Cover Page

Official Title: A Comparison of Two Forms of Intensive Voice Treatment for Parkinson's Disease

NCT: NCT03700684

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Background

Motor impairment is a hallmark feature of Parkinson's disease (PD). The motor-based symptoms are characterized by reduced amplitude and speed of movement and difficulty initiating and coordinating movement. An important functional consequence of these motor-based impairments is a marked reduction in speaking intensity. This condition, known as hypophonia, is estimated to effect approximately 75% of patients in some stage of the disease process.

Our two current, evidence-based treatments for hypophonia, LSVT LOUD® and the SpeechViveTM, use high effort speech tasks to increase motor output across the speech mechanism. While LSVT LOUD® and the SpeechViveTM share the same therapeutic target (increased speech intensity), they differ substantially in the type of cueing used in therapy. LSVT LOUD® targets louder speech using internal, self-initiated cues. The SpeechViveTM, in contrast, elicits louder speech using a naturalistic, external noise cue. While data show that LSVT LOUD® and the SpeechViveTM both yield significant improvements in sound pressure level (SPL)/vocal intensity, the supportive physiologic adjustments used by speakers are not well understood. Our long-term goal is to improve voice rehabilitation for persons with PD. Our objectives are to determine the influence of treatment on the respiratory and laryngeal adjustments used by speakers with PD to support increased speech volume, and to identify the perceptions of physical and mental effort associated with each form of therapy. Our central hypothesis is that treatment strategy will differentially impact the physiologic systems that support louder speech and mediate speaker perceptions of effort. We plan to objectively test our central hypothesis and, thereby, attain the objective of this application by pursuing the following two specific aims:

Aim 1: To examine physiologic adjustments in respiratory and laryngeal function in response to treatment utilizing internal cueing (LSVT LOUD®) and external cueing (SpeechViveTM) strategies. Based on published research and preliminary data, we hypothesize that the external cueing treatment will elicit more efficient respiratory and laryngeal patterns during louder speech, in comparison to the internal cueing treatment.

Aim 2: To assess participants' level of perceived physical and mental effort associated with LSVT LOUD® and SpeechViveTM therapies. We hypothesize that speakers with PD will assign lower ratings of perceived physical and mental effort for SpeechViveTM therapy, in comparison to LSVT LOUD®. This hypothesis is predicated on programmatic differences in training intensity level and cognitive load.

Methods

Participants: Thirty-six individuals with a neurological diagnosis of idiopathic PD will be enrolled for study in West Lafayette, Indiana (and surrounding areas) and in Amherst, Massachusetts (and surrounding areas). Participants will be randomly assigned to one of three groups: LSVT LOUD® (n=12), SpeechViveTM (n=12), non-treatment PD control (n=12). Participants assigned to the non-treatment control group will be sampled at the same time points as the experimental groups. The sample size has been chosen to detect a 5 dB SPL difference with a study power of 0.8 and significance level of 0.05. Inclusionary criteria include: (i) problems with speech volume as determined by an ASHA-certified speech-language pathologist, (ii) unaided hearing in at least one ear (to accommodate the SpeechViveTM), (iii) non-smoking in the past 5 years, (iv) no recent history of respiratory illness; (v) no neurological conditions other than PD and no history of neurosurgeries, (vi) free of depressive symptoms (Beck Depression Inventory score < 19), (vii) no voice therapy or voice therapy maintenance within the last six months, (viii) negative laryngeal pathology as determined by a videolaryngoscopic examination. Participants who present with normal vocal fold closure or incomplete vocal fold closure will be included for study. Patients with vocal fold lesions, hyperadduction, or other laryngeal pathology will be excluded and referred for treatment.

Methods and Analysis: LSVT LOUD® and SpeechViveTM follow a standardized treatment protocol which will ensure treatment fidelity across sites. The research personnel responsible for administering treatment will be LSVT LOUD®-certified and trained in the SpeechViveTM protocol. Data will be collected at three time points for each group: pre-treatment, mid-treatment, and immediately post-treatment. In accordance with specific aim 1, outcomes measures will include sound pressure level (SPL), utterance length, respiratory kinematic patterns, and laryngeal aerodynamic patterns. Pre-to-post treatment changes in SPL will serve as a primary indicator on the effectiveness of each intervention technique. SPL and utterance length will be captured and analyzed during a two-minute monologue task. Respiratory and laryngeal aerodynamic data will be collected and analyzed during connect speech. Respiratory kinematic data will be captured using inductance plethysmography to transduce the movement of the ribcage and abdomen during a monologue and reading task. Laryngeal aerodynamic data will be captured during a sentence-level task (‘‘Buy pop or pop a papa”) using a circumferentially-vented pneumotachograph mask. In accordance with specific aim 2, a modified version of the National Aeronautics and Space Administration Task Load Index (NASA-TLX) [46] will be used to examine the participants’ perceived level of physical and mental effort associated with LSVT LOUD® and SpeechViveTM therapies. Following each treatment session, participants will be instructed to complete the computerized NASA-TLX scale and assign a visual analogue rating for the Mental Demand (how much mental and perceptual activity was required) and Physical Demand (how much physical activity was required) domains. Higher scores reflect speakers’ perceptions of increased effort.

