Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
PLORAS version 1

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Clinical investigation or other study of a medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

(●) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a UKCA/CE UKNI/CE Mark, or a UKCA/CE UKNI/CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No

c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

d) Will the study involve any other clinical procedures with participants (e.g. MRI, ultrasound, physical examination)? ○ Yes ◉ No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- ☑ England
- ☐ Scotland
- ☑ Wales
- ☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ◉ England
- ○ Scotland
- ○ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which applications do you require?

- ☐ IRAS Form
- ☑ NHS/HSC Research and Development offices
- ☐ Social Care Research Ethics Committee
- ☑ Research Ethics Committee
- ☐ Confidentiality Advisory Group (CAG)
- ☐ HM Prison and Probation Service (HMPPS)

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre (BRC), NIHR Applied Research Collaboration (ARC), NIHR Patient Safety Translational Research Centre (PSTRC), or an NIHR Medtech and In Vitro Diagnostic Co-operative (MIC) in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◉ Yes ○ No

The NIHR Clinical Research Network (CRN) provides researchers with the practical support they need to make clinical studies happen in the NHS in England e.g. by providing access to the people and facilities needed to carry out research "on

the ground".

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR CRN. ***Submission of a Portfolio Application Form (PAF) is no longer required.***

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

◉ Yes ○ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
Some MSc Speech and Language Sciences students from University College London undertake their final year research project with us. This includes collecting and analysing data, and writing up results.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Basic science study involving procedures with human participants

The student should complete this form on behalf of the Chief Investigator. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
PLORAS version 1

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Predicting Language Outcome and Recovery After Stroke

A2-1. Educational projects

Name and contact details of student(s):

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Professor	Cathy	Price
Address	12 Queen Square London		
Post Code	WC1N 3AR		
E-mail	c.j.price@ucl.ac.uk		
Telephone	020 3448 4362		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ○ Student
- ◉ Academic supervisor

◯ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Cathy	Price
Post	Principal Investigator of Language		
Qualifications	PhD		
ORCID ID			
Employer	University College London		
Work Address	12 Queen Square London		
Post Code	WC1N 3AR		
Work E-mail	c.j.price@ucl.ac.uk		
* Personal E-mail			
Work Telephone	020 3448 4362		
* Personal Telephone/Mobile	07973243789		
Fax			

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
		Pushpsen	Joshi
Address	UCLH/UCL Joint Research Office, part of the Research Directorate 4th Floor, West 250 Euston Road, London		
Post Code	NW1 2PG		
E-mail	UCLH.RandD@nhs.net		
Telephone			
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	13/0435
Sponsor's/protocol number:	
Protocol Version:	7
Protocol Date:	13/10/2022
Funder's reference number (enter the reference number or state not applicable):	224562/Z/21/Z
Project website:	www.ucl.ac.uk/ploras

Registry reference number(s):

The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):

ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number
Integrated Research Application System (IRAS) number	133939
NIHR Central Portfolio Management System (CPMS) ID	15511
Research Ethics Committee (REC) reference	13/LO/1515
UCL Data Protection Reference number	Z6364106/2013/08/42

A5-2. Is this application linked to a previous study or another current application?

(●) Yes ( ) No

Please give brief details and reference numbers.
This project is continuation of the project: Neural Basis of Language 00/N032 which was created prior to the implementation of IRAS

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

The aim of the study is to provide a clinical protocol that will predict speech and language outcome and recovery after stroke. The system we are developing takes a structural brain image of a new stroke survivor with a language disorder (aphasia) - with or without a motor speech disorder (dysarthria, dyspraxia) - and produces probabilistic estimates of long term outcome, based on how the speech and language abilities of other stroke survivors with 'matching' lesions changed over time.

The project rests on a database that records three types of information from many hundreds of stroke survivors including: i) speech, language and communication abilities (from participant-reported outcome measures and objective assessment), ii) brain imaging data (from structural Magnetic Resonance Imaging or Computerised Tomography), with associated information (e.g. time post-stroke), and iii) sensory and demographic information (vision, hearing, age, education, ethnicity, etc.). Critical lesion sites for speech and language symptoms are identified by linking i) and ii) above. A combination of all data types (i, ii and iii) then enters the PLORAS system, which predicts the degree, type and time course of recovery in new stroke survivors, and how this might be affected by speech and language therapy.

In order to be successful, we need to study large numbers of stroke survivors who have, or had, post-stroke aphasia (with or without dysarthria/dyspraxia). The information from this study will enable us to make predictions about likely recovery patterns in future stroke survivors with speech and language difficulties. This will help guide both clinical and experimental therapeutic interventions.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Managing patient expectations:
Some stroke survivors will hope that we can provide medical diagnostic information or other information/advice that might help their recovery. We inform participants verbally and in writing via our information booklet that we do not provide treatment, however, we may be able to offer a prediction for their recovery and provide information to help them find treatment.

Informed consent:
The study will be explained to stroke survivors using language that is accessible to their level of communication. Our information booklet is designed to be accessible to participants with aphasia, to convey the goal of the study and what it involves. Potential participants will be encouraged to take their time to consider whether they wish to take part in the study.

Interested and eligible stroke survivors will be consented to the study (with the support of a consultee where necessary) by Clinical Research Network (CRN) staff or the PLORAS research team after they have been informed about the study. The initial consent form includes provision of the participant's contact details and identifiers (name, date of birth and NHS number) and permission to share the following information with the PLORAS team: i) hospital brain imaging and associated reports, ii) stroke details and other relevant medical information, and iii) speech and language therapy records. In addition, participants can agree/disagree to be contacted about other stroke research activities and the PLORAS newsletter. After entering the study, the PLORAS Team may ask for further participant consent, depending on the type of assessment that is being made.

PLORAS Team members taking consent will have completed Good Clinical Practice Training and the Health Research Authority (HRA) 'Research involving participants lacking mental capacity' module (or similar). They will also be familiar with the Mental Capacity Act's key principles and two stage test of capacity (2005). Principle Investigators at study sites will be responsible for ensuring that staff consenting participants are suitably trained to take informed consent, including assessing capacity/adhering to the Mental Capacity Act (2005), establishing any advanced decisions or statements from the participant and consulting a consultee around study consent, where appropriate.

Consent may be obtained using paper or electronic methods. The participant (or their consultee where appropriate) will be asked to provide their signature via wet-ink or a simple electronic signature. Depending on the assessment/form, the simple electronic signature might be a stylus or finger drawn signature, a typed name, or a tick box in a declaration form. A copy of the consent forms (or declaration forms if using a consultee) will be provided to the participant/consultee and also retained by the PLORAS Team (saved electronically and stored on the PLORAS database).

Adults lacking capacity to consent may be enrolled with the involvement of a personal consultee who is a person that cares for the participant (not professionally or for payment), is interested in their welfare, and is willing to help. They will probably be a family member, but could be another person (e.g. close friend). If no personal consultee is available or willing, participants will be asked who can be consulted about their participation in the research. This may include family members or friends or an advocate. The consultee advises on what the participant's wishes and feelings would be if they were able to consent for themselves, and on whether they should take part. The consultee does not give consent, only advice, and will be asked to sign a consultee declaration form. If, after enrolment, the consultee has concerns or thinks the participant should be withdrawn they should contact the PLORAS Team.

The participant will not be recruited to the study if the researcher feels that their decision to enter the study has been co-erced by another individual and/or is not representative of their wishes. The participant will be encouraged to withdraw from the study if at any time they demonstrate verbal or non-verbal indications that they are distressed. Given our patient group we believe it is justifiable to include a means for a family member or friend to give written consent on the participant's behalf.

Risks, disadvantages and benefits:
There is a small risk that some patients, particularly those with communication difficulties, may become upset and/or fatigued by the language questionnaires and assessments which by their nature are focused on their area of difficulty. Steps will be taken to reduce this by encouraging the patient to take regular breaks, reiterating their right to withdraw and by the sensitive approach of our team of researchers who are all speech and language therapists or have received training from speech and language therapist colleagues. Patients are also given the option to complete the language testing on another day if they wish to continue with the study after a period of rest.

Some participants may be invited to contribute to our related study ELORAS ("Explaining Language Outcome and

Recovery After Stroke") which involves having a functional MRI brain scan. This would be the case for participants who had damage to particular brain regions of interest that we know are important for language. The particular risks and benefits for this are covered in the information for that study (REC ref: 19/LO/1755, IRAS ID: 265430).

Confidentiality and data protection:
This study will comply with: UCL Data Protection Policy; Common Law Duty of Confidentiality; Data Protection Act 2018; UK General Data Protection Regulation (UK GDPR); Computer Misuse Act 1990; NHS Code of Practice on Confidentiality; Good Clinical Practice; The International Conference on Harmonisation of Tripartite Guidelines (CPMP/ICH/135/95), including all aspects of data collection and management.

List of all data to be collected:

1. Participant consent responses including their contact preferences.
2. Personal data including: name, DOB, contact details (and, if necessary, additional contact details e.g. of a friend or family member).
3. Clinical data including: brain imaging (with associated reports), NHS number, stroke date and type, stroke symptoms, selected National Institute of Health Stroke Scale Scores, time since onset of symptoms, aphasic syndrome subtype, relevant information about other neurological conditions and past medical history, other factors that might affect neurological function and communication, clinical speech and language assessment reports, etc.
4. Other data: other languages spoken, details for Speech and Language Therapy department, co-enrolment to other studies, details about participant's access to technology.
5. Questionnaire data, including: About You questionnaire, Communication Recovery questionnaire, Multilingual questionnaire, Language Practice questionnaire.
6. Formal language assessment scores/transcripts completed for research (e.g. using the Comprehensive Aphasia Test).
7. Communication between PLORAS Team and participant/carer/Study Site, etc.
8. Audio and video recordings of participants, either individually or during group discussions.
9. Transcriptions of group discussions.

This project is covered by the UCL Data Protection Registration, reference number Z6364106/2013/08/42, section 19, research: health research.

Data collected from participants will be uploaded directly and securely to the PLORAS database and automatically encrypted where appropriate. CDs with clinical scan data will be shredded after the scans have been uploaded to the database. Paper data (which may include a copy of consent forms) are stored in a locked cabinet at UCL. Paper files will be archived at the UCL Records Office when they no longer need to be referred to. All data in the database and cabinets can only be accessed by authorised personnel. The degree of access depends on what the data are being used for. I.e. only authorised members of the PLORAS Patient Team can access personal data (name, address, date of birth etc.) to check participant eligibility and contact participants regarding their involvement in the study (e.g. to administer the questionnaires and assessments) or to arrange follow-up activities. Other members of the PLORAS Team (e.g. analysis-only team) can access non-identifiable data for data-analysis and publication (rather than participant recruitment and testing). Researchers outside the PLORAS Team do not have any access to the database. Those conducting ethically approved studies can be sent data from the PLORAS Team. This will not include any personal information unless the participant has already participated in the other team's study.

A Data Sharing Agreement has been produced by UCL and will need to be signed by all Study Sites before any data is transferred to the PLORAS Team at UCL. This outlines agreed methods for secure data transfer from Study Sites to the PLORAS Team at UCL. This includes use of encrypted e-mail (i.e. NHS mail or using encryption software that would meet AES-256 standard) or direct and secure upload to the PLORAS database.

For data uploaded to the PLORAS database the connection between the user and our servers will be secured via https. The data will be uploaded directly to the PLORAS database as soon as possible and is not stored on any third-party servers. The data collected is automatically encrypted where appropriate. Access will only be available via the PLORAS database (our internal server). This server, and hence the data, is password protected and can only be accessed by authorised members of the PLORAS Research Team.

Occasionally, it is necessary for PLORAS to transfer personal data, this will be done using encrypted e-mail (i.e. NHS mail or using encryption software that would meet AES-256 standard), or encrypted files (sent via UCL dropbox or department networks).

Professor Cathy Price (CI) is the custodian of the data which will be stored for 20 years after study end, providing an extremely rich data set for future investigations. After this time, all personal data will be destroyed in accordance with all applicable legal and regulatory requirements, including the UK General Data Protection Regulation (UK GDPR) and Data Protection Act 2018, and any amendments thereto. UCL will act as the data controller of such data for the study.

Eventually, the plan is to transfer anonymised datasets to an open source database for widespread use and new applications.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☑ Cross-sectional study
- ☑ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

The study also has longitudinal elements i.e. carrying out repeat language measures and assessments with participants whose aphasic symptoms persist.

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The main objective is to create a clinical tool that will enable future stroke patients with aphasia to be given specific, individualized prediction information on the likely recovery of their language skills e.g. "based on the recovery of other patients with the same region of damage it is likely to take 2 years to recover your speech. This was the case for 90% of previous patients with this region of damage."
In order to achieve this objective our primary research questions ask (A) which brain regions are consistently, or inconsistently, associated with language impairments; and (B) how does the degree and rate of recovery from these impairments depend on lesion site and other factors.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

A secondary objective is to try to understand how recovery takes place. This will involve inviting participants to participate in our other on-going study 'Explaining Language Outcomes and Recovery After Stroke' for which we already have ethics approval (19/LO/1755). This replaces our former 'Neural Basis of Language and Object Recognition' study (00/N032). We hope that the combined approach will be useful to other projects (by other investigators) who are developing and testing new therapies.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Currently, it is not possible for clinicians to provide helpful, personalised and accurate predictions of how speech and language might recover after brain damage because the factors explaining why stroke survivors recover at different rates are not understood. Our approach is to understand, and control and utilize sources of inter-participant variability. In order to do this, we need to collect data from hundreds of stroke survivors who vary from one another in terms of the lesion location and a wide range of demographic factors (e.g. age, education, ethnicity, etc.). The same speech and language assessments are used with all participants. This allows us to compare different groups of participants while controlling for all experimental factors. Our current database, with brain scans and language assessments late after stroke from more than 2000 participants, indicates that the most effective predictor of speech and language recovery is lesion site (assessed from the brain scans).

Previous studies have demonstrated that damage to many left hemisphere brain areas can disrupt speech and language but they have not demonstrated that the effects of damage to the same region are consistent across large populations of patients. Indeed, the effect of damage to one region may depend on the degree of concurrent damage to other brain regions or non-lesion factors such as therapeutic interventions. In the last decade, technical advances in the analysis of neuroimaging data have improved the precision with which we can identify lesion location while computational advances allow us to combine and compare data from large populations of participants. We therefore have new approaches to tackle old problems.

Our study investigates the extent to which variability in the speed and degree of speech and language recovery arises from (i) the availability of intact neural structures that can learn to support lost functions, and (ii) non-lesion factors (e.g. therapy type/dose or demographics) that affect the ability to use these intact structures. This requires an investigation into how the effect of lesion and non-lesion variables interact with one another. For example, when lesion site is controlled, we expect to find that recovery is slower or less complete when early speech and language impairments co-occur with other impairments (e.g. perceptual or memory difficulties); and, conversely, faster and more complete when receiving more intensive early therapy. In both examples, stroke survivors may have the neural resources available to support recovery but vary in whether or not they learn to engage these resources effectively.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Our methodology involves combining three types of information from stroke survivors including: i) speech, language and communication abilities (from participant-reported outcome measures and objective assessment), ii) brain imaging data (from structural Magnetic Resonance Imaging or Computerised Tomography), with associated information (e.g. time post-stroke), and iii) sensory and demographic information (vision, hearing, age, education, ethnicity, etc.). A combination of all data types (i, ii and iii) then enters the PLORAS system, which predicts the degree, type and time course of recovery in new stroke survivors, and how this might be affected by speech and language therapy.

Participants will be asked to sign an initial consent form to confirm that they understand the study information booklet, agree to take part in the study, and are happy to share the following with the PLORAS team: i) their hospital CT/MRI brain scans, ii) their speech and language therapy (SALT) records, and iii) other relevant medical information. They will then complete a short participant interview (approx. 30 minutes) with a research practitioner (or a member of the PLORAS team) which involves answering questions about how their stroke affected them and whether they have access to technology for online data collection. A friend or family member may be able to help them answer the questions. For most participants the initial consent form and interview are completed whilst they are in hospital, however this may also be done by the PLORAS team at a later date. Once consented to PLORAS, we will obtain a copy of the data the participant agreed to share in the initial consent form (their hospital CT/MRI brain imaging, relevant medical records and details of speech and language therapy).

Enrolled participants will then be contacted separately by members of the PLORAS team to complete further questionnaires. These may be administered to participants and/or their carers via online video conferencing, over the phone, by post, or via email. All participants will be invited to complete an ‘About You’ questionnaire (which collects demographic information such as vision, hearing, age, education, ethnicity, etc. and takes approx. 10 minutes to complete) and a ‘Communication Recovery Measure’ asking about their speech and language abilities (this collects information about how the stroke affected their speaking/understanding/reading/writing and takes approx. 20-45 minutes to complete).

Where applicable, participants will be asked to complete other questionnaires. For example, those who speak other languages will be asked to complete a ‘Multilingual’ questionnaire (which asks how their languages were affected by the stroke and takes approx. 15-30 minutes to complete). Participants receiving speech and language therapy, will be asked to complete a ‘Language Practice’ questionnaire (which takes approx. 20-45 minutes to complete and asks about the everyday language use and the amount and type of speech and language therapy received). The PLORAS team will also contact their speech therapist to complete a complementary ‘Therapy’ questionnaire (which asks about the amount/frequency/timing of therapy, and factors that may affect the provision of or participant response to therapy).

The PLORAS team will continue to contact participants every 3 to 6 months to repeat the ‘Communication Recovery Measure’ and to ask about their speech and language therapy (if applicable), until either: their language difficulties recover, they no longer wish to take part or the study funding is not renewed.

During the course of their participation, the PLORAS team may invite some participants to complete standardised speech and language assessments such as the Comprehensive Aphasia Test (i.e. for participants whose self-report aphasic symptoms persist for more than three months post-stroke or who report being less severe than predicted

from their brain scan) or the Aphasia Impact Questionnaire-Concise (i.e. for participants who still report aphasia or have impaired scores on the Comprehensive Aphasia Test at 6-12 months.

Depending on a participant's symptoms and enthusiasm to participate further, they may be invited to take part in supplementary activities such as: tests of apraxia; language assessments in other languages spoken, functional magnetic resonance imaging (fMRI) to understand which parts of their brain have learnt to support their recovered speech and language abilities, and/or discussion forums to help us improve our research methods. Separate consent will be obtained for any subsequent involvement outside the main study activities. Participants can withdraw from the study or refuse to take part in further activities at any time.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [x] Management of the research
- [x] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
We are committed to involving patients in our research plans, and will seek their input into our research processes and procedures, including the delivery of recovery prognoses, the contents and administration of our assessments and the implementation of the study results into clinical practice. This may include small focused discussion groups, or short questionnaires/surveys, taking place in person or online. These will be carried out on an ad hoc basis. If suitable, patients may be invited to take part in ongoing involvement in the research as part of a committee or advisory panel.

We plan to carry out public engagement activities including but not limited to:
• Patient-focused events offering stroke survivors the opportunity to contribute to our research
• Events for healthcare professionals and associated practitioners
• Aphasia awareness raising events
• Advice for the design of our on-line language assessments.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection

- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [x] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit: 105	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

In order to be included in the study, participants must meet the following criteria:
• A medical diagnosis of one or more strokes (at any time in past) in cerebral or cerebellar regions. The cause of the stroke can be ischemic or haemorrhagic. It must be visible (>1cm3) on a brain scan (according to lesion-measuring software or Consultant/Radiologist report).
• Evidence of mild, moderate or severe spoken communication difficulties post-stroke. Evidence can be from a variety of sources, such as the multidisciplinary team, interactions with the patient or patient/carer reports. Patients may also have motor speech disorder (dysarthria, dyspraxia) in addition to language difficulties (aphasia). The severity of aphasia can be assessed, according to the National Institute of Health Stroke Scale (https://www.stroke.nih.gov/documents/NIH_Stroke_Scale_508C.pdf).
• Able to complete our questionnaires/assessments with or without assistance. Formal language assessments, which are standardised on an English-speaking population, will only be conducted on patients who were fluent speakers of English prior to their strokes. This is to ensure that errors are not the result of learning English as an additional language. Patients who do not speak English are still included, using patient-reported outcome measures, if they have someone who can translate our questionnaires, which are written in English. Understanding recovery in multiple languages will contribute to our ongoing evaluations of how prediction accuracy is influenced by the language spoken, the number of languages spoken and proficiency of each spoken language.
• No hearing and vision problems (unrelated to stroke) that cannot be corrected (unable to be certain that symptoms/errors on assessment result from stroke rather than poor vision/hearing only).
• Capacity to consent or have a family member/close friend (consultee) who can sign a declaration form indicating the participant's wishes.
• Willingness to participate
• Not under the age of 18 (our ethics approval is for adults only).
• No significant medical or psychiatric co-morbidity that might influence attention to, interpretation of, or co-operation with, any of the assessments.
• No other neurological condition in addition to stroke e.g. Dementia, Multiple Sclerosis, Parkinson's Disease, Motor Neurone Disease. This is to ensure that symptoms/errors noted during assessments result from the stroke rather than other conditions. Controlled epilepsy and meningiomas can be included, unless neurosurgery for these or other conditions resulted in aphasia.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

We exclude patients who:
• Had strokes that only damaged the brainstem, or were the consequence of a subdural haematoma or subarachnoid haemorrhage, because these sites are already known not to be related to speech or language impairments.
• Had strokes that never resulted in spoken communication difficulties.

