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Emotional and language recovery in aphasia (ELLA)

Submission date
17/09/2025

Recruitment status
Recruiting

Registration date
03/10/2025

Overall study status
Ongoing

Last Edited
08/10/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Following a stroke, around one third of people will have aphasia. This is a language disability that affects speaking, understanding, reading, and writing. We want to test a new therapy for people living with aphasia that targets language recovery, confidence, and emotional wellbeing. We have had excellent results in our university clinic. Now we want to see if it will work well in NHS settings, and what kind of support and training is necessary to deliver it.

Loss of language can be devastating: aphasia has been described as 'identity theft', and it is common that people with aphasia become depressed, anxious and isolated. People with aphasia want treatment to focus on improving both language and emotional wellbeing, yet they describe struggling to access mental health support due to their language difficulties. Further, once home they often receive limited language therapy, yet language therapy is most effective when people receive at least 20 hours.

We have developed a new therapy for language recovery and emotional wellbeing through running a series of workshops with five people with aphasia, three family members and four Speech and Language Therapists. We also met with experts in psychological therapy. We then trialled the new therapy in our university clinic with eight people with aphasia. We found that people improved in how confident they felt talking in different situations and made significant progress with their own personal goals (e.g., feeling at peace, ordering in a cafe). All participants were highly positive about combining psychological and language therapies within a single treatment.

Who can participate?
Adults who have aphasia as a result of a stroke can take part in the study. Participants need to be able to give informed consent and be willing to take part in therapy sessions and assessments.

What does the study involve?
Phase One: we will develop training packages, including online resources and support. We want to explore what training and support will help therapists in the NHS deliver the new therapy.
Phase Two: we will recruit 42 people with aphasia: half of them will receive the new therapy; half of them will receive standard care. The therapy is up to 23 therapy sessions spaced across 7 to

12 weeks, with some sessions delivered by experienced Speech and Language Therapists, and some by students or rehabilitation assistants who will be given careful support.
We will interview people with aphasia, family members and therapists about their experiences. We will also assess participants' confidence communicating, language, quality of life and emotional wellbeing. We will assess everyone when they start in the study, and then 3 and 6 months later.

What are the possible benefits and risks of participating?
Participants may enjoy taking part. They may find it interesting to talk about their stroke and their life in the research visits. It may help other people with aphasia in the future. There are no medical risks or dangers to taking part. Participants will still receive normal NHS care. The main disadvantage to taking part is that participants will give up some time.

Where is the study run from?
East London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Sarah Northcott, sarah.northcott@city.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

334237

Protocol serial number
CPMS 58506, NIHR207125

Study information

Scientific Title
EmotionaL and Language recovery in Aphasia (ELLA): a feasibility study developing a novel intervention for people living with post-stroke aphasia

Acronym
ELLA

Study objectives
1. Feasibility of developing and delivering a training package, resources and support that enable delivery of ELLA within NHS services
2. Acceptability of ELLA to people with aphasia, family members, and clinicians when delivered in NHS community services and perceived mechanisms of change
3. Feasibility of delivering ELLA within NHS community services, including barriers and facilitators
4. Feasibility and acceptability of study processes including recruitment and retention of participants, treatment fidelity, and documentation of usual care
5. Feasibility of conducting a future definitive RCT investigating clinical and cost effectiveness; determining primary outcome measure and sample size of future definitive trial

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/10/2025, Wales REC 5 (Health and Care Research Wales, Floor 4, Crown Building, Cathays Park, Cardiff, CF10 3NQ, United Kingdom; -; Wales.REC5@wales.nhs.uk), ref: 25/WA/0236

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
There are two stages to the ELLA study. Phase one (months 1 to 11) is the preparatory stage, including developing training and resources. Phase two (months 12 to 27) is a feasibility randomised controlled trial.

We will recruit 42 participants living with post-stroke aphasia from 6 to 8 community NHS services. Participants will be randomly allocated to either the ELLA intervention or treatment as usual.

The intervention will be up to 23 ELLA therapy sessions spaced over 7 to 12 weeks. The therapy has been designed to be delivered by an experienced Speech and Language Therapist, with some sessions optionally delegated to be delivered by either student Speech and Language Therapists or rehabilitation assistants, under the oversight of the experienced therapist. The therapy targets language and emotional recovery, integrating evidence-based interventions. ELLA will be instead of equivalent language therapy, but in addition to all other usual NHS care. It can be delivered in person or online.

Participants allocated to the control arm will receive standard NHS Speech and Language Therapy plus all other usual care.

Outcomes will be communicative participation, mood, language, and quality of life. Participants will be randomised to either intervention or control. Participants with aphasia will be assessed at baseline (prior to receiving the intervention), 3 months, and 6 months post-randomisation. Participants with aphasia will be supported through collecting outcome measures in face-to-face interviews, by an experienced Speech and Language Therapist or other clinician with specialist training in facilitating the communication of people with aphasia. They will be able to select whether they wish to see the researcher in person (for example, in their own home) or online.

A purposive sample of participants with aphasia, significant others, therapists, and student or assistant therapists will be invited to take part in in-depth interviews. We are interested in how people experience the intervention. Interviews will take place at the venue of the participant's choice (for example, their own home or online). Therapists will also complete brief questionnaires about their experiences of receiving the training, and pre- and post-study questionnaires exploring their experience of work and delivering therapy.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes.
Outcomes 1- 4 will be calculated using numbers presented in the CONSORT diagram; progression will be assessed using the traffic light criteria.
1. Proportion eligible/ screened measured using screening logs at the end of the 6 months recruitment period, ≥30% progress; 20-29% amend; <20% stop
2. Proportion who consent/ screened measured using consent forms at the end of the 6 months recruitment period, ≥60% progress; 40-59% amend; <40% stop
3. Recruitment over the course of the study measured using monthly consent rate over the 6-month recruitment period, ≥32 progress; 20-32 amend; <20 stop
4. Retention at 6 months post randomisation measured using follow up numbers of participants completing 6-month assessment (those who have not withdrawn or are lost to follow up), ≥80% or greater progress; 64-79% amend; <64% stop
5. Proportion who adhere measured using therapy logs to determine if participants have received at least 12 sessions at the end of the treatment period, ≥60% progress; 49-59% amend; <49% stop

Key secondary outcome(s))

1. Communicative participation - measured using the Communicative Participation Item Bank at baseline, 3 and 6 months
2. Psychological distress - measured using the General Health Questionnaire - 12 item version at baseline, 3 months and 6 months
3. Health-related quality of life - measured using the Stroke and Aphasia Quality of Life scale - 39 item version (SAQOL-39g)
4. Language - measured using the Western Aphasia Battery- Revised at baseline and 6 months
5. Quality of life - measured using European Quality of Life measure (5 dimensions, 5 levels) (EQ5D5L) at baseline, 3 months and 6 months

Completion date
30/04/2027

Eligibility

Key inclusion criteria
Participants with aphasia:
1. Aged 18 years old or over
2. Diagnosis of post-stroke aphasia (clinician assessment)
3. Living in the community
4. Capacity to give informed consent

Significant others:
1. Nominated by a participant with aphasia
2. Be in contact with the person with aphasia at least once per week
3. Mental capacity to make an informed decision

Treating therapists:
1. Aged over 18 years old
2. Able to make a fully informed, considered decision
3. Have full DBS clearance
4. Have successfully completed the ELLA training

Speech and Language Therapists:
1. Qualified and registered with HCPC as a Speech and Language Therapist
2. Work at least part of the week with people with aphasia
3. Able to supervise student SLTs and therapy assistants or apprentices
4. Have completed the City St George's required training for student supervision as appropriate

Speech and Language Therapy students:
1. Current student at City St George's, University of London

Therapy assistants, apprentices, or rehabilitation support workers:
1. Currently working with people with aphasia at least part of the week
2. Under the supervision of a qualified SLT

Participant type(s)
Patient, Health professional, Learner/student, Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Participants with aphasia:
1. Lack capacity to make an informed decision
2. Have a diagnosis of dementia
3. Have a co-existing degenerative or terminal co-morbidity
4. Have severe uncorrected visual or hearing problems
5. Did not speak English fluently prior to the stroke, according to self or family report
6. Ongoing debilitating psychiatric disorder or complex mental health needs that would interfere with their ability to receive ELLA (e.g., psychosis, but not low mood)
7. Live outside the area of the community services
8. Already participating in a Speech and Language Therapy or mental health research study
9. Unable to tolerate two or more therapy sessions a week

Significant others:
1. Lack mental capacity to make an informed decision
2. Have a co-existing degenerative or terminal co-morbidity
3. Have severe uncorrected visual or hearing problems
4. Do not speak fluent English which would compromise their ability to take part in an interview

Treating therapists:
1. Do not work with people with aphasia
2. Have not attended or failed the ELLA training
3. Are students with reasonable adjustments which preclude them from delivering the ELLA intervention

Date of first enrolment
05/01/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

East London NHS Foundation Trust
Robert Dolan House
9 Alie Street
London
United Kingdom
E1 8DE

Study participating centre
Hounslow and Richmond Community Healthcare NHS Trust
Thames House
180-194 High Street
Teddington
United Kingdom
TW11 8HU

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Guys and St Thomas' NHS Foundation Trust
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
St George's University Hospitals NHS Foundation Trust
St George's Hospital

Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Oxleas NHS Foundation Trust
Pinewood House
Pinewood PLACE
Dartford
United Kingdom
DA2 7WG

Sponsor information

Organisation
East London NHS Foundation Trust

ROR
https://ror.org/01q0vs094

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository. We anticipate we will store them on figshare. This will be fully anonymised data, shared after publication of the results of the study. We do not intend to share qualitative data, as we believe this has the potential to identify participants, and may change the dynamic of qualitative interviews.

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 1.0	18/07/2025	01/10/2025	No	Yes
Participant information sheet	version 3	02/10/2025	08/10/2025	No	Yes