

CONSENT FORMS (Speaker and Listener)

Title of Research Study

A multidimensional study of articulation deficits in Parkinson's disease

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TITLE OF RESEARCH STUDY

A multidimensional study of articulation deficits in Parkinson's disease

Investigator: Austin Thompson, M.S. CCC-SLP (308 Warren Building, athompson4@fsu.edu),
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KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to participate in a research study because you are an individual diagnosed with Parkinson's disease or a neurologically healthy control speaker. To participate in this research, you may or may not have a speech disorder secondary to neuromotor diseases (such as Parkinson's disease), but you must have no history of hearing and language difficulties; no known structural abnormalities of the oral, pharyngeal and respiratory mechanisms; must not have an implanted or attached device that utilizes electromagnetic control (e.g., pacemaker, infusion pump, transcutaneous electrical nerve stimulation [TENS] device, continuous blood glucose monitors, or insulin pumps); and no history of taking medications known to affect orofacial movements. Additionally, you must have either (1) received a full COVID-19 vaccination series or (2) have not tested positive for COVID-19 or come in contact with someone who has tested positive for COVID-19 within the past 10 days.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of the research is to examine the way how speech articulation movements of patients with various motor speech disorders are different from those of healthy speakers, and what kind of movement modifications are made when speakers with motor speech disorders voluntarily adjust the level of speech rate, loudness, and intelligibility.

How long will the research last, and what will I need to do?

Your one-time participation will take approximately 1.5-2 hours.

If you decide to participate in this research, we will place a total of 6 sensors on your tongue (tongue front, tongue back), lips (lower lip, upper lip), jaw, and forehead. With sensors attached to those orofacial areas, you will be asked to read speech materials (e.g., paragraph) following the investigator's instruction.

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

Is there any way being in this study could be bad for me?

We don't anticipate any risks to you from participation in this study. However, because of the use of the speech-movement tracking equipment, this experiment includes exposure to radiofrequency

electromagnetic signals generated by the data acquisition device. However, the exposure is far less than the maximum permissible exposure (MPE) outlined by the Institute of Electrical and Electronics Engineers (IEEE) standards. More information about this can be found in the detailed risks.

Additionally, the sensors are applied to the articulators using dental glue. At the end of the experiment, the sensors are expected to be removed easily by sliding your tongue under the upper teeth. If not, the examiner will take the sensors off; in our previous experiences, a very small percentage of participants have reported some discomfort while removing the sensors (comparable to band-aid removal). We will also provide toothpicks and a carbonated drink to take off residual glue if any remains after sensor removal (the glue mostly comes off with the sensors).

We are not concerned about the possibility of swallowing sensors because (1) sensors are wired (we do not use wireless sensors for this reason) and (2) sensors will stay away from the throat. The closest sensor to the throat will be placed 2.5 cm away from the tongue tip.

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

However, possible benefits to others include contributing data to a fuller understanding of the underlying neuropathologies of speech related to various neurological conditions. The findings are also expected to help improvement of our current diagnosis and management of speech disorders associated with a variety of diseases including Parkinson’s disease.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator, Austin Thompson at (985) 231-8700, or Yunjung Kim, at (850) 645-4804.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- 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.

How many people will be studied?

We expect about 60 people here will be in this research study, including 30 clinical speakers and 30 control speakers.

What happens if I say “yes” to being in this research?

Your participation will involve, (1) the collection of general background information (age, height, educational history, and disease history, if applicable), (2) a hearing screener, (3) collection of a bite plate, and (4) reading various passages and sentences while wearing sensors.

For the bite plate, we will create an impression of your bite using melted wax plates. This is used in the calibration of the measurement device in our study.

For the data collection, we will place a total of 6 sensors on your tongue (tongue front, tongue back) lips (lower lip, upper lip), jaw, and forehead (see Figure 1). With sensors attached to those orofacial areas, you will be asked to read speech materials (e.g., paragraph) following the investigator's instruction. Your one-time participation will take approximately 1.5 - 2 hours.

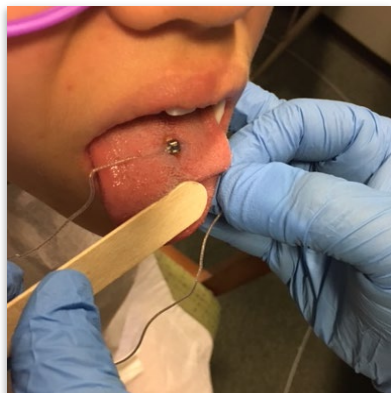


Figure 1.
Left: Sensor being applied;
Right: participant with all six
sensors applied.

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

You can leave the research at any time, and it will not be held against you. If you decide to leave the research, you will be pro-rated for your time and effort. This means that if you decide to discontinue the data-collection session, you will be paid for the amount of time spent in the session.

Is there any way being in this study could be bad for me? (Detailed Risks)

We don't anticipate any risks to you from participation in this study. However, because of the use of the speech-movement tracking equipment, this experiment includes exposure to radiofrequency electromagnetic signals generated by the data acquisition device. IEEE Standard C95.1 specifies maximum-permissible exposure (MPE) limits to prevent biological injury from electromagnetic energy. MPEs are effectively the peak electrical and magnetic field strengths that a person may be exposed to without harmful effects. IEEE std. C95.1 specifies an MPE of 163 A/m (amperes per meter) for any device that emits signals within the frequency range of 0.1 Hz to 3kHz (“radio-wave signals”). The system we use (The Wave System) generates an electromagnetic field from 3kHz signals with exposure less than 163 A/m. The World Health Organization states that acute effects are only likely to occur for static magnetic fields when there is movement in the field, such as the motion of a person or internal body movements, such as blood flow or heartbeat. A person moving within a field above 2 T can experience sensations of vertigo and nausea, and sometimes a metallic taste in the mouth and perceptions of light flashes (<http://www.who.int/peh-emf/publications/facts/fs299/en/>). 163 A/m corresponds to only 0.000204 T.

