with lip buzz (SOVT)	Forward focus with lip buzz (SOVT)	Forward focus with lip buzz (SOVT)
4. Low impact Adductory power exercise on the musical notes C-D-E-F-G	Baseline Phonation Time	First 3 weeks: Maximum Phonation Last 3 weeks: Average 3-week phonation time	Maximum Phonation Time

3.6 Weekly Check-Ins

After learning VFEs, participants attended weekly check-ins with a trained research assistant for six weeks and weekly average phonation times were calculated for each participant. Technique was adjusted as necessary with the help of supervising clinicians. Also, home log sheets were collected from participants at each check-in. Adherence was

collected via home practice logs and tabulated in terms of number of practice sessions missed. Therefore, if not all four exercises were completed, it was counted as a missed practice. The weekly VFE MPTs were not calculated for the baseline group due to the nature of their assigned phonation times, there was no variation. Twenty percent of all research-assistant conducted sessions were monitored by a SLP, and an additional twenty percent were monitored by a first-year graduate student trained in the use of VFEs.

3.7 Post-Intervention Data Collection

After six weeks, participants then discontinued daily practice and post- intervention data were collected. VFE MPT was collected at the final session after six weeks of intervention to analyze attainment of pre-established MPT goals between and within the three groups. At the post-intervention session participants completed the first trial of each exercise on their own and the blinded SLP provided feedback for the second trial, if necessary, to ensure proper technique and accurate collection of MPT. The same Participant Rating Scale completed at baseline was re-administered and MPTs were collected for all groups. Table 3.2 outlines the measures taken each week for each group.

Table 3.2: Outcome Measures Obtained by Week

	Baseline Week	Week 2	Week 3	Week 4	Week 5	Week 6	Post-Intervention Week
Laryngeal Examination	✓						
CAPE-V	✓						
VRQoL	✓						
Maximum Airflow Volume	✓						
Maximum Phonation Time	✓	SG and 3G	SG and 3G	SG	SG	SG	✓
Baseline Phonation Time		BG	BG	BG	BG	BG	
3-week Average Phonation Time				3G	3G	3G	

* ✓ indicates all three groups completed the task

Once the final MPT at the post-intervention session was obtained, percent to goal attainment was calculated at baseline and after intervention for each participant.

Percentage point change was also calculated for each subject between these two time points (baseline and post intervention). This change score was determined by calculating the difference between baseline percent to goal and percent to goal after intervention. To analyze the significance of these calculated scores, a one-way ANOVA as well as 3 post hoc paired sample t-tests (one run for each group) were used. Statistical significance was set at $p \leq 0.0125$, following application of a Bonferroni correction. These tests were applied to compare the difference in the primary outcome measure (percent to VFE MPT goal) among groups and within groups between the two time points (baseline and post

intervention). Percent to goal was determined to be the best measurement of improvement because MPT will inherently be different for each participant because individual lung capacity / MAV varies.

Additional paired sample t-tests were run to compare percent to goal from baseline to the midpoint (week 3) as well as midpoint to the final session in both the standard group and 3-week group.

3.8 Chapter Summary

Chapter three outlined the methods for answering the research question. Results are presented and analyzed in Chapter four.

CHAPTER 4. RESULTS

4.1 Demographics

A total of 34 participants between the ages of 18-40 were recruited from the University of Kentucky and the greater Lexington community. Two subjects failed to show up to the baseline session and one individual was disqualified due to a heightened gag reflex that made her unable to tolerate the rigid endoscopic examination. Eight participants discontinued participation and were unable to be replaced with new recruits due to semester time constraints. Therefore, a total of 23 subjects completed the study. Participants were non-smokers with normal voice and hearing within functional limits. In addition, subjects did not have a history of uncontrolled asthma nor professional vocal training. In the baseline group ages ranged from 20-38; the mean was 24.5. In the 3-week group ages ranged from 18-30; the mean was 23.1. In the standard group ages ranged from 18-40; the mean was 24.6. A one-way ANOVA indicated no significant difference in age between groups. Refer to Table 4.1 for age-related information.

Table 4.1: One-way ANOVA for Age

Group	Mean Age	Standard Deviation	p - value
Baseline	24.5	6.9	0.850
3-Week	23.1	4.2	
Standard	24.6	6.8	

*significance 0.05

4.2 Attrition

The baseline group (BG) consisted of 11 subjects, 5 of whom discontinued their participation. The 3-week group (3G) consisted of 10 subjects, 1 of whom discontinued

participation. The standard group (SG) contained 10 subjects, 2 of whom chose to discontinue their participation. This resulted in a withdrawal rate of 45%, 10% and 20% from the baseline, 3-week and standard groups, respectively. Participants who withdrew from the study could not be replaced due to semester time constraints. Attrition information by group is presented in Table 4.2.

Table 4.2: Sustained Duration Assignments

Group	Initial No. of Participants	Discontinued Participants	Final No. of Participants
Baseline	11	5/11 = 45%	6
3-Week	10	1/10 = 10%	9
Standard	10	2/10 = 20%	8

4.3 Adherence

Participant adherence with weekly check-ins was 100% overall. Each participant attended a weekly check-in. All home practice logs were returned except two logs from one participant. The average number of missed sessions in the baseline group was 12.5 out of a possible 84 sessions over the course of six weeks of intervention. Two participants in this group missed 17 or more practices, indicating less than 80% adherence to the voice program. The average number of missed sessions in the 3-week group was 8.4. Two participants in this group missed 17 or more practices, indicating adherence less than 80%. The average number of missed sessions in the standard group was 9.3. One participant in this group did not maintain 80% adherence to the voice program. Adherence is organized below in Table 4.3.

Table 4.3: Adherence to Home Practice by Group

Group	Mean Practices Missed	Participants missing ≥ 17 practice session (less than 80% adherence)
Baseline	12.5	2
3-Week	8.4	2
Standard	9.3	1

4.4 Baseline Measures

Two one-way ANOVAs demonstrated equivalence between the groups at baseline based on two variables. These variables were age, which was already addressed above as well as percent to goal at baseline session.

A significance value of 0.05 was used. The resulting p-value for percent to goal at baseline is listed in Table 4.4. Based on the p-value for age ($p = 0.850$) as well as baseline percent to goal ($p = 0.229$), the groups were not significantly different at the baseline session

Table 4.4: One-way ANOVA for Percent to MPT goal at Baseline Session

Group	Mean Age	Standard Deviation	p - value
Baseline	41.4	11.1	0.229
3-Week	39.6	13.5	
Standard	31.7	7.6	

*significance at 0.05

4.5 Outcome Measure

After data collection, average weekly VFE MPTs were calculated for the 3-week and standard groups. Participants in the baseline group were able to reach their baseline phonation time 99% of the time. One participant had difficulty one week due to an upper respiratory infection.

The average change score between baseline and post intervention was 15.7%, 17.4% and 20.8% in the baseline, 3-week and standard groups, respectively. A one-way ANOVA indicated there was no statistically significant difference among groups.

Table 4.5: One-way ANOVA of Change Scores

Group	Change Score	Standard Deviation	p - value
Baseline	15.7	11.43	0.686
3-Week	17.4	13.25	
Standard	20.8	7.48	

*significance ≤ 0.0125

Paired sample t-tests indicated both the 3-week group and standard group demonstrated significant improvement in percent to MPT goal after six weeks (3-week group - $p = 0.008$; standard group - $p = 0.001$). The baseline group did not demonstrate significant change toward MPT goal between the two time points ($p = 0.020$). Resulting means, standard deviations and p-values from the analysis can be viewed in Tables 4.5 and 4.6 as well as Figure 4.1 and 4.2.

Figure 4.1: Change Score Percentage by Group

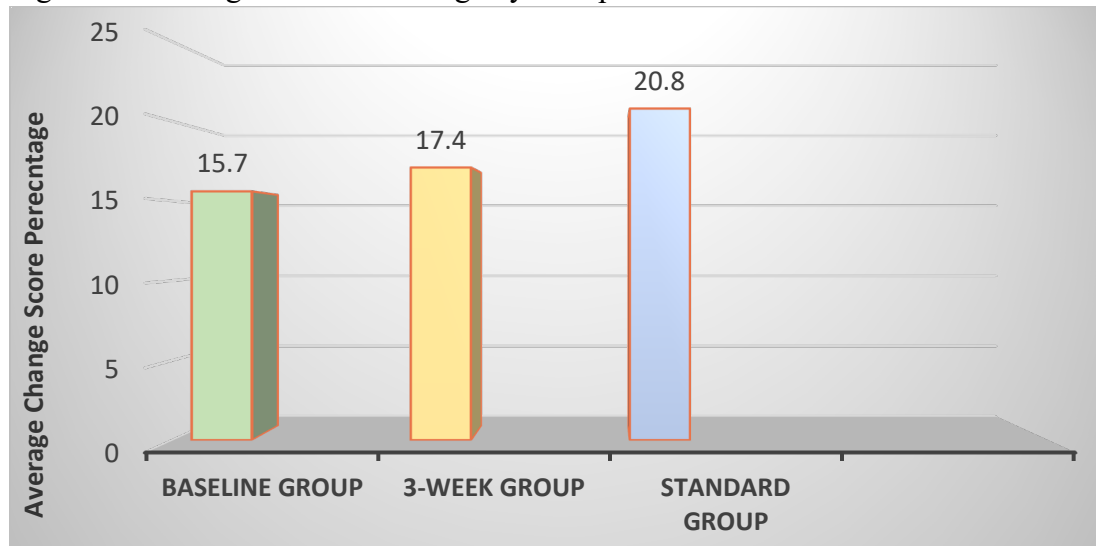


Figure 4.2: Average Percent to MPT goal pre and post intervention

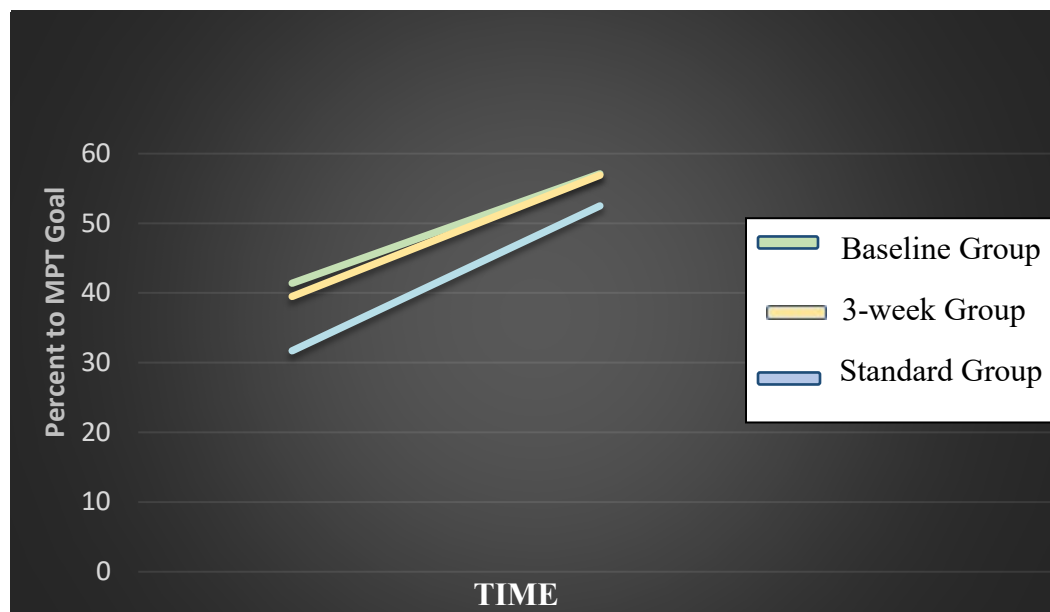


Table 4.6: Sample paired t-tests Pre and Post Intervention

Group	Avg Percent to MPT goal at Baseline	Avg Percent to MPT goal Post-Intervention	p - value
Baseline	41.4%	57.1%	0.020
3-Week	39.5%	56.9%	0.008*
Standard	31.7%	52.5%	0.001*

