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Sentence therapy for post-stroke aphasia: UTILISE telerehabilitation

Submission date	Recruitment status	[X] Prospectively registered
05/07/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/07/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/09/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

One consequence of a stroke can be aphasia – difficulty understanding and producing language. The condition can result in significant limitations in taking part in conversations with family and friends, engaging in employment and using spoken and written language to access media. It has profound effects on well-being and quality of life. Aphasia typically impairs both vocabulary and grammar, and there has been considerable advance in the management of lexical impairments. However, there has been less progress in therapies for sentence processing. This is a problem as everyday interactions involve listening to and using sentences. We apply a usage-based approach to sentence processing impairments in aphasia. This approach involves a focus on high-frequency phrases and sentences that are used in everyday conversations.

The researchers will examine the outcomes in sentence understanding and production of a telerehabilitation model of therapy delivery. Participants self-deliver the intervention via an app with remote monitoring by a researcher/clinician. The user can administer the therapy at convenient times and locations with the aim that overcoming barriers to accessing therapy will result in high-intensity rehabilitation. The intervention – called UTILISE - stimulates sentence understanding and production of high-frequency sentences in two listening tasks, and one production task. The app also includes automatic speech recognition so that users gain rapid and precise feedback on their speech attempts. In addition to stimulation of the core sentences, new vocabulary items are introduced into the phrases in order to increase the flexibility and creativity of speech.

The researchers measure the participants' language abilities twice before therapy starts to discover if their behaviour is stable before intervention. All participants are then loaned an iPad loaded with the app. They will access the app for 4 weeks. The researchers then re-measure language abilities immediately after the therapy period and again after an 8-week period to determine the longer-term effects of the therapy. Some participants will be asked to have an MRI brain scan if this procedure is suitable for them, but this is an optional part of the study.

Who can participate?

Adults with aphasia who have had a stroke at least 4 months ago. Participants must previously be competent in speaking English and use English frequently at home. Participants must have sufficient visual and auditory acuity to interact with the app.

What does the study involve?
Participants travel to University College London to complete two baseline sessions. In these sessions, language ability, cognitive skills and self-reported perceptions of life after stroke are measured, and samples of speech are recorded. After the second session, the participant is loaned an iPad on which the UTILISE app is installed and shown how to use the iPad and app. Participants are encouraged to use the app at home for 4 weeks with remote monitoring and support from the research team. After the intervention, participants return to University College London and the effects of the treatment are measured. There is also the opportunity for the person with aphasia to give feedback on the app in a semi-structured interview. Family members can also take part in semi-structured interviews to discuss their experience of telerehabilitation. Behaviour is measured again 8 weeks later to discover if any changes are maintained once the therapy stops. Participants with aphasia have the option to take part in a focus group to discuss their experience of telerehabilitation.

What are the possible benefits and risks of participating?
The possible benefits of participating are that individuals access the UTILISE sentence therapy app for 4 weeks of self-directed intensive therapy with remote support from the research team. This may lead to improved sentence understanding and production. There are no known side effects associated with computer therapy. However, participants might not benefit from this therapy and find the tasks frustrating.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
October 2022 to April 2025

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

Who is the main contact?
Prof. Rosemary Varley, rosemary.varley@ucl.ac.uk

Study website
https://www.cognitionandgrammar.net/utilise

Contact information

Type(s)
Principal Investigator

Contact name
Prof Rosemary Varley

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LCD-2022-18 v1

Study information

Scientific Title
UTILISE-2: a telerehabilitation app for sentence difficulties in post-stroke aphasia

Acronym
UTILISE-2

Study objectives
1. Does the UTILISE-2 therapy app improve connected speech production and spoken sentence comprehension in comparison to waitlist/usual care control?
2. Are any therapy effects maintained over an 8-week no-treatment period?
3. What is the impact of the intervention on an aphasia severity score?
4. What is the impact of the intervention on perceptions of quality of life?
5. What is the relationship between self-delivered dose and treatment outcomes?
6. How acceptable is the telehealth model of UTILISE therapy to people with aphasia and their family members?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/01/2023, UCL Psychology & Language Sciences (Language & Cognition) (Chandler House, 2 Wakefield Street, London, WC1N 1PF, United Kingdom; +44 (0)20 7679 8692; f.kyle@ucl.ac.uk), ref: LCD-2022-18

Study design
Single centre interventional single-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, University/medical school/dental school

Study type(s)
Treatment, Efficacy

Participant information sheet
https://www.cognitionandgrammar.net/s/Intervention-Study-Information-Sheet-for-Participants-with-Aphasia_Approved.pdf

Health condition(s) or problem(s) studied
Sentence processing impairments in post-stroke aphasia

Interventions
After first baseline assessment, participants are randomised with a 1:1 ratio to Immediate or Deferred treatment conditions. Randomisation is stratified by sex and employs block randomisation. Researchers are blind to block size. Participants in the Immediate condition complete a second baseline assessment 4 weeks later and then immediately start the intervention. Participants in the Deferred condition complete a second baseline assessment at 8 weeks after the first baseline and act as a waitlist/usual care control. They then enter the intervention phase.

The intervention (UTILISE-2) consists of an app-based behavioural intervention available to participants on a loaned iPad for a 4-week period. The computerised intervention comprises three tasks: Task 1: attention to auditory sentence stimuli; Task 2: an auditory word monitoring paradigm; Task 3: sentence production with a gradual increase in sentence length and creativity with feedback given using automatic speech recognition. All stimuli include high-frequency phrase/sentence frames. The treatment is self-delivered by participants at home for the 4-week intervention period. The research team will monitor interaction with the app and offer remote support should a participant alert them via the in-app 'help' facility. Participants are encouraged to engage with the app for at least 1 hour per day (ideally in short 20-30 minute blocks). The app records engagement so that therapy dose/intensity can be tracked.

For both study arms, outcomes are measured at the end of the treatment phase and again after an 8-week no-treatment/maintenance period.

Intervention Type
Behavioural

Primary outcome measure
1. Sentence comprehension measured using a count for total items correct on the Test for Reception of Grammar (TROG-2) at two baseline timepoints and two outcome timepoints
2. Fluency and connectivity of speech measured in narrative samples by automated language analysis (FLAT) via combination ratio (number of three-word combinations/total number of words) at two baseline timepoints and two outcome timepoints

Secondary outcome measures
1. Retrieval and grammaticality of treated and matched control sentences measured using a study-specific story completion test at Baseline 2 and immediately after the intervention
2. Quality of life measured by score on the Communication Outcomes After Stroke at Baseline 1 and immediately post-treatment
3. Sentence production in narrative speech profiled with other FLAT variables (mean length of utterance, function word ratio and frequency of words and their combinations) at two baseline timepoints and two outcome timepoints
4. Overall aphasia severity measured by scores on the Quick Aphasia Battery at second baseline and immediate and maintenance outcome timepoints

Overall study start date
01/10/2022

Completion date
15/04/2025

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Pre-morbid competence in English and frequent use of English post-stroke
3. Pre-morbidly right-handed with left-sided stroke; or pre-morbidly left-handed with right-sided stroke
4. At least 4 months post-onset of stroke which resulted in aphasia
5. Presence of moderate to severe aphasia, characterised by spoken sentence comprehension impairment (scoring <16 blocks correct on TROG-2) and/or spoken sentence production difficulties (incomplete and/or simple sentences) at baseline assessment
6. Capacity to give informed consent
7. Sufficient auditory and visual capacity to interact with the therapy app

Participant type(s)
Patient, Carer, Service user

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria

1. Significant other neurological disorder (e.g. neurodegenerative illness)
2. History of speech and language disorder prior to stroke (e.g. developmental language disorder)
3. Concurrent involvement in another therapy study
4. Previous involvement in the UTILISE-1 therapy study
5. Severe apraxia of speech: unable to repeat high-frequency single words and short sentences

Date of first enrolment
10/07/2023

Date of final enrolment
04/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
Language & Cognition
Chandler House
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Sponsor information

Organisation
University College London

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Sponsor type
University/education

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ROR
https://ror.org/02jx3x895

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
Multi-level dissemination is planned, including people with aphasia and their family members, clinicians and the academic community. Publication is planned in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon reasonable request from Rosemary Varley (rosemary.varley@ucl.ac.uk).

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			07/07/2023	No	Yes

Protocol (other)	15/08/2023	12/09/2023	No	No