Spasticity in children and young people with non-progressive brain disorders: management of spasticity, co-existing motor disorders and their early musculoskeletal complications

Physical therapy (physiotherapy and/or occupational therapy)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Dodd,K.J., Taylor,N.F., Graham,H.K., A randomized clinical trial of strength training in young people with cerebral palsy, Developmental Medicine and Child Neurology, 45, 652-657, 2003 **Ref ID** 75865 **Country/ies where the study was carried out** Australia **Study type** Randomised controlled trial **Aim of the study** To determine whether a home-based strength-training programme could (1) increase the strength of the ankle plantarflexors, knee	**Sample size** Sample size: 21 children and adolescents **Characteristics** Characteristics -Intervention group n=11 GMFCS I: 2 GMFCS II: 2 GMFCS III:7 Sex M/F: 4/7 -Control group n=10 GMFCS I: 5 GMFCS II: 3 GMFCS III: 2 Sex M/F: 6/4 No significant differences between the groups in all the previous or in height and weight or in any of the outcomes of interest **Inclusion criteria** -aged between 8 and 18 years with spastic diplegic CP -able to walk independently, with or without a gait aid, and to be able to	**Interventions** Interventions 1. Six-week strength training programme -intervention and equipment: Three strengthening exercises designed to target the ankle plantarflexor, knee extensor, and hip extensor muscle groups: a. bilateral heel raises in which the participant stood on the edge of a stable, light-weight portable step (height 20cm) and raised and lowered his or her heels through the full available range b. bilateral half squats in which from a standing position, the participant slowly squatted until knees were flexed to between 30 and 60°. A large inflatable ball (55cm diameter) was placed between the lower back of the	Recruitment: potential participants were identified by one of the authors from the outpatient records of the Hugh Williamson Gait Laboratory at the Royal Children's Hospital, Victoria, Australia Sample size calculation: based on a systematic review of strength training in CP (Dodd et al. 2002). Numbers in each group (n=11) were based on a conservative estimate of effect size of d=1.20, allowed for a significance level of 0.05, and a power of 0.80 (Howell 1987). Effects sizes (d) of greater than 1.2 have been reported for increasing muscle strength and activity in children with CP. Randomisation and allocation concealment: participants were allocated	GMFM D-standing (%) (mean/SD) -at baseline Experimental: 75.2 (14.4) Control: 74.6 (20.9) -at 18 weeks Experimental: 80.4 (13.2) Control: 80.7 (15.0) NS (p value not reported) GMFM E-walking, running and jumping (%) (mean/SD) -at baseline Experimental: 52.8 (31.3) Control: 68.3 (30.1) -at 18 weeks Experimental: 58.2 (31.3) Control: 67.8 (28.6) NS (p value not reported) GMFM total (%) (mean/SD) -at baseline Experimental: 64.2 (27.8) Control: 71.7 (24.9)	**Limitations** Small sample size and calculation based on outcome not relevant to our review. Power analysis revealed that if the effect size were maintained and the sample size increased to n=26 in each group, there was an 80% chance that the comparison for dimension E of the GMFM would have reached statistical significance. One participant in the control group did not complete the 18-week follow-up test due to recent surgery on the lower limbs. **Other information** All of the participants had been involved in active orthopaedic management before participation in this trial. Seventeen of the 21 young people had undergone multilevel orthopaedic surgery a mean of 34 months (range 24–52 months) before the trial commenced. One young person had undergone isolated calf

extensors, and hip extensors and (2) improve physical activity and walking ability in young people with spastic diplegic CP **Study dates** Not stated **Source of funding** Not stated	follow simple commands **Exclusion criteria** -a fixed flexion deformity at the knee, hip greater than 25°, or fixed equinus of more than 10° -current participation in other management strategies such as serial casting, botulinum toxin, or recent orthopaedic surgery (less than 12 months), and -participation in a strength-training programme within the previous three months	participant and the wall to help guide and standardise the exercise; and c. step-ups where the participant stepped onto and off portable steps -setting:unclear, presumably hospital -frequency and duration: the training load was adjusted by adding free weights to a backpack worn by the participant. Once the initial load was determined, participants were instructed to complete three sets of between eight and 10 repetitions of each exercise, three times a week for six weeks. Each exercise session took between 20 and 30 minutes. -who delivered: physiotherapists 2. Normal daily activities: Included school and sport. Participants were also able to attend their normal physiotherapy programme, provided therapy did not include a progressive resistance exercise programme.	randomly to either the strength training or control group using a concealed method. Twenty-two identical pieces of paper were placed in an opaque container, 11 with the words 'experimental group' and 11 with the words 'control group' written on them. In another opaque container, the name of each participant was written on 21 separate pieces of paper. Allocation was achieved by drawing a piece of paper from each container. This process continued until all participants were allocated to a group Outcomes assessed 1. Dimensions D and E of the Gross Motor Function Measure (GMFM; Russell et al. 1993) When assessed: at baseline, and at 6 and 12 weeks How assessed: participants were asked to attempt each of the items up to three times without using any assistive	-at 18 weeks Experimental: 69.6 (21.4) Control: 74.3 (21.4) Walking speed (m/min) (mean/SD) -at baseline Experimental: 47.4 (23.3) Control: 49.5 (24.5) -at 18 weeks Experimental: 48.6 (23.3) Control: 51.4 (16.5) Adverse events Total number of events: 3 (apparently all in the experimental group, none reported for the control group) There was no adverse event that led to participants missing a training session. One participant reported pressure on the shoulders from the backpack. As a result, weights were carried in a home-made vest to distribute the load more evenly. Two participants reported mild foot and ankle discomfort during the heel raise exercise. To alleviate this, the physiotherapy	lengthening without multilevel surgery. Three of the younger participants had been managed with botulinum toxin for dynamic equinus on 1–3 occasions. At the time of the trial, all participants were orthopaedically well-aligned with no major equinus deformities. It was expected that the amount of physiotherapy and the level of sport and physical activity the children participated in would not be different between the two groups due to the random allocation procedures Participants were provided with an exercise diary that detailed each exercise and enabled participants to record the weights used and the number of sets and repetitions completed at each exercise session. At the end of the second and fourth week of the exercise programme the physiotherapist visited the participant at home to check the way in which exercises were being performed and to adjust the training load. At the end of the trial the young people in the control group confirmed that they had not participated in a progressive strength-training programme during the trial.

		Typically, physiotherapy for school age children with CP in the state of Victoria is limited to a school consultation of around 45 minutes once or twice a month. **Comparison** Six-week strength training programme + normal daily activities vs. normal daily activities	devices. The best attempt was recorded 2. Self-selected walking speed When assessed: at baseline, and at 6 and 12 weeks How assessed: Participants were given standardised instructions: 'Walk to the end of the walkway at your normal walking speed. This is not a race, don't go fast'. Participants used their normal walking aids if appropriate. The walk was timed over the middle 10 metres of a 14-metre linoleum covered walkway using a stopwatch. A physiotherapist who was blind to group allocation and experienced in assessing movement disorders took all outcome measures. Blinding was maintained until after the final assessment had been completed. 3. Adverse events: Unclear how, when and who measured them	trainer modified the exercise so that ankle dorsiflexion did not exceed the plantigrade position.This modification enabled these participants to continue without incident.	All baseline, six-week, and 18-week measurement sessions were held in the La Trobe University Movement Rehabilitation Laboratory

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Full citation Dodd,K.J., Taylor,N.F., Graham,H.K., Strength training can have unexpected effects on the self-concept of children with cerebral palsy, Pediatric Physical Therapy, 16, 99-105, 2004 **Ref ID** 75866 **Country/ies where the study was carried out** Australia **Study type** Randomised controlled trial **Aim of the study** To use a randomised, controlled trial to test the prediction that participation in a home-based progressive resistance strength-training program would increase the self-concept of children with cerebral palsy **Study dates** Not stated **Source of funding**	**Sample size** N = 17 children **Characteristics** Age: 8 to 16 years GMFC (level) I = 6 (35%) II = 4 (24%) III = 7 (41%) No significant differences between both groups in age, height, weight or gender. There was a trend for children assigned to the experimental group to be more physically disabled as measured by the GMFCS (p=0.09) **Inclusion criteria** - spastic diplegic cerebral palsy - ability to walk independently with or without a gait aid - cognitive ability to follow simple commands **Exclusion criteria** - fixed flexion deformity at knee or hip > 25degrees or fixed equines of > 10 degrees - current participation in other management strategies such as serial casting, BoNT or recent orthopaedic surgery - participation in a strength-training program within the previous 3 months	**Interventions** Progressive resistance exercise. Frequency and duration: 3 sets of each exercise 3 times per week for the six weeks of the program Setting: home Who delivered: parents supervised by a physical therapist at first session and followed up on the second and fourth week to ensure compliance **Comparison** Normal daily activities including school and sports. Participants were also able to attend their normal physical therapy program provided that therapy did not include a progressive resistance exercise program	Recruitment Potential participants were identified by one of the authors from the outpatient records of gait laboratory of a large metropolitan children's hospital.The 17 children recruited for this study comprised most of the 21 participants of a previous RCT examining the effects of strength training for children and adolescents with cerebral palsy on improving muscle strength and physical activity. Sample size calculation Refer to Dodd 2003 Randomisation and Allocation Concealment Identical pieces of paper were placed in an opaque container, half with the words experimental group and half with the words control group written on them. In another opaque container, the name of each participant was written on a separate piece of paper. Allocation was	Self perception (Global self-worth) (score 0 to 4) (mean/ -Experimental group (n = 10) Baseline: 3.41 (0.38) 6 Weeks: 3.55 (0.40) 18 Weeks: 3.57 (0.45) -Control group (n = 7) Baseline: 3.27 (0.52) 6 Weeks: 3.21 (0.63) 18 Weeks: 3.41 (n = 6) (0.49) NS at any time period when comparing experimental and control groups	**Limitations** Small sample size and calculation based on outcome not relevant to our review Randomisation was not totally successful as there was a trend for children randomly assigned to the experimental group to be more physically disabled. One participant in the control group did not complete the 18-week follow-up test due to recent surgery on her lower limbs ITT analysis not conducted 3 other participants originally included in the RCT are not included here and it is unclear why **Other information** Retest Reliability of self-perception (Global self-worth) Mean test (SD): 3.28 (0.52) Mean Retest (SD): 3.21 (0.64) ICC (2,1): 0.76 Mean difference: -0.06 (0.42) ICC: interclass correlation coefficient

Supported by a La Trobe University Faculty of Health Sciences Research Grant			achieved by drawing a piece of labelled paper from each container. This process continued until all the children were allocated to a group. <u>Blinding</u> - Single blinding: A physical therapist who was blind to group allocation took all outcome measures. Blinding was maintained until after the final assessment had been completed <u>Outcomes assessed</u> - -Self-perception When measured: At baseline, 6 weeks and at a follow up session held 18 weeks after the initial assessment Who measured: The participants were given standardised instructions for completing the 36-item questionnaire Instrument/test: Self-Perception Profile for Children		

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Full citation Fowler,E.G., Knutson,L.M., Demuth,S.K., Siebert,K.L., Simms,V.D., Sugi,M.H., Souza,R.B., Karim,R., Azen,S.P., Physical Therapy Clinical Research Network (PTClinResNet), Pediatric endurance and limb strengthening (PEDALS) for children with cerebral palsy using stationary cycling: a randomized controlled trial, Physical Therapy, 90, 367-381, 2010 **Ref ID** 75913 **Country/ies where the study was carried out** USA **Study type** Randomised controlled trial **Aim of the study** To examine the effects of a stationary cycling intervention on muscle strength, locomotor	**Sample size** N=62 children **Characteristics** Age categories/years (n) a. 7 to 11 Cycling group: 20 Control group: 18 b. 12 to 18 Cycling group: 11 Control group: 13 Selective voluntary motor control (n) a. Fair Cycling group: 17 Control group: 15 b. Good Cycling group: 14 Control group: 16 Mobility (n) a. GMFCS I Cycling group: 11 Control group: 8 b. GMFCS II Cycling group: 8 Control group: 6 c. GMFCS III Cycling group: 12 Control group: 17	**Interventions** Cycling intervention - Intervention: each 60-minute cycling session was divided into 2 phases: lower extremity strenghtening and cardiorespiratory endurance - Equipment: stationary bycicle designed for rehabilitation. Features included a semirecumbent design with a wide padded seat, trunk support, foot straps and a unique "cyclocentric" lower-limb-loading feature to provide resistance - Setting: community-based pediatric physical therapy clinics - Frequency and duration: 3 times/week, total 30 sessions within a 12-week period - Who delivered: physical therapists, each demonstrated 90% competency for the performance of critical components **Comparison** No cycling intervention (control group)	Recruitment: participants were recruited via flyers and brochures placed in clinics and schools, mailed or posted on disability-related websites. A telephone screening was performed for potential participants who contacted the investigators. Sample size calculation: power analyses determined that a sample size of 58 participants (29 intervention, 29 control) would have 80% power to detect a moderate effect size of 0.7 associated with a 15% strenght improvement. This gain was a conservative estimate based on improved peak knee extensor and flexor moments following an isokinetic knee strenghtening program Randomisation: blocked by age group (7 to 11 years, 12 to 18 years) and selective voluntary motor control ability (good, fair) to minimise effects of maturation and physical impairment.	Thirty-Second Walk Test (30sWT): change from baseline (mean (95% CI)) Cycling group: 1.2 (-3.9 to 6.2) Control group: 3.4 (-1.7 to 8.4) NS GMFM-66: change from baseline (mean (95% CI)) Cycling group: 1.2 (0.5 to 1.8) Control group: 0.5 (-0.2 to 1.3) NS Adverse events (cycling group only) Total number: 24 Complaints of mild pain, soreness or muscle cramping: 17 Observed falls: 6 (no other details reported) Skin rash related to HR sensor: 1	**Limitations** The outcome on which the sample calculation was based is not relevant for our review ITT analysis not conducted Participants with no available outcome data (n=4): during the intervention period 2 participants withdrew for personal reasons and 2 others did not maintain the criteria necessary for inclusion and were withdrawn by the investigators (one child initiated an intensive sports programme and the other child underwent a medical treatment for vision) **Other information** If formal physical therapy had been initiated or discontinued recently, data collection was postponed until 3 months had elapsed. For the duration of the study, participants who were receiving physical therapy were asked to maintain their present regimen

endurance, preferred walking speed and gross motor function in children with spastic diplegic cerebral palsy (CP) **Study dates** Not reported **Source of funding** Grant from the Foundation for Physical Therapy Corporate donations or discounts: Biodex Inc, Freedom Concepts, Helen's Cycles, Santa Monica, National AMBUCS Inc and Sam's Club.	No significant differences at baseline were found for demographic data, participant characteristics or outcomes of interest **Inclusion criteria** -spastic diplegia -aged between 7 and 18 years -ability to follow simple verbal directions -ability to walk independently with or without assistive device, for short distances (GMFCS levels I to III) -good or fair selective voluntary motor control for at least one limb (Good: defined as the ability to isolate both knee and ankle movement out of synergy (knee extension with the hip positioned in flexion; ankle dorsiflexion with the knee positioned in extension). Fair: defined as the ability to isolate knee extension but not ankle dorsiflexion) **Exclusion criteria** -orthopaedic surgery, neurological surgery or baclofen pump implantation within the preceding 12 months -serial casting or new orthotic devices within the preceding 3 months -initiation of oral medications that affect the neuromuscular system (eg, baclofen) within the preceding 3 months -initiation of physical therapy, exercise, sports activity or change in assistive devices for walking within the preceding		Allocation concealment: not reported Outcomes assessed - (Body function and activity levels of the ICFDH) - 1. Thirty-Second Walk Test (30sWT) How assessed: children were asked to walk at their preferred speed. The distance completed in 30 seconds was recorded. Test was performed on a circular path at a nearby track or school gymnasium 2. GMFM-66 How assessed: scores were obtained using section D (standing) and E (walking, running and jumping) Outcomes evaluators were blinded to participants group assignment and had to pass a rigorous standarisation procedure for each outcome measurement protocol by demonstrating 90% competency.		

	3 months -inability or unwillingness to maintain age-appropriate behaviour -serious medical conditions such as cardiac disease, diabetes or uncontrolled seizures -current participation in a fitness program that included a minimun of once-weekly cardiorespiratory endurance exercise -significant hip, knee or ankle joint contractures preventing passive movement of the lower limbs through the pedaling cycle, and -bilateral poor selective voluntary motor control (inability to isolate knee or ankle joint motion out of synergy)		Outcomes were assessed at baseline and following the 12-week intervention period 3. Adverse events Unclear how and who assessed them -		

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Full citation Lee,J.H., Sung,I.Y., Yoo,J.Y., Therapeutic effects of strengthening exercise on gait function of cerebral palsy, Disability and Rehabilitation, 30, 1439-1444, 2008 **Ref ID** 76046 **Country/ies where the study was carried out** Korea **Study type** Randomised controlled trial **Aim of the study** To assess the effectiveness of strengthening exercises of the lower limbs on improvement of muscle strength and gait function **Study dates** Not stated **Source of funding** Not stated	**Sample size** N = 17 children **Characteristics** Age/years (range): 4 to 12 Diagnosis Diplegia: 9 (53%) Hemiplegia: 8 (47%) There was no significant difference in distribution of age, sex and type of spastic cerebral palsy between the two groups **Inclusion criteria** -spastic diplegic or hemiplegic -ability to ambulate with or without assistive devices or orthosis **Exclusion criteria** -inability to follow commands from therapists -fixed contracture at the knee or hip joint for more than 25 degrees -medical or orthopaedic diseases that prevented exercise -orthopaedic surgery of the lower limb or injection of an antispastic drug	**Interventions** Progressive resistive exercise: targeting the muscle groups of lower limbs. Frequency and duration - 60 minute sessions three times per week for 5 weeks Setting: school Equipment: The intervention consisted of warm up stretching exercise, isotonic, isokinetic and a cool down exercise. For the isotonic exercise, one of three weights, 0.25 kg, 0.45 kg or 0.9 kg, was selected to provide resistance to voluntary muscle contraction in the form of adjustable weight cuffs attached by Velcro straps to the subject. Select weight was determined by the physical therapist depending on the ability of the children Who delivered: physical therapist **Comparison** Conventional physical therapy including NDT, range of motion exercise, and gait training Frequency and duration 5 weeks.	Recruitment Participants were recruited from an outpatient's clinic. Sample size calculation Not reported Randomisation Participants were allocated randomly to either the experimental group or control group using concealed methods Allocation concealment Not clear Outcomes assessed -Functional tests (GMFMT, GMFMD, GMFME) When measured: at baseline, immediately after completing the program and 6 weeks after completing the program Who measured: all measures taken by the same physical therapist Instrument/test: GMFM -Gait analysis (walking	Walking (speed) (cm/s) (mean/SD) -Experimental group (n = 9) Pre-training: 54.7±30.7 Post training: 74.6±38.7 Follow-up at 6 weeks: 78.2±39.3 -Control group (n = 8) Pre-training : 69.8±43.0 Post training: 68.2±42.9 p<0.05 when compared to control group Follow up at 6 weeks: 67.8±37.2 p<0.05 when compared to control group Optimisation of function (GMFM) GMFM T-total (mean/SD) -Experimental group (n = 9) Pre-training: 86.5±13.3 Post training: 86.9±13.4 Follow up at 6 weeks:87±13.5 -Control group (n = 8) Pre-training : 85.2±13.4 Post training: 85.4±13.5 Follow up at 6 weeks: 85.7±13.3	**Limitations** No blinding of outcomes assessors and not clear who performed gait analysis Small sample size and no calculation Method of randomisation and allocation concealment used not clearly stated **Other information**

			speed) When measured: At baseline, post-training and six week follow-up Who measured: Not clear Instrument/test: Computerised gait analysis was measured using Orthotrack 6.2.4 system. The child was asked to walk independently but was allowed to use an assistive device if necessary	<u>GMFM D-standing (mean/SD)</u> -Experimental group (n = 9) Pre-training : 73.5±25.7 Post training : 73.7±26.6 p<0.05 when compared to control group Follow up at 6 weeks: 73.8±26.6 -Control group (n = 8) Pre-training: 74.5±23.7 Post training: 74.6±23.7 ; (p<0.05) Follow up at 6 weeks: 75.4±22.7 <u>GMFM E-walking, running and jumping (mean/SD)</u> -Experimental group (n = 9) Pre-training : 61.6±34.1 Post training: 62.7±34.1 p<0.05 when compared to control group Follow up at 6 weeks: 63.0±34.4 -Control group (n = 8) Pre-training : 61.4±33.9 Post training :61.4±33.9 (p<0.05) Follow up at 6 weeks: 61.8±34 (Unless otherwise stated differences between groups	
				were not statistically significant)	

