ISRCTN10401966 https://doi.org/10.1186/ISRCTN10401966

Early testing of a supported self-management programme to help stroke survivors with aphasia and their families to develop strategies and confidence to manage life after stroke

Submission date
05/10/2022

Recruitment status
No longer recruiting

Registration date
07/10/2022

Overall study status
Completed

Last Edited
31/01/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Aphasia is a common and debilitating condition which may affect stroke survivors' ability to speak and understand what other people say, read or write. Aphasia often has a substantial impact on daily life. Researchers have developed a one-to-one support programme known as a 'self-management intervention' to help stroke survivors and their families develop confidence and strategies to cope with the impact of stroke and aphasia. In this study, speech and language therapists in two community stroke services will integrate the programme into their usual practice. The researchers will look at how feasible it is to deliver the self-management intervention in practice and how feasible it is to collect information about whether it works. This will provide the information necessary to test the intervention on a bigger scale, to understand whether it improves the participants' quality of life.

Who can participate?
Stroke survivors with aphasia who are aged 16 years or over, who are less than 1 year post-stroke and who have been referred for speech and language therapy from a participating community service. Family members/close friends of a stroke survivor with aphasia who is participating in the study (or who lacks the capacity to participate in the study) may also take part if they are aged 16 years or over and if they provide support (practical and/or emotional) for the stroke survivor with aphasia at least once a week.

What does the study involve?
Stroke survivors with aphasia (and/or family members/close friends) will be invited to join the study by the participating service. They will be asked to fill out some questionnaires about their health and wellbeing when they join the study and again about 6 months later. The researchers will ask permission for a researcher to observe (or video record) some of the speech and language therapy sessions participants receive to see if the self-management programme is

being delivered as intended. Some participants will also be invited to take part in an interview with a researcher to see if they liked the programme and whether there were any unforeseen problems.

What are the possible benefits and risks of participating?
Being involved may not benefit participants directly. However, it may help improve future services and support for stroke survivors with aphasia and their family members/friends. Some participants may find some of the topics covered in the questionnaires upsetting. However, participants do not have to answer any questions they do not wish to. Some participants may feel uncomfortable being observed during therapy. However, the observation can be stopped at any time.

Where is the study run from?
Bradford Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
October 2018 to June 2025

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

Who is the main contact?
Dr Faye Wray, f.d.wray@leeds.ac.uk (UK)

Contact information

Type(s)
Scientific

Contact name
Dr Faye Wray

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

291314

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49223, IRAS 291314

Study information

Scientific Title
Feasibility study of a supported self-management intervention for stroke survivors with aphasia (StarStep study)

Acronym
StarStep

Study objectives
To explore the feasibility of implementing the supported self-management intervention in practice and the feasibility of data collection procedures. The data collected will inform processes for a future definitive randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/06/2021, East of England- Essex Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8106, +44 (0)207 104 8227; essex.rec@hra.nhs.uk), ref: 21/EE/0115

Study design
Non-randomized; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Rehabilitation, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Based on a large programme of preliminary research which included working together with stroke survivors with aphasia, their family members and speech and language therapists, the researchers have developed a supported self-management intervention. In this study, the researchers will look at how feasible it is to deliver the self-management intervention they have developed in two community-based speech and language therapy services. The intervention will be integrated within the usual therapy sessions provided by speech and language therapists in

participating services. The number of speech and language therapy sessions provided varies by service and clinical need, however, data suggests that on average stroke survivors will receive seven sessions. Sessions are usually held once per week. The intervention is designed to be delivered one-to-one by speech and language therapists as part of speech and language therapy. The intervention is designed to be flexible so that it can be tailored to the needs and wishes of the individual. The approach includes an accessible guide with information for stroke survivors with aphasia, a guide for family/friends, a toolkit for speech and language therapists (with activities to do in therapy) and training for speech and language therapists.

