



Frequently Asked Questions

Identification/Eligibility

How many people should I send out the project summary information to at once?

- Different PIs have used different strategies to do this and there is no right answer. It probably depends on which sort of patients you are targeting initially. If you are sending the information to current/recently discharged patients or people who know you well, it is more likely that you will get a higher response rate and therefore more to follow up on at once. Therefore, maybe send out the summary to less people all at once (e.g. 5). However, if you are sending out information to people who were discharged several years ago or people you have never had contact with, it might be worth sending out the summary to more people at once (e.g. 10) so that you can expect to have at least some response.

Can you clarify the exclusion criteria about someone not being eligible if they are using computer therapy for word finding?

- Someone who is **currently** using a **computer programme** designed to provide **word finding therapy** is not eligible to take part in the Big CACTUS study.
- If someone has a word finding therapy app/programme on their tablet/computer but they are no longer using it, it would be worth checking why this is. If it was just because they have been ill but plan to start using it again now they are better, they would not be eligible. However, if they had just got bored of using it, they are unlikely to begin using it again and therefore they may be eligible.
- Computer programmes/apps should be considered to be therapy if there is a) provision of some form of feedback and b) progression through different activities
- Some patients in Sheffield are using Grid player but this is designed as a communication aid rather than to provide word finding therapy. Patients may be using the app to repeat words in response to pictures but if there is no feedback and no progression through different activities, this is no different to naming objects in a room or naming things in photo albums or copying a family member saying a word which may well happen across this patient group anyway.

Can somebody continue doing non-computerised word finding therapy while on the study?

- Yes, this is part of their usual care so we want to measure what input they are having for their communication difficulty on the activity logs but we don't want them to stop this.

Follow up assessments

When are the follow-up assessments due?

- The timepoints for all participants refers to the time from the date of randomisation. Therefore, even if they are in the computer therapy arm and didn't get the software installed until several weeks after randomisation, the 3 month phone call should still take place as close to the 3 month time point as possible. Likewise, although some participants may not have the computer intervention for the whole 6 months, the reason for the 6 months is so that they have can

practice for a long time (a sustained amount of practice) rather than because 6 months is the exact time they need to have it available for.

If a participant did not get the software until several weeks after randomisation, the 6 month follow up is still due at 6 months from the date of randomisation BUT is still accepted as long as it is performed within one month (4 weeks) of the expected timepoint, which means they could have a little longer using the software. For example, if the 6 month follow-up is due on 1st February, the 28th February is the last possible date it can be completed. The 9 month follow up would still be due on 1st May (as it is 9 months since randomisation), but it could be completed until 28th May for it to be accepted.

Outcome Measures Therapists

Who is eligible to be an Outcome Measures Therapist?

- The contract information states that it should be a band 6 Speech and Language Therapist who can be an Outcome Measures Therapist. However, we recognise that an experienced band 5 Speech and Language Therapist who is ready for a band 6 role could also take on this responsibility.

StepByStep

Which operating systems does StepByStep v5 run on?

- At the moment it only runs on Windows devices. Laptops or computers can be either Windows 7 or Windows 8. Tablets must be Windows 8.
- It is also worth noting that if the participant has a PC which is Windows 7 or 8, it would be helpful to check the monitor shape. The software is not set up to display properly on the old square monitors but instead need a landscape view monitor (like a laptop has).

What do I do if there is a delay in the participant accessing StepByStep or if access is prevented at some point during the intervention period?

- Complete the StepByStep access form with details of when the participant gained access to StepByStep and any details about times when they could not have access due to computer failure or StepByStep software issues. We do not want to capture information about participants' holidays/illnesses on this form. Also use this form to record the date that the keyfile was taken from the participant's software.

Even when I follow the instructions on slides for setting up the repetition task, the task doesn't look like a repetition task – what am I doing wrong?

- You are not doing anything wrong. Unfortunately there is a slight glitch in the software which means that this may happen. However, press the back arrow to come out of the task and then when you re-enter the task, it should be resolved. It will only be the first time that you try to use this task that you will notice any problem with it.

I am having difficulty adding new vocabulary to an exercise when in exercise view

- Sometimes the selection bar at the top of the screen disappears. This seems to happen mostly if you have been clicking through pictures quickly. To rectify this, try toggling across to the library view. You will see the items you have already chosen in the bar at the top. If you need to, you can then toggle back to the exercise view and the bar should still be there. If you do not need to use the exercise view, it might be easier to stay in the library view.

Is the timing indicator accurate for the naming assessment?

- Please ensure you have done the update that was sent to you by Jane Mortley and then all items on the assessment (including the first item presented) will be accurately timed using the timing indicator on the next button.

Why do I get an error message when I try to backup a participant's key file?

- Check that you have not saved the participant ID as containing a forward slash (/) as this can cause an error to happen. You can see the ID on the patient management screen. If you have used a forward slash in the ID, open that participant and then click on settings (top right hand corner of the management view) and edit. Change the ID to using a space or a dash instead of the slash and then click on the disk to save. This should have resolved the error.

How do we provide the opportunity for those not in the intervention arm to use the software after the study?

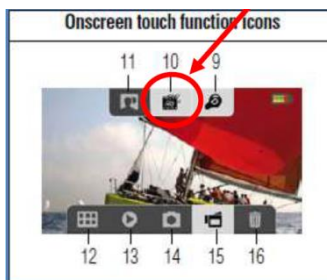
The information sheet states that Big CACTUS participants can have a go with the computer software at the end of the study if they like. It also states that therapists will loan or assist with looking for funding to purchase computers if they do not have one of their own.





- At the end of a participant's time in the control group, or the attention control group (i.e. 12 months after they have been randomised) they may request a go with the StepbyStep programme
- This is not part of the trial and so does not have to follow any set protocol. Provision of software and hardware and the amount of time this is provided for will be at the local therapist's discretion and will depend on local resources.
- If participants have their own computer options include:
 - Installing the month StepbyStep free trial for them to have a go with from a trial disk owned by the therapist
 - If the participant has competent family/carers, the therapist could signpost them to the StepbyStep website to order their own month trial disk
- If participants do not have their own computer or if they wish to have a longer trial than 1 month:
 - Therapists may be able to loan one of the lap tops or tablets used for the participants in the computer arm of the trial
 - Alternative options are to apply to local charitable trusts for hardware if you have contacts with any of these.

- Clinician licenses allow more than one client to use the software. These cost in the region of £500. If clinician licenses were purchased initially for use in the trial, these can be reused for loan to participants who would like a go. (when and for how long to loan these is at the therapist's discretion)
- If clinician licenses are not available locally, the Big CACTUS team centrally have some funds from the Tavistock trust which we can use to provide a clinician license if needed.
- Therapists can also direct participants who wish to try out software to the aphasia software finder to look for other software that may interest them and which suits their needs.
<http://aphasiastsoftwarefinder.org/>

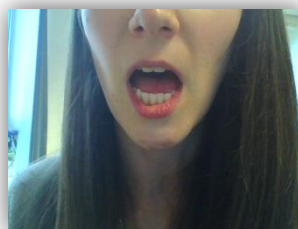
How do I record video prompts?

- Use the Toshiba video camera provided from the training. Change the settings on the camera to be a lower resolution so that it is compatible with the software. The default camera settings is full HD 1080/30 but this results in the keyfile being too large to backup. To change the resolution, turn on the camera; touch the HD symbol on the touchscreen (number 10 below); choose the last option (VGA 480/30).



	Full HD 1080/30	Records videos at 1920 x 1080p 30fps resolution.
	HD 720/60	Records videos at 1280 x 720p 60fps resolution.
	HD 720/30	Records videos at 1280 x 720p 30fps resolution.
	VGA 480/30	Records videos at 640 x 480p 30fps resolution. ←

- You can now record the prompts. Remember to record a close up of your mouth for the word initial and whole word videos but the semantic video prompt can show your body and hands too so that you can use gesture etc to support.



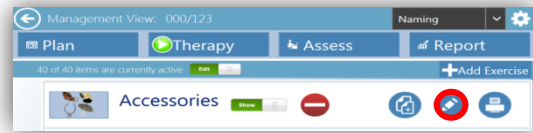
Which prompts do I need to record videos for?

Only record videos for the prompts that will be useful for that participant e.g. if they do not benefit from semantic cues, there is no point in you recording word meaning videos for any of the vocabulary.

Do the ticks in the library of StepByStep really show which videos are saved for each prompt?

In theory yes they do but you need to have done the update to StepByStep that Jane Mortley sent to you. If not, it may not be accurate. Either way, you should follow the instructions below as to how to check the videos that are recorded for each item and the sentences for each item. Re-record prompts if required using the video camera and add to the software by clicking the file button under the corresponding video box and then check the sentences that are there.

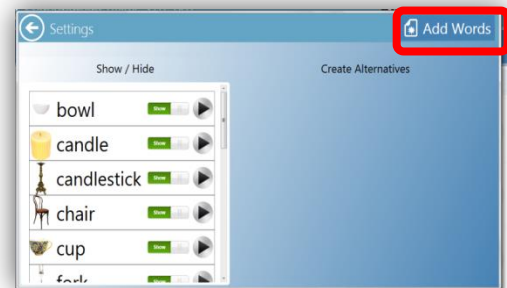
- To check which items in a topic have videos, click on the pencil next to that vocabulary topic



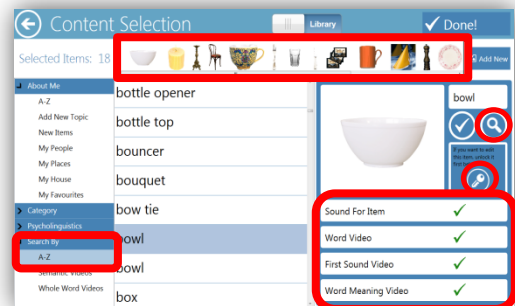
- Click on 'words'



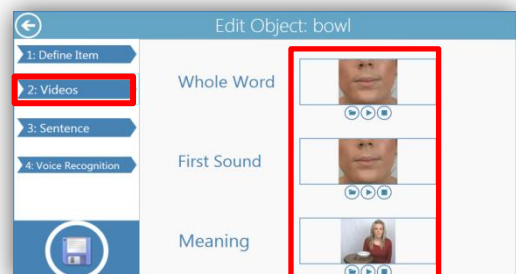
- Then click on 'add words.' Make a note of the words in the topic now as this will save you a lot of time if (more likely, when) you accidentally delete a word in the next stage. You could just take a photo of them on your phone or write them down



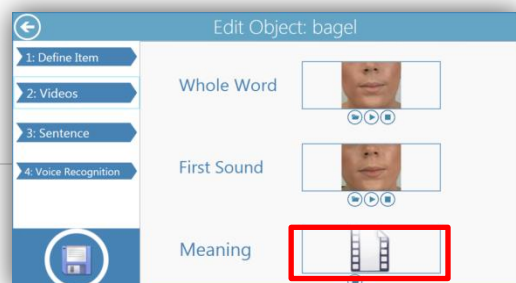
- You are taken to the library view with all the words in this topic shown in the bar at the top
- Use the search by A-Z to select each item and the videos/recordings saved are shown with a tick or cross
- Click on the key and then the pencil to edit



- Click on 'videos' and check that there are videos saved for the prompts you are using for this participant as in this example
- Click 'back' if no changes need saving



- There is no video prompt for semantic cue for this word so if semantic cues are needed for this participant, you would need to record one. If not needed by the participant, do not spend your time recording video



Is the timing for the naming assessment accurate on StepByStep?

Yes, the next button changes colour at 5 seconds and then again at 10 seconds which you can use to facilitate scoring the assessment. However, the timing for the first item begins before the first picture is shown (while there is a dialogue box still open in front of the picture). Therefore, you need to manually time the first item but then you can refer to the next button to facilitate your scoring for all other items.

What is the difference between the sequence and steps launch modes?

The steps launch means that when hen the participant starts to use the therapy and clicks on a vocabulary topic to work on, it will automatically open at the last step that was being worked on in that topic (or if it has not been worked on yet, it will open at the first step). If the participant does not want to work on the same step as last time, they can click 'back' and then it takes them to the screen with the different steps where they can choose the step they want to start working on. This is what would happen if the sequence launch was selected.

Why are the sentence levels not showing up when I am trying to personalise a participant's keyfile to be on the intervention arm?

Topics which you set up (personalised to your participant) and either only contain 'new' words that were not in the StepByStep library or none of the words chosen from the library to be in that topic have a sentence recorded will not allow you to add sentence levels when setting up a person's therapy steps. This means that some participants will not be practising some of their topics at sentence level. Jane has explained that this is because none of the words in these topics have any sentences recorded at the time the exercise (vocabulary topics) was set up.

To overcome this, when setting up the 100 words into topics for participants, please ensure that one word in each topic has a sentence recorded for the item by adding sentences to one item (unlock the item from the library view, click on the pencil to edit and then click on the sentences tab. Write the sentences in and audio record them, click on the disk to save and then remember to click on the tick to select that word so it goes into the bar at the top and into the participant's topic.

As long as one word in each topic has either one or two sentences recorded for it, either one or two sentence steps (accordingly) will be shown for them to practice through.

If you realise retrospectively that a participant you have already set up the words for has not got sentence steps showing for particular topics and you feel they are likely to get to the point of practising vocabulary at sentence level, follow the instructions below.

- From the management view, click on the pencil next to each topic to check which topics have sentence steps showing or not
- Ensure you have taken a photo of the words within the topics that do not have sentence steps (once you click on 'words')
- Return to the management view (plan) and click on the copy button next to a topic that has the sentence steps showing. This takes you into the exercise view. Toggle across to the library view and click on 'about me' and 'new items' or search for the items in the topic you are trying to re-create (refer back to your photo)
- Once all the items for that topic are in the bar at the top click 'done' and rename the topic.

- Click on the pencil next to this newly recreated topic to check the sentence steps are there then delete the old exercise (topic) containing the same vocabulary without the sentence steps.
- Repeat this process for the other topics which do not have sentence steps

If you don't think that this participant is likely to practice the vocabulary at sentence level but they have some topics with vocabulary that will work at sentence level, you could always leave the settings as they are. Then prompt your assistant/volunteer that if/when the participant begins practising at sentence level, to let you know and you can then give them instructions on how to copy the settings from other vocabulary topics so that they can practice all topics at sentence level (as above).

Video Conversations

What do I need to remember when filming the video conversations?

- Make sure that both you and the participant are in shot as your body language/facial expressions etc. can all impact on how effective the participant is at communicating and how many external cues they need, *including participants' attempts to draw and write* (Flip the screen round so that you can check that you are both in shot)
- Use your external microphone (check it is pushed in all the way) and point it between you and the participant
- Record a test video of no more than 30 seconds, play it back to make sure you can hear and see your conversation.

Memory Stick and returning things to CACTUS HQ

How and when do I have to return USB and consent forms to CACTUS HQ?

- Post the USB with the saved video conversations back to CACTUS HQ separately to the consent forms. This is because the USB is anonymised with just the participant ID whereas the consent forms contain participant names and therefore if posted together, they could be linked.
- Please send the USB back once a month if possible
- The consent forms can just be sent back as and when is convenient

How do I access files on USB/memory stick?

You have an encrypted memory stick and therefore if open the file before unlocking the stick, it will appear as though there is nothing on it. When you insert the memory stick you are likely to get a pop up box called 'autoplay' appear as below. If this does not appear, go into My Computer



- Click on Run DTLplus_Launcher.exe from the 'autoplay' menu or the same icon (DTL+G3) from My Computer. Type in the password and click 'login'. Now you can view the files on the memory stick as you would on a regular memory stick.

Volunteer/Assistants

Do all volunteers/assistants need to be taken out on their first visit?

Yes. Take the volunteer/assistant with you on their first visit to show them how the patient needs to be encouraged to use their personally tailored exercises on the specific piece of hardware that they are using and to ensure there are no unforeseen difficulties which can be discussed after the session in a 'debrief'. We recognise that assistants may have more prior understanding than volunteers and are employed or that some volunteers may be very experienced. However, for the purposes of this study, the only distinction that is made is between trained SLTs and untrained personnel (assistants and volunteers). Therefore the training and support that you offer should be the same for all volunteers and assistants.

Randomisation

How do I randomise a participant to the study?

Go to the live randomisation website on your phone or on a computer:

<https://www.scram.shef.ac.uk/organisations/sctru/studies/big-cactus/>

Log in using your site's personal username and password given to you at the training. Fill in all the information, confirm the participant is eligible and has consented, click the "Confirm" button **once** to randomise.

It is important that you only click ONCE, or the participant will be randomised to several groups!

Usual Care

On the Usual Care form, does the information about travelling distance and mode of transport refer to the participant or the treating therapist?

For the distance travelled and mode of transport it doesn't matter if it is the participant or the therapist travelling. As it is a measurement that will be used by our health economists, they just want to factor in any travel involved in an intervention, regardless of who it is that had to travel. On the database we have also added options for "No cost" and "Don't know".