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Does arm training early after a stroke increase the contribution of the non-affected brain side to recovery?

Submission date	Recruitment status	[X] Prospectively registered
11/11/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/11/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/09/2021	Circulatory System	

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, usually by a blood clot blocking an artery or a bleed (haemorrhage). One of the most common complications of a stroke is weakness on one side of the body (hemiparesis). Following a stroke, many patients require extensive rehabilitation so that they can regain movement and keep their independence. Recovering arm movement after a stroke is possible due to the brain's ability to form new connections. By repeating special exercises, the uninjured part of the brain is able to form new connections, leading to short- and long-term improvement in arm function. Animal experiments have shown that early after stroke is the only time that the mechanisms responsible for this can take place. The aim of this study is to find out whether intensive training (arm exercises) is only effective at establishing these new brain connections if given early after stroke.

Who can participate?
Adults who have had a stroke within the past 3 weeks and are suffering from arm weakness.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group complete a course of intensive arm exercises designed to improve movement in their weak arm over 6 days. Those in the second group receive normal care following their stroke and complete the exercises after three months have passed. For participants in both groups, their ability to move and control their arm is measured at the start of the study, after the 6 days of exercise and after three months.

What are the possible benefits and risks of participating?
All participates will have the benefit of receiving or being offered additional arm training either early or later after stroke, which might improve their aim function. They will also have an in-depth assessment, and information about their arm function and any changes throughout the

study. The risks associated with single pulse TMS as planned in this trial are very low and patients will be monitored to avoid any possible complications. The arm training may be tiring for participants, however this will also be monitored by the research team.

Where is the study run from?
Salford Royal NHS Foundation Trust (UK)

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

Who is funding the study?
Stroke Association (UK)

Who is the main contact?
Dr Ulrike Hammerbeck

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
19819

Study information

Scientific Title
Does high repetition reaching training early after a stroke promote recovery by strengthening connections from the hemisphere unaffected by the stroke?

Study objectives
Early after stroke, intensive arm training can promote a functionally useful contribution from the unaffected brain hemisphere.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee North-West – Greater Manchester West research Ethics Committee, 29/09/2015, ref: 15/NW/0703

Study design
Randomised; wait-list controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
40 participants with arm weakness are randomly allocated to two groups:

Intervention group: Patients will receive early (within the first 6 weeks after stroke) intensive training over 6 days to improve the movement in their arm. Proximal arm training consisting of horizontal reaching movements while gravity is eliminated. A training session consists of 400 repetitions of a 20cm reaching movement. Movement accuracy is measured and rewarded.

Control group: Patients receive usual care only for three months, following which they receive the intensive training over 6 days.

The way that early reaching training affects the strength of new connections in the brain is measured by using brain stimulation techniques after the intervention. To see if these changes are lasting, the measure will be repeated 3 months after the stroke.

Intervention Type
Other

Primary outcome(s)
Motor Evoked Potential to Transcranial Magnetic Stimulation Measures at baseline, 6 and 12 weeks after stroke.

Key secondary outcome(s))
1. Arm function measured by Motricity Index and Fugl-Meyer score at baseline, 6 and 12 weeks after stroke
2. Reaching accuracy is determined at baseline, 6 and 12 weeks after stroke
3. Feasibility of protocol measured by exit interview at 12 weeks after stroke

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Acute stroke patients from Salford Royal Foundation Trust (SRFT)
2. Mild to moderate proximal upper limb weakness (MRC muscle scale 4 or less)
3. Able to reach at least 15cm while supported in the arm-trainer
4. Full upper limb function pre-morbidly

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Contraindications to transcranial magnetic stimulation (TMS), i.e. metal implants or epilepsy.
2. Previous stroke
3. Shoulder pain over 3/10 on visual analogue scale
4. Unable to give informed consent.
5. Severe neglect
6. Complete sensory loss
7. Suspected or confirmed pregnancy

Date of first enrolment
15/11/2015

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Salford Royal NHS Foundation Trust
Clinical Sciences Building
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Salford
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Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
Stroke Association

Alternative Name(s)
TheStrokeAssociation, TheStrokeAssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article		09/08/2021	03/09/2021	Yes	No
Results article		04/07/2021	03/09/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes