

O0958-M

Treatment of Emotional Prosodic Disorders in
Parkinson's Disease

NCT01956266

June 26, 2014



Subject Name: _____ Date _____

Title of Study: Treatment of Emotional Prosodic Disorders in Parkinson's Disease

Principal Investigator: Susan A. Leon, PhD, CCC-SLP VAMC: North Florida/South Georgia Veterans Health System



INFORMED CONSENT FORM
to Participate in Research



INTRODUCTION

Name of person seeking your consent: _____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any VA or other benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, concerns, complaints, wish to discuss problems or talk to someone independent of the research staff, obtain information, or offer input, please call either of the following offices: (1) the University of Florida Institutional Review Board (IRB) office at (352) 273-9600; or (2) the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 374-6069.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")



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For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

Treatment of Emotional Prosodic Disorders in Parkinson's Disease

3. Who can you call if you have questions concerns, or complaints about this research study?

Principal Investigator: Susan A. Leon, PhD

Phone numbers: (352) 376-1611 x 5059

(352) 284-1903

4. Who is paying for this research study?

The primary sponsor of this study is the Department of Veteran Affairs Rehabilitation Research and Development Service. The University of Florida, Department of Neurology is providing funds to compensate study participants.

5. Why is this research study being done?

The purpose of this research study is to compare two treatments for deficits in prosody resulting from Parkinson's disease (PD). Prosody includes the pitch, loudness and rate a person uses when speaking. PD often affects prosody and can result in difficulty controlling or changing pitch, loudness and rate when speaking which can make the person with PD's voice sound flat or without as much variation. Both treatments directly address these deficits but use different methods. All treatment will be provided by the Principal Investigator, Dr. Leon, who is a licensed and clinically certified speech-language pathologist (CCC-SLP).



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You have been asked to be in this research study because you are an adult who has been diagnosed with Parkinson's disease.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Normal clinical care is medical or other treatment or services that you would receive even if you did not participate in this research study.

This is a research study and will not affect your normal clinical care. Parts of our evaluation are sometimes used in clinical settings (for example neuropsychological tests or dysarthria assessment) but we are only conducting these evaluations for the purpose of this research.

7. What will be done only because you are in this research study?

During your initial testing session we will perform the following assessments:

Dysarthria Testing:

You will be asked to repeat sounds, words, or phrases or to make simple movements with your mouth (for instance, showing how to blow out a match).

Speech Intelligibility Testing:

You will be asked to read sentences that will increase in length.

With your permission, this will be audio recorded so that the investigator can have other trained speech pathologists rate how well they are able to understand each of the sentences you read. We will always inform you when we start or stop any recording. The recordings will not identify you by name and will be stored on a VA share drive that is password protected. When we complete this form, you will be given another form on which you can indicate whether you give permission to be audiotaped.

Tests of recognition and expression of emotional tones of voice and facial expression:

You will be shown pictures of faces showing different emotional expressions (for example sad or happy) and asked to name the emotional expression. Similarly, you will hear words or sentences spoken using differing emotional tones of voice and be asked to name the emotion expressed by the tone of voice. You will then be asked to



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imitate some of the emotional expressions or tones of voice. You will also be asked to briefly describe some pictures and then to give them a rating from 1 to 7 for how pleasant or unpleasant you felt the picture was and the intensity of the picture.

With your permission, this will be audio and video recorded so that the investigator can later have trained judges rate the accuracy and intensity of the tones of voice produced by all the participants. We will always inform you when we start or stop any audio recording. The recordings will not identify you by name and will be stored on a VA share drive that is password protected. When we complete this form, you will be given another form on which you will indicate whether you give permission to be audio taped.

Questionnaires and Assessments:

1. Montreal Cognitive Assessment – this screening tool assesses memory and thinking.
2. Tasks of verbal memory including digit span where you will be asked to repeat numbers, and a task of letter-number sequencing.
3. Beck Depression Inventory – II (BDI-2) this questionnaire asks questions about symptoms of depression.
4. Lille Apathy Rating scale – this questionnaire assesses your interest and motivation in engaging in social and daily activities.
5. Toronto Alexithymia Scale – 20 – this questionnaire assesses how strongly you understand and experience emotions.
6. Interpersonal Reactivity Index – this questionannaire assesses how much empathy you may feel in different common situations (for instance, while watching a sad movie).
7. The Parkinson's Disease Quality of Life Index- this questionnaire assesses the impact Parkinson's disease symptoms may have on your daily life and activities.
- 8.

If you are experiencing symptoms of depression, we recommend you follow up for treatment with your Primary Care Physician as soon as possible.

