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A study of how stroke can impact how we think and feel in the long term. How common is it to have problems with processing information and feelings after stroke and what are the underlying causes?

Submission date
16/06/2021

Recruitment status
No longer recruiting

Registration date
16/06/2021

Overall study status
Completed

Last Edited
05/12/2023

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
A stroke can affect the way your brain understands, organises, and stores information. This project aims to determine the nature of cognitive problems 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.

Who can participate?
Only individuals who have previously been recruited to the Oxford Cognitiive Screen Study can participate in this study.

What does the study involve?
The study involves participating in paper-based assessments that will be carried out remotely over the telephone – voice call or video call. Assessment packs will be participants, and the researcher will go through them with them during the pre-arranged telephone call appointment (s). Participants 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.
The second assessment period will be carried out remotely over the telephone, in the same way as the first assessment period. This will be done one year after the first assessment period.

The study will involve a series of short questionnaires and tests that will assess functional abilities in activities of daily living, how the stroke impacted participants' quality of life, as well as 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.
We will also ask participants are happy to wear an activity tracker 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 taken over a 7-day period, but it doesn't track the type of activity. It records the amount of hours slept indirectly in the absence of movement for longer periods at night. The sensor does not record location (No GPS data). Monitors will be removed after 7 days and returned via a prepaid envelope.
In addition to phone assessments, we will look at participants' medical records to check information relevant to the study. We would also like to look at any brain scans that have been taken as part of routine care. All data collected will be de-identified and names will be kept separately from any research data.

What are the possible benefits and risks of participating?
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 participants do experience any anxiety or distress during the assessment, they may stop at any time and/or pause to ask questions.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
April 2019 to October 2022

Who is funding the study?
Stroke Association (UK)

Who is the main contact?
Prof Nele Demeyere, nele.demeyere@psy.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
259478

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 259478

Study information

Scientific Title
Long term psychological consequences of stroke: prevalence, mechanisms, trajectories and impact

Acronym
OX-CHRONIC

Study objectives
The aim of this project is to determine the prevalence, nature, trajectories and wider impact of cognitive impairment in long term stroke survivors, in relation with mood, fatigue, and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2019, Health Research Authority, (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 19/SC/0530

Study design
Single centre prospective cohort study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied

Prevalence of psychological consequences of stroke

Interventions

The purpose of the long-term follow-up assessments is to provide in-depth neuropsychological profiling using clinical screening tools in combination with more detailed cognitive testing batteries. Tests and questionnaires will be identical between both waves. Assessment tools were selected based on extensive use in research with stroke survivors in which acceptable levels of reliability and validity have been reported. Furthermore, the overall package of assessment tools was designed to limit the burden on participants. We achieved this by piloting assessments with stroke survivor representatives from our Study Management Team and Steering Committee. As a result, the test battery should provide in-depth assessments that will accurately capture the psychological consequences of stroke in a way that the results can be related back to existing literature.

The study involves participating in paper-based assessments that will be carried out remotely over the telephone – voice call or video call. Assessment packs will be participants, and the researcher will go through them with them during the pre-arranged telephone call appointment (s). Participants 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)

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Intervention Type

Other

Primary outcome(s)

1. Dementia status using DSM-5 criteria and based on medical records, cognitive testing and impairment in function of activities of daily living assessed by two trained physicians at wave 1 and wave 2
2. Domain specific impairment is measured using the Oxford Cognitive Screen (OCS) at wave 1 and wave 2.
3. Global cognitive impairment is measured using the Montreal Cognitive Assessment (MoCA) at wave 1 and 2.
4. Activities of daily living is assessed using Nottingham Extended ADL at wave 1 and 2.

Key secondary outcome(s))
1. Language abilities measured using the Boston Naming Test at wave 1 and 2.
2. Verbal Fluency measured using the Letter Fluency and Categories fluency tests at wave 1 and 2.
3. Executive function measured using the Hayling Test, Trails Making Tests A and B, and OCS-Plus Trails at wave 1 and 2.
4. Working Memory measured using the Digit Span Forwards and Backwards test at wave 1 and 2.
5. Episodic Memory measured using the Logical Memory Test Part 1 and 2, and the Picture Memory Test at wave 1 and 2.
6. Visual Spatial Ability measured using the OCS-Plus Figure Copy test and the Rey Complex Figure Copy Test at wave 1 and 2.
7. Spatial Attention measured using the Star Cancellation test at wave 1 and 2.
8. Mood disorders measured using the Hospital Anxiety and Depression Scale, Geriatric Depression Scale, and the Apathy Evaluation Scale at wave 1 and 2.
9. Fatigue measured using the Fatigue Severity Scale at wave 1 and 2.
10. Sleep Quality measured using the Sleep Condition Indicator at wave 1 and 2.
11. Cognitive Reserve measured using the Cognitive Reserve Index at wave 1 and 2.
12. Quality of life measured using the Stroke Impact Scale, and the EQ-5D-5L at wave 1 and 2.
13. Care-giver perspectives measured using the Informant Questionnaire on Cognitive Decline in the Elderly, Caregiver Strain Index, and Informant Assessed Geriatric Depression Scale at wave 1 and 2.

Completion date
25/10/2022

Eligibility

Key inclusion criteria
OX-CHRONIC directly leverages existing data. A cognitive screening programme based within the acute stroke unit, capturing the Oxfordshire area has been ongoing since 2012. Participants in this study have been assessed for stroke specific cognitive impairments during acute recovery and at six-month follow-up. Participants agree to be followed up 6 months later with a home visit to assess psychological consequences of stroke and quality of life. Participants who completed the follow-up and gave explicit opt-in consent for re-contacting for further research will be contacted to take part in this two-year follow-up study. Importantly, there is a minimum two-year interval between stroke and the first new assessment for OX-CHRONIC.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
105

Key exclusion criteria
1. The participant is too unwell to be able to stay awake or concentrate for 30 minutes
2. The participant or consultee/proxy has insufficient English comprehension to complete assessments,

Date of first enrolment
05/02/2020

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
Translational Neuropsychology Group
Department of Experimental Psychology
Radcliffe Observatory Quarter
Oxford
United Kingdom
OX2 6GG

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Stroke Association

Alternative Name(s)
TheStrokeAssociation, TheStrokeAssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/11/2023	05/12/2023	Yes	No
Protocol article		26/10/2021	28/03/2023	Yes	No
Dataset	OX-Chronic results dataset	27/03/2023	28/03/2023	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version v2	15/09/2020	08/07/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes