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Treating post-stroke speech difficulties by computer therapy

Submission date	Recruitment status	[_] Prospectively registered
13/05/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/05/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/01/2016	Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Stroke and other forms of brain injury can disrupt people's thinking and behaviour in a number of ways. A common complication experienced by people following a stroke is an impairment of speech and language, called apraxia of speech (AOS). AOS results in reduced speech intelligibility, fluency and speed, and as a result an individual’s ability to communicate thoughts and needs is impaired. AOS is viewed by many clinicians as a ‘difficult to treat’ disorder. This is because treatment to stimulate new and improved organisation in damaged parts of the brain requires intensive, well-structured stimulation tasks. However, it is often difficult to achieve the necessary levels of stimulation within the framework of standard treatment consultations. A major factor in this is the limited amount of time clinicians are able to spend with patients. Self-administered, home-based computer therapy creates the opportunity to improve rehabilitation outcomes by allowing patients to take some control over their treatment. It also helps to increase the amount of time a patient spends carrying out brain stimulation tasks. The aim of this study is to see whether a computer-based speech therapy programme for AOS improves speech clarity in post-stroke patients. It also aims to see if this type of treatment is acceptable to patients and their families. It will also assess the financial costs associated with this type of treatment.

Who can participate?
Adults diagnosed with speech production problems following a stroke.

What does the study involve?
All participants take part in both interventions, however the order in which they are carried out is randomised. Initially, participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given a computer software programme to use at home. The software is a speech intervention aimed at stimulation and production of whole words, and putting words into sentences. Those in group 2 (control group) are given a software programme that involves visual puzzles and is not predicted to improve speech production. Participants take part in one of the interventions for 6 weeks, and then they cross over to the other group to take part in the other intervention for a further 6 weeks. Participants are asked to complete questionnaires and take part in clinical assessments during the study period.

What are the possible benefits and risks of participating?
At the end of the study, some participants might be able to say some words more easily and clearly. The therapy is a behavioural intervention and is therefore unlikely to cause harm. However, a participant might become frustrated if unfamiliar with using a computer. There are no specific risks associated with participating in this study. It is very unlikely that speech would get worse, but it might not change at all, or there might be only very small improvements.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
April 2008 to March 2011

Who is funding the study?
The BUPA UK Foundation

Who is the main contact?
Prof R Varley

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MAY07/16

Study information

Scientific Title
Self-administered behavioural intervention for communication impairments following stroke

Study objectives
1. Are there changes in speech production for treated items only, or do any improvements generalise to untreated words?
2. Is the intervention acceptable to service users and is it cost effective?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Sheffield, 25/03/2008, ref: 08/H1308/14.

Study design
Single centre intervention trial with a cross-over design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Post-stroke speech production impairments (apraxia of speech and aphasic word production impairment)

Interventions
All participants will take part in both interventions, the order will be randomised:
1. Intervention group use a participant-administered software therapy designed specifically for this study (Sheffield Word (Sword)) that treats whole word production for six weeks
2. Control group use a sham-participant-administered software program that involves completion of visual-spatial tasks for six weeks

Intervention Type
Behavioural

Primary outcome measure
Accuracy of word production in naming and repetition measured by:
1. Naming accuracy
2. Repetition accuracy
3. Word duration
4. Connected speech (narrative) samples
Control measures:
1. CAT Spoken sentence to picture matching
2. PALPA48 Written word to picture matching

Secondary outcome measures
1. Health economic assessment (health-related quality of life, resource use & societal costs) measured by:
1.1. EQ-5D Health questionnaire
1.2. SF-12v2. Health Status questionnaire
1.3. Costs questionnaire
2. Acceptability to service users and families of self-administered computer therapy

Overall study start date
01/04/2008

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. Patients experiencing unilateral left-hemisphere lesion(s)
2. Minimum 6 months post onset of stroke
3. Diagnosis of apraxia of speech

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Not pre-morbidly competent in English
2. Insufficient auditory and visual acuity to interact with a laptop computer
3. Currently receiving impairment-based speech/language therapy
4. Presence of degenerative neurocognitive impairment

Date of first enrolment
15/04/2008

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Western Bank
Sheffield
United Kingdom
S10 2TN

Sponsor information

Organisation
University of Sheffield

Sponsor details
Research Office
Western Bank
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United Kingdom
S10 2TN

Sponsor type
University/education

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Research organisation

Funder Name
The BUPA UK Foundation

Results and Publications

Publication and dissemination plan
Full reporting planned for 2015.

Intention to publish date
01/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No