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INVESTIGATING SWALLOWING IN PARKINSON'S DISEASE.

INFORMATION LEAFLET

Please Read the Information in This Leaflet Carefully. If You Have Any Further Questions About the Study, Do Not Hesitate to Contact the Researchers Using the Following Details.

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What is this research about?

Parkinson's disease is a neurological disorder which primarily affects movement. The main symptoms of Parkinson's disease are tremor, slow movement, and stiff muscles. Swallowing and breathing are also impaired as the disease advanced. This research study aims to improve our understanding of how Parkinson's disease affects swallowing and breathing. To achieve this, we will examine muscle activity and tongue strength during swallowing and breathing, in people with and without Parkinson's disease. We are also interested in measuring the response of breathing, swallowing and tongue strength to medication (levodopa).

If you agree to participate in this study, you will be asked to complete a series of breathing and swallowing exercises which will include breathing for 60 seconds, swallowing your saliva and swallowing small volumes of water. During these exercises, sensors will be placed on your skin to record muscle activity (surface electromyography, sEMG) and movement in your neck, cheeks, and chest. The sound of breathing and swallowing will be recorded using the microphone of a smartphone. Your grip strength and the strength of your tongue will also be measured using force measurement devices.

If you agree, we will perform the exercises twice, while you are OFF your medication for Parkinson's disease (levodopa) and again when you have taken your medication (levodopa), but you are not obliged to do both conditions.

NB: You should consult with your doctor before agreeing to participate OFF levodopa.

Who is organising the research study?

Researchers from the Neuromuscular Systems Lab at the School of Electrical and Electronic Engineering, University College Dublin (UCD) led by Dr Emer Doheny.

Why are we doing this research?

This research aims to improve understanding of how swallow function and breathing are affected by Parkinson's disease, and by medication (levodopa). We are also investigating how swallow function is related to tongue strength.

The results will provide insights to muscle activation in Parkinson's disease and how swallowing and breathing are affected by changes in muscle activation patterns, and by medication in people diagnosed with Parkinson's disease.

Why have you been invited to take part?

We are looking for adult volunteers over the age of 18 who have been diagnosed with Parkinson's Disease, have been prescribed levodopa and have maintained a stable dose of levodopa for a period of 3-6 months. Participants must **not** have smoked within the last 5 years or have been diagnosed with any respiratory or other neurological disease.

What will happen if you decide to take part in this research study?

If you agree to participate in this study, you will be invited to visit our laboratory in UCD.

Before you attend the laboratory, the researchers will explain the protocol and you will be given time to ask questions about the protocol and the research study in general. You will also be asked if you agree to participate while you are 'off' your medication.

If you agree to participate while 'off' medication, you will attend the laboratory in the morning before you take your first dosage of levodopa. It will involve delaying taking your medication. You will perform the protocol described below, then take your medication, and repeat the protocol after 60 minutes. If you are not happy to take part while 'off' your medication, you can still take part while 'on' your medication.

When you visit the laboratory for the experiment, the researchers will explain the protocol to you again and you will be given another opportunity to ask questions about the protocol and the research study in general.

If you are happy to participate in this research study, you will then be asked to complete consent forms, and the researchers will record your height, weight, age, gender, and time since diagnosis with Parkinson's disease.

You will then be asked to complete a clinical assessment, the Movement Disorder Society's version of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS). The MDS-UPDRS

consists of a series of questions and a motor examination, which takes approximately 30 minutes. The MDS-UPDRS motor examination is a comprehensive clinical assessment of the motor signs of Parkinson's disease, and assesses your speech, rigidity, finger and hand movement, toe, and foot movement, standing up, walking, balance, and tremor.

Surface electromyography (sEMG) sensors (Delsys Trigno, 2000 Hz) and inertial sensors (Delsys Trigno, 100 Hz) will be placed on your cheeks, chin, and neck to measure muscle activity and movement. A respiratory belt (BIOPAC System, Goleta, CA, USA) will be worn around your chest to measure the movement of your chest as you breathe. Audio (sound) will also be recorded using the microphone of a smartphone.

You will then be asked to complete the following series of exercises while you are sitting, and sEMG, inertial and respiratory data are recorded:

1. Relax for 60 seconds.
2. Complete as many "dry" saliva swallows as possible over a period of 30 seconds.
3. Single swallow water of volume 3 - 5ml (pre-measured).
4. Sip consecutively water of volume 90 -100ml (pre-measured).
5. Press your tongue as hard as possible against a force sensor attached to a laboratory bench for 5 seconds. Repeat this twice, with a three-minute rest between attempts.
6. Hold a hand dynamometer and apply maximum grip force for up to 3 seconds. You will do this three times for both hands, with a three-minute rest between attempts.

If you performed the protocol while 'off' medication, you will then be asked to take your usual dosage of levodopa. Bottled water will be provided. After a rest period of one hour in our waiting/resting area, you will repeat the above experiments and the motor examination of the MDS-UPDRS.

Note: The researchers will follow all health and safety protocols, however, please note that the laboratory is not staffed by a medical professional.

How will your data be used?

After the experiment, the MDS-UPDRS data, force, muscle activity (sEMG), sound (audio), breathing (respiration), and movement (inertial) data recorded will be stored on a UCD-managed password protected Google drive. The data will be further analysed and combined with data from other volunteers. Results from analysis of the collective data from all participants will be included in scientific papers and presentations.

How will your privacy be protected?

- The sensor data (sEMG, inertial, audio, respiration) will be stored securely, along with personal information including your age, biological sex, and clinical information in a de-identified format on a password protected UCD-managed google drive. These data will not contain any information that will link you to the data. They will be stored indefinitely in case improvements in analysis techniques may allow for further analysis on future date. This will allow the data to be re-used to minimise the burden on potential participants or duplication of studies.

- Audio data are potentially identifiable. There will be no personal content on the audio recordings. They will be stored on a password protected UCD-managed google drive and will not be linked to your name or any other personal information.
- Consent forms, which include personal data (your name and contact details), will be stored separately in hard copy format in a locked cabinet in Dr. Emer Doheny's office and will be destroyed after four years.
- The results will be published as group data, and it will not be possible to identify individual subjects.
- The data being gathered do not provide any information that can be used as a diagnostic method.
- If you consent to photographs and/or videos, any possible feature of identification will be removed before the data are stored or published.

What are the benefits of taking part in this research study?

There are no direct benefits for partaking in this study. In the long term, this study will provide insights to muscle activation in Parkinson's disease and how swallow function is affected by changes in muscle activation patterns.

What are the risks of taking part in this research study?

- There is very little risk involved in participating in this research study.
- There is a minor risk of tiredness of the tongue or hand whilst performing the tongue strength and grip tests.
- You may also experience a reaction to the sEMG electrodes or gel that are placed on the skin, similar to what you might experience when with surgical tape or sticking plasters.
- If you agree to participate while 'off' your medication for Parkinson's disease (levodopa), you are likely to experience more severe movement symptoms (tremor or rigidity) until your take your medication.
- The study will require a commitment of about 3 hours of your time.

Can you change your mind at any stage and withdraw from the study?

You can withdraw from the study at any time, either during the study or within 6 months after participation.

If you wish to withdraw, simply contact Dr Emer Doheny or Afua Appiah at their email address provided at the beginning of this leaflet. You do not need to provide any explanation. After the results have been published, you can request that your data is not included in any future analysis.

As a participant, you have the following rights (and the right to request them from the researchers): right of access, right to rectification, right to erasure, right to restrict processing, right to data portability and right to object.

How will you find out what happens with this project?

If you would like to find out more about the results of this study and related studies, you can contact the Principal Investigator at emer.doheny@ucd.ie and she will be happy to provide this information to you.

If you have any further questions relating to this study, do not hesitate to contact the researchers at:

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