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REGAINING CAPACITY PARTICIPANT INFORMATION SHEET
The National Young Stroke Study (NYSS)

We would like to invite you to continue to take part in our research study.

While you were unwell in hospital and not able to make a decision about taking part in our study, a consultee (a relative or friend who knows you well or a clinician looking after you) gave advice that they thought you would not object to it. Now that you are well again, we want to ask you to decide whether you are happy to take part.

Summary of key facts

This is a study involving completing a questionnaire through an interview with the local study team. The questionnaire takes approximately 30 minutes and involves questions about your past medical history, life style related factors and family history. After the initial study assessment, there will be no additional visit or follow-up with direct contact with the study team. We will obtain follow-up information about any of your medical conditions through centralised record linkage for up to 30 years. We are hoping to recruit all patients under the age of 55 years who have had an acute stroke in order to understand key risk factors for strokes at younger ages.

What is the purpose of the study?

We have seen a doubling in the number of new stroke cases in adults under the age of 55 years in the last 10 years in the UK and in other high-income countries. However, the reasons for this increase remain unclear. The purpose of the study is to find out how traditional stroke risk factors that are more common at older ages, such as high blood pressure, diabetes, high cholesterol level, smoking and obesity, might contribute to the occurrence of stroke at younger ages. We are also hoping to find out if emerging stroke risk factors also play a role in the rising number of young stroke cases, such as long working hours, stress and mental health conditions.

Why have I been invited?

You have been invited because you are under the age of 55 years and have had a stroke diagnosed by one of the NHS hospitals in England that are collaborating in the study.

We are intending to involve all patients who have had a stroke under the age of 55 years nationally over the next 2 years which will be approximately 2000 in total.

Do I have to take part?

No. You do not have to take part in the study. It is your choice whether to do so or not. If you decide not to continue, this will not affect your normal clinical care. If you decide you do want to continue taking part at first and then change your mind, you can stop at any time without having to give a reason. If you

decide that you want to withdraw from what has already been done, please refer to the section on withdrawal on page **3 so we can handle data already collected according to you wishes.**

What will happen to me if I decide to continue to take part?

If you decide to continue to take part, you will be asked to sign a consent form. Depending on what point you are now at in the study (the research team will explain what has already been completed), a researcher will ask you some questions about your past medical history, life-style related factors, family history, birth history and other stroke risk factors. The research team will also ask you as well as collect relevant information from the medical notes about the stroke episode you suffered from. The interview can be done face-to-face whilst you are still at the hospital or by phone after you are discharged. It will take approximately 30 minutes to complete.

In addition, we will also intend to obtain follow-up information about your health through your medical notes or data gained from central NHS health records (such as NHS England/NHS Central Register) for 30 years after the stroke. There is no other study procedure involved.

What should I consider?

This is an observational study and taking part in the study will not affect your current or future care. No new drugs or other treatments will be tested. Involvement in other research studies will not affect your participation in the current study.

Are there any possible disadvantages or risks from taking part?

The study involves a questionnaire over the phone that will take approximately 30 minutes to complete. Most of the questions are about your past medical history, family history and life-style related factors. We will also ask about recent stress and your past mental health conditions, which might cause some distress. If any question triggered any unpleasant or stressful memory, we would immediately pause and we will also skip those questions should you wish.

What are the possible benefits of taking part?

We hope the information we get from this study may help us to understand why stroke is increasing at younger ages and eventually help to inform better preventative measures. We will publish updated and summarised study results on the study website (https://www.ndcn.ox.ac.uk/research/xx <study webpage>).

Will my taking part in the study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential with all paper files stored in access controlled rooms and all electronic data on encrypted databases held on a secure server managed by the University of Oxford. Where possible, all stored data has assigned a study code that is used instead of a name or other direct identifier. Any information about you that leaves the hospital/GP surgery will have your identifiable data removed so that you cannot be recognised from it. We also intend to use NHS England to check your contact details or health status in future.

Only authorised research staff working with this study can have access to your data, although responsible members of the University of Oxford and the relevant NHS Trust(s) may be given access to

data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

Your help is greatly appreciated but we will not be able to offer reimbursement.

What will happen to my data?

UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom, is the sponsor for this study and is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records, NHS England and other central NHS registries in order to undertake this study and will use the minimum personally identifiable information possible. We will keep identifiable information about you for 30 years after the study recruitment has finished whilst administrative follow-up is ongoing. We will store any research documents with personal information, such as consent forms securely at the University of Oxford for 10 years after the end of the study as part of the research record

The local study team may use your name, NHS number, home address, and contact details, to contact you about the research study but only your name, date of birth and NHS number will be entered and kept on the central study database. The local study team will keep identifiable information about you including the original copy of the consent form for 12 months after the study has finished.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting the Wolfson Centre for Prevention of Stroke and Dementia on 01865-231601 or at our website https://www.ndcn.ox.ac.uk/research/national-young-stroke-study. Further details are also included in the Privacy Notice which is in the appendix of this information sheet.

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

Your participation is voluntary and you can withdraw at any time, without giving any reason by contacting the study team: Email *nyss@ouh.nhs.uk* or telephone 01865 231601 or write to us at the address above. Withdrawal will not affect the care you receive from the NHS.

If you withdraw from the study, unless you state otherwise, any data collected up to your withdrawal will be anonymised and used for research as detailed in this participant information sheet. You will not be identified by those data.

What will happen to the results of this study?

It is likely that the results of this study will be published in medical journals after completion of the research but you will not be identified in any report or publication. We will also send newsletters with any key update and results of the study to you.

What if we find something unexpected?

We do not expect to find anything unexpected as the study only involves information collection. However, in the unlikely event of seeing any new information from the questionnaire being clinically significant, the NYSS research staff doing the interview will discuss the implications with you, seek your approval and report to the clinical team you are under and arrange for further investigations as necessary.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you have a concern about any aspect of this study, please speak with the central study team in Oxford on 01865-611277 or on email: linxin.li@ndcn.ox.ac.uk. They will do their best to answer your questions.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Linxin Li, phone number: 01865-611277, email: linxin.li@ndcn.ox.ac.uk, or you may contact the University of Oxford Research Governance, Ethics and Assurance team (RGEA) office on 01865 616480, or the head of RGEA , email rgea.complaints@admin.ox.ac.uk

How have patients and the public been involved in this study?

The Wolfson Centre for Prevention of Stroke and Dementia has an active Patient and Public Involvement (PPI) group which has helped to review this study information sheet. They have also offered valuable advice on how we present and address some more sensitive questions (such as those about stress and mental health conditions) during the completion of the questionnaire.

Who is organising and funding the study?

This research is being organised by Dr Li at the Wolfson Centre for Prevention of Stroke and Dementia, University of Oxford. The study is funded through the NIHR Advanced Fellowship Dr Li has secured. Your doctor will not be paid for including you in this 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 participants' interests. This study has been reviewed and given favourable opinion by the North West - Greater Manchester South Research Ethics Committee.

Further information and contact details:

If you would like any further information, please ask the researcher who is discussing this information sheet with you or by contact the Thames Valley Young Stroke Study office on 01865-231601.

Thank you for considering taking part.