

# Theta Burst Stimulation for motor impairment after stroke

<b>Submission date</b> 29/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/07/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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**  
3279; G0401353

## Study information

**Scientific Title**  
Enhancing the effect of physical therapy for motor impairment after stroke with Theta Burst Stimulation

**Acronym**

## TBS Study

### Study objectives

In this study we plan to investigate whether brain stimulation can be used as an add-on treatment to consolidate the benefit from patterned upper limb physiotherapy and induce further hand motor improvement in chronic stroke patients.

To stimulate the brain we plan to use Theta Burst Stimulation (TBS), a novel paradigm of repetitive transcranial magnetic stimulation (TMS), aiming to increase cortical excitability of the affected (ipsilesional) hemisphere.

According to evidence so far, we believe that increased ipsilesional excitability can be achieved by:

1. Direct facilitation of the affected hemisphere (ipsilesional facilitation)
2. Inhibition of the unaffected hemisphere (contralesional inhibition)

Primary aim:

To investigate whether daily treatment with TBS followed by patterned physical therapy for a period of two weeks can lead to significant and sustained improvement of hand motor behavior in chronic stroke patients.

Secondary aims:

1. To study the physiological correlates of the potential behavioral gains
2. To identify physiological predictors of likelihood of response to the proposed intervention, so that appropriate patients may be targeted in future trials

Physiological correlates will be studied using TMS and functional magnetic resonance imaging (fMRI) as detailed below.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

NHNN and ION Joint Research Ethics Committee approved on the 25/02/2005 (ref: 04/Q0512 /108)

### Study design

Randomised interventional treatment trial

### Primary study design

Interventional

### Study type(s)

Treatment

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

Topic: Stroke Research Network; Subtopic: Rehabilitation; Disease: Therapy type

### Interventions

Physical therapy (physiotherapy):

The protocol for physical therapy has been developed in collaboration with the therapy services

department at the National Hospital for Neurology and Neurosurgery. It expands upon previous protocols by ensuring the equivalence of task intensity, repetition rate and verbal feedback across subjects. Treatment will be task oriented and individualised based on the findings of a questionnaire about current functional difficulties and an objective examination.

#### **Theta Burst Stimulation:**

TMS is a well tolerated method of stimulating the human cortex through the intact scalp. We will employ a new pattern of repetitive TMS called Theta Burst Stimulation (TBS). Each burst consists of 3 low intensity (80% aMT, see further on) stimuli, repeating at high frequency (50Hz). Bursts are repeating at 5Hz, i.e. the "theta" rhythm of the EEG. A total of 15 pulses are delivered per second. TBS effect on corticospinal excitability can be either inhibitory or facilitatory, depending on the pattern.

Follow up length: 3 months

Study entry: single randomisation only

#### **Intervention Type**

Other

#### **Phase**

Not Applicable

#### **Primary outcome(s)**

Action Research Arm Test, measured at initial assessment, 2 day post-intervention follow-up, 1 month follow-up and 3 month follow-up.

#### **Key secondary outcome(s)**

1. Electrophysiological measures of corticospinal excitability, intracortical interactions and interhemispheric balance, measured at initial assessment, 2 day post-intervention follow-up, 1 month follow-up and 3 month follow-up
2. Functional Magnetic Resonance Imaging: Measurement of motor and sensory related brain activation only performed at initial and two day post intervention follow-up

#### **Completion date**

31/12/2010

## **Eligibility**

#### **Key inclusion criteria**

1. History of a single ischaemic stroke, initially affecting the hand
2. Minimum interval since stroke onset one year (no upper limit)
3. Residual impairments of hand function (strength and/or dexterity)
4. Some degree of hand movement defined as present wrist extension ( $\geq 20\%$ ) and ability to grasp
5. Capable of giving informed consent
6. Aged 18 - 80 years, either sex

#### **Participant type(s)**

Patient

#### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Intracerebral hemorrhage
2. Large ischaemic lesions involving almost the whole MCA territory
3. Significant tone problems in the hand (greater than 2 in the Ashworth Scale)
4. Severe cognitive impairment defined as mini-mental state examination (MMSE) less than 20
5. Residual aphasia or visual field defect (greater than or equal to 2 in the relative item of the National Institutes of Health Stroke Scale [NIHSS])
6. Past or current history of other neurological or psychiatric disease including epilepsy, previous or recurrent stroke and peripheral neuropathy
7. Major systemic illness
8. Use of anticonvulsant, psychotropic or sedative or medication
9. Excessive use of alcohol or other substances
10. Accepted contraindications for TMS (presence of metal in the head (excluding the mouth), intracardiac lines, cardiac pacemakers)

**Date of first enrolment**

01/11/2005

**Date of final enrolment**

31/12/2010

**Locations**

**Countries of recruitment**

United Kingdom

England

Italy

**Study participating centre**

**Institute of Neurology**

London

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# Sponsor information

## Organisation

University College London Hospitals NHS Foundation Trust (UK)

## ROR

<https://ror.org/042fqyp44>

# Funder(s)

## Funder type

Research council

## Funder Name

Medical Research Council (MRC) (UK) (ref: G0401353)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## 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="#">Results article</a>	results	01/10/2012		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes