



Study to assess the clinical and cost effectiveness of aphasia computer treatment vs usual stimulation or attention control long term post stroke (Big CACTUS)

BACKGROUND

Big CACTUS is a pragmatic randomised controlled trial (RCT) to compare outcomes for people with persistent aphasia using computerised speech and language therapy at home with those having usual care (standard speech and language therapy provision or general daily communication activity), or attention control (daily completion of puzzle book activities). Aphasia is a communication disorder in which the ability to understand spoken language, read, write and express oneself through speech is compromised thus having an impact on either having capacity for some decisions or demonstrating capacity.

Big CACTUS recruited 276 people with aphasia who had had a stroke at least 4 months previously. They were randomly allocated to one of three groups: 1) usual speech and language therapy care; 2) daily use of computerised speech and language therapy for 6 months, tailored by a speech and language therapist and supported by a volunteer or speech and language therapy assistant; or 3) daily completion of puzzles and supportive telephone calls from a researcher to mimic the activity/attention the computerised speech and language therapy group received. All groups received usual speech and language therapy. Outcomes included a change in ability to find treated words of personal relevance in a bespoke naming test (impairment) and change in functional communication in conversation.

ARRANGEMENTS FOR INCLUDING PEOPLE WITH APHASIA WHO LACKED CAPACITY TO CONSENT

The trial ensured informed consent where possible by offering a range of information styles to suit different language profiles and severities of aphasia. In addition to an information sheet written in lay language with key words emboldened, we provided options of picture support and other aphasia friendly strategies, or PowerPoint slides for presentation by a researcher with gesture or describing in different words etc. Where the language impairment was too severe to demonstrate we capacity even with support, participants were shown videos of what would happen so relatives could judge their interest in taking part, and carers read the finer detail and signed a carer declaration that they thought their relative was interested in participating.

DEVELOPMENT AND USE OF A CONSENT SUPPORT TOOL

In order to provide information in a format consistent with each individual's language ability, a Consent Support Tool (CST) was developed with the assistance of people with aphasia and their carers in the PPI advisory group. The CST is a short screen used by SLTs at the initial stage of recruitment and the result indicated which style of information the individual was most likely to understand, and therefore which version of the study information sheet was most appropriate. The tool has been validated and is available for use in other studies ([see J&R Press website](#)).

KEY POINTS

People living with the condition (aphasia) were involved in the development of all the consent and dissemination materials.

One size does not fit all - it was important to have multiple options available when providing information about the study and when seeking consent.

It shouldn't be assumed that an individual has understood the information in the adapted style - check the person's understanding by using methods such as asking forced alternative questions, yes/no questions, picture selection.

Ensure there are sufficient costs budgeted for developing the adapted materials and to support public involvement activities.

Films are expensive to make - but are well worth it!



Study to assess the clinical and cost effectiveness of aphasia computer treatment vs usual stimulation or attention control long term post stroke (Big CACTUS)

CHALLENGES AND SOLUTIONS

Maximising individuals' ability to understand the study information

A group of people with aphasia and their carers (the project PPI group) were heavily involved in the production of the accessible range of [information sheets](#) and in the development and testing of the [Consent Support Tool](#). Three different styles of information sheet were available to enable as many participants as possible to be involved in their own decision whether to consent to their participation in this study. Patient information sheet 1 was in large print with key words emboldened (for those who can understand written paragraphs). Patient information sheet 2 was for those who can read simple sentences but not full paragraphs. It follows standard aphasia friendly principles with one idea presented per page in short simple sentences of large font. Key words are emboldened and each idea is represented by a pictorial image. Patient information sheet 3 was for those who can understand with significant support. Each idea is presented on a power point slide with simple text, key words emboldened and picture support. Each sentence should be presented in turn by the speech and language therapist, read aloud to the potential participant and supported with gesture, showing objects and drawing. The next sentence is then presented.

Supporting the consent and consultation process

The Consent Support Tool helped identify individuals who were not able to provide their own consent (those with severe aphasia who find it difficult to understand information, even with the support of adapted/pictorial information formats). These potential participants were shown a short video clip of the [computer programme being used](#) and of someone [working on a puzzle book](#). Participants providing their own informed consent were provided with an aphasia friendly consent form and asked to initial all boxes before signing. If potential participants with severe aphasia indicated an interest, a personal consultee (in Scotland the person's legal representative or nearest relative) was asked to read the full information sheet and a covering letter detailing their responsibility, and to sign a declaration form on behalf of their relative with aphasia (in Scotland they will be asked to sign a consent form).

Identifying appropriate methods for dissemination

The PPI group also led the project dissemination plan which consisted of aphasia friendly flyers with key messages for clinics and notice boards, and for trial participants there was a [results booklet](#) with aphasia friendly key messages on the right hand pages and more detail on the left hand pages for people with aphasia, carers, clinicians and commissioners.

The PPI group decided the best way of disseminating the project results was through a short film. The trial team worked with a specialist content maker (Optical Duke Box) to produce the [film](#) (which can also be viewed on the [Big CACTUS website](#)). Big CACTUS has been used as an impact case study for the NIHR. The work also won the UK Stroke forum PPI prize in 2017.

FURTHER DETAILS

Big CACTUS was funded by the National Institute for Health Research (NIHR) Health Technology programme. Information about the project, including the protocol and links to publications, can be found here:

<https://www.journalslibrary.nihr.ac.uk/programmes/hta/122101#/>

The full project report, including a scientific summary can be found here:

<https://www.journalslibrary.nihr.ac.uk/hta/hta24190#/>

The Big CACTUS trial website which contains examples of the accessible information sheet designed using aphasia-friendly principles, patient information slides, and aphasia-friendly results booklet is here:

<https://www.sheffield.ac.uk/scharr/research/centres/ctru/big-cactus>

Contact:

Dr Rebecca Palmer
r.l.palmer@sheffield.ac.uk