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Full citation Liao,H.F., Liu,Y.C., Liu,W.Y., Lin,Y.T., Effectiveness of loaded sit-to-stand resistance exercise for children with mild spastic diplegia: a randomized clinical trial, Archives of Physical Medicine and Rehabilitation, 88, 25-31, 2007 **Ref ID** 76060 **Country/ies where the study was carried out** Taiwan **Study type** Randomised controlled trial **Aim of the study** To investigate the effectiveness of the loaded sit-to-stand (STS) exercise on motor activity, muscle strength, and physiologic cost for children with mild spastic diplegia **Study dates** Not reported **Source of funding**	**Sample size** N=20 children **Characteristics** Experimental group Mean age: 85.6±20.8 Sex: 7M/3F GMFCS: 4 level I, 6 level II Control group Mean age: 91.3±17.5 Sex: 5M/5F GMFCS: 6 level I, 4 level II There were no statistically significant differences at baseline regarding socio-demographic, clinical characteristics or outcomes of interest between both groups at baseline **Inclusion criteria** (1) aged between 5 and 12 years old (2) spastic diplegia (3) the GMFCS10 level I or II (4) able to stand up from a chair independently and maintain standing for more than 5 seconds without falling (5) able to follow verbal instructions (6) without obvious limitation in the passive range of motion of lower extremities	**Interventions** - Type of intervention: additional loaded STS exercise at home besides their regular PT - Equipment: Body vests and lead weights were specially made for the loaded STS test and loaded STS exercise. Lead pieces weighed either 1 or 0.5kg. During the loaded STS test or loaded STS exercise, an appropriate amount of weight was put into the pockets of the body vest - Setting: home - Frequency and duration: 3 sets per day, 3 days a week for 6 weeks. - Who delivered: a trainer (unclear their professional affiliation) taught the exercises to the children and their caregivers. Caregivers supervised the children at home **Comparison** - Type of intervention: regular PT only - Setting: unclear - Frequency and duration: 6	Recruitment Before randomisation authors asked the physical therapists, physicians, and special educators of 7 medical centres, teaching hospitals, and schools to help recruit the children with spastic diplegia who met the inclusion criteria Sample size calculation Based on a systematic review of strength training in children with CP (Dodd et al, 2002) authors calculated the sample size to be 9 children per group, 18 in total. The effect size was 1.20 and the power was 80%, with a 1-tailed significance level of 0.05 Randomisation Children were stratified by their GMFCS level (I or II) and age (≥8y or <8y) and then randomly allocated to either the experimental or the control group. Randomised block design Allocation concealment	GMFM goal dimension score (%) (mean/SE) -Actual pre-training Experimental: 76.6 (4.4) Control: 83.1 (3.2) -Actual post-training Experimental:79.8 (4.1) Control:83.5 (2.8) -Adjusted post-training Experimental: 82.7 (0.7) Control: 80.6 (0.7) Mean Square and F values: 21.82 $F_{1, 17}$=4.81 P (1 tailed): 0.02 Gait speed (m/min) (mean/SE) -Actual pre-training Experimental: 56.9 (5.1) Control: 63.8 (3.0) -Actual post-training Experimental: 58.4 (5.0) Control: 62.0 (2.6) -Adjusted post-training Experimental:61.3 (1.7) Control: 59.0 (1.7) Mean Square and F values: 24.56 $F_{1, 17}$=0.87 P (1 tailed): 0.18 (NS)	**Limitations** Sample size calculation was based on an outcome not relevant for our review **Other information** Although the investigators attempted to standardise the frequency and volume of the training, the children did not perform exactly as expected because of other activities. All children of the experimental group had loaded STS exercise at least twice a week, and 3 children exercised more than 3 times a week because the caregivers wanted more than what was asked. Children in both groups decreased or stopped PT services during this study because of the fear of the SARS epidemic in Taiwan. In general, children of the control group received PT more frequently during the study period.

Supported by the National Science Council, Taiwan (grant no. NSC90-2314-B-002-315).	(7) able to attend physical therapy (PT) treatment at least once a week before and during this study while keeping up with regular treatment programs (8) had not received any strength-training program in the past 3 months before the study and (9) parental commitment to allow participation without altering current therapy or activity **Exclusion criteria** (1) have orthopaedic intervention, selective dorsal rhizotomy, or botulinum toxin injection to the lower extremities within 6 months (2) orthopaedic problems or medical conditions that prevented children from participating in the exercises	weeks. - Who delivered: unclear The regular PT programs in both groups included passive range of motion exercises, positioning, balance training, functional training, and neurodevelopment training.	Not reported <u>Outcomes assessed</u> -Function Instrument/test:Dimension D (13 items) and dimension E (24 items) of the GMFM-88, which measure motor activities in standing, walking, running, jumping, and hopping. Item scores for each goal dimension of GMFM-88 (GMFM goal dimension score) were added together and converted to yield a percentage score for that dimension. The GMFM goal dimension score was derived by averaging the percentage scores for dimension D and E in this study. -Gait speed Instrument/test:Gait speed in meters per minute was calculated using the time it took the child to walk the 10-m distance converted to meters per minute. Before the test, the tester had given the children instruction, such as “I’d like you to walk in the way you would normally do.”		

			The average velocity of 3 separate trials was used as the self-selected speed At the beginning and end of this study, 1 blinded tester who is a physical therapist with paediatric assessment experience (including GMFM-88, gait speed) for 6 years conducted the outcome measures and demographic data collection. The assessments for all the participants were conducted at about the same period of the day, so that all assessments would be performed in the morning for the same child. At the end of a 6-week interval, the same blinded tester conducted outcome measures, including GMFM goal dimension scores and walking speed.		

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Full citation Unger,M., Faure,M., Frieg,A., Strength training in adolescent learners with cerebral palsy: a randomized controlled trial, Clinical Rehabilitation, 20, 469-477, 2006 **Ref ID** 76312 **Country/ies where the study was carried out** South Africa **Study type** Randomised controlled trial **Aim of the study** To evaluate the impact of an eight-week strength training program targeting multiple muscle groups using basic inexpensive free weights and resistance devices, on gait and perceptions of body image and functional competence **Study dates** Not stated **Source of funding** Not stated	**Sample size** N = 37 adolescents **Characteristics** Age (range): 13 to 18 years Experimental: n=21 Control: n=10 No significant differences between groups for age, height, gender and severity allocation **Inclusion criteria** - aged between 13 and 18 years. - ability to be independently ambulant with or without a walking aid - in good general health - ability to understand instructions in either English or Afrikaans **Exclusion criteria** - history of spasticity-altering surgery such as baclofen pump or selective dorsal rhizotomy, orthopaedic or neurosurgery in the previous 12 months or botulinum toxin infection(s) in the previous six months - history of participation in sports at provincial or international level during the trial period	**Interventions** Progressive resistive exercise during school hours - Setting: unclear - Frequency and duration: 1 to 3 times per week for 8 weeks - Who delivered: programme was designed in consultation with their therapist. A research assistant was given instructions on performance criteria by the researcher and assisted with the implementation and supervision of the exercise programmes **Comparison** No intervention	Recruitment 37 adolescents from a school that caters for children with special needs who met the inclusion criteria Sample size calculation Not reported Randomisation Pretesting was followed by systematic randomisation into either groups with every third name drawn from a hat being allocated to the control group Allocation concealment Not reported Outcomes assessed a. Three dimensional gait analysis (velocity (we will use the term walking speed)) When measured: at baseline and immediately after programme finished (8 weeks) Who measured: research assistants blinded to group allocation both at baseline and post-testing Instrument/test: six-camera video-based motion-capturing system.	Walking speed (mm/s) (mean/SD) Experimental group (n=24) Pre-training: 1075.6 (235.4) Post-training:1119.3 (232.5) NS Control group (n=13) Pre-training: 1128 (132.0) Post-training: 1171.4 (141.9) NS Self perception of body image (composite score/25) (mean/SD) Experimental group (n=24) Pre-training: 23.9 (4.1) Post-training: 25.9 (3.4) Control group (n=13) Pre-training: 19.0 (3.2) Post-training: 20.5 (3.3) P = 0.01 (experimental vs. control, but unclear whether this refers to post-training values or to mean difference of change from pre-training) Self perception of functional competence (composite score/25)(mean/SD) Experimental group (n=24) Pre-training: 19.9 (3.4)	**Limitations** Small sample size and no calculation Baseline characteristics: children in the control group differed significantly from the experimental group from weight (p=0.02) and distribution of involvement (diagnosis) (p=0.03) ITT analysis not conducted 2 adolescents in the experimental group were withdrawn before post testing due to “absenteeism” from the program (criterion not predefined) and one was withdrawn after post-testing and before analysis because of sport participation. 3 adolescents in the control group were after post-testing and before analysis: one because of sport participation, one for incorrect diagnosis (unclear what this meant) and one because participating in a progressive resistance exercise programme Unclear why authors used a 2:1 randomisation **Other information**

			Adolescents instructed walk barefoot at a comfortable speed and without orthotics down and 1-m carpeted walkway. A walking aid was allowed and 3 to 8 trials were recorded. b. Self-perception (body image and functional competence) When measured: at baseline and immediately after programme finished (8 weeks) Who measured: research assistants blinded to group allocation both at baseline and post-testing Instrument/test: self administered questionnaires. Themes relating to body image identified from the physical appearance and attributes subscale of the Piers Harris Children's Self-Concept Scale. Themes for functional competence were decide on in consultation with the school therapy and included activities required by the child for successful functioning in his or her environment. Each statement was qualified using a	Post-training: 21.3 NS Control group (n=13) Pre-training: 19.0 (3.2) Post-training: 21.3 (3.3) NS	

			Likert-type scale in which the numeric values were replaced by descriptive phrases. Adolescents selected the most applicable phrase. Composite scores for each section were calculated and analysed		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments

Full citation
Newman,C.J., Kennedy,A., Walsh,M., O'Brien,T., Lynch,B., Hensey,O., A pilot study of delayed versus immediate serial casting after botulinum toxin injection for partially reducible spastic equinus, Journal of Pediatric Orthopedics, 27, 882-885, 2007

Ref ID
64814

Country/ies where the study was carried out
Ireland

Study type
Randomised controlled trial

Aim of the study
To compare delayed versus inmediate casting as an adjunct to botulinum toxin therapy for partially reducible spastic equinus

Study dates
Between August 2004 and March 2006

Source of funding

Sample size

Characteristics
Total sample size

n=12 children

Characteristics

Age: 3 1/2 to 7 1/2 years
Sex: 6 boys, 6 girls

Type of CP:
-spastic diplegia: 5
-spastic hemiplegia: 7

No significant differences between both groups in baseline measurements (mean age, mean weight and outcomes of interest)

Inclusion criteria
-diagnosis of CP presenting as spastic diplegia or spastic hemiplegia
-a true equinus gait pattern with forefoot initial ground contact (excluding apparent equinus due to crotch)
-independent walking without assistive devices
-triceps surae spasticity
-plantar flexion contracture with a decreased slow passive ankle dorsiflexion 0 degree or less with knee extended

Exclusion criteria

Interventions
Background interventions

Each affected calf was injected with 10 U/kg Desport in 2 divided doses (to the medial and lateral gastrocnemius)
Topical application of eutectic mixture of local anaesthetics cream was applied to injection sites 30 minutes before injection
All children continued their weekly physical therapy regimen (not described)

Comparison 1
Cast immediately after injection (6 children, 8 limbs)

Comparison 2
Cast 4 weeks after injection (6 children, 9 limbs)

Casts were replaced weekly for 3 weeks, each time in increasing maximal passive dorsiflexion

Comparison

Recruitment
Consecutive sample of children from outpatient clinic

Sample size calculation
Not performed

Randomisation and allocation concealment
Block design randomisation sequence where for every 2 children enrolled, 1 would be assigned to each group. Group allocation was concealed until the injection

Outcomes assessed
Gastrosoleus spasticity and ankle range of motion in the Tardieu scale.

Ankle dorsiflexion was measured with a handheld goniometer, with the foot in subtalar neutral, knee extended, child supine. Both a fast (R1) and a slow passive stretch (R2) were applied, assessing the angle at which the spastic catch ocurred and the total passive range of motion (demonstrating a degree of fixed contracture) respectively. The difference

Gastrosoleus spasticity (Modified Tardieu) (degrees) (mean change/SD)

a. from before injection to 3 months after casting

Immediate: -7.0 (6.7)
Delayed: -16.2 (5.4)
p=0.007

a. from before injection to 6 months after casting
Immediate: 2.9 (9.9)
Delayed: -12.1 (6.1)
p=0.002

Passive range of motion (degrees) (mean change/SD)

a. from before injection to 3 months after casting

Immediate: 9.8 (8.1)
Delayed: 7.8 (5.2)
NS

b. from before injection to 6 months after casting

Immediate: 6.0 (9.2)
Delayed: 6.4 (6.0)
NS

Adverse effects

-Pain

Limitations
No power calculation performed
Outcomes assesor not blinded to group allocation
Potential bias introduced by children concurrently receiving non described routine physiotherapy

Other information

The first author was supported by grants from the Swiss National Science Foundation , CEREBRAL (Swiss Foundation for Children with Cerebral Palsy)	-having previously undergone orthopaedic surgery		between both angles (R2-R1) was a measure of the degree of dynamic spasticity Who assessed: assessments were undertaken by the principal investigator When assessed: both outcomes were assessed at 3 and at 6 months after casting	Immediate: 3 children complained of pain that required recasting during the first 48 h after having their first cast applied Delayed: 0 P=0.08 (NS) No other procedural complications were recorded	

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Full citation Aarts,P.B., Jongerius,P.H., Geerdink,Y.A., Van,LimbeekJ, Geurts,A.C., Effectiveness of modified constraint-induced movement therapy in children with unilateral spastic cerebral palsy: A randomized controlled trial, Neurorehabilitation and Neural Repair, 24, 509-518, 2010 **Ref ID** 75716 **Country/ies where the study was carried out** Netherlands **Study type** Randomised controlled trial **Aim of the study** To investigate whether 6 weeks of modified constraint-induced movement therapy (mCIMT) followed by 2 weeks of bimanual task-specific training (mCIMT-BiT) in	**Sample size** N=50 children **Characteristics** a. mCIMT-BiT (n=28) Sex: 14 F/14 M Age: 4.8 (1.3) years GMFCS: 27 GMFCS I/ 1 GMFCS II b. UC group (n=22) Sex: 7 F/14 M Age: 5.1 (1.7) years GMFCS: 21 GMFCS I/ 1 GMFCS II No significant differences between both groups in relation to sociodemographic characteristics or outcomes of interest at baseline **Inclusion criteria** - CP with a unilateral or severely asymmetric, bilateral spastic movement impairment - Aged 2.5 to 8 years - Manual Ability Classification System (MACS) scores I, II or III **Exclusion criteria** - Intellectual disability such that simple tasks could not be understood or executed (ie, developmental age less than 2 years) - Inability to combine the study protocol with the regular school program	**Interventions** Modified constraint-induced movement therapy + bimanual task-specific training (mCIMT-BiT) (n=28) - Type of intervention, frequency and duration: Functional training during 3-hour afternoon sessions, 3 days per week for 8 weeks (6 weeks of modified constraint-induced movement therapy (mCIMT) followed by 2 weeks of bimanual task-specific training (mCIMT-BiT)) During the first 6 weeks restraint of the unaffected arm and hand was applied. Children were told that they were pirates and that their best arm was injured and had to be kept in a sling. Their affected arm had to be used for all activities, especially to handle a sword. In all these therapy sessions the principles of shaping and repetitive task practice were applied. Immediate feedback on task performance and results was given. During the last 2 weeks the emphasis was on task-specific	Recruitment Children were recruited from 8 rehabilitation centres. They and their parents were first approached and informed by their treating physiatrist or occupational therapist. A screening was performed by two OT from the recruiting rehabilitation centre Randomisation Within 48h after inclusion each participant was randomised to either group by throwing a dice with equal probabilities. Sample size calculation 36 children (18 per group) were required to obtain a power of 90% to detect at least a moderate treatment effect (Cohen's d^{20} value>0.5) on the Assisting Hand Assessment (AHA; SD=12.22) and/or ABILHAND-Kids (SD=5.28) using a 2-sided significance level of 0.05. taking into account a maximum attrition rate of 30% (due	AHA (range 0 to 100) -change from baseline at week 9 CIM-BiT: 6.8 (8.2) U Care: 2.5 (6.3) -change from baseline at week 17 CIM-BiT: 6.4 (5.7) U Care: 1.7 (5.5) COPM-S (range 0 to 10) -change from baseline at week 9 CIM-BiT: 3.7 (1.6) U Care: 1.4 (1.1) -change from baseline at week 17 CIM-BiT: 3.6 (1.6) U Care: 1.6 (1.3) COPM-P (range 0 to 10) -change from baseline at week 9 CIM-BiT: 3.5 (1.3) U Care: 1.2 (1.1) -change from baseline at week 17 CIM-BiT: 3.5 (1.3) U Care: 1.3 (1.2) GAS, goal (% children that	**Limitations** Immediately after randomisation 2 children withdrew from the UC group due to family circumstances **Other information** At the end of the study protocol (week 17) the children who had been allocated to the UC group were also offered the opportunity to participate in an mCIMT-BiT group All data handling and analyses were carried out by an independent statistician who was blinded to group allocation

children with unilateral CP improves the spontaneous use of the affected limb in both qualitative and quantitative terms more than usual care (UC) of the same duration **Study dates** Not reported **Source of funding** Johanna Children Fund (JFK; grant number 2007/0199-1100	- Inability to walk independently without a walking aid	exercises in goal directed bimanual play and self-care activities without restraint. These 2 weeks were used to to train individual goals that were set by the parents, using GAS - Setting: Rehabilitation centre and home - Who delivered: OT, PT and parents **Comparison** Usual care (UC) (n=22) - Type of intervention, frequency and duration: Regular rehabilitation programme for 8 weeks: individual OT and or PT twice a week in 0.5- to 1-hour sessions (total time 1.5 hours/week). During each OT or PT child was engaged in exercises to stretch affected arm, to improve its weight bearing capacity and to use affected arm and hand as good assist. In addition parents and teachers were instructed to stimulate the children at least 7.5 hours a week to use affected arm and hand as an assist in daily activities - Setting: Rehabilitation centre, home and school	to the intensity of the program), 52 children needed to be randomised Outcomes assessed All assessments were conducted by the same occupational therapist at the primary rehabilitation centre, who was unaware of the individual study phase of any particular child, blinded for group allocation and not involved in any other aspect of the study. AHA tapes were scored by a certified OT who was blinded for group allocation and test session. All assessments were conducted at week 9 and week 17 a. Assisting Hand Assessment (AHA) When measured: Instrument/test: AHA questionnaire b. Canadian Occupational Performance Measure (perception of current performance (COPM-P) and satisfaction with current performance (COPM-S) Instrument/test: COPM	showed an increase of 2 points or more compared to baseline) -at week 9 CIM-BiT: 82 U Care: 23 -at week 17 CIM-BiT: 86 U Care: 36	

		- Who delivered: OT, PT, parents and teachers	questionnaire. Ratings are on a 10-point scale; scores closer to 10 indicate better performance and increased satisfaction. By means of the COPM training goals were set by the parents c. GAS, goal (% children that showed an increase of 2 points or more compared to baseline) Instrument/test: GAS Scaling. Perceived outcome was scaled from -3 to +2. -3 indicated level lower than the initial performance level, -2 indicated an unchanged level of performance, -1 a level lower than desired outcome, +1 somewhat more improvement than expected and +2 much more improvement than expected Parents scored their children at each measurement		

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation McNee,A.E., Will,E., Lin,J.P., Eve,L.C., Gough,M., Morrissey,M.C., Shortland,A.P., The effect of serial casting on gait in children with cerebral palsy: preliminary results from a crossover trial, Gait and Posture, 25, 463-468, 2007 **Ref ID** 76102 **Country/ies where the study was carried out** UK **Study type** Randomised controlled trial (cross over) **Aim of the study** To evaluate the effect of short term stretch casting on gait in children with spastic cerebral palsy compared to the natural history **Study dates** Not stated **Source of funding** Sports Aiding medical Research for Kids (SPARKS)	**Sample size** N=9 children **Characteristics** - Immediate casting (n=5) Sex: 3M/2F Mean age: 7 years, 3 months Type of CP: 3 diplegia, 1 L hemiplegia, 1 R hemiplegia GMFCS: 3 GMFCS I, 1 GMFCS II, 1 GMFCS III - Delayed casting (n=4) Sex: 1M/3F Mean age: 6 years, 11 months Type of CP: 3 diplegia, 1 R hemiplega GMFCS: 2 GMFCS I, 2 GMFCS II **Inclusion criteria** -spastic CP -mild fixed ankle plantarflexion contractures -clinical recommendation of serial casting to improve ankle dorsiflexion range made previous to study **Exclusion criteria** -BoNT injections in the past 6 months -Previous surgery of the calf musculature	**Interventions** Intervention and comparison Serial casting versus usual care For each group there was a control and a casting period. One group received immediate casting (n=5) and one group received casts after a 3-month period (n=4) Below knee casting was applied by the same physiotherapists for each child. Following each weekly change of cast passive ankle dorsiflexion range was reassessed. Another cast was applied if ankle dorsiflexion range had increased and the target range had not yet been achieved. Casting was ceased if no further gain in range was achieved or if the target amount of dorsiflexion, typically 10 degrees, was achieved Six of the children wore an ankle foot orthosis (AFO) either unilaterally or bilaterally during the day prior to the casting period and all had worn orthoses in the past (unclear the group distribution of these children) **Comparison** See above for details	Recruitment Unclear Sample size calculation Not performed Randomisation and allocation concealment Not reported Outcomes assessed a. Passive ankle dorsiflexion Instrument/test: hand held goniometer b. Walking speed Instrument/test: Three dimensional gait analysis (3DGA). Children walked barefoot at a self-selected speed When measured: both outcomes were measured over the first 5 weeks and over the 12 weeks for both the control period and the casting period	Passive dorsiflexion (knee flexed) (degrees) (mean/SD of the change) a. 0 to 5 week Casting: 7.55 (2.54) Control: -2.45 (2.9) P<0.01 b. 0 to 12 week Casting: 5.3 (4.5) Control: -6.36 (9.6) P=0.01 Passive dorsiflexion (knee extended) (degrees) (degrees) (mean/SD of the change) a. 0 to 5 week Casting: 3 (4.67) Control: -2.55 (3.4) P=0.02 b. 0 to 12 week Casting: -1 (2.8) Control: -2.45 (5.4) NS Walking speed (m/s) (mean/SD of the change) a. 0 to 5 week Casting: 0.04 (0.2) Control: 0.05 (0.2) NS	**Limitations** Small sample size and no calculation performed Unclear who measured the outcomes **Other information** 13 weeks was chosen as the study interval for a crossover trial based on the findings from Corry et al (1998) study that ankle returned to the baseline value at 12 weeks following casting

				b. 0 to 12 week Casting: -0.01 (0.1) Control: 0.02 (0.2) NS	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Katz-Leurer,M., Rotem,H., Keren,O., Meyer,S., The effects of a 'home-based' task-oriented exercise programme on motor and balance performance in children with spastic cerebral palsy and severe traumatic brain injury, Clinical Rehabilitation, 23, 714-724, 2009 **Ref ID** 76012 **Country/ies where the study was carried out** Israel **Study type** Randomised controlled trial **Aim of the study** To evaluate the feasibility and the ability to recruit and retain children with severe traumatic brain injury or cerebral palsy and their families, to a simple home-based exercise programme and to assess the immediate and short	**Sample size** n=20 children **Characteristics** <u>Experimental group (n=10)</u> Mean age: 8.2 (3.8) years Sex: 7 M/3 F Cause of spasticity: 5 TBI/5 CP <u>Control group (n=10)</u> Mean age: 9.2 (2.7) years Sex: 7 M/3 F Cause of spasticity: 5 TBI/5 CP No significant baseline differences between both group regarding socio-demographic and clinical characteristics or relevant outcomes measured **Inclusion criteria** General criteria: -aged 7 to 13 years -able to stand up from a chair independently and maintain standing for more than 5 seconds without falling -without obvious limitation of the passive range of motion of lower extremities Children with post traumatic brain injury (TBI) fulfilled in addition the following criteria:	**Interventions** -Type of intervention and setting: Home-based task oriented exercise. Sit-to-stand and step-up with each leg in forward and sideward directions. They were also instructed to continue with their regular daily activities -Frequency and duration: Three sessions of five 1-minute exercises daily, 5 days/week for 6 weeks -Who delivered: Therapist familiarised child and parent with the exercises at the start of the trial. Children performed exercises at home under parental supervision. Therapist set a day each week to call child and parent to hear and answer any questions and solve any problems that arose during programme **Comparison** Regular daily activities including school and sports for 6 weeks (Note: the control group was offered the programme immediately after the trial period)	<u>Recruitment</u> Children were either outpatients or former patients of a rehabilitation hospital <u>Randomisation and allocation concealment</u> Children were randomised by using a sealed envelope to either group <u>Outcomes assessed</u> -Walking velocity Instrument/test: Unconstrained 10-m walk test. Measurements were made within the mid range of a 14-m long walkway When measured: immediately after programmed finished (at 6 weeks from baseline) Who measured: Unclear -Adverse effects Unclear how and who measured them	<u>Walking velocity (m/s) (mean (SD)</u> a. Initial scores (baseline, t_0) Experimental: 0.96 (0.12) Control: 1.02 (0.19) NS b. Change scores after 6 weeks (t_1 - t_0) Experimental: 0.04 (0.1) Control: 0.01 (0.1) NS <u>Adverse effects</u> None reported	**Limitations** Very small sample size and no calculation performed Unclear who measured the outcomes **Other information** One child in the intervention group did not complete the programme and was lost to follow up before final assessment. His results were incorporated into the final analysis but it is unclear why he did not complete the programme

