A randomised controlled trial of different intensities of physiotherapy and collaborative goal-setting in children with cerebral palsy.

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 Nervous System Diseases 19/11/2009

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

MCH 13-17

Study information

Scientific Title

Study objectives

Does more intensive physiotherapy or collaborative goal-setting increase motor function or performance in children with cerebral palsy?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled 2x2 factorial design trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cerebral palsy

Interventions

Following 6 months baseline observation (A), the children were stratified and randomised into 4 treatment groups. A 2x2 factorial design was used to compare current amounts of physiotherapy with intensive amounts and the use of generalised aims with specific, measurable goals negotiated with each child, carer, teacher and the child's own physiotherapist. Following the 6 month treatment period (B),there was a further 6 month period of observation (A). Each child received one of four treatment regimes during the treatment period (B) provided by their own physiotherapist.

- 1. Current pattern of physiotherapy continued for each child as usual
- 2. Current pattern of physiotherapy provided more intensively
- 3. Physiotherapy guided by collaborative goal-setting at the current intensity
- 4. Physiotherapy guided by collaborative goal-setting and provided more intensively

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Changes in motor function and performance were assessed using the Gross Motor Function Measure [Russell et al. 1993] and the Gross Motor Performance Measure [Boyce et al. 1998].

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/06/1999

Eligibility

Key inclusion criteria

A convenience sample of children with bilateral cerebral palsy classified on the Gross Motor Function Classification System [Palisano et al. 1997] living in the community.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/12/1996

Date of final enrolment

01/06/1999

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Rehabilitation Research Unit

Southampton United Kingdom SO16 6YD

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Mother and Child Health National Research and Development Programme (UK)

Results and Publications

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	01/01/2001		Yes	No