Clinical Impact of Respiratory-Swallow Training on Refractory Dysphagia in OP HNC

(1010498-19)

Agency: VA RR&D (Merit)

Principal Investigator/Study Chair: Bonnie Martin-Harris, PhD, CCC-SLP, BCS-S, ASHA Honors

Version #5

Participant Name:	**Date:**
Title of Study: **Clinical Impact of Respiratory-Swallow Training on Refractory Dysphagia in OP HNC**	
Principal Investigator: Dr. Bonnie Martin-Harris	

SUMMARY

The research is being conducted *to* determine the benefits, if any, of a respiratory-swallow training (RST) program on eating, drinking, health, and quality-of-life. Also, we will look at the usefulness of adding a home practice component to the RST. Both Veterans and Non-Veterans may participate in this study. It is estimated approximately 30% of the total participants enrolled will be non-Veterans, with the majority being Veterans. You are being asked to participate in this research study because you have been treated for oropharyngeal, oral cavity cancer, laryngeal, or hypopharyngeal head and neck cancer but continue to have swallowing problems despite previous swallowing therapy.

51 participants will be enrolled in this study so that 40 participants will be randomized. The overall duration of this study will be 5 years. Your participation is estimated to last approximately 7 – 8 months for 13-14 visits, which includes a possible one month of no intervention, one month of participation in RST and 3 follow-up visits at 1-month, 3-months, and 6-months. Each RST session lasts approximately 1-hour, with 2 sessions completed each week for 4 weeks (8 total).

If you agree to join the study, you will be asked to complete the following research procedures: Screening Procedures: You will need to pass a series of screening tests in order to move on to the experimental portion of the study. There are 2 groups of people involved, one group (study) that immediately starts RST, one group (control) who will wait one month to start RST. You may already be familiar with some of the screening tests.

Your participation will last for a total of 7-8 months depending on the group you are randomly assigned into. Benefits cannot be promised or guaranteed, but there may be some benefit from swallow study observations and/or participation in the RST program. Recommendations may be made for medical care or diet modifications based on observations by the speech-language pathologist.

The most common risks of participation are:
Likely
o Aspiration risk: When you eat and drink, there is a risk that foodstuffs may enter your windpipe (aspiration). During the swallow study, the speech-language pathologist will be able to see this if it happens. If a particular amount or thickness of food is prone to enter your windpipe, we will not use those types of foods or liquids during the experimental portion of the study. The small amounts of food or liquid used during the swallow study or during the experimental portion minimize any harmful effects, even if some enter your airway. Larger volumes of these foodstuffs entering the airway, or entering repeatedly, may cause a pneumonia.

Rare
o Radiation risk: You will receive a small additional radiation dose each time the swallow studies (MBSS) are completed. This dose is less than you receive each year from natural sources of radiation in the environment and is well below the levels that are thought to result in a significant risk of harmful effects.

o Questionnaires/surveys risk: Although not anticipated, you may experience discomfort due to the types of questions being asked. If this occurs, you do not have to answer all the questions.
o Loss of confidentiality or privacy risk: As with participation in any research study, there is a slight risk of loss of confidentiality. The investigators conducting this study will take steps to minimize this risk by recording data in ways that cannot be linked to you except by those conducting the study. Access to data that may identify you will be limited to the investigators conducting the study.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care. Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible.

Disclosure of New Information: If any significant new findings develop during the course of the research regarding the treatment of your swallowing problems or which may impact on your decision to continue to participate, the investigator will discuss them with you.

ALTERNATIVES: The alternative is for you to choose not to participate.

Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not included here. If you are interested in participating, a member of the study team will review the full information with you. You are free to not participate or stop participating at any time during or after the consenting process.

INTRODUCTION
You are being invited to participate in a research study that is being carried out at the Edward Hines Jr. VA Hospital. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. If you have any questions about your rights as a human research participant at any time before, during, or after participation, please contact the Institutional Review Board (IRB) at (708) 202-2811 for assistance. If you have questions about this study, you may contact the Principal Investigator, Dr. Bonnie Martin-Harris, 847-467-0407.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

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DESCRIPTION OF RESEARCH BY INVESTIGATOR

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand these principles that apply to all individuals who agree to participate in the research project below:

1. Taking part in the research is entirely voluntary.

2. You may not personally benefit from taking part in the research, but the knowledge obtained may help the health professionals caring for you better understand the disease/condition and how to treat it.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If, during your participation in the research project, new information becomes available concerning your condition (disease) or concerning better therapies which would affect your being in the research project, your doctor will discuss this new information with you and will help you make a decision about continuing in the research.

5. The purpose of the research, how it will be done, and what your part in the research will be, is described below. Also described are the risks, inconveniences, discomforts, and other important information, which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have been treated for oropharyngeal, oral cavity cancer, laryngeal, or hypopharyngeal head and neck cancer but continue to have swallowing problems despite previous swallowing therapy. With this research we hope to determine the benefits, if any, of a respiratory-swallow training (RST) program on eating, drinking, health, and quality-of-life. Also, we will look at the usefulness of adding a home practice component to the RST. Both Veterans and non-Veterans may participate in this study. It is estimated approximately 30% of the total participants enrolled will be non-Veterans, with the majority being Veterans.

51 participants will be enrolled in this study so that 40 participants will be randomized.

DURATION OF THE RESEARCH

The overall duration of this study will be 5 years. Your participation is estimated to last approximately 7 - 8 months for 13 visits, which includes a possible one month of no intervention, one month of participation in RST and 3 follow-up visits at 1-month, 3-months and 6-months. Each RST

session lasts approximately 1-hour, with 2 sessions completed each week for 4 weeks (8 total). This research study is expected to take approximately 6 years. Your individual participation in the project will take 7-8 months depending on the group you are randomized into.

STUDY PROCEDURES

At the time of your first study visit, this is what will happen:

- Study personnel will ask general history information including age, sex, smoking status, and alcohol use. This should take less than 5 minutes.
- Cognition screen – You will complete a brief screen of your thinking abilities called the Montreal Cognitive Assessment or MoCA.
- Breathing test (pulmonary function test, [PFT]) – You will blow into a machine while a technician records your airflow levels. This should. Take less than 10 minutes.
- Swallow study (modified barium swallow study [MBSS]) – This is an X-ray test that takes rapid pictures of movements of your mouth and throat while you eat and drink different volumes and textures of barium for a maximum of 12 swallows. Also, during the swallow study, your breathing will be measured using a nasal cannula that lies right inside your nose and elastic bands around your chest and stomach. This should take less than 30 minutes. Measures are collected later by the study team using images from the swallow study that are related to if what you eat and drink enter your airway or not, and how the structures in your mouth and throat move when you swallow to understand the nature of your swallowing problem.
- M.D. Anderson Dysphagia Inventory (MDADI) questionnaire – This is a 20-item questionnaire that evaluates the impact of your swallowing problem on your quality of life.
- Functional Oral Intake Scale (FOIS) – You will describe what foods and liquids you tolerate at home, and whether or not you have a feeding tube. Having a feeding tube does not disqualify you from participating in the study as long as you can tolerate at least one liquid consistency during your swallow study.
- Performance Status Scale for Head and Neck Cancer Patients (PSS-HN) – This is a 3-section questionnaire that evaluates the impact of your swallowing and speech difficulties.

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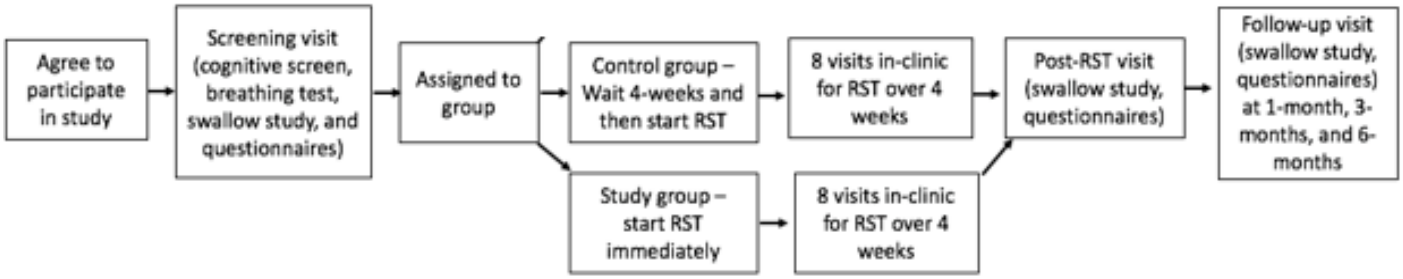

You will be able to participate in the experimental portion of the study if you do not have a severe lung disease, are able to drink some liquid, and can pass the cognitive screen.
If you decide to take part in this study, this is what will happen:

Screening procedures: You will need to pass a series of screening tests in order to move on to the experimental portion of the study. There are 2 groups of people involved, one group (study) that immediately starts RST, one group (control) who will wait one month to start RST. You may already be familiar with some of the screening tests.
At the time of your first study visit, this is what will happen:
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• Performance Status Scale for Head and Neck Cancer Patients (PSS-HN) – This is a 3-section questionnaire that evaluates the impact of your swallowing and speech difficulties.
You will be able to participate in the experimental portion of the study if you do not have a severe lung disease, are able to drink some liquid, and can pass the cognitive screen.

Randomization process: All eligible participants will be assigned to either the study group or control group by computer. Neither you nor the study team can choose which group you are in.

Cross-over process: If you are assigned to the control group, you will not receive any treatment for the first 4 weeks of the study. After 4 weeks, you will undergo an additional swallow study and then begin receiving the experimental RST program as outlined below.

Experimental procedures (RST): You will participate in clinic-based RST sessions with a speech-language pathologist. Initially, you will learn to identify an optimal breathing and swallowing pattern on printed cards. Next, you will learn how to perform an optimal breathing and swallowing pattern yourself. To do this, you will wear a device (a “transducer”) around your ribcage and a small microphone on your neck that connects to a computer that monitors your breathing and swallowing patterns. A training program on the monitor will provide you visual and auditory feedback related to your breathing and swallowing patterns. You will participate in 2 therapy sessions weekly for approximately 4 weeks (approximately 8 sessions). Each session will last less than 60 minutes. After the RST program is finished, you will complete the NASA Workload Index which is a 7-item scale to determine how hard the RST training was for you to complete.

<u>All of your clinic-based RST sessions will be videotaped.</u> This will be done using the front-facing camera located on the computer itself. These video recordings will be used to match up what the computer signals say about your breathing to what you are actually doing during those times as well for training purposes for study staff. These recordings will not be shared outside of Hines VA Hospital.

<u>Location of RST:</u> You have the choice of receiving the RST sessions either at the Hines VA or at the clinic at Northwestern University in Evanston, IL.

<u>Control Group Procedures:</u> For the first 4 weeks of the study, you will not have any treatment beyond what you have had to date. You will continue to use whatever skills have been taught for eating, drinking, and breathing earlier in your care for head and neck cancer. We will have a follow-up visit with you at the end of 4 weeks, and at that time, you will cross-over and be started on the RST program as described above. After the RST program is finished, you will then participate in the follow-up procedures described below.

Follow-Up Procedures: You will undergo the following procedures immediately after the RST portion of the study has ended (week 4 if you are in the study group or week 8 if you are in the control group), and then again at 1-month, 3-months, and 6-months after completing RST.

- Swallow study (modified barium swallow study, MBSS) – This is an X-ray test that takes rapid pictures of movements of your mouth and throat while you eat and drink different volumes and textures of barium for a maximum of 12 swallows. Also, during the swallow study, your breathing will be measured using a nasal cannula that lies right inside your nose and elastic bands around your chest and stomach. This should take less than 30 minutes. Measures are collected later by the study team using images from the swallow study that are related to if what you eat and drink enter your airway or not, and how the structures in your mouth and throat move when you swallow to understand the nature of your swallowing problem.

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Performance Status Scale for Head and Neck Cancer Patients (PSS-HN) – This is a 3-section questionnaire that evaluates the impact of your swallowing and speech difficulties.

POTENTIAL BENEFITS

We can't promise that you will get any benefits from taking part in this research study. However, the information we get from this study might help us treat future patients. Benefits cannot be promised or guaranteed, but there may be some benefit from swallow study observations and/or participation in the RST program. Recommendations may be made for medical care or diet modifications based on observations by the speech-language pathologist.

CONFIDENTIALITY

Protected Health Information and other study-relevant information will be collected for the study, including age, head and neck cancer diagnosis, and cancer treatment. Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Information published or presented about the results of the study will be in a form that does not identify any particular participant. In order to comply with federal regulations, records identifying you may be reviewed by the members of the research team, the representatives of the sponsor VA RR&D of this study, authorized representatives of the IRB, VA, Federal agencies, such as the Food and Drug Administration (FDA), the Office of Research Oversight (ORO), the Office for Human Research Protection (OHRP) and the Government Accounting Office (GAO) may have access to the records. By signing this document, you consent to such inspection.

Taking part in this study will involve collecting private information about you, including your Social Security Number. We are collecting Social Security numbers which is required to establish a chart to document study participation. This information will be protected in the following ways:

- All records are locked in filing cabinets, on computers protected with passwords, only the authorized study personnel will have access to this information.
- Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you, unless otherwise specified in the separate authorization form, "Consent for Production and use of Verbal or Written Statements, Photographs, Digital Images, and/or Video or Audio or Audio Recording by VA" (VA-10-3203).

The information collected for this study will be kept confidential. If you are a non-Veteran receiving clinical services (e.g., using the laboratory, radiology, audiology, etc.) as part of this study, an electronic medical record will be created for you. You will be given a VA Notice of Privacy Practices (NOPP), and we will ask you to sign an acknowledgement saying that you have received this notice.

There are times when we might have to show your records to other people. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration, (FDA), the Government Accounting Agency (GAO) or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as members of the Research Administration staff of Edward Hines Jr. VA. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all veteran and non-veteran research participants. By signing this document, you consent to such inspection.

This informed consent form does not give the study doctor permission to access, record, and use your private health information. You will be given a separate HIPAA form which provides more information about how your private health information will be used in this study, who will have access to your records, and how you can revoke (take back) your permission in the future. You will not be able to participate in this study if you do not sign the separate HIPAA authorization form.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:*

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

Payment Offered for Participation:

You will be compensated for your participation in the study to assist you with support of your time and travel. You will receive $40 for each swallow study and $30 for each RST session for a potential

maximum of $440 if you are assigned to the treatment group or a potential maximum of $480 if you are assigned to the control group. Payment will be made with a check within 4 weeks of completing a study visit. An IRS 1099 form will be issued to all participants who receive payments, as the compensation will be considered income.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

According to federal regulations (Title 38 CFR17.85), the VA will provide necessary medical treatment to you as a research participant if you are injured by participation in this research project approved by the Research & Development Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, this care will be provided at this VA facility.

This does not apply to treatment for injuries that result from non-compliance by you with study procedures.

Participation in this research may involve risks that are currently unforeseeable. According to the federal regulations, (Title 38 Code of Federal Regulations (CFR) 17.85), The VA will provide necessary medical treatment to you as a research subject if you are injured by participation in this research project. Except in limited circumstances, this care will be provided at this VA facility. This requirement does not apply to treatment for injuries that result from non-compliance by you with study procedures. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You have not released this institution from liability for negligence.
In case (If) there are any medical problems, complaints, concerns, or if you have questions about the research, you can call Dr. Martin-Harris at 847-467-0407 during the day, or after hours. Emergency and ongoing medical treatment will be provided as needed.

Additionally, if you have any questions about the research; **your rights as a research subject; you want to discuss problems with the research process; offer input or have other concerns;** you may contact/call the Chairperson of the Institutional Review Board (IRB) or the IRB Administrative Office at: 708-202-2811.

A description of this clinical trial will be available on http://www.clinicaltrials.gov (NCT03377270) as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctors or other staff, and it will not affect the usual care that you receive as a patient.

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Participation is voluntary and the participant (you) can withdraw from the study at any time. You do not have to take part in this study and refusal to participate will involve no penalty, consequences, or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty, consequences, or loss of VA benefits. The investigator may withdrawal you from the study if you are unwilling or unable to follow study procedures or have worsening breathing problems, lung disease, or pneumonia

If you choose to withdraw after consenting or participating in some of the research activities, the data already collected to your withdrawal, the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data.

SIGNIFICANT NEW FINDINGS

Disclosure of New Information: If any significant new findings develop during the course of the research regarding the treatment of your swallowing problems or which may impact on your decision to continue to participate, the investigator will discuss them with you. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your study doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your study doctor could also decide it to be in your best interests to withdraw you from the study. If so, they will explain the reasons and arrange for your usual medical care to continue.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

If you are not able to meet the inclusion criteria, complete the RST goals, or maintain follow-up appointments to complete participation the study investigator maintains the right to terminate your participation.

FUTURE USE OF DATA OR SPECIMEN

- Your de-identified data collected as a part of this research study may be used for future research studies without an additional informed consent.
    - The data will be stored on secured servers at the Hines VA and Northwestern University.
    - Only IRB-approved study personnel will have access this data.

CLINICALLY RELEVANT RESEARCH RESULTS

- Results will not be shared with participants

ADDITIONAL CONTACT INFORMATION

If at any time before, during or after your participation in this study you have questions or concerns, want to get additional information, lodge a complaint, or offer your input with a person who is not part of the study team, you can contact the IRB Administrator at 708-202-2811.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____ _____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.
By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of Person Obtaining consent	_____ Signature of Person Obtaining Consent	_____ Date