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Does psychological treatment improve the outcome after stroke?

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	**Condition category**	[ ] Individual participant data
17/06/2019	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
MS33

Study information

Scientific Title
Does psychological treatment improve the outcome after stroke?

Study objectives
Depressed mood may affect about 40% of elderly people after a stroke, especially during the first year. It is a major determinant of quality of life for patients and carers, and may delay functional and social recovery. The condition may not be recognised, and even if it is, the best treatment is not known.
The aim of this study was to assess the effectiveness of a psychological intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Cerebrovascular disease, stroke

Interventions
1. Psychiatric nurse therapist offering six hourly sessions of a problem-solving type of cognitive-behaviour therapy
2. Voluntary visitor with no special training offering a similar time of support and advice
3. Nothing beyond normal rehabilitation

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Patients and carers were assessed at entry, at 6 months and at 12 months.
Measurements of patients comprised:
1.1. Present State Examination
1.2. General Health Questionnaire 28 (GHQ-28)
1.3. Beck Hopelessness scale
1.4. Frenchay Activities Index
1.5. Barthel ADL Scale
1.6. Mini Mental State Exam,
1.7. Nottingham Health Profile
2. Carers were assessed by
2.1. GHQ-28
2.2. Nottingham Health Profile
2.3. Social Adjustment Scale

2.4. Carers Strain Index
3. Information was also collected on contacts with general practitioners and hospital service, use of medication especially antidepressants, and satisfaction with care received.
4. Resource use over the 12 months was also measured.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/02/2000

Eligibility

Key inclusion criteria
448 patients were recruited from hospitals in Leeds and Bradford within one month of suffering a stroke. Median age of patients was 73, and 40% lived alone.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
450

Key exclusion criteria
Patients with significant cognitive or communication difficulties

Date of first enrolment
01/06/1995

Date of final enrolment
01/02/2000

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leeds
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15 Hyde Terrace
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Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Cardiovascular Disease and Stroke National Research and Development Programme (UK)

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	01/03/2001		Yes	No
Results article	results	14/06/2019	17/06/2019	Yes	No