Rehabilitation of arm function

Submission date Recruitment status Prospectively registered 23/01/2004 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 23/01/2004 Completed [X] Results [] Individual participant data **Last Edited** Condition category 21/12/2009 Circulatory System

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Nadina Lincoln

Contact details

School of Psychology University of Nottingham University Park Nottingham United Kingdom NG7 2RP +44 (0)115 9515315

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MS41

Study information

Scientific Title

Study objectives

After suffering a stroke most patients have problems using the affected arm and hand, but achieve varying degrees of recovery over the ensuing months. Most patients receive routine physiotherapy.

The aim of this study was to investigate the use of more intensive physiotherapy to see if this improved arm and hand function.

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 rehabilitation

Interventions

Participants were allocated to one of three treatment groups

- 1. Routine physiotherapy (RPT)
- 2. Qualified physiotherapist (QPT)
- 3. Assistant physiotherapist (APT)

The patients in the last group were assessed initially by a qualified physiotherapist who then supervised the treatment of each patient by the assistant weekly. Routine physiotherapy involved about 2-3 hours a week for all disabilities, while patients in the other two groups received 2 hours of additional treatment for their arm each week for 5 weeks (ten hours in total).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The principal measures used at five weeks:

- 1. Rivermead Motor Assessment Arm Scale
- 2. Action Research Arm Test.

Secondary outcome measures

Other tests measured

- 1. dexterity
- 2. grip
- 3. motor function
- 4. self- care
- 5. other daily living abilities

The later assessments comprised four of these tests.

Outcomes were assessed after five weeks, three months, and six months.

Overall study start date

01/10/1994

Completion date

01/04/1998

Eligibility

Key inclusion criteria

Patients with admitted to Nottingham City Hospital following a stroke were entered in the study between one and five weeks later, after giving consent. All patients had normal arm function prior to the stroke, and were assessed as able to accept the physiotherapy programme.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

282 (Added 19/11/09)

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/10/1994

Date of final enrolment

01/04/1998

Locations

Countries of recruitment

England

United Kingdom

Study participating centre School of Psychology Nottingham United Kingdom

NG7 2RP

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Cardiovascular Disease and Stroke National Research and Development Programme (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	01/03/1999	Yes	No
Results article	results on analysis of arm impairment severity $% \left\{ \left(1\right) \right\} =\left\{ \left(1$	01/06/1999	Yes	No