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Performance-based selective training for robot-mediated upper limb rehabilitation after stroke

Submission date
27/03/2018

Recruitment status
No longer recruiting

Registration date
12/06/2018

Overall study status
Completed

Last Edited
22/03/2019

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
One of the undesirable consequences of stroke is loss of function of a body part, known as motor impairment, which can have lasting harmful impact on daily living activities. A very common consequence of stroke is difficulty in controlling upper limb movements (hand or arm; for example reaching the arm towards an object). Training of the upper limb (for example, via physiotherapy, occupational therapy, robot-mediated therapy) may help to improve upper limb function. However, in many cases recovery of upper limb movement is very limited, despite therapy. Therefore there is a need to develop better rehabilitation methods for the upper limb. This study aims to examine whether recovery of arm movements after stroke can benefit from personalised training in which the set of practiced movements in each exercise run, is selected based on the individual's profile of impaired performance (assessed before the practice run).

Who can participate?
Adults aged 18 or over who have had a stroke over 6 months previously

What does the study involve?
Participants are randomly allocated to one of two groups.
Those in the first group train with movements which are selected individually for each participant, whereas those in the second group train with a set of movements which are used in multiple studies about robot-assisted rehabilitation. Participation of each individual is spread out over three months, albeit its main period – which involves most of the robot-assisted movement exercise - is concentrated in 6 weeks.
The first two appointments (two weeks apart) include clinical assessments for upper limb impairment and evaluation of vision and cognitive conditions. These assessments are conducted by an experienced physiotherapist. The results of these assessments indicate eligibility to take part in the rest of the study. For eligible participants the assessments' results are included as part of the research results, to inform about the baseline level of upper limb impairment - before training.
Before the main period of the study eligible participants participate in an MRI scan to inform about brain areas affected by the stroke and their activity.
During the main 6 weeks of the study the participants take part in four robot-assisted exercise appointments every week (except the first week which includes two initial exercise

appointment). Each appointment lasts between 1 and 1.5 hours, including multiple rest breaks. It involves exercise with a range of arm movements. A handle of a robotic device is attached to the affected hand (using a special glove) and if needed, it produces gentle assisting force on the hand to guide its movement and help to complete it on time. The robotic device also records information about the movement performance.
A few days after the end of the main period the participants participate in another clinical assessment appointment and another MRI scan, to evaluate the effect of the exercise on the upper limb impairment and on the brain. The final two follow-up appointments are taken four weeks after the end of the training. One appointment involves final clinical assessment and the other appointment is a final evaluation of performance with the robot-assisted exercises.
To evaluate the benefit of our new therapy approach we compare the training effect between the two groups of participants.

What are the possible benefits and risks of participating?
Whilst the study aims to investigate the benefit of a new method of exercise in improving recovery of the upper limb in stroke patients there is no guarantee that participants will receive direct benefit from taking part. However participants may feel satisfied knowing that they contributed to research which aims to improve upper-limb recovery.
MRI scans risks: only MR eligible individuals participate in scan appointments and the regulations of running an MRI scan are kept strictly. Under these conditions the risks are minimal. An MRI scan may not be convenient as it involves lying still inside a narrow tunnel alone without moving. The scan is also very noisy, but the noise level is reduced by wearing ear plugs and ear protection. The participants are provided with a buzzer to press if they feel they need to stop the scan.
Arm movement exercise risks: The intensive exercise can potentially lead to physical or mental fatigue. This is reduced by providing frequent rest breaks. The force provided by the robot is limited to levels which are not harmful. The robot is equipped with an emergency button. In case of sign of distress, the experimenter presses the button which switches off the robot immediately.
People who are highly sensitive to movement of their limb were not included in this study.

