

Participant Information Sheet – Picture Support

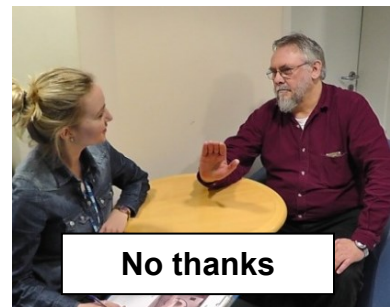
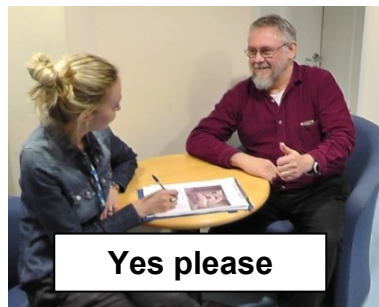
Version 2: November 2013 | Reference number: 13/LO/1515

Study Title: Predicting Language Outcome and Recovery After Stroke (PLORAS)

You are being invited to **take part** in a **research study**.



You can **decide** to **take part** or **not**.



Read about the research before you decide.

Yes? No?
Maybe?



Talk to others such as friends and family to **help you decide**.
Take your time to decide if you want to **take part or not**.

What do you think?



Ask research staff questions.

What will I be asked to do?



For more information:



E-mail: ploras@ucl.ac.uk



Tel: 0207 813 1538 or 07984 111 585



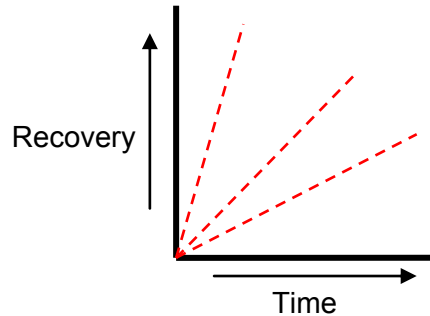
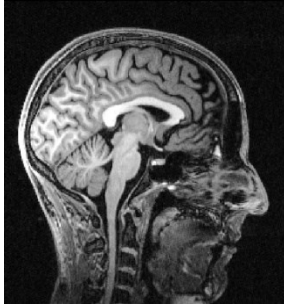
Website: www.ucl.ac.uk/ploras



Write to: PLORAS Research Team
12 Queen Square
London
WC1N 3BG

What is the study for?

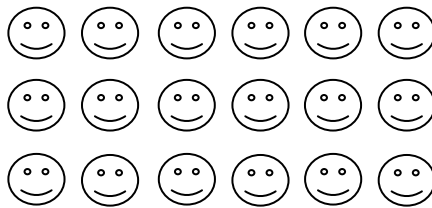
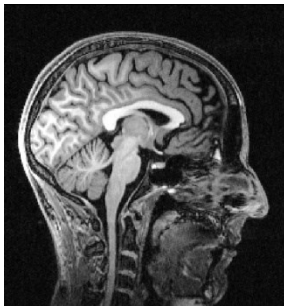
We want to **learn** how the **brain recovers speech and language** after **stroke**.



Why have I been chosen?

We would like to look at **how stroke affects many different people** – to look for **patterns**.

We will **look** at the **brains of hundreds** of different people.



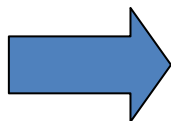
...500+

You have had a **stroke** and we think you **may be suitable** for this **project**.

We are **including people with and without speech and language difficulties**.

How does the PLORAS study work?

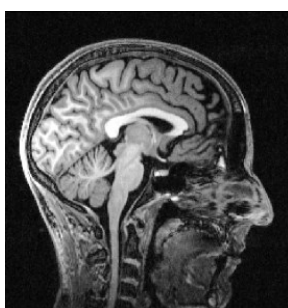
We use **MRI scanners** to take a picture of the brain.



We carry out **language assessments**.



We look for **patterns** between the **brain scan**, **language assessment**, and **time since stroke**.



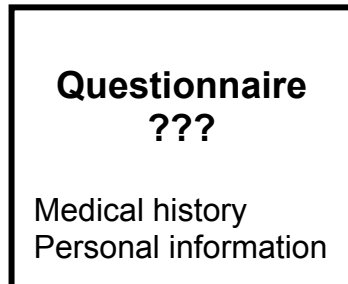
This will help us to **understand**:

- Why **some people** have **difficulties with speech and language** after their stroke and others do not;
- Why **some people** **quickly recover speech and language** after their stroke, but others take much longer.

What will happen if I say 'yes' to the research?

1. Screening questionnaire

You will be given a **screening questionnaire**.



2. Contact from the PLORAS Research Team

Someone from the **PLORAS Research Team** will **contact you**.

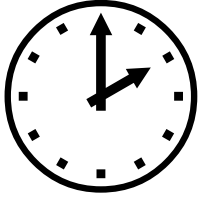
They will **tell you**:

- If you can be **included** in the study.
- If you can have an **MRI scan at our research centre**.
- If we need to use a **copy of a brain scan** you've already had in hospital.



3. Appointment

You will be given a **2-3 hour appointment**, when it is **convenient for you**.



Appointment = 2-3 hours

MRI scan

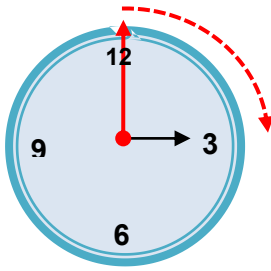
You will have an **MRI scan**.



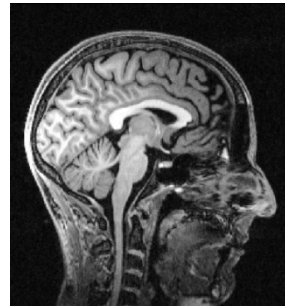
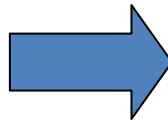
You will need to **lie still** in the MRI machine.



A structural MRI scan takes **15 minutes**.



We will take a **picture** of your **brain**.

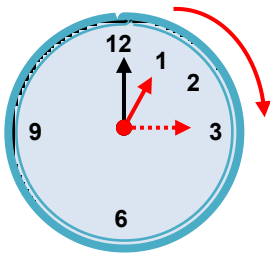


Language assessment

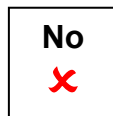
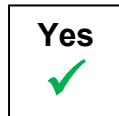
We will **test** your **speaking, understanding, reading and writing, and thinking skills**.



The tests might take **2 hours** in total.



We might need to **film** the tests so we can look at them in detail later.
You can say **no** to **filming**.



Answering questions

We will ask you some **questions about your stroke and recovery**.



Hearing and vision test

We will also **test** your **hearing and vision**.

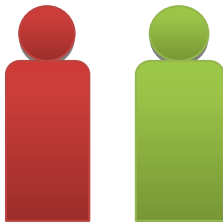


Important points about the appointment

Appointments are at our **research centre** in **London**.



You can bring a **friend** or **family** member.



A PLORAS researcher will look after you.



You will be asked to **sign a consent** form to say:

- You **agree to take part**.
- You have **read and understand this information sheet**.

Sign here: *John Smith*

You can **rest** at any time.



You can **stop** at any time.



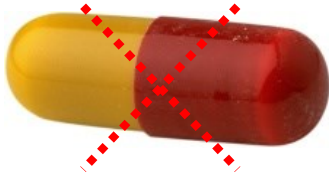
We can do the **language assessment** on a **different day** if you are tired.

<i>Mon</i>	<i>Tues</i>	<i>Wed</i>	<i>Thurs</i>	<i>Fri</i>
x	x	x	x	✓

We can do the **language assessment** at **your house** if you want.



It is **not a medical appointment** – we cannot give advice or treatment.

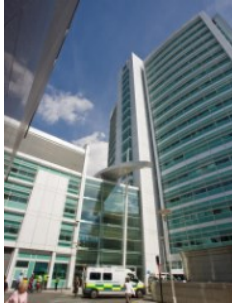


We may be able to give you **information about clinics** or **support groups**.

What if I can't have an MRI scan?

We will **ask** your local **hospital** for a **picture** of your **brain** if we cannot scan you.

We will get them in a **safe way** so they **don't get lost**.

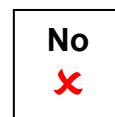
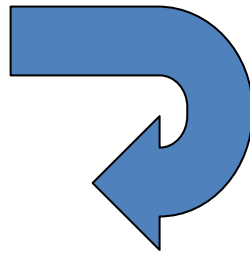


How long will I be in the PLORAS study for?

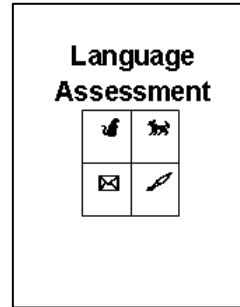
Taking part only involves **one appointment**.

We may **contact you** to **ask you to return** to have **another MRI scan and language assessment at a later date** to see if there has been any change.

You can say **'yes'** or **'no'** to **returning**.



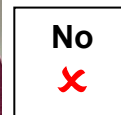
We may also ask if we can get **copies of brain scans and other assessments** you had in **hospital**.



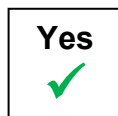
Is it my choice to take part?

Yes – it is your choice.

You can say **'yes'** or **'no'** to doing the research.



If you say **'yes'**, **you** or someone you know (**friend or family**) will sign a **form** to say 'yes'.



Sign here: *John Smith*

If you **change your mind** you can say **'stop'** at any time.



Will I get any money?

You will get **£10** for every **hour** of **research** at our **research centre**.



1 hour = £10

We will **pay** for your **train, bus, taxi** or **petrol**.



You will **not get any expenses** for the time it takes to fill in the **screening questionnaire**.

**Questionnaire
???**

Medical history
Personal information



Benefits

We can give you a **picture of your brain scan**.

There are **no other personal benefits**.



It will **not help you recover**.

It might **help other people recover** in the **future**.



Is there anything bad about taking part?

There are **no known side effects to MRI** (when guidelines are followed) and it is **painless**.



Safety guidelines

A **radiographer** will ask for your **medical** and **surgical history**.

They will ask about any **injuries** involving **metal**, or **metal work** you have done.

You will need to **complete** and **sign** a **checklist** before the scan.

Medical history:

Surgery Yes No

Metal in eye Yes No

Tattoos Yes No

Etc...



You will need to **remove metal** things, for example **necklaces**, **watches** and **money**.

This is because the **MRI machine** has a **strong magnet**.



You will need to **remove** your **glasses**.



You will need to **remove** any **make up**.



We **cannot include** you if you are (or think you could be) **pregnant**.



If you have had an **operation** where **metal** was put in your body, we might need to **X-ray** you.



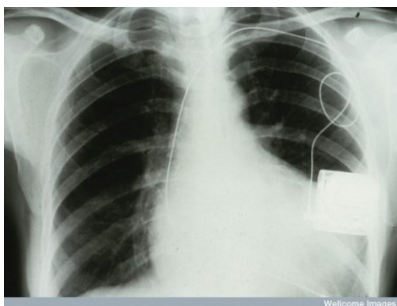
If **metal** has been in your **eye**, we might need to **X-ray** you.



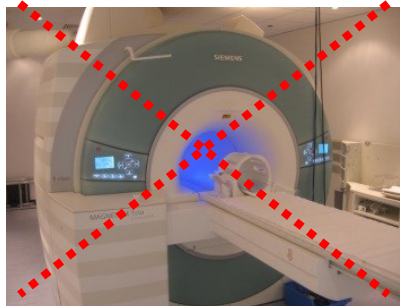
What if something goes wrong?

We follow **strict safety guidelines**.

We may not be able to carry out a scan because of **technical difficulties**, **safety regulations** or if you do not feel well.



Implant in body



No scan

If you have any **complaints** about the way you have been treated, **spea**k to the researcher or **Chief Investigator**.



If your **complaint** is not dealt with **satisfactorily**, contact:

University College London Hospitals Complaints

☎ **020 3447 7413**

✉ **complaints.officer@uclh.nhs.uk.**

UCL has **insurance** for participants.

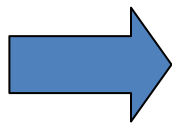
In the **unlikely event** that you **experience any harm or injury**, you may be **able to claim compensation** if it is proved that **UCL staff were at fault**.

Please make the **claim in writing to the Chief Investigator**, Professor Cathy Price.

If the **study** is being **carried out in a hospital** the **hospital is still responsible** for your care.

UCL are not responsible for staff at other hospitals – NHS or private.

If an **unexpected abnormality** is seen on your **MRI brain scan**, we will **contact your GP**.

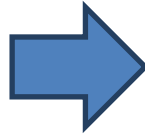


GP

Will personal information about me be safe?

Information about you will be stored in our PLORAS Database.

Name: **John Smith**
Date of Birth: **12/06/1953**
Address: **10 The Street,
LONDON**
Medical History: **Stroke,
etc.**



Database
Participant Name:
Date of Birth:
Participant Address:
Medical History:
Language Assessment Results:
MRI Scan:

Other researchers who have ethical approval will be able to access your data with your name and address removed.

Database
Participant Name: XXXXXXXX
Date of Birth: 12/06/1953
Participant Address: XXXXXXXX
Medical History: Stroke, etc...
Language assessment results:
MRI scan:



Other studies with
ethical
approval

Paper files will be kept in a locked cabinet and only accessed by relevant team members.

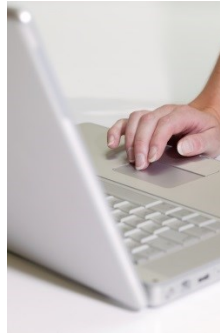
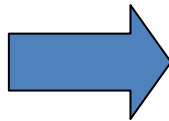


Videos will be kept on a computer in our research centre.

They can only be **accessed** by **authorised personnel**.

You will be **asked to sign a consent form** and you can **choose what your video will be used for**.

Videos will not be destroyed - unless you request this, but will be kept in our PLORAS Database.



The **data controller** will be the **UCLH NHS Trust**.

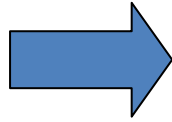
University College London Hospitals 
NHS Foundation Trust

The **researcher responsible** for keeping your information **safe** is **Professor Cathy Price**.

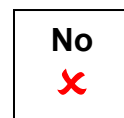
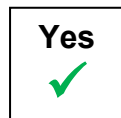


Consent

You may be asked if you are **happy for your data to be shared with other studies**.

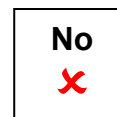
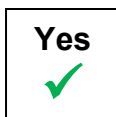
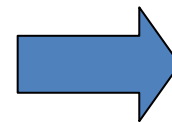


We will **only share your data with them if you agree to this**.



Consent is an ongoing process.

You can **withdraw your consent for processing of your data at any time**.



If you **lose capacity** and we are made aware of this **we will not contact you** but we will **keep your data and continue to use it confidentially**.



What will happen at the end of the research?

It will take **years** to **finish** the **research**.

2013, 2014, 2015, 2016...

When we have an **MRI scan** of **lots of people**:

- We will **write** about **what we learned** in **scientific journals**.
- You will be given the **full results** of the research when it is **finished**.
- We will **not write your name** or **where you live** in the study.



~~Mr J. Smith
10 The Street
LONDON~~

Who is paying for the research?

The **Wellcome Trust** pays for:

- Our MRI machines.
- Our research centre.
- Other medical research.

Supported by

wellcometrust

Who has checked the research?

The **London Queen Square Research Ethics Committee** have read about our research and **given us permission** to do it.



Supported by
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University College London Hospitals **NHS**
NHS Foundation Trust