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A comparison of two forms of speech therapy (SLT) for people with multiple system atrophy (MSA; a rare condition of the nervous system that causes gradual damage to nerve cells in the brain) type C (that is characterised by cerebellar ataxia [poor muscle control])

Submission date
16/12/2022

Recruitment status
No longer recruiting

Registration date
16/12/2022

Overall study status
Completed

Last Edited
17/07/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Communication problems are a frequent consequence of MSA-C, but there is currently is no effective treatment for speech problems that has been properly evaluated. A number of small pilot studies have recently demonstrated that speech therapy can help people with MSA-C with their communication. Unfortunately they all involved very intensive treatment that is difficult to provide through the NHS because of the required time commitment from the clinician.
A previous study by the research team demonstrated that a mixture of individual and group therapy could improve the speech and communication confidence for people with progressive ataxia and put less strain on therapist resources. This study will find out whether the same is the case for people with MSA-C, and also compare the novel treatment with the effects of regular NHS therapy. This will provide the basis for a follow on larger study to find the most effective treatment for people.

Who can participate?
We plan to recruit 24 people to the study. Participants need to fulfil the following criteria:
• Have a confirmed diagnosis of the cerebellar type of MSA (MSA-C)
• Experience mild to moderate speech or voice problems, i.e. have noticeable issues with your speech but not be completely unintelligible to people who don't know you very well
• Not have any other neurological or speech problems
• Have sufficiently good hearing and vision to take part in the study
• Be aged 18 or over
• Be able to use technology to join in online meetings with the therapist (we can provide the necessary tools if you don't own them yourself)
• Be a fluent English speaker

What does the study involve?
Treatment will be delivered online in participants' homes. Altogether, your involvement would last around 4 months in total made up of two assessments before therapy, 6 weeks of therapy, and two further assessments, one immediately and one about 6 weeks after therapy.

What are the possible benefits and risks of participating?
We anticipate that participants will benefit from either of the interventions by improving their communication and/or their confidence. There are no known negative side effects of any of the assessment or treatment procedures.

Where is the study run from?
Strathclyde University in Glasgow in collaboration with the Sheffield Ataxia Clinic (UK)

When is the study starting and how long is it expected to run for?
December 2023 to September 2024

Who is funding the study?
MSA Trust (UK)

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

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
322064

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
sponsor ref 15078, IRAS 322064

Study information

Scientific Title
ClearSpeechTogether versus standard NHS speech intervention: A single, mixed method, rater blinded pilot randomised controlled trial for people living with MSA-C

Study objectives
1. Both approaches will be acceptable to participants
2. Feasibility of the ClearSpeechTogether (CST) approach will be demonstrated
3. Participants in both arms of the study to improve their communication effectiveness and confidence

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/04/2023, North West - Greater Manchester West Research Ethics Committee (Barlow House 3rd Floor 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8057, 2071048065; gmwest.rec@hra.nhs.uk), ref: 23/NW/0037

Study design
Interventional single centre mixed method rater blinded pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Speech impairment in Multiple System Atrophy, cerebellar type (MSA-C)

Interventions
This study is a pilot study that aims to establish the feasibility of running a larger scale RCT to test the effectiveness of a novel peer supported group intervention (ClearSpeechTogether, Arm 1). At the same time the acceptability and potential communication benefits of this approach will be compared to standard NHS therapy (Arm 2) which acts as the control arm.
All participants will be assessed twice over the course of one week before the start of therapy to gather multiple baseline data. They will then be offered 6 weeks of treatment, followed by two further assessments immediately and eight weeks post-intervention.
Intervention:
Arm 1 (ClearSpeechTogether) will involve a six week programme of individual SLT (four sessions over two weeks), followed by four weeks of peer support group sessions where participants will meet on a daily basis, Monday to Friday, for one hour and work through exercises with each other. They will each complete some individual vocal warm-up exercises immediately before they join the group. A non-clinical volunteer will attend the sessions to provide technical support, but will not guide the exercises or participate in the group. The SLT will join the group on a Friday, monitor individuals for progress or potential adverse effects, and explain the tasks for the following week. The SLT will also be available for questions throughout the week. Depending on the progress of each individual, the SLT can decide to offer further individual sessions during the group phase.
The treatment will focus on two aspects – effective voice production and clear speech. Clear speech has been shown to be effective as a concept to improve intelligibility and is generally achieved by the patient speaking louder and over-articulating, thus speaking slower and with more articulatory accuracy. In addition, given the phonatory problems associated with MSA-C, effective voice production will be essential to support speech. The SLT will focus most of the individual sessions on voice production and introduce the concept of clear speech towards the end in preparation for the group exercises. During the group phase, participants will then practise these concepts in speech tasks which will build from single word exercises in week 1 to read presentations and free speech in week 4. They will be provided with a manual that guides them through the exercises.

Arm 2 comprises of six individual weekly, one hour long sessions, comparable to what is standard in the NHS. The exact focus of these sessions will be left to the decision of the SLT, however, in line with Arm 1, they will be working within the remit of improving voice quality and articulation and patients should work at paragraph reading / free speech level by the end of the treatment. Participants will also be provided with the manual to practise at home on a daily basis.