The sensors used in the study are intended to allow for natural articulation of speech with minimal discomfort. Neither the adhesive nor the strips used to adhere the sensors to the orofacial structures are known to cause any adverse reaction (note there is no latex coating, so no risk for individuals with latex allergies). As with any adhesive, a small percentage of the population may have mild, temporary allergic reactions.

We do not concern about the possibility of swallowing sensors because (1) sensors are wired (we do not use wireless sensors for this reason), and (2) sensors will stay away from the throat. The closest sensor to the throat will be placed 2.5 cm away from the tongue tip.

After the experiment, the sensors are expected to be removed easily by sliding your tongue under the upper teeth. If not, the examiner will take those off; in our previous experiences, a very small percentage of participants have reported some pain (comparable to band-aid removal). We will also provide toothpicks and a carbonated drink to take off residual glue if any remains after sensor removal (the glue mostly comes off with the sensors).

COVID-19 Precautions

We want you to know about what we will do to help protect you and others from COVID-19.

First, completion of a full COVID-19 vaccination is strongly recommended. No unvaccinated person may take part in this study if they test positive for COVID-19 or have come into close contact with someone with COVID-19, for at least 10 days after testing positive or close contact.

We will therefore ask some questions to screen research participants and study staff to see if they have tested positive for COVID-19 or been exposed to someone with COVID-19 in the past 10 days, and if so whether before then they had been vaccinated. If you think that at any time before or during this study you may have been exposed to COVID-19 and you were not vaccinated before then, or if you do not want to tell us if you have been exposed or vaccinated, then you may not take part in this study. Letting us know about your exposure or vaccination is your choice. Study staff may or may not include licensed medical doctors and may not be able to give you any medical advice on your own risk for COVID-19, so please talk to your own doctor if you have questions. Information about COVID-19 can be found at this web site: <https://www.cdc.gov/coronavirus/2019-ncov/your-health/index.html>.

Second, we will try to make sure when possible that everyone stays a safe distance (6 feet) from one another. This is called “social distancing.” We will let you know if for some activities study staff may need to be closer to you, but staff will only be closer if absolutely necessary. We will take all the steps needed to protect you.

Third, use of masks are strongly recommended. We will let you know whether for some activities you should wear a mask. In those cases, if you don’t want to use a mask then we may take other precautions to protect you and others. If needed we will provide masks to you.

Fourth, we make sure to clean anything that will be touched by you or anyone else, and we will throw away disposable items like masks and gloves. At certain times we may ask you to wash or sterilize your hands, and we will do the same. We will provide you with hand wash and sanitizer.

Fifth, we may limit the number of people and time in any face-to-face activity to only the minimum amount required.

If at any time you don’t feel safe with the steps that we will take to protect you and others from exposure to COVID-19, please let us know and we will stop. We want to be sure to answer your questions and to take any other steps that you feel we should take to protect you while you are taking part in this activity.”

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

What else do I need to know?

If you agree to take part in this research study, we will pay you \$50 for your time and effort. This amount is pro-rated, meaning if you decide to leave the study during the session, you will be paid for the amount of time spent in the session.

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

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KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are a speaker of English with no history of hearing loss.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of the research is to examine the way how speech articulation movements of patients with various motor speech disorders are different from those of healthy speakers, and what kind of movement modifications are made when speakers with motor speech disorders voluntarily adjust the level of speech rate, loudness, and intelligibility.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 30 – 60 minutes.

If you decide to participate in this research as a listener, you will be asked to listen and rate audio recordings following the investigator's instruction.

More detailed information about the study procedures can be found under *“What happens if I say yes, I want to be in this research?”*

Is there any way being in this study could be bad for me?

We don't anticipate any risks to you from participation in this study.

More detailed information about the risks of this study can be found under *“Is there any way being in this study could be bad for me? (Detailed Risks)”*

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

However, possible benefits to others include contributing data to a fuller understanding of the underlying neuropathologies of speech related to various neurological conditions. The findings are also

Permission to Take Part in a Human Research Study

expected to help improvement of our current diagnosis and management of speech disorders associated with a variety of diseases including Parkinson's disease.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Permission to Take Part in a Human Research Study

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator, Austin Thompson at (985) 231-8700, or Yunjung Kim, at (850) 645-4804.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- 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.

How many people will be studied?

We expect about 80 listeners to participate in this study.

What happens if I say “yes” to being in this research?

If you decide to participate in this research as a listener, you will be asked to listen to and rate the intelligibility (or how easily understandable) of speakers reading sentences through an online survey. You will be played a reference speaker that is assigned an intelligibility rating of 100. You will then be tasked with rating the intelligibility of speakers reading various sentences in relation to the reference speaker.

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

You can leave the research at any time it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

We don't anticipate any risks to you from participation in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

What else do I need to know?

If you agree to take part in this research study, you will receive extra credit for a course within the School of Communication Sciences and Disorders.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

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

Electronic Signature of subject

Date