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Cost effectiveness of Aphasia Computer Treatment versus Usual Stimulation or attention control long term post stroke

Submission date 18/02/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/02/2014	**Overall study status** Completed	
Last Edited 07/12/2023	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Aphasia is a language disorder affecting understanding, talking, reading and writing, often as a result of a stroke. People with aphasia rarely receive speech and language therapy for more than a few months after a stroke. They may receive continued support from stroke groups and carers or relatives. There is evidence that people can continue to improve their language skills for several years. There is also evidence that people with aphasia can use computer software independently for structured language practice. This study investigates whether people who have had aphasia for more than 4 months can get better at finding the correct words by using computer exercises, and whether offering computer therapy is good value for money.

Who can participate?
Those identified as having had a stroke, with a diagnosis of aphasia, 4 months or more after the stroke, aged 18 years or above.

What does the study involve?
A Research Speech and Language Therapist (SLT) will visit potential participants at home to assess their language and daily life activities. The SLT will use a consent support tool to identify the style of information the potential participant is most likely to understand to be able to give informed consent. For those with severe aphasia the researcher will seek advice from a carer, relative or legal representative about whether or not the potential participant should take part. Participants will be randomly allocated to one of the following three groups:
1. Continuing with usual activities/therapy
2. Using the computer therapy exercises
3. Carrying out daily puzzle book activities
Usual care will involve a range of activities as this varies across the country, such as face to face speech and language therapy support, or attendance at support groups. The computer therapy will be tailored to the individuals' needs by an SLT, using a computer program specifically designed to help people with aphasia improve their word finding ability, called StepByStep. Participants will be encouraged to practice daily, and trained volunteers or SLT assistants will provide support with language practice and computer use. Participants allocated to do puzzle

book activities will be provided with books of standard puzzles to be carried out each day. A member of the research team will contact the participants or carers once a month to mimic the attention provided by volunteers in the computer therapy arm. Participants will be in the study for 12 months and have their treatment for 6 months, with follow-up assessments at 6, 9 and 12 months.

What are the possible benefits and risks of participating?
The initial study showed greater ability to find words and have a conversation, and improved confidence. The only risk identified was fatigue (tiredness). Participants will have the opportunity to keep the software on their own computer at the end of the study. The SLT will help those that did not receive the computer treatment during the study to borrow a computer and software at the end of the study.

Where is the study run from?
Participants will be recruited from about 20 speech and language therapy departments across the UK, from current and past patient records and contacts with longer-term voluntary support groups.

When is the study starting and how long is it expected to run for?
January 2014 to September 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Liz Cross
e.a.cross@sheffield.ac.uk

Study website
http://www.sheffield.ac.uk/scharr/sections/dts/ctru/bigcactus

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15733; HTA 12/21/01

Study information

Scientific Title
Cost effectiveness of Aphasia Computer Treatment versus Usual Stimulation or attention control long term post stroke: a randomised trial

Acronym
Big CACTUS

Study objectives
This research will establish whether people with post stroke aphasia can continue to improve their ability to talk after completion of traditional NHS therapy, and whether this can be achieved cost effectively by offering computer treatment at home.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds West REC, 13/01/2014, ref: 13/YH/0377

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Stroke Research Network; Subtopic: Primary Care, Rehabilitation; Disease: Therapy type

Interventions
Participants will be randomly allocated to either:
1. Continuing with usual activities/therapy only
2. Using the computer therapy exercises with usual care
3. Carrying out daily puzzle book activities with usual care

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Current primary outcome measures as of 20/02/2018:
1. The change in word finding ability of words personally relevant to the participant will be measured by a picture naming task (100 words with a maximum of 2 points each). The word finding score will be expressed as a percentage of the total score and change in the percentage 6 months from baseline will be calculated
2. Improvement in functional communication will be measured by blinded ratings of video recorded conversations between a SLT and participants, using the activity scale of the Therapy Outcome Measures
Added 18/04/2018: The outcomes are measured at 6, 9 and 12 months.

Previous primary outcome measures:
1. The change in the number of words (of personal relevance to the participant) named correctly at 6 months will be measured by a picture naming task
2. Improvement in functional communication will be measured by blinded ratings of video recorded conversations between a SLT and participants using the activity scale of the Therapy Outcome Measures and number of target words used in conversation, at 6 months

Secondary outcome measures
Current secondary outcome measures as of 20/02/2018:
1. Improvement in patient perception of communication will be measured using the COAST - a patient reported measure of communication participation and related quality of life
2. Use of learnt vocabulary in the context of conversation will be measured using a checklist of target words during rating of the videoed conversations at 6 months
Added 18/04/2018: The outcomes are measured at 6, 9 and 12 months.

Previous secondary outcome measures:
Improvement in patient perception of communication will be measured using the COAST - a patient-reported measure of communication participation and related quality of life

Overall study start date
01/01/2014

Completion date
12/09/2017

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Diagnosis of stroke(s)
3. Onset of stroke at least 4 months prior to randomisation
4. Diagnosis of aphasia, subsequent to stroke, as confirmed by a trained speech and language therapist.
5. Word retrieval difficulties tested by the naming test of the Comprehensive Aphasia Test [25] (score of 10-90% 5-43/48).
6. Ability to perform a simple matching task with the StepbyStep© programme (to confirm sufficient vision and cognitive ability to participate in the intervention)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 285; UK Sample Size: 285

Total final enrolment
278

Key exclusion criteria
1. They have another premorbid speech and language disorder caused by a neurological deficit other than stroke (a formal diagnosis can be reported by the participant or relatives and confirmed by the recruiting speech and language therapist).
2. They are unable to repeat words (suggesting presence of severe dyspraxia)
3. They require treatment for a language other than English (as the software is in English)
4. They are currently using the StepbyStep© computer programme or other computer speech therapy aimed at word retrieval/naming

Date of first enrolment
01/09/2014

Date of final enrolment
18/08/2016

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
United Kingdom
S10 2JF

Study participating centre
Humber NHS Foundation Trust
United Kingdom
HU10 6ED

Study participating centre
Newcastle Upon Tyne Hospitals NHS Foundation Trust
United Kingdom
NE7 7DN

Study participating centre
Northern Health & Social Care Trust
United Kingdom
BT41 2RL

Study participating centre
Belfast Health & Social Care Trust
United Kingdom
BT9 7AB

Study participating centre

South Essex Partnership University NHS Foundation Trust
United Kingdom
SS11 7XX

Study participating centre
NHS Greater Glasgow and Clyde
United Kingdom
G12 0XH

Study participating centre
Cwm Taf University Health Board
United Kingdom
CF45 4SN

Study participating centre
Derbyshire Community Health Services NHS Trust
United Kingdom
DE45 1AD

Study participating centre
Nottinghamshire Healthcare NHS Trust
United Kingdom
NG3 6AA

Study participating centre
Northern Lincolnshire & Goole NHS Foundation Trust "
United Kingdom
DN15 7BH

Study participating centre
Livewell Southwest (Plymouth Community Healthcare)
United Kingdom
PL4 7PY

Study participating centre

Norfolk Community Health and Care NHS Trust
United Kingdom
NR2 3TU

Study participating centre
Somerset Partnership NHS Foundation Trust
United Kingdom
TA6 4RN

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
United Kingdom
CB21 5EF

Study participating centre
Northamptonshire Healthcare Foundation Trust
United Kingdom
NN15 7PW

Study participating centre
Dorset HealthCare University Foundation Trust
United Kingdom
BH17 0RB

Study participating centre
City Hospitals Sunderland NHS Foundation Trust
United Kingdom
SR4 7TP

Study participating centre
Abertawe Bro Morgannwg University Health Board (ABMUHB)
United Kingdom
SA12 7BR

Study participating centre

NHS Ayrshire and Arran
United Kingdom
KA6 6AB

Sponsor information

Organisation
University of Sheffield (UK)

Sponsor details
Research and Innovation Services
New Spring House
231 Glossop Road
Sheffield
England
United Kingdom
S10 2GW

Sponsor type
University/education

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be disseminated in June 2018. Publication in a high impact peer reviewed journal planned for 2018/19.

Intention to publish date
10/07/2019

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 14/06/2019:
All data requests should be submitted to the corresponding author for consideration. Please note exclusive use will be retained until the publication of major outputs. Access to anonymised data may be granted following review.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Rebecca Palmer (r.l.palmer@sheffield.ac.uk). All data collected (anonymised) will become available after publication of the report and main peer reviewed paper in 2018 for 10 years from the end of study date. The trialists would individually consider each request before deciding whether to give which (if any) data. They would ensure secure transfer of information and stipulate terms of use of the data within a data sharing agreement. They have consented participants to anonymised data sharing. Shared data would always be anonymised as far as possible.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/01/2015		Yes	No
Results article	results	01/09/2019	12/08/2019	Yes	No
Results article	results	01/04/2020	06/05/2020	Yes	No
Results article	results	23/11/2020	18/12/2020	Yes	No
Other publications	impact for NHS SLT departments that participated in Big CACTUS	07/12/2022	12/12/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative exploration of the computerized speech and language therapy approach	05/12/2023	07/12/2023	Yes	No