H00011523
V.2 06/29/2021

| | | |
|---|---|---|
| **ID:**<br>**H00011523** | **Speech, Linguistic and Acoustic Markers in Parkinson's Disease** | **NCT04273672** |

**UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL**
**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

***Title of research study:*** Speech, linguistic and acoustic markers in Parkinson's disease (SLAM-PD)

***Investigator:*** Kara Smith, MD

***Sponsor:*** University of Massachusetts Memorial Medical Center Neurology Department

## *Heading 1: What should you know about a research study?*

You are being invited to participate in this study either because you have Parkinson disease, or because you are eligible to be a control subject in a study about Parkinson disease.

Your participation is entirely voluntary.

You do not have to be in this research study. If you join the study, you can stop or leave at any time with no changes in the quality of the health care you receive.

You can ask all the questions you want before deciding if you want to be in this study.

## *Heading 2: Learn more about this study*

## Why are we doing this research?

Parkinson disease (PD) patients commonly experience changes in speech and communication. It may be possible to use speech to monitor symptoms, including both motor (movement or physical) symptoms and cognitive (memory, thinking) symptoms. We will analyze your speech and language skills to learn about the differences between PD patients and non-PD patients. Our goal is to understand how speech and language characteristics change in PD depending on PD symptoms, effects of medications, and genetics. We will use technology such as smartphone applications to see if technology could be used to monitor speech in PD in the home settings.

## How long will the research last?

The main study consists of a screening session and a study visit less than 3 months apart. If you agree to participate in the smartphone app portion of the study as well, this will continue for 4 weeks following the study visit.

## How many people will be studied?

100 people with PD and 50 non-PD controls will be in this study.

## What happens if I say yes, I want to be in this research?

Your initial screening visit with the study team will be no longer than 30 minutes. This visit may occur in the offices of the study team or by videoconference.

During the initial visit:

- You will take a brief test of cognition (mental/thinking abilities)

You will be asked a few screening questions about your medical history. The study visit will occur sometime in the following 3 months and last approximately 3-4 hours. This may occur in the offices of the study team or the clinic.

During the study visit:

- You will provide basic information about you and your medical history, complete short questionnaires about your symptoms and undergo a brief examination (if you have PD)
- Your voice will be recorded during a series of vocal exercises and reading aloud
- You will undergo evaluations of your thinking abilities, such as concentration and memory, your visual-spatial reasoning and others
- You will perform movement and walking tasks similar to a typical neurology clinic visit. During some of these tasks, four sensors that detect movement (accelerometers) will be affixed to your chest, waist and feet.
- You may be asked to perform tasks on a Microsoft Surface tablet such as copying shapes or words which will record your voice with a microphone and facial expressions with a videocamera
- You will be asked to do a language comprehension task on a computer
- Those in the phone app sub-study will receive instruction and demonstration on how to perform the tasks on the smartphone app

For those in the phone app sub-study, you will use the smartphone app once a week for 4 weeks.. The app will automatically prompt you to perform assessments once a week. These assessment sessions will each take 10 minutes or less. They may include tests of cognition (mental/thinking abilities) or tasks that ask you to speak about a topic or describe a picture.

At week 4, you will be contacted by telephone or videoconference by the study team.

- This encounter will last approximately 5 minutes. You will be asked to provide feedback regarding the experience with the app. If you have not completed the 4 app sessions at this time, you will be asked to continue for up to 4 additional weeks or until the 4 app sessions are complete.

After the study visit, the study team may also contact you by phone if further color discrimination testing is deemed necessary based on your speech task performance. The rationale for further color discrimination testing is based on prior research showing that Parkinson's disease contributes to some degree of color discrimination deficit. If you agree to do the color discrimination testing, you will take a D15 Color Hue Test and a traditional Stroop Test via Zoom. Each assessment should take no more than 5 minutes to complete.

None of the tests or procedures involved in this study are part of your regular medical care.

Reasonable accommodations will be made for those with visual impairments.

This research is a collaboration with Aural Analytics, Inc.. Aural Analytics is a digital software company studying voice-based technology to diagnose and monitor brain diseases. Aural Analytics will receive information from the app tasks such as audio files of your speech. This data will be stored and shared in a highly secure manner.

## Will you be collecting any specimens from me?

We will take a one-time sample of 5 tablespoons of blood for genetic testing.

You cannot opt out of giving blood for this study. If you do not provide a sample, you cannot be in the study.

If you agree, this sample will also be banked for use in future studies. Your specimen would be banked in a confidential database for people with Parkinson's Disease. The samples will be labelled with a code and not with an individual's name. Only the PI and study coordinator can connect your name to your genetic results. The key code will be kept in a locked office. Other researchers may request information from the bank.

Please place a checkmark or X in the box which fits your response.

I agree to donate my blood to future studies:

☐ Yes

☐ No

Although this research will not include whole genome sequencing, we cannot predict what will be done in future studies. Whole genome sequencing is the process of analyzing the complete DNA sequence of an organism's genome at a single time. This would include all of your genes, including genes that may relate to other disease-related risk factors or conditions.

## *Heading 3: Risks and Benefits*

## What are the risks of being in this study?

One of the risks of being in this study is that your personal information could be lost or exposed. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected.

You may find the tasks on the smartphone app time-consuming or frustrating. There is a small risk this study could increase stress.

Because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers, except those with fewer than 15 employees, to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If you do not share information about taking part in this study, you may reduce this risk.

With blood draw comes the risk of slight pain due to the needle puncture. The point of blood draw may become black and blue but this is harmless. The arm drawn from may be sore. Infection, light-headedness and fainting are also possible but unlikely.

## What are my responsibilities if I take part in this research?

If you take part in the research, you will need to follow instructions to the best of your abilities for the cognitive and speech tasks. You will need to perform the tasks when prompted by the smartphone app.

## Will being in this study help me in any way?

You will not benefit in any way from participation in this study. However, the results of the study may advance knowledge about Parkinson disease in order to help others in the future.

## Will being in this study cost me any money?

You will be responsible for all fees related to smartphone data usage, according to your smartphone carrier agreement and plan.

## Will I be given any money or other compensation for being in this study?

You will receive a $20 gift card for your participation.

## *Heading 4: Privacy and Rights*

## What happens to information about me?

We will try to limit access to your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. The UMMS Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) and other representatives of UMMS may need to review your records. As a result, they may see your name, but they are required not to reveal your identity to others. Your identity will remain confidential in any study results that are made public.

Information will be shared with collaborators at the NIH, Aural Analytics, Inc. , MIT Lincoln laboratories, Stepp Lab, VA Puget Sound Health Care System, and UMass Amherst including basic clinical information, genetic information, information from the movement sensors, and video files of your facial expressions and audio files of your speech. This information will not contain your name. It will be shared and stored using only secure, encrypted networks (Aural Analytics' server and the Amazon Cloud).

## What are my other options?

You do not have to be in this study. If you decide not to be in the research now or later, it will not affect your usual care and it won't be held against you.

## What happens if I say yes, but I change my mind later?

You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research. However, you can ask us to destroy any information that identifies you so that no one can tell the data belonged to you. Our contact information is below.

## *Heading 5: Contact us*

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team at:

Kara Smith, MD
UMass Memorial Medical Center- University Campus
Department of Neurology
55 Lake Ave. North
Worcester, MA 01655
(774) 455-4209

kara.smith@umassmemorial.org

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research.

| | |
|---|---|
| Signature of subject | Date |
| Printed name of subject | |
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | |

You may be contacted in the future regarding opportunities to participate in related and follow-up studies. Contact may be via phone, email or mail but will not labeled with any information that would disclose your health information.

You may opt out of such future contact by initialing here. _____ Date _____