ISRCTN56078830 https://doi.org/10.1186/ISRCTN56078830

Communication And Low Mood (CALM) study

Submission date 24/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/06/2010	**Overall study status** Completed	
Last Edited 30/11/2012	**Condition category** Circulatory System	

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
2497

Study information

Scientific Title
Communication and Low Mood: a multicentre randomised controlled trial of behaviour therapy aimed at improving mood in people with aphasia following a stroke

Acronym
CALM

Study objectives
Over 130,000 people have a stroke each year in England and Wales and about one third of these will have aphasia (communication impairment). This can mean they have difficulty speaking, reading, writing or understanding language.

Depression is common in people who have had a stroke and can have a negative effect on rehabilitation. There is some evidence that people with aphasia are more likely to become depressed. However, people with aphasia are usually excluded from research into mood after stroke and depression is often not treated.

The CALM study is divided into two parts: a survey and a treatment trial.

Survey:
Part one of the study is a survey to find out what factors are related to low mood in people with aphasia due to a stroke, for example, disability and severity of aphasia. It will provide useful clinical information to aid the identification of those who are at risk of having low mood and will inform the development of effective interventions.

Treatment Trial:
Part two of the study is a multicentre randomised controlled trial to evaluate whether a psychological treatment, called behaviour therapy, is effective at treating low mood in people with aphasia due to a stroke. Behaviour therapy aims to improve mood by increasing the time people spend doing things they enjoy. This is relevant for people with aphasia who may stop doing everyday activities and hobbies after their stroke. Behaviour therapy is appropriate for people with aphasia as it is practical and can be adapted for people with communication problems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee approved on the 8th December 2004 (ref: 04/Q2403 /148)

Study design
Multicentre randomised interventional process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Stroke Research Network, Mental Health Research Network; Subtopic: Rehabilitation, Mental effects due to physical disease or brain damage; Disease: Depression, Therapy type

Interventions
Behaviour therapy:
This consists of up to 20 one hour sessions of therapy for up to three months from an assistant psychologist delivered at the patient's place of residence (e.g. at home, in hospital, in a nursing home).

Control group:
Usual care for three month period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Stroke Aphasic Depression Questionnaire (SADQ; 21 item hospital version), measured 3 and 6 months after randomisation.

Secondary outcome measures
Measured 3 and 6 months after randomisation:
1. Visual Analogue Mood Scales (VAMS) 'sad' item
2. Visual Analogue Self-Esteem Scale (VASES)

Overall study start date
21/10/2005

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Stroke
2. Aphasia

3. Low mood (greater than 6 on Stroke Aphasic Depression Questionnaire Hospital Version [SADQ-H] or greater than 50 on "sad" subscale of Visual Analogue Mood Scales [VAMS])
4. Aged at learst 18 years old, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 30; UK sample size: 30

Key exclusion criteria
1. Dementia
2. Blind or deaf
3. Received treatment for depression in the five years prior to stroke

Date of first enrolment
21/10/2005

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Work, Health & Organisations
Nottingham
United Kingdom
NG8 1BB

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
University Park
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
The Stroke Association (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	01/05/2013		Yes	No