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

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 21/01/2010	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Helen Rodgers

Contact details
University of Newcastle
Centre for Health Services Research
21 Claremont Place
Newcastle upon Tyne
United Kingdom
NE2 4AA
+44 (0)191 222 8025
helen.rodgers@newcastle.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

rctc135 R1805/6630

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 vies 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?
Results article	results	01/09/2003		Yes	No