• Have hearing and vision problems (unrelated to stroke) that cannot be corrected (unable to be certain that symptoms/errors on assessment result from stroke rather than poor vision/hearing only).
• Lack capacity to consent and do not have a family member/close friend available to act as a consultee.
• Are under the age of 18.
• Have a significant medical or psychiatric co-morbidity that might influence attention to, interpretation of, or co-operation with, any of the assessments.
• Have other neurological conditions in addition to stroke e.g. Dementia, Multiple Sclerosis, Parkinson's Disease, Motor Neurone Disease.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Written informed consent taken	1	0	15-30 minutes	Completed with research staff (e.g. research assistants/practioners/nurses/associates) at time and place of recruitment Completed with research staff (e.g. research assistants/practitioners/nurses/associates) at time and place of recruitment and where relevant at time of additional behavioural data collection (by PLORAS team).
Participant Entry Form	1	0	30 minutes	Completed with the participant and/or their consultee by researchers/health professionals at any of the PLORAS study sites or by participants at home - in writing, online or over the telephone.
About You Questionnaire	1	0	10 minutes	Completed by participant, with support from PLORAS staff, via telephone, post, online questionnaire, e-mail or face to face.
Multilingual Questionnaire	1	0	15-30 minutes	Completed by participant, with support from PLORAS staff, via telephone, post, online questionnaire, e-mail or face to face.
Language Practice Questionnaire	1-6	0	20-45 minutes	Completed by participant, with support from PLORAS research staff, via telephone, post, online questionnaire, e-mail or face to face.
Communication Recovery Measure	1-6	0	20-45 minutes	Completed by participant, with support from PLORAS research staff, via telephone, post, online questionnaire, e-mail or face to face.
Aphasia Impact Questionnaire-Concise	1-6	0	20-45 minutes	Completed by participant, with support from PLORAS research staff, via telephone, post, online questionnaire, e-mail or face to face.
Video or audio sample of conversational speech	1	0	2-3 minutes	PLORAS research staff ask patient to talk about when they had the stroke on video (or just audio if preferred)
National Institute of Health Stroke Scale assessment Modified Rankin Scale Assessment	1-2	1	5 minutes	Completed by a member of the research team, care team or PLORAS research team, in the research setting, with participants who are recruited via a clinical source.

A21. How long do you expect each participant to be in the study in total?

Participants will be contacted every 3 to 6 months to repeat the Communication Recovery Measure until either: their language difficulties recover, they no longer wish to take part or the study funding is not renewed. Participants can withdraw from the study or refuse to take part in activities at any time.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

There is a small risk that some participants, particularly those with communication difficulties, may become fatigued and/or frustrated by the language questionnaires and assessments which focus on their area of difficulty. Steps will be taken to reduce this by encouraging the patient to take regular breaks, reiterating their right to withdraw and sensitive handling from our team of researchers who are all speech and language therapists or have received training from speech and language therapist colleagues. Patients are also given the option to complete the language testing on another day if they wish to continue with the study after a period of rest.

A24. What is the potential for benefit to research participants?

There are no direct benefits to participants taking part in this study and we do not provide treatment. However, (i) we find that our participants are usually enthusiastic to contribute to the research and find out more about their own abilities; (ii) for some participants, we can provide a confident prediction about their speech and language recovery and (iii) if needed, we can provide information to help them find treatment.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).*

Participants will primarily be recruited and identified at PLORAS Study Sites by health professionals. Participants can be recruited (i) directly from a variety of settings (e.g. hospital wards and clinics) as per local Clinical Research Network (CRN) permissions, (ii) indirectly, e.g. using hospital and research databases, or (iii) from the community (e.g. stroke groups and events).

Participants can also self-refer to PLORAS after being informed about the study from other sources, e.g. health professionals (not affiliated to a Clinical Research Network study site), collaborators (e.g. speech and language therapists and other research studies), existing research participants, via the community (e.g. at stroke clubs, presentations and exhibitions) and via the media (e.g. print and online advertisements, TV/radio coverage, websites, Facebook, Twitter, leaflets and posters). Participants can contact us via telephone/email, or via the PLORAS Registration Form on the PLORAS website.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(●) Yes ( ) No

Please give details below:
Yes medical notes, clinical imaging and electronic records regarding participants may be screened by members of staff from the Clinical Research Network/Primary Care Network, health care professionals involved in the participant's care and members of the research team who have an honorary contract with the NHS site. For participants who are recruited outside of the Clinical Research Network, members of the PLORAS research team will request the aforementioned personal information for screening purposes with the participant's consent.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to

patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

Patient medical records can only be accessed for screening by Clinical Research Network staff, health care professionals involved in the patient's care and members of the research team who have an honorary contract with the NHS site. First level screening would involve briefly checking the patient's medical notes and clinical imaging or liaising with the medical team to check whether the patient meets the inclusion/exclusion criteria before approaching them with details of the study.
Second level screening would involve helping the patient to complete a consent form and 'Participant Entry Form'. PIs at study sites will be responsible for local arrangements and compliance. Copies of relevant sections of patient's medical notes and clinical imaging will be obtained by members of the PLORAS research team for all patients following their consent. Written consent for this will be obtained from patients prior to requests being made. These relevant sections of medical notes and clinical imaging may need to be viewed by the radiographers at the Department of Imaging Neuroscience, UCL, for participants invited to take part in our related study ELORAS ("Explaining Language Outcome and Recovery After Stroke") as part of MRI safety screening. All persons with access to confidential data will have training in data protection and confidentiality.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ◉ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Posters:
Will be displayed in conference and event settings,community centres, NHS primary and secondary care settings e.g. clinics and hospitals, around UCL
Leaflets:
Will be distributed via health professionals, at conferences and events, via stroke clubs, via charities such as Stroke Association and Different Strokes, via willing existing participants, via NHS primary and secondary care settings e.g. clinics and hospitals and via other relevant researchers.
Adverts:
Will be placed in newspapers (any of local, national, specialist), magazines such as Stroke News, SAGA, Retirement today and on websites e.g. Gumtree
Websites and online:
We may recruit some participants via our own website (www.ucl.ac.uk/ploras), via our Facebook page and profile and via our Twitter account and via the websites and social media of related organisations e.g. Stroke Association, Different Strokes, specific language groups etc.

A29. How and by whom will potential participants first be approached?

This will depend on the setting. In clinical settings the participants will first be approached by a clinician involved directly in their care or a member of the Clinical Research Network team or researchers with an honorary clinical contract. Initial contact may be face-to-face, by telephone or post.
Participants may also be approached at stroke clubs, community groups, conferences and events by researchers (who may occasionally include sufficiently trained MSc/PhD students).

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for

children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

After they have been informed about the study, interested and eligible stroke survivors will be consented to the study (with the support of a consultee where necessary) by Clinical Research Network staff or the PLORAS research team. after they have been informed about the study.

PLORAS Team members taking consent will have completed Good Clinical Practice Training and the Health Research Authority (HRA) 'Research involving participants lacking mental capacity' module (or similar). They will also be familiar with the Mental Capacity Act's key principles and two stage test of capacity (2005). Principle Investigators at study sites will be responsible for ensuring that staff consenting participants are suitably trained to take informed consent, including assessing capacity/adhering to the Mental Capacity Act (2005), establishing any advanced decisions or statements from the participant and consulting a consultee around study consent, where appropriate.

After entering the study, the PLORAS Team may ask for further consent, depending on the type of assessment that is being made.

Consent may be obtained at study sites and by the PLORAS Team using paper or electronic methods. The participant (or their consultee where appropriate) will be asked to provide their signature via wet-ink or a simple electronic signature. Depending on the assessment/form, the simple electronic signature might be a stylus or finger drawn signature, a typed name, or a tick box in a declaration form.

A copy of the consent forms (or declaration forms if using a consultee) will be provided to the participant/consultee. A copy will also be retained by the PLORAS Team (saved electronically and stored on the PLORAS database) and the study site that referred them (if applicable).

Adults lacking capacity to consent may be enrolled with the involvement of a personal consultee who is a person that cares for the participant (not professionally or for payment), is interested in their welfare, and is willing to help. They will probably be a family member, but could be another person (e.g. close friend). If no personal consultee is available or willing, participants will be asked who can be consulted about their participation in the research. This may include family members or friends or an advocate. The consultee advises on what the participant's wishes and feelings would be if they were able to communicate consent for themselves, and on whether they should take part. The consultee does not give consent, only advice, and will be asked to sign a consultee declaration form. If, after enrolment, the consultee has concerns or thinks the participant should be withdrawn they should contact the PLORAS Team.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

(●) Yes ( ) No

A31. How long will you allow potential participants to decide whether or not to take part?

We will encourage participants to take their time and as long as they need in when deciding whether or not to take part. and We make it clear that there is no rush to make a decision as the study will be recruiting for a number of years. We will typically assume that patients no longer wish to participate if they have not been in contact for 6 months or more and have not responded to follow-up messages. This will be indicated on our participant database but we will keep all records in case of future contact from the participant.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

(●) Yes

( ) No

( ) Not Known

If Yes, please give details and justify their inclusion. If Not Known, what steps will you take to find out?

There is no reason for participants who are taking part in other research not to take part in our study, particularly as our study does not involve treatment.
Where there is any cross-over between procedures carried out by ourselves and that of other research teams with stroke patients we will aim to support each the other research team in recruitment (by informing patients of other studies). We will also actively try to 'share' participant's data (with consent) to avoid duplication of procedures for participants.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

We have produced accessible participant-facing documents to support those with communication difficulties.
It is a pre-requisite for our study that participants speak English. If a participant prefers to communicate in another language, a family member (who is fluent in both the native language of the participant and English) will be needed to translate parts of the questionnaire.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

As above, it is a pre-requisite for our study that participants speak English. If they have better communication in Welsh, a family member who is fluent in both English and Welsh can assist by translating parts of the questionnaire into Welsh.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

As this is a long-term study (at least 5 further years) it is likely that some participants will lose capacity to consent before the end of the study. Due to the large number of participants it will not be feasible to monitor capacity to consent however if information is brought to our attention e.g. via contact with the participant or from a medical professional on their behalf we will not request any further data from the participant. We will continue to use their anonymised data in the research, given that the data were collected with informed consent.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- [x] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [x] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [x] Manual files (includes paper or film)
  - [ ] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [x] Laptop computers

Further details:
Access to medical records by those outside the direct healthcare team:
For participants who are not recruited via the Clinical Research Network (i.e. self-referring participants), it may be necessary for members of the PLORAS research team to access their records (with consent) to check they can be included in the study.

Electronic transfer by magnetic or optical media, email or computer networks:
Personal data can be transferred to PLORAS either via encrypted e-mail (i.e. NHS mail or using encryption software that would meet AES-256 standard) or direct and secure upload to the PLORAS database. For data uploaded to the PLORAS database the connection between the user and our servers will be secured via https. The data will be uploaded directly to the PLORAS database as soon as possible and is not stored on any third-party servers. The data collected is automatically encrypted where appropriate. Access will only be available via the PLORAS database (our internal server). This server and hence the data is password protected and can only be accessed by authorised members of the PLORAS Research Team.

Where it is necessary for PLORAS to transfer personal data, this will be done using encrypted e-mail (i.e. NHS mail or using encryption software that would meet AES-256 standard), or encrypted files (sent via UCL dropbox or department networks).

Use of personal addresses, postcodes, faxes, emails or telephone numbers:
Personal contact details will be provided to us by participants and will be stored in the PLORAS database and on paper in locked cabinets at UCL. These details will only be accessed by authorised members of the PLORAS team who need to contact the participant (i.e. to check eligibility, administer questionnaires/assessments or to arrange follow-up activities).

Publication of direct quotations from respondents
It is possible that quotations from participant's e.g. speech samples or comments about the research may be included in some publications, without names (or with pseudo-names e.g. "stroke survivor John says...") unless consent has been sought.

Use of audio/visual recording devices:
Much of the Comprehensive Aphasia Test (CAT) will be videoed and/or audio recorded (with consent) for later analysis. Some of our participant involvement activities (such as focus groups and events) could potentially involve audio/visual recording. In such cases, participant consent will be obtained prior to use of such devices.
We may share quotations from participant's speech in some publications, without names or further consent. Sometimes, we use a pseudo name (e.g. "stroke survivor John says...")

Storage of personal data:
Data collected from participants will be uploaded directly and securely to the PLORAS database and automatically encrypted where appropriate. CDs with clinical scan data will be shredded after the scans have been uploaded to the database. Paper data (which may include a copy of consent forms) are stored in a locked cabinet at UCL. Paper files will be archived at the UCL Records Office when they no longer need to be referred to. All data in the database and cabinets can only be accessed by authorised personnel. The degree of access depends on what the data are being used for, membership to the PLORAS team and appropriate training.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Paper files are stored in locked file-cabinets in a building that is accessed via a key-card.
Electronic data are stored on a database which is only accessible to members of the research team.
All data in the database and cabinets can only be accessed by authorised personnel. The degree of access depends on what the data are being used for, membership to the PLORAS team and appropriate training.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

This study will comply with:
• UCL Data Protection Policy
• Common Law Duty of Confidentiality
• Data Protection Act 2018
• UK General Data Protection Regulation (UK GDPR)
• Computer Misuse Act 1990
• NHS Code of Practice on Confidentiality
• Good Clinical Practice
• The International Conference on Harmonisation of Tripartite Guidelines (CPMP/ICH/135/95), including all aspects of data collection and management.

Data collected from participants will be uploaded directly and securely to the PLORAS database and automatically encrypted where appropriate. CDs with clinical scan data will be shredded after the scans have been uploaded to the database.
Paper data (which may include a copy of consent forms) are stored in a locked cabinet at UCL. Paper files will be archived at the UCL Records Office when they no longer need to be referred to. All data in the database and cabinets can only be accessed by authorised personnel. The degree of access depends on what the data are being used for, membership to the PLORAS team and appropriate training.

Only authorised members of the PLORAS Patient Team can access personal data (name, address, date of birth etc.) to check participant eligibility and contact participants regarding their involvement in the study (e.g. to administer the questionnaires and assessments) or to arrange follow-up activities.
Other members of the PLORAS Team (e.g. analysis-only team) can access non-identifiable data for data-analysis and publication (rather than participant recruitment and testing).
Researchers outside the PLORAS Team do not have any access to the database. Those conducting ethically approved studies can be sent data from the PLORAS Team. This will not include any personal information unless the participant has already participated in the other team's study.

Research data will be stored securely for 20 years after the study end in case the researchers need to check it. After this time, any participant identifiable data will be destroyed. Participants will not be identified in any publication arising from this study.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Only authorised members of the PLORAS Patient Team can access personal data (name, address, date of birth etc.) to check participant eligibility and contact participants regarding their involvement in the study (e.g. to administer the questionnaires and assessments) or to arrange follow-up activities.

Personal data may be provided to other researchers working on projects that the participant has also participated in and completed a consent form for, to avoid duplication of the participant providing this information.

For participants who are also taking part in our related study ELORAS ("Explaining Language Outcome and Recovery After Stroke"; REC ref: 19/LO/1755, IRAS ID: 265430), radiographers at the Department of Imaging Neuroscience (UCL) will have access to personal data, for safety reasons.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

At 12 Queen Square on password protected computers by members of the research team (including Masters and doctorate students) under the guidance of the CI (Professor Cathy Price). Data may be analysed on external computers by members of the research team and collaborators, only when in coded form (i.e. using patient ID numbers).

Post-COVID, members of the PLORAS team may work remotely using a password protected UCL laptop. They may use this to connect to a computer at UCL's Department of Imaging Neuroscience or to connect to departmental network via VPN.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Professor	Cathy	Price
Post	Principal Investigator of Language Studies		
Qualifications	PhD		
Work Address	Department of Imaging Neuroscience (UCL)		
	12 Queen Square		
	London		
Post Code	WC1N 3AR		
Work Email	c.j.price@ucl.ac.uk		
Work Telephone	020 3448 4362		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ◉ Over 3 years

If longer than 12 months, please justify:
Our patient database will contain a wealth of valuable information about stroke and aphasia that can be analysed in numerous ways and as such it is justifiable to keep the data for many years.

A44. For how long will you store research data generated by the study?

Years: 20
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

Paper files will be kept in locked cabinets at the Department of Imaging Neuroscience, UCL. The cabinets are accessed by key card. When the files no longer need to be regularly accessed they will be archived at the University

College London Records Office. UCL Records Office provides a service to UCL staff and maintains manual / hard copy records in a safe and secure off-site location. Access to stored records is strictly controlled.
Electronic data will remain on our database, which is password protected and only accessible by authorised members of the PLORAS Research Team.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50-1. Will the research be registered on a public database?

The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

○ Yes ◉ No

Please give details, or justify if not registering the research.
This is not a clinical trial and has not therefore been registered.

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study?*Tick as appropriate:*

☑ Peer reviewed scientific journals

- [x] Internal report
- [x] Conference presentation
- [x] Publication on website
- [x] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [x] Other (please specify)

Newsletter to patients and other interested health professionals/researchers/members of the public and on our website www.ucl.ac.uk/ploras

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Individual references to patients will be anonymised e.g. 'patient 1'

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
Via our annual newsletter and website. Possibly also via written feedback to research participants; presentation to participants or relevant community groups.

5. Scientific and Statistical Review

A54-1. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [x] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
Independent external review has been given by: The Wellcome Trust who selected the study for funding. Within the CI's host organisation it has been reviewed by the Head of Department (Professor Martina Callaghan) and Scientific Director (Professor Karl Friston) and all members of the research team.

A copy of the external reviews from the Wellcome funding application can be provided upon request.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [x] Other review by independent statistician

☐ Review by company statistician

☑ Review by a statistician within the Chief Investigator's institution

☑ Review by a statistician within the research team or multi−centre group

☐ Review by educational supervisor

☐ Other review by individual with relevant statistical expertise

☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Professor	Karl J.	Friston
Department	Department of Imaging Neuroscience		
Institution	University College London, UCL		
Work Address	12 Queen Square		
	London		
Post Code	WC1N 3AR		
Telephone	02034484344		
Fax			
Mobile			
E-mail	k.friston@ucl.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Cross-validation. Predictions of language outcome and recovery are generated from lesion site, time post stroke and other variables in one sample and tested (i.e. validated) in another sample of patients.

A58. What are the secondary outcome measures?*(if any)*

New and Replication of scientific findings.
Publications

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	5000
Total international sample size (including UK):	6000
Total in European Economic Area:	1000

Further details:
It is difficult to estimate the exact number of patients that we need to recruit but we have made estimates in terms of 1000s as we already have a number of national and international collaborators interested in participating in the project.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Data from every participant we include will add value to everyone's confidence in future prognoses. The proposed sample size is therefore dictated by the cost of staff to monitor participant recovery and analyse the factors influencing recovery. Wellcome have awarded us funds to monitor recovery in 1000 additional participants (September 2022-2027). We will continue to apply for funding to ensure the accuracy and confidence in future prognoses. A sample size of 1000, will allow us to:
• Systematically dissociate the multiple variables that influence the degree and speed of recovery over time, for example, the exact location of the stroke, the amount and type of therapy received, and the pre-stroke language experience of the participant. Our prognoses for future stroke survivors depend on understanding these variables.
• Generate confidence in our predictions for future stroke survivors by increasing the number of previous participants who contribute to the prediction. For example, we can be more confident if a prediction is based on the consistency of recovery profiles from a hundred previous participants, with the same lesion features, than if the prediction is only based on data from 10 previous participants.
• Identify and learn about participants who have unusual symptoms, lesions, demographics and/or recovery profiles. This will allow us to generate and test hypotheses about when and why our prognoses are inaccurate. In practice, no test sample will ever be large enough to completely obviate the need to record exceptions (as is recognised, for example, in the way new drugs are trialled). This is why we will continue to apply for funds to increase our participant sample - and share our data with other researchers whose goal is to improve the lives of patients with post-stroke aphasia.

A61-1. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Building on conceptual and computational developments over recent years, we have developed a new approach for identifying critical lesion sites that consistently result in speech and language difficulties.

Our methods for identifying critical lesion sites are based on a search for rules that relate brain lesions to cognitive impairments in powerfully predictive ways. The search is iterative and constrained, through what might be called a 'solution-space'. The starting point for the search is a 'reasonable' solution. For example, a thresholded 'lesion-overlap map' for patients with a particular symptom. This identifies areas that are the most consistently damaged in a population of patients with the same symptom. The regions of highest lesion-symptom consistency are then converted into a rule which relates the likelihood of damage in each region, and each combination of regions, to a functional impairment. Searching for the rule can proceed in a number of ways. Our implementation is a stochastic optimisation algorithm, which works by making an iterative series of small changes to a given solution. If the change produces a better solution, it is kept and this is repeated until no further improvements can be found. The best solution is a set of lesion sites that are present in "all" patients with a particular lesion site; and "none" of the patients who do not have damage to the same area. This allows us to predict that new patients with the identified lesions will have impaired function, whereas those without the identified lesions are likely to make a faster recovery.

Although we anticipate that the most powerful predictor of recovery is lesion site, we are also investigating other factors that influence the speed of recovery. These include age of the patient, time post stroke, intellectual abilities and therapeutic interventions.

The predictive value of all rules is validated in new samples of patients.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Alex	Leff
Post	Clinical Senior Lecturer & Honorary Consultant Neurologist		

Qualifications	PhD, MD
Employer	University College London
Work Address	Institute of Cognitive Neuroscience Alexandra House 17 Queen Square, London
Post Code	WC1N 3AR
Telephone	020 7679 1177
Fax	
Mobile	
Work Email	a.leff@ucl.ac.uk

Title	Forename/Initials	Surname
Dr	Tom	Hope

Post	Research Fellow
Qualifications	PhD
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	020 3448 4375
Fax	
Mobile	
Work Email	t.hope@ucl.ac.uk

Title	Forename/Initials	Surname
Professor	David	Green

Post	Professorial Research Fellow/Emeritus Professor
Qualifications	PhD, MBA
Employer	University College London
Work Address	410 Division of Psychology and Language Sciences London
Post Code	WC1E 6BT
Telephone	020 7679 7567
Fax	
Mobile	
Work Email	d.w.green@ucl.ac.uk

Title	Forename/Initials	Surname
Mrs	Rachel	Bruce

Post	Research Manager
Qualifications	MSc
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	020 7813 1538
Fax	

Mobile	
Work Email	r.bruce@ucl.ac.uk

Title	Forename/Initials	Surname
Dr	Kenji	Yamamoto

Post	
Qualifications	MD
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	
Fax	
Mobile	
Work Email	a.yamamoto@ucl.ac.uk

Title	Forename/Initials	Surname
Mrs	Andrea	Gajardo Vidal

Post	Research Assistant
Qualifications	
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	020 7813 1538
Fax	
Mobile	
Work Email	andrea.gajardo.11@ucl.ac.uk

Title	Forename/Initials	Surname
Mr	Diego	Lorca Puls

Post	Research Assistant
Qualifications	
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	020 7813 1538
Fax	
Mobile	
Work Email	d.puls@ucl.ac.uk

Title	Forename/Initials	Surname
Dr	Jenny	Crinion

Post	Collaborator
Qualifications	PhD

Employer	University College London
Work Address	Institute of Cognitive Neuroscience Alexandra House 17 Queen Square, London
Post Code	WC1N 3AR
Telephone	020 7679 1129
Fax	
Mobile	
Work Email	j.crinion@ucl.ac.uk

Title	Forename/Initials	Surname
Dr	Nick	Ward

Post	Collaborator
Qualifications	MD
Employer	University College London
Work Address	Sobell Department of Motor Neuroscience and Movement Disorders Queen Square House, Queen Square London
Post Code	WC1N 3BG
Telephone	0845 155 5000
Fax	
Mobile	
Work Email	n.ward@ucl.ac.uk

Title	Forename/Initials	Surname
Mrs	Hayley	Woodgate

Post	Behavioural Data Collection Manager & Speech and Language Therapist
Qualifications	BSc
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	020 7813 1538
Fax	
Mobile	
Work Email	h.woodgate@ucl.ac.uk

Title	Forename/Initials	Surname
Miss	Shamima	Khan

Post	Recruitment & Imaging Data Collection Manager
Qualifications	BSc
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	020 7813 1538
Fax	
Mobile	

Work Email	shamima.khan@ucl.ac.uk

Title	Forename/Initials	Surname
Miss	Sophie	Roberts

Post	Research Assistant & Speech and Language Therapist
Qualifications	MSc
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	020 7813 1538
Fax	
Mobile	
Work Email	sophie.roberts@ucl.ac.uk

Title	Forename/Initials	Surname
Mrs	Kate	Ledingham

Post	Research Assistant
Qualifications	MSc
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	020 7813 1538
Fax	
Mobile	
Work Email	kate.ledingham@ucl.ac.uk

Title	Forename/Initials	Surname
Mr	Andre	Selmer

Post	Contract Software Architect
Qualifications	
Employer	Bytewise Software Solutions
Work Address	4 Carolina Place Finchampstead, Wokingham Berkshire
Post Code	RG40 4PQ
Telephone	
Fax	
Mobile	
Work Email	andre.selmer@bytewisesoftware.com

Title	Forename/Initials	Surname
Miss	Storm	Anderson

Post	Research Assistant & PhD Student
Qualifications	MSc
Employer	University College London

Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	020 7813 1538
Fax	
Mobile	
Work Email	s.anderson.17@ucl.ac.uk

Title	Forename/Initials	Surname
Ms	Sharon	Geva

Post Qualifications	Post Doctoral Researcher
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	
Fax	
Mobile	
Work Email	s.geva@ucl.ac.uk

Title	Forename/Initials	Surname
Miss	Justyna	Ekert

Post Qualifications	PhD Student
Employer	University College London
Work Address	Institute of Neurology 12 Queen Square London
Post Code	WC1N 3AR
Telephone	
Fax	
Mobile	
Work Email	justyna.ekert.14@ucl.ac.uk

Title	Forename/Initials	Surname
Ms	Emily	Upton

Post Qualifications	Research Assistant
Employer	University College London
Work Address	Institute of Cognitive Neuroscience 17-19 Queen Square London
Post Code	WC1N 3AZ
Telephone	
Fax	
Mobile	
Work Email	emily.upton.11@ucl.ac.uk

	Title	Forename/Initials	Surname
	Miss	Danielle	Trout
Post	Research Assistant		
Qualifications			
Employer	University College London		
Work Address	Institute of Neurology		
	12 Queen Square		
	London		
Post Code	WC1N 3AR		
Telephone	020 7813 1538		
Fax			
Mobile			
Work Email	d.trout@ucl.ac.uk		

	Title	Forename/Initials	Surname
	Mr	Douglas	Neville
Post	Research Assistant		
Qualifications			
Employer	University College London		
Work Address	Institute of Neurology		
	12 Queen Square		
	London		
Post Code	WC1N 3AR		
Telephone	020 7813 1538		
Fax			
Mobile			
Work Email	douglas.neville.20@ucl.ac.uk		

	Title	Forename/Initials	Surname
	Miss	Anisha	Desai
Post	Freelancer		
Qualifications			
Employer	University College London		
Work Address	Institute of Neurology		
	12 Queen Square		
	London		
Post Code	WC1N 3AR		
Telephone	020 7813 1538		
Fax			
Mobile			
Work Email	anisha.desai@ucl.ac.uk		

	Title	Forename/Initials	Surname
	Mr	Ruben	Lourenco Pereira
Post	Freelancer		
Qualifications			
Employer	University College London		
Work Address	Institute of Neurology		
	12 Queen Square		

	London
Post Code	WC1N 3AR
Telephone	020 7813 1538
Fax	
Mobile	
Work Email	ruben.pereira@ucl.ac.uk

Title	Forename/Initials	Surname
	Daniella	Carrasco

Post	Research Assistant and Speech and Language Therapist
Qualifications	
Employer	University College London
Work Address	Institute of Neurology
	12 Queen Sqaure
	London
Post Code	WC1N 3AR
Telephone	02078131538
Fax	
Mobile	
Work Email	

Title	Forename/Initials	Surname
	Elizabeth	Farrell

Post	Research Assistant and Speech and Language Therapist
Qualifications	
Employer	University College London
Work Address	Institute of Neurology
	12 Queen Square
	London
Post Code	WC1N 3AR
Telephone	02078131538
Fax	
Mobile	
Work Email	elizabeth.farrell.22@ucl.ac.uk

Title	Forename/Initials	Surname
	Maria	Murga

Post	Postgraduate Researcher
Qualifications	
Employer	University College London
Work Address	Institute of Neurology
	12 Queen Square
	London
Post Code	WC1N 3AR
Telephone	
Fax	
Mobile	
Work Email	mbm148@pgr.aru.ac.uk

	Title	Forename/Initials	Surname
		Johanna	Hjerling
Post	Voluntary Research Assistant		
Qualifications			
Employer	University College London		
Work Address	Institute of Neurology		
	12 Queen Square		
	London		
Post Code	WC1N 3AR		
Telephone			
Fax			
Mobile			
Work Email			

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	UCLH/UCL Joint Research Office, part of the Research Directorate
Given name	Pushpsen
Family name	Joshi
Address	4th Floor, West, 250 Euston Road
Town/city	London
Post code	NW1 2PG
Country	United Kingdom
Telephone	
Fax	
E-mail	UCLH.RandD@nhs.net

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical Investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] No application for external funding will be made

What type of research project is this?

- ○ Standalone project
- ○ Project that is part of a programme grant
- ○ Project that is part of a Centre grant
- ◉ Project that is part of a fellowship/ personal award/ research training award
- ○ Other

Other – please state:

Please give details of funding applications.

Organisation	Wellcome Trust
Address	Gibbs Building 215 Euston Road London
Post Code	NW1 2BE
Telephone	02076118888
Fax	
Mobile	
Email	

Funding Application Status: ◉ Secured ○ In progress

Amount: 3,309,491

Duration
Years: 5
Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
Biomedical Science

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
		Pushpsen	Joshi
Organisation	UCLH/UCL Joint Research Office, part of the Research Directorate		
Address	4th Floor, West		
	250 Euston Road		
	London		
Post Code	NW1 2PG		
Work Email	UCLH.RandD@nhs.net		
Telephone			
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

North Thames

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 20/08/2013
Planned end date: 31/08/2027
Total duration:

Years: 14 Months: 0 Days: 12

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☐ Scotland
- ☑ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study approx 50

Does this trial involve countries outside the EU?

◉ Yes ○ No

- ☑ USA
- ☑ Other international (please specify)

UK, Canada, China, Chile, perhaps many other countries that are currently being recruited.

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- ☑ NHS organisations in England 50
- ☑ NHS organisations in Wales
- ☐ NHS organisations in Scotland
- ☐ HSC organisations in Northern Ireland
- ☐ GP practices in England
- ☐ GP practices in Wales
- ☐ GP practices in Scotland
- ☐ GP practices in Northern Ireland
- ☐ Joint health and social care agencies (eg community mental health teams)
- ☐ Local authorities
- ☐ Phase 1 trial units
- ☐ Prison establishments
- ☐ Probation areas
- ☐ Independent (private or voluntary sector) organisations
- ☑ Educational establishments 1
- ☐ Independent research units
- ☐ Other (give details)

Total UK sites in study: 51

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

(●) Yes ( ) No

A73-2. If yes, will any of these organisations be NHS organisations?

(●) Yes ( ) No

If yes, details should be given in Part C.

A73-3. Approximately how much time will these organisations expect to spend on screening records and/or provision of information to potential participants, and how will the costs of these activities be funded?

10 minutes screening patient notes
10-15 minutes providing information to potential participants
Study sites will seek NIHR reimbursement via accrual data which will reflect their contribution in terms of numbers of participants.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The management of the research will be covered by UCL insurance for negligent harm.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The management of the research will be covered by UCL insurance for negligent harm.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of

investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- [x] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [ ] Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

- (•) Yes
- ( ) No
- ( ) Not sure

A79. Please select the level of commercial participation in this project.

- (•) None
- ( ) Industry funding, but not industry sponsored
- ( ) Industry funding and industry sponsored
- ( ) Industry sponsored, but not industry funded

A80. Please select the main subject area of research. Additional sub-topics may be selected, if required

- [x] Age and Ageing
- [ ] Anaesthetics
- [ ] Cancer (includes malignant haematology
- [ ] Cardiovascular
- [x] Clinical
- [ ] Critical Care
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Dermatology
- [ ] Diabetes
- [ ] Ear, Nose and Throat
- [ ] Gastrointestinal
- [ ] Genetics
- [ ] Health Services Research
- [ ] Hepatology
- [ ] Immunology and Inflammation
- [ ] Infectious Disease and Microbiology
- [ ] Injuries and Accidents
- [ ] Medicines for Children (does not include Paediatrics)
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal (Rheumatoid Arthritis is a separate category)

- [ ] Nervous System Disorders
- [ ] Non-malignant Haematology
- [ ] Ophthalmology
- [ ] Oral and Dental
- [ ] Paediatrics (does not include Medicines for Children)
- [ ] Primary Care
- [ ] Public Health Research
- [ ] Renal
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Rheumatoid Arthritis
- [x] Stroke
- [ ] Surgery
- [ ] Urogenital

9. Has the study been the subject of a scientific review/opinion (Expert Panel)?

○ Yes ○ No

If yes, please provide a copy of the review as part of your application.

B. All research other than CTIMPs

In this sub-section, an adult means a person aged 16 or over.

B1. What impairing condition(s) will the participants have?

The study must be connected to this condition or its treatment.

All the patient participants will have had a stroke. In some cases this will impair the patient's language and cognitive skills and/or their ability to write (both cognitive and physical). It is for these participants that we may seek consent via somebody indicated by the patient - a close family member or friend.

B2. Justify the inclusion of adults unable to consent for themselves. It should be clear why the research could not be carried out as effectively if confined to adults capable of giving consent.

We are studying the effects of and recovery from brain damage to a person's language system. It is important that we include patients who, due to damage to brain areas that support language and cognition, may not be able to access all of the details of the study and/or be able to form letters and words to give informed written consent and may struggle to clearly communicate consent via other means of communication. If we do not include these patients we will be missing a subset of impaired patients. This means that the clinical tool which we are developing from the research will not be able to give clinical predictions and prognoses for these type of patients.

B3. Who in the research team will decide whether or not the participants have the capacity to give consent? What training/experience will they have to enable them to reach this decision?

Members of the PLORAS Research Team (who may be UCL students) who have had training and experience in communicating with people with aphasia and understanding of the issues around consent in this population. They will have completed Good Clinical Practice Training and the Health Research Authority (HRA) 'Research involving participants lacking mental capacity' module (or similar). They will also be familiar with the Mental Capacity Act's key principles and two stage test of capacity (2005).

Principle Investigators at study sites will be responsible for ensuring that staff consenting participants are suitably trained to take informed consent, including assessing capacity/adhering to the Mental Capacity Act (2005), establishing any advanced decisions or statements from the participant and consulting a consultee around study consent, where appropriate.

B4. Does the research have the potential to benefit participants who are unable to consent for themselves?

○ Yes ◉ No

B5. Will the research contribute to knowledge of the causes or the treatment or care of persons with the same impairing condition (or a similar condition)?

◉ Yes ○ No

If Yes, please explain how the research will achieve this:

Understanding the effects of damage in patients with a range of impairment severity and location of damage within the brain will enable us to understand recovery in these patients. This will enable future similar patients to be given prognostic information about their likely recovery. We believe that in the long term this will help with developing new therapies for these patients which can be tested against a recovery baseline developed by our research.

B6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy?

◉ Yes ○ No

If Yes, please give an assessment below. Highlight any risk, burden or discomfort specific to these participants and say what will be done to minimise it. You may refer back to your answers to Questions A22 and A23.

There is a small risk that some patients, particularly those with communication difficulties, may become fatigued and/or frustrated by the language questionnaires and assessments which focus on their area of difficulty. Steps will be taken to reduce this by (i) encouraging the patient to take regular breaks, (ii) reiterating their right to withdraw and (iii) sensitive handling by our team of researchers who are all speech and language therapists or have received training from speech and language therapist colleagues. Patients are also given the option to complete the language testing on another day if they wish to continue with the study after a period of rest.

Some participants may be invited to contribute to our related study ELORAS ("Explaining Language Outcome and Recovery After Stroke") which involves having a functional MRI brain scan. This would be the case for participants who have damage to particular brain regions that are known to be important for language processing. The particular risks and benefits for this are covered in the information for that study (REC ref: 19/LO/1755, IRAS ID: 265430).

Questions B7 and B8 apply to any participants recruited in England and Wales.

B7. What arrangements will be made to identify and consult persons able to advise on the presumed wishes and feelings of participants unable to consent for themselves and on their inclusion in the research?

Researchers will aim to identify a "personal consultee". This is someone who (i) has a role in caring for a participant who lacks capacity or (ii) is interest in the participant's welfare. Typically, a personal consultee is a family member or friend who does not have financial benefit and is not acting in a professional role. If no personal consultee is available or willing, the researcher may approach a nominated consultee. Where possible participants will be asked who they would like to be consulted about their participation in the research. This may include family members or friends or an advocate.

Please enclose a copy of the written information to be provided to consultees. This should describe their role under section 32 of the Mental Capacity Act and provide information about the research similar to that which might be given to participants able to consent for themselves.

B8. Is it possible that a participant requiring urgent treatment might need to be recruited into research before it is possible to identify and consult a person under B7?

○ Yes ◉ No

If Yes, say whether arrangements will be made instead to seek agreement from a registered medical practitioner and outline these arrangements. Or, if this is also not feasible, outline how decisions will be made on the inclusion of participants and what arrangements will be made to seek consent from the participant (if capacity has been recovered) or advice from a consultee as soon as practicable thereafter.

B9. What arrangements will be made to continue to consult such persons during the course of the research where necessary?

N/A

B10. What steps will you take, if appropriate, to provide participants who are unable to consent for themselves with information about the research, and to consider their wishes and feelings?

We will provide an accessible information booklet and seek involvement of a personal consultee where appropriate who can advise on what the participant's wishes and feelings would be (if they were able to communicate consent for themselves).

Our language measures and assessments will be administered by members of the PLORAS team who have had training and experience in communicating with people with aphasia and understanding of the issues around consent in this population. They may use other means of non-verbal communication such as gesture and drawing where appropriate. We have also purchased some communication support materials from Speakability (an aphasia charity) to use with participants.

B11. Is it possible that the capacity of participants could fluctuate during the research? How would this be handled?

As this is a long-term study (at least 5 further years) it is likely that some participants will lose capacity to consent before the end of the study. Due to the large number of participants it will not be feasible to monitor capacity to consent however if information is brought to our attention e.g. via contact with the participant or from a medical professional on their behalf we will not request any further data from the participant. We will continue to use their anonymised data in the research, given that the data were collected with informed consent.

B12-1. What will be the criteria for withdrawal of participants?

Any verbal or non-verbal indication that the patient wishes to be withdrawn. They may also be withdrawn at the request of a family member/close friend acting as a consultee or by a medical professional involved in their direct care.

B13. Describe what steps will be taken to ensure that nothing is done to which participants appear to object (unless it is to protect them from harm or minimise pain or discomfort).

Participants will be closely monitored for any verbal or non-verbal indication that they object to procedures at any stage. Research activities discontinue with any indication that participants are uncomfortable.

B14. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant?

The consultee will be asked whether the procedures of the study are in conflict with any advance decisions or statements by the participant.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site	Investigator Name
IN1 ☐	◉ NHS/HSC Site ○ Non-NHS/HSC Site Country: England	Forename: Syed Middle name: Family name: Haider Email: syedhaider1@nhs.net Qualification (MD...): Dr Country: United Kingdom

Organisation name	COUNTESS OF CHESTER HOSPITAL NHS FOUNDATION TRUST
Address	THE COUNTESS OF CHESTER HEALTH PARK
	CHESTER
	CHESHIRE
Post Code	CH2 1UL
Institution name	COUNTESS OF CHESTER HOSPITAL NHS FOUNDATION TRUST
Department name	
Street address	THE COUNTESS OF CHESTER HEALTH PARK
Town/city	
Post Code	CH2 1UL

Participant Identification Centres

PIC Type	Centre	Individual(s)

IN4 ☐	◉ NHS/HSC Site ○ Non-NHS/HSC Site Country: England	Forename: Narayanamoorthi Middle name: Family name: Saravanan Email: Narayanamoorthi.Saravanan@nca.nhs.uk Qualification (MD...):

Country	United Kingdom
Organisation name	NORTHERN CARE ALLIANCE NHS FOUNDATION TRUST
Address	SALFORD ROYAL STOTT LANE SALFORD GREATER MANCHESTER
Post Code	M6 8HD

Institution name	NORTHERN CARE ALLIANCE NHS FOUNDATION TRUST
Department name	
Street address	SALFORD ROYAL
Town/city	STOTT LANE
Post Code	M6 8HD

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN7 ☐

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Jane
Middle name	
Family name	Sword
Email	j.sword@nhs.net
Qualification (MD...)	
Country	United Kingdom

Organisation name	ROYAL DEVON UNIVERSITY HEALTHCARE NHS FOUNDATION TRUST
Address	ROYAL DEVON UNIVERSITY NHS FT BARRACK ROAD EXETER
Post Code	EX2 5DW

	ROYAL DEVON UNIVERSITY

Institution name	HEALTHCARE NHS FOUNDATION TRUST
Department name	
Street address	ROYAL DEVON UNIVERSITY NHS FT
Town/city	BARRACK ROAD
Post Code	EX2 5DW

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN8 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Forename	Louise
Middle name	
Family name	Shaw
Email	Louisej.shaw@nhs.net
Qualification (MD...)	
Country	United Kingdom

Organisation name	ROYAL UNITED HOSPITAL BATH NHS TRUST
Address	COMBE PARK
	BATH AVON
Post Code	BA1 3NG

Institution name	ROYAL UNITED HOSPITAL BATH NHS TRUST
Department name	
Street address	COMBE PARK
Town/city	
Post Code	BA1 3NG

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN10 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Organisation name	PLYMOUTH HOSPITALS NHS TRUST
Address	DERRIFORD HOSPITAL DERRIFORD ROAD PLYMOUTH DEVON
Post Code	PL6 8DH

Forename	Azlisham
Middle name	
Family name	Mohd Nor
Email	a.mohdnor@nhs.net
Qualification (MD...)	
Country	United Kingdom

Institution name	PLYMOUTH HOSPITALS NHS TRUST
Department name	
Street address	DERRIFORD HOSPITAL
Town/city	DERRIFORD ROAD
Post Code	PL6 8DH

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN17 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Organisation name	THE ROYAL WOLVERHAMPTON HOSPITALS NHS TRUST
Address	NEW CROSS HOSPITAL WOLVERHAMPTON ROAD

Forename	Nasar
Middle name	
Family name	Ahmad
Email	ahmad.nasar@nhs.net
Qualification (MD...)	Dr
Country	United Kingdom

	HEATH TOWN WOLVERHAMPTON WEST MIDLANDS
Post Code	WV10 0QP

Institution name	THE ROYAL WOLVERHAMPTON HOSPITALS NHS TRUST
Department name	
Street address	NEW CROSS HOSPITAL
Town/city	WOLVERHAMPTON ROAD
Post Code	WV10 0QP

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN19 ☐

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Robert
Middle name	
Family name	Luder
Email	r.luder@nhs.net
Qualification (MD...)	
Country	United Kingdom

Organisation name	NORTH MIDDLESEX UNIVERSITY HOSPITAL NHS TRUST
Address	STERLING WAY
	LONDON GREATER LONDON
Post Code	N18 1QX

Institution name	NORTH MIDDLESEX UNIVERSITY HOSPITAL NHS TRUST
Department name	
Street address	STERLING WAY
Town/city	

Post Code N18 1QX

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN28 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Forename	Alex
Middle name	
Family name	Leff
Email	a.leff@ucl.ac.uk
Qualification (MD...)	
Country	United Kingdom

Organisation name	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST
Address	250 EUSTON ROAD
	LONDON
	GREATER LONDON
Post Code	NW1 2PG

Institution name	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST
Department name	
Street address	250 EUSTON ROAD
Town/city	
Post Code	NW1 2PG

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN34 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Organisation name	UNIVERSITY HOSPITALS DORSET NHS FOUNDATION TRUST
Address	MANAGEMENT OFFICES POOLE HOSPITAL LONGFLEET ROAD POOLE
Post Code	BH15 2JB

Forename	Suzanne
Middle name	
Family name	Ragab
Email	Suzanne.ragab@poole.nhs.uk
Qualification (MD...)	
Country	United Kingdom

Institution name	UNIVERSITY HOSPITALS DORSET NHS FOUNDATION TRUST
Department name	
Street address	MANAGEMENT OFFICES
Town/city	POOLE HOSPITAL
Post Code	BH15 2JB

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN36 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Organisation name	BARKING, HAVERING AND REDBRIDGE UNIVERSITY HOSPITALS NHS TRUST

Forename	Grace
Middle name	
Family name	Fawehinmi
Email	grace.fawehinmi@nhs.net
Qualification (MD...)	
Country	United Kingdom

Address	QUEENS HOSPITAL ROM VALLEY WAY ROMFORD ESSEX
Post Code	RM7 0AG

Institution name	BARKING, HAVERING AND REDBRIDGE UNIVERSITY HOSPITALS NHS TRUST
Department name	
Street address	QUEENS HOSPITAL
Town/city	ROM VALLEY WAY
Post Code	RM7 0AG

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN43 ☐

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Emma
Middle name	
Family name	Richards
Email	emma.richards34@nhs.net
Qualification (MD...)	
Country	United Kingdom

Organisation name	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST
Address	NORTHERN GENERAL HOSPITAL HERRIES ROAD SHEFFIELD SOUTH YORKSHIRE
Post Code	S5 7AU

Institution name	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION

	TRUST
Department name	
Street address	NORTHERN GENERAL HOSPITAL
Town/city	HERRIES ROAD
Post Code	S5 7AU

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN52 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Forename	Thomas
Middle name	
Family name	Harrison
Email	Thomas.Harrison@bartshealth.nhs.uk
Qualification (MD...)	
Country	United Kingdom

Organisation name	BARTS HEALTH NHS TRUST
Address	THE ROYAL LONDON HOSPITAL 80 NEWARK STREET LONDON
Post Code	E1 2ES

Institution name	BARTS HEALTH NHS TRUST
Department name	
Street address	THE ROYAL LONDON HOSPITAL
Town/city	80 NEWARK STREET
Post Code	E1 2ES

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN53 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Organisation name	EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST
Address	ST HELIER HOSPITAL WRYTHE LANE CARSHALTON SURREY
Post Code	SM5 1AA

Forename	Reena
Middle name	
Family name	Dhami
Email	r.dhami@nhs.net
Qualification (MD...)	
Country	United Kingdom

Institution name	EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST
Department name	
Street address	ST HELIER HOSPITAL
Town/city	WRYTHE LANE
Post Code	SM5 1AA

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN54 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Organisation name	CROYDON HEALTH SERVICES NHS TRUST
Address	MAYDAY UNIVERSITY HOSPITAL

Forename	Enas
Middle name	
Family name	Lawrence
Email	enaslawrence@nhs.net
Qualification (MD...)	
Country	United Kingdom

	LONDON ROAD
	THORNTON HEATH SURREY
Post Code	CR7 7YE

Institution name	CROYDON HEALTH SERVICES NHS TRUST
Department name	
Street address	MAYDAY UNIVERSITY HOSPITAL
Town/city	LONDON ROAD
Post Code	CR7 7YE

Participant Identification Centres

PIC Type	Centre	Individual(s)
(●) NHS (England)		
( ) NHS (outside England)		E-mail:
( ) Non-NHS		

IN56 ☐

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Laszlo
Middle name	
Family name	Sztriha
Email	laszlo.sztriha@nhs.net
Qualification (MD...)	
Country	United Kingdom

Organisation name	KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST
Address	DENMARK HILL
	LONDON GREATER LONDON
Post Code	SE5 9RS

Institution name	KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST
Department name	
Street address	DENMARK HILL
Town/city	
Post Code	SE5 9RS

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN66 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Organisation name	ST GEORGE'S HEALTHCARE NHS TRUST
Address	ST GEORGE'S HOSPITAL BLACKSHAW ROAD TOOTING LONDON GREATER LONDON
Post Code	SW17 0QT

Forename	Gillian
Middle name	
Family name	Cluckie
Email	Gillian.cluckie@stgeorges.nhs.uk
Qualification (MD...)	
Country	United Kingdom

Institution name	ST GEORGE'S HEALTHCARE NHS TRUST
Department name	
Street address	ST GEORGE'S HOSPITAL
Town/city	BLACKSHAW ROAD
Post Code	SW17 0QT

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN67 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Jonathan
Middle name	
Family name	Birns

Country: England

Organisation name	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST
Address	TRUST OFFICES GUY'S HOSPITAL GREAT MAZE POND LONDON GREATER LONDON
Post Code	SE1 9RT

Email	Jonathan.Birns@gstt.nhs.uk
Qualification (MD...)	Dr
Country	United Kingdom

Institution name	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST
Department name	
Street address	TRUST OFFICES
Town/city	GUY'S HOSPITAL
Post Code	SE1 9RT

Participant Identification Centres

PIC Type	Centre	Individual(s)
(●) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN69 ☐

( ) NHS/HSC Site
(●) Non-NHS/HSC Site

Forename	Cathy
Middle name	
Family name	Price
Email	c.j.price@ucl.ac.uk
Qualification (MD...)	
Country	United Kingdom

Institution name	University College London/Institute of Neurology
Department name	Imaging Neuroscience
Street address	12 Queen Square
Town/city	London
Post Code	WC1N 3AR

Institution name	University College London/Institute of Neurology
Department name	Imaging Neuroscience
Street address	12 Queen Square

Town/city London
Post Code WC1N 3AR
Country United Kingdom

Participant Identification Centres

PIC Type	Centre	Individual(s)
○ NHS (England) ○ NHS (outside England) ◉ Non-NHS		E-mail:

IN70 ☐

◯ NHS/HSC Site
◉ Non-NHS/HSC Site

Forename Cathy
Middle name
Family name Price
Email c.j.price@ucl.ac.uk
Qualification (MD...)
Country United Kingdom

Institution name University College London
Department name Birkbeck UCL Centre for Neuroimaging
Street address 26 Bedford Way
Town/city London
Post Code WC1H 0AP

Institution name University College London
Department name Birkbeck UCL Centre for Neuroimaging
Street address 26 Bedford Way
Town/city London
Post Code WC1H 0AP
Country United Kingdom

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN76 ☐

◉ NHS/HSC Site
◯ Non-NHS/HSC Site

Forename Shahid
Middle name Kausar
Family name
Email shahid.kausar@dgh.nhs.uk
Qualification (MD...) Dr
Country United Kingdom

Country: England

THE DUDLEY

Organisation name	GROUP OF HOSPITALS NHS FOUNDATION TRUST
Address	C BLOCK RUSSELLS HALL HOSPITAL PENSNETT ROAD DUDLEY WEST MIDLANDS
Post Code	DY1 2HQ

Institution name	THE DUDLEY GROUP OF HOSPITALS NHS FOUNDATION TRUST
Department name	
Street address	C BLOCK
Town/city	RUSSELLS HALL HOSPITAL
Post Code	DY1 2HQ

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN81 ☐

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Thomas
Middle name	
Family name	Harrison
Email	thomas.harrison1@nhs.net
Qualification (MD...)	Dr
Country	United Kingdom

Organisation name	HOMERTON UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
Address	HOMERTON ROW LONDON GREATER LONDON
Post Code	E9 6SR

	HOMERTON

Institution name	UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
Department name	
Street address	HOMERTON ROW
Town/city	
Post Code	E9 6SR

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN83 ☐

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Peter
Middle name	
Family name	Anderton
Email	peter.anderton@dbh.nhs.uk
Qualification (MD...)	DR
Country	United Kingdom

Organisation name	DONCASTER AND BASSETLAW HOSPITALS NHS FOUNDATION TRUST
Address	DONCASTER ROYAL INFIRMARY ARMTHORPE ROAD DONCASTER SOUTH YORKSHIRE
Post Code	DN2 5LT

Institution name	DONCASTER AND BASSETLAW HOSPITALS NHS FOUNDATION TRUST
Department name	
Street address	DONCASTER ROYAL INFIRMARY
Town/city	ARMTHORPE ROAD
Post Code	DN2 5LT

Participant Identification Centres

PIC Type	Centre	Individual(s)

◉ NHS (England) ◯ NHS (outside England) ◯ Non-NHS		E-mail:

IN85 ☐

◉ NHS/HSC Site
◯ Non-NHS/HSC Site

Country: England

Forename	Imran
Middle name	
Family name	Ashraf
Email	imran.ashraf@dvh.nhs.uk
Qualification (MD...)	Dr
Country	United Kingdom

Organisation name	DARTFORD AND GRAVESHAM NHS TRUST
Address	DARENT VALLEY HOSPITAL DARENTH WOOD ROAD DARTFORD KENT
Post Code	DA2 8DA

Institution name	DARTFORD AND GRAVESHAM NHS TRUST
Department name	
Street address	DARENT VALLEY HOSPITAL
Town/city	DARENTH WOOD ROAD
Post Code	DA2 8DA

