

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

| | | |
|--|---|---|
| Submission date 11/11/2015 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/11/2015 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 03/09/2021 | Condition category Circulatory System | <input type="checkbox"/> 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, 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 participants will have the benefit of receiving or being offered additional arm training either early or later after stroke, which might improve their arm 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
Dr Ulrike Hammerbeck

ORCID ID
<https://orcid.org/0000-0003-2657-4347>

Contact details
Clinical Sciences Building
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

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
Stott Lane

Salford
United Kingdom
M6 8HD

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 |