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Speech after stroke recovery study (SAYS)

Submission date
17/08/2023

Recruitment status
No longer recruiting

Registration date
21/09/2023

Overall study status
Ongoing

Last Edited
06/11/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Dysarthria, where speech is less clear, slurred or sounds different is the most common form of speech impairment after stroke. It is distressing for those affected and can have a major effect on a person's confidence to mix and talk to other people. There is little research into dysarthria and it's recovery. Existing studies all measure different things.
The Speech after stroke recovery study (SAYS) is funded by the Stroke Association. It will measure the core outcome set (COS), identified in our earlier study (COS-Speech), to assess stroke survivors with dysarthria up to 3 times in their first 18 months post-stroke.

Who can participate?
We will invite 150-200 stroke survivors, who are in hospital or being seen by community therapy services, to take part in the study. To take part they must:
-be over 18
-have had a stroke within the last 6 weeks
-have been identified as having dysarthria

What does the study involve?
Study participants will be involved in the study for up to 18 months. They will be assessed by a research therapist within the first 8 weeks of their stroke. Follow-up assessment will take place around 6 months and 16 months after their stroke. Assessments will take place face to face or using remote technology and will take up to one hour. It may be possible to complete some parts of the assessments by phone.

We will invite up to 25 of the participants to take part in voice recorded interviews to tell us more about their speech recovery pathway, and the impact of dysarthria on their life.

What are the possible benefits and risks of participating?
The SAYS study is a low risk observational study with no direct benefit to the participant for taking part other than they will receive additional assessment and contact from researchers. Participants may find it beneficial to discuss their experience of stroke during the qualitative interviews from a support perspective. The risk of participation may be the potential for the assessments or interviews to cause upset as people reflect on their speech and how this might impact their life. We have support mechanisms in place to support participants taking part in the study.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
May 2023 to November 2026

Who is funding the study?
The Stroke Association (UK)

Who is the main contact?
Claire Mitchell, claire.mitchell@manchester.ac.uk

Study website
https://sites.manchester.ac.uk/cos-speech

Contact information

Type(s)
Scientific

Contact name
Dr Claire Mitchell

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
322537

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57834, SA PDF 21\100017, IRAS 322537

Study information

Scientific Title
Speech after stroke recovery study: exploring speech recovery over time

Acronym
SAYS

Study objectives
Speech recovery after stroke improves over an 18 month period. Clinical tools from the Core Outcome Set for Speech are feasible to use and provide a clinically relevant measure of change on individual assessment. Dysarthria impacts stroke survivors affecting their everyday lives.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/09/2023, East of England - Cambridge Central Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8089; cambridgecentral.rec@hra.nhs.uk), ref: 23/EE/0181

Study design
Longitudinal cohort study with embedded qualitative study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community, Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Stroke

Interventions
Baseline assessment
Once a participant has been consented a suitably qualified member of the research team will arrange to conduct the baseline assessment. This assessment should be completed as soon as practical after the client has been consented, and within 8 weeks of the participants stroke. This will typically take place face to face, at a place and time convenient to the participant. There may be occasions where this will need to be conducted remotely. The assessments should take less

than 45 minutes. Should the assessments, research team members observation and participant feedback demonstrate that the dysarthria has resolved then no further follow up may be required.

Outcome assessments
Outcome assessments will take place at timepoint 1 (6 months ± 1 month) and timepoint 2 (16 months ± 2 months) by a suitably qualified member of the research team. Assessments will take approximately 45 minutes. Where possible these assessments will take place using remote technology; where this is not possible they will take place
face to face. It may be possible to conduct some of the assessments by phone. Should the assessments, research team members observation and participant feedback demonstrate that the dysarthria has resolved then no further follow up may be required.

Qualitative interviews
We will invite a sample of up to 15 participants to take part in qualitative interviews at timepoint 1. Up to 10 of these participants will be invited to take part in a second interview at timepoint 2. If it is not possible to follow-up 10 of the same participants at additional participants will be invited to take part in one interview at timepoint 2. Interviews will take approximately 30-45 minutes. Participants for the qualitative interviews will be selected using purposive sampling to ensure a mix of stroke and dysarthria severity; ethnicity; sex, social situation (living alone/ with others).

Analysis
In keeping with the aims of the study, our analyses will be mostly descriptive to demonstrate recovery over time and to establish feasibility of using this set of outcome measures and the variability (standard deviation) of each outcome assessment. In addition, we will undertake exploratory comparisons of participant outcomes. The "Minimal important change" values of the outcome assessments will be determined using the anchor-based approach. This approach will involve comparing the scores from the assessments with the participant-reported rating of change, i.e. the anchor measure.

Interviews will be digitally recorded and transcribed verbatim to allow for thematic analysis; we will use NVivo 11(QSR International) to organise and manage the coding of the qualitative interview data to allow for the generation of themes. We will start thematic analysis following the first interviews. The research team will undertake all stages of the analysis. We will anonymise and code data, and then organise into themes. To minimise bias, multiple researchers will contribute to the data analysis and theme generation.

Intervention Type
Behavioural

Primary outcome measure
Communication after Stroke Scale (COAST) at baseline, TP1 (6 months), TP2 (16 months)

Secondary outcome measures
All at baseline TP1 & 2 (unless noted otherwise):
1. Oral musculature movement and intelligibility is measured using Frenchay Dysarthria assessment
2. Speech outcome at impairment, activity, participation and well-being is measured using Therapy Outcome Measure Dysarthria
3. General well-being looking at mobility, self-care, usual activities, pain/discomfort, and anxiety

/depression are measured using EQ5D5L
4. Disability or dependence following in daily activities is measured using Modified Rankin
5. Participants view of their speech change measured using Likert scale
6. Participants acceptability of assessments and impact of speech on everyday life measured using Qualitative interviews at TP1 & 2 only

Overall study start date
01/05/2023

Completion date
01/11/2026

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Clinical diagnosis of stroke (ischaemic or haemorrhagic)
3. <= 6 weeks post stroke (may be recruited and take part up to 8 weeks post-stroke)
4. Dysarthria identified at screening (positive for dysarthria on item 10 on NIHSS on admission) or during routine therapy assessment
5. Capable of giving informed consent or has a personal or professional consultee

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

Total final enrolment
200

Key exclusion criteria
Patient has been identified for end of life care.

Date of first enrolment
26/10/2023

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
University of Manchester

Sponsor details
Oxford Road
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United Kingdom
M13 9PL
+44 161 275 5436
fbmhethics@manchester.ac.uk

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
Stroke Association

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/11/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Claire Mitchell Claire.mitchell@manchester.ac.uk on request, anonymised data until the regulatory period when data is deleted following the end of the trial.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.2	06/09/2023	01/11/2023	No	No