

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

<b>Submission date</b> 09/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/08/2009	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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**

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

### 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 measure**

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

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

### **Secondary outcome measures**

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

### **Overall study start date**

01/06/2003

### **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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

220-230 over 15 months in two centres (Leeds & Bradford)

**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**

England

United Kingdom

**Study participating centre**

Department of Health Care for the Elderly

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**Sponsor information****Organisation**

UK Department of Health - Policy Research Programme

**Sponsor details**

Department of Health

Room 716

Wellington House  
133-135 Waterloo Road  
London  
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SE1 8UG

**Sponsor type**

Government

## 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

**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?
<a href="#">Results article</a>	results	01/09/2009		Yes	No