Study Protocol

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

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Background

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. The recently published 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 very 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 programs have not been clinically evaluated. In addition, patients have not been given the opportunity to offer feedback on their use of such self-administered intervention tools. Such feedback could offer important insight into the specific challenges and de-motivators they may experience which may impact on their 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.

Research Aim

This current project aims to investigate the efficacy of a component of one of these programmes (auditory sentence processing) and obtain detailed feedback from participants on its use.

This intervention pilot 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. Following an initial training session, participants will self-administer the therapy programme in their own homes, without requiring a clinician's presence. This particular virtual therapy platform will allow the researchers remotely:

- Examine performance data of participants (accuracy and progress)
- Adapt or adjust therapy stimuli and level of difficulty in response to each participant's abilities e.g. make tasks easier/ more difficult, provide additional therapeutic tasks.

- Precisely measure time spent on tasks by participants, facilitating examination of the impact of therapy intensity and ensure adherence to intervention protocol.
- Identify and respond to indicators of poor engagement with therapy programme.

Recruitment

Participants will be invited to participate in the research. Participants 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. Each participant will be provided with the participant information sheet and given an opportunity to ask questions about the research. Participants will be aware and consent to being video-recorded for all assessment and interview sessions which will capture a range of communication abilities, for example, some participants may use pen and paper or gesture only which cannot be captured through audio recording alone. Participants will undergo a number of assessments to confirm they meet inclusion criteria of the study (hearing assessment and language assessment outlined below). Participants who consent to be involved in the research will be randomly allocated to the phase of the research (as outlined below).

Trial Design

The proposed research project 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 'sham' computer program not targeting post-stroke aphasia deficits (e.g. visuo-spatial, attention and memory tasks). The two phases will be separated by a 4-week no intervention/wash out period. There will be follow-up assessments to examine maintenance following the end of the two Phases. In accordance with good research practice, order of intervention phase will be randomly assigned to participants and individuals collecting outcome measure data will be blinded to phase of intervention. This experimental design is based on recently published, methodologically robust research (Varley et al., 2016; Whiteside et al, 2012) which evaluated post-stroke speech impairment using rehabilitation software. However, apart from the methodological design, the currently proposed project is very different to Varley's project in terms of communication deficits targeted and therapeutic content. In addition this proposed study will employ a more advanced, clinically suitable therapeutic platform enabling remote monitoring of participant performance and potential adjustment of therapy if required.

Computer programmes

Language stimuli

The language rehabilitation stimuli will comprise of auditory sentence comprehension tasks which include 16 different levels of difficulty in terms of complexity of sentence comprehension, each level comprising 20 sentences. Participants will hear a sentence and choose the picture that represents that sentence from a selection of four pictures (one correct

target and three distractors). Participants have as much time as they wish to view the pictures before clicking a button to receive the auditory sentence. They get feedback on whether they have chosen the correct or incorrect target. If they select the correct target they proceed to the next item. If they select the incorrect target they listen to the sentence once more and try again. If this is still incorrect the correct target is highlighted and they hear the sentence and the programme indicates the correct target picture. Participants will start at Level 1 and proceed through the levels until they have been in the programme for 6 weeks. The programme is designed so that the clinician monitoring their performance can add additional tasks and increase or decrease level of difficulty of task depending on their abilities.

Non-language "sham" stimuli

The 'sham' non-linguistic stimuli will comprise a range of tasks that will stimulate participants' attention, memory and visuo-spatial skills but will contain very limited language. There are a range of tasks already available in the programme which can be used, including:

- Matching shapes and pictures
- Choosing the odd-one-out pictures
- Categorising pictures
- Semantic relationships – pictures
- Clock setting times
- Calculating costs

Allocation to Phase

In order to reduce selection bias, all participants will be randomly assigned to Phase 1-Phase 2 or Phase 2-Phase 1 using an appropriate system (e.g. computer generated, Random tables etc.) by an individual not involved in the research and who is blinded to intervention protocol and participant details.

Procedures carried out

Participants will attend an induction session for each intervention phase to train them in the use of the software for both programs - stimuli used in this session will not be included in the treatment programme. Participants will be advised that the minimum number of daily/weekly therapy hours will be 1 hour daily/5 days per week; this will be the same for both Phases. Participants will be contacted by the co-investigator after the initial session to determine if there are any difficulties using the programmes. In addition, they will arrange an observation session to view the participant using the programme and to ascertain any additional support requirements, in terms of the practicalities of using the computer programme. This co-investigator will not be involved in the randomisation process or measuring post-therapy outcomes.

Collection of Data

An outline of the protocol for gathering data:

- Baseline Measures – Multiple baseline assessments with 2-4 week interval between assessments
- Phase 1 - Self-administered virtual therapy programme targeting communication deficits experienced by people with aphasia (6 weeks intensive)
- Post-therapy assessment
- Washout period – Participants will have no intervention during the 4-week rest between phases
- Phase 2 – Self-administered virtual 'sham' therapy programme (e.g. visuo-spatial, attention or memory tasks) not targeting aphasia deficits (6 weeks intensive)
- Post-therapy assessment
- Rest period – Participants will have no contact during this 4-week rest period
- Maintenance assessment – Maintenance of any effects will be examined at 1 month and 4 month time points following the final therapy assessment as follows:

Two aspects of the intervention will be followed up one month following the end of the second intervention phase:

(i) Re-assessment of baseline outcome measures to establish the maintenance of any potential changes and,

(ii) Discussion with participants in order to obtain detailed feedback into how they experienced using the self-administered computer-based therapy, for example, what helped motivate or hinder them in engaging with the computerised intervention programme. This will also allow us to explore the participants' perspective in using this programme compared to face-to-face therapy with a clinician present.

One aspect of the intervention will be followed up four months following the end of the second intervention phase:

(i) Re-assessment of baseline outcome measures to establish the maintenance of any potential changes.

Data will include

- Language related measures
- Cognitive measures
- Control measures
- Quality of life measure
- Technology Screening
- Hearing Assessment
- Feedback questionnaire
- Semi-structured interviews

Baseline Measures	**Language related measures** Western Aphasia Battery – classification and severity of aphasia PALPA comprehension of single words - to establish no auditory processing difficulties at single word level (nouns) VAST comprehension of single words - to establish no auditory processing difficulties at single word level (verbs) Test of Reception of Grammar (TROG) – auditory comprehension of sentences (using eye-tracker) Software programme Assessment - auditory comprehension of sentences (using eye-tracker)

	Software programme conversation video clips - auditory comprehension of sentences in conversation. **Quality of Life measure** – An aphasia accessible quality of life measure will be selected has been developed to evaluate if participants indicate a change in QoL following the intervention **Hearing Screening** – a Hearing Screening Questionnaire and Pure tone audiometry assessment will be complete **Technology Screening** – a baseline measure of each participants reported confidence and use of technology devices before and after their stoke **Cognitive related measures** (not expected to improve following language therapy, could improve following 'sham' task) Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) – cognitive processing including attention and memory Montreal Cognitive Assessment (MOCA) – cognitive processing **Control tasks** (not expected to improve) PALPA - Repetition of words PALPA – Repetition of nonwords and phrases PALPA – Sentence repetition
EFFICACY – Post-Phase 1 and Phase 2 assessments	**Auditory Comprehension of Sentences** Test of Reception of Grammar (TROG) – auditory comprehension of sentences (using eye-tracker) Software programme Assessment - auditory comprehension of sentences (using eye-tracker) Software programme conversation video clips - auditory comprehension of sentences in conversation. **Cognitive Assessments** Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) – cognitive processing including attention and memory
Maintenance assessment	**Language Related Measures** Western Aphasia Battery – classification and severity of aphasia Auditory Comprehension of Sentences Test of Reception of Grammar (TROG) – auditory comprehension of sentences (using eye-tracker) Software programme Assessment - auditory comprehension of sentences (using eye-tracker) Software programme conversation video clips - auditory comprehension of sentences in conversation. **Control Assessments** PALPA repetition of words PALPA repetition of non-words PALPA sentence repetition **Cognitive Assessments** Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) – cognitive processing Montreal Cognitive Assessment (MOCA) – cognitive processing **Quality of life measure**

Eye-Tracking Technology

This pilot trial will evaluate the potential of eye-tracking technology in providing additional and more in-depth information on the online decision-making processes used by participants with aphasia as they select the correct target picture from three other distractor pictures – TROG and software programme Assessment only. This data will also allow for further

correlation with user feedback data. For a small number of people from the general population the eye-tracker is unable to calibrate eye movements. Therefore we must assume that this may also be the case with this population. The process of calibration with the eye-tracker will identify these participants and strategies will be trialed to see if they can engage in the programme e.g. putting tape at the left side of the screen and encouraging them to view all of the stimuli. These participants will be included in the study. However, for such participants responses to assessments will be gathered using a pen and paper method.

Analysis of Data

Quantitative data will be analysed used statistical analysis. Due to the nature of the timelines and the type of data it is likely that multifactorial analysis will be required (ANOVA). Qualitative data will be analysed using thematic analysis.

Time commitment

Each participant will complete two 6 week intervention programmes with a 4 week break between these two phases. The total duration of the research for each participant is 43 weeks from the point of recruitment to the programme. This time includes pre-intervention baseline measures and follow-up measures at 1 and 4 months post phase 2.

Information provided to participants

Participants will be provided with information on the research via an aphasia accessible information sheet. This will allow participants to decide if they wish to consent to participate. Individuals will also be invited to ask any questions and these will be answered by the PhD researcher. Participants will also be advised that they can withdraw from the research at any time and do not need to provide any explanation.

Output

The research outlined above will inform service providers and people with aphasia about the potential language outcomes with self-administered computer delivered aphasia rehabilitation. This will expand the evidence base with respect to efficacy as well as stakeholder views about undetaking the intervention.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Adults with acquired language deficits post-stroke
- Participants who are at least 6 months post-onset of Stroke
- Participants who have daily access to a PC or Laptop computer and have Internet access (as course is online)
- In order to ensure that participants have a full understanding of the research protocol and can give fully Informed Consent, participants will be given aphasia-accessible

information sheets and consent forms, and also provided with this information verbally in order to enhance understanding. This process will be supported by a Speech & Language Therapist who is experienced in working with this population. Those participants with aphasia considered too severe to give this fully informed consent, specifically those with severe auditory sentence processing will not be recruited to this study.
- Patients will not be receiving Speech and Language Therapy from other sources but may attend if they also attend other support services e.g. Charity groups, Social groups etc.

Exclusion Criteria:
- Hearing loss below 40dB on any frequency between 250Hz and 4kHz
- Due to the intensity of the therapy programme, and to keep treatment fidelity patients who are currently attending Speech and Language Therapy elsewhere during the study and assessment period would not be permitted to attend during that time.

Potential Risks and Benefits

There are very limited risks to participants:

1. During the hearing screening assessment participants may be informed that they present with hearing loss they were not aware of. In this situation we will offer to send a report informing their GP.
2. 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.
3. There are no risks associated with the eye-tracker. The Tobii T120 eye-tracker meets European safety standards EN 62471 for products using LED lights. Tobii Eye Trackers have been tested and approved according to the European standard IEC/EN 62471. The light emitted from the eye-tracker meets this standard is not harmful to the human eye (Tobii Technology, 2013).

There are a number of potential benefits from this feasibility study:

1. Participants may potentially benefit from receiving this intensive Speech & Language Therapy in terms of their communication abilities. However, as part of the process of consent, participants will be made aware that there may not be a significant improvement in their communication following the therapy programme.
2. The findings from this study will contribute to the evidence base about the efficacy of this particular method of providing intensive therapy for sentence processing comprehension deficits. The findings may also inform Stakeholders about the usability of this type of therapeutic input from the patient's perspective.

Methods used to ensure confidentiality:

Current robust clinic procedures will be followed where all participant data will be strictly confidential in accordance with UCC practice. Participant data will be accessed only by the Chief and Co-Investigators.

All patient identifying information will be anonymised by allocating each participant a code or pseudonym. Paper documents will be securely stored in a locked filing cabinet. Electronic data will be stored on a password-protected computer at UCC. Participants will not be identifiable from any reports or publications.

References

1. Brady MC, Kelly H, Godwin J, Enderby P, Campbell P. (2016) Speech and language therapy for aphasia following stroke. Cochrane Database of Systematic Reviews, Issue 6. Art. No.: CD000425. DOI: 10.1002/14651858.CD000425.pub4
2. Varley, R., Cowell, P.E., Dyson, L., Inglis, L., Roper, A. and Whiteside, S.P., 2016. Self-Administered Computer Therapy for Apraxia of Speech Two-Period Randomized Control Trial With Crossover. Stroke, 47(3), pp.822-828.
3. Whiteside, S.P., Inglis, A.L., Dyson, L., Roper, A., Harbottle, A., Tyder, J., Cowell, P.E. and Varley, R. A. (2012) Error reduction therapy in reducing struggle and grope behaviours in apraxia of speech. Neuropsychological Rehabilitation,, 22(2); 267-294.