Pilot Study to Improve Therapeutic Outcomes for Dysphagia After Radiation Therapy

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Consent to Participate in Research Study
Pilot Study to Improve Therapeutic Outcomes for Dysphagia after Radiation Therapy

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Sponsor: The Stout Family Endowment to the Eye & Ear Foundation will be provide the IOPI devices being used in this research.

What is the purpose of this study? You are being invited to participate in a research study because you had radiation therapy and now are having difficulty swallowing. This form describes a research study this hospital is doing. The purpose of this study is to see if doing certain exercises will help people swallow better. You are being invited to participate in the study because we want to learn more about the way to help people swallow without choking or breathing food or liquids into their lungs. Individuals who decide to participate in this research will be enrolled into one of two groups in an alternating fashion. 100 men and women who are 18 years and older will be enrolled into this study.

Your participation in this research is voluntary.

Whether you participate in this study is completely up to you to decide. You do not have to participate in order to get treatment for your swallowing difficulties. If you decide to participate, you may change your mind at any time. Before agreeing to participate in this study, let us read this form with you. Then, please ask any questions you have.

How long will the study last? The study will last about 8 weeks for most individuals, (but could potentially last for up to 16 weeks), and will take place during your regularly scheduled clinical visits related to your swallowing problem.

What does the study involve? You physician has decided that you may benefit from therapy designed to help with your swallowing difficulties. If you decide to participate, you will be assigned to one of two therapy groups.

Group 1: Standard Swallowing Therapy.
Your research participation will consist of two visits, 8 weeks apart that will be conducted at your regular clinical visits. If you are in this group, you will receive standard therapy for your swallowing problems. Standard therapy is the non-research treatment you would receive during regular (non-research) clinical care. Standard therapy is not experimental but the information from your therapy will be used for research purposes. Standard therapy is tailor made to each individual. Your clinicians will take information from your swallowing evaluations to create the best swallowing therapy program for you. This could include changes in your posture, different swallowing techniques such as multiple swallows or something called liquid wash. Changes in your diet may also be a part of the swallowing therapy. The goal of therapy is to increase strength and endurance over the 8 week period. The interventions that were found most helpful on your swallowing exam will be emphasized during these 8 weeks.

Crossover Arm: If, at the end of your 8 weeks of standard therapy, you and your clinician determine that you need additional swallowing therapy, you will be given the opportunity to participate in the "crossover arm" of this research. This would involve you undergoing the same therapy program as the individuals in group 2, which involves the additional use of a tongue strengthening device called the Iowa Oral Performance Instrument (IOPI). (please see the detailed description below under "Group 2" and *Tongue Press Exercises and Diary Documentation*) If you participate in the crossover arm, your study participation would include 3 visits in total and your overall participation time would be approximately 16 weeks.

Group 2: standard swallowing therapy **and** tongue press exercises.
Your research participation will consist of two visits, 8 weeks apart that will be conducted at your regular clinical visits. If you are in this group, you will receive the same standard swallowing therapy that we just described for group 1, but you will also be asked to do tongue press exercises at home during the 8 weeks. The tongue press exercises are considered experimental. All data collected from routine care and the tongue press exercises may be used for research purposes.

Tongue Press Exercises and Diary documentation: The tongue press exercise consists of pressing a sensor between your tongue and the roof of your mouth. The exercise device is called the Iowa Oral Performance Instrument (IOPI). The IOPI is an FDA registered medical device. This device will measure the amount of "squeeze" between your tongue and the roof of your mouth. The IOPI will indicate when you have hit your target value by displaying green lights. You will press on the sensor with your whole tongue (front and back), reach the target pressure, hold it for 3 seconds, then relax. You will take the IOPI home with you and do 10 repetitions of the exercise, three times a day on three specified days per week for 8 weeks. You will be given an instruction packet to help you to remember which days you are to be performing the exercises. It will take approximately 30 minutes to be trained on how to perform the exercises properly as well as how to record the exercises properly in the diary that will be provided to you. It will take approximately 5–10 minutes to complete 30 repetitions of the exercise.

