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Online group and peer support speech therapy for people with progressive ataxia

Submission date
26/02/2021

Recruitment status
No longer recruiting

Registration date
02/03/2021

Overall study status
Completed

Last Edited
16/12/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Ataxia is a term for a group of disorders that affect co-ordination, balance and speech. People with progressive ataxia often suffer from communication difficulties. Currently, few of them are offered regular speech therapy to address these difficulties, and this has been made worse during the COVID-19 lockdown. The lockdown also meant that people with ataxia had less opportunities for social interaction, and that can make speaking worse than usual. In addition, staying isolated is not good for people's mental health and wellbeing. The aim of this study is to investigate whether a small number of speech therapy sessions combined with group meetings of people with ataxia to practise speaking together can be as effective as seeing a speech therapist for many sessions individually.

Who can participate?
Patients aged over 16 with progressive ataxia who do not have any other neurological problems or communication problems that are not caused by their ataxia.

What does the study involve?
Participants will be tested twice 1 to 2 weeks before and twice after the intervention (immediately following therapy and 6 weeks later). The intervention itself consists of a 6-week programme and is delivered completely online. The researchers will offer four individual sessions with a speech and language therapist (SLT), to establish some good speaking behaviours that will serve as the basis for the exercises. After that, participants will meet online on Zoom for approx. 1 hour from Monday to Friday to work through speech exercises together. An SLT will join the group each week to check on progress and guide activities for the week. The SLT will also be available to meet with individuals if they run into any difficulties during the week. In addition, a volunteer will be available to support participants with technical issues during the group sessions. The therapy programme is based on a previous study that showed benefits for participants for their voice as well as their confidence in communicating. The participants will be split into two groups of five people each in order to keep the group size manageable and allow everyone to contribute during the session. The researchers will measure whether participants' communication improved, what they thought about practising in groups and how tiring this was, whether they managed to join all the sessions, and whether we provided sufficient support from the SLT with this model.

What are the possible benefits and risks of participating?
It is hoped that participants' communication will improve as part of this treatment. If it does not, the researchers might be able to suggest other methods that could have more success based on their individual presentation so that they can seek further treatment with their local NHS speech and language therapy department. Whatever the individual outcomes, it is hoped that the research will have wider benefits to 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 have tried to take this into account by using the group format so they can get some rest during the session while the other participants are taking a turn. In addition, they will monitor their response to treatment closely and make adjustments during its course where necessary. There are no known negative side effects of the treatment or any of the assessment tasks.
Participants also need to consider that they will not be able to access any further speech treatment until the final evaluation 6 weeks after the end of their treatment. The researchers will indicate to them at the end of the therapy block whether they feel they would benefit from further input and they should make the necessary arrangements at that point.

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

When is the study starting and how long is it expected to run for?
August 2020 to December 2021

Who is funding the study?
Ataxia UK

Who is the main contact?
Prof. Anja Lowit
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
12810

Study information

Scientific Title
A joint model of online speech and language therapist intervention and peer support to enhance communication effectiveness and participation in people with progressive ataxia

Study objectives
The aim of this pilot study is to investigate whether the regular practice of therapist guided speech exercises within a virtual peer group environment can improve communication effectiveness and participation in speakers with progressive ataxia.

Primary question:
1. Can a joint model of speech and language therapist (SLT) intervention and peer group support result in improved communication effectiveness and participation as measured by speech outcomes and qualitative evaluation of participant views?
Secondary Questions:
2. Does this mode of input enable regular participation and avoid negative impacts on the fatigue levels of participants?
3. Is the balance between SLT input and peer group practice appropriate?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2020, Strathclyde University Ethics Committee (16 Richmond St, Glasgow, G1 1XQ, UK; +44 (0)141 5524400; ethics@strath.ac.uk), ref: UEC20/92

Primary study design
Interventional

Study design
Single-centre interventional rater-blinded controlled pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Progressive ataxia

Interventions
Each participant will be assessed four times, twice pre-treatment, and twice post-treatment. Pre-treatment assessments will take place 1-2 weeks apart. Post-treatment assessments will take place immediately after and 6 weeks following the end of the intervention.

The treatment will follow the principles of LSVT, and be supplemented with a clear speech approach. The overall duration will be 6 weeks. During these, each participant will receive four individual sessions with an SLT (spread over 2 weeks). Subsequently, they will meet as a group (group size 5 participants) online via Zoom for approx. 1 hour Mondays to Fridays for a further 4 weeks to work through speech exercises. An SLT will join the group once a week to check on progress and guide activities for the week. The SLT will also be available to support individuals should they run into any difficulties during the week. A volunteer will be available to support participants with technical issues during the peer support sessions.

Intervention Type
Behavioural

Primary outcome(s)
1. Speech data evaluated acoustically (sustained vowel length) as well as perceptually by naïve listeners (voice quality, intelligibility and naturalness) across all four assessment points
2. Patient perceptions of therapy outcomes and delivery format assessed using qualitatively analysed interview data from assessment 3

Key secondary outcome(s)
1. Fatigue measured using the Fatigue Rating Scale at assessments 1 and 3
2. Attendance patterns measured using attendance records during the 6-week intervention period
3. Need for additional sessions measured using attendance records during the 6-week intervention period

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. People with progressive ataxia and associated mild to moderate dysarthria
2. The lower age limit will be 16 years
3. Participants require adequate vision and hearing to participate in the prescribed activities

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
9

Key exclusion criteria
1. Other medical conditions
2. Speech and language impairments beyond those associated with their ataxia

Date of first enrolment
25/01/2021

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Strathclyde University
School of Psychological Sciences and Health
Glasgow
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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
Current individual participant data (IPD) sharing statement as of 10/01/2022:
The datasets generated during and/or analysed during the current study are/will be available upon request from Anja Lowit (a.lowit@strath.ac.uk). Relevant subsets will be published alongside the paper and deposited in the Strathclyde University data repository.
Type of data: anonymised speech recordings, acoustic analysis results, anonymised patient details
When the data will become available: March 2022
For how long: indefinitely
By what access criteria data will be shared including with whom: for research purposes with other researchers
For what types of analyses: further acoustic and linguistic analysis of data
By what mechanism: researchers should contact the chief investigator to establish appropriate means of data transfer and ensure the relevant agreements are in place
Whether consent from participants was obtained: yes
Comments on data anonymization: data will be fully anonymised
Any ethical or legal restrictions, any other comments: N/A

Previous individual participant data (IPD) sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Anja Lowit (a.lowit@strath.ac.uk).
Type of data: anonymised speech recordings, acoustic analysis results, anonymise patient details
When the data will become available: January 2022
For how long: indefinitely
By what access criteria data will be shared including with whom: for research purposes with other researchers
For what types of analyses: further acoustic and linguistic analysis of data
By what mechanism: researchers should contact the chief investigator to establish appropriate means of data transfer and ensure the relevant agreements are in place
Whether consent from participants was obtained: yes
Comments on data anonymization: data will be fully anonymised
Any ethical or legal restrictions, any other comments: N/A

IPD sharing plan summary
Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/08/2022	16/12/2022	Yes	No