[Trust letterhead]

PARTICIPANT INFORMATION SHEET (PIS 1)

1. Study title

Cost effectiveness of **aphasia computer treatment** versus usual stimulation or attention control long term post **stroke** (CACTUS)

2. 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. 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** carefully and 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 or not you wish to take part.

Thank you for reading this.

3. What is the purpose of the study?

People with aphasia rarely receive 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 structured language practice. This project investigates:

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

2) whether offering computer therapy is good **value for money**,

4. Why have I been chosen?

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

5. Do I have to take part?

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 and be asked to sign a consent form. If you decide to take part you are still **free to withdraw at any time and without giving a reason**. Deciding not to take part, or withdrawing from the project will not affect your rights to any health, or voluntary services.

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

If you decide to take part, a **research speech and language therapist will visit you at home** or at **the group that you attend**. The therapist will carry out **assessments** of your language and daily life activities. Part of the assessment will include a **video recording of a conversation** between you and the therapist. This will be sent securely to the study team at Sheffield University for analysis. They will not know any personal information about you e.g. your name or contact details.

The therapist will help you to think of words that you would like to be able to say. The therapist will also check that you are able to see pictures on a computer screen. 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**

- continuing with your **usual activities/therapy** only

  or

- using the **computer** therapy exercises for 6 months

  or

- Carrying out daily **puzzle book** activities

The allocation is **random** and cannot be influenced by your speech and language therapist or the research team. You have an **equal chance** of being allocated to each of the groups above.

If you are asked to use the computer program the research speech and language therapist will put the **StepByStep** software onto your own computer, or provide you with a lap top computer if you do not have your own. The therapist will show you how to use the therapy program and make sure the exercises suit you. You will be asked to try and **use the computer for at least 20-30 minutes a day over 6 months**. You will be offered a **volunteer or a speech and language therapy assistant to help** you. They will visit at least once a month and you can contact them to ask advice between visits if you need to. During this time you will be asked to keep a **diary** to write down anything that is difficult or distressing about the treatment. You should continue to do any other activity or therapy that you usually do.

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

The **researcher** will **visit** you again **3 times** to repeat **language assessments** to see if your **word finding** has **improved**.

We would like to test participants in all of the study groups.

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

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. **StepByStep** contains a library of over 13,000 exercises using more than 2,500 high quality photographs and speech feedback to help practice saying words.

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. If this happens you may decide to stop using the computer program.

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 have the opportunity to experience word finding therapy with the computer. If you did use the computer and you wish to continue, you may keep the software on your own computer. If you do not have your own computer your speech and language therapist will assist you by lending you a machine or assisting you to apply for charitable funding to purchase one.

11. What if something goes wrong?

If you wish to complain about any aspect of the way 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].

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

Dr. David Fletcher, 'Registrar and Secretary' of the University of Sheffield, by post (Registrar and Secretary's Office, Firth Court, Western Bank, Sheffield, S10 2TN)

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

We will ask you for your address and telephone number at the beginning of the study so that we can provide you with puzzle books and newsletters about how the project is going. However, this information will be stored separately to your results. No publications or other public information will identify you personally.

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

The results of this research study will be published in scientific journals and will be presented to stroke survivors and professionals after the end of the study (in about 5 years).

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, to protect your interests. This study has been reviewed and given favorable opinion by _______________Research Ethics Committee.

Contact for further Information

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

[PI contact details]

Thank you for reading about this study.