Stroke-IMPaCT Study

The Study Invitation

This **study** is looking at **links** between the **immune system** and **cognitive decline** after stroke. The results of this study could lead to targeted treatments and improved recovery for people who have a stroke in the future.

- The **immune system** helps to keep the body healthy and fights off infections. It is a collection of special cells, organs, and processes.
- **Cognitive decline** is memory, thinking and processing problems which develop over time.

This information sheet will **help you decide** if you want to be part of this study.

Please **ask** us as many questions as you like. You can also ask others, such as your friends or family.

About the research

What is the study about?

- Up to a third of people experience **cognitive decline** after a stroke.
- People don't know why some people experience cognitive decline and others don't.
- Patients **report** that cognitive decline impacts their quality of life.
- There are currently no treatments.

What is the study looking at?

- We have previously made scientific discoveries that suggest cognitive decline may be caused by changes in the immune system which occur early after a person has a stroke.
- These discoveries suggest that it **may be** possible to treat the causes of post-stroke cognitive decline.
- The **aim** of this study is to improve our understanding of the links between immunity, cognition and changes within the brain caused by a stroke.
- This could help lead to targeted treatments for post-stroke cognitive decline.

Why me?

You have recently had a **stroke**; you are aged over 45 years old and you live in the Greater Manchester area. You may be **eligible** to take part in this study.

Who will conduct the research?

A **specialist team** of clinicians (e.g., Doctors and Nurses) and researchers who investigate stroke and immunology. The team is led by Professor Craig Smith, of Salford Royal NHS Foundation Trust (SRFT). The collaborators in this study are based at The University of Manchester and The University of Stanford in California, USA.

The University of Manchester is the Study Sponsor for all research taking place in the UK.

What would my involvement be?

To attend **up to 6 visits** with our research team over the **next 3 and a half years***.
*If we acquire further funding there could be an opportunity to attend additional appointments, but you do not have to do this.

Transportation

We can arrange, book and pay for your **taxi transport** to and from all the visits or **reimburse you for** your travel and parking costs.

What happens at each visit?

Visit 1- Sign up

When? Up to **4 days** after your stroke (usually **in hospital**).

Where? At Salford Royal Hospital.

How long? Up to **1** hour

What?

- We will record information e.g., your age, sex, stroke details, current medications, the results from recent investigations (including heart trace and brain imaging) and other health issues.
- We may ask you this information directly or find this information in your medical records.
- You may be asked complete a short test (MoCA) to assess your memory and problem-solving skills.

Visit 2- Blood Sampling

When? Up to **4 days** after your stroke. This could be performed during **visit 1**.

Where? At Salford Royal Hospital.

How long? Approximately **5** minutes.

What?

- We will collect a blood sample of up to **50ml** (10 teaspoons). Please see page 7 and 8 for more information about blood sampling.
- If you are discharged before you give this blood sample, we can arrange a taxi to bring you back within 4 days of your stroke for this purpose.

Visit 2b- Brain Imaging Scan

- You **DO NOT** have to do this. This option is only given to **eligible** people who did not have a brain imaging (MRI) scan as an in-patient.
- We will give you more information about this if you are eligible.
- For example, if you have metal implants including a pacemaker, suffer from claustrophobia or have an allergy to the contrast dye, you may not be eligible.

When? Within **30** days of your stroke.

Where? At Salford Royal Hospital or Manchester Clinical Research Facility.

How long? Approximately 30 minutes

What?

- Some people will have an MRI scan when they are admitted to hospital. If this is you, we will look at the results to find out some information.
- If you **do not have** an MRI scan when you are an inpatient and you are eligible you may be invited back to the hospital to have one within 30 **days** of your stroke.
- We will arrange a **convenient** time for your appointment.

Visit 3: Blood Sampling & Cognitive Assessments

When? Approximately **6** months after your Stroke

Where? At Salford Royal Hospital

- We will send you a **letter** about your appointment about **2** weeks before you are due to attend this appointment.
- We will also contact you by **telephone** to confirm that the appointment is convenient for you.
- You may bring a friend or relative with you to your visits.

How long? Up to about **2.5 hours**.

What?

- We will collect a blood sample **50ml** (10 teaspoons).
- You will be asked to complete **several questions** to assess your health, changes to your lifestyle and memory.

