



**Belfast Health and
Social Care Trust**

Participant Information Sheet

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Lead Researcher: Dr Emma Louise Cunningham

Centre Number: Belfast Trust/Queen's University Belfast

Study Number: Trust R&D Ref: 09069PP-OPMS **REC Ref:** 10/NIR01/5

IRAS ID: 40972

Title of Project: Predicting the risk of postoperative delirium: Use of neuropsychology, serum and CSF biomarkers and genetics to predict risk of postoperative delirium – follow up of study participants

Invitation

When you were in hospital having your hip or knee replaced between 2012 and 2014 you very kindly took part in a research study entitled “Predicting the risk of postoperative delirium: Use of neuropsychology, serum and CSF biomarkers and genetics to predict risk of post-operative delirium”.

We would like to invite you to continue to be involved in the study. This would be entirely up to you. Before you decide, we would like you to understand why this research is being done and how you would be involved. Please feel free to talk to others about the study if you wish.

The first part of this Participant Information Sheet tells you the purpose of the study and what will happen if you take part. Then, we give you more detailed information about the study.

Our team would be delighted to talk to you about this research and any questions you might have. Please contact us by telephone, post or email using the contact details on the last page if you have any questions.

Why are we doing this research?

It is common for people to develop temporary problems with their memory or thinking, called delirium or subsyndromal delirium, after surgery (from here on we will refer to these problems as delirium). Our study was initially designed to help us understand why some people develop delirium and some people do not.

Following on from this we now want to try and find out more about what happens in the longer term to patients who have delirium after surgery.

This research will help doctors and nurses to advise future patients who have delirium after surgery what might happen to their memory in the following years. It will also hopefully help us to better treat patients who get delirium after surgery.

Why am I being invited?

Between 2012 and 2014 you were one of 315 people having hip and knee replacements in Musgrave Park Hospital who took part in our study.

A doctor (either Dr Tim Mawhinney or Dr Emma Cunningham) spoke to you before your operation and did some memory and concentration tests with you. They came to see you in hospital in the days after the operation and did some more short tests with you.

We are now inviting everyone to continue their involvement in the study with a phone call and then, if they wish, a study visit which can be to their own home.

Most people in the study did not have delirium after their surgery but it is important that we follow up as many people as possible to be as sure as we can of our results. We are inviting **all** people who participated in the original study for follow-up. Being invited does **not** mean you had delirium or any problems with your memory or thinking after surgery, nor that you should expect any.

Further information about this study can be found at www.qub.ac.uk/xxx (*website to be confirmed, will contain information approved during this substantial amendment process*).

What does continuing with the study involve?

If you continue with the study you will have a single phone call with our research team and then an optional, single, one-off, study visit which can be in your own home.

Telephone Call

A doctor or nurse from our team will arrange a date and time to telephone you. They will speak to you for about 15 minutes and ask you about your general health and how easy or difficult you find day to day activities. If you live with someone we will ask them how they think your memory is.

Study Visit

Once the current covid-19 restrictions are lifted you will be invited to have a one-off study visit with a doctor or nurse. This will last up to two hours. You will repeat the memory and thinking tests you did at the time of your surgery several years ago. The researcher will take one sample of your blood. Your companion will also be asked a few questions about your memory (this can be in person or over the phone if they are not present).

The study visit can be in your own home – a research doctor or nurse will visit you – or in the university/hospital (Northern Ireland Clinical Research Facility in Belfast City Hospital or Musgrave Park Hospital or the Centre for Public Health in Queen's University (need to edit depending on chosen site)). You can decide whether you would like it to be in your home or at the university/hospital (*site TBC*).

(The following is to comply with social distancing if required) You will have a telephone call with a researcher before the study visit who will explain things to you. They will also ask if you or your intended companion have any symptoms of covid-

19. If you or your companion have any symptoms of covid-19 we will rearrange the appointment.

If you or your companion develop covid-19 symptoms on the day of your appointment do not attend – we will rearrange your appointment. You, and your companion if you bring one, will telephone us and wait in the car once you arrive in the car park. The researcher will come and meet you and bring you into the clinic via a side entrance where available. You will wash your hands and be given a surgical mask. After the appointment you will be shown how to remove your mask safely and will wash your hands again.

Alternatively, we can visit you in your own home. You will have a telephone call with a researcher beforehand who will explain things to you. They will also ask if you or your companion have any symptoms of covid-19. If you or your companion have any symptoms of covid-19 we will rearrange the appointment. Researchers will not visit if they have any symptoms of covid-19. The researcher will wear a clean uniform and a surgical mask, gloves and an apron. They will clean their hands with alcohol before they enter your home. All paper and blood sampling equipment they bring into your home will have been cleaned and be in a premade pack that has been made up for at least 7 days to prevent and carriage of covid-19 into your home.

What if I care for someone who needs ongoing supervision or help?

If you care for someone we can ensure two researchers are with you for the study visit if you like. One to sit with the person you care for and one to go through the study visit with you.

What if I have dementia or other health problems that mean I might prefer not to do the study visit?

We can discuss this during the telephone call and if you decide then you would prefer not to have the study visit that is ok. We want to give as many people as possible the opportunity to take part in this follow-up study so please let us know if you have any questions or suggestions about how we can make the telephone call and study visit easier for you.

What if I do not have a companion or family member for you to ask about my memory or would prefer you didn't talk to them?

That is fine. We will only speak to your companion on the telephone and during the study visit if you are happy that we do so.

What are the potential disadvantages and risks of taking part?

There is no treatment or change to treatment involved in this study therefore the risks and disadvantages are minimal. Two potential disadvantages are the time it will take and the discomfort of having a blood sample. The phone call will take around 15 minutes of your time. The study visit will take up to two hours.

What are the possible benefits of taking part?

By taking part in this follow up visit you will help us understand what we should tell people who have delirium after surgery and what they can expect to happen to their memory or thinking in the years after their surgery.

Thousands of people locally and millions of people around the world have surgery every year. Many of these people will develop delirium and at the minute we do not know what to tell them to expect from their memory and thinking afterwards.

Because you were in the study between 2012 and 2014 we can compare your memory and concentration tests between then and now. This is a rare opportunity to collect this special information for a large number of people.

Do I have to take part?

Your ongoing participation in the study is entirely voluntary. If you choose not to continue with the study your usual care will not be affected in any way. You can withdraw from the study at any time.

Please take time to consider whether you are willing to continue participation in this study. Talk to your family and friends if you wish. You can share any of this written information with others. Others can contact us to ask for more information about the study on your behalf if you wish.

What if there is a problem?

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 (*contact details TBC* including Dr Emma Cunningham, Clinical Lecturer and Consultant Geriatrician, Centre for Public Health, Queen's University Belfast, telephone 02890978971, email emma.cunningham@qub.ac.uk; emmaz.cunningham@belfasttrust.hscni.net).

You can also speak to the Research Governance Managers in the Belfast Trust or Queen's University Belfast. If you are unhappy and wish to complain formally, you can contact the Complaints Officer at Complaints Department, BHSC, Musgrave Park Hospital, Belfast, BT9 7JB, by telephone on 02895048000, or by email at complaints@belfasttrust.hscni.net.

Will my taking part in the study be kept confidential?

Yes. We will keep all the information that we collect during the course of the research strictly confidential. The information will be stored and used securely according to the standard procedures of Queen's University of Belfast. We may share our research data with other researchers where it means we can combine our knowledge to gain more useful results. Any and all data shared will be anonymous.

Involvement of your General Practitioner (GP)

If you permit us, we will let your GP know that you are taking part in our study. Information held and maintained by the National Health Service and Health and Social Care Trusts, including your General Practitioner, may be used to help contact you or provide information about your health.

What will happen to any samples I give?

We will take a single blood sample during the study visit. We will store the samples securely in the Queen's University Laboratories. Your details will not be identifiable to anybody else. We will keep your samples for possible use in other studies on delirium in the future. We have a licence from a government agency that shows we keep samples in a safe and secure way. We may share your samples with other universities and health care institutions that have expertise in analysing them. Any such practice will be subject to usual legal procedures. Your personal details, for example, name, date of birth or address will not be on the samples and will never be shared with anyone else.

What will happen to the results of the research study?

We plan to publish the results of this research in peer reviewed scientific journals and to present the findings at local and international conferences as appropriate. This lets other doctors know what we have found. They can then decide if our results are useful and could help people with delirium after surgery around the world. We will also inform local interested patient groups about the overall results of the study. All our results come from us combining participants' information. We will always keep your individual information confidential. No results will ever identify participants.

Who is funding the research?

This study is being funded by Alzheimer's Research UK. The researchers are not being paid for including you in the study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by Office for Research Ethics Committees in Northern Ireland.

Further information and contact details

Information about research in general can be found at www.invo.org.uk. Further information about this study is available at www.qub.ac.uk/xxx (to be confirmed).

If you have any questions or would like further information about this research study you can contact the Primary Joint Unit on 02895047125 and/or the research team on *contact details TBC* will include Dr Cunningham, Centre for Public Health, Queen's University Belfast, telephone 02890978971, *postal address and email*.

If you would like to talk to another doctor who is not involved in this research study about whether you should take part, you can contact *contact TBC*.

You can also speak to the Research Governance Managers in the Belfast Trust or Queen's University Belfast.

This information sheet is your copy to keep. We will give you a copy of the consent form as well.

Thank you.