Social-environmental, psychological and physical approaches to stroke rehabilitation

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/04/2003		Protocol		
Registration date 25/04/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
30/10/2009	Circulatory System			

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 93/03/11

Study information

Scientific Title

Study objectives

This COllaborative STroke Audit and Research (COSTAR) group study will evaluate "social", "psychological" or "physical" approaches to rehabilitation of stroke patients in the community, aiming to help families adjust to life after a stroke and reduce long term distress. About 400 patients will be recruited to a randomised controlled trial in Newcastle to receive one, two or none of the interventions in a factorial design allowing the three approaches and the interactions between them to be assessed. This study will be linked with trials of cognitive /behavioural therapy, community occupational therapy and "leisure rehabilitation" being undertaken in Nottingham and with other controlled trials of similar services being planned at other COSTAR centres, in an "epi-analysis" (pre-planned collaboration using standard clinical measures). This large collaboration will provide reliable information on the cost-effectiveness of different forms of community care for stroke patients and their families.

Please note that, as of 25 January 2008, the anticipated end date of this ISRCTN record was updated from 29 February 2000 to 30 November 2001.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial with a factorial design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Stroke patients

Interventions

- 1. Social rehabilitation
- 2. Psychological rehabilitation

- 3. Physical rehabilitation
- 4. Standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/12/1995

Completion date

30/11/2001

Eligibility

Key inclusion criteria

Patients having recently suffered a stroke

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

400

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/12/1995

Date of final enrolment

30/11/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Department of Medicine (Geriatric Medicine)

Newcastle upon Tyne United Kingdom NE9 6SX

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/en/index.htm

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	01/02/2001		Yes	No