

# A study to investigate whether provision of a short term, exercise and education programme for adults with acquired brain and spinal cord pathology will lead to an increase in levels of independent activity and self efficacy for exercise behaviours.

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/09/2009	<b>Condition category</b> Nervous System Diseases	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0259142786

## **Study information**

**Scientific Title**

**Study objectives**

To examine whether undertaking a physiotherapy led exercise and education programme will increase confidence to carry out exercise independently and improve levels of daily activity in those patients with acquired brain and spinal cord pathologies.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised single blind placebo controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Other

**Participant information sheet**

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

Brain diseases

**Interventions**

The study will be randomised, single blind, placebo controlled experimental trial. Appropriate participants will be subject to random sampling following consent and then assigned to either a treatment group or control group. The intervention to be examined includes a short, exercise and education programme undertaken immediately on discharge from hospital. The development of this programme followed discussions with various in patients receiving rehabilitation following brain and spinal cord injury surrounding their concerns for ongoing exercise and activity when they are at home. Both the treatment and control groups will undertake the standard discharge procedures of follow-up clinic reviews and referral to out

patient physiotherapy as appropriate. The treatment group will also receive the intervention. Validation outcome measures will be utilised to measure the effects of the intervention. Following data collection, the information will be subject to statistical analysis and the results reported. A pilot study will be undertaken to review the appropriateness of the chosen methodology.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. Exercise Self Efficacy Measure - Paper containing measure on order from library.
2. Human Activity Profile - Questionnaire on activity levels.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/08/2004

**Completion date**

01/06/2006

**Eligibility****Key inclusion criteria**

1. Disorder of movement caused by brain or spinal cord pathology.
2. Ability to carry out independent exercise.
3. Physical level which includes independent sitting balance and transfer ability.
4. Able to exercise safely without constant supervision.
5. Age 16-65.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

44 (added 09/09/09)

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/08/2004

**Date of final enrolment**

01/06/2006

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**The Walton Centre for Neurology and Neurosurgery**

Liverpool

United Kingdom

L9 7LJ

## **Sponsor information**

**Organisation**

Department of Health

**Sponsor details**

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**

The Walton Centre for Neurology and Neurosurgery NHS Trust (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2009		Yes	No