



CONSENT FORM

Finding the best way to provide feedback in online diagnosis and tracking of Parkinson's disease

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This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you are a member of one of the three categories below: 1) Diagnosed with Parkinson's, 2) In high risk of being diagnosed with Parkinson's in future due to genetic or environmental reasons, 3) An age-matched control group.
- The purpose of the study is to obtain feedback on a web-based tool that we hope will improve healthcare access for many under-served people and investigate the best possible ways of informing someone on whether he/she has symptoms of Parkinson's disease.
- Your participation in this study will last for about 30 minutes
- There are minimal risks related to your participation, which are listed below.
- You will not benefit from being in this study.

Purpose of Study is to obtain feedback on a web based tool that we hope will improve healthcare access for many under-served people and investigate the best possible ways of informing someone on whether he/she has symptoms of Parkinson's disease.

Millions of people around the world -- particularly older adults -- are suffering from Parkinson's disease (PD). We are building a system where anyone from anywhere in the world can perform the standard tests -- modulating facial expressions, speech, or gestures -- using a computer browser and receive an automated assessment on Parkinson's symptoms.

Description of Study Procedures

If you agree to participate in the study, you will be guided through a website where you will watch a video of another person conducting a set of tasks, get feedback of their PD diagnosis and/or progression and get their set of resources about nearby PD clinics, support groups and prevention advices. At each step of the study, you will be asked a set of questions to assess the usefulness of the corresponding step. We will also collect your audio response for a chosen set of questions.

Here is a detailed description of each of the steps mentioned above:

- A. You will enter your email in our custom website to login to the it. The email will be used for processing payment and ensuring that one person takes part in the study once. Your email will be deleted before the data analysis phase begins as part of de-identifying the data. We will also take your gender, age, and whether you have been diagnosed with Parkinson's to properly report the findings of the study. This data will be used as measures of the study to determine how subjects of different age and gender differed in their feedback.
- B. You will watch pre-recorded video of a **research assistant (RA)** doing a *subset* of the following tasks:
 - a. Facial Expression Task: The RA will sit at rest for 10 seconds. A timer on the web application will allow them to see how much time is left.
 - b. Audio task: The RA will recite the following sentences: "The quick brown fox jumps over the lazy dog. The dog wakes up and chases the fox into the forest."
 - c. Finger Tapping: The RA will tap the index finger on the thumb 10 times as quickly and as big as possible. First, they need to do this on the right hand and then left hand.
 - d. Hand Movements: The RA will make a tight fist with the arm bent at the elbow so that the palm faces the web interface. The RA will do this for 10 times as fully and as quickly as possible for both hands.
 - e. Pronation-supination Movements of Hands: The RA will extend both of the

arms out in front of his/her body with the palms down; then to turn the palm up and down alternately 10 times as fast and as fully as possible.

- f. Postural Tremor of Hands: The RA will stretch both of the arms out in front of the body with palms down. The wrist should be straight and the fingers comfortably separated so that they do not touch each other.
 - g. Eye gaze tracking: The RA will follow a moving ball across the screen with their eyes.
 - h. Vocalization test: The RA will vocalize the sound “ahhh...” for as long as they can.
 - i. Scripted Speech: The RA will read aloud a short paragraph of text.
 - j. Spontaneous Speech: The RA will answer a simple question such as “what did you have for breakfast”.
 - k. Facial expression mimicry: The RA will mirror an expression shown on the computer display. For example, mirroring a smile, disgust or surprise expression.
 - l. Head pose task: The RA tilts their head up and down and or left and right (i.e., nodding yes or no).
 - m. Limb movement task: while seated, the RA will move their limbs as shown in a video (e.g., touching nose with your index finger).
- C. You will answer a set of questions to measure the system’s usefulness and usability. Those questions will be designed to measure whether:
- a. Instructions were clear and unambiguous
 - b. The system led the RA through all the tasks properly
 - c. The system is beneficial for PD community
 - d. They will recommend the website to friends and family.
 - e. The predictions were presented in a clear, concise and understandable manner.
- D. You will watch a recorded screen of the RA getting a feedback page with PD

diagnosis and progression (if applicable), breakdown of the performance for each of the tasks, and how the RA's performance compares with the rest of the population who used this system.

- E. You will answer a set of questions to measure the feedback's usefulness and usability. Those questions will be designed to measure whether:
 - a. Whether you understood each of the provided feedbacks
 - b. Whether the graph comparing the RA' performance with the rest of the population was meaningful to you.
- F. You will be shown a video of the RA receiving some resources that can help Parkinson's patients to cope up with the disease. The resources include:
 - a. Nearby doctors and hospitals providing PD treatment
 - b. Information about online (facebook groups, reddit community) and in-person PD support groups near them.
 - c. Prevention advice (exercise, diet) to prevent or slow down the progression of PD.
- G. You will answer a set of questions to measure whether the provided resources were useful. The questions will measure whether:
 - a. The resources were relevant
 - b. They are likely to use them
 - c. The prevention advises were helpful
- H. We will ask the you whether you want a system that can track how your PD symptoms change over the years in future. Your response will be used to design a follow-up study that can measure progression of PD symptoms.
- I. We will collect audio recording of you regarding:
 - a. What you liked about the system
 - b. What you disliked about it.
 - c. The suggestions to improve the system.

- d. Potential harms the system can cause and how to alleviate them.

The study should take around 30 minutes to complete. You will be able to close the web-application anytime you want. However, you will need to complete the study to get the payment. The web application allows you to take rest in between the tasks if you want to. During the tests, the web-application will collect the audio data using the microphone of the computer while you answer a set of selected questions. After the completion of the tests, the web-application will upload the data to our secure web server. This web server is password protected and only the study personnel will have access to this data.

Number of Subjects

The study will be divided into three subsets of the population: People diagnosed with Parkinson's, healthy controls, and people in high risk of being diagnosed with PD (due to genetic and environmental reasons). Moreover, we will solicit feedback from a handful of neurologist expert in treatment of PD. Approximately, 300 participants will be recruited from each of the three subsets of population (900 participants in total).

Risks of Participation

There are minimal risks related to your participation in the study. If you are a subject diagnosed with PD, you may feel stress. To minimize this the web application will allow you to stop the application anytime you want. There is a potential risk of breach of confidentiality during the transmission of data. All data will be securely transmitted from the web application and de-identified before data analysis. Data collected from surveys will be transmitted in encrypted form and stored in a secure database housed at the University of Rochester. There is also a potential risk of loss of privacy due to collection of voice and use of your email address.

Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent to participate indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email.

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Benefits of Participation

There are no direct benefits to you; however, the data collected may inform future research and increase understanding of Parkinson disease (PD).

Costs

There is no cost for you in participating in this study. However, no support is provided for computer and internet access, and so it is up to you to secure these utilities.

Payments

At the beginning of the study, we will collect the email of the participants. After completing the program (watching the recorded videos, filling out and recording the surveys) we will ask you whether you want to receive an Amazon gift card (\$15) or not. If you want to have it, we will send the gift card to your email address. It may take up to three working days after the study to complete the payment. We will not pay for the cost associated with the internet connection.

Confidentiality of Records

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will store the data in password protected databases. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators, or the study sponsor. If this does happen, we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort, please contact Dr Ehsan Hoque at 1-814-218-9449

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone ((585) 276-0005 or (001)(877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.
