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CONSULTEE INFORMATION SHEET
The National Young Stroke Study (NYSS)

We'd like to invite your relative/friend/partner/patient to take part in our research study. Based on advice from the clinical team, your relative/friend/partner/patient is currently unable to decide for himself/herself whether to participate in this research. To help decide if he/she should join the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings. Before you decide, it is important that you understand why the research is being done and what it would involve for your relative/friend/partner/patient. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

Summary of key facts

This is a study involving collection of details of the stroke, the past medical history, and other risk factors for stroke of your relative/friend/partner/patient. 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 medical conditions of your relative/friend/partner/patient 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 has your relative/friend/partner/patient been invited?

They have been invited because they 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 they have to take part?

No. Participating in the study is entirely voluntary. If you believe your relative/friend/partner/patient will not have objection to taking part, you will be asked to sign a consultee declaration form. You will be given a copy of this information sheet and signed consultee declaration form to keep. If you provide advice about your relative/friend/partner/patient taking part you are still free to withdraw them at any time and without giving a reason. Advice that they would not want to take part, or to withdraw at any time, will not affect the standard clinical care they receive.

What will happen to them if they take part?

The research team will collect their past medical history, life-style related factors, family history and other risk factors for stroke from their medical notes. They will also record information about their stroke episode. In addition, the research team will also intend to obtain follow-up information up to 30 years about their health through their medical notes or data gained from central NHS health records (such as NHS England/NHS Central Register). They will not be contacted again.

What will happen if your relative/friend/partner/patient regained capacity during the study?

In circumstances where your relative/friend/partner/patient recovers capacity sufficiently to be able to give informed written consent during their time in hospital or during any early supported discharge where they are still in regular contact with the local stroke team, they will be provided with the 'Regaining Capacity Participant Information Sheet' and will be informed about research activities that took place while they lacked capacity. If they decided to consent, they will then complete the questionnaires with the research team on factors that we were not able to get from their medical notes. If they decide at this point to decline consent, they will be asked whether the data already collected can be kept in anonymised form, or whether it should be removed from the study.

What should I consider for my relative/friend/partner/patient?

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

Are there any possible disadvantages or risks from taking part?

Only information gathering from medical notes will be involved and there is no foreseeable risk.

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 their taking part in the study be kept confidential?

All information collected about them 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 the participant that leaves the hospital/GP surgery will have their identifiable data removed so that they cannot be recognised from it. We also intend to use NHS England to check their health status in future.

Only authorised research staff working with this study can have access to their 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 your relative/friend/partner/patient be reimbursed for taking part?

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

What will happen to their data?

UK Data protection regulation requires that we state the legal basis for processing information about the participant. 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, is the data controller, and is responsible for looking after their information and using it properly.

We will be using information from them and their 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 them 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 consultee declarations 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 their name, NHS number, home address, and your contact details, to contact you about the research study in order to get your advice, but only their 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 the participant including the original copy of the consultee declaration form for as long as the medical records are retained.

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

You can find out more about how we use this 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 believe they don't want to carry on with the study?

Their participation is voluntary and you can withdraw them 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 they receive from the NHS.

If you withdraw them from the study, unless you state otherwise, any data collected up to their withdrawal will be anonymised and used for research as detailed in this consultee information sheet. They 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 your relative/friend/partner/patient who is participating in the study will not be identified in any report or publication.

What if we find something unexpected?

We do not expect to find anything unexpected as the study only involves information collection from the participant's medical notes which are already known to the clinical team managing them.

What if there is a problem?

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

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

If you or the participant wish to complain about any aspect of the way in which the participant have been approached or treated, or how their information is handled during the course of this study, please 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. The doctor of the participant will not be paid for including them 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.