A randomised trial of a comprehensive stroke information service for patients and carers.

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers HSR/067 R180/05588

Study information

Scientific Title

Study objectives

To determine the effectiveness of a multi-disciplinary Stroke Education Programme for stroke patients and their informal carers in improving health status, by enhancing their knowledge of the causes and consequences of stroke and the availability of community support

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

 Stroke educational programme (SEP):
One 1-hour small group educational session for inpatients followed by six 1-hour sessions after discharge
A control group to receive conventional stroke unit care

Intervention Type Other

Phase Not Specified

Primary outcome measure

Patient and informal carer perceived health status (SF-36) at six months post stroke

Secondary outcome measures

- 1. Knowledge of stroke
- 2. Satisfaction with services
- 3. Emotional outcomes of patients and informal carers
- 4. Informal carer stress
- 5. Disability

Overall study start date

06/01/1996

Completion date

31/05/1998

Eligibility

Key inclusion criteria

In-patients and their carers, randomised within one week of stroke or when mentally stable

Participant type(s) Patient

Age group Other

Sex Both

Target number of participants 204 patients, 176 carers (added 21/01/10; see publication)

Key exclusion criteria Does not match inclusion criteria

Date of first enrolment 06/01/1996

Date of final enrolment 31/05/1998

Locations

Countries of recruitment England

United Kingdom

Study participating centre

Centre for Health Services Research 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?
<u>Results article</u>	results	01/12/1999		Yes	No