

Exercise training early after stroke: a feasibility study

Submission date 30/04/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/04/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/11/2011	Condition category Circulatory System	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AP0875

Study information

Scientific Title

Study objectives

Hypothesis:

It is practical for all stroke patients to undertake early exercise training (ET), regardless of level of impairment.

Brief summary:

Patients meeting the inclusion criteria will be randomised into one of two groups, usual care or intervention (ET). In addition to usual care, patients in the ET group will be individually taught a series of basic exercise activities for the arms and legs which can be done lying, sitting or standing, depending upon which of these positions the patient can maintain and prefers. Patients will be encouraged to perform those activities which they can, for up to 30 minutes 3 times per week. Once patients are confident of the activities they will be given simple, quirky prompts to remind them what to do. Data will be collected at baseline and at 3 months post-stroke.

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)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Stroke

Interventions

Patients meeting the inclusion criteria will be randomised into one of two groups, usual care or intervention. The patients in the intervention group, will, in addition to their usual therapy, be taught a series of basic exercise activities for the arms and legs. Patients will be encouraged to perform the exercises for up to 30 minutes, three times per week.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Arm and leg function: the Motor Assessment Scale

Secondary outcome measures

1. Functional dependence: the Barthel Index
2. Psychological well-being: the GHQ 12 questionnaire
3. Tone: the modified Ashworth Scale
4. Power: the Medical Research Council Scale
5. Hand posture: the Tod Scale
6. A qualitative assessment of attitudes of patients, carers and staff to exercise training

Overall study start date

01/09/2002

Completion date

30/09/2003

Eligibility**Key inclusion criteria**

1. Diagnosis of stroke
2. Surviving to week two
3. Still in hospital
4. Medically stable
5. Able to follow simple verbal instructions
6. 18 years of age and over, either sex

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Non-stroke
2. Died or care transferred into the community before week 2
3. Medically unstable
4. Unable to follow simple verbal instructions
5. Under 18 years of age
6. Non-consent

Date of first enrolment

01/09/2002

Date of final enrolment

30/09/2003

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Clinical Practice Research Unit

Preston

United Kingdom

PR1 2HE

Sponsor information**Organisation**

Action Medical Research (UK)

Sponsor details

Vincent House

Horsham West Sussex

United Kingdom

RH12 2DP

Sponsor type

Charity

Website

<http://www.action.org.uk/>

ROR

<https://ror.org/01wcqa315>

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

actionmedres, action medical research for children, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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