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

Submission date
01/08/2022

Recruitment status
No longer recruiting

Registration date
04/08/2022

Overall study status
Completed

Last Edited
04/08/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Friedreich's ataxia is an inherited disorder that affects some of the body's nerves and causes difficulty walking, a loss of sensation in the arms and legs, and impaired speech. Evidence for the effectiveness of speech treatment to improve communication for people with Friedreich's ataxia is steadily increasing. A few different treatment approaches have recently been reported, each of them showing some benefits for different aspects important to communication, including the quality of the voice, intelligibility of speech, and communication confidence. However, whilst they each showed promise, no study has been able to show conclusively so far that it can achieve the desired communication benefits for people with progressive ataxia across the board. The critical next step to achieve this is to run a larger scale trial that tells us whether speech therapy is indeed effective across people with ataxia and also, which approach works best. Before this, researchers want to carry out one more pilot study of a newly developed model to help them decide whether this should be considered in the larger trial in future. They need to find out how acceptable this is for people with Friedreich's ataxia, and whether there is any indication it results in better communication.

Who can participate?
Patients aged 18 years and over with Friedreich's ataxia who experience mild to moderate speech or voice problems, which means people can still understand most of what they say although they might need to listen more carefully

What does the study involve?
The treatment is called LSVT Artic. It includes intensive articulation practice in four 1 hour sessions per week over 4 weeks. It has had positive results for intelligibility in people with Parkinson's disease. The treatment will be offered online. Participants will be assessed twice before treatment at 4-week intervals and twice after treatment, immediately and 6 months later.

What are the possible benefits and risks of participating?
This therapy has not been done with people with ataxia before and it is not known whether it works. It is hoped that participants' communication will improve as part of the treatment. If it

does not, the researchers might be able to suggest other methods that could have more success depending on their speech symptoms. Whatever the outcomes, it is hoped that the study will have wider benefits for people with ataxia and lead to improvements in care in the long term. The treatment is relatively intensive and participants might experience some fatigue following sessions. The researchers will closely monitor their response to treatment and make adjustments during its course where necessary. There are no known negative side effects of the treatment or any of the assessment tasks.

Where is the study run from?
Strathclyde University (UK)

When is the study starting and how long is it expected to run for?
January 2022 to October 2023

Who is funding the study?
Ataxia UK

Who is the main contact?
Prof Anja Lowit, a.lowit@strath.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Anja Lowit

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Additional identifiers

Protocol serial number
UEC22/24

Study information

Scientific Title

A feasibility study of LSVT Artic to improve speech performance in people with Friedreich's ataxia

Study objectives
It is hypothesised that LSVT Artic will improve participants' intelligibility immediately after treatment and 6 months later.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/03/2022, Strathclyde University Ethics Committee (University of Strathclyde, 16 Richmond St, Glasgow, G1 1XQ, UK; +44 (0)141 548 3707; ethics@strath.ac.uk), ref UEC22/24

Primary study design
Interventional

Study design
Single-centre interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Friedreich's ataxia

Interventions
Participants are offered a course of 16 sessions of LSVT Artic over the course of 4 weeks. Prior to this they will have completed a no treatment phrase of the same duration. LSVT Artic consists of four consecutive sessions per week lasting 60 minutes focusing on clear speech production. This will be practised on individual sound segments initially, followed by single words, short then longer phrases, passage reading and free conversation. In addition to the weekly sessions, participants will be asked to complete homework exercises.

Intervention Type
Behavioural

Primary outcome(s)
Speech outcome measures consisting of:
1. Speed of syllable repetitions (p, t, k, p-t, n-g, oo-ee & oo-ah) is expressed as the average number of repetitions in 5 seconds over 5 attempts at baseline (weeks 1 & 4) and post-treatment (weeks 8 and 32);
2. Clarity of syllable repetitions is judged by trained listeners over 5 attempts at baseline (weeks 1 & 4) and post-treatment (weeks 8 and 32);
3. Intelligibility and naturalness of the reading passage are rated with a Direct Magnitude Evaluation method by trained listeners at weeks 1, 4, 8 and 32;
4. Intelligibility and naturalness of 1 minute monologue samples are rated on a visual analogue scale by trained listeners at weeks 1, 4, 8 and 32.

Key secondary outcome(s)

1. Vowel space is measured through LPC analysis of word repetitions at weeks 1, 4, 8 and 32;
2. Communication confidence is rated on a 1-10 scale by participants at weeks 1, 8 and 32;
3. Communication participation is measured using the Communication Participation Item Bank (Baylor et al. 2013) at weeks 1, 8 and 32.

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of Friedreich's ataxia
2. Mild to moderate speech impairment
3. No previous SLT input
4. No history of other neurological or developmental problems affecting speech or language
5. Fluent English speaker
6. Enough hearing and visual ability to follow the therapy programme over Zoom and read large print therapy materials
7. Access to a computer, tablet or smartphone and a good enough internet connection to take part in online therapy.
8. Above 18 years of age
9. Not in receipt of other speech treatment from the NHS or private sector during the duration of this study, or have received such treatment in the past

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Diagnosis of another type of ataxia
2. Previously in receipt of SLT
3. Presence of other neurological or speech and language problems
4. English language skills too poor to allow reliable evaluation of speech patterns
5. Below 18 years of age
6. No access to necessary technology
7. Vision and hearing too impaired to allow participation in assessment and treatment sessions

Date of first enrolment
04/04/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Strathclyde University
School of Psychological Sciences and Health
40 George St
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United Kingdom
G1 1QE

Sponsor information

Organisation
University of Strathclyde

ROR
https://ror.org/00n3w3b69

Funder(s)

Funder type
Charity

Funder Name
Ataxia UK

Alternative Name(s)
Ataxia

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will be shared openly through the university repository. Data will include an excel file with acoustic analyses and listener ratings that will be stored on the Strathclyde University data repository. Where participants have consented to share their speech recordings, acoustic data files will also be available. Data will be accessible by contacting the repository administrator (researchdataproject@strath.ac.uk) or the principal investigator. All data will be fully anonymised and only gender, date of birth and medical diagnosis information will be shared. Data will be available indefinitely from the date of publication of results.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	22/07/2022	04/08/2022	No	Yes
Participant information sheet	Poster for recruitment version 2.0	22/07/2022	04/08/2022	No	Yes