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

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/01/2019	Mental and Behavioural Disorders	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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).

Secondary outcome measures
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.

Overall study start date
01/04/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
180

Key exclusion criteria

1. Patients will be excluded form 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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
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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

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