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# School of Medicine, Dentistry and Health Sciences

# Department of Audiology and Speech Pathology

## ***Project: SpeechATAX: Intensive home based biofeedback driven speech treatment for hereditary ataxia***

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### Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don’t understand or want to know more about.

Your participation is voluntary. If you don’t wish to take part, you don’t have to. If you begin participating, you can also stop at any time.

### What is this research about?

You are invited to participate in a study to help us evaluate the effectiveness of a home-based speech treatment for people with hereditary ataxia. This is a new treatment which is largely delivered via tablet, and therefore requires minimal contact between the patient and the speech pathologist. We hope that this type of treatment will be more user-friendly and accessible for many people with ataxia. By agreeing to participate, you will be helping us to answer the question of whether this treatment improves the speech of patients with ataxia over a one-month period.

### Who is eligible to participate?

To participate in this project, you must have a confirmed diagnosis of hereditary ataxia.

Please note that you will not be selected to participate in the study if any of the following apply:

* + You are younger than 18.
	+ You are not competent in both written and spoken English.
	+ You are unable to dedicate half an hour per day, 4-5 times per week for a month to the vocal exercises prescribed by the speech pathologist.
	+ You have a neurological disorder other than confirmed genetic diagnosis of a hereditary ataxia (e.g., epilepsy, stroke).

### What will I be asked to do?

* Should you agree to participate you will complete assessments at different time points across the study, including two pre- and two post-treatment assessments. They will take about 60 minutes. Your speech will be recorded on a head-mounted microphone using a standard laptop computer and data will be used to analyse of potential speech changes. The head-mounted microphone is very light and comfortable and is similar to microphones used by call centres.
* You will be participating in a one-month block of therapy delivered via computer in your own home. Treatment requires a commitment of half an hour to forty-five minutes per day, four to five days per week for one month. The therapy involves practicing a range of vocal exercises specified by a speech pathologist. While performing these exercises, you will be watching a visual representation of your voice which will be generated by software. In your initial treatment session, the speech pathologist will explain and demonstrate how to use the software, complete the exercises and interpret the visual feedback provided by the software.
* Speech samples will be encrypted and stored on a secure server which is password protected and only accessible to team investigators.

### What are the possible benefits?

* This home-based speech treatment has been investigated in a preliminary trial with participants showing improvements in their overall speech intelligibility.
* SpeechATAX is designed to target and improve the vocal control, prosody (intonation) and overall speech intelligibility of people with hereditary ataxias.

### What are the possible risks?

* The speech tasks are quite simple and are typically included in clinical examination. A speech pathologist or speech pathology student will observe your first sessions of vocal exercises to ensure you are performing them in a safe way that will not be harmful to your voice
* If you become distressed at any time during the experiment, you are free to stop your involvement in the study without consequence.
* If you are not happy with completing any of the tasks, you can simply leave them out of the protocol.
* There are no health risks or special requirements linked to withdrawing.
* The project has received clearance by the Human Research Ethics Committee (HREC).

### Do I have to take part?

* Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.
* You may have been asked to participate in this study because you are a client of the Ataxia clinic. Please note that your decision whether or not to participate will not affect the quality of care or your access to care within the clinic in any way.
* You are encouraged to discuss the study and your potential involvement with a family member or someone you trust.
* Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.
* If you decide to withdraw from this project, please notify a member of the research team before you withdraw. There are no health risks or special requirements linked to withdrawing.

### Will I hear about the results of this project?

* Information about the study findings will be provided following the completion of the study.
* The findings of the overall study will be published in peer reviewed journals and can be accessed by participants.
* Patient-advocacy groups and organisations including the Friedreich Ataxia Research Association (Australia) will be informed of the results of this research.

### What will happen to information about me?

* All data collected will only be identifiable by a unique study ID number and your contact details will be known by the research coordinator only. All data files that are saved will not contain any identifying information. Data will be collected and analysed by different researchers.
* All information will be stored for a minimum of seven years after the completion or publication of the study, whichever is the later.
* In any publication, information will be provided in such a way that you cannot be identified. Your name will not be used on files we collect data from or in our databases of information collected. Consent forms and other identifiable material will be stored separately. Your speech samples will not be used in any public presentations of collected data.

### Who is funding this project?

This study is funded by the Friedreich Ataxia Research Alliance (USA), Friedreich Ataxia Research Alliance (Ireland), Friedreich Ataxia Research Association (Australia), Medical Research Future Fund, National Ataxia Foundation (USA) and Ataxia Charlevoix-Saguenay (Canada).

### Where can I get further information?

If you would like more information about the project, please contact the researchers; Hannah Reece (Research Officer), Phone: 03 8344 7687 Email: hannah.reece@unimelb.edu.au.

### Who can I contact if I have any concerns about the project?

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: HumanEthics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.