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A randomised controlled trial evaluation of structured routine follow-up after a disabling stroke

Submission date 09/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 28/11/2005	**Overall study status** Completed	
Last Edited 25/08/2009	**Condition category** Circulatory System	

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
N/A

Study information

Scientific Title

Study objectives
Research questions:
1. The primary research question is to determine if protocol driven, routine reviews of disabled stroke patients promote improved clinical and health economic outcomes (independence, mood, carer burden, secondary prevention compliance, service resources used)
2. The secondary question investigates the effects of stroke review clinic context by a comparison between two types of clinic structure

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)
Not Specified

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

Interventions
The control group will receive existing care arrangements including a service information pack and a structured discharge summary to general practitioners detailing secondary prevention, rehabilitation goals, expected community care services and a new recommendation to the primary health care team that the patient should be contacted at 6 months in accord with the National Service Framework requirement. We believe that the latter recommendation creates a fairer and more realistic comparison group in the context of expected clinical behaviour changes associated with the National Service Framework implementation. At present about half of stroke patients will see their general practitioner by 6 months but the contact is brief, unstructured and of limited patient value.

The patients in the intervention group will receive existing care supplemented by a review clinic attendance at 5-6 months post-stroke onset (some flexibility is required for service operational reasons). Additional visits will be organised if indicated but the emphasis will be on co-ordination of inputs rather than frequent attendances. Two follow-up clinic approaches will be used:
1. An existing secondary care-based review clinic in Leeds. This clinic is medically-led, with some nursing support and established links to therapy and social care services.
2. Multidisciplinary review clinics in Bradford. These are being established in each of three Primary Care Trust, locality-based rehabilitation centres. A nurse (with some mental health training) and a therapist will jointly lead the clinics. Through joint working, it is anticipated that new ways of working will evolve so the clinic will be truly interdisciplinary. Stroke consultant physician support will be available to the clinic through participation in post-clinic meetings, also attended by social service and relevant primary care staff.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Patient: extended activities of daily living (Frenchay Activities Index)

Carer: Well-being (General Health Questionnaire-28)

Key secondary outcome(s))
Patient: disability (Barthel Index); mood (Hospital Anxiety and Depression Scale); health status (EQ-5D); service satisfaction (Homesat)

Carer: strain (Carer Strain Index)

Resource use: health, social and voluntary sector service use, and secondary prevention and psychotropic medication will be recorded using proforma questionnaires developed for our previous community stroke trials, supplemented by specific inquiry of service databases for high cost resources such as care home or hospital admissions

Completion date
31/05/2006

Eligibility

Key inclusion criteria
Patients with a new stroke associated with persisting disability and or language impairment at 4 months post-stroke onset. A persisting disability is defined as a Barthel Index score at 4 months lower than their pre-stroke score.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients without new disability
2. Patients whose main problem is vascular dementia
3. Patients considered to have a poor 6 month survival prognosis because of co-morbidity

Date of first enrolment

01/06/2003

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Health Care for the Elderly
Bradford
United Kingdom
BD5 0NA

Sponsor information

Organisation
UK Department of Health - Policy Research Programme

Funder(s)

Funder type
Government

Funder Name
Department of Health - Policy Research Programme to support the National Service Framework for Older People (Older People and their Use of Services - 'OPUS')

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	01/09/2009		Yes	No