

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.

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

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Sponsor information

Organisation

Department of Health

Sponsor details

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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?
Results article	results	01/04/2009		Yes	No