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ◯ NHS (outside England) ◯ Non-NHS		E-mail:

IN94 ☐

◉ NHS/HSC Site
◯ Non-NHS/HSC Site

Country: England

Forename	Khalid
Middle name	
Family name	Rashed
Email	Khalid.rashed@ydh.nhs.uk
Qualification (MD...)	Dr
Country	United Kingdom

Organisation name	SOMERSET NHS FOUNDATION TRUST

Address	TRUST MANAGEMENT LYDEARD HOUSE MUSGROVE PARK HOSPITAL TAUNTON
Post Code	TA1 5DA

Institution name	SOMERSET NHS FOUNDATION TRUST
Department name	
Street address	TRUST MANAGEMENT
Town/city	LYDEARD HOUSE
Post Code	TA1 5DA

Participant Identification Centres

PIC Type	Centre	Individual(s)
(●) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN95 ☐

( ) NHS/HSC Site
(●) Non-NHS/HSC Site

Forename	Matthew
Middle name	
Family name	Lambon-Ralph
Email	matt.lambon-ralph@manchester.ac.uk
Qualification (MD...)	PhD, Professor
Country	United Kingdom

Institution name	University of Manchester
Department name	School of Psychological Sciences
Street address	
Town/city	Manchester
Post Code	

Institution name	University of Manchester
Department name	School of Psychological Sciences
Street address	
Town/city	Manchester
Post Code	
Country	

Participant Identification Centres

PIC Type	Centre	Individual(s)

	○ NHS (England) ○ NHS (outside England) ◉ Non-NHS		E-mail:

IN96 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Forename	Carinna
Middle name	
Family name	Vickers
Email	carinna.vickers@somersetft.nhs.uk
Qualification (MD...)	
Country	United Kingdom

Organisation name	SOMERSET NHS FOUNDATION TRUST
Address	TRUST MANAGEMENT LYDEARD HOUSE MUSGROVE PARK HOSPITAL TAUNTON
Post Code	TA1 5DA

Institution name	SOMERSET NHS FOUNDATION TRUST
Department name	
Street address	TRUST MANAGEMENT
Town/city	LYDEARD HOUSE
Post Code	TA1 5DA

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN99 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Forename	Chris
Middle name	
Family name	Patterson
Email	chris.patterson1@nhs.net
Qualification (MD...)	Dr
Country	United Kingdom

Organisation name	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST

Address	BRADFORD ROYAL INFIRMARY DUCKWORTH LANE BRADFORD WEST YORKSHIRE
Post Code	BD9 6RJ

Institution name	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST
Department name	
Street address	BRADFORD ROYAL INFIRMARY
Town/city	DUCKWORTH LANE
Post Code	BD9 6RJ

Participant Identification Centres

PIC Type	Centre	Individual(s)
(●) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN101 ☐

(●) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Udayaraj
Middle name	
Family name	Umasankar
Email	udayaraj.umasankar@nhs.net
Qualification (MD...)	Dr
Country	United Kingdom

Organisation name	LEWISHAM AND GREENWICH NHS TRUST
Address	UNIVERSITY HOSPITAL LEWISHAM LEWISHAM HIGH STREET LONDON
Post Code	SE13 6LH

Institution name	LEWISHAM AND GREENWICH NHS TRUST
Department name	

Street address	UNIVERSITY HOSPITAL LEWISHAM
Town/city	LEWISHAM HIGH STREET
Post Code	SE13 6LH

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN110 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Forename	Branimir
Middle name	
Family name	Nevajda
Email	branimir.nevajda@btuh.nhs.uk
Qualification (MD...)	Dr
Country	United Kingdom

Organisation name	MID AND SOUTH ESSEX NHS FOUNDATION TRUST
Address	PRITTLEWELL CHASE
	WESTCLIFF-ON-SEA
Post Code	SS0 0RY

Institution name	MID AND SOUTH ESSEX NHS FOUNDATION TRUST
Department name	
Street address	PRITTLEWELL CHASE
Town/city	
Post Code	SS0 0RY

Participant Identification Centres

PIC Type	Centre	Individual(s)

IN111 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Forename	Helen
Middle name	
Family name	Day
Email	helen.day3@nhs.net
Qualification	

(MD...)

Country United Kingdom

Organisation name	MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST
Address	MAIDSTONE HOSPITAL HERMITAGE LANE MAIDSTONE KENT
Post Code	ME16 9QQ

Institution name	MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST
Department name	
Street address	MAIDSTONE HOSPITAL
Town/city	HERMITAGE LANE
Post Code	ME16 9QQ

Participant Identification Centres

PIC Type	Centre	Individual(s)

IN113 ☐

◯ NHS/HSC Site

◉ Non-NHS/HSC Site

Forename Rebecca

Middle name

Family name Palmer

Email r.l.palmer@sheffield.ac.uk

Qualification (MD...)

Country United Kingdom

Institution name	University of Sheffield
Department name	School of Health and Related Research
Street address	The Innovation Centre, 217 Portobello
Town/city	Sheffield
Post Code	S1 4DP

Institution name	University of Sheffield
Department name	School of Health and Related Research
Street address	The Innovation Centre, 217 Portobello
Town/city	Sheffield
Post Code	S1 4DP
Country	United Kingdom

Participant Identification Centres

PIC Type	Centre	Individual(s)
○ NHS (England) ○ NHS (outside England) ◉ Non-NHS		E-mail:

IN115 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Forename	Kiruba
Middle name	
Family name	Nagaratnam
Email	Kirubananthan.Nagaratnam@royalberkshire.nhs.uk
Qualification (MD...)	Dr
Country	United Kingdom

Organisation name	ROYAL BERKSHIRE NHS FOUNDATION TRUST
Address	ROYAL BERKSHIRE HOSPITAL LONDON ROAD READING
Post Code	RG1 5AN

Institution name	ROYAL BERKSHIRE NHS FOUNDATION TRUST
Department name	STROKE UNIT (LEVEL 1, BATTLE BLOCK)
Street address	ROYAL BERKSHIRE HOSPITAL
Town/city	LONDON ROAD
Post Code	RG1 5AN

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN116 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Sally
Middle name	
Family name	Hunt

Country: England

Email	sally.hunt4@nhs.net
Qualification (MD...)	
Country	United Kingdom

Organisation name	LIVEWELL S/W
Address	LOCAL CARE CENTRE MOUNT GOULD HOSPITAL PLYMOUTH
Post Code	PL4 7PY

Institution name	LIVEWELL S/W
Department name	Mount Gould Hospital (1st Floor, Beauchamp Centre)
Street address	LOCAL CARE CENTRE
Town/city	MOUNT GOULD HOSPITAL
Post Code	PL4 7PY

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN125 ☐

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Dawn
Middle name	
Family name	Lamb
Email	dawn.lamb@ncic.nhs.uk
Qualification (MD...)	
Country	

Organisation name	NORTH CUMBRIA INTEGRATED CARE NHS FOUNDATION TRUST
Address	PILLARS BUILDING CUMBERLAND INFIRMARY INFIRMARY STREET CARLISLE
Post Code	CA2 7HY

Institution name	NORTH CUMBRIA INTEGRATED CARE NHS FOUNDATION TRUST
Department name	
Street address	PILLARS BUILDING
Town/city	CUMBERLAND INFIRMARY
Post Code	CA2 7HY

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN126 ☐

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Sarah
Middle name	
Family name	Whitehouse
Email	sarah.whitehouse5@nhs.net
Qualification (MD...)	
Country	

Organisation name	NORTH TEES AND HARTLEPOOL NHS FOUNDATION TRUST
Address	UNIVERSITY HOSPITAL OF HARTLEPOOL HOLDFORTH ROAD HARTLEPOOL
Post Code	TS24 9AH

Institution name	NORTH TEES AND HARTLEPOOL NHS FOUNDATION TRUST
Department name	
Street address	UNIVERSITY HOSPITAL OF HARTLEPOOL
Town/city	HOLDFORTH ROAD
Post Code	TS24 9AH

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN129 ☐

○ NHS/HSC Site
◉ Non-NHS/HSC Site

Forename	Andrea
Middle name	
Family name	Dennis
Email	andrea.dennis@nhs.net
Qualification (MD...)	
Country	

Institution name	Medway Community Healthcare
Department name	
Street address	MCH House, Gillingham Business Park,
Town/city	Gillingham, Kent
Post Code	ME8 0PZ

Institution name	Medway Community Healthcare
Department name	
Street address	MCH House, Gillingham Business Park,
Town/city	Gillingham, Kent
Post Code	ME8 0PZ
Country	United Kingdom

Participant Identification Centres

PIC Type	Centre	Individual(s)
◉ NHS (England) ○ NHS (outside England) ○ Non-NHS		E-mail:

IN130 ☐

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Country: England

Forename	George
Middle name	
Family name	Thomas
Email	george.thomas2@nhs.net
Qualification (MD...)	Dr
Country	

Organisation name	SOUTH TEES HOSPITALS NHS FOUNDATION TRUST
Address	JAMES COOK UNIVERSITY

	HOSPITAL
	MARTON ROAD
	MIDDLESBROUGH
Post Code	TS4 3BW

Institution name	SOUTH TEES HOSPITALS NHS FOUNDATION TRUST
Department name	STRIVE - Academic Centre
Street address	JAMES COOK UNIVERSITY HOSPITAL
Town/city	MARTON ROAD
Post Code	TS4 3BW

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN131 ☐

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Rachel
Middle name	
Family name	Glover
Email	
Qualification (MD...)	
Country	

Organisation name	NORTH CUMBRIA INTEGRATED CARE NHS FOUNDATION TRUST
Address	PILLARS BUILDING
	CUMBERLAND INFIRMARY
	INFIRMARY STREET CARLISLE
Post Code	CA2 7HY

Institution name	NORTH CUMBRIA INTEGRATED CARE NHS FOUNDATION TRUST
Department name	

Street address	PILLARS BUILDING
Town/city	CUMBERLAND INFIRMARY
Post Code	CA2 7HY

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail:

IN134 ☐

(•) NHS/HSC Site
( ) Non-NHS/HSC Site

Country: England

Forename	Sarah
Middle name	
Family name	Thompson
Email	sarah.thompson36@nhs.net
Qualification (MD...)	Principal Speech and Language Therapist
Country	

Organisation name	KINGSTON HOSPITAL NHS FOUNDATION TRUST
Address	GALSWORTHY ROAD KINGSTON UPON THAMES KINGSTON UPON THAMES
Post Code	KT2 7QB

Institution name	KINGSTON HOSPITAL NHS FOUNDATION TRUST
Department name	
Street address	GALSWORTHY ROAD
Town/city	KINGSTON UPON THAMES
Post Code	KT2 7QB

Participant Identification Centres

PIC Type	Centre	Individual(s)
(•) NHS (England) ( ) NHS (outside England) ( ) Non-NHS		E-mail: