

# Does an early intensive interdisciplinary upper limb therapy programme following acute stroke improve outcome?

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/01/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# Study information

## Scientific Title

### Study objectives

To evaluate an early intensive interdisciplinary upper limb therapy programme for patients with acute stroke.

#### Objectives

1. To compare the upper limb impairment and function of stroke patients who receive an early intensive therapy programme targeting the upper limb (the intervention group) with those receiving conventional care (the control group) at 3 and 6 months post stroke.
2. To compare disability and quality of life of the intervention and control group at 3 and 6 months post stroke.
3. To compare the prevalence of post stroke upper limb pain between the intervention and control group at 3 and 6 months post stroke.
4. To develop a joint physiotherapy and occupational therapy record for the intervention group.
5. To describe and quantify the therapy received by the intervention and control group in the 6 months post stroke.
6. To elicit the views of patients and carers about the therapy they have received.
7. To determine the net financial costs and benefits of an early intensive upper limb therapy programme following acute stroke.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

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

Cerebrovascular disease

**Interventions**

1. Early intensive therapy programme targeting the upper limb (intervention group)
2. Conventional care (control group)

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Action Research Arm Test at 6 months post stroke

**Secondary outcome measures**

1. Motricity score (3 months and 6 months post stroke)
2. Upper limb function assessed by:
  - 2.1. Action Research Arm Test (3 months)
  - 2.2. Frenchay arm test (3 months and 6 months)
3. Disability assessed by Nottingham Extended Activities of Daily Living (E-ADL) (3 months and 6 months)
4. Nottingham Health Profile (6 months)
5. Upper limb pain (3 months and 6 months)
6. Patient and carer satisfaction (modified Hospsat & Homsat 6 months)

**Overall study start date**

03/01/1999

**Completion date**

03/01/2002

**Eligibility****Key inclusion criteria**

All patients admitted to North Tyneside General Hospital within 10 days of acute stroke who are resident within the borough will be assessed against the following eligibility criteria:

1. Pre-stroke Oxford Handicap Scale 1-3
2. Motor impairment of the upper limb
3. Medically stable
4. No previous major upper limb problem likely to influence assessments
5. Patient able to give informed consent

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

123 (added 21/01/10; see publication)

**Key exclusion criteria**

A register of reasons for exclusion will be kept

**Date of first enrolment**

03/01/1999

**Date of final enrolment**

03/01/2002

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Newcastle**

Newcastle upon Tyne

United Kingdom

NE2 4AA

## **Sponsor information**

**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

# Funder(s)

## Funder type

Government

## Funder Name

NHS Executive Northern and Yorkshire (UK)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2003		Yes	No