

# Outcome Measures Therapist Handbook



Name of PI:

Contact details:



# Contents

Welcome to Big CACTUS .....	2
Introduction .....	3
Big CACTUS .....	5
Data Collection.....	8
Database .....	8
Informed Consent .....	9
StepByStep Personal Vocabulary Assessment .....	10
Self-Report Outcome Measures .....	12
Video Conversations .....	14
CAT Naming Objects.....	16
Information about Usual Care .....	17
Serious Adverse Events .....	18
Other Important Forms .....	20

# Welcome to Big CACTUS

Thank you for agreeing to do the Outcome Measures for the Big CACTUS study. We really appreciate your time and skills as we investigate the clinical and cost effectiveness of aphasia computer treatment. Performing the outcome measures is a vital role without which the study would not be possible.

This handbook provides you with information about *Big CACTUS* and your important role within it.

*Thank You*



THE TAVISTOCK TRUST FOR APHASIA



## Introduction

Speech and Language Therapy to improve language ability is often limited beyond the first few months post stroke but there is growing evidence that improvement can continue long term with **intensity, repetitive practice, feedback and salience**. The problem is that the intensity of treatment required to achieve improvements in the chronic phase would increase demands on often limited SLT resources. Therefore, we need to investigate flexible and cost effective means of service delivery to this group.

### ▶ Long term self-managed computer treatment

This approach contains three main components:

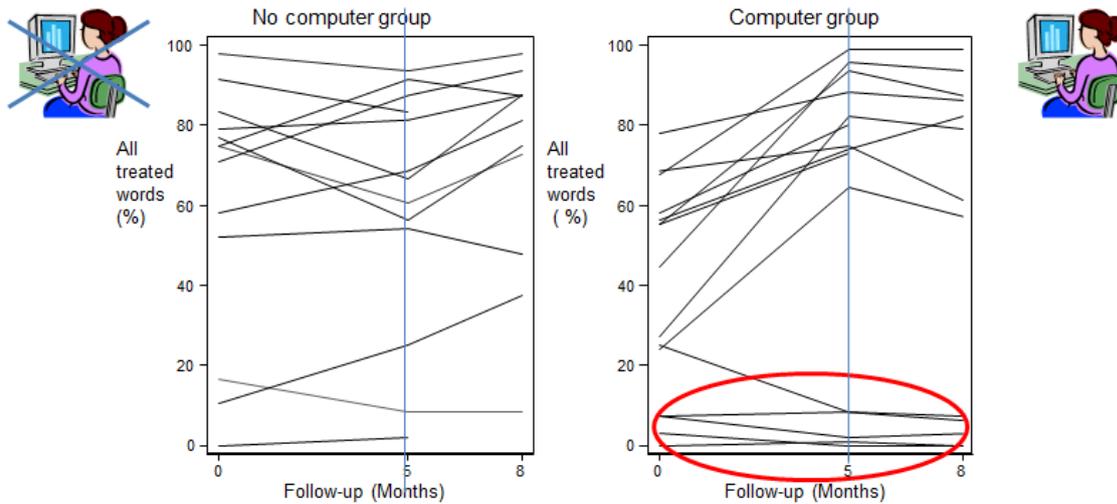
- **Light touch speech therapy input**  
Assessment and tailoring schedule of targeted and personalised word finding exercises using StepByStep<sup>®</sup> software
- **Self-managed regular practice**  
Client to practise exercises independently for 20-30 minutes daily
- **Volunteer support**  
Volunteer/SLTA assistance with practical management of the hardware or software and to encourage use of new vocabulary ('use it or lose it')

### ▶ Pilot Study

CACTUS – 'Cost effectiveness of aphasia computer therapy versus usual stimulation' (funded by NIHR RfPB programme) was a single blinded, pragmatic parallel-group, RCT design. It used the StepByStep approach using computer software for word finding for 5 months versus usual stimulation. From the pilot study we found:

- 89.3% of people approached were interested in receiving self-managed word finding treatment with a computer
- 34 participants were recruited in 12months (2 areas of UK) – 1.4 per month
- Over 75% of participants completed 5 month outcome measures
- 11/15 participants completing the treatment practiced at least 20 minutes 3 times a week for 5 months
- 11/15 had the offer of volunteer support
- For every 5 hours of SLT time and 4 hours of time from a volunteer, participants were able to carry out on average 25 hours of independent practice on the computer

- Computer group improved naming by **19.8%** (ITT) more than the control group 5 months from baseline which is statistically significant at the 5% level of significance (P=0.014, confidence interval 4.4% – 35.2%)



- Participants who were unable to name 10% of their personal words at baseline did not make the progress seen by other participants in the computer group
- People were able to name more of their personally chosen vocabulary than the standard vocabulary after the intervention period
- The intervention would represent a cost effective use of resources as the ICER threshold is usually £20,000 per additional QALY gained (in the UK) but there are uncertainties e.g. relapse rate, changes over time in patients who are not treated
- Participants and their carers also rated the intervention positively:

### Clinical outcomes

**WORD FINDING**  
*'She knows what she wants to say but it can be difficult to get it out but she has improved since doing that program'*

**SENTENCES**  
*'She's had her stroke 30 years and she's never strung a sentence together. It was quite nice when she said 'what have you been doing?'*

**GENERALISATION**  
*'I like...avocado please [mimed pointing to object]'*

**CONFIDENCE**  
*'her confidence is more and she can say things without being frightened of saying the wrong thing'*

### Computer therapy process

**PERSONALISATION**  
*'There was certain input into what was on it [the program] from her about places that she liked'*

**REPETITION**  
*'there's repetition which gets things in better than just you know, like an hour a week or something with a Speech Therapist'*

**INDEPENDENCE**  
*'a lot of the time P would sit and do it himself and I didn't have to be stood by him.'*

# Big CACTUS

Big CACTUS is aiming to be a definitive RCT running from 2014-2018 including 285 people with aphasia in UK. It is funded by the National Institute of Health Research (NIHR) - Health Technology Assessment Programme with support from the Tavistock Trust for Aphasia. There are three arms:

- using **computer therapy** exercises (+ usual activities/therapy) **95 participants**
- daily **puzzle book** activities (+ usual activities/therapy) **95 participants**
- continuing with **usual activities/therapy** only **95 participants**

The intervention uses StepByStep software (version 5.0 which is new). A speech and language therapist will set up 100 words for each participant which the participant has chosen themselves, and will tailor the steps/exercises to individual needs based on assessment results. The participant will practice with the software exercises for 20-30 minutes daily (minimum of 3 times a week). Volunteers or assistants will be trained to provide support (either 30 minutes every 2 weeks or 1 hour each month). They will support software use, help to change levels of difficulty, encourage repetition of exercises and feed back to speech and language therapist. The intervention period will last 6 months and during this time the CACTUS HQ team will send participants a 'negative effects form' to complete each month and return to CACTUS HQ to collect safety information.

## ▶ Study objectives

- To establish whether self-managed computerised speech and language therapy for word finding increases the ability of people with aphasia to use vocabulary of personal importance (**impairment**)
- To establish whether self-managed computerised speech and language therapy for word finding improves functional communication ability in conversation (**activity**)
- To investigate whether people receiving self-managed computerised speech and language therapy and their carers perceive greater changes in social participation in daily activities and quality of life (**participation**)
- To establish whether self-managed computerised speech and language therapy is cost effective for persistent aphasia post stroke
- To identify whether any effects of the intervention are evident 12 months after therapy has begun

## ► Outcome measures

The primary outcome measures are:

- Number of personally relevant words that participants can say: **impairment**
- Ability to have a video recorded conversation which is rated by independent therapists using the activity scale of the TOMS: **activity**
- Patient and carer questionnaire – Communication Outcomes After Stroke (COAST): **participation & wellbeing**

There are also some secondary measures which will be taken. These are the **CAT naming objects test** – to look at whether or not generalisation occurs to non-treated words, **EQ5D and CarerQol** – for health economics to look at cost effectiveness, and the **number of personal words used in semi-structured conversation**. All outcome measures will be taken at 6 months, 9 months and 12 months.

## ► Eligibility criteria

Participants will be included if:

- Aged 18 or over
- Diagnosis of stroke(s)
- Onset of stroke at least 4 months prior to randomisation
- Diagnosis of aphasia, subsequent to stroke, as confirmed by a trained speech and language therapist
- Ability to retrieve 10-90% of words on the CAT Naming Objects sub-test (score of 5-43/48)
- Ability to perform a simple matching task in StepByStep with at least 50% accuracy (score of at least 5/10; to confirm sufficient vision and cognitive ability to participate in the intervention)
- Ability to repeat at least 50% of words in simple word repetition task in StepByStep program (score of at least 5/10)

Participants will be excluded from the study if:

- They have another pre-morbid speech and language disorder caused by a neurological deficit other than stroke e.g. brain injury (a formal diagnosis can be reported by the participant or relatives and confirmed by the recruiting speech and language therapist)
- They require treatment for a language other than English (as the software is in English)
- They are currently using the StepByStep computer programme or other computer speech therapy aimed at word retrieval/naming

## ▶ Big CACTUS team at sites

As an Outcome Measures Therapist, you are a vital part of the Big CACTUS team at your site. The chart below shows each key member of the team at your site along with the main responsibilities for each role. We need at least 20 sites across the UK to recruit 15 participants each in order to satisfy the statistical requirements of the study. Please note that the PI and Lead Therapist can be the same person.

Principal Investigator (PI)		
Responsibility for the trial at site, including responsibility for the safety of trial participants		
<b>Lead Therapist</b> <ul style="list-style-type: none"> <li>Identify and recruit participants</li> <li>Baseline measures and 3 month follow-up phone call</li> <li>Randomising</li> <li>Tailoring StepByStep</li> <li>Training others</li> <li>Filling in on-going forms and inputting onto database</li> <li>Data queries</li> </ul>	<b>Outcome Measures Therapist</b> <ul style="list-style-type: none"> <li>Conducting 6, 9 &amp; 12 month outcome measure assessments</li> <li>Inputting these results onto the database</li> <li>Liaising with the PI</li> </ul>	<b>Therapy Assistant/ Volunteer</b> <ul style="list-style-type: none"> <li>Attending training</li> <li>Supporting participants in the intervention arm</li> <li>Completing feedback forms and sending them back to the lead therapist</li> </ul>

## ▶ Big CACTUS HQ team

If you have any queries, please see below as to who is best suited to help you. If you are not sure who to contact, contact the Trial Manager in the first instance.

<b>Chief Investigator</b> Rebecca Palmer 				
<b>Trial Manager</b> Liz Cross <ul style="list-style-type: none"> <li><i>First point of contact</i></li> </ul>  <p>E: <a href="mailto:e.a.cross@sheffield.ac.uk">e.a.cross@sheffield.ac.uk</a>            T: 0114 222 0762</p>	<b>Researchers</b> Madeleine Harrison/ Ellen Bradley <ul style="list-style-type: none"> <li><i>Second point of contact</i></li> </ul>   <p>E: <a href="mailto:madeleine.harrison@sheffield.ac.uk">madeleine.harrison@sheffield.ac.uk</a>            T: 0114 222 5424;            E: <a href="mailto:e.bradley@sheffield.ac.uk">e.bradley@sheffield.ac.uk</a>            T: 0114 222 0843</p>	<b>Research SLT</b> Helen Hughes <ul style="list-style-type: none"> <li><i>SLT related queries</i></li> <li><i>StepByStep guru</i></li> </ul>  <p>E: <a href="mailto:h.hughes@sheffield.ac.uk">h.hughes@sheffield.ac.uk</a>            T: 0114 222 5425</p>	<b>Clerical Support</b> Katie Walker/Kathryn McKellar <ul style="list-style-type: none"> <li><i>Admin support incl. printing, expenses, &amp; puzzle books.</i></li> </ul>   <p>E: <a href="mailto:k.m.walker@sheffield.ac.uk">k.m.walker@sheffield.ac.uk</a>            T: 0114 222 0892            E: <a href="mailto:k.mackellar@sheffield.ac.uk">k.mackellar@sheffield.ac.uk</a>            T: 0114 222 0763</p>	<b>Data Men</b> Tim Chater/ Chris Ellis <ul style="list-style-type: none"> <li><i>Receive your data</i></li> <li><i>Involved in data queries</i></li> </ul>  <p>E: <a href="mailto:bigcactus-data@sheffield.ac.uk">bigcactus-data@sheffield.ac.uk</a></p>

## Data Collection

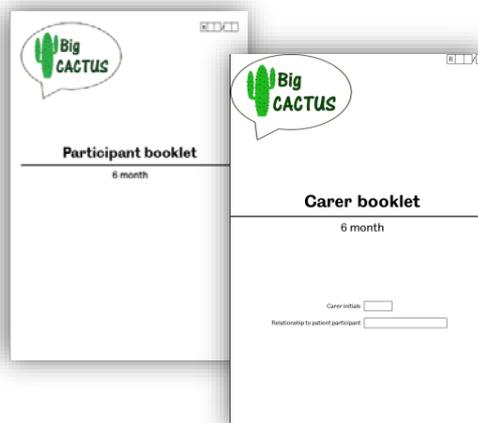
When carrying out research, it is essential to follow the Good Clinical Practice Guidelines. These cover the legislation, guidance and good practice that relates to the conduct of clinical trials in the UK. These define a Case Report Form (CRF) as:

*“A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject” (ICH)*

CRFs are used to collect data about study participants. They are working documents and should help the site to conduct the trial. They are essential study documents along with the Site File and source documents and may be used for inspections or audits.

For the data you collect, you should complete the paper CRF first and then enter this manually onto the electronic database. If you cross out or make any changes on the paper form, please date and initial the changes, and ensure the database is changed accordingly. Paper versions of forms must be filed away confidentially in a locked filing cabinet/cupboard.

For the purposes of the outcome visits, the CRF is split into two booklets. There is a participant booklet and a carer booklet for each outcome timepoint (6, 9 and 12 months). Please ensure the Lead Therapist has completed the front cover of the carer booklet with carer initials and relationship to patient prior to your visit.



## Database

Lead Therapists and Outcome Measures Therapists are expected to transfer the data they have collected on the paper CRF onto the electronic database. There are instructions on how to use the database saved on the Big CACTUS USB stick and laptop. Each site has a username and password to access the database. The information that is put onto the database is presented at meetings and to funders as the trial progresses so it is important to ensure the data is added to the database in a **timely way** and is **accurate**. If you leave any boxes blank, you will receive data queries, so try and ensure that you have not omitted any data you have accessible. If particular information is not available, you can write a field note on the database to explain this. If you have any problems or queries about the database or do not have the time or computer/internet access to input your data, please contact Big CACTUS HQ for assistance.

# Informed Consent

Mental Capacity is the ability to make a decision; in this case the decision is about whether or not they want to participate in the Big CACTUS study. A person is unable to make a decision for himself if he is unable to:

- (a) **understand** the information relevant to the decision,
- (b) **retain** that information,
- (c) use or **weigh** that information as part of the process of making the decision, or
- (d) **communicate** his decision (using talking, sign language or any other means)

According to the Mental Capacity Act (2005) ‘a person is not to be regarded as unable to understand the information relevant to a decision if he is able to understand an explanation of it given to him in a way that is appropriate to his circumstances (using simple language, visual aids or any other means)’.

In order to present information in an understandable way, we need to know the language skills of the individual. We have designed and evaluated a Consent Support Tool (CST) for this purpose (Jayes & Palmer, 2014) which provides a quick indication of the amount of spoken and written information understood, as well as an exploration of how a person most easily expresses their ideas. The person’s language profile is then used to determine the form of written information to provide:



Level of written and verbal comprehension	Information style	Participant information sheet (PIS)
Able to read full sentences in a paragraph	Written information using lay terminology with key ideas highlighted.	PIS 1 – standard
Able to read 3 key words in a sentence	Written information using full range of standard aphasia friendly conventions.	PIS 2 – aphasia friendly
Able to read 2 key words <b>and</b> have understanding of spoken words at 2 key word level	Each key idea is presented on a separate power point slide using key written words and illustrations or animations. The visual presentation of the information is also supported by spoken explanations, drawing and gesture.	PIS 3 – total comm. approach
Verbal <b>or</b> written understanding less than 2 key words	Simple pictures and key words, & a short video clip are used to inform the individual about the key topic area and to establish their general feelings about it. <b>Fully informed consent needs to be sought from a relative or carer.</b>	PIS 4 – video

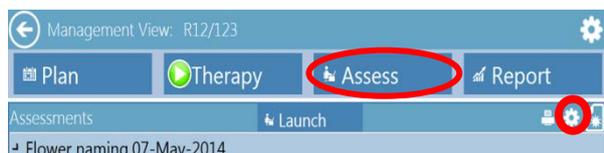
If informed consent has been provided by a relative or friend, please be aware that the relative or friend has a right to withdraw the participant from the study.

## StepByStep Personal Vocabulary Assessment

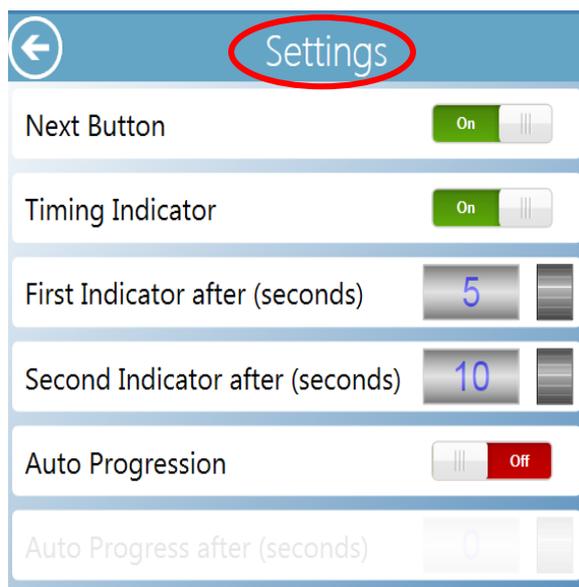
The primary outcome measure of impairment (how many personally relevant words the participant is able to say) is measured using StepByStep which generates an assessment. The Lead Therapist should have printed off and filed a copy of the assessment scoresheet in an outcome folder for each participant. Before you visit to carry out this assessment, ensure you have a copy of this participant's scoresheet and that the assessment settings on StepByStep are set up as below.

### ► Tailoring the assessment

Open StepByStep on the therapist laptop and select 'patient management'. Choose the correct participant from their randomisation number. Select the 'Assess' tab and then select the assessment called 'Big CACTUS naming assessment' to highlight it and then click on the assessment settings button.



Check that the settings match settings and adjust as required (although it should be like this as standard). Click on the back button to return to then previous screen.



### ► Launching the assessment

At the participant's house, open StepByStep and select the correct participant from the patient management screen. Click on the 'Assess' tab and highlight the assessment then click 'launch.' Type in a name for the assessment with the timepoint i.e. '6 month follow up.' You then receive a prompt to 'press ok to start' so make sure the participant is sitting so that they can see the screen and understands what you want them to do before clicking ok. **Please note** that at present, the timing of the first picture begins while the 'press ok to continue' dialogue box is open (before the first picture is shown) so you will need to time the first picture manually – although this should be updated shortly.

## ▶ Running the assessment

The 100 pictures will be presented in a pre-defined randomised order (which is the same each time the assessment is presented so matches the scoresheet). Use the same instructions and scoring as on CAT naming objects test. Ask ‘what is that a picture of?’ and score each item 0/1/2 points:

- **2 points** if correct with no cues within 5 seconds
- **1 point** if correct but delayed (5-10 seconds) and/or if self-correction
- **0 points** for an incorrect response or over 10 seconds

If the participant names the picture accurately but appears unsure, wait until the ‘next’ button turns orange (at 10 seconds) and then click this button to progress to the next picture. If participant is confident in attempt, click on the next button to progress.



The next button for the first 5 seconds (a correct response while this colour with no self-corrections would score 2 points)



The next button from 5-10 seconds (a correct response while this colour would score 1 point)



The next button from 10 seconds (a correct response while this colour would score 0 points)

Please note that at present, the timing of the first picture begins while the ‘press ok to continue’ dialogue box is open (before the first picture is shown) so you will need to time the first picture manually – although this should be updated shortly

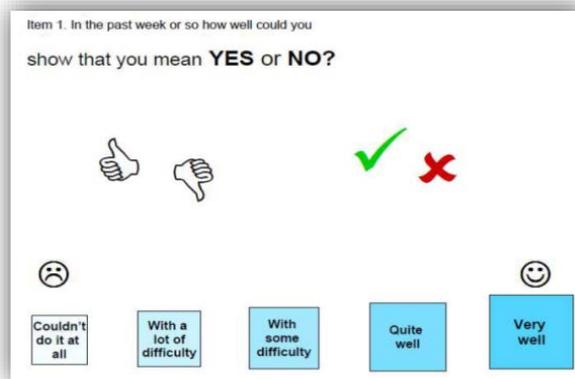
## ▶ Assessment practicalities

If someone comes into the room or the phone starts ringing and disturbs the participant or if the participant has a coughing fit, note which colour the next button is on and pause the assessment. Then then time from this point when you resume the assessment. Do not explain the scoring process to the participants and give neutral feedback when possible. Score each item accordingly in the participant booklet. You don’t need to add up the results unless you want to for yourself as the database will do this when you enter the results onto it.

# Self-Report Outcome Measures

## ► COAST

The COAST scale is to be completed by the participant at baseline with the Lead Therapist and then at each follow-up visit by the Outcome Measures Therapist. It contains 20 questions, each of which has a 5 point scale for the participant to choose from. Ask the participant each question and show them the scale below – ranging from the very worst problem they could have on the left to having no problems at all on the right, with stages in between. Offer as much assistance as required using total communication methods.



Some questions may be interpreted as cross modal e.g. unable to use the phone because difficulty picking it up/ dialing the number. Try and encourage the participant to focus on the impact their communication difficulty has on these things when rating on these questions rather than any associated physical difficulties.

Mark down the participant’s response for each item in the CRF. If after various prompts/encouragements no answer is given, mark as ‘NR’ for ‘no response.’ If the response is unclear even after prompts/encouragements, mark as ‘U.’

## ► Carer COAST

This contains the same questions as the COAST but this time it is completed by the carer about the **participant’s communication difficulties** and the impact they have on the **carer’s quality of life**. It is found in the carer booklet. Encourage the carer to choose one of the boxes for each response and not to choose between boxes. Assist the carer with completing it if required but if not, you could continue to complete the outcome measures for the participant. NB **DO NOT** complete the Carer COAST if:

- There is no carer
- The carer did not consent to participate in research study
- The carer present is different to the one who consented (check the carer’s initials match those on the front of the carer booklet)

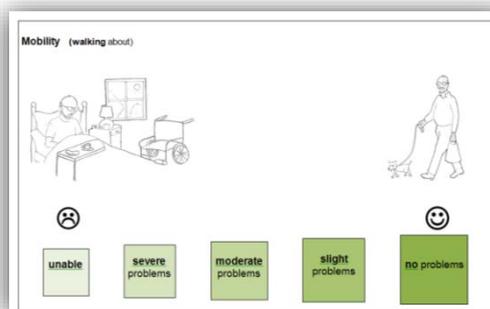
## ► EQ5Ds

The EQ5Ds look at a person's general health and wellbeing and they are used by health economists to establish 'quality adjusted life years.' There are 3 different versions to complete, each of which are described below:

### ► EQ-5D-5L (aphasia friendly)

The participant should be assisted to complete the accessible version of the EQ5D. There are 5 questions about the participant's health today looking at mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

The scale works in a similar way to on the COAST. Use total communication methods to help the participant understand and make an appropriate response then document this response in the CRF.



The final page asks the participant to rate how good or bad they are feeling today on a scale from 100 which is the 'best imaginable health state' to 0 which is the 'worst imaginable health state.' Feel free to re-word the question to aid comprehension but the important thing to convey is that we want to know how they are feeling on the day they are completing the outcome measure.

### ► EQ-5D-5L (proxy 2)

This is to be completed by someone who knows the participant well. It does not have to be the designated 'carer' who is completing the items in the carer booklet but it can be. It is to be completed 'by proxy' which

means completing the form on behalf of the participant and showing how they believe the participant feels about different aspects of life – not how the carer thinks they would feel in that position. As this outcome measure is about the participant, it is found in the **participant booklet**. Complete the date and ask the 'well-known other' to complete the questions as above, ticking only one box under each of the five headings. The rating scale on the last page is for the well-known other to complete by proxy also (how they feel the participant would rate themselves).

## ▶ EQ-5D-5L (carer)

If there is a carer and they have consented to participate in the study (check initials match on front cover of carer booklet), they should be asked to complete an EQ5D about **themselves**. All questions including the rating scale on the final page should be completed about themselves. This is found in the **carer booklet**.

## ▶ CarerQoL

This measure is to be completed by the carer (if there is one and they have consented to participate – check initials on front page) about themselves about their quality of life and can be found in the **carer booklet**. Complete the date and then ask them to complete the form but offer assistance as required. Prompt them to draw an 'X' in one box for each question (not between boxes). Ask the carer to complete the scale at the bottom. Explain it ranges from completely unhappy to completely happy and ask them to draw an 'X' on the scale to show how happy they currently feel.

## Video Conversations

Video conversations are the source of the second **primary outcome measure** looking at an improvement in functional communication taken at baseline, 6 months, 9 months and 12 months (giving the participant the opportunity to say what they want to be able to say). The videos will be rated by a **blinded** SLT from the central team using the **activity scale** of the Therapy Outcome Measures. The number of target words used in the conversation will also be measured as a secondary outcome.

## ▶ Preparation

The Lead Therapist will have chosen the questions to be asked for the participant at baseline and the **same questions** need to be asked at each outcome measure visit. Before you visit the participant to carry out the outcome measures, check in the participant's outcome measure folder. There should be three copies of the questions to be asked (one copy for each outcome timepoint).

## ▶ Practicalities

Each site will be given a **video camera** with **SD card**, **external microphone**, **mini tripod** and **case**. Ensure the camera is



charged up and the SD card is in the camera before you leave the office to go to the participant's house for the video conversation. At their house, set up the camera on the tripod and adjust as required and switch on the camera.



Plug in the external microphone and place near to where you will be sitting. Flip the screen round so you can check you are **both in shot** when you sit back down.

Use the **remote control** to start recording. A small red circle will appear in the top left corner of the screen to indicate that it is recording which will disappear when you stop recording



## ► Conversation

Use a **total communication** approach as you feel is indicated during the questions using gesture and facial expression as appropriate. Take paper and a pen to use as you feel is required to support the conversation. Ensure you **ask all** the questions as selected by the Lead Therapist. The first two questions will be the **standard questions** that every participant is asked and then there will be a further 6-10 questions for each participant relating to the vocabulary they have chosen. Ask follow-up/prompt questions if required during the conversation if the participant is having difficulty answering the questions or if the conversation is not flowing for example.

## ► Admin

Before visiting the participant for the follow up assessment, ensure you have a copy of the questions to ask from the outcome file. After the visit, complete the **proforma** in the outcome CRF showing the date of the conversation, the number of questions asked and ticking to show that you have attached a copy of the questions asked. Then transfer the video file of the conversation to the encrypted USB stick and save a copy onto the laptop, saving it as participant ID and assessment timepoint (6 month, 9 month or 12 month follow-up) and then return the USB to the Lead Therapist, writing the date of this on the proforma. The Lead Therapist will then return the USB to CACTUS HQ at the end of the month

# CAT Naming Objects

## ▶ Background

The Naming Objects subtest of the Comprehensive Aphasia Test is a standardised naming test used in routine practice to establish severity of word finding deficit. It is being used as part of this study to establish eligibility for the study and to provide a baseline of participant's word finding ability. Outcome Measures Therapists will also be using it as an outcome measure at 6 months, 9 months and 12 months to look at the generalisation of treatment to non-treated words.

## ▶ Implications in research

Administering this naming test in the Big CACTUS study is different to in clinical practice where one speech and language therapist often does the baseline and outcome assessment. This is because different therapists will carry out the assessment at baseline to outcome. Also, results will be measured between participants in different groups so assessments carried out by different therapists across the country will be compared. Therefore, it is **VITAL** that all Lead Therapists and Outcome Measures Therapists administer and score the assessment in the same way. For this reason, it is recommended that you carry out benchmarking/inter-rater reliability sessions at your site to ensure consistency of scoring between all therapists involved in the study.

## ▶ Administering

Show the participant the picture, ask "what's that a picture of?" and start timing. If the participant is unable to name the picture or names it incorrectly, wait until 10 seconds has passed and then provide a phonemic cue or give them the answer. They will score a point if they self-correct before 10 seconds. If a visual misperception is suspected, provide a semantic cue. **DO NOT** discontinue if 8 consecutive incorrect responses are given as you are prompted to in clinical practice.

## ▶ Scoring

The CAT naming test is scored taking into account how promptly a correct response is given:

- **2 points** if correct with no cues within 5 seconds
- **1 point** if correct but delayed (5-10 seconds) and/or if self-correction
- **0 points** for an incorrect response or over 10 seconds

Therefore, it is **essential** that timing responses is accurate or a participant’s score may vary by up to 24 points if a therapist counts either too fast or too slow. Use your phone or a watch to help your timing or count using **‘elephants’**



The following are acceptable and if they occur should not cause any subtraction to the score:

- Regional variants of target  
*e.g. ‘cig/ciggy/fag’ for ‘cigarette’*
- Common abbreviations  
*e.g. ‘brush/phone’ for ‘hairbrush/telephone’*
- Dysarthric errors/stammer/self- correction of pronunciation errors  
*e.g. ‘tamera’... ‘camera’*

If a cue (semantic or phonemic) is provided, the response should be scored as 0. If the participant has cued themselves in to find the word by circumlocution of topic word or description, score as a self-correction (1 point)

*e.g. “you wear it on your head... it’s a hat”  
“food... pizza”*

For the outcome assessments, you can add the total for your own interest but the database will calculate the score for the subtest when you input the results.

## Information about Usual Care

As part of the trial, information about usual care is going to be collected about each participant. This includes:

- Conversation with family and friends
- Attendance at voluntary/support groups
- Care received for communication difficulties

This information is to be collected about **all trial participants** at **all timepoints** (baseline, 3, 6, 9 and 12 months). The Outcome Measures Therapist is responsible for collecting this information at the 6, 9 and 12 month follow-up visits. Use this form to show information about communication with up to nine family members or friends and information about attendance at local/voluntary support groups.

**Information about usual care**

Date of completion: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]

Conversation with family and friends

Has the participant had any communication with family and friends in the past three months?  Yes  No

Please complete one line for up to nine family members or friends that the participant has communicated with

Relationship (e.g. daughter/husband/ neighbour)	Initials	Frequency					Mode of communication (tick of all that apply)				
		Daily (or several times per day)	A few times a week	Weekly	Frequently	Less frequently	Video call	Telephone	Message	Text	Group
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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This is the main point at which you might become **unblinded** during the study so please try to remind the participant that anything they have been doing with the Lead Therapist needs to be kept as a **secret** from you. Then ask them, apart from anything to do with the Lead Therapist, what care they have received for their communication difficulties **outside of the trial** in the past 3 months and document on the form below. (Please note that if you do become unblinded at any point during the study, you need to complete the **Unblinding form**). Also either you or the Lead Therapist will have to supplement the information collected from the participant by searching electronic databases, patient records, and/or speaking to colleagues. This is your responsibility to do but if you do not have the time or access to resources to do this, it is for you to ask your Lead Therapist if they are able to do this for you.

**Information about usual care**

Care received for communication difficulties

Has the participant received care for their communication difficulties in the past three months?  Yes  No

Please record details of care received for communication difficulties by the participant **outside of the trial**. Supplement information collected from the participant by searching electronic databases and patient records, and speaking to colleagues.

Date of therapy	Clinician/assistant AFO band (1-9)	Therapy goal	Therapy type(s) and duration			Mode of therapy			Mode of transport (if face-to-face)
			Impairment-based intervention	Compensatory intervention	Support	Indirect	Face-to-face	Distance travelled (kms and hrs)	
			<input type="checkbox"/> Yes <input type="checkbox"/> No						
			<input type="checkbox"/> Yes <input type="checkbox"/> No						
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			<input type="checkbox"/> Yes <input type="checkbox"/> No						
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			<input type="checkbox"/> Yes <input type="checkbox"/> No						
			<input type="checkbox"/> Yes <input type="checkbox"/> No						
			<input type="checkbox"/> Yes <input type="checkbox"/> No						
			<input type="checkbox"/> Yes <input type="checkbox"/> No						
			<input type="checkbox"/> Yes <input type="checkbox"/> No						
			<input type="checkbox"/> Yes <input type="checkbox"/> No						

## Serious Adverse Events

During the trial, any “untoward clinical event” that occurs to the participant has to be recorded as either an **Adverse Event (AE)** or a **Serious Adverse Event (SAE)** which include increased fatigue, onset or worsening of fits or seizures, worsening vision or visual difficulties, increasing frequency or severity of headaches, accidents (e.g. falls) or injuries.

This study is considered to be **low risk** so we do not expect a lot of SAEs. However, events are reported as SAEs for this trial if they result in death, are life-threatening or require hospitalisation. Further stroke related events (including death related to stroke) should be recorded as an AE on the **Adverse Event Prompt Form** but NOT reported as SAEs (and therefore there is no need to fax an SAE form), as these are unfortunately expected within this population.

**Adverse event prompt form**

Date of completion: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Negative effects / events

In the last three months, has the participant:

- had more tired than usual?  Yes  No
- had any fits or seizures, or worsening of fits and seizures?  Yes  No
- had worsening vision or visual difficulties?  Yes  No
- had increasing number or increasing severity of headaches?  Yes  No
- had any accidents (e.g. falls) or injuries?  Yes  No
- reported any other negative effects or events?  Yes  No

If 'yes' to any of the above, please complete one line in the table below for each episode

Category	Date (day/month/year)	Details	Serious? (death, hospitalisation, permanent disability, etc.)
	[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]		<input type="checkbox"/> Yes <input type="checkbox"/> No
	[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]		<input type="checkbox"/> Yes <input type="checkbox"/> No
	[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]		<input type="checkbox"/> Yes <input type="checkbox"/> No
	[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]		<input type="checkbox"/> Yes <input type="checkbox"/> No
	[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]		<input type="checkbox"/> Yes <input type="checkbox"/> No

Hospital admissions

Has the participant had any hospital admissions (overnight stays) in the last 3 months? (Including overnight clinics)  Yes  No

If 'yes' please complete one line in the table below for each admission

Date (day/month/year)	Reason for admission	Number of nights	Serious? (death, hospitalisation, permanent disability, etc.)
[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]			<input type="checkbox"/> Yes <input type="checkbox"/> No
[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]			<input type="checkbox"/> Yes <input type="checkbox"/> No
[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]			<input type="checkbox"/> Yes <input type="checkbox"/> No
[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]			<input type="checkbox"/> Yes <input type="checkbox"/> No
[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]			<input type="checkbox"/> Yes <input type="checkbox"/> No

If a hospital admission (or anything else considered a serious adverse event) has occurred, please complete a separate SAE Form immediately and fax to Sheffield DTU within 24 hours of observation. Note: Do NOT consider an AE for hospital admissions for reasons as these are unfortunately expected and in the trial.

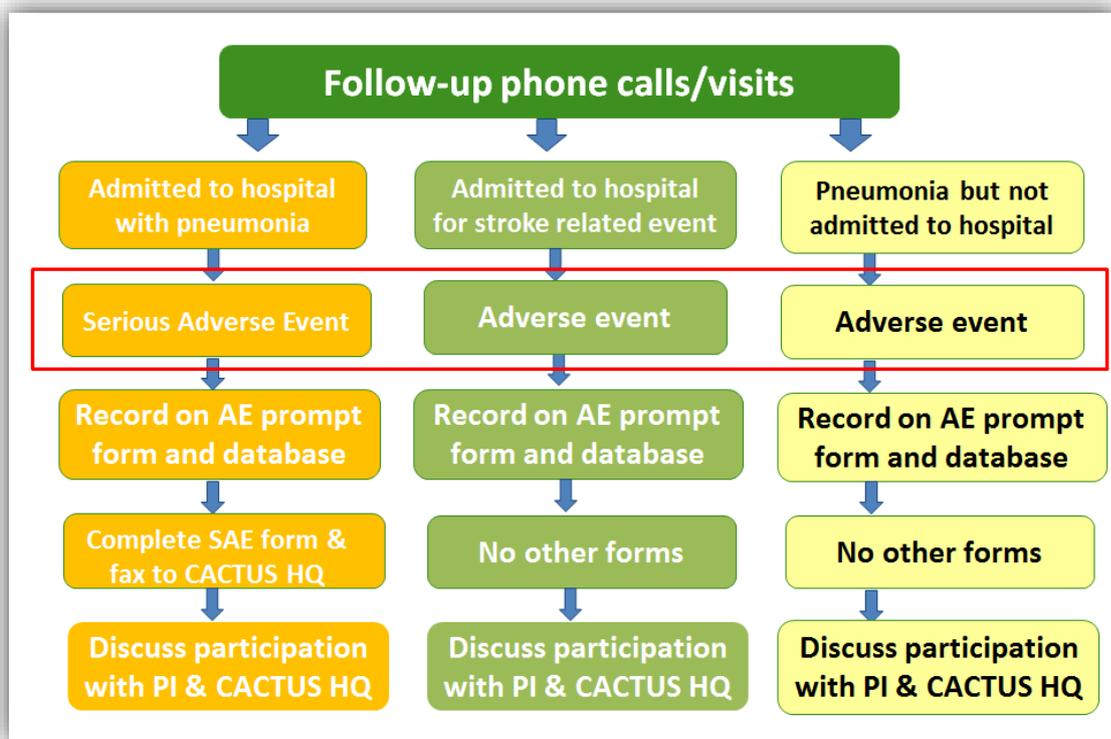
It is important to consider if participation in the trial has caused the event as action may then need to be taken e.g. for the participant to stop using the computer therapy or the puzzle books. The **Adverse Event Prompt Form** will be used by Lead Therapists at baseline and 3 months after randomisation, and by Outcome Measures Therapists at follow-up visits (at 6, 9 and 12 months) to ask how the participant’s health has been and to prompt you to find out if they have had any “events” in last 3 months.

If, from completing the Adverse Event Prompt form, you realise or suspect there has been an **SAE** e.g. admission to hospital with an overnight stay, complete the **Serious Adverse Event Form immediately** and **fax** to Sheffield CTRU **within 24 hours of discovery**.

If the participant has died from a non-stroke related event such as a heart attack, (and therefore will be discontinued from the study) record this on study completion/discontinuation form in addition to completing the **Serious Adverse Event Form** as above.

Use the flow chart below for further guidance as to whether an event is considered as an AE or SAE but if you are in doubt:

- Complete the Adverse Event Prompt Form
- Complete the SAE form and give to the PI to sign and fax to Sheffield CTRU
- Then phone Sheffield CTRU to discuss



## Other Important Forms

### ▶ Unblinding

As an Outcome Measures Therapist, you should remain blinded to which group the participant is in throughout your involvement in the study. Please **do not try to guess** or work out which group the participant is in because this may bias the results. However, if you **suspect** you have become aware of which group the participant is in, it is important that you record this on the **unblinding form**. Every case of **treatment unblinding** or **suspected unblinding** must be documented with reasons as to why or how it occurred. You will not be in trouble for becoming unblinded but we need to record it so that we can accurately report on the blinding process and outcome assessments.

### ▶ Study completion/discontinuation

It is necessary to record whether a participant has completed the study i.e. if they complete all their follow-up visits, or if they are discontinued from the study because they (or a representative or the PI) feel it appropriate to withdraw them from the study. Please complete the **study completion/discontinuation form** at the end of the study or when a participant is discontinued from the study and return to the PI to sign. If you are unable to complete this form due to time constraints, please ask the PI to complete it.

### ▶ Intervention/attention control withdrawal

Participants (or their representatives) may decide to withdraw from the group they were allocated to e.g. stop having puzzle books or stop using StepByStep. If they withdraw from the group they should still continue in the study if possible i.e. continue to have follow-up visits. Whether they continue to have follow-ups or not, withdrawal from the intervention or attention control needs to be documented on the **Intervention/attention control withdrawal form**. This form needs to be completed by the lead therapist or PI. Please bring it to their attention if a participant indicates a wish to withdraw.

### ▶ Protocol non-compliances

If you notice that something is not being done according to the protocol in the trial, please discuss with your PI as this needs to be documented on the **Protocol non-compliance form**.

