

## Participant Information Sheet

### Study title

Can intensive practice of articulation exercises improve speech in people with Friedreich's ataxia?

### Invitation to participate in a research study

You are invited to participate in an online study investigating the feasibility of delivering intensive speech therapy for people with progressive ataxia via Zoom. This study is co-funded by Ataxia UK, LSVT Global, and run by Strathclyde University. LSVT Global is a company with the goal of improving speech and movement in patients with neurological disorders. The company trains speech clinicians and physical and occupational therapists in evidence-based treatments they have developed.

In order to take part, we need you to have a confirmed diagnosis of Friedreich's ataxia. You should also have a mild to moderate level of speech impairment, which means people can still understand most of what you say although they might need to listen more carefully. You should be a fluent English speaker, have enough hearing and vision to follow the therapy programme over Zoom and read large print therapy materials, and not have any other neurological (e.g. stroke) or communication problems (e.g. stammer). You should also be above 18 years of age, and not receive other speech treatment from the NHS or private sector during the duration of this study, or have received such treatment in the past. Finally, you need to have access to a computer, tablet or smartphone and a good enough internet connection that will allow you to use Zoom to take part in the therapy. You should be able to operate this either yourself or with the help of a carer. Also, you (and possibly your carer) need to be available for the duration of the assessment and treatment period.

Please note that we can only admit a small number of participants to this study and have to match them closely for the type and severity of the speech symptoms. This means we might not be able to enter everybody who volunteers in the study at this point in time even if you fulfil all of the above criteria.

### Who is carrying out the research?

The research is being carried out by Prof Anja Lowit, who is the Chief Investigator. She will be assisted by speech and language therapists (SLT) from LSVT Global who will deliver the treatment, and a Strathclyde Speech and Language Therapy student who will analyse the data and help with some of the assessments. The SLTs will be based in the US and therapy sessions are most likely organised in the afternoons to account for the time difference.

### Do I have to take part?

No. Participation in this study is entirely voluntary, and whether or not you would like to be involved is up to you. If you decide that you would like to join the study, we will ask you to sign a consent form. If you join the study but then change your mind, you can leave at any time without giving a reason.

### What will I be asked to do if I take part?

There are two blocks of activity: assessment and therapy. All activities will be completed online, i.e. you will not need to travel to a clinic or be visited by a researcher at any point.

Assessment: The study involves four assessments. There will be two sessions, four weeks apart, before therapy. We will record your speech in both, and, in addition, ask you to complete some questionnaires and tell us about your concerns and what you would like to achieve from therapy in the first session. This is followed by two more assessments, one immediately after you finish treatment, and another 6 months later. As before we will record your speech, ask you to fill in the questionnaire again and also conduct a short interview about what you thought of the therapy.

programme, any difficulties you experienced, etc. The speech assessments take about 15 min, and the sessions including the interviews around 45 min. If you are too tired after the speech assessment to continue, we can also arrange a separate time for the interviews.

**Treatment:** The treatment will run for 4 weeks. During this time you will meet with a speech and language therapist (SLT) 4 times a week, and are expected to do homework practice as well. The sessions will take between 45 and 60 min each. The therapy focuses on improving your articulation of words and sentences.

From start to finish, you will be involved in the study for around 4 months. Please note that during the treatment phase, you will need to be able to concentrate fully on your speech treatment and ideally be available for all the sessions.

**Technology:** We will send you information on how to record your voice and provide you with the necessary technology to do so and participate in the therapy sessions. In case you have concerns about confidentiality when doing therapy online, we have attached an information sheet on the use of videoconferencing software for therapy. Please don't hesitate to ask further questions. You can be assured that from our side we will do our utmost to protect your privacy, all meetings will have password protected access and those running the session will ensure they are using suitably private accommodation to prevent others from listening in to the conversations.

#### **What are the possible benefits of taking part?**

This therapy has not been done with people with ataxia before and we therefore do not know whether it works. We hope that your communication will improve as part of the treatment. If it does not, we might be able to suggest other methods that could have more success depending on your speech symptoms. In this case, we will pass this information on to you so that you can seek further treatment with your local NHS speech and language therapy department. Whatever the outcomes, we hope that our research will have wider benefits to people with ataxia and lead to improvements in care in the long term.

#### **What are the possible disadvantages and risks of taking part?**

The treatment is relatively intensive and you might experience some fatigue following sessions. We will closely monitor your response to treatment and make adjustments during its course where necessary. We will also attempt to schedule the assessment and treatment sessions at a time when you think you'll be less tired. There are no known negative side effects of the treatment or any of the assessment tasks we will ask you to perform.

You also need to consider that you will also not be able to access any further speech treatment until we have performed our final evaluation 8 weeks after the end of your treatment. We will indicate to you at the end of the therapy block whether we feel you would benefit from further input and you should make the necessary arrangements at that point. NHS waiting lists are currently 9-12 months, so it is unlikely that having to wait for your final assessment will impact on your ability to access further treatment.

#### **Will my information be kept private?**

The university operates a cloud server, called OneDrive, which can be used by staff to store data and by people outside the university to transfer files to staff securely. Any information or recordings you share with us, and any information we collect from you will be saved on this server. This includes your consent forms, personal details, completed questionnaires, interview transcripts, as well as recordings of the assessment sessions. We will password protect any documents that contain personal information, such as your contact details. Any other files will be saved with your code name, so these files cannot be linked back to you. None of your personal information will be shared with anyone outside the research team without your permission.

We will also video-record the online assessment sessions in order to have a backup should your recording go wrong, and also to help us listen to the interviews again and make sure we captured everything you said correctly. We will remind you that we are recording a session every time this happens. We will destroy these video-recordings as soon as we have received your audio-recording and typed up your interview responses (a maximum of 6 months after they were collected). Only members of the research team will have access to the information collected.

All personal data will be processed in accordance with data protection legislation. Please read our [Privacy Notice for Research Participants](#) for more information about your rights under the legislation.

Because collecting data from rare conditions like ataxia can be difficult, we sometimes share speech samples with other researchers around the world to study the speech symptoms further. If you agree to us doing this, we will make excerpts of your anonymised audio data (e.g. long 'ahhh' sounds, some conversational speech about generic, non-personal topics) together with some demographic information such as your age, gender, and diagnosis available. Other researchers can then contact the project team if they would like to gain access to the recordings for academic purposes (i.e. research and education).

Please note that you can choose not to make your recording available for this by not agreeing to question 8 on the consent form. This will not affect your participation in the therapy study. You can also change your mind at a later date and ask us to remove your data at any time.

#### **What will happen to my information after the study has finished?**

We will keep your personal information for one year after the end of the study. This is to allow us to contact you if we have further queries and tell you about the results of the study.

After the 12 months period, we will proceed to destroy all your personal, identifiable data. If you have agreed for us to share your speech recordings and background information for future research and teaching purposes, it remains on the University's secure research data repository indefinitely unless you ask us to remove them. In this case you need to retain your participant ID so that we can identify your data. If you would prefer us not to share your data, then we will keep the speech recordings for a further 10 years, and only the research team will be able to access these data.

We will destroy all your data immediately if you decide to withdraw from the study at any point.

#### **Who has reviewed this study?**

This study has been considered and approved by the Strathclyde University Ethics Committee.

#### **If you have a complaint about any aspect of this study**

If you are unhappy with any aspect of this study and wish to make a complaint, or discuss your concerns, please contact the Ethics Secretariat at Strathclyde University, [ethics@strath.ac.uk](mailto:ethics@strath.ac.uk) or telephone 0141 548 3707.

#### **Do you have any questions?**

This information sheet is yours to keep. If you have any further questions about the study, please don't hesitate to contact a member of the research team below.

#### **What do I do now?**

If you feel that you might like to be involved in the study, or to find out more please email or call Anja Lowit:

Email: [a.lowit@strath.ac.uk](mailto:a.lowit@strath.ac.uk)

Telephone: 07986080537

**The Chief Investigator for this study is:**

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