

Communication And Low Mood (CALM) study

Submission date 24/06/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 24/06/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/11/2012	Condition category Circulatory System	☐ 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

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

Measured 3 and 6 months after randomisation:

1. Visual Analogue Mood Scales (VAMS) 'sad' item
2. Visual Analogue Self-Esteem Scale (VASES)

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 least 18 years old, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre

Institute of Work, Health & Organisations

Nottingham

United Kingdom

NG8 1BB

Sponsor information**Organisation**

University of Nottingham (UK)

ROR

<https://ror.org/01ee9ar58>

Funder(s)**Funder type**

Charity

Funder Name

The Stroke Association (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	01/05/2013		Yes	No