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Evaluate the effectiveness of computer therapy for people with aphasia who have auditory comprehension difficulties

Submission date
08/07/2019

Recruitment status
No longer recruiting

Registration date
16/07/2019

Overall study status
Completed

Last Edited
30/08/2022

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Post-stroke aphasia refers to an acquired impairment of the language system, affecting the ability to communicate effectively through spoken or written modalities, negatively impacting on the ability to function independently in society. Being a heterogeneous patient group there is no universally accepted treatment that can be applied to every patient with aphasia and clinicians often choose from a range of methods to facilitate rehabilitation e.g. impairment-based therapy and social participation approaches. Cochrane review (Brady, Kelly, Godwin, Enderby and Campbell, 2016) indicates benefits from intensive speech and language therapy. However, given the current economic climate, intensive rehabilitation is a “desired” rather than “required” component of therapy for our resource-limited healthcare system. Therefore alternative methods of rehabilitation, such as a self-administered (not requiring the physical presence of the clinician), remotely monitored, virtual therapy platform that facilitates the delivery of intensive intervention in a cost-effective manner is desirable. There are a range of computer software rehabilitation programmes available for both clinicians and patients to purchase, however, the efficacy of the majority of these programmes have not been clinically evaluated. In addition, patients have been given limited opportunities to offer feedback on their use of such self-administered interventions. Feedback from people with aphasia could offer important insight into the specific challenges they may experience which may impact on their motivation and ability to engage in and succeed in therapy. This would also better inform the clinicians when considering their patients for self-administered computer-based therapy.

Who can participate?
Adults over 18 years of age with aphasia will be recruited via speech and language therapy clinicians and voluntary support services for those with acquired brain injuries in the Munster area of Ireland.

What does the study involve?
We will compare two different computer-based intervention programmes. Half the participants

will have 'treatment A' first. Half the participants will have 'treatment B' first. Allocation to treatment phase is determined by a computer-generated blocked randomisation list. Participants will not be advised which treatment they receive first.

What are the possible benefits and risks of participating?
Participants may potentially benefit from receiving this intensive Speech & Language Therapy intervention in terms of their communication abilities. However, this is not guaranteed. The findings from this study will contribute to the evidence base about the efficacy of this particular method of providing intensive therapy for auditory comprehension deficits. The findings may also inform Stakeholders about the usability of this type of therapeutic input from the patient's perspective. There are very limited risks to participants. However, during the hearing screening assessment participants may be informed that they present with hearing loss that they may not be aware of. In this situation we will offer to send a report informing their GP. Given the intensity of the rehabilitation participants may experience fatigue, however, this is highlighted in the information sheet and they will be asked to consider this in their decision to participate. There are no risks associated with the eye-tracker which meets European safety standards EN 62471 for products using LED lights.

Where is the study run from?
The study is run from University College Cork, however the programmes are self-administered in the participants' own homes.

When is the study starting and how long is it expected to run for?
Study recruitment commenced in June 2017 and continued until February 2018. The study is no longer recruiting.

Who is funding the study?
The study is funded by the Health Research Board, Ireland, under the Research Training Fellowship for Healthcare Professionals Award 2016

Who is the main contact?
For further information please contact Dr Helen Kelly, helen.kelly@ucc.ie

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HRB-HPF-2016-1700

Study information

Scientific Title
Evaluating the efficacy of a Self-Administered, Remotely Monitored, Therapy for People with Post-Stroke Aphasia who present with Auditory Sentence Processing Deficits

Acronym
SARMTAC

Study objectives
This intervention feasibility study is designed to evaluate the effectiveness of a self-administered, remotely monitored, virtual therapy platform for people with aphasia, specifically auditory sentence processing deficits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2016, Clinical Research Ethics Committee of the Cork Teaching Hospital (Lancaster Hall, 6 Little Hanover Street, Cork; +353-21-490 1901; crec@ucc.ie), ref: ECM 4 (o) 08 /11/16 and ECM 3 (f) 10/01/17.

Study design
This is a case-series experimental two-phase cross-over treatment 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 aphasia specifically auditory comprehension impairment

Interventions
This is a case-series experimental two-phase cross-over treatment design, comparing a self-administered rehabilitation programme targeting language deficits experienced by people with post-stroke aphasia, and a self-administered control computer program not targeting post-stroke aphasia deficits (e.g. visuospatial, attention and memory tasks). The two phases are separated by a 4-week no intervention/wash-out period. Follow-up assessments examine maintenance following the end of the two Phases. In accordance with good research practice, the order of intervention phase is randomly assigned to participants. Individuals analysing outcome measure data are blind to the phase of the intervention. Random allocation to phase is carried out using a computer-generated list which is managed by an individual not involved in the study.

Participants are randomly allocated to either a language intervention programme followed by control programme OR control programme followed by a language intervention programme. Allocation to phase uses a computer-generated blocked randomization list, allowing for three levels of stratification of aphasia severity; mild, moderate and severe. Each allocation is enclosed in a sealed opaque envelope, and not opened until participant allocation. The research team is blind to the allocation process.

Participants self-administer the remotely monitored computerised home programme activities. They are advised to spend a minimum of 5 hours per week over the 6-week phase on each programme. Each phase is separated by a 4-week washout period. The language intervention programme comprises auditory sentence comprehension tasks of 16 different levels of difficulty in terms of complexity of sentence comprehension. The control programme comprises non-language tasks including visual memory, visual matching and pattern recognition. There are 21 levels with increasing difficulty.

Intervention Type
Other

Primary outcome measure
1. Aphasia type and severity are measured using the Western Aphasia Battery at baseline, post-phase 1, post-phase 2, follow up at 4 weeks and 16 weeks.
2. Sentence comprehension is measured using a Test of Reception of Grammar at baseline, post-phase 1, post-phase 2, follow up at 4 weeks and 16 weeks.
3. Auditory comprehension sentence, paragraph and conversation levels are measured using e-ACT – a language outcome measure developed for the study and administered on a computer and eye-tracker at baseline, post-phase 1, post-phase 2, follow up at 4 weeks and 16 weeks.

Secondary outcome measures
1. Neuropsychological status is measured using the Repeatable Battery for the Assessment of Neurological Status at baseline, post-phase 1, post-phase 2, follow up at 4 weeks and 16 weeks.
2. Quality of life following Stroke is measured using Stroke and Aphasia Quality of Life Scale-39 at baseline, post-phase 1, post-phase 2, follow up at 4 weeks and 16 weeks.
3. Repetition is measured using the Psycholinguistic Assessment of Language Processing in Aphasia subtest 7 (word repetition), 8 (non-word repetition) and 12 (sentence repetition) at baseline, post-phase 1, post-phase 2, follow up at 4 weeks and 16 weeks.
4. Written naming is measured using the Psycholinguistic Assessment of Language Processing in Aphasia subtest 53 at baseline, post-phase 1, post-phase 2, follow up at 4 weeks and 16 weeks.
5. Quality of life measure developed for the study that investigated the quality of life related to specific everyday language activities at baseline, post-phase 1, post-phase 2, follow up at 4 weeks and 16 weeks.
6. Usability and cognitive workload are measured using a feedback questionnaire midway through each phase.
7. Usability is measured using a structured observation midway through each phase.
8. Participants' perspective of usability and engagement with the programmes is measured using interviews midway through each phase and in a final exit interview, 4 weeks after the end of Phase 2.

Overall study start date
01/10/2016

Completion date
31/10/2018

Eligibility

Key inclusion criteria
1. Adults, over 18 years of age
2. Presenting with acquired language deficits (aphasia) post-stroke
3. At least 6 months post-onset of stroke
4. Have daily access to a PC or Laptop computer and have Internet access (as course is online)
5. Can give fully informed consent
6. Not receiving Speech and Language Therapy at the time of the study but may attend support services e.g. charity social groups which don't include Speech and Language Therapy input.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

We recruited 12 participants for this feasibility study

Total final enrolment
12

Key exclusion criteria
Bilateral hearing loss below 40dB on any frequency between 250Hz and 4kHz

Date of first enrolment
20/06/2017

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
Ireland

Study participating centre
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Sponsor type
University/education

ROR

https://ror.org/03265fv13

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Ireland

Results and Publications

Publication and dissemination plan
Data is currently being analysed and findings will be published in a peer-reviewed journal in due course.

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the nature of the data collected (e.g. video and audio files) and participants provided consent for the data to be used for this research only and that the data would be viewed solely by the researchers in this study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/10/2019	24/10/2019	No	No
Protocol file			30/08/2022	No	No