Multi-centre trial of out patient occupational therapy for stroke

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		[_] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited 20/11/2009	Condition category Circulatory System	[_] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers MS138

Study information

Scientific Title

Study objectives

To evaluate the effects of leisure therapy and conventional occupational therapy (OT) on the mood, leisure participation and independence in Activities of Daily Living (ADL) of stroke patients six months and twelve months after hospital discharge.

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) Other

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Cerebrovascular disease and stroke

Interventions

Community occupational therapy aimed at promoting independence in activities of daily living (ADL) was compared to occupational therapy aiming to promote leisure activity, or no trial intervention. Maximum of 10 visits over six months in treated patients.

Intervention Type Other

Phase Not Specified

Primary outcome measure

- 1. Personal ADL (Barthel ADL Index)
- 2. Instrumental ADL (Nottingham Extended ADL scale)

3. Mood (GHQ-12)

- 4. Leisure activity (abbreviated Nottingham Leisure Questionnaire)
- 5. Handicap (London Handicap Scale)
- 6. Global outcome (Oxford Handicap Score, and International Stroke Trial Questions)

Secondary outcome measures

Not provided at time of registration

Overall study start date 31/01/1997

Completion date

31/01/2000

Eligibility

Key inclusion criteria

In 4/5 centres, patients with stroke were recruited at discharge from hospital. In the other centre patients were seen in an out-patient clinic.

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 209 (Added 19/11/09)

Key exclusion criteria Those discharged to institutional care were excluded.

Date of first enrolment 31/01/1997

Date of final enrolment 31/01/2000

Locations

Countries of recruitment England

United Kingdom

Study participating centre Ageing and Disability Research Unit Nottingham United Kingdom NG7 2UH

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?
<u>Results article</u>	results	01/02/2001		Yes	No