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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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
21/01/2010

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Action Research Arm Test at 6 months post stroke

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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
United Kingdom

England

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)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

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