Does psychological treatment improve the outcome after stroke?

Recruitment status No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status Completed	Statistical analysis plan		
	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting Overall study status Completed		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Allan House

Contact details

Department of Psychiatry University of Leeds 15 Hyde Terrace Leeds United Kingdom LS2 9LT +44 (0)113 233 2725 a.o.house@leeds.ac.uk

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

Study design

Randomised controlled trial

Primary study design

Interventional

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 Leeds

United Kingdom LS2 9LT

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