

# An investigation into the effect of including a goal-orientated independently practised exercise programme in early stroke rehabilitation

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 07/10/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Ms Judith McLain

### Contact details

Swindon Intermediate Care Centre  
Downs Way  
Swindon  
United Kingdom  
SN3 6BW

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

N0647150885

# Study information

## Scientific Title

### Study objectives

To evaluate the effects of goal-orientated individualised exercise and activity programmes practised independently in the first three months of stroke in addition to normal therapy, both from the perspective of the patient and the clinician's evaluation of the patient's performance. To pilot the intervention to establish evidence for or against the feasibility of including independently practised goal-orientated exercise programmes in early stroke rehabilitation. The results of the study, if positive, will inform a power calculation and design of a full randomised controlled trial.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

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

Stroke

### Interventions

A single-blinded RCT pilot using blocked randomisation in blocks of 4. Goal-orientated individualised exercise and activity programmes practised independently in the first three months of stroke in addition to normal therapy.

### Intervention Type

Other

### Phase

Not Applicable

**Primary outcome measure**

1. Canadian Occupational Performance Measure (COPM)
2. Motor Assessment Scale (MAS)
3. Barthel Index
4. Patient diary
5. Patient telephone questionnaire

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/05/2003

**Completion date**

01/11/2003

## **Eligibility**

**Key inclusion criteria**

Patients admitted to the stroke ward and medically able to understand and comply with the protocol. Inclusion criteria:

1. Inpatients within 6 weeks of diagnosis of first stroke confirmed by computed tomography (CT) scan
2. Medically stable and undergoing rehabilitation on a stroke and neurological unit
3. In the opinion of the researchers, have the ability to understand and comply with carrying out an exercise and activity programme on their own
4. Patients must be able to give informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

16 to 20 patients to be recruited during the six months of the study

**Key exclusion criteria**

1. Complex medical problems that prevent compliance with study protocol
2. The patient is likely to be discharged within two weeks of admission to the stroke and neurological unit

**Date of first enrolment**

01/05/2003

**Date of final enrolment**

01/11/2003

## Locations

### Countries of recruitment

England

United Kingdom

### Study participating centre

**Swindon Intermediate Care Centre**

Swindon

United Kingdom

SN3 6BW

## Sponsor information

### Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

### Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

### Sponsor type

Government

### Website

<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

### Funder type

Government

### Funder Name

Pan-Bath and Swindon Primary Care Research Collaborative (UK)

**Funder Name**

NHS R&D Support Funding (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