If your performance on the initial tests indicates that you are eligible to participate in this study, you will return for another session where you will be asked to read approximately 100 sentences aloud and your responses will be audio recorded for later analysis by trained judges. There will then be a four week break. After the break you will return and again read the same sentences. You will then be randomly assigned to one of two treatment groups and will receive 8 sessions of treatment over three weeks. These will be scheduled at your convenience with 2-3 sessions in each week. However, only one treatment session per day is permitted. At the end of the 8



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treatment sessions, we will again have a session to do the testing described in question 7, and a session in which you will read the list of sentences aloud.

There will be another four week break, after which you will return for a final visit to read the sentences aloud again. If you are eligible and complete all visits, there will be a total of 14 visits involved in this study. Pre- and post-treatment testing sessions will last approximately 60-90 minutes. If at any time you need a break or rest period, we will take a break and will have light refreshments on hand as well for these longer testing sessions. Outcome measure administration (reading the list of approximately 100 sentences) and all treatment sessions will each be approximately 30-45 minutes long.

All of your answers to these questionnaires and surveys, along with all of your other research data, will be kept in strict confidentiality.

The Principal Investigator listed in question 3 of this form will monitor how you do during the research. If you have any questions about the research procedures now or at any time during the study, please contact Dr. Leon at the numbers listed in question 3 of this form.

8. How long will you be in this research study?

Your participation in this study may last up to 4 months. If you agree to participate after we have gone through all the information on this form and sign the consent form, we will do the initial testing described in question 7 above.

9. How many people are expected to take part in this research study?

Up to 58 people may take part in this study.

**WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND
WHAT ARE YOUR OPTIONS?**

10. What are the possible discomforts and risks from taking part in this research study?



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There is the potential risk of accidental exposure of confidential research data. All researchers involved in this study have received training to minimize this risk as much as possible.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

Other possible risks to you may include: fatigue, anxiety or embarrassment related to difficulty performing some or all of the tasks. You may also experience difficulty with keeping some of your appointments over the four month span of the study. We will work with you and reschedule appointments as needed. Another possible risk is that while the treatment may be beneficial for some participants, it is possible that it may not benefit you.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform Dr. Leon before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

If you wish to discuss the risks or discomforts described above or any discomforts you may experience, please ask questions now or call Dr. Leon at the numbers listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study?

It is possible that the treatment will improve your ability to control the prosodic aspect of your speaking. However, it is also possible that you will not benefit from treatment.

11b. How could others possibly benefit from this study?



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This research has the potential to help improve treatment strategies for the disorders of speech prosody that often affect individuals with PD.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, Dr. Leon, the Principal Investigator listed in question 3, may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

Participation in this study is completely voluntary. You may choose not to participate or withdraw participation at any time. Not participating will have no impact on the quality of your healthcare.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact Dr. Leon (352) 376-1611x5059 or (352) 284-1903. She will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- 1) You do not meet one or more of the exclusionary criteria after the initial pretreatment testing session.



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- 2) You are unable to understand the directions for the treatment or testing.
- 3) You show signs of significant discomfort from the treatment or testing procedure.



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Veterans Health System**WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?****14. If you choose to take part in this research study, will it cost you anything?**

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), 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 VA-provided medical care and services that are not part of this study.

15. Will you be paid for taking part in this study?

Participants will be compensated for participation through the Department of Neurology at the University of Florida (UF Project#00047258). Participants will be compensated 75.00 dollars for each of the pre- and post-treatment testing sessions. Participants will be compensated 45.00 dollars for each of the treatment sessions and outcome measure administration sessions. The compensation will be distributed at three intervals.

1. After the participant has completed pretreatment testing (75.00) and two administrations of the outcome measure (45.00 x 2), he or she will be mailed compensation by check for those sessions. If a participant is found in pretreatment testing to show no signs of impairment in recognition or expression of affective prosody or exhibits any other exclusionary criteria, he or she will still be compensated for the pretreatment testing (\$75).
2. After the participant completes treatment, the third outcome measure administration and post testing (\$45 x 8 treatment sessions + \$45 for outcome measure + \$75 for post treatment test), he or she will be mailed compensation by check for those sessions.
3. After the participant completes the final outcome measure administration four weeks after treatment is completed (\$45), he or she will receive a final check.



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The expected time of delivery is approximately 4 weeks for each payment to process. If you choose to withdraw from the study, you will be compensated for any testing or treatment sessions you have completed. If you complete all possible testing and treatment sessions you will receive compensation totaling 840 dollars.

If you are paid more than \$25 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total \$600 or more or you are a nonresident alien, payment will be processed through the University of Florida Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). If you have questions about the collection and use of your Social Security Number, please visit: <http://privacy.ufl.edu/SSNPrivacy.html>

16. What if you are injured because of the study?

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact Dr. Leon at (352) 376-1611x5059 during the day and (352) 284-1903 after business hours. If you seek emergency hospitalization



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in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Certain federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research, may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.



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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

Signature of Person Obtaining Consent Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting Date