Speech after stroke recovery study: exploring speech recovery over time

Short title: Speech after stroke recovery study (SAYS)

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1. Synopsis

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Background
Dysarthria, an impairment of the neuromuscular control for speech, affects the clarity and intelligibility of speech and is a common consequence of stroke. Despite high prevalence of dysarthria in stroke survivors there is little research. Furthermore, there is limited clinical knowledge about the pattern of both short and long term recovery in the general stroke population. More information is needed for stroke survivors, clinicians and researchers.

The Speech after stroke recovery study (SAYS) will progress the work of the COS-Speech study (Mitchell et al 2023) which will identify a core outcome set (COS) and measurement tools to be used clinically and in research into dysarthria after stroke. SAYS will use this COS to follow-up stroke survivors for up to 18 months post-stroke. We will explore the feasibility and acceptability, to stroke survivors, of using this battery of assessments whilst developing a rich understanding of speech recovery after stroke and the impact of dysarthria on those affected. Furthermore we will use anchor-based predictive modelling approach to establishing clinically relevant benchmarks of change on outcome assessments used.

Aims
Longitudinal study
- To develop a better understanding of speech recovery over time.
- To establish clinically relevant benchmarks of change on individual assessment
- To explore the feasibility of using the tools identified to measure the core outcome set for speech (COS-Speech) at various time points post-stroke.

Qualitative study
- To explore the impact of speech problems after stroke.
- To explore the acceptability, to stroke survivors, of using the battery of outcome measures identified in COS-Speech.

Design
Pragmatic, mixed method, longitudinal cohort study with embedded qualitative study, informed by collaborative patient, public and carer involvement (PCPI).

Setting

Participants will be identified and recruited from patients in the Hyper Acute Stroke Units (HASU), Stroke Units and community stroke teams across Greater Manchester, East Cheshire and East Lancashire (the area covered by the clinical research network-Greater Manchester).

Inclusion criteria

- Over 18 years old
- Clinical diagnosis of stroke (ischaemic or haemorrhagic)
- Typically <= 6 weeks post-stroke but with flexibility to recruit up to 8 weeks post-stroke
- Dysarthria identified at screening (positive for dysarthria on item 10 on NIHSS on admission) or during routine assessment by an NHS health professional
- Capable of giving informed consent, or has a personal consultee on recruitment to the study

Exclusion criteria

- Patient has been identified for end-of-life care.

Planned sample size

Longitudinal study: approximately 150-200 stroke survivors screened positive for dysarthria.

Qualitative study: A sub-sample of 15 to 25 participants

Methodology

We will recruit patients from those identified as having dysarthria on routine screening on admission to one of the hyperacute stroke units, or by a therapist after transfer/discharge from the HASU. We will aim to recruit participants up to 6 weeks post-stroke however there will be some flexibility to extend this to 8 weeks to avoid excluding people who may need a little longer. Baseline assessments will be completed as soon as possible after recruitment, but within 8 weeks post-stroke. Participants will be followed up, at two time points, over eighteen months to measure recovery over time. We will use anchor-based predictive modelling approach to establishing clinically relevant benchmarks of change on outcome assessments used.

We will invite a sample of up to 15 participants (to data saturation), with capacity to consent, to take part in qualitative interviews at timepoint 1 (T1) to explore impact of dysarthria on the individual. Up to 10 of these participants will be invited to take part in a second interview at timepoint 2 (T2). If it is not possible to follow-up 10 of the same participants at T2 additional participants will be invited to take part in one interview at T2. Participants for the qualitative interviews will be selected using purposive sampling to maximise diversity e.g. a mix of stroke and dysarthria severity; ethnicity; sex, social situation (living alone/ with others).

Study outcome measures (longitudinal study)
Participants will be assessed using standardised measures including the following:
Speech specific assessments:

- Communication Outcome after Stroke Scale (COAST): takes approximately 25 minutes to complete
- Therapy Outcome Measures (TOMs) dysarthria, completed by the assessor
- Frenchay dysarthria assessment-2 (FDa-2): takes approximately 20 minutes to complete

Quality of life/ disability measures

- EQ5D5L: takes approximately 2-3 minutes to complete
- Simplified modified Rankin scale questionnaire (smRSq): takes approximately 1-2 minutes to complete

Participants will also rate anchors for speech and acceptability of assessments on a Likert scale.

In addition to completing these assessments, the researcher will record:

- Participants' rating of acceptability of assessments on a Likert scale
- Participants' social situation
- Work/other occupation situation
- Current speech therapy/ communication therapy

Assessment will take place as follows:

- Baseline assessment: <= 8 weeks post stroke
- Outcome assessment time point 1 (T1): 6 months post stroke (±1 month)
- Outcome assessment time point 2 (T2): 16 months post stroke (±2 months)

Analyses
Analyses will be mostly descriptive to establish feasibility of implementation of the COS and assessment tools and to describe recovery.
The qualitative interviews will be transcribed and uploaded to NVivo 11 (QSR International) and analysed using thematic analysis.

