

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

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| Submission date 29/09/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 29/09/2006 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 07/10/2014 | Condition category Circulatory System | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <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

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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 fo 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration