**PARTICIPANT INFORMATION SHEET**

**Oxford Chronic Stroke Study** *Long-term psychological consequences of stroke: prevalence, trajectories and impact*

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take the 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.*

**What is the purpose of the study?**

This project aims to determine the nature of cognitive problems (how people remember and process information) at more than two years after stroke. We hope to gain understanding in how memory and thinking problems of varying severities impact on people’s daily life and recognize which information is important for identifying individuals who are at risk of developing declining cognition, such as dementia. In general, this study aims to improve how we look for and care for emotional, thinking and memory problems in long-term stroke survivors by assisting clinical teams, policy-makers, and future treatment research studies.

**Why have I been invited?**

You have been invited because you have had a stroke, and have already been assessed by our research team right after the stroke and 6-months later. We would like to examine any emotional, memory or thinking problems you may be experiencing long after your stroke. We aim to include 200 participants in this research, as well as up to 200 carers.

**Do I have to take part?**

No - it is entirely up to you whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and are not required to provide a reason for doing so. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of any future care that you receive.

**What will happen to me if I take part?**

You will be contacted and asked to participate in in paper-based assessments that will be carried out remotely over the telephone – voice call or video call, your choice. Assessment packs will be mailed to you well in advance, and the researcher will go through them with you during the pre-arranged telephone call appointment(s). You may be voice-recorded in order to facilitate scoring of certain tasks (for example naming and reading tasks, where more detailed scoring can take place if there are some problems with speech)

The first assessment period consists of a series of relatively short assessments that will be completed over **multiple telephone call** **appointments, each lasting approximately 30 – 45 minutes (1 hour maximum)** and *up to a maximum of 4 hours in total.*  There will be time to take breaks and make sure you are not becoming fatigued.

With the further easing of COVID-19 restrictions in the future, it is hoped that the second assessment period, which will occur one year later, could be completed via **two face-to-face** **follow-up visits,** no more than two weeks apart. The visits will be at your home or our research centre (whichever you prefer) with one of our trained researchers.

However, if one year later, the risk of COVID-19 remains high with government restrictions in place, the second assessment period will be carried out remotely over the telephone, in the same way as the first assessment period.

The study will involve you going through a series of short questionnaires and tests that will assess how well you manage your functional abilities in activities of daily living, how the stroke had an impacted your quality of life, as well as your language, memory, sight and problem-solving abilities. All of the questionnaires and assessments are relatively short, completed in a matter of minutes with opportunities for breaks at any time, if necessary.

Some of the tests will be paper-based, while others will be completed entirely over the phone. In some parts of the phone assessment, you may be voice-recorded in order to facilitate scoring of certain tasks (for example naming and reading tasks, where more detailed scoring can take place if there are some problems with speech).

In addition to phone assessments, we will look at your medical records to check information relevant to the study. With your permission, we would also like to look at any brain scan you have had taken as part of routine care. All data collected will be de-identified, which means that anything that could identify you personally will be removed, and your name will be kept separately from any research data.

We will also ask you if you are happy to wear an activity monitor for a maximum of 1 week, which is completely optional. The sensor is the size of a watch and will be worn on the wrist to monitor physical activity. It records activity level continuously, such as movement/how many steps you take over a 7-day period, but it doesn’t track the type of activity. It records the amount of hours you sleep indirectly in the absence of movement for longer periods at night. The sensor does not record your location (No GPS data). You will be asked to remove the monitor after 7 days and return it via a prepaid envelope.. You will not have to charge the device within that time period.



We ask you to do nothing different from your daily life activity. Your normal daily routine should remain unaffected when volunteering for this study. The collected data is initially stored on the device, and will be extracted by us once you give the tracker back to the research team. Your data can be shared with you and your care providers (GP, carers etc), if you are interested and agree. The responsibility for the devices lies with the research team. If you discover any problems or discomfort with the device, you can take it off without any worry. We will pick it up on our next visit.

**What are the risks or disadvantages of taking part?**

There are no evident risks involved in carrying out the tests. Since the tests are simple paper-based assessments carried out remotely over the telephone, there is nothing invasive involved and therefore this research is low risk. If you do experience any anxiety or distress during the assessment, you may stop at any time and/or pause to ask questions.

**What are we doing to reduce the risk of spreading COVID-19?**

The study complies with the most updated government policies in respect of COVID-19, and the following mitigations are put in place to ensure the health and safety of participants and researchers.

**Sending of questionnaires and assessment mailing packs**

Public Health England (PHE) has advised that people receiving parcels are not put at any additional risk of contracting the virus. According to PHE, under most circumstances, the amount of infectious virus on any contaminated surfaces is likely to have decreased significantly by 24 hours, and even more so by 48 hours.

How long any of the virus survives will depend on a number of factors, for example:

• What surface the virus is on

• Whether it is exposed to sunlight

• Differences in temperature and humidity

• Exposure to cleaning products

Receiving questionnaires and assessment packs through the post would not put you at risk. However, as an addition precaution, we would suggest that you leave the mail in a sunny place and not to open it until the researcher calls or at least 2 days from receiving it.

**Wrist monitor**

Each wrist monitor will be thoroughly washed and disinfected before and after each use. Disinfectant disposable wipes will also be included in each mailing packs and you will be encouraged to disinfect the wrist accelerometer before wearing it.

**What are the possible benefits of taking part?**

We cannot promise the study will help you in any specific way, but it will hopefully aid in identifying lasting problems you may be experiencing as a result of your stroke. This may then be helpful in guiding the course of treatment and monitoring you may receive. It could also help to improve the diagnosis and management of future chronic stroke patients.

**What will happen to the results of the research study?**

The results from these tests will be used to analyse cognition over a long period, extending from shortly following stroke to years after. This will allow for the characterization of any patterns of recovery or decline and the identification of any potential risk factors for long-term decline. The data will be reported in scientific papers with the aim of helping clinical teams. Additionally, de-identified results of the study will be summarized and communicated to all participants at the end of the study through a report written for them, which will be sent to each participant in a hardcopy through the post. Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis).

**What will happen if I do not want to carry on with the research study?**

You are free to withdraw from the study at any time without giving a reason. This will not affect your future medical care or ability to participate in further studies. You may request that any information collected about you up until that point will be destroyed and not used in analysis. Unless you request this, your data up until the point of withdrawal will be used.

If you want to withdraw from the study, there will be a tiered withdrawal option presented:

* Withdraw from active follow-up or subsequent visits +/- further communication
* Withdraw consent or permit data obtained up until the point of withdrawal to be used
* Withdraw or allow research team to continue to access your medical records/any relevant hospital data that is recorded as part of routine standard of care; i.e. brain scans, disease progression, etc.

**What if there is a problem?**

* The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that your relative suffers any harm as a direct consequence of their participation in this study
* If you wish to complain about any aspect of the way in which you or your relative/friend have been approached or treated during the course of this study, you should contact Prof Nele Demeyere (Chief Investigator) ([nele.demeyere@psy.ox.ac.uk](mailto:nele.demeyere@psy.ox.ac.uk) – 01865 271340) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email [ctrg@admin.ox.ac.uk](mailto:ctrg@admin.ox.ac.uk)
* The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care your relative receives as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact 01865 221473 or visit <http://www.ouh.nhs.uk/patient-guide/pals.aspx>.

**Will my data be kept confidential?**

All information that is collected about you during the course of the research will be kept strictly confidential; participants will be identified by a unique study code. Please be aware that, in the unlikely event of the disclosure of information that might mean the participant or others may be at risk of harm, confidentiality may be broken and such information disclosed to relevant third parties (e.g. the participant’s GP or the police).

The data collected for this study will be stored securely on University of Oxford password-protected computers and only the researchers conducting this study will have access to this data.

Responsible members of the University of Oxford and Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations

**What will happen to my data?**

Our procedures for handling, processing, storing and destroying your data are all compliant with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. 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 is the data controller and is responsible for looking after your information and using it properly.

We will using data from collected from your medical records and from the test interviews to undertake this research and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 3 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study as part of the research record.

Audio recordings will be de-identified just as any other data collected and stored on a secure hard drive. We are only using these recordings to aid scoring of erroneous data, so they will not be transcribed. We will destroy the audio recordings when all analyses are finished. No recordings will ever be made public or published in any way.

You will not receive an individual assessment report; however, we will distribute and make public reports written for the general public summarising study results.

De-identified data will be archived and can be shared with other researchers, here and abroad and with commercial companies, for scientific reuse.

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 Chief Investigator.

**What will happen to the results of this study?**

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**Participation in future research**

If you agree, we would like to retain your contact details to inform you of future research opportunities for which you may be eligible. These details and a copy of your consent form would be held for an indefinite period, separately from the rest of the study data and would not be shared outside of our department. You can opt out any time by contacting the research team using the details on this letter. Agreeing to be contacted does not oblige you to take part in any future research.

**Who is organising and funding the research?**

The research is sponsored by the University of Oxford and funded by the Stroke Association, UK.

**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 South Central-Berkshire REC (19/SC/0530) Research Ethics Committee.

You will be given a copy of the signed consent form to keep along with this information sheet. Thank you for considering taking part and taking the time to read this sheet.

***Contact Details***

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