*significance ≤ 0.0125

In terms of percent to goal from baseline to the midpoint, results indicated that the SG made significant improvement, ($p = 0.001$), while the 3-week group did not ($p = 0.018$). There were two participants in the in the 3-week group that did improve. The first participant regressed by 2.08% and the second participant regressed by 3.08 For the standard group, the average percent to goal at baseline was 31.7% and average percent to goal at the midpoint was 44.2%. The average change score was 12.6% for the SG as compared to 12.2% for the 3G between baseline and midpoint. From midpoint to final session, the average change score was 8.3% in the SG and 5.%1 in the 3G. However analysis comparing percent to goal from the midpoint to final session demonstrated that both the standard group ($p = 0.004$) and 3-week group ($p = 0.012$) made statistically significant progress. Tables 4.7, 4.8, 4.9 and 4.10 provide the resulting means, standard deviations and p-values for both group at both time periods. Figure 4.3 provides another method of viewing the information provided in the tables.

Table 4.7: Paired sample t-test for the Standard Group percent to goal from Baseline to Midpoint

Time Point	Mean	Standard Deviation	p value
Baseline	31.7	7.6	≤ .001*
Week 3	44.2	5.7	

Table 4.8: Paired sample t-test for the 3-Week Group percent to goal from Baseline to Midpoint

Time Point	Mean	Standard Deviation	p value
Baseline	39.6	13.5	.018
Week 3	51.8	19.2	

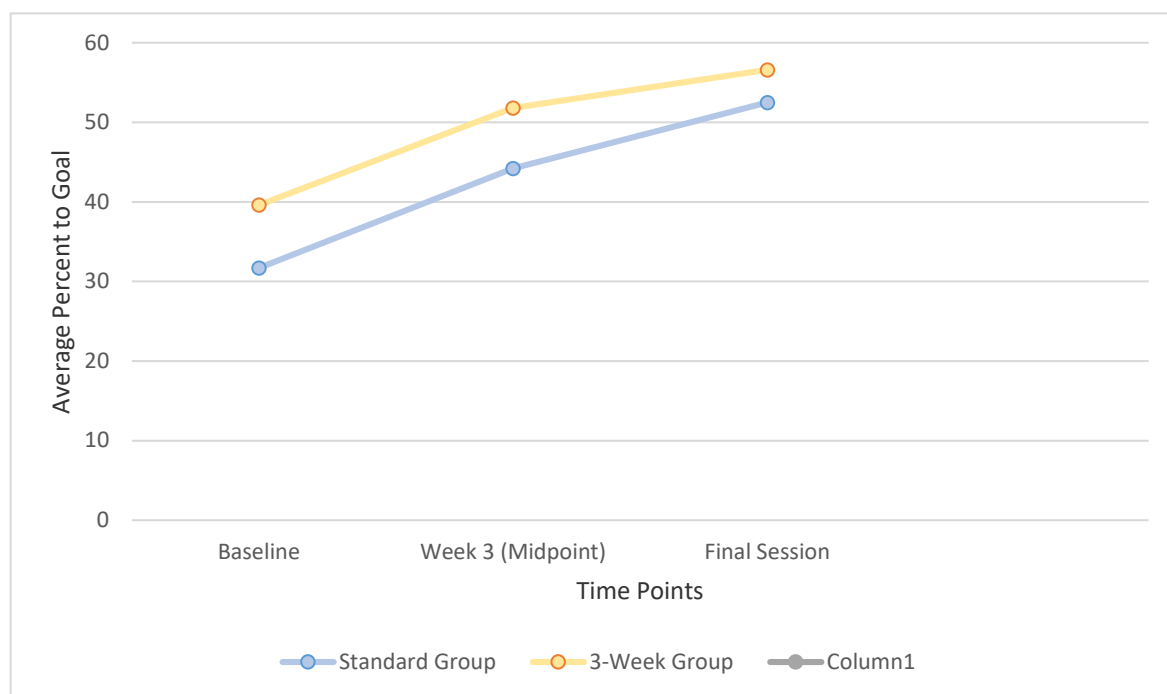
Table 4.9: Paired Sample t-test for the Standard Group percent to goal from Midpoint to Final Session

Time Point	Mean	Standard Deviation	p value
Week 3	44.2	5.7	.004*
Final	52.5	8.6	

Table 4.10: Paired Sample t-test for the 3-Week Group percent to goal from Midpoint to Final Session

Time Point	Mean	Standard Deviation	p value
Week 3	51.8	19.2	.012*
Final	56.6	19.4	

Figure 4.3: Average Percent to Goal at 3 time points (Baseline, Midpoint and Final



session)

4.6 Summary of Outcome Measures

The primary outcome measure (percent to MPT goal) was examined in this study at two time points. Overall the 3-week and standard groups made statistically significant improvement towards percent to MPT goal, with the standard group showing the greatest improvements, as measured by change score. The first hypothesis was that maximally sustained phonation would result in greater improvements toward MPT goal. The results of this study reject this alternative hypothesis. The second hypothesis was that the baseline group would not demonstrate significant improvements toward MPT over the course of six weeks. The results of this study failed to reject this alternative hypothesis.

4.7 Chapter Summary

Chapter four served to present the statistical results of the data analysis. Chapter five will discuss the significance of these findings, study limitations and future directions of research.

CHAPTER 5. DISCUSSION

5.1 Review of Purpose

Vocal Function Exercises (VFE) comprise four exercises, in which the first and fourth tasks require maximally sustained phonation. VFEs have been shown to be efficacious for a variety of populations and are frequently modified to meet the needs of a variety of patients. Although treatment modifications to the standard VFE program are often made by clinicians, studies have not systematically investigated these alterations to determine their exact contribution to treatment efficacy. The current line of research began in order to determine the essential components of the standard VFE protocol. To date, compliance monitoring, dosage and vocal tract posture have been identified as active ingredients (Ellis & Beltyukova, 2011; Bane et al., 2017; Bane et al., 2018).

The purpose of this study was to investigate the effect of maximally sustained phonation on VFE efficacy by altering the required lengths of tasks one and four of the standard protocol. It is unclear whether maximally sustained phonation is necessary or whether shorter practices of sustained tones can accomplish similar results. The primary outcome measure to assess efficacy was the VFE outcome measure of MPT, as calculated by percent to goal acquisition. This outcome measure was collected at two different time points: baseline (pre-intervention) and post-intervention (week six).

5.2 Review of Methodology

A total of 34 participants with normal voice were randomized into one of three groups and completed VFEs according to the assigned phonation times of exercises one and four. All participants attended weekly check-ins and completed daily home practice

of the four exercises, two times each, twice daily for six weeks. There was no variation to tasks two and three of the protocol. The baseline group completed exercises one and four as long as was achieved at the baseline session. The 3-week group sustained the exercises for as long as possible the first three weeks, then to their average 3-week MPT for the remaining three weeks of the protocol. The standard group sustained tasks one and four for as long as possible for all six weeks. After six weeks, daily VFE practice and weekly check-ins were discontinued.

5.3 Review of Results

Group homogeneity. One-way ANOVAs demonstrated that the three experimental groups were not statistically different at baseline for age and percent to goal acquisition.

Summary of outcome measures. Results from paired t-tests following application of a Bonferroni correction demonstrated the baseline group did not make significant improvement in percent to MPT goal ($p = 0.02$). However, the 3-week group ($p=0.008$) and the standard group ($p = 0.001$) did make statistically significant progress toward percent to goal attainment after six weeks of VFEs.

When examining the groups at the midpoint of intervention (week three), the standard group demonstrated significant improvement in MPT at this time point ($p = 0.001$), while the 3-week group did not ($p = 0.018$). From week three to the post-intervention session, both the standard ($p = 0.004$) and 3-week ($p = 0.012$) groups made statistically significant progress toward percent to goal.

The first study hypothesis was that the standard group will demonstrate the greatest improvements in MPT. We reject this alternative hypothesis. The second hypothesis was that the baseline group would not demonstrate significant improvement toward MPT goal after six weeks of intervention. We fail to reject this alternative hypothesis based on our data.

Attrition. The baseline group had the greatest attrition, at 45% (n=5).

Adherence. Maximally sustained phonation may affect adherence and subsequently overall therapeutic outcomes. For example, an increased MPT may inherently motivate that person to adhere to the prescribed exercise protocol. Therefore, if sustained phonation increases, the patient may be more inclined to allot more time for home practice. The alternative scenario would be that although MPT is increasing, the person may not want to dedicate more time to practice or may be unable to allot more time for home practice. The relationship between adherence and MPT will be discussed in greater detail in the following section.

In this study, the baseline group reported the lowest adherence (mean practices missed: 12.5); the standard group reported better adherence (mean practices missed: 9.3); the 3-week group reported the best adherence (mean practices missed: 8.4). Furthermore, the standard group only had one participant fall below 80% adherence, while the 3-week and baseline groups both had two participants fall below 80% adherence, meaning 17 or more practices were missed. The two individuals in the 3-week group that were unable to adhere to at least 80% of the VFE home practice protocol were also the two participants in the group that failed to improve at the midpoint or at the final post-intervention session. Their phonation times shortened. Since compliance monitoring is an active

ingredient of the VFE protocol (Ellis & Beltyukova, 2011), patient compliance to the prescribed schedule may have confounded the results of this study.

5.4 Significance of the Study

This study is the fourth in a series of research designed to systematically dismantle VFEs to identify its active ingredients. The purpose of this specific investigation was to examine the necessity and effects of maximally sustained phonation in this behavioral voice therapy. Maximally sustained phonation tasks may have direct implications on effectiveness as well as efficiency in completing the VFE program and may affect time spent during home practice, dosage, and possibly adherence. Therefore, isolating maximally sustained phonation as an ingredient within the standard VFE protocol and investigating its importance in treatment efficacy was needed.

Contribution to literature on maximally sustained phonation. A total of 29 outcome studies have demonstrated VFEs are efficacious in improving the normal, pathological and well-trained voice. The standard VFE protocol requires maximally sustained phonation for the first and fourth exercises. This study is the first to systematically investigate VFEs performed with varying phonation times for tasks one and four. There has only been one identified study that investigated the effects of phonation time of voice exercises, which is presented in the literature review in chapter two (Menezes et al., 2010).

Menezes, Ubrig-Zancanella, Cunha, Cordeiro, Nemr, and Tsuji (2010) conducted a prospective clinical study examining the relationship between tongue trill performance duration and vocal changes in dysphonic women. The experimental group consisted of 27

women with vocal nodules who completed tongue trills, while the control group was given a placebo tapping exercise. Voices were recorded and assessed following each task at different durations: one minute, three minutes, five minutes and seven minutes. The voice samples were evaluated by blinded speech-language pathologists and the results indicated significant vocal improvement at five minutes with the tongue trill exercises. However, this study did not clearly state how the tasks were completed within the seven minutes allotted. It did not describe if the tongue trills were repeated as many times as possible within the given time or simply sustained for as long as possible.

As stated previously, maximum phonation time is used as a discharge criterion in voice therapy utilizing VFEs. According to Stemple (2014), once a patient reaches their predetermined MPT goal and “the voice quality and overall vocal symptoms have improved, then a tapering maintenance program is recommended” to finish out the course of therapy (p. 260). This means that achieving one’s VFE MPT goal is an important indication that the voice has improved. However, is maximally sustained phonation necessary to improve vocal function using VFEs? To answer this question, sustained phonation time was systematically altered for the first and fourth exercises of the VFE protocol to determine if maximally sustained phonation is necessary to improve voice production. This study is significant because the results have provided evidence to support two possible approaches for incorporating maximally sustained phonation within the VFE program, without compromising treatment efficacy.

Clinical implications. Clinicians routinely and rightly tailor evidence-based voice interventions to meet the needs of individual patients. As a speech-language pathologist (SLP) individualizes therapies they must consider several variables. These variables

include patient diagnosis, prognosis, rate of recovery, patient goals for therapy, patient buy-in, patient motivation, patient capability and opportunity to complete home practice as well as clinician factors. Unfortunately, there is a finite amount of evidence to inform clinical choices to modify these protocols with confidence that treatment fidelity is maintained. This line of research has begun a reverse engineering of Vocal Function Exercises by systematically modifying a single, potentially active ingredient and determining its exact contribution to treatment efficacy. These studies directly guide SLPs as to the degrees of freedom they have within one evidence-based intervention and inform clinical choices made to individualize a treatment protocol. Hence, the present study specifically provides clinicians evidence as to whether maximally sustained phonation should be done for the full course of therapy or whether set durational practice can be implemented with comparable results.

The evidence demonstrated that maximally sustained phonation of VFEs one and four over the course of six weeks resulted in the greatest improvements toward percent to goal. Thus, if a patient has the motivation, capability and opportunity to complete home practice in such a manner, maximum sustained phonation should be encouraged. The 3-week group also improved significantly toward percent to MPT goal after the six weeks of intervention. Yet it is unclear whether or not participants in this group would have kept up with the standard group, if participants were to have continued the intervention until 100% of goal was met.

However, the results of this study also suggest that the use of set phonation time may be incorporated after an individual has first made improvements with maximally sustained phonation. For example, in a disordered population, patients could have much

shorter baseline MPTs, so the effect and importance of this active ingredient (maximally sustained phonation) could be magnified. Maximally sustained phonation may be a key component of the VFE protocol to improve vocal quality which may not be developed with short sustained tones based on the findings of this study, Sandage and Hoch (2017) and Menezes et. al (2010).

The clinical importance of maximum sustained phonation is supported by the fact that the baseline group did not demonstrate statistically significant improvement in MPT and demonstrated the greatest attrition. Therefore, disallowing maximally sustained phonation during the entire VFE protocol may result in reduced MPT possibly because physiologic improvement was not made, or perhaps the client was unable to see progress. This lack of perceived/observable progress may affect patient buy-in, adherence and drop-out. Patients may be less motivated and willing to invest their time, effort and money to complete the course of therapy if changes are not observed. Thus, maximally sustained phonation over the course of the VFE protocol must be incorporated in some way by the clinician. It is important the patient make progress, but more importantly see and record such progress.

During the first three weeks of intervention, the standard group and 3-week group received the same intervention: maximum duration of exercises one and four. However, the standard group demonstrated significant progress at midpoint ($p = 0.001$), while the 3-week group did not ($p = 0.018$). Yet, from midpoint to final session both groups (standard group: $p = 0.004$ and 3-week group: $p = 0.012$) made significant improvement even though subjects in the 3-week group were limited to a set phonation time. One reason for this finding might be that some individuals require greater exposure/dosage to maximally

sustained phonation to demonstrate improvement. Also, the poor adherence by some individuals may have influenced these results. Two participants in the 3-week group did not maintain 80% adherence to home practice. One of these participants regressed by 2.08% and the other regressed by 3.08% in terms of percent to MPT goal from baseline to final session.

Overall, this study provides evidence suggesting two approaches for incorporating maximally sustained phonation time in the VFE protocol. It is up to the clinician to determine the most beneficial program for the patient based on patient preferences, research evidence as well as clinical expertise. This study provides evidence that maximally sustained phonation is vital for the efficacy of the VFE program.

Delimitations and limitations. The present study contains certain limitations, one of which is unverified adherence to home practice. Several elements were incorporated into the methodology to address this concern. First, each week participants were provided home practice log sheets to record MPT data for every practice and these were returned weekly. Second, adherence to the protocol was emphasized during the consent process and baseline session. Participants verbally stated understanding and during the initial session they were asked to set two alarms in their phone as reminders to complete home practice. This task was on the study checklist research assistants used during the baseline session to ensure all steps were covered before subjects exited the clinical laboratory. Third, participants received weekly reminders via text message from either the first-year graduate student or research assistants. Lastly, participants were provided an audio file during the baseline session via text message or email to guide and facilitate home practice. Despite these efforts, the accuracy of adherence could not be verified. Other

limitations may have included variable motivation and confidence in VFE technique. Weekly check-ins to tweak technique and encourage participants were meant to attenuate these factors as much as possible.

Additionally, several delimitations were present in this study. First the present study addressed the effects of maximally sustained phonation on individuals with normal voice, therefore conclusions regarding the pathological voice cannot be drawn. Second the small sample size only allows for these data to be used for preliminary purposes. Third, only three variations of sustained phonation were investigated, therefore conclusions regarding various other approaches to altering the use of maximally sustained phonation cannot be drawn. Fourth, subjects that discontinued their participation in the study were not replaced. Fifth, although participants were educated about phonotraumatic behaviors and verbally agreed to abstain from these, vocal hygiene was not systematically tracked and was not reported. Finally, there was no one month follow-up conducted in the study, therefore conclusions regarding maintenance cannot be drawn. It is important to note that investigating long-term maintenance was not the intended target of this study, however it would have provided greater insight into the lasting effects of maximally sustained phonation.

Finally, undergraduate research assistants guided, instructed and completed data collection during weekly check-ins instead of speech-language pathologists. The RAs lacked the clinical expertise of a voice clinician, therefore the feedback and instructions provided by the research assistants were unlikely to be of the high caliber expected from a voice pathologist. To address this concern, 20% of all weekly check-ins were monitored by licensed speech-language pathologists and an additional 20% were monitored by a

first-year graduate student. Research assistants were also trained by SLPs with extensive experience instructing and using VFEs in therapy. These trainings included mock sessions to practice critiquing and providing meaningful feedback to participants. Each final pre-intervention session was conducted with a blinded SLP present to critique technique, if necessary, and ensure the accuracy of MPT data collection.

5.5 Implications of Future Research

Further investigation is required to determine if there are other efficacious sustained phonation times for exercises one and four within the VFE protocol. One potential research design would be to use set phonation times (the baseline group) with increased treatment time (> six weeks) and/or increased dosage (practice each exercise four times rather than twice). As stated earlier, maximally sustained phonation will inherently require longer practice time as a patient continues to improve. Traditionally, patients are told that practice will take about 10 minutes both in the morning and evening. However, this will not be the case for certain patients that are sustaining phonation for longer times (in seconds) that require time to catch one's breath between trials. Therefore, it would be worth investigating whether a baseline group provided with more weeks to practice and increased frequency of practice may have led to similar outcomes in maximum phonation time (the primary outcome measure).

Additionally, since VFEs have been determined to be efficacious for the disordered voice, it may be of interest to explore sustained phonation within a specific pathology/ disordered population to investigate whether similar results arise from altering the required phonation times of tasks one and four of the VFE protocol. Including more

of an extensive test battery (i.e. VRQoL, CAPE-V, etc.) would be appropriate within a study on a disordered population. This would allow for conclusions to be drawn to that specific patient population and would strengthen the clinical relevance of this line of research.

Future research should also include more rigorous patient monitoring to ensure compliance. This is important because it has been well documented in the literature that the dropout rate for those who initiate voice therapy is as high as 65% (Hapner, Maira & Johns, 2009). Ellis and Beltyukova (2011) have already found that a compliance-monitored group performing the standard protocol of VFEs improved significantly more than an unmonitored VFE group. Future studies should consider incorporating technology assisted rehabilitation to more reliably track adherence to home practice.

5.6 Conclusions

In summary, varying maximally sustained phonation during VFEs alters improvement toward MPT goal attainment in normal voice. Maximally sustained phonation may be most efficacious, however a tailored program, which allows for set phonation times at some point during therapy may also lead to improved MPT. However, eliminating maximally sustained phonation may prevent individuals from reaching their MPT goal or may increase drop out. It appears that maximally sustained phonation contributes to VFE efficacy in the normal voice population and is therefore an active ingredient within the VFE protocol.

5.7 Chapter Summary

Chapter five served to discuss the results of this study, their significance, and their clinical implications. Limitations and delimitations, as well as directions for future research studies were also outlined in this chapter.

APPENDIX A. RECRUITMENT FLYER

UNIVERSITY OF KENTUCKY RESEARCH

VOLUNTEERS NEEDED

FOR A STUDY OF
VOICE
PRODUCTION

APPROVED
By Mallory Powell at 9:32 am, Jan 17, 2018



Researchers at the University of Kentucky College of Health Sciences need participants as a part of a study they are conducting. Testing involves a one time throat examination and voice quality measures. You would need to come in one time for an hour and six times for less than 30 minutes. In addition subjects will be asked to complete voice exercises twice daily that require no more than eight minutes.

You may be eligible to participate if you:

- Are between 18 and 40 years old;
- Are a non-smoker for the past 5 years
- Have not had a year or more of vocal training;
- Do not have a history of uncontrolled asthma; and
- Have not participated in a previous voice treatment study.

 **Research**
An Equal Opportunity University

www.UKclinicalresearch.com

For more information,
please contact:
Mariah Morton
Email: memo264@uky.edu
Phone: (503) 863-4912

Voice Production

COMDIS-010_flyer #

APPENDIX B. CONSENT FORM

Combined Consent and Authorization to Participate in a Research Study

VOCAL FUNCTION EXERCISES FOR NORMAL VOICE: THE EFFECTS OF VARYING DURATION

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study that will examine how to improve effectiveness of a voice exercise program called Vocal Function Exercises. You are being invited to take part in this research study as a volunteer in one of three groups, and your group assignment will be determined randomly. If you volunteer to take part in this study, you will be one of about 30 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Mariah Morton of the University of Kentucky, Department of Communication Sciences and Disorders. Mariah Morton is a Master's level graduate student. She is being guided in this research by her faculty advisor, Joseph Stemple, Ph.D., CCC-SLP. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

With this study, we hope to learn more about how varying duration of certain voice exercises will affect how efficiently your voice works.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not take part in this study if you are younger than 18 or older than 40 years of age. If you have a history of uncontrolled asthma, do not speak English, are a smoker or have stopped smoking within the last 5 years, have previously participated in a voice treatment study, have received prior voice therapy or laryngeal surgery, or have a year or more of voice training, you should not take part in this study. If you have a known diagnosis of laryngeal pathology (e.g. nodules, cyst, polyp) you should not participate in this study.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of Kentucky in the Laryngeal and Speech Dynamics Laboratory located in room 106 of the Charles T. Wethington building. You will be asked to come in for an initial assessment lasting one hour. You will also be asked to return weekly a total of six additional times for an exercise session lasting 30 minutes or less. These sessions will take place over the course of seven consecutive weeks during the Spring 2018 semester. In addition, you will be asked to complete twice daily voice exercises at home in the morning and in the evening, which will take you about eight minutes each time. The total amount of time you will be asked to volunteer for this study is 14 hours over the next six weeks.

WHAT WILL YOU BE ASKED TO DO?

When you arrive, we will confirm normalcy of your voice and larynx. This will include:

- Voice self-assessment: You will be asked to fill out a questionnaire on the quality of your voice. This questionnaire is a validated and reliable typically delivered as a standard of care tool.
- Visual examination of the larynx: A slender, tubular instrument known as a rigid endoscope will be attached to a digital camera and recorder. This will be passed through the mouth and lightly rest on the tongue in order to observe your vocal cords. This exam does not require any anesthetic or medication. The exam will take about five minutes and will be performed by a trained speech-language pathologist. This procedure is a typical, standard of care procedure.
- Maximum airflow volume: Using a handheld mask, we will measure the amount of air you can exhale from your lungs after a maximum inhalation. This measure may be repeated several times to ensure consistency and is a typical, standard of care procedure.
- Auditory-perceptual rating: A speech-language pathologist who specializes in voice will listen to your speaking voice and rate its quality and characteristics. This tool is valid and reliable and is a typical, standard of care tool.

You will be randomly assigned to one of three groups. All groups learn and complete the same exercises, however the length of time exercises are performed will vary. The voice exercise is a standard of care procedure. Your performance on these exercises will be tracked over time and measured weekly. You will be asked to practice these exercises two times each, twice daily for six weeks. This will take approximately 15 minutes a day

Research visits:

Visit No.	Purpose	Procedures
1	Session 1 and baseline	Voice self-assessment; voice rating by speech therapist, visual exam of vocal cords, maximum exhalation measure, learn Vocal

		Function Exercises (VFEs)
2	Session 2	Complete vocal exercises and questionnaire
3	Session 3	Complete vocal exercises
4	Session 4	Complete vocal exercises
5	Session 5	Complete vocal exercises
6	Session 6	Complete vocal exercises
7	Session 7 and Post data Collection	Complete vocal exercises and questionnaire

Groups:

Group	Duration of exercises 1 & 4 of Vocal Function Exercises (VFEs)
1	Sustain exercises as long as possible.
2	Sustain exercises one and four for as long as possible for the first three weeks, at which time MPT for the first three weeks will be averaged. Participants will then sustain exercises one and four to average MPT for the remainder of the intervention.
3	Sustain exercises one and four only for as long as was achieved at baseline at week 1

Exercises:

Exercise	Description
1	Warm up exercise- sustain nasal vowel “ee” as long as possible
2	Stretching exercise- glide upward from lowest to highest note on the word “knoll”
3	Contracting exercise- glide downward from highest to lowest note on the word “knoll”
4	Low impact endurance exercise- sustain the musical notes C-D-E-F-G for as long as possible on “oll”

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

During initial assessment, a scope which is attached to a camera will be placed in your mouth to view your vocal cords. There is a chance you may gag during this examination, in which case the camera will be removed. Some individuals demonstrate a strong gag reflex, and may be unable to participate in the exam or in the research study. If your vocal cords show any visible abnormalities, you will be referred to an Ear, Nose, and Throat physician in the Kentucky Clinic or another ENT doctor of your choice. If a referral is made, you will be responsible for any costs associated with any subsequent

medical assessments or treatment. Medical care for any abnormalities detected will not be provided by the study nor will costs for such be borne by the study.

There are no known risks associated with measuring the air in your lungs using a hand-held mask that you will place around your mouth and nose as you exhale.

Possible minor and reversible side effects of vocal exercises include mild swelling of the vocal cords and muscular soreness. This may result in temporarily decreased vocal quality, for example hoarseness. We do not expect this to occur and have trained speech-language pathologists to help guide your technique with voice exercises.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. However, individuals with normal voice are capable of improving their voice production to produce voice more efficiently. Additionally, your willingness to participate may, in the future, help speech-language pathologists more effectively treat voice disorders.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or grade in any of your classes.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

It is not expected that you will incur any cost a result of your participation in this study. If you travel by car, you may park in the Kentucky Clinic parking garage on Huguelet Dr., and we can validate your parking ticket. If you remain parked in that location for longer than your validation stamp, you are responsible for covering parking costs, which is \$0.75/ hour.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will keep private all research records that identify you to the extent allowed by law. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write

about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Your personal information will be accessible only to research personnel. Officials at the University of Kentucky may look at or copy pertinent portions of records that identify you.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study, you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study; your academic and/or employment status will not be affected.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe that you have gotten hurt or sick as a result of participation in this study, you should contact Mariah Morton at mariah.morton@uky.edu or 503-863-4912 or Dr. Joseph Stemple at jcstem2@uky.edu or 859-218-0556. In case of abnormal finding during laryngeal examination, you will be referred to the UK Voice and Swallow Clinic and UK ENT (or another ENT of your choice). Should you choose to proceed with evaluation/treatment, you and/or your insurance company will be responsible for the costs of all care and treatment.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are negatively affected by this study. Depending on your insurance, your care costs may be paid by Medicaid if you have coverage (if you have questions regarding Medicaid coverage you may call 1-800-633-4227). A co-payment/ deductible from you may be required by your insurer or Medicaid even if your insurer or Medicaid has agreed to pay the costs. The amount of this co-payment or deductible may be substantial. You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Mariah Morton, at 503-863-4912. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regard to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

POTENTIAL FUTURE USE

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by investigators regarding your willingness to participate in future research studies about how to prevent, detect, or treat voice disorders?

☐ **Yes** ☐ **No** _____ **Initials**

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data collected from you may be shared with other investigators in the future. If that is the case data will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

We have no financial disclosures to include for the present study.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Your name, age, email, telephone number, and demographic information (ethnicity, gender)
- Visual images from laryngeal examination/ audio-visual recordings of your voice
- Lung volumes, time averages, home practice data
- Questionnaires and auditory-perceptual ratings regarding your voice

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky representatives.

Your information will be shared with the people listed in this document

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- Current or future healthcare at the University of Kentucky
- Current or future payments to the University of Kentucky
- Ability to enroll in any health plans (if applicable)
- Eligibility for benefits (if applicable)

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Mariah Morton, B.A. at 900 South Limestone, Suite 120, Lexington, KY 40503 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

Signature of research subject

Date

Printed name of research subject

Name of [authorized] person obtaining informed consent/HIPAA authorization

Signature of Principal Investigator or Sub/Co-Investigator

APPENDIX C. VOCAL HYGIENE HANDOUT

Vocal Hygiene Education

What is vocal hygiene? The following suggestions are meant to guide you in taking care of your voice and overcoming and preventing some voice problems. Vocal hygiene is positive change – suggestions that will make you feel better and make you sound better too!

Drink lots of water: The entire voice producing mechanism (mouth, throat, vocal folds and lungs, too) needs moisture to work efficiently. If you do a lot of talking (on the telephone, group meetings, one-on-one discussion) or singing, always have water nearby and take frequent sips. Sometimes, when people are not in the habit of drinking water, they don't even realize that they are thirsty until after they begin drinking. And water is good for the health of your entire body.

Limit Caffeine and Alcohol use: Both Caffeine and alcohol have significant drying effects on tissues of the mouth and throat. A way to stay well hydrated is to limit use of products that dehydrate vocal fold and oral structures.

Don't smoke and completely eliminate tobacco use: Smoking cigarettes, pipes, cigars and other substances can seriously harm your overall health, and damage the entire respiratory system including the upper airway, throat, mouth and nose. The heat and inhaled chemicals cause inflammation, swelling, sometimes irreversible damage, and cancer. The only way to counter the effects of smoking is to stop.

Eliminate habitual and frequent throat clearing. We all must clear our throats on occasion, but recognize that when you clear your throat you are "slamming" the vocal folds together hard. This can damage the vocal folds by causing inflammation and localized irritation.

Control and limit vocal loudness. Do not speak louder than the situation or environment demands. Don't "compete vocally". Avoid yelling, loud cheering, speaking over loud noises. Use non-vocal methods to get the attention of others (i.e., clap your hands, raise your arm, blow a whistle, ring a bell, turn lights on and off). Use amplification in large or noisy places. Don't try to "out talk" others by increasing loudness. Be aware of how you use your voice in talking over music, over the TV, communicating up and down stairs in the home, calling the dog, etc.

Balance extra vocal demands with voice rest. If you have to give a lecture or you know that you will be speaking for extended periods of time, try to reduce voice use before and after these episodes. If you must talk a lot at work, try to reduce the amount of talking outside of work. Listen more and talk less. If you know that you will be using your voice heavily in the evening (giving a lecture, talking in a noisy environment), then rest your voice more during the day and after the evening is over.'

Use caution with medications (over-the-counter and prescription). Decongestants, allergy medicines and some other drugs tend to release fluid from body tissues, including the vocal folds. If your doctor has recommended that you take these medicines, you need to try to counteract their drying effect by increasing your water intake. Ask your doctor if there are any alternative medicines that don't have such a drying effect. Please consult your cancer care team before administering any new medication.

APPENDIX D. VRQoL
Otolaryngology Associates, P.C.
Voice Related Quality of Life (V-RQOL)

Name: _____

Date: _____

We are trying to learn more about how a voice problem can interfere with your daily activities. On this paper, you will find a list of possible voice-related problems. Please answer all questions based upon what your voice has been like over the past 2 weeks. There are no “right” or “wrong” answers.

Considering both how severe the problem is when you get it, and how frequently it happens,
 please rate each item below on how “bad” it is (that is, the amount of each problem you have). Use the following scale for rating the amount of the problem.

- 1 = None, not a problem
- 2 = A small amount
- 3 = A moderate (medium) problem
- 4 = A lot
- 5 = Problem is “as bad as it can be”

Because of my voice:	How much of a problem is this?				
1. I have trouble speaking loudly or being heard in noisy situations.	1	2	3	4	5
2. I run out of air and need to take frequent breaths when talking.	1	2	3	4	5
3. I sometimes do not know what will come out when I begin speaking.	1	2	3	4	5
4. I am sometimes anxious or frustrated (because of my voice).	1	2	3	4	5
5. I sometimes get depressed (because of my voice).	1	2	3	4	5
6. I have trouble using the telephone (because of my voice).	1	2	3	4	5
7. I have trouble doing my job or practicing my profession (because of my voice).	1	2	3	4	5
8. I avoid going out socially (because of my voice).	1	2	3	4	5
9. I have to repeat myself to be understood.	1	2	3	4	5
10. I have become less outgoing (because of my voice).	1	2	3	4	5

The overall quality of my voice during the last two weeks has been (please circle):

Poor Fair Good Very Good Excellent

Hogikyan ND, Sethuraman G. Validation of an instrument to measure voice-related quality of life (V-RQOL). Journal of Voice. 1999. 13:557-569.

APPENDIX E. CAPE-V

Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V)

Name: _____

Date: _____

The following parameters of voice quality will be rated upon completion of the following tasks:

1. Sustained vowels, /a/ and /i/ for 3-5 seconds duration each.

2. Sentence production:

a. The blue spot is on the key again.

b. How hard did he hit him?

c. We were away a year ago.

d. We eat eggs every Easter.

e. My mama makes lemon muffins.

f. Peter will keep at the peak.

3. Spontaneous speech in response to: "Tell me about your voice problem." or "Tell me how your voice is functioning."

Legend: C = Consistent I = Intermittent
MI = Mildly Deviant
MO = Moderately Deviant
SE = Severely Deviant

									SCORE
Overall Severity	_____					C	I		_____/100
	MI	MO	SE						
Roughness	_____					C	I		_____/100
	MI	MO	SE						
Breathiness	_____					C	I		_____/100
	MI	MO	SE						
Strain	_____					C	I		_____/100
	MI	MO	SE						
Pitch	(Indicate the nature of the abnormality): _____					C	I		_____/100
	MI	MO	SE						
Loudness	(Indicate the nature of the abnormality): _____					C	I		_____/100
	MI	MO	SE						
_____	_____					C	I		_____/100
	MI	MO	SE						
_____	_____					C	I		_____/100
	MI	MO	SE						

COMMENTS ABOUT RESONANCE: NORMAL OTHER (Provide description): _____

ADDITIONAL FEATURES (for example, diplophonia, fry, falsetto, asthenia, aphonia, pitch instability, tremor, wet/gurgly, or other relevant terms): _____

Clinician: _____

APPENDIX F. STUDY CHECKLIST

Participant No.: _____			
Informed Consent (circle one)	Yes	No	
Group: (circle one)	No Goal	Delayed Goal	Goal
VRQOL	Score (10-50): _____	Overall Quality: _____	
CAPE-V	Overall Quality (>29 disqualifies): _____		
Max Airflow Vol: _____ mL			
Goal	MAV/ 80mL/s = _____ / 80mL/s = _____ s		
Strobe (circle one)	Normal	Abnormal (please specify: _____)	
Vocal Hygiene Ed (circle one)	Yes	No	
Taught Exercises	Yes	No	

Baseline MPT w/ SLP	Yes	No
Compliance (log, video, reminders)	Yes	No

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