

Psychological treatment for depression in aphasic stroke patients: a randomised controlled trial

Submission date 29/09/2006	Recruitment status Stopped	☐ Prospectively registered
Registration date 29/09/2006	Overall study status Stopped	☐ Protocol
Last Edited 25/01/2019	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

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

N0192165295

Study information

Scientific Title

Psychological treatment for depression in aphasic stroke patients: a randomised controlled trial

Study objectives

To evaluate the effectiveness of behavioural treatments for low mood following stroke in people who have communication problems.

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)

Treatment

Health condition(s) or problem(s) studied

Mental and Behavioural Disorders: Depression

Interventions

This study uses a randomised controlled trial design (RCT). In this RCT aphasic patients with low mood will be randomly allocated to one of three groups: behavioural psychotherapy, attention placebo, no intervention. The attention placebo group is required to evaluate whether any improvement in mood in the behavioural treatment group is due to the content of the therapy or the fact that patients are receiving attention and interacting with someone regularly. The no intervention group is required to examine any spontaneous recovery in mood that occurs without any additional intervention. Patients in behavioural therapy group will receive up to 20 one hour sessions of therapy. Therapy duration is at discretion of therapist. Patients in attention placebo group will receive a comparable number of visits from psychologist. Patients in control group receive no contact with psychologist. Intervention will be administered by psychologist trained with stroke patients.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary outcome measures will be completed at 3 months and 6 months after randomisation to assess mood: Visual Analogue Mood Scales (VAMS) and Stroke Aphasic Depression Questionnaire (SADQ).

Key secondary outcome(s)

The secondary outcome measures will be completed at 3 months and 6 months after randomisation to assess any change in activity level: Extended Activities of Daily Living Scale (EADL) and Nottingham Leisure Questionnaire.

Completion date

01/12/2007

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

It is intended that 180 patients will be recruited, one-third (60) of these will be randomly allocated to a control group (no intervention group). Stroke patients with aphasia will be eligible for inclusion in the study. They will have been referred to the Speech & Language Therapists (SALT) in Nottingham with aphasia.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Key exclusion criteria

1. Patients will be excluded from the study if they are blind or deaf as it will not be practical to administer the assessments using standardised methods with these patients. These patients are still important, but a future study would be required to determine how assessments and therapies could be adapted for patients with severe vision and hearing problems.
2. Patients with dementia documented in their medical notes will be excluded as these patients may not have a reliable insight into their mood and the difficulties they face following their stroke.
3. Patients who received treatment for depression in the 5 years prior to their stroke will also be excluded as this study is concerned with patients who become depressed after their stroke.
4. Patients who live more than 40 miles from the recruiting centre will be excluded as it will not be practical for the researchers and therapist to visit these patients.

Date of first enrolment

01/04/2005

Date of final enrolment

01/12/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Queens Medical Centre

Division of Rehabilitation and Ageing

B Floor Medical School

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Queen's Medical Centre University Hospital NHS Trust

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration