



[Trust logo/letterhead]

## PATIENT INFORMATION SHEET (PIS2)



# “CACTUS”



## 1. Study title

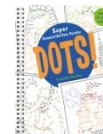
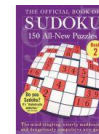
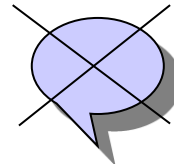
**C**ost effectiveness

of **A**phasia **C**omputer **T**reatment

versus **U**sual **S**timulation

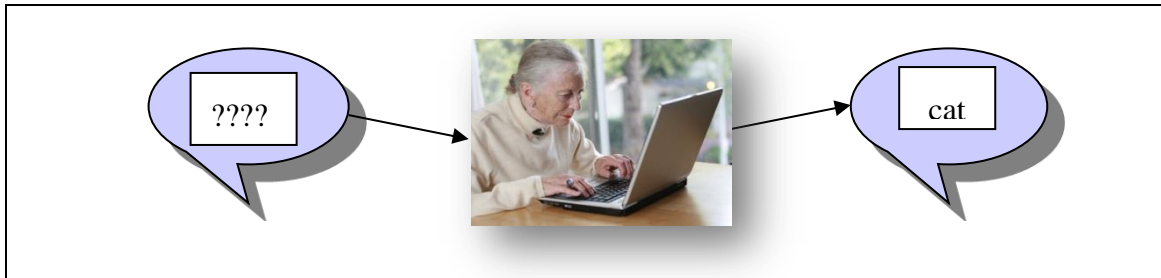
or attention control (puzzles)

long term post stroke



## 1. Invitation

**You** are being invited to take part in a **research study** to evaluate the use of a **computer** program to help you **find your words** more easily.





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Before you decide it is **important** for you to **understand** why the research is being done and **what it will involve**.

Please **take time to read** the following **information**. 

**Discuss it** with **friends, relatives** and your **speech and language therapist** if you wish.

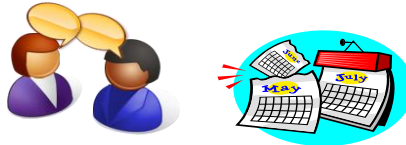
**Ask** us if there is anything that is **not clear** or if you would like **more information**.



Take **time to decide** whether you wish to take part. 

## 2. What is the purpose of the study?

People with **aphasia** rarely have **speech and language therapy** for **more than a few months** after a stroke.



They may receive continued **support** from **stroke groups** and **carers/relatives**.

There is evidence that **people with aphasia** can use **computer** software **independently** for language practice.

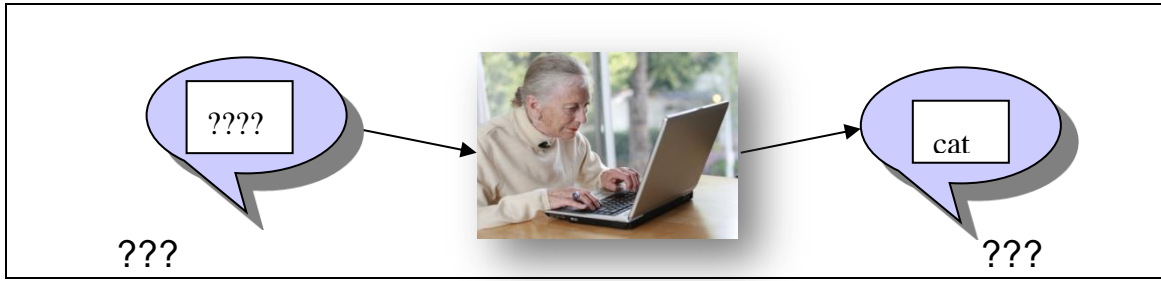


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We want to know:

1) if people who have had **aphasia** for **more than 4 months**  
can get **better** at finding the **correct word** by using **computer exercises**



2) if offering **computer therapy** is good **value for money**

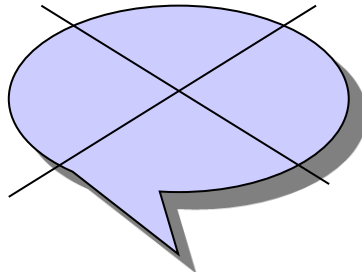




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#### 4. Why have I been chosen?

**You** have **aphasia** from your **stroke**  
and find it **difficult to find the words** you wish to say.



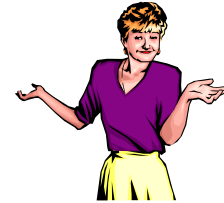




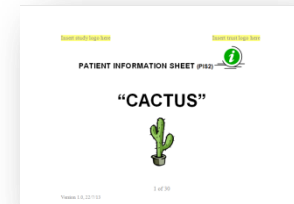
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## 5. Do I have to take part?

No. It is **up to you** to decide whether or not to take part.



If you do decide to take part you will be given this **information sheet** to keep.



You will be asked to **sign a consent form**.





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If you decide to take part you are still free to **withdraw** at any time. You **do not** need to give a **reason**.



Not taking part, or withdrawing from the project **will not** affect your **rights** to any **health, or voluntary services**.

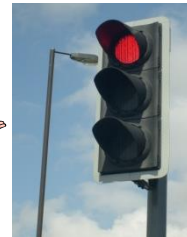


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The consent form asks whether you agree to be contacted about **future research**.

It is **up to you** to decide



If you **do not** want to be contacted about **future research**,  
you can **still take part** in **this project**.

## 6. What will happen to me if I take part?

A research **speech and language therapist** will **visit** you **at home**.



The therapist will carry out **assessments** of your **language**.  
This will include a **video recording** of a short **conversation**.





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The therapist will help you to think of **words** that you would like to be able to **say**.

I	like	the
little	a	can
see	red	blue
do	my	you
all	and	we
big	look	yellow
green	down	are
on	not	one
two	three	four
five	here	is
come	play	brown
it	jump	run
said	what	black
in	funny	me
orange	at	away
go	to	will

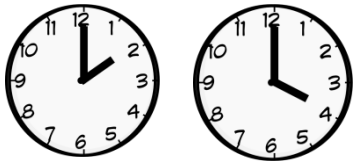
The therapist will also check that you are able to **see pictures** on a **computer** screen.



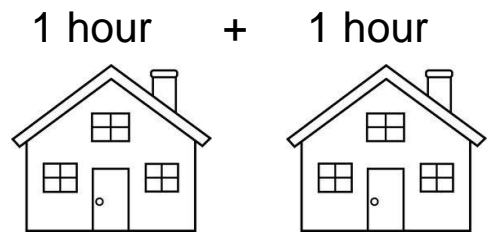


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These tests may take **up to two hours**.



The therapist may visit you **twice** to complete the tests.



A **computer system** will randomly allocate you to **either**:

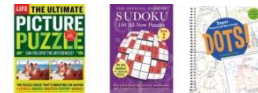
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- using the **computer therapy** exercises



or

- Carrying out daily **puzzle book** activities



or

- continuing with your **usual activities**



You have an **equal chance** of being in any one of the groups above.



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If you are asked to use the **computer** program you will be offered a **volunteer or speech and language therapy assistant** to help you.





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The research therapist will put **StepByStep software** on your **computer**



Or provide you with a **computer** if you haven't got one and make sure the **exercises suit you.**

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You will be asked to use the **computer** for **20-30 minutes** each day over **6 months**.

6 months



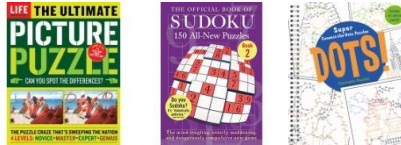
You will be asked to **record** anything that is **difficult** or **distressing** about the treatment.



You should continue to do any other activity or therapy that you usually do.

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If you are asked to complete **puzzle book** activities,



the **therapist** will provide you with a **book of puzzles** that are not too hard and not too easy for you.

You will be asked to complete **one puzzle each day**.



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A member of the **research team** will **telephone** you **each month** to see if you are ready for a **new book**



They will ask you **what sort of puzzle book** you would like next.

If you finish the puzzle book early, **you** can **telephone** the research team to ask for a **new one**.



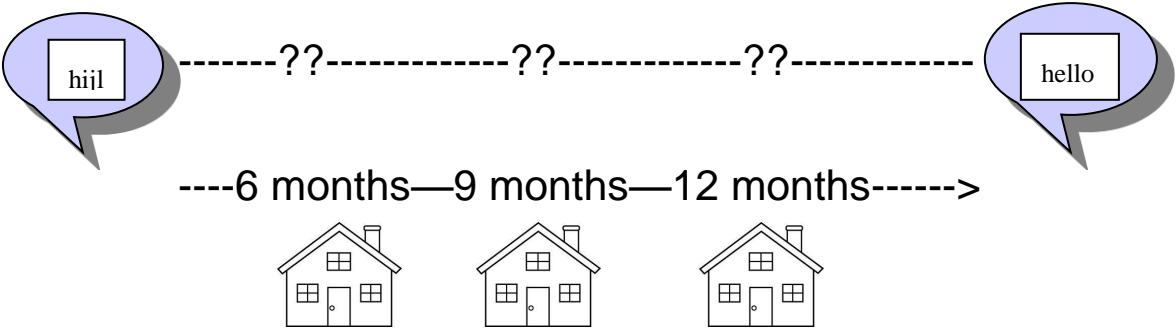
This will continue for **6 months**.

You should continue to do any other activity or therapy that you usually do.



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**Whichever group** you are in  
the **researcher** will **visit** you again **3 times** to  
repeat **language assessments**  
to see if your **word finding** has **improved**.

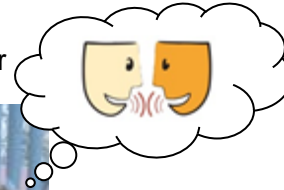


If a **friend** or **family member** is there when the researcher visits we will ask them what they think about your communication.

Researcher

Participant

Carer



We will also ask them about being a carer.



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## 7. What is the computer program being tested?

The **computer program** you will use is called **StepByStep**.



It is a program specifically designed to **help people with aphasia** improve their **word finding** ability.


It is now being **used** by some **speech and language therapists** during therapy sessions.



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## 8. What are the side effects of taking part?

We **do not expect** any **side effects** from taking part.

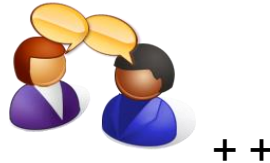
If the **computer** program **does not suit your needs** or **does not act as expected**, it may cause **frustration**. 

You may **decide to stop** using the computer. 



## 9. What are the possible benefits of taking part?

Taking part will give you the opportunity to have **further language practice**



and **feedback** on how well you are doing from the **computer**.

This may help you to **find your words** easier.

## 10. What happens when the research study stops?



If you **did not** get to use the **computer** during the study and **wish to**,

your speech and language therapist will **lend** you a **computer** and the **software**

so you can **have a go** at **word finding** therapy with the **computer**.

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If you **did** use the **computer** and you **wish to continue**, you may **keep** the **software** to put on your own computer.

If you do not have your own computer your speech and language therapist will **assist** you by **lending you a computer** or accessing **funding** to purchase one.



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## 11. What if something goes wrong?



If you wish to **complain** about how you have been approached or treated in this study, you can use the National Health Service complaints mechanisms.

This will not affect the services you receive in any way. If you have any complaints or concerns, please contact the study manager, [Name], [Tel].

OR

You can use Sheffield University complaints procedure and contact the following person:

[Name] 'Registrar and Secretary' of the University of Sheffield, by post (Office of the Registrar and Secretary, Firth Court, Western Bank, Sheffield, S10 2TN)



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## 12. Will my taking part in this study be kept confidential?

All **information** which is collected about you will be **kept confidential**. Your name **will not** be shown.

Joe Bloggs --> M68A

Only **authorised** people will be **allowed** to see your **information**.



### 13. What will happen to the results of the research study?

The **results** of this research study will be **published** in scientific journals after the end of the study and to **stroke survivors** and **professionals**.





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## 14. Who is organizing and funding the research?

The research is organised by the **University of Sheffield** and funded by the **Department of Health** (National Institute for Health Research Health Technology Assessment programme).

The **sponsors** of this study will **pay** (name of hospital department or research fund) for including you in this study.

## 15. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a **Research Ethics Committee**. This study has been reviewed and given favorable opinion by \_\_\_\_\_ Research



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Ethics Committee.

## Contact for further Information ++

If you have any **questions** regarding this study, please contact the investigator:

[Name of principle investigator]



[Telephone no.]



[Email]





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**Thank you** for reading about this study

