Information Sheet for Participants in Research Studies

You will be given a copy of this information sheet.

Title of Project: Reconstructing Sentence Processing in Aphasia

This study has been approved by the UCL Research Ethics Committee

(Project ID Number: 8123/001)

Who we are

Prof Rosemary Varley

✉ rosemary.varley@ucl.ac.uk

☎ 020 7679 4234

Fern Rodgers

✉ f.rodgers@ucl.ac.uk

☎ 020 7679 5785

Dr Amir-Homayoun Javadi

✉ a.h.javadi@kent.ac.uk

☎ 01227 827770

Dr Jane Warren

✉ jane.warren@ucl.ac.uk

Dr Claudia Bruns

✉ c.bruns@ucl.ac.uk

☎ 020 7679 4292

Work address:

Division of Psychology and Language Sciences
University College London (UCL)
Chandler House
2 Wakefield Street
London WC1N 1PF

Thank you for reading this.

1. What you need to know

You are being invited to take part in a research study. Before you decide to take part, it is important for you to understand **why** the research is being done and **what it will involve**.

Please **take time to read** the information carefully and discuss it with your family and friends. Ask if anything is not clear or if you want **more information**.

Take time to decide if you wish to take part.

2. Why are we doing this research?

Some people find listening to and talking in **sentences** difficult after a **stroke**.

We want to find out if a **new therapy** can **help** people with difficulties understanding and producing sentences.

3. Why me?

You have **difficulties understanding sentences** and **speaking** following a **stroke**.

4. Do I have to take part?

No. You can decide.

If you want to take part, you can keep this information sheet.

A researcher will invite you to **Chandler House** at UCL in **Bloomsbury**.

You will need to **sign a consent form** to show you are happy to take part.

Even if you decide to take part, you can **stop** the study at **any time** and without giving a reason.

If you withdraw from the study, we will ask you if you want the information that has been collected to be destroyed.

If you say **no**, this will **not** influence your relationship with UCL.

If you say **no**, you will still get your **normal help**.

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

There will be **three stages** in the study.

You will **come to UCL Chandler House** for all meetings.

There will be **18 meetings** in total.

It is **not** possible to do the therapy at home or anywhere else because it involves specialist equipment. You must be **able to travel to university**.

You will **first** come for **assessments** so we can measure your language and other abilities **before** the **therapy**.

There will be **2** meetings, each taking **60-70 minutes**. You can take a **break** in a meeting whenever you need one.

If the therapy and research procedures are suitable for you, you will come for a **brain scan** called **magnetic resonance imaging (MRI)**. You will be in the scanner for **20 minutes**.

You will then come to **therapy** for **3 days a week for 4 weeks** (a total of **12 visits**).

Each therapy session will take **60-70 minutes**.

18 meetings

Stage 1

Stage 2

Therapy

After the **therapy** has **finished** there will be **3** meetings. Two of these are to see if your ability in listening to and producing words and sentences has changed. This will tell us if the therapy is effective and useful for other people with strokes.

In your last meeting, you will have another **brain scan**. You will be in the scanner for **20 minutes**.

We will pay you **£10** towards your expenses for **each meeting**.

Stage 3

Stage 1: Measuring language before therapy

You will come to **UCL Chandler House** for your **first meeting** that takes around **80-90 minutes**.

We will ask **questions** about your stroke and your abilities. We will also ask questions about your **medical history**, to check if therapy and research procedures are suitable for you. Some questions may feel **embarrassing**.

Examples are: Do you have any metal in your body? For female participants: Is there a chance you may be pregnant? Do you have a contraceptive coil?

You will do some tests. These include

- naming pictures,
- listening to words and sentences,
- repetition of words and
- tests of processing information.

Your speech will be **audio** recorded.

This will allow us to understand the difficulties you have before therapy.

We will also **video record** one test, but your **face** will **not** be on the film. You **do not** have to agree to the video and you can still take part in the research.

As soon as there is space available, you will be invited to attend your **next** meeting. This takes around **80-90 minutes**.

We will measure your language **again** to find out if there is any **change** in your speaking **before the therapy starts**.

Stage 2: Therapy

The **therapy** has three parts.

You will listen to and produce sentences using a computer. A researcher will help you with the computer.

We use **3 tasks** on the computer.

- 1) You listen to pairs of sentences of increasing length.

You decide if the pairs were the same or not.

- 2) You listen to words and sentences.

You push a button when you hear a certain word in a sentence.

- 3) You practice saying sentences. The computer program will record your speech.

You can **stop** the treatment at any time, without having to give a reason.

Stage 3: Measuring language after therapy

At the end of the therapy, and again **8 weeks** after the last meeting, we will ask you to repeat the **tests** to see if your understanding of sentences and speaking have changed.

You can tell us **what you thought about the therapy**.

We will tell you if your test scores have changed (if you want to know this).

You will also have two **brain scans** called **magnetic resonance imaging** or **MRI**.

You will be in the scanner for approximately **20 minutes** both times.

The scanner can be **unpleasant** for people who do **not like small spaces** (claustrophobia).

If you have claustrophobia, this part of the research project may not be suitable for you, but you are still welcome to have the behavioural therapy.

Before you have a scan, we will **check** that **MRI** scanning is **safe** for you.

We will ask you **questions** and check that you have **no metal** in your body.

The scans will take place at a nearby building (26 Bedford Way, London WC1H 0AP).

You can still take part in the study, even if MRI is not suitable for you.

6. What are the alternatives for treatment?

We are only offering this **experimental intervention**.
Your speech and language therapist or GP might be able to advise you about alternative forms of therapy.

7. What are the side effects of any treatment received when taking part?

There are **no known side effects** associated with the intervention tasks.

MRI scanning is **safe** for people with **no metal** in their bodies.

Some people don't like lying in the **small space** inside the scanner.

The scanner is **noisy**.

Sometimes you can feel **tingling** in your arms or legs during a scan, but this is **not** dangerous.

If you are **uncomfortable** at **any time** during the scan, you can **press a button** and the scan will be **stopped** straight away.

8. What are the possible disadvantages and risks of taking part?

It will **take up your time**.

You may find it **tiring** or **distressing**.

You may become **frustrated** if you feel you are not improving. However, we will provide you with support throughout the study.

This is a new and experimental intervention, so **the intervention might not help you**.

If it does **not** help you, things will stay the same as they are now.

9. What are the possible benefits of taking part?

You may **enjoy** taking part.

You may be **helped** by the therapy.

You will **help us learn more** about what could be good about the therapy.

10. What happens when the research study stops?

The **therapy will not** be **available** after the research study finishes.

However, if the intervention is successful, we hope that similar therapy programs may be available in future.

11. What information will be collected?

We will ask you some **questions** about the date of your stroke and what you feel about your current abilities.

We will collect information on your **listening and reading words and sentences**, and processing information.

We will make **audio recordings** of your speech.

You will have **MRI scans**. This gives information about the **effect** of the **stroke** on your **brain**.

12. Who will see the results about me?

Only **members of the researcher team** will see the **information** about you and listen to the recordings of your speech.

The **audio recordings** can be **destroyed after analysis is complete**.

The scans used in this research are **not** designed to find any abnormalities apart from your stroke. Sometimes an MRI scan may show something **unexpected** in your brain. If this happens, you will be contacted directly by one of the MRI unit's senior staff to inform you of the finding and advise on obtaining further evaluation via your **GP**.

We will **ask you if you agree** to share your information with your **speech and language therapist**.

We will **tell other researchers** (in the UK and across the world) about the results.

We hope to **publish the results in journals and presentations at conferences**.

When we **present** the results of this study, we will **take out** your real **name**.

No one **outside the study** will know **who you are** from the results.

The results of the study may be useful for **other researchers**. For example, evidence from different treatment studies can be combined to see what is the most effective form of therapy.

We will **ask you if you agree** to your anonymised scores being **shared** with other researchers.

Again, no one **outside the study** will **who you are** from these scores.

13. COVID-19

We have new safety procedures to **reduce risk** of COVID-19 infection.

We are following UCL and government guidelines, However, we cannot completely remove the risk.

We will ask you to read a **COVID-19 information sheet** that will tell you more and sign a **COVID- 19 consent form**.

It is **your decision** whether to take part.

14. What if something goes wrong?

If you **take part** in the research and **if you think** you were **harmed** there are **people to talk to**.

If you are harmed by taking part in this project, there are no special compensation arrangements.

If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.

If you wish to **complain**, or have any **concerns** about any aspect of the way you have been approached or treated during the course of this study, you can

contact Prof Rosemary Varley

Department of Language & Cognition

2 Wakefield Street

London WC1N 1PF

rosemary.varley@ucl.ac.uk

Tel. 020 7679 4234

If you do **not** receive a satisfactory response, you can

contact Dr Fiona Kyle

Chair of Ethics Committee,

Language & Cognition

f.kyle@ucl.ac.uk

Tel. 020 7679 8692

15. Will my details be kept confidential?

Yes, your details will be stored on **password-protected devices** and **destroyed after use**.

You will be given an **anonymous code** and no one will know who you are in any report of the study.

Your information will be collected and stored in line with the Data Protection Act 2018.

If you agree, we will store your **audio** recordings for up to 8 years. The **video** recording will be destroyed at the end of the study.

Information that has been provided in confidence and **personal information** will **not** be **used or shared without** your **consent**.

Anonymised data will **not** be **shared** with other researchers **without** your **consent**.

16. Local Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk.

Your personal data (name and contact details, medical history relevant to this study) will be processed for the purposes outlined in this notice. The **lawful basis** that would be used to process your personal data will be the provision of your **consent**.

You can provide your consent for the use of your personal data in this project by completing the **study consent form**.

Your personal data will be processed so long as it is required for the research project. If you agree, we can keep it for possible future studies. We will anonymise or pseudonymise the personal data you provide.

You can find **further information** on how UCL uses participant information in our 'general' privacy notice for participants in research studies:

<https://www.ucl.ac.uk/legal-services/privacy/ucl-general-research-participant-privacy-notice>

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

17. Who has approved the study? The study has been approved by the UCL Research Ethics Committee. They say that this research can happen . They say that it is safe and has been planned properly .
18. Who is organising and funding the research? This research is funded by the Stroke Association .
19. Contact for further information If you need more information, please contact Fern Rodgers at f.rodgers@ucl.ac.uk