

# Non-invasive brain stimulation for dysphagia after acute stroke

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| <b>Submission date</b><br>01/04/2015   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>02/04/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>28/02/2017       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

A stroke occurs when the blood supply to part of the brain is cut off. Around one in two stroke sufferers will have difficulties with swallowing which can complicate their recovery and reduces quality of life. Swallowing problems happen when the part of the brain that controls swallowing is injured by the stroke itself. Swallowing recovers naturally in a proportion of people when the healthy side of the brain adapts and takes over the control of swallowing. There is new evidence that stimulating the healthy side of the brain can speed up this natural recovery process (called plasticity). The aim of this study is to find out if low current brain stimulation to the healthy side of the brain can speed up swallowing recovery and improve quality of life after stroke, and to establish the most effective dose of the treatment.

### Who can participate?

Patients having difficulty swallowing (dysphagia) after having suffered a stroke

### What does the study involve?

Not provided at time of registration

### What are the possible benefits and risks of participating?

The results of this study will provide evidence for using this new approach for dysphagia rehabilitation. The expectation is that this portable user-friendly non-invasive stimulation will be rapidly rolled out into a larger study for use in rehabilitation and lead into changes in practice at a national level in the NHS.

### Where is the study run from?

University of Manchester (UK)

### When is the study starting and how long is it expected to run for?

April 2015 to September 2017

### Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?  
Dr Emilia Michou  
Emilia.Michou@manchester.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Emilia Michou

**Contact details**  
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## Additional identifiers

**Protocol serial number**  
18688

## Study information

**Scientific Title**  
Randomised controlled dose response trial of transcranial direct current stimulation for dysphagia after acute stroke

**Study objectives**  
The aim of this research project is to find out if low current brain stimulation to the healthy side of the brain in stroke patients with dysphagia can speed up swallowing recovery and improve quality of life after their stroke and to establish the most effective dose of the treatment.

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=18688>

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
12/NW/0262

**Study design**

Randomised; Interventional; Design type: Treatment

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Topic: Stroke; Subtopic: Acute Care, Rehabilitation; Disease: Device used, Therapy type

**Interventions**

Dose response of transcranial direct current stimulation

**Intervention Type**

Device

**Primary outcome(s)**

Changes in safety of swallowing based on formal assessments

**Key secondary outcome(s)**

N/A

**Completion date**

01/09/2017

## **Eligibility**

**Key inclusion criteria**

1. All patients with dysphagia following acute anterior or posterior cerebral circulation stroke that present dysphagia for the first time, within the first weeks from symptoms and up to 6 weeks post stroke. The presence of dysphagia will be based on the results of screening procedures by the research team. Patients will be always recruited after 48-72 hours post lesion
2. There is no age limit
3. Patients must be medically stable
4. Lesions have to be verified on imaging techniques, either magnetic resonance (MR) scan or computerised tomography (CT), information which will be collected

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

## **Key exclusion criteria**

1. Advanced dementia
2. Other neurological conditions that may explain swallowing difficulty (dysphagia)
3. Previous history of dysphagia
4. Presence of cardiac pacemaker or implanted cardiac defibrillator
5. Any metal in the head or eyes
6. Use of medication which decreases seizure threshold
7. A diagnosis other than stroke is suspected (e.g. brain tumour)
8. Any severe concomitant chronic medical condition that compromises cardiac or respiratory status,
9. Significant structural abnormalities of the mouth or throat
10. Patients requiring oxygen treatment will be excluded at point of entry to prevent further compromise to already impaired respiratory system
11. Patients may be reconsidered for recruitment if they are successfully weaned off oxygen treatment

## **Date of first enrolment**

01/04/2015

## **Date of final enrolment**

01/09/2017

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

#### **University of Manchester**

Clinical Sciences Building, Dept. of GI Sciences

Hope Hospital

Stott Lane

Salford

Greater Manchester

United Kingdom

M6 8HD

## **Sponsor information**

### **Organisation**

University of Manchester

ROR

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## 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="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |