

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

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

Bradford

United Kingdom

BD5 0NA

Sponsor information**Organisation**

UK Department of Health - Policy Research Programme

Sponsor details

Department of Health

Room 716

Wellington House
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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?
Results article	results	01/09/2009		Yes	No