

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.

You have not had a stroke, so we would like you to act as a control participant.

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.



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- 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 are aged over 45 years old, live in the Greater Manchester area and have not had a stroke. **We would like you to act as a ‘healthy’ non-stroke control.**
- If you have existing health conditions or recent infection, please discuss this with the research practitioner and they will advise you on whether or not you are eligible to take part.

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 Hospital. 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.

Who is funding the research project?

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

What would my involvement be?

Donating a blood sample of:

- a. approximately 57.5ml (or 12 teaspoons)
- b. on three occasions at a minimum of six monthly intervals over the next five years.

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If you are interested



1. the researcher will conduct a short telephone assessment lasting no longer than 15 minutes to check you are eligible to take part.
2. The researcher will ask about current health conditions and medications and check you have not had any recent infections.
3. you will be invited to attend Salford Royal Hospital at a time convenient to you.
4. The researcher will ask you to sign a consent form



5. The researcher will collect your blood sample
6. The researcher will ask if you are willing to donate further two further blood samples approximately 6 monthly intervals. If you agree, the researcher will retain your contact information (telephone number, email address and postal address).


What will happen to the blood I donate?

The blood sample will be analysed by a different researcher to the one who takes your consent and blood sample.

- 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 Hospital or Manchester Clinical Research Facility.

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Where will my blood be stored?

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- 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 3.
- Please note: it will not be possible to remove your sample/data after they have been fully anonymised

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.

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

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What happens if I do not want to take part or if I change my mind?

- 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 pages 9 and 10).
- Withdrawal from the study will not affect your standard of care.
- 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 request, provided they have not been anonymised (names and identification removed).

What are the possible benefits of taking part?



- There is no promise of direct benefit to you by taking part in the study.
- You will help to increase what is known about cognitive decline after stroke, which may lead to new treatments in the future.

What are the possible disadvantages of 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.
- As with all research, there is a chance that we may find something we were not expecting. If this should occur, the research team would inform the senior doctor who is leading the research study and, with your consent, we will inform you and, if necessary your GP.

Data Protection and Confidentiality

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”.
- Risk factors for stroke (including taking certain medications e.g. statins or blood pressure lower medication).

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 which protect your rights.
- These state that we must have a legal basis (specific reason) for collecting your data.
- For this study, the specific reason 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 laws, The University of Manchester is the **Data Controller** for this study.
- This means that we are **responsible** for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used.

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- The study team at Salford Royal Hospital and The University of Manchester will have access to your personal information so that they can arrange your appointments.
- They will delete this information as soon as it is practical to do so.
- Your name and any other identifying information will not be used on any research records, as it will be removed and replaced with a random ID number that is unique to you.
- Your consent form will be retained for 25 years at Salford Royal Hospital.
- The data will be retained in paper format, including the initial screening questionnaire.

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. data 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 after the study ends.
4. Could be used in order to support additional 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).

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- Full anonymisation is likely to take place after completion of the final participant assessment and prior to the analysis of samples and data.

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

- 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.

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.

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- 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.

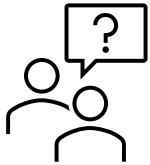
Formal Complaints: If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road,

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 a week)**
- Email: acute.research@nca.nhs.uk

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

Thank you for taking the time to read this information sheet