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Brain-based predictors of the ability to learn a new skill in stroke

Submission date
07/06/2016

Recruitment status
No longer recruiting

Registration date
16/06/2016

Overall study status
Completed

Last Edited
07/05/2021

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off. Around 80% of strokes are ischemic strokes, in which the arteries that supply the brain with oxygen become narrowed or blocked, causing severely reduced blood flow (ischemia). This can lead to serious complications, depending on which part of the brain is deprived of oxygen and for how long. One of the most common complications of stroke is impaired movement in the arms or legs, caused by lack of oxygen to the area of the brain which controls movement. This study aims to analyse the brain's electric activity during the motor (movement) learning process, in order to find out if the brain activity of stroke patients during learning to perform a movement would be different from healthy people of the same age.

Who can participate?
Right-handed adults who had a stroke which affects their arm function, and healthy right-handed adults of the same age (preferably from the stroke patient’s close social circle).

What does the study involve?
Current as of 07/09/2017:
All participants attend three study visits. The first study involves an assessment of hand function through a simple movement tests rated on a scale. On the second study visit, participant’s brain skills are tested, which involves undergoing a number of puzzle-solving, memory and recall tasks. For the stroke patients, if an MRI scan of their brain is available, this is reviewed in order to look at the characteristics of the damage caused by the stroke. In the final study visit, the participant’s movement skills are further assessed. This involves being connected to to an EEG machine (which records the brain’s electrical activity) while completing 96 reaching movements, then another 96 with a robot adding force against the movement and then 96 without any force applied.

Previous:
All participants attend four study visits. The first study visit takes place soon after stroke, while the patient is still on the stroke ward. This involves an assessment of hand function through a questionnaire and simple movement tests rated on a scale. For the stroke patients, if an MRI scan of their brain is available, this is reviewed in order to look at the characteristics of the

damage caused by the stroke. On the second study, which takes place a month later, participants have their hand function measured again. On the third study visit (one month after stroke), participant's brain skills are tested, which involves undergoing a number of puzzle-solving, memory and recall tasks. In the final study visit (one month after stroke), participants movement skills are further assessed. This involves being hooked up to an EEG machine (which records the brain's electrical activity) while completing 96 reaching movements, then another 96 with a robot adding force against the movement and then 96 without any force applied.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Queens Hospital, Romford (UK)

When is the study starting and how long is it expected to run for?
October 2015 to October 2018

Who is funding the study?
University of East London (UK)

Who is the main contact?
Ms Adela Desowska
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
EXPT3

Study information

Scientific Title
Are there brain-based predictors of the ability to learn a new skill in healthy ageing and are they altered by having a stroke?

Study objectives
Primary hypothesis:
Well recovered stroke patients show the ability to learn new movements with success.

Secondary hypothesis:
Well recovered stroke patients show a different pattern of brain activation than age matched controls while performing the same motor adaptation task.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London-Harrow REC, 09/02/2017, IRAS 195798, ref: 16/LO/1975

Study design
Single-centre case-control study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Stroke

Interventions
Current interventions as of 07/09/2017:
22 patients who have had their first-ever stroke, affecting initially their right hand function and 22 age-matched controls attend four study visits.

Visit 1:
On the first study visit, all participants undergo an initial hand function assessment in the stroke follow-up clinic. This involves the following test:
1. Fugl-Meyer Assessment – Upper extremity: The Fugl-Meyer assessment is a scale of motor function impairment designed for post-stroke hemiplegic patients. The maximum score is 100 points, with 66 points dedicated to upper limb function assessment - achieved when the participants function is not affected. The participant's task is to perform specific movements of the upper and lower arm and hand. The movements and reflexes are rated on a 3 point scale. We will only use the upper extremity assessment which takes approximately 30 minutes depending on the level of residual arm function (thus a score of 66 corresponds to full recovery of arm function).

Visit 2:
On the second study visit, participants complete a battery of neuropsychological tests. This involves:
1. Oxford Cognitive Screen - A rapid cognitive screen that was designed specifically for the stroke population. It reports scores in different cognitive domains, screening also for aphasia and visual neglect.
2. California Verbal Learning Test – Revised: Each participant is asked to learn a 16-item shopping list
3. Brief Fatigue Inventory (BFI): A five minute questionnaire designed to assess the severity of fatigue in the last 24 hours and the impact that it has on the daily functioning in 6 items.

Visit 3:
On the final study visit, participants have their motor function and motor adaption tested. This involves:
Measuring the motor abilities of each participant in order to differentiate the effects of learning, motor function and motor learning during the data analysis. The motor function of the participants will be tested in the following tasks:
1. Robot-mediated evaluation test: This test engages upper arm and forearm muscles. It will be administered using the same robotic manipulandum at the end of the motor adaptation procedure. The tests take approximately 12-15 mins to complete.
2. Grip force measure and pinch force measure will be measured using a dynamometer and pinchmeter– electronic sensors attached to the same amplifier as the EMG electrodes (Biometrics Co Ltd UK). The participant's task would be to squeeze the dynamometer or the pinchmeter as hard as they can for three seconds following one practice trial. The test will be administered to both dominant and non-dominant hand.
3. Finally, motor adaptation is tested. This is done while the participant is undergoing an EEG and complete tasks with a robotic arm. On a video screen in front of the robot, the participant can see a circle with a centre point and 8 peripheral points. The position of the robotic arm is shown on the screen as a circular cursor point. The central point is the starting position at each trial. The task of the participant is to move the cursor towards a lit-up point at a certain time after the point is lit. The participants receive feedback whether their movement was early, late or on time. Whilst a movement is performed, the robot can impose a force field disturbance to the movement of the participant.

Previous interventions:
21 patients who have had their first-ever stroke, affecting initially their right hand function and 21 age-matched controls attend four study visits.

Visit 1:
On the first study visit, all participants undergo an initial hand function assessment on stroke ward. This involves the following two tests:
1. Fugl-Meyer Assessment – Upper extremity: The Fugl-Meyer assessment is a scale of motor function impairment designed for post-stroke hemiplegic patients. The maximum score is 100 points, with 66 points dedicated to upper limb function assessment - achieved when the participants function is not affected. The participant's task is to perform specific movements of the upper and lower arm and hand. The movements and reflexes are rated on a 3 point scale. We will only use the upper extremity assessment which takes approximately 30 minutes depending on the level of residual arm function (thus a score of 66 corresponds to full recovery of arm function).
2. DASH (Disabilites of the Arm, Shoulder, and Hand test, Hudak et al., 1996): This is a self-reported hand and arm function questionnaire, focusing on assessing the ability to perform everyday life actions.

If there are clinical MRI available in the hospital archive, the participants are asked for consent to use them to record lesion characteristics.

Visit 2:
Approximately one month post stroke, the patients are contacted by telephone and the DASH hand function measure is administered once again to assess recovery. If the hand function is recovered, the participants are invited to take part in Visit 3 and 4. If not, they are contacted again by telephone approximately 6 months after stroke.

Visit 3:
On the third study visit, participants complete a battery of neuropsychological tests. This involves:
1. Graded Naming Test: In which the participant's task is to name the pictures presented by the experimenter
2. Bells test: The participant is required to circle all bell signs that are presented among other symbols
3. Montreal Cognitive Assessment: A 10 minute assessment in which the participant solves 11 cognitive tasks assessing his attention, memory, visual skills, naming, verbal fluency and orientation. It is administered in 10 minutes
4. California Verbal Learning Test – Revised: Each participant is asked to learn a 16-item shopping list

Visit 4:
On the final study visit, participants have their motor function and motor adaption tested. This involves:
1. Brief Fatigue Inventory (BFI): A five minute questionnaire designed to assess the severity of fatigue in the last 24 hours and the impact that it has on the daily functioning in 6 items. Following this, the motor abilities of each participant are also measured in order to differentiate the effects of learning, motor function and motor learning during the data analysis. The motor function of the participants will be tested in four tasks:
2. Robot-mediated evaluation test: This test engages upper arm and forearm muscles. It will be administered using the same robotic manipulandum in the end of the motor adaptation procedure. The tests take approximately 12-15 mins to complete.
3. Grip force measure and pinch force measure will be measured using a dynamometer and pinchmeter– electronic sensors attached to the same amplifier as the EMG electrodes (Biometrics Co Ltd UK). The participant's task would be to squeeze the dynamometer or the pinchmeter as hard as they can for three seconds following one practice trial. The test will be administered to both dominant and non-dominant hand.
4. Finally, motor adaptation is tested. This is done while the participant is undergoing an EEG and complete tasks with a robotic arm. On the screen of the robot, the participant can see a circle with a centre point and 8 peripheral points. The position of the robotic arm is shown on the screen as a circular cursor point. The central point is the starting position at each trial. The task of the participant is to move the cursor towards a lit-up point at a certain time after the point is lit. The participants receive feedback whether their movement was early, late or on time. Whilst a movement is performed, the robot can impose a force field disturbance to the movement of the participant.

Intervention Type
Behavioural

Primary outcome(s)

Current primary outcome measures:
Neural correlates of motor adaptation are measured using EEG recording during the motor adaptation task on the third study visit.

Previous primary outcome measures:
Neural correlates of motor adaptation are measured using EEG recording during the motor adaptation task on the fourth study visit.

Key secondary outcome(s))

Current secondary outcome measures as of 07/09/2017:
1. Motor adaptation is measured using robot's kinematic recording during the motor adaptation task on the third study visit
2. Motor adaptation is measured using EMG recording during the motor adaptation task on the third study visit
3. Motor function is measured using :
3.1. The robot-mediated evaluation test on the third study visit
3.2. A dynamometer on the third study visit
3.3. A pinchmeter on the third study visit
3.4. The Fugl-Meyer assessment on the first and second study visit
4. Verbal learning is measured by CVLT on the second study visit
5. Lesion size is measured using a clinical MRI scan, if available and this measure doeas not involve any additional study visits

Screening measures:
1. Fatigue is screened using the Oxford Cognitive Screen on the second study visit
2. Aphasia is screened using the Oxford Cognitive Screen on the second study visit
3. Visual neglect is screened using the Bells test on the second study visit

Previous secondary outcome measures:
1. Motor adaptation is measured using robot's kinematic recording during the motor adaptation task on the fourth study visit
2. Motor adaptation is measured using EMG recording during the motor adaptation task on the fourth study visit
3. Motor function is measured using :
3.1. The robot-mediated evaluation test on the fourth study visit
3.2. A dynamometer on the fourth study visit
3.3. A pinchmeter on the fourth study visit
3.4. The Fugl-Meyer assessment on the first and third study visit
3.5. The DASH assessment on the first and second study visit
4. Verbal learning is measured by CVLT on the third study visit
5. Lesion size is measured using a clinical MRI scan, if available and this measure doeas not involve any additional study visits

Screening measures:
1. Fatigue is screened using the Brief Fatigue Inventory (BFI) on the fourth study visit
2. Aphasia is screened using the Graded Naming Test (GNT) on the third study visit
3. Visual neglect is screened using the Bells test on the third study visit

Completion date

01/10/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/09/2017:
Patients:
1. Adults over 18 years old
2. Stroke affecting arm function
3. Right handed before the stroke
4. With no neurological history before the stroke
5. Recovered 6 months after stroke or earlier
6. With no history of seizures post-stroke
7. With good command of English

Controls:
1. Participants matched with patients by age
2. Adults over 18 years old
3. Right handed
4. With no neurological history
5. With good command of English

Previous inclusion criteria:
Patients:
1. Adults over 18 years old
2. Left middle cerebral artery stroke
3. Stroke affecting arm function
4. Right handed before the stroke
5. With no neurological history before the stroke
6. Recovered 6 months after stroke or earlier
7. With no history of seizures post-stroke
8. With good command of English

Controls:
1. Participants matched with patients by age and socioeconomic status, preferably from their close social circle
2. Adults over 18 years old
3. Right handed
4. With no neurological history
5. With good command of English

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients:
1. Neurological disorders that could influence the EEG data recording
2. Left-handedness before stroke
3. No recovery of arm function 6 months after stroke
4. Inability to be assessed due to not sufficient command of English

Controls:
1. History of neurological disorders that could influence the EEG data recording
2. Left-handedness
3. Inability to be assessed due to not sufficient command of English

Date of first enrolment
02/01/2017

Date of final enrolment
01/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queens Hospital
Barking, Havering and Redbridge University Hospitals and Trust
Rom Valley Way
Romford Essex
United Kingdom
RM7 0AG

Sponsor information

Organisation
University of East London

ROR
https://ror.org/057jrqr44

Funder(s)

Funder type
University/education

Funder Name
University of East London

Alternative Name(s)
UEL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The participant level data are kept confidential and will not be made available. The data will be pseudonymised and stored in a secure setting with access only for the research team. The data will be kept at the research lab for 10 years for future analysis.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Thesis results			07/05/2021	No	No