

Study Title: Treatments of Acquired Apraxia of Speech

NCT #: NCT01483807

Document: Consent Document

Date of consent approval by IRB: November 22, 2015

Participant Name: _____ Date: _____

Title of Study: Treatments of Acquired Apraxia of Speech

Principal Investigator: Julie L. Wambaugh, PhD. VAMC: Salt Lake City (660)Consent Version Date: November 18, 2015

Sponsor Name: _____

DESCRIPTION OF RESEARCH BY INVESTIGATOR: The purpose of this study is to test the application of Sound Production Treatment (SPT) utilizing blocked practice (for example, all words that begin with /b/ are practiced then all words that begin with /g/ are practiced) and random practice (for example, all treatment words are practiced in random order). SPT is a type of therapy for apraxia of speech, a speech disorder resulting from damage to the brain, specifically to the part of the brain that controls the planning of articulation for speech. Apraxia of speech is considered to represent a breakdown in communication between the brain and the speech articulators (e.g., tongue, lips), so that speech sounds are not produced as intended by the speaker. SPT has been found to improve speech production skills with persons with apraxia of speech. More research is needed to determine if blocked practice will benefit a person's speech production differently than random practice.

TO POTENTIAL PARTICIPANTS: Federal regulations require written informed consent before participation in a research study. This is to be certain that research participants know the nature and risks of the study, as they make a decision to take part or not. You are asked to read the following information and discuss it with the investigator, so that you will be fully informed about this research study and how it may affect you. Your signature on this form means that you have been fully informed and that you freely give your consent to participate.

BACKGROUND: You are being asked to take part in a research study being carried out by Dr. Julie Wambaugh of the VA Salt Lake City Health Care System. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you volunteer to take part in this research study. The therapy being studied in this investigation, Sound Production Treatment was designed to help persons with apraxia of speech improve the accuracy of speech production. Specifically, patients are asked to repeat modeled words, phrases, and/or sentences with cues provided as necessary for correct production. The cueing steps include: minimal pair contrast, integral stimulation, articulatory placement cueing, and feedback. Steps provided are based on a response-contingent hierarchy (i.e., steps are applied only as needed). The length of your participation will be about 8 months, which will involve 3 sessions per week, each lasting 1 hour for the majority of the study.

STUDY PROCEDURES: As part of the study, you will be asked to take several speech and language tests and a hearing test at the start of therapy. You will also be asked to talk with project staff about common topics and pictures so that Dr. Wambaugh can listen to your everyday speech and language. After testing, you will receive individual speech therapy in which you will be asked to practice producing words, phrases, and/or sentences. The therapy that you will receive is considered to be accepted clinical practice.

After therapy ends, you will again be asked to take several speech and language tests. Additionally, at 2, 6, and 10 weeks following the end of therapy, you will be asked to produce words, phrases, and/or sentences again.

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Institutional Review Board
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Treatment will take place either at the Salt Lake City VA Medical Center or in your home. You will receive therapy from a certified speech- language pathologist. All sessions will be audio-recorded. Part of the experimental design used in this study is called a *single-subject design*. This type of design is often used when a treatment is in the early stages of testing because it allows for precise study of treatment effects and does not require large numbers of subjects to draw conclusions.

Each individual subject serves as his or her own control. Additional subjects allow for additional control. The design requires repeated measurement of the speech behaviors of interest before the start of treatment. After the behaviors are shown to be stable, changes that occur with treatment can be attributed to the therapy.

At the end of the study, additional therapy (individual or group) *may* be available to you, at the Salt Lake City VA Medical Center, free of charge. This will depend upon how much time the project staff has available and if your remaining speech/language problems are likely to benefit from additional therapy, as determined by Dr. Wambaugh. This therapy will be conducted by either a project staff member who is clinically certified or by a master's level clinician who is completing his/her clinical training (supervised by a certified staff clinician).

RISKS: It is possible that you may become tired or frustrated while taking part in this study. Otherwise, there are no known risks to you from any of the procedures. If you do become tired or frustrated, you should tell the staff member working with you so that you can take a break or discontinue your participation.

BENEFITS: You may benefit from this study by improving your speech production skills and/or accuracy. However, we cannot promise this benefit. Others may benefit from your part in this study, in that the results may help the researchers to learn for whom treatment is or is not effective and also to develop more effective treatments.

ALTERNATIVE PROCEDURES: There are other training programs for the kind of communication problem that you have. The most effective therapies for treating apraxia of speech after brain-injury are not known at this time. Not participating in this research study is also an option.

CONFIDENTIALITY: The results of this study may be presented at scientific meetings or published in professional journals. Your name and any other identifying information will not be revealed in any such presentation or publication. We will keep all research records that identify you private to the extent allowed by law. However, representatives from the Research Service at the VA Medical Center, and VA Rehabilitation Research and Development may inspect and/or copy the records that identify you. Your name will not be used on any records (e.g., test forms, computer files, tapes, etc.). You will be identified by a letter-number combination (e.g., A1) and only Dr. Wambaugh and her professional staff (speech pathologists) will be able to see a "key" which links your name to your "id" number. Records about you will be kept in locked filing cabinets or on computers



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protected with passwords. Your social security number will be requested for travel reimbursement. You can withhold your social security number and still participate. All information about this study will be kept in locked filing cabinets and secure-password protected computer system in the Aphasia/Apraxia of Speech Research Laboratory at the VA Salt Lake City Health Care System. At the end of the study all computer files will be stored onto disks. All paper files, disk, and tapes will be stored by Dr. Wambaugh at the Aphasia/Apraxia of Speech Research Laboratory according to the VA records control schedule. We will do everything we can to keep your records private, but cannot guarantee this.

Representatives from the Department of Veterans Affairs may inspect and/or copy the records that identify you. We will do everything we can to keep your records private, but cannot guarantee this.

PERSON TO CONTACT: If you have questions, complaints or concerns about this study, or if you think you may have been injured from being in this study, you can contact Dr. Wambaugh at 801-582-1565 ext. 1363 (9am to 4pm) or 801-942-0893 after work hours.

INSTITUTIONAL REVIEW BOARD: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

MEDICAL TREATMENT OR COMPENSATION FOR INJURY: The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

VOLUNTARY PARTICIPATION: You do not have to take part in this study. Your participation is voluntary and your refusal to participate will involve no penalty or loss of rights or benefits to which you are entitled. You may withdraw anytime from this study or refuse to participate in parts of the study without penalty or loss of rights or benefits. You do not need to give a reason if you decide not to participate or want to withdraw after you have agreed to participate. If you do wish to withdraw from the study, you should tell the speech pathologist working with you that you no longer want to participate and your participation will be ended.



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UNFORESEEABLE RISKS: In addition to the risks listed above, you may experience a previously unknown risk or side effect.

RIGHT OF INVESTIGATOR TO WITHDRAW: The investigator can withdraw you without your approval if you are hospitalized for an extended period of time or if any additional neurological events occur that may affect your communication ability.

COSTS TO PARTICIPANTS AND COMPENSATION: You will not receive any payment for participating in this research. You may be reimbursed for your travel costs to the VA hospital from your residence in Salt Lake City or surrounding region at the current federal government rate (for example, the present rate is 56.5 cents per mile; you may ask your therapist what the current rate is at any time). Reimbursement will be provided at your request. You will merely need to tell your therapist how many miles you travel to and from the VA Salt Lake City Medical Center and she will keep track of the number of visits that you make and submit the travel reimbursement once per month. If you do not reside in the vicinity of Salt Lake City and choose to temporarily reside in this area to receive this treatment, you will not be reimbursed for any food, lodging, or moving costs. Your reimbursement will be limited to travel costs to and from your temporary residence and the VA Salt Lake City Medical Center. A veteran participant will not be required to pay for care and services (treatment) received as a participant in a VA research project. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

NEW INFORMATION: You will be provided with any new information that develops during the study that may affect your desire to participate.

NUMBER OF PARTICIPANTS: There will 32 brain-injured patients participating in this project.

RESEARCH PARTICIPANTS' RIGHTS

I have read or have had read to me all of the preceding information. Dr./Mr./Ms.

_____ has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but I will not be identified in publications by name, photograph, or other identifiers. My records, including my name and results of my participation, may be revealed as required by laws and regulations of state



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and federal agencies. A copy of this consent form will be filed in my medical record chart at the VA Salt Lake City Health Care System.

If I have any questions about this study or if any problems arise during the study, I can call:

Dr. Julie Wambaugh at 801-582-1565 ext. 1363 DURING THE DAY and Dr. Julie Wambaugh at 801-942-0893 AFTER HOURS. If any medical problems occur in connection with this study, the VA Salt Lake City Health Care System will provide emergency care.

If I have concerns or questions about this research study that the investigator has not answered, I can contact an official of the Institutional Review Board for Human Studies by calling 801-581-3655 or the VA Salt Lake City Health Care System Research Compliance Officer at 801-584-1271.

I am aware of my rights as a participant, and I voluntarily consent to participate in this study. I confirm that I have read this consent and authorization document which explains what this study is about and how and why it is being done. I will receive a signed consent form or a photocopy of it.

I agree to participate in this research study as you have explained in this document.

_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date



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WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

- ☐ The participant is illiterate
- ☐ The participant is visually impaired
- ☐ The participant is physically unable to sign the consent form. Please describe:

☐ Other (please specify):

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

Name of Witness

Signature of Witness

Date

