



Study Title: Voice sample collection of people with Dysarthria speech condition and Parkinson's disease.

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Co-investigators: list of names and organisations that will have direct contact with data only, no direct contact with participants.

Name	Organisation
Alek Dudko	UBC Computer Engineering Dept.
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Background & Introduction

According to the US Department of Health 17.9 million people in the USA have difficulty speaking. Some are born with speech impediments, others are afflicted from Parkinson's disease, stroke, or brain trauma. "Effortless communication is not an option for all people" (Beukelman & Ray, 2010) because effective communication is essential for self-determination, learning and development, education, personal care, social engagement, and employment. It is also essential for medical care, and Patient- and Family-Centred Care.

Effective communication is now accepted as an essential component of quality care and patient safety Skyline Innovation's flagship product "Flow" is a Software as a Service that uses artificial intelligence (AI), voice recognition, and natural language processing. Flow is for people with speech issues who need to communicate over distance. Flow remedies lapses in communications that frustrate both parties to a conversation. Our simple-to-use technology seamlessly autocorrects any mispronounced words thereby keeping the conversation flowing.

Purpose of Study

We are inviting you to take part in this study because you have expressed interest in participating. Skyline Innovation has an academic partner with UBC Computer Engineering Department, and undergraduate students have been working on developing the Machine Learning Algorithm to replace any miss-spoken words. During this software development voice samples from people with Parkinson's Disease, we used to test and calibrate the system. These samples were from databases collected by and for other research projects, and the group of students had to request permission in some cases to be granted access. Unfortunately, most of these databases had samples recorded using poor quality settings, equipment, or are not suitable for computer aided objective analysis, or combinations of other factors. While trying to test the system these samples were not fit to calibrate the prototype to the standard required. We are now exploring the possibility of attempting to build a new database, with more current technology equipment and software, for instants today mobile phone microphone is of much higher quality than a landline of 10 years ago.

Description of study Procedures

To collect as many samples as possible and follow any Covid restrictions still in place. A Web Application seemed the best solution, this would allow people to remotely record their voice samples in their setting.

An Email would be distributed with the necessary links to the website and then have easy-to-follow instructions.

The website will prompt the user to read a short few sentences while recording this voice sample, the user will be able to listen to this recording once and decide to submit or try again and re-record another sample if not satisfied or withdraw the sample altogether.

No personnel information will be collected, asked for, or used. All voice samples will be anonymous.

Submitting a sample is the equivalent of consent to use the sample for quality assurance and calibration of the prototype.

The process of recording a single sample takes less than 2-3 minutes.

Number of Samples

Aims to collect 1000 individual samples, and ideally each person to provide 3 different samples reading from 3 different statement samples.

Start Date and completion of study

Start: April 2nd, 2022

Completion: December 31st, 2022

Participant (Inclusion/Exclusion Criteria)

The participant has been invited because today's mobile tablets and telephones have higher quality microphones and systems in place to be able to record a higher quality sample than in the past, for example, the traditional telephone. These samples no longer are fit for a purse with today's Cloud base technology.

Inclusion

In the first samples we require only voice samples with mild speech issues, this is designed to enable the machine learning algorithm to start processing smaller problems with unknown or mispronounced words.

Exclusion people with severe speech issues, non-dysarthria speech.

Risk of Participation

There have been no risks identified with participating and submitting voice samples. More details are given in the Data Security section.

The benefit of Participation

As the population ages, the number of people with Parkinson's is going to double by 2030. Unless a cure is discovered very soon, a drug for the masses normally takes over a decade to pass FDA approval. Supporting people with speech issues with a technological solution is going to benefit many people, not only friends and family but also healthcare workers. Preventing Social Isolation is the main key benefit to this problem

Costs

There will be no cost to participate in this study, and therefore no reimbursement for participants.

Confidentiality of Records

More details are given in the **Data Security section**.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part. As all voice samples are submitted Anonymously and no identifying marks are stored within the Database, therefore drawing after submitting voice samples is not possible.

Recruitment

Through online social media, connecting with Cause-related support groups.

Consent Process

The interested participant should understand that “consent” is assumed once a person has recorded their voice sample and pressed the “Submit” button only.

If a person using the Voice Web Application, records their voice sample, does not press any other button this will not be seen as a submission, therefore this recording will not be submitted to Database.

If a person “Play” their sample back, this also will not submit a recording, and will not be included in the database.

There is no place to add a signature for consent as this would not be anonymous.

In summary, only a user recording their voice and pressing the “Submit” is giving consent. To have their voice sample saved into a database. Which is only to be used between Skyline Innovation and UBC Researchers.

Delete or Removal

While a person is using the Voice Donate Web Application at the time of recording, you have the opportunity to delete or remove the voice sample you have just recorded. Once a person has closed the Application Windows, or the Web Application, because there have been no names or other identification collected, it will not be possible to delete a voice sample if it was already submitted.

Data Security

Each participant will record their voice reading from a preset script, short passage, or sequence of words. These recordings will be stored in a database that is encrypted and password protected. Each voice sample will have no personal identifiers, making each sample completely anonymous. research findings will not be stored publicly or accessible publicly.

The only people with access to the data are all those listed in the co-investigator on page one of this document.

Dissemination

No final report, public, or internal report documentation is being produced from the direct collection of samples. If parties are interested in knowing more about how these samples are being used in research and development. Please contact info@skylineinnovatio.ca with the subject title: Voice sample research and development.

UBC Vancouver: “If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at 604-822-8598 or if long distance e-mail RSIL@ors.ubc.ca or call toll free 1-877- 822-8598.”

Ethics Guidelines

Many organisations use a variety of systematic methods to improve their functioning and performance. These activities may take the form of quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal education requirements. These activities are within the mandate of such organisations and are generally administered in the ordinary course of their operations.

Under the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, studies conducted for such purposes are distinguished from research requiring REB review. According to Articles 2.1 and 2.5 of the TCPS:

Research is “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation”, whereas quality assurance and improvement studies, “when used exclusively for assessment, the management or improvement purposes, do not constitute research”.

Although QA/QI activities often look research-like and may contain methods used in research studies (e.g. surveys, interviews, etc.), because the purpose of such activities differs from the intent of the research, they are outside the scope of REB review. Although QA/QI studies may raise ethical issues that benefit careful consideration by the project team, the consent procedures for such studies generally depart from those required for research.

However, where one of the goals of such QA/QI activities is to “extend knowledge”, they may fall under the TCPS definition of research and therefore require review.

As there is a high degree of uncertainty about where the line between research and QA/QI should be drawn, the checklist provided by UBC Ethics Research is an aid to help researchers determine whether their study requires ethics review. Skyline Innovation methodology and processes for this study do not require a full board ethics review, as of January 2022.