Interventions for Patients With Alzheimer's Disease and Dysphagia

NCT03682081

5/28/2024

UNIVERSITY OF WISCONSIN-MADISON

Research Participant Information and Consent Form

Title of the Study: Lingual Strengthening in Patients with Memory Loss

Principal Investigator: Dr. Nicole Rogus-Pulia, phone: (608) 256-1901 extension 11697

DESCRIPTION OF THE RESEARCH

You are invited to participate in this research study about improving swallow problems for people with memory problems. This study will help determine if performing tongue press exercises and using a saliva substitute improve swallowing ability in people with memory problems.

You have been asked to participate because you are a caregiver for someone who has been diagnosed with memory issues and may also have swallowing problems.

This study is being done at the University of Wisconsin-Madison (UW-Madison) and the William S. Middleton Memorial Veterans Hospital (Madison VA). A total of about 120 patients and 120 caregivers will participate in this study.

Funding for this study is provided by the National Institute on Aging.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research you will be asked to complete surveys about your role as a caretaker and demographic information with a member of the research team on the day the person you care for is enrolled in the study. This will take about 30 minutes. If the person you care for is determined to have swallowing problems, you and the person you care for will then be randomized to one of four study groups.

Each study group will have a different type of swallowing therapy for 8 weeks. The type of therapy the person you care for will receive depends upon which group is assigned. You may need to assist the person you care for with the therapy. The assignment to a group will be done randomly, like flipping a coin (by computer), meaning that assignment to each group is equally likely. You will complete follow-up surveys again at the in-person follow-up visit of the person you care for that will take 30 minutes.

Dual Enrollment: If you and your study partner are enrolled in this study **and** the SSBL SPHERE study within the same 6-month period, you will not have to repeat the surveys previously completed as part of this study. Instead, the study team will count your responses on one set of surveys for both studies, to reduce the time and burden of repeating the same surveys.

Group 1: Standard Swallowing Therapies: Participants in this group will receive standard therapy for swallowing problems. Standard therapy is the non-research treatment patients would receive during regular (non-research) clinical care. Standard therapy is not experimental. This therapy may include: 1) modifying the foods your loved one eats or the fluids they drink; 2) changing their posture when they eat or drink (for example, by a simple chin tuck) or using a maneuver taught by their therapist (for example, holding their breath, swallowing, then coughing); 3) having them eat more slowly or in a quiet environment to make swallowing easier and safer; or 4) asking them to perform range of motion or vocal exercises for speech and/or swallowing.

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Group 2: Saliva substitute: Participants assigned to this group will receive the same swallowing therapy that we just described for Group 1 but will also be provided with a saliva substitute, Biotene® Oral Balance Gel. Participants will apply approximately 1 cm of gel with a finger to your tongue and mouth three times a day for 8 weeks.

Group 3: Tongue press exercises: Participants in this group will receive the same swallowing therapy that we just described for group 1, but will also be asked to do tongue press exercises at home for up to 8 weeks. The tongue press exercises are considered experimental.

Tongue Press Exercises: The tongue press exercise consists of pressing a sensor between the tongue and the roof of mouth. A pressure measuring machine called the Iowa Oral Performance Instrument (IOPI) will read the pressure (measuring the amount of squeeze) between the tongue and the roof of mouth. Participants will be given a target pressure value to aim for when doing the exercises. Participants will take the IOPI device home and do 20 repetitions of the exercise (10 for front, 10 for back), three times a day on three days per week for 8 weeks. It will take approximately 10 minutes to complete 20 repetitions of the exercise - so about 30 minutes total on the days that exercise is performed.

Group 4: Saliva substitute plus tongue press exercises: Participants assigned to this group will perform the tongue press exercises with the IOPI as described above. Participants will also be provided with the Biotene® Oral Balance Gel to apply to their tongue and mouth three times per day.

All Groups: Regardless of which group participants are in, participants will be asked to come to the hospital up to 2 times total. These visits will be scheduled once at the beginning of the study (week 1) and at the end of the study (week 8).

At each visit, here is what you will be asked to do:

Baseline Visit:

You will be asked to complete surveys about your demographic information and your role as a caretaker, which include questions about the activities you perform and burdens you experience as a caretaker. You will then be randomized to a treatment group.

If assigned to a group that uses Biotene, you will be given a tube of Biotene oral gel and instructed on how to help the individual you care for use it during the first week of the study.

If assigned to the treatment group that uses tongue strengthening, a member of the study team will show you how to use the Iowa Oral Performance Instrument (IOPI), the tongue strengthening device that the person you care for will use to exercise their tongue during the next 8 weeks. You may need to assist with these exercises if the person you care for needs help. This visit will take approximately 1.5 hours to complete, not including time spent for clinical care such as the swallow study and consultation with the clinician.

Telephone visits:

A member of the study team will call you or set up a WebEx meeting throughout the duration of the study to see how the individual you care for are doing. If you are in a group that did tongue press

exercises, the tongue strength of the person you care for will be re-measured, which you may need to help with if the person you care for needs assistance.

Follow-up assessments will take place at 7 days, 14 days, 28 days, and 42 days following randomization. These phone or WebEx calls will take approximately 20 minutes. Ninety days and 180 days following randomization, we will call to ask about any hospitalizations or incidences of pneumonia that the person you care for has experienced. Additionally, 180 days following randomization, we will send you and the person you care for surveys to be mailed back in.

Week 8 Visit (Final):

You and the individual you care for will return to the clinic after 8 weeks. You will fill out some additional surveys about your role as a caretaker, which include questions about the activities you perform and burdens you experience as a caretaker. This visit will take about an hour to complete, not including time spent for clinical care.

We are requesting your email address so we can communicate with you about this study and perform follow up visits via WebEx. Communicating via email and using WebEx for the follow up visits is optional. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. You do not have to provide your email address to participate in this study.

HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?

We have strict rules to protect your personal information. We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information or biospecimens that may identify you in a legal proceeding or in response to a legal request without your consent. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission. However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring the safety of this study. We will also share data that has been de-identified with collaborators who will use it to validate a survey instrument included in this study.

Who at UW-Madison can use my information?

Members of the UW-Madison research team
UW-Madison regulatory and research oversight boards and offices

Who outside the UW-Madison may receive my information?

U.S. Office for Human Research Protections
Food and Drug Administration (FDA)
The study sponsor, National Institute of Aging
Researchers at other universities who study swallowing
Qualitative Health Research Consultants (QHRC)

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

Will information from this study go in my medical record?

None of the information we collect from you will go in the medical record.
Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form. However, once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for reasons other than the ones described in this form, such as a research study about another kind of disease. It also means that the information could be shared with researchers working at institutions that are not listed above.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. Let the researchers know if you choose to leave the study. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

By signing this form you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. The data collected will be kept indefinitely. This may be linked to other data sources in the future to answer other research questions related to transitional care. You may withdraw your permission at any time by writing to the person whose name is listed below:

Nicole Rogus-Pulia
Williams S. Middleton VA Hospital
GRECC (11G), Room D4240
2500 Overlook Terrace
Madison, WI 53705

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

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If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

ARE THERE ANY RISKS TO ME?

There is a risk that your information could become known to someone not involved in this study.

ARE THERE ANY BENEFITS TO ME?

You are not expected to benefit directly from participating in this study. Your participation in this research study may benefit other people in the future by helping us learn more about how to improve care for patients who have memory and swallowing problems.

Will being in this study cost me anything?
There will be no cost to you for the study visits that are part of this research study.

Will I be paid or receive anything for being in this study?
You will receive $50 for each in-person assessment (baseline, 8 weeks). You will receive $5 for the follow up phone calls and the 180-day follow-up phone call with surveys (total of $125 for full participation).

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS?

You may ask any questions about the research at any time. If you have questions about the research after you leave today you should contact the study coordinator at (608) 262-9995 or the Principal Investigator, Dr. Nicole Pulia at (608) 256-1901 extension 11697. "If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems."

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OTHER RESEARCH OPPORTUNITIES

You may be eligible for other research opportunities within the Swallowing and Salivary Bioscience Lab (SSBL) or with other researchers collaborating with the SSBL. Please indicate below if you would like to be contacted about other research opportunities you may be eligible for.

_____YES, I would like to be contacted about other research opportunities

_____NO, I would NOT like to be contacted about other research opportunities

AGREEMENT TO PARTICIPATE IN THIS STUDY AND PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use my health information as described above.

Name of Caregiver Participant (printed):_____

_____ _____
Signature Date

Name of person obtaining consent (printed):_____

_____ _____
Signature Date

****You will receive a copy of this form****