

Does psychological treatment improve the outcome after stroke?

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/06/2019	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

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
Department of Psychiatry
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