



National CJD Research & Surveillance Unit
Western General Hospital,
Edinburgh, EH4 2XU

Enhanced CJD surveillance in the older population (Scotland A REC ref:15/SS/0196)
Participant Information Sheet & Consent Form (Participants) version 3, 30/10/2017

Study Principal Investigator: Dr Anna Molesworth, PhD
Telephone: 0131 537 1980
Email: anna.molesworth@ed.ac.uk

THE 65+ DEMENTIA STUDY INFORMATION FOR PATIENTS

We understand that you have been diagnosed with a type of dementia. We would like to invite you to take part in our research study on dementia in people aged 65 and above.

Before you decide, we want you to understand why this research is being done and what it would involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

The 65+ Dementia Study Team

We are doctors, scientists and nurses from University of Edinburgh and NHS Lothian who have a special interest in patients with dementia, including a particular type of dementia due to prion disease. Prion diseases are a very rare group of diseases that affect nerve cells in the brain and spinal cord. Prion disease can exist in different forms, but the most common is Creutzfeldt-Jakob Disease (CJD). We provide doctors with information about prion disease, and advice on how to look after their patients. We also do research into some of the causes of prion disease. This research project may help us to find out what caused your dementia.

If, having read this leaflet, you are interested in the research, then we can arrange a meeting either in the clinic or at your home at a time that is most convenient for you and any family members you wish to be present. The purpose of this visit is to discuss

the study and what is involved. **One of our research team will go through this information leaflet with you and answer any questions you have.**

What is the purpose of this study?

There are about 850,000 people living with dementia in the UK, the majority in people aged 65 year or over. Around 100 people in the UK are diagnosed with prion disease every year, however we think that more might be infected but their illness may not have been recognised, perhaps because the signs and symptoms are similar to different forms of dementia. **This research will use patient assessment, blood samples or mouth swabs, brain scans and samples of brain tissue from people in Lothian when they die, to find if prion disease is being missed and why.**

Why have I been asked to take part?

We understand that this is a difficult time for you. All patients aged 65 and over who have recently had a diagnosis of dementia are being considered. There are many different types of dementia, and in the majority of patients the diagnosis can be made with confidence. However, because the signs and symptoms of dementia vary from patient to patient, we find that some characteristics are less common than others. You are being invited to join this study because you have some of these less common features and studying them may help us understand your type of dementia, why you developed your current illness and if it might be due to prion disease. This could benefit others in the future.

Do I have to take part?

No. It is up to you to decide whether you wish to take part in the research or not. If you do wish to participate, we will ask you to sign a consent form. You are still free to withdraw at any time, 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.

If you lose your capacity to make an informed decision about participation in the study after you have joined, then your previous wishes will be respected and the study will continue under existing consent arrangements. In these situations we will check with your representative that they are happy with these arrangements. We will then ask you to renew your consent when capacity is regained.

What will happen to me if I take part?

There are five parts to the research. You can decide which parts you wish to contribute to.

1. Assessment by the 65+ dementia study team

We would like to ask you some questions about your current illness and your memory and mood, and examine your ability to move. This will take about 1 hour, and will help us better understand your illness and if you have any symptoms or signs that might be due to prion disease. We will also review your medical notes to help investigate what may have caused your illness.

In some instances we may offer you the opportunity to undertake a magnetic resonance imaging (MRI) brain scan at a brain research imaging centre for research purposes, if you have not already had one organised by your doctor as part of your standard patient care. This scan might help identify a cause of your dementia.

MRI is a safe and painless procedure that uses a combination of powerful magnets and radio waves to create detailed pictures of your brain, which are then reviewed by a doctor qualified in medical imaging to help us in our research.

MRI will take approximately 30 minutes to one hour to complete. It does not involve any exposure to x-rays or other forms of radiation, and there is no evidence that the scanning poses any risk to the body. However, because not everyone can have an MRI scan, for example they are not always possible for people who have had certain types of implants fitted, we will check beforehand that it is perfectly safe for you to be scanned.

The research team will be able to explain more about this process when you meet with them, so you will have the opportunity to discuss this and the investigation will not proceed without your agreement.

2. Medical history questionnaire

We would also like to ask you some questions about your past medical history and any family history of dementia, the answers to which will be recorded on a questionnaire form. This will take about 30 minutes. The information you provide,

together with a detailed review of your medical notes, may help us identify possible causes for dementia.

3. Blood sample or mouth (inner cheek) swab

If you agree, we will also ask whether you wish to donate 2ml (just under half a teaspoon) of your blood, so we can study genetic influences on neurological conditions. If a blood sample cannot be obtained, if you agree we will swab the inside of your mouth. This will involve brushing a cotton-tipped swab against the inside of each of your cheeks six times.

We are looking at the prion protein gene and at one part in particular, called the "codon-129 genotype", which helps us to understand the different forms of prion disease. To find out the codon-129 genotype, some of your genetic material (DNA) will be extracted from the blood sample or inner cheek swab.

4. Checking how you get on in the future

We would like to follow your progress on the hospital patient management system and will contact you on a regular basis by telephone in order to assess your illness and answer any questions you may have. How often we call you will vary from person to person according to the nature of your illness, but is likely to be within 1 month of joining the study and every 3 months thereafter. You may also contact us with questions and concerns any time you would like. A follow-up home visit may be suggested, with your agreement, if we feel a further clinical assessment or MRI scan could be helpful.

5. Examination of brain tissue

With all forms of dementia, the only way to be certain as to the exact cause of someone's symptoms is to perform a post-mortem examination. This means that we therefore are inviting you to consider donating samples of your brain to the Edinburgh Brain & Tissue Bank when you die, to assist us in this and future research. More information will be provided in relation to this in a separate information sheet.

Will my taking part in the study be kept confidential?

Yes. There are strict laws which safeguard your privacy and your identity is totally confidential. No identifying details will ever be made public. We have a policy for data

protection, confidentiality and information security and regular training is required for all staff and research partners.

How will information about me be handled?

The study is run by a team from the National CJD Research and Surveillance Unit (NCJDRSU) working with colleagues from the University of Edinburgh and NHS Lothian. Information is processed by this team with the help of medical statistics, computing and administrative staff, and all staff have a professional duty of confidentiality. All information is held in secure, password-protected databases at NCJDRSU, the Brain Research Imaging Centre and Edinburgh Brain & Tissue Bank; paper records are kept locked up when not in use. Access to your personal information is for the purpose of this study only and is restricted to authorised personnel on a need-to-know basis.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsors (University of Edinburgh and NHS Lothian) to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsors are responsible for overall management of the study and providing insurance and indemnity.

What happens to the results of my assessment and brain scan?

You would not normally be told the outcome of the research investigations. However, for any person having a MRI scan there is the possibility that an abnormality may be found that was previously unknown about that could have an impact on your care. If this was to occur or if, as a result of the clinical assessment or MRI, we encounter evidence of prion disease, then we would discuss the findings with the local medical consultant in charge of your care and your GP, and either ourselves or your doctor will then discuss these findings with you.

Can you tell me more about the codon-129 genotype?

Your genes can affect your health in different ways. Firstly, an abnormality in a gene may directly cause illness or secondly, a normal variation in a gene, such as the codon-129 genotype, may make illness more or less likely when in combination with other factors.

We all have a codon-129 genotype. It does not cause prion disease, but in combination with other risk factors, may make prion disease more likely. The codon-129 genotype also affects the different types of illness in people who already have

prion disease. To find out the codon-129 genotype, some of your genetic material (DNA) will be extracted from the blood sample or mouth swab and tested in our laboratory. Any remaining blood and genetic material will then be disposed of after the study has ended. Alternatively, if you agree, rather than disposing of the genetic material it can be stored by us for use in future genetic research into prion disease and other neurological conditions.

What do you mean by future genetic research?

Current knowledge of the genetics of neurological conditions is limited but as understanding increases there may be new studies that we can undertake to have a better understanding of these disorders. These new studies may, for example, involve genetic testing for individual genes or looking at all your genes - a process called whole genome scanning. In turn this could help prevent disease, develop diagnostic tests or lead to new and better treatments.

What happens to the samples I have donated for future research?

The genetic material and samples of brain tissue will be retained indefinitely in a secure laboratory and used in an anonymised form for future medical research to benefit human health. They will then be disposed of lawfully when they have served this purpose. This may mean that we may work with other national and international research centres, sometimes including commercial organisations. We cannot predict every type of project but all research that we support is ethically approved. The samples are donated to researchers freely and neither you nor your relatives would benefit financially from any developments of this kind, even if the research results in the development of new treatments or diagnostic tests.

We may share with researchers information we have collected as part of the research, but no information that could identify you personally will be made available to research staff and your samples will be coded so that researchers who analyse these samples will not know who you are. This also means that you will not be told your results.

What if we think you may have prion disease?

It is very unlikely that you have prion disease, however, if prion disease is suspected then, with your clinician's approval, you would be offered an immediate onward referral to the National CJD Research & Surveillance Unit (NCJDRSU) for further assessment.

What are the possible benefits of taking part?

You may not get a direct benefit from taking part in this study, however if we suspect prion disease there may be the possibility of you and your family receiving additional care and emotional and practical support through the National CJD Care Package.

By participating in this research you will be helping us better understand the symptoms of dementia, and the reasons why people may develop less common symptoms and how a diagnosis of prion disease can be missed. This may help us to learn how we can improve the detection of prion disease in those aged 65 and over. This has potential benefits for the diagnosis of other NHS patients, their management and care, and in protecting public health. This could in the future inform routine practice in Lothian and elsewhere.

What are the possible disadvantages and risks of taking part?

Our initial visit will take between two to three hours – this may seem a long time but it will enable us to discuss the study fully with you, and for you to ask any questions you may have. This also allows time for the assessment and review however this can be completed on a separate visit should you wish. The process of taking of blood may be a little uncomfortable or leave some bruising. Some patients may find the MRI scanning process claustrophobic – but the radiology staff who will be running the scan will be watching out for this and if this happens to you, the scan would not have to continue.

We will do our best to deal with any issues that worry you. You will also be given our contact details so you can speak to us at any point in the study if you have concerns.

What happens when the study is finished?

The study will run until March 2020. Samples will be retained until the end of the study, after which arrangements will be made for the disposal of any material not destined for long-term storage. Tissue samples that are suspected to be CJD or any other prionopathy will routinely be retained in the CJD Brain and Tissue Bank (part of the Edinburgh Brain Bank).

Information about you will be retained for a minimum of 5 years past completion of the last date of testing of samples for the final participant, and then it's retention will be reviewed with a view to permanent disposal or long-term archiving for future research, audit or as part of your medical record.

Will my doctors be informed about my participation?

Yes. We will contact your GP and the consultant in charge of your care to let them know, as a professional courtesy, that you have agreed to take part in this study and to request to see your medical notes. We will also discuss the results of our investigations with them if this is relevant to your treatment and care.

Can I agree now and change my mind later?

Yes. It is possible to withdraw from any or all parts of the study if you change your mind later on. The information we hold about you can be deleted to the minimum required for audit purposes and where relevant to your medical record, and will not be used in research. You can also withdraw permission for any samples to be tested up until the time they are tested and your sample will be destroyed.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to a member of the 65+ dementia study research team who will do their best to answer your questions. If you wish to make a formal complaint, please contact the NHS Lothian Patient Experience Team by calling 0131 536 3370, or emailing feedback@nhslothian.scot.nhs.uk.

What will happen to the results of the study?

The results of the study will be written up for publication as journal articles and presented at national conferences and worldwide. We will also report our findings to the funding bodies, relevant expert panels and other stakeholders. Summary information will also be available through information published on the NCJDRSU website and we can send this to you directly if you wish. You will not be identifiable in any reports or published results.

Who is overseeing the research?

This study is lead by the NCJDRSU with oversight from an external steering committee and is co-sponsored by the University of Edinburgh and NHS Lothian. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC). A favourable ethical opinion has been obtained from Scotland A REC.

Thank you for taking the time to read this information leaflet.

If you would like further information please contact one of the study team:

Mrs Gemma Logan (Research Nurse)
Professor Richard Knight (Consultant Neurologist)
Dr Anna Molesworth (Principal Investigator)

National CJD Research & Surveillance Unit,
University of Edinburgh
Centre for Clinical Brain Sciences,
Western General Hospital,
Crewe Road,
Edinburgh
EH4 2XU

Telephone: 0131 537 1980
Email: gemma.logan2@nhs.net

Independent advice about the study is available from:

Mrs Chris Lerpiniere (Research Nurse)
Centre for Clinical Brain Sciences
Chancellors Building
49 Little France Crescent
Edinburgh
EH16 4SB

Telephone: 07872 416010
Email: chris.lerpiniere@nhslothian.scot.nhs.uk

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