Participant Information Sheet

Reducing risk of stroke and DementIa In patientS with COVert cERebrovascular disease: a pilot and development study (DISCOVER)

You are invited to take part in the DISCOVER study.

According to our records, you may be eligible for our study because:

- You are 65 years or older.
- You have had a CT or MRI scan done in the last 5 years.
- You have no medical history of a stroke, dementia, Parkinson's disease, multiple sclerosis or metastatic cancer.

- To help you decide whether or not 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 following information carefully.
- Talk to others about the study if you wish.
- Contact us if there is anything that is not clear.
- Let us know if you would like more information.
- Take time to decide whether or not you wish to take part.

If you are interested:

Please read this information sheet.

Do ask any questions you may have.

What is the purpose of the study?

Covert cerebrovascular disease (CCD) doubles the risk of stroke, dementia and death but it is unclear what the best strategy to reduce these risks is.

- Brain scans are usually ordered to check for injury to the brain, such as after a fall, or for people who have recurring headaches. The scans may sometimes reveal other brain changes affecting the blood vessels in the brain, which is also called covert cerebrovascular disease (CCD).

- People with CCD face double the risk of stroke, dementia and death compared to those who do not have CCD. The best way to find out how CCD should be managed to reduce these risks is to perform a type of study called a randomised trial.

- However, such trials need large numbers of people with CCD to get meaningful results, and it is very difficult to find and approach people with CCD.

- Therefore, the aim of this study is to test suitable ways of identifying and approaching people with CCD to take part in research. We will investigate if the methods used are acceptable to patients, and the rates of successful study enrolment and follow-up.

- Learning how best to approach people with CCD will help us and other researchers to design better randomised trials on CCD in the future.

- We used one of two methods to identify you as a suitable participant in this study:
    - using electronic health record data that is collected by NHS Lothian eligible people were identified using an approach involving using natural language processing (NLP) to extract information from patients records as part of an ethically approved research project supported by DataLoch and validated by NHS Lothian clinicians. As part of a separately approved clinical study called DISCOVER, this approach was then applied to identify potential participants. The list was reviewed and letters sent out by the research team who are part of the NHS Lothian care team.
    - contacting clinicians who referred their potentially eligible patients to DISCOVER.

In order to proceed with the study, we need your informed consent to participate. This Participant Information Sheet describes the DISCOVER study and what taking part will involve.

Why have I been invited to take part?

You have been asked to take part in the DISCOVER study because you are 65 years or older and you had a CT or MRI scan in NHS Lothian in the last 5 years. You also have no history of stroke, dementia, Parkinson's disease, multiple sclerosis or metastatic cancer.

Do I have to take part?

- **No, 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 study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

Information and consent

You will be given **as much time as you need** to read the information and consider whether you would like to take part.

If you are interested in taking part in the study, you will be invited to talk to a study doctor or nurse and ask any questions.

If you decide to take part, a member of the research team from your local clinic will ask you to sign a consent form either in-person, remotely from home or online.

Collection of information about you, your diagnosis and your close contacts

At a face-to-face appointment, a doctor or nurse in the research team will ask you some simple questions about your health and collect some information from your medical records about your previous and current health.

They will record information about whether you have had any problems with your speech or memory. They will ask for details about your day-to-day activities.

Your blood pressure will be checked to make sure that it is well controlled.

The doctor or nurse will record your speech and you will have a short test of your thinking skills and memory. The results will be compared to follow-up tests later on in the study.

They will record your contact details for these follow-up tests to monitor your progress and the contact details of a close personal contact you identify who has agreed to provide information about how you get on when you cannot be reached for safety if new information is available, or the study is stopped.

Everyone registered with a GP has their own unique number. This is known as a CHI number in Scotland. We will collect your CHI number and your GP contact details because it helps us to identify you correctly.

Follow-up tests

We will need to follow up with you to check whether or not the CCD is affecting your current brain health. This will **not** involve another face-to-face appointment.

Instead, the research team will repeat the speech recording **over the telephone**.

The memory and thinking skills test will be sent either in **the post** or by **email**, depending on what you prefer, in the form of a questionnaire for you to complete.

- These follow-up tests will be done 3 times - around **3, 6 and 12 months** after your first appointment.

- We will also monitor your health over this time using your electronic health records collected by NHS Lothian.

- Throughout the study, there will be **no** medicines, extra scans, or blood tests involved.

Summary of commitment

Your participation in DISCOVER will involve **1 face-to-face appointment** at the clinic and **up to 3 telephone calls** and **emails/ letters** for **up to 12 months**.

The first appointment at the clinic, when we will ask you for details about your health, test your memory and record your voice, will take approximately **2 hours**.

We will pay for the cost of travelling to your face-to-face appointment, please talk to a member of the study team about this.

The other follow-up tests will be done by phone, post or email. Each telephone call should last no longer than **20 minutes**.

You will be able to phone the study team to ask any questions.

You will be able to withdraw your consent and stop taking part in DISCOVER at any time, and this will not affect your usual care.

What are the possible benefits of taking part?

There are no direct benefits to you from taking part in this study. The results from this study will help us to treat others in the future.

What are the possible disadvantages of taking part?

It might be inconvenient to find time to travel to the clinic for the first appointment, or to complete the follow-up tests.

What if there are any problems?

If you have a concern about any aspect of this study, please refer to the contact details at the end of this document to identify the most appropriate person to answer your question.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal NHS Scotland complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study?

