

Does psychological treatment improve the outcome after stroke?

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|--|---|---|
| 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/1995

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

Age group

Other

Sex

Both

Target number of participants

448

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

England

United Kingdom

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)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Cardiovascular Disease and Stroke National Research and Development Programme (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 | 01/03/2001 | | Yes | No |
| Results article | results | 14/06/2019 | 17/06/2019 | Yes | No |