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A randomised trial to evaluate improved routine communication to patients and carers after stroke

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 02/10/2012	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RCRC9C YOUNG R&D

Study information

Scientific Title

Study objectives
The provision of clear information following a stroke has been identified as a key component of good care by both health professionals and patients. The provision to the patient and family of understandable, appropriate and correct information may be effective in positively influencing post-stroke home care. However, a number of recent reports have demonstrated that the implementation of this policy into routine practice may be difficult to achieve. Several small studies in the UK have highlighted the difficulties in successfully implementing strategies for information provision. No evidence of effectiveness in reducing anxiety or improving social functioning has been reported but there was a suggestion that the patients were more satisfied with their level of knowledge and appreciated booklets. It is likely that the method of delivering the information is as important as its content. Simply providing information, particularly when set in a complex area such as stroke, may be too simplistic as it is too passive an approach.
A more active, educational approach may be successful. Thus a formal educational or teaching programme specifically designed for patients and carers may have some special relevance. Such an experimental educational programme was established and evaluated in the USA and reported positive effects including improving caregiver stroke knowledge and family coping strategies. To develop this work further we are going to evaluate by randomised trial the effectiveness of a short educational programme for patients and caregivers after stroke.
Research Questions
1. That a structured package of information provision for patients recovering from stroke and their carers is associated with improved to usual (unstructured) information provision.
2. That a structured package delivered by a facilitator is more effective than either simple provision of the structured information, or usual care.
The primary outcome of interest is patient and carer understanding of stroke, with a secondary outcome of reduction in handicap.

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)

Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular diseases: Cerebrovascular disease

Interventions
1. Group 1 Unstructured information provision
2. Group 2 Structured information provision - the Stroke Recovery Programme
3. Group 3 Stroke Recovery Programme delivered by a facilitator

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Knowledge about Stroke and Service questionnaire
2. London Handicap Scale

Secondary outcome measures
1. Patients will be asked to complete
1.1. Patients Satisfaction Questionnaire
1.2. Frenchay Activities Index
1.3. Hospital Anxiety and Depression Scale
2. Carers will be asked to complete
2.1. General Health Questionnaire
2.2. Carers Satisfaction Questionnaire
An estimate of the resource use will be made by recording the time taken by the three specialist nurses during the one-to-one sessions with patients and carers.

Overall study start date
11/01/1999

Completion date
12/01/2002

Eligibility

Key inclusion criteria
The Bradford Stroke Unit receives patients of any age shortly after stroke onset (average 11 days) who are sufficiently medically stable to participate in a rehabilitation programme. On admission patients and their carers (if available) will be screened for recruitment into the trial within three days of transfer. Patients will be eligible for the trial if they have a diagnosis of acute stroke and give informed consent. Thus we will be recruiting a heterogeneous study sample of patients (n=220) with various stroke impairments and differing ethnic backgrounds.

For patients with server aphasia or stroke related cognitive impairment the main emphasis of the information provision will be directed toward the main carer.

Participant type(s)
Patient

Age group
Other

Sex
Not Specified

Target number of participants
220

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
11/01/1999

Date of final enrolment
12/01/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bradford Hospitals NHS Trust
Bradford
United Kingdom
BD5 0NA

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
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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?
Results article	results	01/11/2004		Yes	No