Both Groups:

Swallowing Questionnaire: You will be asked to complete a questionnaire asking you to rate your swallowing problem. This will take less than a minute. We will ask you to complete this questionnaire before you begin therapy and approximately 8 weeks later when you return to the office after completing your therapy.

Dietary Questionnaire: You will be asked to complete a questionnaire related to the food and liquids that you eat to help rate your swallowing problem. This will take 5-10 minutes. We will ask you specific questions to help the research staff to complete this questionnaire both before you begin therapy and approximately 8 weeks later when you return to the office after completing your therapy.

What are the risks of this study?

Tongue Exercises: You may experience some tongue or jaw soreness as result of the exercises. Adjustment in target pressure value will be made as needed to decrease discomfort.

Questionnaires: There may be questions that make you uncomfortable. Please understand that you may skip any questions that you do not wish to answer.

Breach of Confidentiality: All records will be maintained in a secured site and / or on password protected computer drives, but just as with the use of your medical information for health care purposes, we cannot guarantee its confidentiality. A copy of this consent will be kept with other study materials in the Department of Otolaryngology.

What are the expected benefits of the study?

It is possible that you may receive medical benefit for participating in this research. The experimental group (Group 2 and/or the Crossover Arm) may see an accelerated improvement in their swallowing function as a result of their participation. However, this cannot be guaranteed. Your participation may also help the study team learn if these types of exercises can help people with swallowing difficulties to

swallow more safely.

What are the other treatments available? If you decide not to participate in the study, you will receive standard therapy treatment for your swallowing problem.

What if I am injured as a result of participation? If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Are there any financial considerations? There will be no additional costs or payments associated with your participation in this research project. The IOPI device will be provided to research participants at no cost, if you were assigned to that group. It will also be provided to those research participants who would like to use it for an additional period of 8 weeks who were originally assigned to the "therapy only" group.
Please understand that the IOPI device MUST be returned to the clinical/research staff at UPMC when your research participation has been completed. You will be responsible for compensation, if the device is not returned.

What are the uses of the research results? The information from this study will be published in professional journals. You will not be identified as being in the study. All the information we learn about you will be stored at a secured site and / or on password protected computer drives.

Who will know about my participation in this study? Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance). (4) University of Pittsburgh Research Conduct and Compliance Office may access identifiable information related to participation for purposes of monitoring the conduct of this study. (5) An order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study? It is a University of Pittsburgh policy that all research records be maintained for 7 years following final reporting or publication of a project, although records can be kept indefinitely.

Medical Record Review: This research study will involve the recording of past, current, and/or future identifiable (pertaining to only you) medical information from your hospital and/or other health care provider (e.g. physician office) records. This information that will be recorded will be limited to information concerning your clinical care (e.g. diagnostic information, medications, medical history, dietary or other strategies utilized for your care). This information will be used to determine your eligibility for this study and to follow your response once you are enrolled in the study.

This research study will result in identifiable information that will be placed into your medical records held at UPMC and the UPMC Cancer Centers. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes your swallowing response to the study, including adverse events (side effects).

May I withdraw, at a future date, my consent for participation in this research study? You may withdraw at any time your consent for participation in this research study. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. If you decide to withdraw from the study, you will be asked to sign a form indicating that your data may remain on record with an anonymous listing (i.e. will not be possible to link the data to their identity) or that you would like all data completely removed. Should you choose to withdraw, you must submit a letter to the principal investigator indicating your desire to withdraw.

It is possible that a member of the research staff may remove you from participation in this research if it is determined that you clinically do not need swallowing therapy or if it is determined that you are unable to complete any portion of this research safely.

Please remember that your care will not be influenced by your decision about this study. If you decide not to participate, you will get the best therapy known at this time.

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VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions, which I have about my rights as a research participant, will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____ _____

Printed Name of Participant Date

_____

Participant's Signature

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Signature of Investigator or Person Obtaining Consent Date

_____ _____

Printed Name of Investigator or Person Obtaining Consent Role in Research Study