Study Duration
Anticipated recruitment start date: 1/09/23 or as soon as possible thereafter
Recruitment end date: 28/2/25
Follow up end date: 31/07/26

End of study
The end of the study is defined as the date of completion of the final outcome assessment which will be on or before 31/07/26.

2. Abbreviations

AE	Adverse event
AR	Adverse reaction
ASU	Acute Stroke Unit
ADL	Activities of Daily Living
Baseline assessment	Initial assessment completed <= 8 weeks post stroke
CI	Chief Investigator
COAST	The Communication Outcome after Stroke Scale
CRN	Clinical Research Network
CSNRT	Community stroke and neurorehabilitation team
EQ5D5L	A self-reported measure of health
FDA-2	Frenchay dysarthria assessment-2
FT	Foundation Trust
GDPR	General Data Protection Regulations
HASU	Hyperacute Stroke Unit
HEARD	Healing, Empowered and Recovering from Dysarthria
NHS	National Health Service
NIHR	National Institute for Health Research
non-CTIMPS	Non-clinical trial of investigational medicinal products
smRSq	The simplified modified Rankin scale questionnaire
MRC	Medical Research Council
mRS	modified Rankin Scale
NCA	Northern Care Alliance
NRES	National Research Ethics Service
NVivo	A qualitative data analysis computer software package
PCPI	Patient, Carer and Public Involvement
RDSS	Research data storage service
SAE	Serious adverse event
SAYS	Speech after stroke recovery study
SD	Standard Deviation
SLT	Speech and language therapist
SSNAP	Sentinel Stroke National Audit Programme
SRFT	Salford Royal NHS Foundation Trust
T1	Time point 1: 6 months post stroke (± 1 month)
T2	Time point 2: 16 months post stroke (± 2 months)
TOMs	Therapy Outcome Measures
UoM	University of Manchester
VPN	Virtual private network

3. Background

Stroke is a sudden interruption of the blood supply to the brain caused by a clot or bleed. It is a common cause of complex disability and affects around 100,000 people a year in the United Kingdom. Dysarthria, an impairment of the neuromuscular control for speech, affects the clarity and intelligibility of speech production (Darley et al., 1969) and is a common consequence of stroke. Our research using the Sentinel Stroke National Audit Programme data, suggested that 52% of inpatient, stroke survivors screen positive for dysarthria and it is the most likely communication impairment after stroke (Mitchell et al., 2020).

Dysarthria includes a wide severity range after stroke with some patients having no useful speech, or are unintelligible to the listener, while at the milder end speech is generally intelligible but there may be lapses in speech accuracy.

There is significant evidence that communication impairment caused by stroke can have a devastating effect on an individual's self-identity, psychological well-being and social interaction which directly leads to a reduced quality of life post stroke (Clarke and Black, 2005, Hommel et al., 2009).

Despite high prevalence of dysarthria in stroke survivors there is little research, our Cochrane review of this topic finding only five studies were suitable for inclusion (Mitchell et al., 2017). There is limited clinical knowledge about the pattern of both short and long term recovery in the general stroke population (Dunn et al., 2016) and more information is needed for stroke survivors, clinicians and researchers (Mackenzie, 2011). Clinical services and clinical trials would benefit from knowing more about recovery of speech over time. In 2021 stroke survivors, carers, researchers and clinicians worked with the James Lind Alliance to identify the top ten priorities for stroke rehabilitation and long term care research. Priority number three was to research "the effects of, and best assessments and interventions for, the range of communication difficulties in stroke survivors".

Following on from the COS-Speech study, which will identify a core outcome set (COS) and measures to be used clinically and in research into dysarthria after stroke, the Speech after stroke recovery study (SAYS) will use this set of measures to follow-up stroke survivors for up to 18 months post-stroke. We will explore the feasibility and acceptability (to stroke survivors) of using this set of measures and develop a rich understanding of speech recovery after stroke and the impact of dysarthria on those affected. Furthermore we will use anchor-based predictive modelling approach to establishing clinically relevant benchmarks of change on outcome assessments used.

The project was peer reviewed as part of the application for the Stroke Association funding and the chief investigator (CI) responded to reviewers' comments.

4. Aims and objectives

Longitudinal study

- To develop a better understanding of speech recovery over time.
- To explore the feasibility of using the tools identified to measure the core outcome set for speech (COS-Speech) at various time points post-stroke.
- To establish clinically relevant benchmarks of change on individual assessments.

Qualitative study

- To explore the acceptability, to stroke survivors, of using the battery of outcome measures identified in COS-Speech.
- To explore the impact of speech problems after stroke.

5. Research sites

We will recruit patients from the HASUs, ASUs, Stroke Units and community stroke teams across Greater Manchester, East Cheshire and East Lancashire (the area covered by the CRN- Greater Manchester). Where possible participants will be recruited while in-patients, however if they are transferred or discharged within the area prior to six weeks we will recruit through local hospitals and community therapy services.

Recruiting sites, subject to local approvals, to include:

Hyper Acute/ Acute Stroke Units

- Salford Royal Hospital, Northern Care Alliance NHS Foundation Trust (FT)
- Fairfield Hospital, Northern Care Alliance NHS FT
- Stepping Hill Hospital, Stockport NHS FT
- Royal Blackburn Hospital, East Lancashire Hospitals, NHS Trust

Stroke Units/ rehab settings

- Manchester Royal Infirmary, Manchester University FT
- Trafford General Hospital, Manchester University FT
- Tameside Hospital, Tameside and Glossop Integrated Care NHS FT
- Royal Albert Edward Infirmary, Wigan and Leigh NHS FT
- Bolton Royal Bolton Hospital, Bolton FT
- Pendle Community Hospital, East Lancashire Hospitals NHS Trust
- Alexandra Court, Wrightington, Wigan and Leigh NHS Foundation Trust

Community therapy teams

- Salford community stroke and neuro rehab team, Northern Care Alliance
- Heywood, Middleton and Rochdale community stroke team, NCA NHS FT
- Oldham community stroke team, NCA NHS FT
- Bury community stroke and neuro rehab team (CSNRT), NCA NHS FT
- Central Manchester CSNRT, Manchester University NHS FT
- North Manchester CSNRT, Manchester University NHS FT
- South Manchester community stroke team, Manchester University NHS FT

- Trafford early supported discharge team, Manchester University NHS FT
- Stockport CSNRT, Stockport NHS FT
- Tameside CSNRT, Tameside and Glossop Integrated Care NHS FT
- Wigan, Withington & Leigh CSNRT, Wrightington, Wigan and Leigh Teaching Hospitals NHS FT
- Bolton Community stroke team, Bolton NHS FT
- East Cheshire community stroke team, University Hospitals of North Midlands NHS Trust
- East Lancs community stroke team, East Lancashire Hospitals NHS Trust

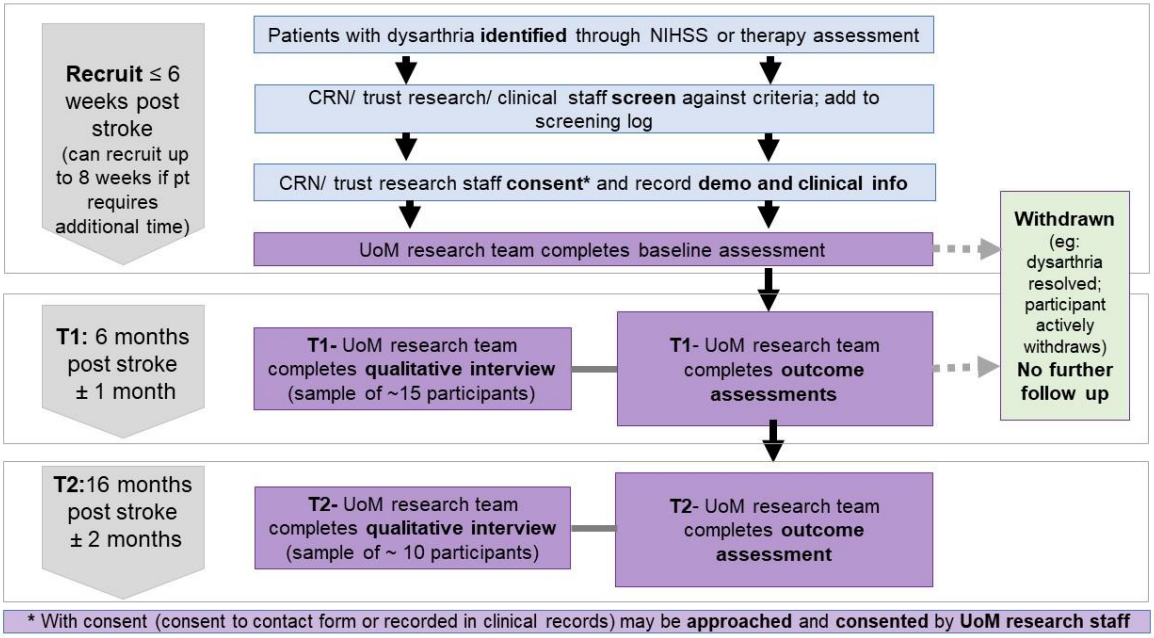
6 Methods

6.1 Design

Pragmatic, mixed method, longitudinal cohort study with embedded qualitative study with collaborative patient, public and carer involvement (PCPI).

See figure 1 for flow chart of study process.

Figure 1: Flow chart of study process



6.2 Sample Size

Longitudinal study: approximately 150-200 stroke survivors screened positive for dysarthria. Qualitative study: A sub-sample of 15 to 25 participants.

Speech recovery over time: The sample size for the longitudinal study is based on a pragmatic choice of how many stroke survivors in the Greater Manchester area are likely to present with dysarthria and the numbers likely to consent to the study over this 18-month recruitment period. This sample size would allow us to estimate the mean change (change in measures from baseline over the follow-up time period) to within 0.16

standard deviations which is a reasonable level of precision. If we are able to recruit more than this, the precision of the estimate will increase. Attrition is difficult to predict as this is a longitudinal study over 18 months duration, but the intention is the original sample size of 150-200 will adequately cover dropout rates and still allow us to estimate the mean change in measures over time.

Feasibility of using the tools identified to measure the core outcome set: This number of 150-200 is more than sufficient for feasibility and will adequately cover attrition from the study to examine this question. Feasibility relates to this being considered a reasonable amount of time taken, according to the stroke survivor in response to this question. We will also examine feasibility of using the tools by looking at the amount of missing data for each tool at each timepoint. A sample size of 150 allows us to estimate the proportion of missing values to within 17 percentage points in the worst-case scenario (where half the values for a measure are missing at a given timepoint). For more realistic levels of missingness (20%) a sample size of 150 would result in estimation to within 6 percentage points.

Establish clinically relevant benchmarks of change on individual assessment: A sample size of 150 is sufficient to evaluate the correlation between measures. For example, this sample size would grant 97% power to test a null hypothesis that the correlation is equal to 0.5 supposing it is actually equal to 0.7.

Recruitment will end either once 200 participants have been recruited, or we have reached the end of the planned recruitment period.

A sub-sample of 15-25 recruited participants (to data saturation) will take part in in-depth qualitative interviews at T1. Up to 10 of these participants will be invited to take part in a second interview at T2. If it is not possible to follow-up 10 of the same participants at T2 additional participants will be invited to take part in one interview at T2.

6.3 Criteria

Inclusion criteria

- Over 18 years old
- Clinical diagnosis of stroke (ischaemic or haemorrhagic)
- Typically <= 6 weeks post-stroke but with flexibility to recruit up to 8 weeks post-stroke
- Dysarthria identified at screening (positive for dysarthria on item 10 on NIHSS on admission) or during routine therapy assessment
- Capable of giving informed consent or has a personal consultee

Exclusion criteria

- Patient has been identified for end-of-life care.

Patients with aphasia along with dysarthria are eligible to take part.

6.4 Study duration

Anticipated recruitment start date: 1/09/23 or as soon as possible thereafter
Recruitment end date: 28/02/25
Follow up end date: 31/07/26

6.5 End of study

The end of the study is defined by the completion of the final outcome assessment which will be on or before 31/07/26.

6.6 Participant identification

Members of the Clinical Research Network (CRN) team/ Trust research staff and/ or members of the clinical team will identify those patients who are identified as having dysarthria during routine screening on admission (i.e. with a score of 1 or 2 on item 10 of the National Institutes of Health Stroke Score) or through multidisciplinary team assessment or through speech and language therapy assessments.

6.7 Screening

Patients identified as having dysarthria will be screened against the inclusion/ exclusion criteria by a member of the CRN team/ Trust research staff / or member of the clinical team. The outcome of screening will be entered on the screening log.

6.8 Recruitment

Study materials, including information sheets, consultee cover sheets, consultee declarations and consent forms, will be provided in a format and presented in a manner to facilitate maximum engagement of participants with cognitive, communication or physical impairments. These may be read to the patient if this is preferred/ most accessible for the individual.

In all cases the patient or consultee will be given sufficient time to consider the information and discuss with others before deciding on participation. Informed consent may be obtained once a potential participant is happy that they have considered the implications and have had any questions answered. Should additional time be required to consider participation, patients may be consented up to 8 weeks post stroke.

6.8.1 Patients with capacity to consent

CRN practitioner/ Trust research or clinical staff will approach patients identified as meeting the eligibility criteria, inform them of the study and provide them with information including the easy access participant information sheet (appendix A). Potential participants will be given time to consider the information, discuss with others and ask any questions they may have.

The CRN practitioner/ Trust research staff will typically be responsible for obtaining informed consent or a consultee declaration. With patient's consent, recorded on the consent to contact form (appendix H) or clearly detailed in medical/ clinical records, a

member of the University of Manchester research team, with suitable letter of access, may meet with potential participants to provide further information on the study and/or gain consent.

Where eligible patients are identified post discharge from hospital by a member of the NHS community therapy team, where there is no access to CRN/ Trust research staff, they should be provided with the consent to contact form (appendix H) which can then be passed onto the UoM (University of Manchester) research team. A member of the UoM research team will contact the patient by the method agreed (phone, email, face to face) to provide more information, answer any questions and take consent.

We will record consent on easy access consent forms (appendix B1). Where a stroke survivor is present but unable to read or write on the consent form for any reason the participant's verbal or non-verbal consent will be witnessed. Where the consent process is taking place over the phone the oral consent form (appendix B2) will be completed by the member of staff taking consent.

6.8.2 Patients lacking capacity to consent

In line with the Mental Capacity Act (2005), we will deem that patients have capacity to consent to this study unless a clinician involved in their care determines otherwise. The CRN practitioner/ Trust research staff taking consent will liaise with the SLT and/or other members of the clinical team in order to ascertain whether they may not have capacity to consent to this study. If there are doubts as to whether a participant has capacity the Assessing Capacity form (appendix C) should be used to assess capacity to consent to the study.

For patients who do not have capacity to consent a personal consultee will be sought. The personal consultee should be someone who knows the patient well and is trusted by them. In most cases it would be someone with a close personal relationship to the potential participant, for example their next of kin, partner or adult child but may include an informal carer or friend. The personal consultee cannot be someone paid to care for the potential participant. The researchers should make every effort to discuss with, and follow the wishes of, the potential participant in respect to who should be their personal consultee. In considering who might be a personal consultee the researcher should ensure that they follow the principles of confidentiality. Should there be no suitable personal consultee the patient should not be recruited to the study.

The CRN practitioner/Trust research staff will provide information to the consultee (consultee information cover sheet appendix D) along with the PIS. The consultee should take into account the potential participant's current, or previously expressed wishes or feelings about research. The consultee will be provided time to consider the information and to ask any questions before being to sign a consultee declaration form (appendix E1). Where the consultee declaration process is taking place over the phone

the oral consultee declaration form (appendix E2) will be completed by the member of staff taking the consultees declaration.

With potential consultee's agreement (recorded on appendix H- consent to contact form), a member of the research team may contact potential consultees to provide further information and/or for completion of consultee declaration form..

Should, at any follow-up, a participant be found to have lost capacity, a personal consultee will be sought. The personal consultee should be someone who knows the patient well and is trusted by them. In most cases it would be someone with a close personal relationship to the participant, for example their next of kin, partner or adult child but may include an informal carer or friend. The personal consultee cannot be someone paid to care for the potential participant. The researchers should make every effort to discuss with, and follow the wishes of, the potential participant in respect to who should be their personal consultee. In considering who might be a personal consultee the researcher should ensure that they follow the principles of confidentiality. Should there be no suitable personal consultee the participant would be withdrawn from the study. Any data collected prior to their withdrawal will be retained, unless a participant/ consultee explicitly requests it is removed. Data can be removed up to the point that it has been fully anonymised (at the end of the study).

Should a participant regain capacity during the course of the study the regained capacity cover sheet (appendix G) and PIS (appendix A) will be provided and a new consent form (appendix B1 or B2) will be completed. This consent form will replace the previous consultee declaration.

6.9 Baseline information/ assessment

Following recruitment the CRN practitioner/Trust research staff / member of the UoM research team will record initial demographic and clinical data including: age; ethnicity; social situation; employment status; date of stroke; first ever or recurrent stroke; stroke type (infarct or haemorrhage); location (right/ left/ bilateral) of stroke; total score and scores on points 4 (facial palsy), 9 (aphasia) and point 10 (dysarthria) of the National Institutes of Health Stroke Scale (NIHSS) on admission; pre-stroke modified Rankin Scale (mRS). See table 1 for information and assessments completed at baseline. Where participants have been discharged from hospital prior to recruitment the CRN practitioners/ research team at the admitting HASU will be contacted for this information.

A member of the UoM research team will make arrangements to complete the baseline assessment which will, in most instances, take place face to face in hospital or in the community at a location convenient to the participant. When this is not possible the assessment may take place using remote technology. The baseline assessment will take place as soon after recruitment as is practical and within 8 weeks of stroke.

The baseline assessment will involve the following:

Speech specific assessments:

- Communication Outcome after Stroke Scale (COAST): takes approximately 25 minutes to complete
- Therapy Outcome Measures (TOMs) dysarthria, completed by the assessor
- Frenchay dysarthria assessment-2 (FDa-2): takes approximately 20 minutes to complete

Quality of life/ disability measures

- EQ5D5L: takes approximately 2-3 minutes to complete
- Simplified modified Rankin scale questionnaire (smRSq): takes approximately 1-2 minutes to complete

In addition, participants will rate acceptability of assessments on a Likert scale: takes less than a minute.

It is anticipated that these assessments will take 45-50 minutes in total and will be completed in one session, however if the participant becomes fatigued or require a break, they will be given the opportunity to rest and/ or complete over several sessions.

Should the baseline assessment, the research team's observations and participant's feedback demonstrate that dysarthria is no longer present, further follow up will not be required. This will be discussed with the participant and their research involvement will end.

6.10 Outcome measurement

Outcome assessment will take place at time point 1 (TP1): 6 months post stroke ±1 month and time point 2 (T2): 16 months post stroke ±2 months. Prior to contacting participants to arrange follow-up assessment the UoM research team will liaise with the CRN/ Trust research team and request that, where possible, electronic mortality checks are conducted.

A member of the UoM research team or CRN will contact participants by phone, text message, post or email to arrange for outcome assessments to be completed by a suitably trained member of the UoM research team. Whenever possible arrangements will be made for the assessments to be completed using remote technology (ie: Zoom).

Where is it not possible to complete the assessments using remote technology they will be completed face-to-face. If the participant is an in-patient face to face assessments will take place in the hospital; if the participant has been discharged face to face assessments may take place in participants' own homes, at the University of Manchester or another location in the community convenient to the participant.

If there are circumstances where it is not possible to complete them face to face or using remote technology the assessment may be completed by phone. It should be noted that it may not be possible to complete all components of the outcome assessment by

telephone, for example the FDa-2. Therefore, if the decision has been made to complete the outcome assessments by phone, as much of each assessment as possible should be completed and the reason for non-completion of any assessments/ parts of assessments should be recorded.

The outcome assessments will include the following (see table 1) at both T1 and T2:

Speech specific assessments:

- Communication Outcome after Stroke Scale (COAST): takes approximately 25 minutes to complete
- Therapy Outcome Measures (TOMs) dysarthria, completed by the assessor
- Frenchay dysarthria assessment-2 (FDa-2): takes approximately 20 minutes to complete

Quality of life/ disability measures

- EQ5D5L: takes approximately 2-3 minutes to complete
- Simplified modified Rankin scale questionnaire (smRSq): takes approximately 1-2 minutes to complete

In addition, participants will rate anchors for speech, and acceptability of assessments on a Likert scale and will be asked for feedback on the impact of dysarthria.

The researcher will also record:

- participants' social situation (e.g.: living at home alone/ at home with others/ care home).
- work/other occupation including if returned in the same capacity/ same number of hours.
- speech therapy/ communication therapy (frequency and duration to date)

It is anticipated that these assessments will take 45-50 minutes in total and will be completed in one session, however if the participant becomes fatigued or require a break, they will be given the opportunity to rest and/ or complete over several sessions.

If at the TI outcome assessment, the research therapist's observations and participants' feedback demonstrate that dysarthria is no longer present, the second follow up will not be required. This will be discussed with the participant and their research involvement may end. If a participant misses the T1 assessment they will remain in the study and be followed up at the next time point unless they explicitly withdraw from the study.

Table 1: Data collection

Measure	Method	Person responsible	Timing				
			Screening	**Discharge**	**Baseline**	**T1**	**T2**
Screen against eligibility criteria	Screening	CRN practitioners*	X				
Demographics: age; sex; ethnicity; social situation; employment status	Extracted from records and/ or from participant	CRN practitioners*			X		
Baseline clinical information: date of stroke; first or recurrent stroke; stroke type (infarct or haemorrhage); location (right/ left/ bilateral) of stroke; total NIHSS; NIHSS score for points 4, 9, 10; pre-stroke mRS	Extracted from records	CRN practitioners*					
COAST	Participant reported outcome measure	UoM research team			X	X	X
FDa-2	Assessment	UoM research team			X	X	X
TOMs	Assessment	UoM research team			X	X	X
EQ5D5L	Participant reported outcome measure	UoM research team			X	X	X
smRSq	Assessment	UoM research team			X	X	X
Impact of dysarthria- subjective	Participant feedback	UoM research team			X	X	X
Likert scale- assessments acceptability	Likert scale	UoM research team			X	X	X
Likert scale- minimally important changes	Likert scale	UoM research team				X	X
Social situation; work status; SLT input	Participant reported	UoM research team				X	X
** CRN practitioners or Trust research staff/ clinical staff with research responsibilities*							

6.11 Participant interviews

Fifteen participants will take part in semi structured interviews at T1, subject to data saturation. Ten of these participants will be invited to take part in a second interview at T2. If it is not possible to follow 10 participants up for a 2nd interview additional participants may be invited to take part in one interview at T2 taking the total number of interviews to be completed at T2 to a maximum of 10. Only participants with capacity to consent to a research interview will be invited to take part.

Members of the UoM based research team, with experience of qualitative interviewing and with enabling communication with stroke survivors (who may have a range of communication, cognitive and sensory difficulties), will carry out the interviews using a topic guide developed with service user partners (Appendix F: interview schedule). Interviewers will utilise a range of communication support strategies including pictures, drawings, assessable language and ensuring participants are given sufficient time to be able to fully participate. We will conduct participant interviews using remote technology, by phone or face to face in a location convenient to the participant. Where possible the interviews will take place at the same time as the outcome assessment and will take place either face to face or by phone. Where this is not possible, or if this would be too tiring for the participant, interviews can be conducted on a separate date.

We will use purposive sampling of participants to include a range of severity of stroke; severity of dysarthria; sex; ethnicity; social situation (ie: living alone/ with others).

6.12 Data Storage Processing and Analysis

6.12.1 Quantitative data

Hard copy data will be stored in a locked filing cabinet in a locked office on the university campus. Responsibility for these files lies with the CI. Electronic data will be stored on the university RDSS, accessible only by password login and VPN. The University network is encrypted and regularly backed up. Access to the data will be limited to only some of the University of Manchester based research team.

In keeping with the aims of the study, our analyses will be mostly descriptive to establish feasibility of implementation of the COS and assessment tools and to describe recovery.

The COAST is the one patient reported measure and we will examine the interclass correlation between the COAST at different time points to see how well scores are correlated over time. We will also examine the mean change in score between different time points to see if the change is significant. We will use the overall percentage score from the COAST and use a mean percentage change.

We will examine the correlation between the COAST and the other speech related measures, the Frenchay Dysarthria Assessment and the Therapy Outcome Measure

for Dysarthria. The purpose of this is to determine the construct validity of the COAST tool against the other measures. We will look at this at the 3 time points.

The "Minimal important change" values of the outcome assessments will be determined using the anchor-based approach (Terwee 2021). This approach will involve comparing the scores from the assessments with the participant-reported rating of change, i.e. the anchor measure.

6.12.2 Qualitative data

In line with the University of Manchester standard operating procedure, a university approved encrypted device will be used to audio record face to face and telephone interviews. Zoom software and cloud space will be used to record online interviews and temporarily store audio recorded data. The data will be uploaded/downloaded onto the university network and stored on the RDSS until the data has been transcribed.

Recorded interviews will not include any identifiable information, however, any names or locations will be redacted when transcribed. Audio recordings will be transcribed by a University of Manchester approved external transcription service. All files will be encrypted and transferred to this service via a secure website. The files will be deleted from this site at the earliest opportunity. The approved service will have signed a confidentiality agreement in line with the University of Manchester SOP.

Audio recordings will be destroyed as soon as the research team is satisfied that that the written transcription has accurately and comprehensively captured the interview data, in line with the data management plan and UoM records retention schedule.

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.

We will store and access the data at UoM through encrypted servers and share with University approved transcription services through password protected electronic transfer systems. We will pseudo-anonymise transcripts giving each participant an individual study identification number (study ID). The key to identify participants from their study ID will be stored on a separate server such that only the University of Manchester research team will have access to the process to identify them.

7. Co-enrolment

SAYS is an observational study requiring follow-up assessment of patients at two points (6 months and 16 months) post-stroke on a number of non-invasive assessments conducted remotely, or face to face by a suitably qualified member of the research team.

As such we see no reason why participants may not be co-enrolled on other observational or interventional studies.

8. Patient, Carer and Public Involvement HEARD Group

Annette Dancer (AD), who has lived experience of stroke and dysarthria, has worked with the research team throughout the planning and application stages of the project. She will continue to do so throughout the study and was involved in setting up the HEARD (Healing, Empowered and Recovering from Dysarthria) advisory group for the preceding COS-Speech study. The HEARD group members, all with lived experience of dysarthria following stroke have met monthly since the group's inception in early 2021.

The HEARD advisory group will work with the research team to provide input and advice on all research activities from study documentation through to the dissemination of results. The group will meet regularly throughout the course of the study as required.

A member of the HEARD advisory group, will sit on the study management group and will feed information in and out of both groups; they will also have access to members of the research team should they wish to discuss issues outside of meetings

HEARD group members will be offered an honorarium and expenses in line with INVOLVE best practice.

9. Safety and risks

9.2 Safety reporting

SAYS is a low risk observational study that does not include an intervention. We will adhere to research ethics safety reporting for non-CTIMPS, specifically we will report to the REC a serious adverse event (SAE) occurring to a research participant only if the CI believed that the SAE is related to the research and is unexpected. We will report within 15 days of the CI becoming aware using the official NRES SAE report form.

Due to the nature of the population being studied a range of AEs and SAEs may occur which would be unrelated to the outcome assessments/interviews e.g. deaths, further strokes, infections, accidental injury linked to the stroke, re-hospitalisation. At each outcome assessments we will ask participants about any significant health consequences of our previous assessment.

9.1 Risks

SAYS is a low risk study, however the following potential risks/ burdens to participants have been identified.

Assessment burden

Up to three assessments will be carried out over an 18 month period. We will attempt to reduce the burden of assessment by offering a window of time for each follow-up

assessment. Where possible we will conduct follow up assessments remotely but if this is not possible or suitable to the participant they will be completed face to face. At each time point the assessments would typically be conducted in one session (approximately 45 minutes) however this could be split into several sessions if the participant would prefer and/ or becomes fatigued.

Potential distress

Assessments and interviews could highlight participants' difficulties/ impairments which may cause distress. Participants will be advised that they do not need to answer any questions that they do not want to and that the assessments/ interviews can be stopped at any time. A distress procedure has been developed for the study which provides guidance to the research staff.

Potential disclosures

Participants may disclose information during assessments or interviews which indicates that they, or someone else, is at risk of harm. As indicated in the PIS, in this situation the researchers may need to break confidentiality. If this is the case it would be discussed with the participant in the 1st instance.

The study will include some remote working for the researchers including visiting of participants within the community and/ or their own home. Risk assessments will be completed prior to conducting any home visits and lone worker procedures are in place.

10. Study monitoring

The UoM based research team will remain in regular contact with sites by email, phone or post and through visits as required during the course of the study to provide training on the study processes including for recording participant recruitment and data collection. No formal monitoring visits will take place.

The research team has formed a Study Management Group which will meet throughout the duration of the study on a quarterly basis, or more frequently as required. The Study management group will the ongoing running of the study, including the clinical and practical aspects, and to ensure that the trial is analysed and reported appropriately. It will consist of:

- Dr Claire Mitchell (Chief investigator)
- HEARD group representative
- Prof Jamie Kirkham
- Prof Audrey Bowen
- Dr Paul Conroy
- Dr Sarah Wallace
- Ms Shahd Benafif

A sponsor representative will be invited to attend.

Additionally the study team will meet a on a monthly basis which will include:

- Dr Claire Mitchell (Chief investigator)
- Ms Shahd Benafif
- Ms Kate Woodward-Nutt

Others will be invited to attend as required.

11. Ethics

The CI will ensure that this study is conducted in full conformity with all relevant legal requirements and the principles of the current revision of the Declaration of Helsinki (last amended October 2013), Good Clinical Practice. (GCP) and the UK Policy Framework for Health and Social Care Research..

11.1 Approvals

The study will be reviewed and a favourable opinion provided by East of England-Cambridge Central NHS Research ethics committee (ref: 23/EE/0181) prior to the start of the study. The CI will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

We will communicate any amendments or changes to protocol to NHS site research teams, local PIs, CRN practitioners and clinical staff involved in the study and provide revised documentation.

11.2 Participant Confidentiality

The CI will ensure that the participant's anonymity is maintained. Data will be pseudo-anonymised during collection. We will identify participants by a unique participant study number only on any documentation associated with the study. Only members of the University of Manchester research team will have access to the key linking ID numbers to participants' personal data. This will be destroyed within 2 weeks of the end of the study. Data will be in accordance with local data protection guidelines, GDPR and in keeping with the Medical Research Council's Personal Information in Medical Research Guidelines.

When contact information is required by the University based research staff for the purpose of carrying out interviews/ outcome assessment this will be stored on password protected spreadsheets on encrypted drives on university computers and will be destroyed at the end of the study. Hard-copy material, such as written consent forms, will be kept in locked filing cabinets within secure office space. Consent forms will be destroyed 5 years after the end of the study.

We will ask participants taking part in interviews not to disclose any personal identifiable information during the course of the recorded interview but if any are disclosed these will be redacted from transcripts.

Where participants have consented to their contact details being stored for the purpose of receiving study updates and a study summary report the end of the study this will be

stored on password protected databases/ spreadsheets on encrypted University servers and will be destroyed when the final report has been sent out.

Where participants have consented to their contact details being stored for the purpose of receiving information about other relevant studies this will be stored on password protected spreadsheets on encrypted University servers and will be destroyed 5 years after the end of the study.

We will keep all information collected during the course of the study strictly confidential. We will only breach confidentiality if required to meet a duty of care e.g. if the researcher becomes aware that someone is at risk of harm. This is explained in participant and consultee information sheets. Should this occur the CI would be made aware and appropriate course of action will be taken, depending on context.

12. Data handling and record keeping

We will complete and store study documentation in accordance with the MRC guidelines for GCP in clinical trials, the local project Data Management Plan (ref: UoM DMP 117174) and other applicable local guidelines. All personal information will be pseudo anonymised as soon as possible. Data will be stored in a password protected excel spreadsheet on the university network. It will only be accessed on a password protected university laptop or desktop and only some members of the UoM research team will have access to this spreadsheet. Only some of the UoM based researchers will have access to the key to de-anonymised data and this will be broken at the end of the study and the data will be fully anonymised.

The CI will retain a link to the study file which will be kept in a secure location. We will retain study documentation according to UoM's record retention schedule and archive in accordance with the Sponsor's recommendations.

Research data will be archived and retained in accordance with the University of Manchester's data archiving policy and data retention policy.

13. Dissemination

13.1 Outputs

We will produce regular newsletters throughout the course of the study providing updates on recruitment and study progress. These will be circulated by mail, text messaging, email, on the study website and on social media (e.g. twitter) to participants and others with an interest in the study who have consented to this.

The protocol will be made available via the study website and on the ISRCTN registry. We will submit work-in-progress and final results presentations at national and international conferences. We will invite people who have had a stroke who partnered us in co-developing the study to contribute to presentations and publications.

We will present and discuss the results with the HEARD group and with stroke patients and carers across Greater Manchester. We will submit a final report to the Stroke Association at the end of the study and an accessible summary of the final results to study participants who have consented to this.

Parts of the study will contribute to a PhD thesis.

13.2 Publication policy

We will determine authorship of any publications resulting from this study on the basis of the Uniform Requirement for Manuscripts Submitted to Biomedical Journals, which states:

- Authorship credit should be based on (1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multicentre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript.
- These individuals should fully meet the criteria for authorship defined above.
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate proportions of the content.

The study management group will authorise all presentations and publications relating to the study.

14. Funding and Resources

The project is funded the Stroke Association (ref: SA PDF 21|100017). In addition Ms. Shahd Benafif's PhD is funded by King Saud bin Abdulaziz University for Health Sciences. No physical resources are required or funded for the study.

15. Compensation arrangements and insurance

The University of Manchester will arrange insurance for research involving human subjects that involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

16. Conflict of interests

AB developed the COAST

CM, AB, PC, SW, AD took part in the COS-Speech study

17. References

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18. Appendices

Appendix A:	Easy access PIS
Appendix B1:	Easy access consent form
Appendix B2:	Oral consent form
Appendix C:	Assessing capacity form
Appendix D:	Consultee information cover sheet
Appendix E1:	Consultee declaration form appendix
Appendix E2:	Consultee oral declaration form
Appendix F:	Interview schedule
Appendix G:	Regained capacity cover sheet
Appendix H:	Consent to contact form