A randomised controlled trial to evaluate the cost-effectiveness of a domiciliary rehabilitation scheme versus usual care in the rehabilitation of stroke patients.

Submission date 23/01/2004	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 23/01/2004	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 15/01/2010	Condition category Circulatory System	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr Paul Roderick

Contact details

Institute of Public Health Medicine University of Southampton Level B, South Academic Block Southampton General Hospital Tremona Road Southampton United Kingdom SO16 6YD +44 (0)2380 796 532 pjr@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Study objectives

 To evaluate the outcomes of a new domiciliary rehabilitation service for stroke patients and their carers in comparison with the usual care provided in geriatric day hospitals.
 To estimate the costs of the different approaches and to thereby determine the relative costeffectiveness of the two models.

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) Other

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Cerebrovascular disease

Interventions

Domiciliary rehabilitation
 Care from geriatric day hospitals

Intervention Type Other

Phase

Not Specified

Primary outcome measure

Assessments at baseline 3, 6 and 12 months post entry to study.

1. Patient functional status and quality of life:

- 1.1. Barthel index
- 1.2. Rivermead mobility index
- 1.3. Philadelphia Geriatric Morale Scale
- 1.4. Frenchay Activities Index

1.5. SF36

- 2. Carer outcomes:
- 2.1. Carer strain index
- 2.2. SF36
- 2.3.GHQ
- 3. Resource use
- 3.1. NHS:
- 3.1.1. rehabilitation
- 3.1.2. inpatient/outpatient
- 3.1.3. GP
- 3.1.4. district nurse
- 3.1.5. speech therapy
- 3.2. Social services:
- 3.2.1. home help
- 3.2.2. meal on wheels
- 3.2.3. day centre

4. Costs of domiciliary rehabilitation, day hospital visit including transport

Secondary outcome measures

Not provided at time of registration

Overall study start date 01/04/1995

Completion date

31/12/1997

Eligibility

Key inclusion criteria Stroke patients age 55+ who required rehabilitation post discharge

Participant type(s) Patient

Age group Senior

Sex Both **Target number of participants** 140 (added 15/01/10; see publication)

Key exclusion criteria Terminal illness, need for day hospital care for social or medical reasons

Date of first enrolment 01/04/1995

Date of final enrolment 31/12/1997

Locations

Countries of recruitment England

United Kingdom

Study participating centre Institute of Public Health Medicine Southampton United Kingdom SO16 6YD

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 South West (UK)

Results and Publications

Publication and dissemination plan Not provided at time of registration

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?
<u>Results article</u>	results	01/07/2001		Yes	No