For specific aim 1, the statistical approach will involve a repeated measures analysis of variance for each outcome variable: SPL, utterance length, respiratory kinematic measures, and laryngeal aerodynamic measures. The within-subject factor will be Session (pre, mid, post) and the between-subject factor will be Group (LSVT LOUD®, SpeechViveTM, and non-treatment control). Participant will be included as a random effect in the model to account for expected inter-subject differences in response to treatment. If the measures exhibit strong skewness or outlying values, we will compare the groups using appropriate non-parametric methods. Bonferroni-adjusted p-values will be used to reduce Type I error. For specific aim 2, each domain score of the NASA-TLX will be statistically analyzed using a separate, repeated measures analysis of variance. Treatment session will be included as a factor in each analysis. The model will include random effects to account for within-subject correlation. If the measures exhibit strong skewness or outlying values, we will compare the groups using non-parametric methods. Bonferroni-adjusted p-values will be used to reduce Type I error.

Consent Form for Participation in a Research Study

Researchers: Kelly Richardson, Ph.D., Assistant Professor
University of Massachusetts Amherst

Jessica Huber, Ph.D., Professor
Purdue University

Study Title: A comparison of two behavioral voice interventions for Parkinson's disease.

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1. WHAT IS THIS FORM?

This form is called a Consent Form. It will give you information about the study so you can make an informed decision about participation in this research project.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks or discomforts that you may have while participating. We encourage you to take some time to think this over and ask questions now and at any other time. If you decide to participate, you will be asked to sign this form and you will be given a copy for your records.

2. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to compare two behavioral voice treatment programs commonly used to treat the speech and voice problems associated with Parkinson's disease.

3. WHO IS ELIGIBLE TO PARTICIPATE?

Subjects must present with i) a diagnosis of Parkinson's disease, (ii) have problems with speaking volume due to Parkinson's disease, (iii) present with a negative history for other neurological involvement (other than Parkinson's disease), (iv) no history of asthma or respiratory problems (COPD, emphysema), (v) no history of head, neck or chest surgery (pacemaker surgery is okay), (vi) non-smoker for the last 5 years, (vii) no currently participating in another treatment study, (viii) access to transportation to and from campus, (ix) typical cognitive skills, (x) free of symptoms of depression, xi) healthy vocal folds xii) no voice therapy or voice therapy maintenance within the last 12 months.

4. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?

The research study will be conducted at (the University of Massachusetts Amherst/Purdue University). You have been assigned to the **non-treatment control group**. As a participant in the control group, you will be asked to participate in three data collection sessions over an eight week period at the university laboratory. Each testing session lastly approximately 90-120 minutes. As a participant in this study, you will not be contacted directly for future studies.

5. WHAT WILL I BE ASKED TO DO?

You could have been placed into one of three groups: LSVT LOUD® treatment, SpeechVive™ treatment, or non-treatment control group. You have been placed in the **non-treatment control group**. As a part of the

control group, you are not eligible for voice treatment. Since this is a treatment study, we will ask you to not engage in other form of therapy (surgical, pharmacological, or behavioral) for the duration of the study. As a research participant, you are ask to attend 3 data collection sessions at the university laboratory with each session lasting 90-120 minutes.

In this first visit to the lab, you will be asked to complete additional screening tasks in order to be certain that you are appropriate to participate in this study. You will first be asked to i) complete a depression inventory to assess your mood, ii) pass a cognitive screening inventory, and iii) participate in a laryngeal examination. As part of the cognitive screening, you will be asked a series of questions related to orientation of place and time, remember a sequence of words for a short period of time (e.g. a few minutes), name objects, and follow a series of short commands. The laryngeal examination will be conducted by a trained member of the research team. For this examination, you will be seated and a Velcro strap will hold a microphone comfortably on the side of your neck. You will be asked to stick out your tongue, which will be held by the examiner with sterile gauze. An endoscope will then be slowly inserted towards the back of your mouth so that a video recording of your larynx (voice box) can be made. The endoscope is a straight blunt metal rod (about the diameter of a "pinky finger") with a tiny camera lens at the end. Neither the endoscope nor the Velcro strap will interfere with your breathing. You will say an "ee" sound and then the endoscope will be removed. The endoscope will be disinfected after each use.

Based on the results of these tests, you may be deemed ineligible to participate. In such instances, you will be compensated for the time you participated at a prorated rate of $10 per hour.

If you are deemed eligible to participate, you will be asked to complete a questionnaire that focuses on your medical history which includes questions about your Parkinson's disease, general health, medications, and any speech and voice problems you may be experiencing. You may skip any question that you feel uncomfortable answering. We will also ask you to release a test score from your neurologist to us which indexes the severity of your Parkinson's disease. You do not need to agree to this release to participate in the study. In addition, you will undergo a brief heading screening which requires you to listen for tones and raise your hand when you hear the tone.

In addition, you will be asked to wear a microphone and perform a variety of speaking tasks including, but not limited to reading sentences, short passages, and/or citing a monologue. You will also be asked to perform different breathing exercises while wearing nose clips including breathing in and out as much as you can into a cardboard mouthpiece. The nose clips and mouthpiece are disposable and are thrown out after use. You will also be fitted with elasticized bands that are worn on the outside your clothing around your rib cage and abdomen. The bands do not impede your ability to breathe. We will ask you to breathe quietly, to breathe in and out as much air as you can, and to move your abdomen in and out. You will also be asked to talk about a topic of interest for several minutes. Lastly, we will place a mask over your mouth and nose. The mask will measure the air as it comes out of your mouth. A small tube will be placed between your lips and behind your teeth. It will not impede your ability to talk. We will ask you to read a sentence several times with the mask in place. The mask and tube will be disinfected after each use. You may take breaks as needed or cease participation at any time. You have just completed your pre-treatment lab session. You will be asked to perform these tasks again in week 4 (mid-treatment) and week 8 (end of treatment).

This is a research study that involves questions related to sensitive topics that may cause distress. As researchers, we do not provide mental health services and we will not be following up with you after this study. However, we want to provide every participant in this study with contact information for available clinical resources, should you decide you need assistance at any time. In a serious emergency, remember that you can also call 911 for immediate assistance. The facilities identified below offers services to individuals who are not affiliated with UMass Amherst/Purdue University.

University of Massachusetts Amherst
Counseling and Psychological Health
127 Hills North
Amherst MA 01003
(413) 545-2337

Purdue University
Counseling and Psychological Services
601 Stadium Mall Drive, Room 224
West Lafayette, IN 47907-2052
(765) 494-6995

6. WHAT ARE MY BENEFITS OF BEING IN THIS STUDY?

Your participation in the study will advance our knowledge of what treatment approaches may help alleviate the speech and voice problems commonly reported by individuals with Parkinson's disease.

7. WHAT ARE MY RISKS OF BEING IN THIS STUDY?

We believe there are minimal physical risks associated with this research study. A possible risk to you however, might include fatigue. To lower the risk of fatigue, you will have periods of rest throughout each laboratory session. You may also request a break at anytime. There is also a risk of a breach of confidentiality. To minimize this risk, you will be assigned a unique identifier which will be assigned to your records and collected voice samples. Your consent form, which contains identifying information, will be stored in a locked filing cabinet in a secured room, only accessible to key research personnel for a period of three years. After three years, all study records will be destroyed. Should a breach of confidentiality occur you will be immediately informed of the breach verbally and in writing. There is also a minimal risk of infection. To minimize this risk, all instruments used during data collection are sterilized with medical grade disinfectant prior to use. The nose clips and mouthpieces will be discarded after one use. The mask and tube will be disinfected after each use. During the examination of the larynx, some people find that they gag temporarily if the endoscope touches the back of their tongue or throat. The sensation is similar to what you may have experienced while brushing your tongue with a tooth brush. In addition, there may be a remote chance of damage to teeth and dental work. A trained member of the research team will guide the endoscope using techniques designed to minimize this risk. The endoscope will be disinfected after each use.

As a participant in this study, you will be asked to provide sensitive information about your physical and mental well-being and demographic data (age, gender, height, weight, race/ethnicity). You may refuse to answer any question without repercussion. There is a low psychological risk that you may be upset by some of the questions centered on health-related issues. We can provide you with a list of mental health professionals in your community, if this information would be helpful.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

The following procedures will be used to protect the confidentiality of your study records. The researchers will keep all study records in a locked file cabinet in a secure room accessible only to project staff. Electronic data files will be stored on a password protected computer in a secure room accessible only to project staff. Copies of all records will also be maintained on a HIPAA and HITECH compliant data sharing platform. All records will be labeled with a unique code. A master key which links participant names with their unique codes will be maintained in a separate and secure location accessible to key research personnel. The master key and data files will be destroyed 3 years after the close of the study. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

9. WILL I RECEIVE ANY PAYMENT FOR TAKING PART IN THE STUDY?

You will be compensated $10/hour for each laboratory session you participate in.

10. EXTRA COSTS TO PARTICIPATE

There are no extra costs for you related to your participation in this study. Parking at (UMass Amherst/Purdue University) will be covered.

11. WHAT IF I HAVE QUESTIONS?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the researcher, Dr. Kelly Richardson, at (413) 545-2007. If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu.

12. CAN I STOP BEING IN THE STUDY?

You do not have to participate in this research project. If you agree to participate, you can withdraw your participation at any time without penalty. Please tell the experimenter if you wish to end your participation at any point in the study. If you wish to withdraw your records or data after you have completed your participation, please contact the primary investigator by phone, email, or writing.

13. WHAT IF I AM INJURED?

The University of Massachusetts does not have a program for compensating subjects for injury or complications related to human subjects' research. This does not waive any of my legal rights nor release any claim I might have based on negligence.

14. CONTACT INFORMATION

If you have any questions about this research project and/or scheduling, you may contact the principal investigator Dr. Kelly Richardson, UMass Amherst, at 413-545-2007 or by email krichardson@comdis.umass.edu. Or you may contact the co-investigator, Dr. Jessica Huber, Purdue University, at 765-494-3796 or by email at jhuber@purdue.edu. If you have any questions about your rights as a participant in a research project, or questions, concerns or complaints about the research and wish to speak with someone who is not a member of the research team, you should contact (anonymously, if you wish) the Human Research Protection Office at the University of Massachusetts Amherst at (413) 545-3428 or by mail at Human Research Protection Office, Mass Venture Center, 100 Venture Way, Suite 116, Hadley, MA 01035.

15. CONFLICT OF INTEREST DISCLOSURE

The following disclosures are made to give you an opportunity to decide if these relationships will affect your willingness to participate in the research study. Dr. Huber, the primary investigator on the study, is the inventor of the SpeechVive™ device. She is on the Board of Directors of SpeechVive™, Inc, the company that manufactures and sells the SpeechVive™ device. She also owns stock in the company. Sandy Snyder, a staff member in Dr. Huber's laboratory, also owns stock in SpeechVive™, Inc. The researchers will not make any attempt to initiate the sale of the SpeechVive™ medical device either during the study or after study completion.

16. DATA SHARING

This research study will adhere to the NIH Grants Policy on Sharing of Unique Research Resources including the "NIH Data Sharing Policy" issued in April 2007; http://grants.nih.gov/grants/policy/data_sharing/.

Final data will be shared primarily through the vehicle of peer reviewed publications and scientific conference proceedings. Raw data will be considered for sharing under the following rules. Raw datasets to be released for sharing will not contain identifiers. Data and associated documentation will be made available to users only under a signed and properly executed data-sharing agreement that provides for specific criteria under which the data will be used, including but not limited to: 1) a commitment to using the data only for research purposes; 2) a commitment to securing the data using appropriate computer technology; and 3) a commitment to destroying or returning the data after analyses are completed.

17. SUBJECT STATEMENT OF VOLUNTARY CONSENT

When signing this form I am agreeing to voluntarily enter this study. I have had a chance to read this consent form, and it was explained to me in a language which I use and understand. I have had the opportunity to ask questions and have received satisfactory answers. I understand that I can withdraw at any time. I understand that will receive a copy of this signed Informed Consent Form.

Participant Signature:	Print Name:	Date:

By signing below I indicate that the participant has read and, to the best of my knowledge, understands the details contained in this document and has been given a copy.

Signature of Person Obtaining Consent	Print Name:	Date:

Consent Form for Participation in a Research Study

Researchers: Kelly Richardson, Ph.D., Assistant Professor
University of Massachusetts Amherst

Jessica Huber, Ph.D., Professor
Purdue University

Study Title: A comparison of two behavioral voice interventions for Parkinson's disease.

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The purpose of this research study is to compare two behavioral voice treatment programs commonly used to treat the speech and voice problems associated with Parkinson's disease.

3. WHO IS ELIGIBLE TO PARTICIPATE?

Subjects must present with i) a diagnosis of Parkinson's disease, (ii) have problems with speaking volume due to Parkinson's disease, (iii) present with a negative history for other neurological involvement (other than Parkinson's disease), (iv) no history of asthma or respiratory problems (COPD, emphysema), (v) no history of head, neck or chest surgery (pacemaker surgery is okay), (vi) non-smoker for the last 5 years, (vii) no currently participating in another treatment study, (viii) access to transportation to and from campus, (ix) typical cognitive skills, (x) free of symptoms of depression, (xi) healthy vocal folds, (xii) no voice therapy or voice therapy maintenance within the last 12 months.

4. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?

The research study will be conducted at (the University of Massachusetts Amherst/Purdue University). You have been assigned to the **LSVT LOUD® treatment group**. As a participant in this treatment group, you will be asked to participate in an eight-week home-based voice treatment program. In addition, you will be asked to attend 3-4 laboratory sessions at the university campus, with each session lastly approximately 90-120 minutes. As a participant in this study, you will not be contacted directly for future studies.