Intervention Type
Behavioural

Primary outcome(s)
1. The feasibility of recruitment methods and uptake, assessed using the number of stroke survivors with aphasia screened, identified as eligible and for whom informed consent/consultee declaration can be obtained at screening/consent
2. The feasibility of intervention implementation and delivery assessed using:
2.1. The feasibility of recruiting and training speech and language therapists to facilitate the intervention, assessed using training data (number of therapists trained compared to the number of therapists eligible for training within the service and a questionnaire assessing speech and language therapists' understanding of the intervention) at the end of training
2.2. Participants' (stroke survivors with aphasia, family members/friends) views of the intervention (including acceptability, unanticipated consequences), assessed using in-depth qualitative interviews at 2 weeks after the end of the intervention
2.3. Facilitators' (speech and language therapists) views of the intervention (including acceptability, barriers and enablers to implementation), assessed using in-depth qualitative interviews once therapists have finished their final sessions with participants recruited to the study
2.4. The fidelity of intervention delivery (including influencing contextual factors), assessed using a number of sources of data including observational data (observations of therapy sessions), quantitative data (cost and resource data/anonymised screening data) and qualitative data (from in-depth interviews and implementation groups) collected at all timepoints throughout the study (screening/consent/baseline/during intervention delivery/3 month follow-up)
2.5. The costs and resource use associated with delivering the intervention, assessed using an intervention log (detailing the number of sessions, therapy time, time spent preparing for sessions and travel time) collected during the intervention
3. The appropriateness of outcome measures assessed using the number of outcome assessments completed, completion rates and missing data (at the participant and item level) at baseline and 3 month follow up

Key secondary outcome(s))
Stroke survivors with aphasia:
1. Quality of life measured using the Stroke and Aphasia Quality of Life Scale (SA-QOL)
2. Symptoms of depression measured using the Patient Health Questionnaire-8 item (PHQ-8)
3. Perceived communication effectiveness measured using the Communicative outcomes after stroke (COAST) scale

Family members/friends:
1. Levels of caregiver strain measured using the Caregiver Strain Index
2. Perceptions of their relatives/friends communication effectiveness measured using the Carer

communicative outcomes after stroke (carer-COAST) scale
3. Perceptions of their relatives/friends symptoms of depression measured using the Stroke Aphasic Depression Questionnaire (SAD-Q-21).

All measures will be collected at baseline and 3-month follow-up.

Completion date
30/06/2025

Eligibility

Key inclusion criteria
Stroke survivors with aphasia:
1. Are aged 16 years or over
2. Have a primary diagnosis of stroke
3. Have post-stroke aphasia (as diagnosed by the treating speech and language therapy service)
4. Are ≤12 months post-stroke
5. Are able and willing to provide informed consent for participating in data collection (e.g. questionnaires or observations or a semi-structured interview) or for whom a consultee declaration is provided (observations only)
6. Living at an address within the remit of a participating community service and referred for speech and language therapy from a participating community service

Family members or friends:
1. Are aged 16 years or over
2. Are a family member/close friend and/or carer of a stroke survivor with aphasia participating in the study or are a family member/close friend and/or carer of a stroke survivor with aphasia who lacks the capacity to consent to participate in the study
3. Are a family member/close friend and/or carer who provides help and support (practical and /or emotional) to the stroke survivor with aphasia at least once a week
4. Are able and willing to provide informed consent

Speech and language therapists:
1. Are employed as a speech and language therapist at a participating community stroke team
2. Has a caseload including stroke survivors with aphasia
3. Has received training in facilitating the self-management intervention
4. Are willing to provide informed consent to participate in the implementation group /observation of intervention delivery/semi-structured interview

Participant type(s)
Patient, Health professional, Carer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

Total final enrolment
26

Key exclusion criteria
Stroke survivors with aphasia:
1. >12 months post-stroke
2. Already in receipt of speech and language therapy from the community stroke team
3. In receipt of end-of-life care (documented in medical notes)
4. Residents in nursing or care homes
5. People with comorbid progressive neurological disorders, e.g. Huntington’s disease, motor neurone disease, Parkinson’s disease, multiple sclerosis

Family members or friends:
1. They are caring for a stroke survivor resident in a nursing or care home or with palliative care needs
2. They are caring for a stroke survivor with a comorbid progressive neurological disorder e.g. Huntington’s disease, motor neurone disease, Parkinson's disease, or multiple sclerosis

Speech and language therapists:
Not applicable

Date of first enrolment
01/02/2023

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Leeds Community Healthcare NHS Trust
Stockdale House

8 Victoria Road
Leeds
United Kingdom
LS6 1PF

Study participating centre
Tameside and Glossop Integrated Care NHS Foundation Trust
Tameside General Hospital
Fountain Street
Ashton-under-lyne
United Kingdom
OL6 9RW

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Stroke Association; Grant Codes: SA PDF 19\100011

Alternative Name(s)
TheStrokeAssociation, TheStrokeAssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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 available upon request from Faye Wray (f.d.wray@leeds.ac.uk). As this is a small, non-randomised feasibility study, sharing of the dataset generated is not anticipated and sharing of qualitative datasets will not be possible for ethical reasons. However, any requests for other data can be made and will be reviewed on a case-by-case basis with the study team. A data-sharing agreement would be required in this instance.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/01/2025	31/01/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	24/05/2021	05/10/2022	No	Yes
Participant information sheet	Accessible version 2.0	24/05/2021	05/10/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes