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Constraint induced movement therapy: A randomised controlled Trial in Children with Hemiplegic cerebral palsy

Submission date
15/06/2011

Recruitment status
No longer recruiting

Registration date
28/07/2011

Overall study status
Completed

Last Edited
06/03/2018

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cerebral palsy is a general term which refers to a set of neurological conditions that affect a child's movement and co-ordination. Neurological conditions affect the brain and nervous system. Cerebral palsy is caused by damage to the brain, which normally occurs before, during or soon after birth. Known possible causes of cerebral palsy include:
Infection in early pregnancy
Difficult or premature birth
Bleeding in the babys brain
Abnormal brain development in the baby
Cerebral palsy remains a major cause of lifelong disability affecting approximately 1 in 500 children. Of those about 30% have hemiplegic cerebral palsy (HPC), where there is muscle stiffness on one side of the body and sometimes causes curvature of the spine. This often lead to major difficulties with manual dexterity and upper limb functional ability and independence. Therapists use a number of strategies in upper limb rehabilitation to treat HPC, however they are poorly understood and their effects have been questioned. Constraint induced movement therapy (CIMT) is a combination of treatment where the unaffected arm is restrained using a splint and cast, while greater use of the affected arm is encouraged. This has been found to be an effective method of treatment for HCP however its use in the pre-school children via the National Health Service (NHS) has not been examined. Our aim is to compare CIMT using longer periods of restraint with CIMT using shorter periods of manual restraint which is standard practice and acts as the control.

Who can participate?
Children with hemiplegic cerebral palsy (HCP) aged 18 months to 48 months (9 months before starting compulsory education) can take part. Children will be excluded if a skin condition is present which may cause problems with splinting/ casting, if there is some abnormal neurological involvement in both upper limbs, if there are any symptoms of movement disorders which cause involuntary muscle spasms and contractions or if the child has received more than 2 weeks of prolonged restraint therapy using a cast/splint within the last 6 months.

What does the study involve?
Participants will have two upper limb assessments: the Assisting Hand Assessment and the Quality of Upper Extremity Skills Test. Parents/guardians will also complete three questionnaires including two quality of life questionnaires (Peds QL Generic Core Scales and the Cerebral Palsy Module). The participants will then be randomly allocated to each of the groups. The treatment period will be for six non-continuous weeks (two week blocks) over ten weeks. Parents /guardians and possibly preschool workers will be expected to carry out a therapy guided programme. The amount of treatment and compliance will be recorded by parents /guardians and therapists. Assessments will be repeated at 10 weeks and a postal questionnaire will be completed by parents/guardians at 24 weeks from the beginning of the trial.

What are the possible benefits and risks of participating?
The children allocated to the prolonged restraint group may become frustrated leading to an increase in poor behaviour as they are not able to use their unaffected hand. Every effort will be made to keep this to a minimum through providing appropriate toys and advice on activity. Clear guidelines are available to therapists and parents/guardians to respond to this. The method chosen for prolonged restraint is removable and parents/guardians will have instructions for removing the splint/cast if needed and contact numbers for further assistance. If there is total non-compliance by the child a decision may be made between the therapist and parent/guardian to discontinue.
The skin on the upper limb which is restrained for a prolonged period may become red and sore. At worse this could become blistered. This will be highlighted to parents/guardians. It would be expected that if this was the case the child would complain and parents/guardians would be able to remove the restraint. As the splint/cast is removable the skin condition can be checked.
The unaffected upper limb while restrained may be less effective in saving reactions. The method of restraint chosen is below elbow to keep this to a minimum. However there may be an increase in injury from falling over. This risk is kept to a minimum by highlighting it to parents /guardians and advising to limit situations which would be especially challenging to balance or offering supervision in these situations.

Where is the study run from?
The study takes place in the participants usual treatment location. This could be in a local clinic, the participants home or pre-school setting.

When is study starting and how long is it expected to run for?
The treatment stage of the study began in July 2010 and will continue until December 2011.

Who is funding the study?
1. West Midlands Strategic Health Authority
2. The Nancie Finnie Charitable Trust

Who is the main contact?
Pauline Christmas
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Contact information

Type(s)
Scientific

Contact name

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Additional identifiers

Protocol serial number
10/H1207/36

Study information

Scientific Title
A randomised controlled trial to compare two methods of upper limb constraint induced movement therapy to improve functional ability in the affected arm in pre-school children with hemiplegic cerebral palsy

Acronym
CATCH

Study objectives
Will therapy with prolonged restraint (removable cast/splint) result in improved functional outcome compared to therapy with brief manual restraint in pre-school children with Hemiplegic Cerebral Palsy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Committee, 22 June 2010, 10/H1207/36

Study design
A multi-centre phase II single blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hemiplegic Cerebral Palsy

Interventions

1. Constraint Induced Movement Therapy will be delivered by the treating therapists
2. It will consist of a combination of restraint of the unaffected upper limb, and therapy to encourage mass practice of the affected upper limb
3. The unaffected upper limb will be restrained from above the wrist, to include the hand for a prolonged period with either a cast, or an off the shelf wrist splint and a crepe bandage to enclose the fingers
4. In order to monitor any unintentional affects due to immobilising the unaffected upper limb, an inspection of skin colour, the presence of any blistering and skin pressure areas and assessment of joint ranges of movement will be carried out after every episode of immobilisation
5. Some parents/guardians may choose to put a sock over the restraint to keep it clean
6. This will be applied in a clinic setting
7. It would be expected that this would be applied on 3 separate occasions
8. Immobilising from below the elbow, allows the unaffected arm to be available for protective saving reactions and be able to continue to participate in some bimanual activities
9. Children with casts or splints are not an unusual event in society so this intervention is relatively non-stigmatising
10. The child may even feel positive about the attention from peers and adults
11. In addition it would be easily adopted more widely into current NHS practice
12. Therapy will take place in the childs usual environment
13. This is at home supervised by parents/guardians or when the child attends nursery, supervised by nursery staff
14. Therapists/therapy assistants will guide this intervention once per week either by face to face contact or on the telephone
15. This is similar to the current intervention which the child receives
16. The therapy will be based on principles of motor learning and particular attention will be paid to the type of activity and the toys used
17. Written information about this home therapy programme will be given to parents/ guardians /nursery staff to guide this intervention
18. At all times activity needs to be as achievable and as enjoyable as possible motivating the child to repeat the activity
19. No attempt will be made to facilitate specific motor patterns
20. It would be expected that the treatment would last for approximately one hour per day
21. However it is not necessary for this time to be continuous
22. If meal times are included most parents/guardians should be able to accomplish this

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
Assisting Hand Assessment (AHA) at 10 weeks

Key secondary outcome(s))
1. Quality of Upper-Extremity Skills Test (QUEST) at 10-weeks
2. PedsQL Generic score and CP module at 10-weeks, and 24-weeks
3. Birmingham Bi-manual Questionnaire (BBQ) at 10-weeks, and 24-weeks

Completion date

31/10/2013

Eligibility

Key inclusion criteria
1. Diagnosis of Hemiplegic Cerebral Palsy
2. Aged between 18 months and 9 months before compulsory education begins

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. Diagnosis/ clinical evidence of bilateral upper limb involvement
2. Diagnosis/ clinical evidence of athetosis or dystonia
3. Any medical condition which would cause problems with the cast e.g. chronic eczema
4. This would be expected to be around 5% of the Population
5. An episode of >2 weeks of prolonged Constrain Induced Movement Therapy using a cast /splint in the previous 6 months

Date of first enrolment
01/07/2010

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (United Kingdom)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
West Midlands Strategic Health Authority (United Kingdom)

Funder Name
Nancie Finnie Charitable Trust (United Kingdom)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes