

# Communication And Low Mood (CALM) study

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| <b>Submission date</b><br>24/06/2010   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>24/06/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>30/11/2012       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Shirley Thomas

**Contact details**  
Institute of Work, Health & Organisations  
University of Nottingham  
International House  
Jubilee Campus  
Wollaton Road  
Nottingham  
United Kingdom  
NG8 1BB  
shirley.thomas@nottingham.ac.uk

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/05/2013   |            | Yes            | No              |