- We will also perform a **physical examination**: including blood pressure, walking, coordination, and recovery from stroke.
- We will also ask your **relative/next of kin** to complete a questionnaire about your health. Your relative's consent will be sought prior to completion.

Visit 4: Approximately one year after visit 3 (about 1½ years after your stroke)

Visit 5: Approximately one year after visit 4 (about 2½ years after your stroke)

Visit 6: Approximately one year after visit 5 (about 3½ years after your stroke)

- ✓ These visits will be a **repeat** of the assessments, questions and blood tests performed at Visit 3.
- ✓ The **arrangements** for your appointment such as transportation and reminders, will be the **same** as for Visit 3.

We may invite you to continue to participate in the study after Visit 6 and attend follow-up at yearly intervals. You are under no obligation to agree to this and the researcher will give you more information about this after Visit 6.

Optional Brain Imaging Scans

- If you are eligible, and we obtain **further funding**, you may be invited to have two extra MRI scans.
- You **DO NOT** have to do this to continue being a part of the study.

When? At **Visits 3 & 5** (or on a different day if you prefer).

Where? At Salford Royal Hospital or Manchester Clinical Research Facility

How long? Up to **2.5** hours in addition to Visit 3 and/ or 5.

What? If you agree to undergo MR brain imaging, we will use some of the blood sample taken at Visits **3 & 5** to measure your kidney function as part of our safety check.

Are there any potential benefits to taking part?

- There is **no** promise of direct benefit to **you** if you participate in this study
- You will receive the **usual standard** of care.
- You may find participation interesting as it does offer you some **extra time** with the research team and the opportunity to complete additional assessments.

Are there any potential disadvantages to taking part?

- When you give blood, you **may experience** a small amount of discomfort and bruising from the blood tests. There is also a very small risk of infection at the point of needle insertion.
- Some of the cognitive assessments take time. Some of the physical tests require movement, e.g., walking. This could be tiring. If you become tired or distressed the researcher can **pause or stop the assessment.**

Will I receive compensation for taking part?

- We can provide **free** transport for you (and your relative/friend) to attend your visits, or we can reimburse travel/parking costs.
- If you are **eligible** to participate in the additional MRI scanning, we will offer you **£30** for attending each research MRI scan to compensate you for your time.

None of the researchers on our team receive payment above their salary for your involvement.

If you are still **interested** in being a part of this study, the next sections will provide you with **the finer** details such as how your **data** will be stored.

What happens if I no longer want to participate in the study?

- You are **free** to withdraw from the study at any time without giving a reason.
- If you wish to withdraw at any time, please **let the researcher know** (contact information on page 14).
- Withdrawal from the study will not affect your standard of care.

Can a researcher withdraw me from the study? And why?

Yes, a researcher can withdraw you from the study:

- If you become unwell and are in hospital.
- If it is felt that the assessment will cause **unnecessary distress** due to a significant change in your cognition.

A change in your cognition **does not mean** that you have lost capacity. However, to avoid distress if this situation was to arise, we have included a **clause on the consent form**, seeking your permission to take the final blood sample if capacity is lost.

- If you choose to withdraw from the study, or the lead researcher withdraws you from the study, your clinical care **will not be** affected.
- In the event of withdrawal from the study, we **seek permission** to retain any blood samples and data to the point of withdrawal.
- However, these **can be** destroyed at your, or your consultee's request, provided they have not been anonymised (names and identification removed).

What will happen to the blood that I donate?

- During the consenting process we will ask you to confirm that you are happy for blood samples you give to be treated as a **gift.**
- We will:
    - Use the samples you give and the results of your cognitive assessments to help us understand links between the immune system and cognition.
    - Split your blood up into different parts e.g., plasma, serum, and cells.

- Most of the sample is used to measure **inflammation** in the blood.
- We will also measure how the cells of the immune system **function** (work) after stroke.
- Some of the blood sample from visit 2 will be used to measure **genetic function** (DNA analysis). For example, researchers may look at your genes and compare them to others who have had a stroke. This will hopefully allow them to identify any patterns and or differences.
- All samples for this study will be analysed at Salford Royal NHS Foundation Trust (SRFT) or Manchester Clinical Research Facility.

Where will my blood be stored?

- Your donated bodily fluids will be stored in our approved laboratory before analysis. This is called a **'biobank'**.
- Some of these bodily fluids will be used very **soon** after you have donated them, while the rest may be stored for a **longer** period.
- If you give us permission, we will be able to **store** your samples in our biobank for as long as we need to.
- This could let us:
  - ✓ Use your blood samples, and the data we collect, during your participation in this study, to help us with **future** ethically approved research such as other, related research once this study has ended.
  - ✓ **Share** samples with other research groups who may have different specialist knowledge and equipment. Some of these groups may be **outside of Europe**.

- **All** your data will be fully **anonymised**. No-one analysing the blood samples, bodily fluids or looking at the research data will know that it is information about you.

If you **do not** want us to retain your samples and data in the biobank you may opt out by ticking '**No'** on the consent form.

- If you agree now but change your mind later, you may contact the research team and inform them of your decision.

- The **consent form** will also include optional consent for genetic analysis and sharing of samples for use in future ethically approved research. For more information – see page 9.

Data Protection and Confidentiality

What information will you collect about me?

- We will need to collect information that could **identify** you, such as your name, contact details and date of birth. This is called "personal identifiable information".
- If you give us **additional** consent, we may also take and store video recordings (see page 11 section "Video Recordings").

Under what legal basis are you collecting this information?

- We are collecting and storing this personal identifiable information in accordance with **UK data protection law**.
- These state that we must have a **legal basis** (specific reason) for collecting your data.
- For this study, the legal basis for collecting this data is that it is "a public interest task" and "a process necessary for research purposes".

What are my rights in relation to the information you will collect about me?

- You have **several rights** under data protection law. For example, you can request a copy of the information we hold about you
- If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research (https://documents.manchester.ac.uk/display.aspx?DocID=37095 and attached).
- If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to **The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL**.
- You also have a right to complain to the Information Commissioner's Office, Tel 0303 123 1113

Will my participation in the study be confidential and my personal identifiable information be protected?

- In accordance with data protection law, The University of Manchester is the **Data Controller** for this project.
- This means that we are **responsible** for making sure your personal information is secure, confidential and used only in the way you have been told it will be used.
- The study team at SRFT and The University of Manchester will have **access** to your personal information
- This information will be anonymised as soon as possible.
- Your name and any other identifying information will be removed and **replaced** with a random ID number that is unique to you.
- Only the research team at SRFT will have access to the key that links this ID number to your personal information.
- Your consent form will be kept securely for 25 years at SRFT.
- The data will be retained in paper format, including the hand completed assessment forms and questionnaires.

With your consent, your anonymised research data:

1. Will be entered on to a computer database hosted by **Stanford University (USA)**. This will include brain imaging, blood sampling and research assessments.
    a. Stanford University is outside the **European Economic Area (EEA)** which has different data and privacy laws.
    b. The research data will not include any **personal identifiable data** e.g. your name and address.
2. Will remain on the **electronic database** for the duration of the study
3. Will be archived indefinitely in an approved **research biobank** hosted by the University of Manchester once the study ends.
4. Could be used to support additional future research in accordance with the UK Policy Framework for Health and Social Care Research.

5. Will only be used for the purpose of **future research** into **stroke**, **inflammation** and **brain injury**, and cannot be used to contact you regarding any other matter.
6. Will not be used to make decisions about future services available to you.
7. May be provided to researchers running other, ethically approved studies at SRFT, The University of Manchester or at other organisations.

Please note:

- If you do not wish your data to be used in this way, you may **opt-out** at any time.
- It will **not be possible** to remove your data or samples after the link between them and your identity has been broken (fully anonymised).
- Full anonymisation is likely to take place after completion of the final participant assessment and prior to the analysis of samples and data.

Video recordings:

- A small proportion of participants will be asked to give additional consent for us to record their cognitive assessments performed at one or more of Visits 3, 4, 5 and 6.

  - This will help us to ensure that our staff are conducting the cognitive assessments in **a consistent** manner.
  - These videos may also be used **for training purposes** at SFRT.

Consent to video recording is optional and you may still participate in the study without agreeing to this.

The video recordings will:

1. **include** your voice and that of the researcher but they will avoid using your name where possible.
2. **show** your face and arms/hands when completing a seated task or your whole body when completing a walking or balance task.
3. not be **digitally altered i**n any way.

4. only be **accessed** by authorised SRFT research team members at SRFT and/ or collaborating psychologists.

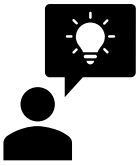
If you do consent to video recording, the researcher will:

1. ensure you are **comfortable** with the recording process and remind you that you are free to stop recording at any time.
2. use secure **recording devices** that are exclusively used for research purposes.
3. **delete** the video file from the recording device immediately after it has been transferred to the secure NHS or University of Manchester server.
4. **password protect** the uploaded file
5. **delete** the recording from the NHS or University of Manchester server by relevant Information Technology (IT) department in accordance with institution policy after the last participant has completed their final follow-up visit.

Potential disclosure:

- If, during the study, we have **concerns** about your safety or the safety of others, we will inform your GP/care team/family member.
- In all research, there is a **small chance** that we may find something that we were not expecting. If this is the case, or if we **identify** anything during your visits that we think requires further follow-up, we may also **contact** your GP.
  Individuals from The University of Manchester and regulatory authorities may need to review the study information for **auditing** and **monitoring** purposes e.g. to make sure the project is being carried out as planned, or in the event of an incident. This may involve looking at identifiable data.

Additional information



- **Information** about data from research MR scanning is on a separate information sheet. You will be given this additional information if you are eligible.
- We will **publish/ present** our research findings in medical journals, as part of PhD theses and at scientific conferences.

- We will also publish a **summary** of our research on our website https://stroke-impact.org/ but this may not be for some time after the end of the study.

- **Information** that could personally identify you **will not** be included in any publication or report.
- Research staff at SRFT will access your electronic patient record (EPR) up to **3 weeks prior** to your scheduled follow-up visits. This will allow them to **send** a letter and **contact** you via telephone to arrange your visit.
- If you **consent** to future contact regarding possible continuation of study participation after visit 6, the research at SRFT will access your electronic patient record (EPR) and write to you with more information at this point. If you do not consent, the research team will not access your EPR for any other purpose after visit 6.
- Giving consent at this time will **not obligate** you in any way and you are free to decline.

Will I be told about what the study finds?

Previous study participants have said that they want to **hear** about the study's progress, **learn** about what the researchers discover and **find out** about similar work happening.

- We would like to send you **information** and **updates** about the study such as newsletters, information about what has been discovered, invitations to events where you could meet other participants, and opportunities to give us feedback.
- At most, you will **receive** approximately 6 pieces of information a year (bi-monthly).
- These updates are **separate** from your appointment notifications.
- The consent form asks for your **permission** for us to add your contact details to a secure database so that we can send you these updates.

Please note:

- You are not obliged to **receive** these updates or **respond** to any of the communications.
- You can '**opt out**' at any time.

- Each **communication** will let you know how you can 'opt out' of further communications or change your preferences.
- We will **store** your contact details on this database for a period of 7 years.
    - We ask for permission for 7 years because the Stroke IMPaCT study will end in 2025, and it will take a couple of years for all of the data to be analysed and published.
- You will be **contacted** by phone and/or letter depending on your preferences three times in the 7th year to ask if you would like to continue to receive updates. If you do not respond, we will automatically remove your details from our database.

Who has reviewed the project?

The study has been reviewed by Wales 3 NHS Research Ethics Committee and has received a favourable opinion.

Who is funding the research project?

Leducq Foundation funds the project as part of their Transatlantic Network of Excellence.

What if I have a complaint?

Minor complaints: If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

You can contact the research team (details at end of the sheet) during working hours or leave a voicemail if out of hours.

Formal Complaints: If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

What do I need to do now?

- Please **consider** whether you wish to take part in the study including discussing with family and friends.
- The research practitioner will arrange to time to re-visit you to answer any questions you may have and to discuss whether you want to take part.
- If you **decide** to take part in the study, we will **arrange** visit 1 immediately.

What if there is a problem or you have any questions?

If you have questions about this research then please contact:
The Acute Research Delivery Team practitioners on:

- Telephone: **0161 206 2188 (7 days week)**
- Email: acute.research@srftn.nhs.uk

If you are interested in further updates regarding this study and our publications, please visit https://strokie-impact.org/ or follow us on Twitter @ImpactStroke

Thank you for taking the time to read this information sheet