5. WHAT WILL I BE ASKED TO DO?

Treatment Overview: You could have been placed into one of three groups: LSVT LOUD® treatment, SpeechVive™ treatment, or non-treatment control group. You have been placed in the **LSVT LOUD® treatment group**. As a part of the study, you will be asked to participate in 60 minutes of voice therapy, 4 days per week, for four weeks. After this time, you will be asked to participate in a home maintenance program where you will be asked to record the day and time of your vocal practice. In the home maintenance program, you will be asked to practice the vocal exercises 4 days per week for 4 weeks. A homework DVD will be provided which provides an overview of the vocal exercises to be completed. The LSVT LOUD® treatment will be provided by an LSVT-certified practitioner. Since this is a treatment study, we will ask you to not engage in other form of therapy (surgical, pharmacological, or behavioral) for the duration of the study.

Number of Days of LSVT LOUD®: 4 days per week Number of Weeks for LSVT LOUD®: 4 weeks
Number of Days of LSVT Maintenance: 5 days per week Number of Weeks for LSVT Maintenance: 4 weeks

Data Collection: In the first visit to the lab, you will be asked to complete several screening tasks in order to be certain that you are appropriate to participate in this study. The first part of the screening was completed with the questions you answered over the phone. To confirm eligibility, you will first be asked to i) complete a depression inventory to assess your mood, ii) pass a cognitive screening inventory, and iii) participate in a laryngeal examination. As part of the cognitive screening, you will be asked a series of questions related to orientation of place and time, remember a sequence of words for a short period of time (e.g. a few minutes), name objects, and follow a series of short commands. The laryngeal examination will be conducted by a trained member of the research team. For this examination, you will be seated and a Velcro strap will hold a microphone comfortably on the side of your neck. You will be asked to stick out your tongue, which will be held by the examiner with sterile gauze. An endoscope will then be slowly inserted towards the back of your mouth so that a video recording of your larynx (voice box) can be made. The endoscope is a straight blunt metal rod (about the diameter of a "pinky finger") with a tiny camera lens at the end. Neither the endoscope nor the Velcro strap will interfere with your breathing. You will say an "ee" sound and then the endoscope will be removed. The endoscope will be disinfected after each use. Based on the results of these tests, you may be deemed ineligible to participate. In such instances, you will be compensated for the time you participated at a prorated rate of $10 per hour.

If you are deemed eligible to participate, you will be asked to complete a questionnaire that focuses on your medical history which includes questions about your Parkinson's disease, general health, medications, and any speech and voice problems you may be experiencing. You may skip any question that you feel uncomfortable answering. We will also ask you to release a test score from your neurologist to us which indexes the severity of your Parkinson's disease. You do not need to agree to this release to participate in the study. In addition, you will undergo a brief heading screening which requires you to listen for tones and raise your hand when you hear the tone.

In addition, you will be asked to wear a microphone and perform a variety of speaking tasks including, but not limited to reading sentences, short passages, and/or citing a monologue. You will also be asked to perform different breathing exercises while wearing nose clips including breathing in and out as much as you can into a cardboard mouthpiece. The nose clips and mouthpiece are disposable and are thrown out after use. You will also be fitted with elasticized bands that are worn on the outside your clothing around your rib cage and abdomen. The bands do not impede your ability to breathe. We will ask you to breathe quietly, to

breathe in and out as much air as you can, and to move your abdomen in and out. You will also be asked to talk about a topic of interest for several minutes. Lastly, we will place a mask over your mouth and nose. The mask will measure the air as it comes out of your mouth. A small tube will be placed between your lips and behind your teeth. It will not impede your ability to talk. We will ask you to read a sentence several times with the mask in place. The mask and tube will be disinfected after each use. You may take breaks as needed or cease participation at any time. You have just completed your pre-treatment lab session. You will be asked to perform these tasks again in week 4 (mid-treatment) and week 8 (end of treatment).

This is a research study that involves questions related to sensitive topics that may cause distress. As researchers, we do not provide mental health services and we will not be following up with you after this study. However, we want to provide every participant in this study with contact information for available clinical resources, should you decide you need assistance at any time. In a serious emergency, remember that you can also call 911 for immediate assistance. The facilities identified below offers services to individuals who are not affiliated with UMass Amherst/Purdue University.

University of Massachusetts Amherst
Counseling and Psychological Health
127 Hills North
Amherst MA 01003
(413) 545-2337

Purdue University
Counseling and Psychological Services
601 Stadium Mall Drive, Room 224
West Lafayette, IN 47907-2052
(765) 494-6995

6. WHAT ARE MY BENEFITS OF BEING IN THIS STUDY?

If the therapy proves effective for you, you may benefit by improved speech loudness and intelligibility. In addition, your participation in the study will advance our knowledge of what treatment approaches may help alleviate the speech and voice problems commonly reported by individuals with Parkinson's disease.

7. WHAT ARE MY RISKS OF BEING IN THIS STUDY?

We believe there are minimal physical risks associated with this research study. A possible risk to you however, might include fatigue. To lower the risk of fatigue, you will have periods of rest throughout each laboratory session. You may also request a break at anytime. There is also a risk of a breach of confidentiality. To minimize this risk, you will be assigned a unique identifier which will be assigned to your records and collected voice samples. Your consent form, which contains identifying information, will be stored in a locked filing cabinet in a secured room, only accessible to key research personnel for a period of three years. After three years, all study records will be destroyed. Should a breach of confidentiality occur you will be immediately informed of the breach verbally and in writing.

During the examination of the larynx, some people find that they gag temporarily if the endoscope touches the back of their tongue or throat. The sensation is similar to what you may have experienced while brushing your tongue with a tooth brush. In addition, there may be a remote chance of damage to teeth and dental work. A trained member of the research team will guide the endoscope using techniques designed to minimize this risk. The endoscope will be disinfected after each use. The audiometer headphones will be disinfected before and after you use them in order to minimize the slight risk that you will come into contact with substances such as bacteria. The nose clips and mouthpieces will be discarded after one use. The mask and tube will be disinfected after each use.

As a participant in this study, you will be asked to provide sensitive information about your physical and mental well-being and demographic data (age, gender, height, weight, race/ethnicity). You may refuse to answer any question without repercussion. There is a low psychological risk that you may be upset by

some of the questions centered on health-related issues. We can provide you with a list of mental health professionals in your community, if this information would be helpful.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

The following procedures will be used to protect the confidentiality of your study records. The researchers will keep all study records in a locked file cabinet in a secure room accessible only to project staff. Electronic data files will be stored on a password protected computer in a secure room accessible only to project staff. Copies of all records will also be maintained on a HIPAA and HITECH compliant data sharing platform. All records will be labeled with a unique code. A master key which links participant names with their unique codes will be maintained in a separate and secure location accessible to key research personnel. The master key and data files will be destroyed 3 years after the close of the study. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

9. WILL I RECEIVE ANY PAYMENT FOR TAKING PART IN THE STUDY?

You will receive eight weeks of voice treatment at no cost to you. In addition, you will be compensated $10/hour for each laboratory session you participate in.

10. EXTRA COSTS TO PARTICIPATE

There are no extra costs for you related to your participation in this study. Parking at (UMass Amherst/Purdue University) will be covered.

11. WHAT IF I HAVE QUESTIONS?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the researcher, Dr. Kelly Richardson, at (413) 545-2007. If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu.

12. CAN I STOP BEING IN THE STUDY?

You do not have to participate in this research project. If you agree to participate, you can withdraw your participation at any time without penalty. Please tell the experimenter if you wish to end your participation at any point in the study. If you wish to withdraw your records or data after you have completed your participation, please contact the primary investigator by phone, email, or writing.

13. WHAT IF I AM INJURED?

The University of Massachusetts does not have a program for compensating subjects for injury or complications related to human subjects' research. This does not waive any of my legal rights nor release any claim I might have based on negligence.

14. CONTACT INFORMATION

If you have any questions about this research project and/or scheduling, you may contact the principal investigator Dr. Kelly Richardson, UMass Amherst, at 413-545-2007 or by email krichardson@comdis.umass.edu. Or you may contact the co-investigator, Dr. Jessica Huber, Purdue University, at 765-494-3796 or by email at jhuber@purdue.edu. If you have any questions about your rights as a participant in a research project, or questions, concerns or complaints about the research and wish to speak with someone who is not a member of the research team, you should contact (anonymously,

if you wish) the Human Research Protection Office at the University of Massachusetts Amherst at (413) 545-3428 or by mail at Human Research Protection Office, Mass Venture Center, 100 Venture Way, Suite 116, Hadley, MA 01035.

15. CONFLICT OF INTEREST DISCLOSURE

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_____ _____ _____ Participant Signature: Print Name: Date:

By signing below I indicate that the participant has read and, to the best of my knowledge, understands the details contained in this document and has been given a copy.

_____	_____	_____
Signature of Person Obtaining Consent	Print Name:	Date:

Researchers: Kelly Richardson, Ph.D., Assistant Professor
University of Massachusetts Amherst

Jessica Huber, Ph.D., Professor
Purdue University

Study Title: A comparison of two behavioral voice interventions for Parkinson's disease.

1. WHAT IS THIS FORM?

This form is called a Consent Form. It will give you information about the study so you can make an informed decision about participation in this research project.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks or discomforts that you may have while participating. We encourage you to take some time to think this over and ask questions now and at any other time. If you decide to participate, you will be asked to sign this form and you will be given a copy for your records.

2. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to compare two behavioral voice treatment programs commonly used to treat the speech and voice problems associated with Parkinson's disease.

3. WHO IS ELIGIBLE TO PARTICIPATE?

Subjects must present with i) a diagnosis of Parkinson's disease, (ii) have problems with speaking volume due to Parkinson's disease, (iii) present with a negative history for other neurological involvement (other than Parkinson's disease), (iv) no history of asthma or respiratory problems (COPD, emphysema), (v) no history of head, neck or chest surgery (pacemaker surgery is okay), (vi) non-smoker for the last 5 years, (vii) no currently participating in another treatment study, (viii) access to transportation to and from campus, (ix) typical cognitive skills, (x) free of symptoms of depression, (xi) healthy vocal folds, (xii) unaided hearing in at least one ear (to accommodate SpeechVive device), (xiii) no voice therapy or voice therapy maintenance within the last 12 months.

4. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?

The research study will be conducted at (the University of Massachusetts Amherst/Purdue University). You have been assigned to the **SpeechVive™ treatment group**. As a participant in this treatment group, you will be asked to participate in an eight-week home-based voice treatment program. In addition, you will be asked to attend 3-4 laboratory session at the university campus, with each session lastly approximately 90-120 minutes. As a participant in this study, you will not be contacted directly for future studies.

5. WHAT WILL I BE ASKED TO DO?

You could have been placed into one of three groups: LSVT LOUD® treatment, SpeechVive™ treatment, or non-treatment control group. You have been placed in the **SpeechVive™ treatment group**. As a part of the study, we will provide you with a device which we will ask you to wear 2-4 hours per day, 5 days per week, for eight weeks. The device will play noise in one of your ears when you speak. When you stop

speaking the noise will turn off so it does not interfere with your ability to listen during a conversation. Since this is a treatment study, we will ask you to not engage in other form of therapy (surgical, pharmacological, or behavioral) for the duration of the study.

Number of Days to Wear Device: 5 days per week
Number of hours to Wear Daily: 2-4 hours/day
Number of Weeks to Wear Device: 8 consecutive weeks

In this first visit to the lab, you will be asked to complete several screening tasks in order to be certain that you are appropriate to participate in this study. The first part of the screening was completed with the questions you answered over the phone. To confirm eligibility, you will first be asked to i) complete a depression inventory to assess your mood, ii) pass a cognitive screening inventory, and iii) participate in a laryngeal examination. As part of the cognitive screening, you will be asked a series of questions related to orientation of place and time, remember a sequence of words for a short period of time (e.g. a few minutes), name objects, and follow a series of short commands. The laryngeal examination will be conducted by a trained member of the research team. For this examination, you will be seated and a Velcro strap will hold a microphone comfortably on the side of your neck. You will be asked to stick out your tongue, which will be held by the examiner with sterile gauze. An endoscope will then be slowly inserted towards the back of your mouth so that a video recording of your larynx (voice box) can be made. The endoscope is a straight blunt metal rod (about the diameter of a "pinky finger") with a tiny camera lens at the end. Neither the endoscope nor the Velcro strap will interfere with your breathing. You will say an "ee" sound and then the endoscope will be removed. The endoscope will be disinfected after each use. Based on the results of these tests, you may be deemed ineligible to participate. In such instances, you will be compensated for the time you participated at a prorated rate of $10 per hour.

If you are deemed eligible to participate, you will be asked to complete a questionnaire that focuses on your medical history which includes questions about your Parkinson's disease, general health, medications, and any speech and voice problems you may be experiencing. You may skip any question that you feel uncomfortable answering. We will also ask you to release a test score from your neurologist to us which indexes the severity of your Parkinson's disease. You do not need to agree to this release to participate in the study. In addition, you will undergo a brief heading screening which requires you to listen for tones and raise your hand when you hear the tone.

In addition, you will be asked to wear a microphone and perform a variety of speaking tasks including, but not limited to reading sentences, short passages, and/or citing a monologue. You will also be asked to perform different breathing exercises while wearing nose clips including breathing in and out as much as you can into a cardboard mouthpiece. The nose clips and mouthpiece are disposable and are thrown out after use. You will also be fitted with elasticized bands that are worn on the outside your clothing around your rib cage and abdomen. The bands do not impede your ability to breathe. We will ask you to breathe quietly, to breathe in and out as much air as you can, and to move your abdomen in and out. You will also be asked to talk about a topic of interest for several minutes. Lastly, we will place a mask over your mouth and nose. The mask will measure the air as it comes out of your mouth. A small tube will be placed between your lips and behind your teeth. It will not impede your ability to talk. We will ask you to read a sentence several times with the mask in place. The mask and tube will be disinfected after each use. You may take breaks as needed or cease participation at any time. You have just completed your pre-treatment lab session. You will be asked to perform these tasks again in week 4 (mid-treatment) and week 8 (end of treatment).

This is a research study that involves questions related to sensitive topics that may cause distress. As researchers, we do not provide mental health services and we will not be following up with you after this study. However, we want to provide every participant in this study with contact information for available clinical resources, should you decide you need assistance at any time. In a serious emergency, remember

that you can also call 911 for immediate assistance. The facilities identified below offers services to individuals who are not affiliated with UMass Amherst/Purdue University.

University of Massachusetts Amherst
Counseling and Psychological Health
127 Hills North
Amherst MA 01003
(413) 545-2337

Purdue University
Counseling and Psychological Services
601 Stadium Mall Drive, Room 224
West Lafayette, IN 47907-2052
(765) 494-6995

6. WHAT ARE MY BENEFITS OF BEING IN THIS STUDY?

If the therapy proves effective for you, you may benefit by improved speech loudness and intelligibility. In addition, your participation in the study will advance our knowledge of what treatment approaches may help alleviate the speech and voice problems commonly reported by individuals with Parkinson's disease.

7. WHAT ARE MY RISKS OF BEING IN THIS STUDY?

We believe there are minimal physical risks associated with this research study. A possible risk to you however, might include fatigue. To lower the risk of fatigue, you will have periods of rest throughout each laboratory session. You may also request a break at anytime. There is also a risk of a breach of confidentiality. To minimize this risk, you will be assigned a unique identifier which will be assigned to your records and collected voice samples. Your consent form, which contains identifying information, will be stored in a locked filing cabinet in a secured room, only accessible to key research personnel for a period of three years. After three years, all study records will be destroyed. Should a breach of confidentiality occur you will be immediately informed of the breach verbally and in writing.

The SpeechVive^{TM} device poses no risks to you. Its amplitude will only be adjusted by a member of the research team. The amplitude of the device cannot be turned up to a level which would cause hearing loss. The loudest level used on the device will be about as loud as a dog barking or a baby crying loudly. During the examination of the larynx, some people find that they gag temporarily if the endoscope touches the back of their tongue or throat. The sensation is similar to what you may have experienced while brushing your tongue with a tooth brush. In addition, there may be a remote chance of damage to teeth and dental work. A trained member of the research team will guide the endoscope using techniques designed to minimize this risk. The endoscope will be disinfected after each use. The audiometer headphones will be disinfected before and after you use them in order to minimize the slight risk that you will come into contact with substances such as bacteria. The nose clips and mouthpieces will be discarded after one use. The mask and tube will be disinfected after each use.

As a participant in this study, you will be asked to provide sensitive information about your physical and mental well-being and demographic data (age, gender, height, weight, race/ethnicity). You may refuse to answer any question without repercussion. There is a low psychological risk that you may be upset by some of the questions centered on health-related issues. We can provide you with a list of mental health professionals in your community, if this information would be helpful.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

The following procedures will be used to protect the confidentiality of your study records. The researchers will keep all study records in a locked file cabinet in a secure room accessible only to project staff. Electronic data files will be stored on a password protected computer in a secure room accessible only to project staff. Copies of all records will also be maintained on a HIPAA and HITECH compliant data sharing platform. All records will be labeled with a unique code. A master key which links participant names with their unique codes will be maintained in a separate and secure location accessible to key research personnel. The master key and data files will be destroyed 3 years after the close of the study. At the conclusion of this study, the

researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

9. WILL I RECEIVE ANY PAYMENT FOR TAKING PART IN THE STUDY?

You will receive eight weeks of voice treatment at no cost to you. In addition, you will be compensated $10/hour for each laboratory session you participate in.

10. EXTRA COSTS TO PARTICIPATE

There are no extra costs for you related to your participation in this study. Parking at (UMass Amherst/Purdue University) will be covered.

11. WHAT IF I HAVE QUESTIONS?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the researcher, Dr. Kelly Richardson, at (413) 545-2007. If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu.

12. CAN I STOP BEING IN THE STUDY?

You do not have to participate in this research project. If you agree to participate, you can withdraw your participation at any time without penalty. Please tell the experimenter if you wish to end your participation at any point in the study. If you wish to withdraw your records or data after you have completed your participation, please contact the primary investigator by phone, email, or writing.

13. WHAT IF I AM INJURED?

The University of Massachusetts does not have a program for compensating subjects for injury or complications related to human subjects' research. This does not waive any of my legal rights nor release any claim I might have based on negligence.

14. CONTACT INFORMATION

If you have any questions about this research project and/or scheduling, you may contact the principal investigator Dr. Kelly Richardson, UMass Amherst, at 413-545-2007 or by email krichardson@comdis.umass.edu. Or you may contact the co-investigator, Dr. Jessica Huber, Purdue University, at 765-494-3796 or by email at jhuber@purdue.edu. If you have any questions about your rights as a participant in a research project, or questions, concerns or complaints about the research and wish to speak with someone who is not a member of the research team, you should contact (anonymously, if you wish) the Human Research Protection Office at the University of Massachusetts Amherst at (413) 545-3428 or by mail at Human Research Protection Office, Mass Venture Center, 100 Venture Way, Suite 116, Hadley, MA 01035.

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