Your decision to take part in DISCOVER is entirely voluntary.
You are free to withdraw at any time and without giving a reason.

- The study doctor may withdraw you from the study early and will discuss the reasons e.g., when you develop a new health problem.
- Your representative may withdraw you from the study early when you develop a new health problem and cannot make decisions for yourself.

Any decision to withdraw will not affect your standard medical care.

- We would like to keep you in the study if you do not want to engage in the follow-up telephone calls and we can collect information about your health from central NHS Lothian records or your GP.

- We would like to continue to follow you to the end of the study if you stop the follow-up tests, and keep collecting data from your health records to help answer our research question.

- If you decide to withdraw from all aspects of the study, please contact your hospital team. We will retain data collected about you before you withdrew.

What happens when the study is finished?

Anonymised information about you will be kept indefinitely so that researchers can look at them again.

This will enable us to address other relevant research questions that we might not have thought of now without having to repeat this research all over again. The University of Edinburgh will archive study information about you for 5 years.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

We will collect your Community Health Index (CHI) number. Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and is personal identifiable information. Your CHI number is being collected to allow us to identify you in your medical records and with your GP. Other personal identifiable information collected will include your:

- Name and initials
- Date of birth
- Sex assigned at birth
- Ethnicity
- Years of education and occupation
- Address, telephone number and email
- GP contact information
- Contact information for a nominated close personal contact whose permission you have obtained - they will not leave NHS Lothian.

Only authorised people will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. **Your data will have a code number assigned instead.**

DISCOVER is run by a team at the University of Edinburgh who will keep all information about you safe and secure.

- Your personal information will be stored securely in a database hosted by the University of Edinburgh for the duration of the study to contact you for follow-up visits. The database will be compliant with the relevant regulations and Sponsor Standard Operating Procedures.

- Only trained and approved members of the study team will be given password-protected access to the study database.

Identifiable data about you will be kept separate from your health information and removed before data are analysed.

We comply with the GDPR and Data Protection Act 2018 and Caldicott principles when sharing or processing their data within the NHS and other organisations involved in the study. The University of Edinburgh/NHS Lothian is the data controller. Hospitals involved in DISCOVER may be required to provide information for official inspections of research conduct made by the sponsor of the study or other regulatory bodies.

Data sharing

De-identified information about you will be kept indefinitely so that researchers can look at them again. Where data are being shared with a third party, there will be an appropriate data sharing agreement between organisations to ensure your information is safe.

- Once we have finished the study, we will keep some of the data so we can check the results.
- Researchers who analyse the data will not be able to identify you and find out your personal information.
- We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS Lothian records/ your hospital/ your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study.

- If this happens, your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh and/or NHS Lothian. Agreeing to be contacted does not oblige you to participate in further studies. You can withdraw from being contacted for the future research.

Where can you find out more about how your information is used?

You can find out more about how we use their information:

- at www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
- by asking one of the study team (see the last page of this sheet)
- by sending an email to dpo@ed.ac.uk (University of Edinburgh Data Protection Officer)

What will happen to the results of the study?

The results of the study will be submitted for publication in professional journals.

We will also make the results available in a format appropriate to the general public on our website, www.clinical-brain-sciences.ed.ac.uk/discover.

The results of DISCOVER study will be publicly accessible on the research registry:

- Clinicaltrials.gov number: NCT06878430

We would be very happy to send you a newsletter twice yearly about the progress and results of the research by post or email, if you wish. When the results of our study are published, we will not include any individual information that identify you.

Who is organising and funding the research?

- The University of Edinburgh and NHS Lothian jointly sponsor the DISCOVER study and take on overall responsibility for this research study.
- The Chief Scientist Office, part of the Health and Wellbeing Directorate of the Scottish Government, funds the conduct of DISCOVER by a grant to the University of Edinburgh.
- DISCOVER is run by the University of Edinburgh.
- Professor William Whiteley is the Chief Investigator in charge of DISCOVER.

Who has reviewed the study?

All research in the NHS Scotland is looked at by an independent group of people, called a Research Ethics Committee.

Research Ethics Committees protect the interests of the participants.

This study has been reviewed and given a favourable opinion by a Research Ethics Committee. All participants are covered by The University of Edinburgh's insurance policy, which needs to be in place before the study starts.

In designing this study, we have taken into account patients' opinions on what's involved in the study. The Patient and Public Involvement (PPI) panel, and other patients/carers with lived experience of stroke, cerebral small vessel disease and vascular dementia, have reviewed and commented upon this participant information sheet.

Who to contact for more information?

You can contact your **local research team** about your participation:

EMERGE Team

Centre for Clinical Brain Sciences, Chancellor's Building

Royal Infirmary of Edinburgh

49 Little France Crescent, Edinburgh EH16 4SB

Telephone: 0131 465 9536

Researcher Contact Details

You can contact the **central research team** if you have any questions:

Dr Fergus Doubal

Reader and Consultant Stroke Physician and Geriatrician

Telephone: 0131 465 9536

Please refer to our website: www.clinical-brain-sciences.ed.ac.uk/discover

Independent Contact Details

You can obtain **independent advice** about this study by contacting:

Dr Neshika Samarasekera

Consultant Neurologist, St Johns Hospital, Livingston

Telephone: 01506 523000

Complaints

The contact for formal complaints is: NHS Lothian Patient Experience Team, Waverley Gate, 2-4 Waterloo Place, Edinburgh. EH1 3EG.

Telephone: 0131 536 3370; Email: feedback@nhslothian.scot.nhs.uk