Where is the study run from?
School of Psychology, University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
November 2012 – December 2016

Who is funding the study?
1. Medical Research Council (UK)
2. Wellcome Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RG_14-017

Study information

Scientific Title
A comparison of the effectiveness of personalised vs. standard robot-assisted rehabilitation of the upper limb in adults with chronic hemiparesis due to stroke

Study objectives
1. Both standard and personalised robot-assisted exercise interventions would lead to reduced motor impairment of the affected upper limb
2. The personalised intervention would lead to superior reduction of motor impairment of the affected upper limb, compared to the standard intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Science, Technology, Engineering and Mathematics Ethical Review Committee of the University of Birmingham, 27/03/2014, ref: ERN_09-528

Study design
Single-blinded randomised (stratified) controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Upper limb hemiparesis due to stroke

Interventions
Participants are allocated to either test or control study group using stratification (a dynamic minimization protocol), balancing impairment (2 levels: upper-limb Fugl-Meyer scoreless or more than 25), age (two levels: younger or older than 60) and dominance (handedness) of the affected limb (2 levels: dominant or non-dominant) between the groups. Each participant, when recruited and following initial clinical assessment, is allocated to the group which has more factors containing fewer allocations in the stratification levels relevant to that patient. If all three factors are balanced, allocation is based on a pre-set alternating. The stratification is conducted using a computerised algorithm. The clinician who conducts screening and clinical assessment is not informed about group allocation.

For both groups the intervention involves robot-assisted training of the upper limb. In the test intervention group the training is with performance-based selection of upper-limb movements. The principle is based on mapping motor performance across a workspace of point-to-point reaching movements and then selecting movements located at regions of the steepest transition between better and worse performance. In the control intervention group the training is with centre-out movements –a common upper-limb robot-assisted intervention method.

For both test and control intervention groups, the study period is divided to three phases. The initial baseline phase consists of five sessions lasting 1-1.5 hours: two identical clinical assessments (CAs), a robot parameter tuning session, a performance mapping assessment and an MRI brain scan (for MR-eligible individuals). The main training phase comprises four sessions per week for five consecutive weeks. In each week, 3 training sessions are followed by a mapping session. Data from the final mapping session of that phase, and from a following CA (conducted within 2-4 days post-training), serves to evaluate post-training outcomes, and an MRI brain scan (for eligible participants). A final CA and mapping sessions are run 4 weeks later (follow-up phase).
The two groups differ only in the selection of movement conditions during training sessions; all other session types are identical in both groups.

Intervention Type
Other

Primary outcome(s)
Upper limb movement is measured by an experienced physiotherapist using the upper-limb Fugl-Meyer (UL-FM) scale (max score: 66), twice before the intervention in two week gap (baseline), few days after the last intervention session (post-training) and 4-weeks later (follow-up).

Key secondary outcome(s))
1. Muscle power is measured using the MRC Muscle Power scale
2. Spasticity is measured using the Modified Ashworth Scale
3. Everyday motor function is measured using the Motor Assessment Scale
4.Functional independence and performance in activities of daily living is measured using the Barthel index
All of the above are assessed by an experienced clinician (physiotherapist) twice before the intervention in two week gap (baseline), few days after the last intervention session (post-training) and 4-weeks later (follow-up)
5. Levels of robot guidance and assistance were measured using the robot's sensors. These data are recorded automatically throughout all the robot-mediated movement sessions and stored in files on a computer. For outcome, we use the average assistance and guidance forces per

movement condition in the following robot-mediated performance assessment sessions: pre-intervention (baseline), few days after the last intervention session (post-training) and 4-weeks later (follow-up)

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Cortical or capsular stroke >6 months before participation and no evidence for another stroke in the last 6 month
3. FMA-UE score within 5 and 50 points, with no more than 5-point difference on repeat testing at two weeks interval
4. Preserved vision across the visual field, allowing detection of all the stimuli displayed during the robot-assisted motor tasks
5. Ability to maintain balance when seated
6. Preserved basic cognitive function including understanding instruction as assessed by Mini Mental State Examination
7. Available during the full period of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Prolonged pain in the affected upper limb or during movement assessed using the Likert Pain Scale or injury in the hemiparetic hand/arm
2. Severe spasticity involving elbow/shoulder movements ≥3 in Modified Ashworth Scale for any tested elbow/shoulder posture
3. Receiving physiotherapy during the study period
4. Cerebellar lesion assessed by MRI or by clinical report as provided by the patient

Date of first enrolment
22/09/2014

Date of final enrolment
16/10/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
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Sponsor information

Organisation
Medical Research Council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from:
Dr. Orna Rosenthal (primary researcher): o.rosenthal@bham.ac.uk
Prof. Chris Mial (Project lead): r.c.miall@bham.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/03/2019	22/03/2019	Yes	No