

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

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/11/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Eva Bower

Contact details

Rehabilitation Research Unit
University of Southampton
Mailpoint 874
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD
+44 (0)1703 79 6466
Evabower@talk21.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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 measure

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].

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/1996

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

Age group

Child

Sex

Both

Target number of participants

56 (Added 19/11/09)

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**

England

United Kingdom

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)

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 Mother and Child Health 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	01/01/2001		Yes	No