All assessment and interventions will be carried out online via videoconferencing tools. Participants will therefore not have to travel to attend sessions.
Sample size:
The target is to recruit 24 people in total, 12 for each arm. The statistical power analysis determined that this should allow replication of the results of a previous study on ClearSpeechTogether, allowing for one or two dropouts.

Randomisation:
Randomisation to the intervention arm will be done by an independent statistician. There will be equipoise in that both interventions target the same speech symptoms, and the control arm represents treatment as usual by current NHS standards. The hypothesis is that arm 1 will have additional benefits for patients by adding group support and more opportunities to practise. In order not to disadvantage arm 2 participants, they will be offered access to group support once their post-treatment assessments are complete.

Intervention Type
Behavioural

Primary outcome measure
1. Feasibility: feasibility for a larger trial will be monitored with the following aspects:
1.1. Levels of interest in the study during the recruitment process (approaches to research team);
1.2. Conversion to consent (considering patient consent and fit with inclusion criteria, target = 75% of those identified agree to participate);
1.3. Rate of recruitment (number of consenting participants in 6 months, target = 24);
1.4. Rate of attrition (target = 75% retention rate);
1.5. Data quality (target = 75 % of participants' own recordings and 90% of researcher back-up recordings of sufficient quality for analysis);
1.6. Access to telehealth (target = 75% of those consenting have access to necessary technology and support to use it).
2. Acceptability: acceptability will be evaluated both from a participant and clinician/health economic perspective:
Participants:
2.1. Adherence to the therapy programme (target = 80% attendance);
2.2. Fidelity to treatment programme (home practice diary - target = 75% completion of daily exercises (assuming some over-reporting); volunteer observations during peer group sessions);
2.3. Fatigue levels (target = less than 10% decline in overall fatigue level on the Fatigue Impact Scale attributed to participation);
2.4. Qualitative feedback regarding the appropriateness of the exercises, the balance between individual and group sessions (Arm 1), quality of support provided in sessions, and the scheduling intensity of the sessions. There is no standardised assessment that captures the wider psychosocial benefits of individual or group intervention. In line with Steginga et al., we will co-create a questionnaire with our advisory group based on our pilot study comments to gather structured feedback that will allow us to capture any added benefits arising from group intervention.

Therapists:
2.5. Fidelity to treatment programme: evaluation of 20% of session recordings;
2.6. Need for additional individual or group support (target = no more than 1 additional session required per participant); we will consult a health economist to identify further parameters that need to be considered in a full RCT;
2.7. Qualitative interview feedback regarding workload management;

2.8. An international survey for SLTs working with MSA-C concerning current practice and potential to integrate ClearSpeechTogether into patient care models.

Secondary outcome measures
Communication: Potential communication benefits will be assessed at each assessment point across all ICF levels, including the physiological (breath support and voice quality), the functional (intelligibility) and participatory levels (communication confidence, impact and participation). We are also including a maximum performance task (syllable repetition (DDK)). Whilst performance in this task is not expected to change with treatment, it can monitor overall physiological decline due to disease progression. Speech will be evaluated both acoustically and perceptually. Within group statistical analyses will be performed to compare In addition, we will collect qualitative interview data to capture patient-reported benefits or problems. Therapist notes will also be reviewed for potential adverse effects (such as vocal strain) arising from the treatments.

Measured at pre- and post-therapy:
1. Communication participation: CPIB scores
2. Intelligibility: perceptual evaluation by 5 blinded trained listeners of read and free speech, acoustic segmental feature analysis
3. Breath support: maximum phonation time (MPT)
4. Voice quality: perceptual assessment by 5 blinded trained listeners for connected speech and prolonged vowels using the Cape-V
5. Syllable repetition: acoustic analysis of rate and variability

Overall study start date
01/02/2023

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Diagnosis of clinically probable MSA-C;
2, Presence of mild to moderate speech impairment;
3, Sufficient (corrected) visual and auditory skills to be able to complete the assessment and therapeutic exercises;
4, Ability to use, or have the necessary home support to use video-conferencing software (equipment will be provided if necessary).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Key exclusion criteria
1. Presence of other health conditions that can affect communication (e.g. stroke);
2. History of previous or concurrent communication impairment unrelated to MSA (e.g. stammer);
3. Cognitive impairment unrelated to MSA;

Date of first enrolment
15/02/2023

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Ataxia Clinic
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Sponsor type

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ROR
https://ror.org/00n3w3b69

Funder(s)

Funder type
Charity

Funder Name
Multiple System Atrophy Trust

Alternative Name(s)
MSA Trust, The MSA Trust, MSAT

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be disseminated via a journal publication at the end of the study. They will also be communicated to the MSA community via the MSA Trust, and to relevant health care professionals via professional journals.

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
Anonymous data sets will be shared via the institutional repository on publication of the results. Original sound files may be available on request if participants provided consent, contact the PI (a.lowit@strath.ac.uk) for further information.

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?
Dataset		22/04/2025	16/07/2025	No	No
Plain English results			17/07/2025	No	Yes