An RCT of a telemedicine intervention for hypokinetic dysarthria in PD

NCT04617496

May 1, 2024

Participant Name: _____ Date: _____

Title of Study: An RCT of a Telemedicine Intervention for Hypokinetic Dysarthria in PD

Principal Investigator: Dr. David Sparrow VA Facility: VA Boston Healthcare System

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Office of Rehabilitation Research and Development. 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. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

We are doing the research to evaluate the effect of a combined speech and exercise intervention on speech outcomes. If you agree, you will complete some questionnaires and have your speech recorded during various speaking situations and participate in one of two programs. You will be in the study for 6 months if you decide to stay for the whole study. We will describe your involvement in more detail later in this form.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer in the study because the program might potentially improve your speech. For a complete description of benefits, refer to the Detailed Information section of this form.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose not to volunteer to be in the study because of the possibility that you may experience discomfort during normal exercise. For a complete description of risks, refer to the Detailed Information section of this form.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. David Sparrow at the VA Boston Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is 857-364-6400

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to compare different approaches to providing a safe exercise program that includes features to enhance speech performance to people with Parkinson's disease.

HOW LONG WILL I BE IN THE STUDY?

We are asking you and approximately 104 veterans to participate in this study. This research study is expected to take approximately 4 years to complete. Your individual participation in the project will take 6 months.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

You will be allowed to participate as long as your physician has no objections to your participation. You will be asked to complete two evaluations over a 6-month period (at baseline and 6 months) at the Jamaica Plain campus of the VA Boston Healthcare System.

At the first visit (baseline), you will be asked to complete some questionnaires and speak in a variety of situations while being recorded. This visit will take approximately 1 hour. If you meet all eligibility criteria, you subsequently will be randomly assigned – that is, by chance – to one of two groups. Both groups will use a special telecommunications system 3 times per week for 6 months at home to complete all sessions.

If assigned to the first group, you will be asked to carry out a structured exercise program in your home using various weights while speaking to an interactive telecommunications system for 6 months. A typical session will last about 45 minutes to 1 hour. If assigned to the second group, you will be taught a lifestyle program using a telecommunications system for 6 months in which you will hear about similar exercises and ways to enhance your speech. In addition, you will be advised about general health topics. A typical session will last about 15 minutes. You will be shipped at no cost to you all study materials and equipment.

At 6 months, you will be asked to come back to the Jamaica Plain campus of the VA Boston Healthcare System to repeat the speaking tasks, which will be recorded, and the questionnaires. This visit will take approximately 1 hour.

During your 6 months of participation, we will call you every month to check on how you are doing. When your participation is complete, you will be asked to ship all study equipment back to us at no cost to you.

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WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you believe you might be pregnant or might have gotten your partner pregnant.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Discomfort or inconvenience involved in this study are those associated with normal mild exercise. You may experience fatigue as your muscles tire or ache during or immediately after exercising.

The risks associated with training include strained and pulled muscles, rapid heart beat, labored breathing, chest discomfort, light-headedness, dizziness and falls. If you experience any of these symptoms, you should stop exercising and contact your physician as well as study staff.

Also, in addition to the risks listed above, you may experience a previously unknown risk or side effect.

If you are or become pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which are currently unforeseeable.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your condition.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

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To protect confidentiality, data will be identified only by study ID number assigned to you. All computer files will be secured using access permissions and assigned passwords to ensure only authorized study personnel will have access to your data. Access permissions and passwords will be changed whenever there has been a change in study personnel. Any required personal information on you will be kept in a separate file and only the Principal Investigator and Study Coordinator will have access permissions granted to this file. All of your paper forms will be secured in a locked fireproof study cabinet. Only the Principal Investigator will have keys to the study cabinet.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Institutional Review Board (IRB), our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule**.**

To comply with state laws and regulations, we may need to share safety-related information such as that relating to child abuse or neglect; elder or disabled person abuse; specific reportable diseases; harm to self or others.

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.

Health Insurance Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. While it is not the intent of this study, other information such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment may be viewed or collected, if necessary, or if there are interviews or surveys where you, as the research subject, provide that information to the research team.

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The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Boston University's Stepp Lab, Research Compliance Officers, Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability Office (GAO), the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or the HIPAA Privacy Rule regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must ask a member of the research team to give you a form to revoke the authorization. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Sparrow and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

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.

Compensation for transportation will be provided by the VA if you require special transportation considerations to travel to the Jamaica Plain campus of the VA Boston Healthcare System. Compensation will be based on total roundtrip mileage at the current GSA mileage rate.

You consent to the release of personally identifying information about you including your name, address, and social security number to the VA so that we may provide compensation to you. You can expect to receive a debit card within 2-6 weeks.

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You consent to the release of personally identifying information about you including your name, address, social security number and bank information (bank name, routing number, and account number) to the VA so that we may provide compensation to you. You will receive payment within 7 to 10 days

If payment is made to you by the VA (whether by direct deposit, or a VA issued debit card), an IRS Form 1099 will be generated regardless of the amount you are paid. The government may garnish the compensation against outstanding debts a Veteran has to the federal government.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: Dr. Pantel Vokonas who is a member of our study team at 857-364-6400.

AFTER HOURS: Page Dr. Pantel Vokonas by calling toll free 1-877-204-5849 and ask the answering service to call or page Dr. Vokonas or a staff member covering for him.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is voluntary. If you refuse to take part, you will not suffer any penalty or loss of benefits to which you are otherwise entitled.

You may withdraw from the study at any time. This will end your participation in the study; however, the research team may continue to use the data that have been already collected before your withdrawal. You will be asked to ship all study equipment back to us at no cost to you.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Your participation in the study can be terminated by the study Principal Investigator if it is determined that it is not safe for you to continue in the study. If terminated, you will ship all study equipment back to us at no cost to you.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

I understand that if I have any medical questions about this research study, I can call Dr. Pantel Vokonas who is a member of our study team at (857) 364-6400 during normal working hours (9am-5pm).

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I understand that if I have any general questions about this research study, I can call Dr. David Sparrow at (857) 364-6400 during normal working hours.

I understand that if I have any medical problems that might be related to this study that during the day I can call Dr. Pantel Vokonas at (857) 364-6400 and after hours I can call toll free 1-877-204-5849 and ask the answering service to call or page Dr. Vokonas or a staff member covering for him.

If you have questions about your rights as a study participant or any complaints, concerns or suggestions about this study, you may contact the Institutional Review Board at (617) 637-3794. The Institutional Review Board is responsible for overseeing the safety of human participants in this study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The study coordinator 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 and authorize the use and disclosure of your health information 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

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