term effects of such intervention on reducing impairment and improving function **Study dates** Not stated **Source of funding** Not stated	-post severe closed head injury (Glasgow Coma Scale score at admission to ER ≤8 for at least 6 hours) -at least 1 year post trauma -independent ambulation (foot orthoses permitted) Children with cerebral palsy (CP) fulfilled in addition the following criteria: -GMFCS I or II **Exclusion criteria** Unable to fulfil simple instructions				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Novak,I., Cusick,A., Lannin,N., Occupational therapy home programs for cerebral palsy: double-blind, randomized, controlled trial, Pediatrics, 124, e606-e614, 2009 **Ref ID** 76144 **Country/ies where the study was carried out** Australia **Study type** Randomised controlled trial **Aim of the study** To assess the effectiveness of an occupational therapy home program (OTHP), compared with no OTHP, with respect to function and parent satisfaction with child function, participation, goal attainment, and quality of upper limb skill in school-aged children with cerebral palsy.	**Sample size** N=36 children **Characteristics** <u>- Experimental group 1 (8-weeks of OTHP)</u> Mean age: 7.33 (1.09) years Sex: 9M/3F Type of CP: 8 spastic diplegia, 3 spastic hemiplegia, 1 ataxia GMFCS level: g level I, 2 level II, 2 level III, 1 level IV, 1 level V <u>- Experimental group 2 (4-weeks of OTHP)</u> Mean age: 7.17 (2.32) Sex: 8M/4F Type of CP: 1 spastic quadriplegia, 2 spastic diplegia, 6 spastic hemiplegia, 1 dystonia, 2 athetosis GMFCS level: 6 level I, 2 level II, 1 level III, 3 level V <u>- Control group (no OTHP)</u> Mean age: 8.50 (2.27) Sex: 8M/4F Type of CP: 1 spastic quadriplegia, 4 spastic diplegia, 5 spastic hemiplegia, 2 dystonia GMFCS level: 5 level I, 1 level II, 3 level III, 1 level IV, 2 level V No significant differences between the three groups regarding sociodemographic, clinical characteristics or outcomes of interest	**Interventions** An individual OTHP was developed for each child in the OTHP group. Programs focused on the goals set and were based on the following interventions: goal-directed training (24 of 24 programs), parent education (24 of 24), programs), handwriting task training (14 of 24 programs), positive behaviour support (9 of 24 programs), adaptive equipment (9 of 24 programs), recreation/sports therapy (6 of 24 programs), strength training (3 of 24 programs), orthotics (3 of 24 programs), play therapy (3 of 24 programs), and constraint induced movement therapy (1 of 24 programs). Parents determined how frequently and for how long they implemented the OTHP. Both groups implemented the program less than daily but 18 (4-week OTHP) or 17 (8-week OTHP) times per month. <u>Intervention 1</u> OTHP for 8 weeks <u>Intervention 2</u> OTHP for 4 weeks	<u>Randomisation and allocation concealment</u> Participants were assigned randomly by an officer at a separate location who was not connected with the study and who had prepared the random assignment schedule and concealed opaque envelopes by using computer-generated random numbers. Participants were assigned randomly to 1 of 3 groups, that is, no OTHP, an OTHP of 4 weeks, or an OTHP of 8 weeks. Participants in the control group had intervention commencement by other study participants concealed from them and commenced an OTHP after the study concluded at 8 weeks <u>Sample size calculation</u> An a priori sample size test of power was performed to identify the probability of detecting clinical effects in the primary outcome measure, the Canadian Occupational Performance	<u>COPM-P (mean difference, 95% CI)</u> - <u>- mean change from baseline at 4 weeks</u> OTHP 4 vs. No OTHP: 1.6 (0.0 to 3.3) p=0.05 OTHP 8 vs. No OTHP: 0.2 (0.1 to 0.3) p=0.01 OTHP 4 vs. OTHP 8: 1.00 (-0.70 to 2.6) NS <u>-mean change from baseline at 8 weeks</u> - OTHP 4 vs. No OTHP: 2.4 (0.7 to 4.2) p=0.01 OTHP 8 vs. No OTHP: 1.4 (0.6 to 2.2) p=0.01 OTHP 4 vs. OTHP 8: 0.7 (-1.2 to 2.6) NS <u>COPM-S (mean, 95% CI)</u> - <u>-mean change from baseline at 4 weeks</u> OTHP 4 vs. No OTHP: 1.6 (0.0 to 3.2) p=0.04 OTHP 8 vs. No OTHP: 0.3 (-0.1 to 0.6) NS	**Limitations** Only 2 participants in the 4-week OTHP group implemented the OTHP for 4 weeks as instructed. **Other information** The mean session length was 15.66 minutes (range: 5– 60 minutes) for the 4-week OTHP and 17.63 minutes (range: 4.28–40 minutes) for the 8-week OTHP. For whole study reporting, the average session length for the 2 groups was calculated as the practical halfway point (16.5 minutes). There was no significant difference in total implementation time between the intervention groups (P=0.49). Most participants (n=9) in the 4-week OTHP group did not discontinue the program after 4 weeks, contrary to instruction, because parents reported that they perceived the program as helpful and they considered it in the best interests of their child to continue. Only 2 participants in the 4-week OTHP group implemented the OTHP for 4 weeks as instructed.

Study dates Between November 2005 and August 2007 **Source of funding** Cerebral Palsy Foundation and the College of Health and Science, University of Western Sydney	**Inclusion criteria** - Diagnosis of cerebral palsy - 4 to 12 years of age - Enrolled in school - Their parents needed to convey a concern about arm use in the screening interview **Exclusion criteria** - Involved in non–OT interventions that focused on developing upper limb use (eg, conductive education) - Receiving OT from another provider, or - The parents stated in the interview that they did not want to carry out OTHP activities	**Comparison** Comparison No OTHP	Measure (COPM), with an α value of 5% and power of 80%, using a minimal clinically important difference of 10%. The analysis accounted for a 20% dropout rate and 20% noncompliance rate. Twelve participants per group were needed to detect clinically worthwhile effects. Outcomes assessed -COPM performance (COPM-P) and COPM satisfaction (COPM-S) scores as adapted for children. The measures ask parents to identify functional problems and to rate the child's performance and their satisfaction with the child's performance on 10-point scales. -Adverse events were to be reported to the treating therapist by the parent via telephone or at an interview. -GAS29 T scores All baseline, 4-week, and	OTHP 4 vs. OTHP 8 0.7 (-1.0 to 2.4) NS~ -mean change from baseline at 8 weeks - OTHP 4 vs. No OTHP: 2.5 (0.8 to 4.3) p=0.01 OTHP 8 vs. No OTHP 1.5 (0.3 to 2.6) p=0.01 OTHP 4 vs. OTHP 8 0.8 (-1.1 to 2.8) NS GAS-T (mean, 95% CI) - -mean change from baseline at 4 weeks - OTHP 4 vs. No OTHP: 22.4 (14.4 to 30.3) p=0.01 OTHP 8 vs. No OTHP: 13.3 (8.6 to 18.0) p=0.01 OTHP 4 vs. OTHP 8: -6.2 (-17.9 to 5.6) -mean change from baseline at 8 weeks - OTHP 4 vs. No OTHP: 37.8 (26.9 to 48.8) p=0.01 OTHP 8 vs. No OTHP: 17.9 (12.4 to 23.4) p=0.01	

			8-week measures were administered by a non-treating occupational therapist who was blinded to study design and group allocation.	OTHP 4 vs. OTHP 8 0.5 (-13.4 to 14.4) NS <u>Adverse events</u> - None reported	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Aarts,P.B., Jongerius,P.H., Geerdink,Y.A., van,Limbeek J., Geurts,A.C., Modified Constraint-Induced Movement Therapy combined with Bimanual Training (mCIMT-BiT) in children with unilateral spastic cerebral palsy: how are improvements in arm-hand use established?, Research in Developmental Disabilities, 32, 271-279, 2011 **Ref ID** 132587 **Country/ies where the study was carried out** The Netherlands **Study type** Randomised controlled trial **Aim of the study** To investigate how the improvements to spontaneous use of an affected upper limb (shown in the trial Aarts et al., 2010) due to	**Sample size** N=50 (52 children were initially randomised, but 2 of those allocated to the Usual Care (UC) group withdrew immediately) **Characteristics** <u>a. mCIMT-BiT (n=28)</u> Sex: 14 F/14 M Age: 4.8 (1.3) years GMFCS: 27 GMFCS I/ 1 GMFCS II Manual Ability Classification system (MACS): I: 9 II: 12 III: 7 Active Wrist Extension (AWE) 1: 11 2: 15 3: 2 <u>b. UC group (n=22)</u> Sex: 8 F/14 M Age: 5.1 (1.7) years GMFCS: 21 GMFCS I/ 1 GMFCS II MACS: I: 7	**Interventions** <u>mCIMT-BiT (n=28)</u> -Type of intervention, frequency and duration: Training to improve the affected arm and hand was given during 3-hour afternoon sessions, three days per week, for eight weeks. Approximately half of the therapy was individual occupational therapy or physical therapy, whereas the rest was in small groups. During the first six weeks, restraint of the unaffected arm and hand was applied, and the affected arm had to be used for all activities. In all sessions, the principles of shaping and repetitive task practice were applied. In the last two weeks, the emphasis was on goal-directed task-specific bimanual training with no restraint. In addition to therapy sessions, the parents were asked to stimulate their child to use the affected arm and hand as much as possible at home, and to register the duration of stimulation on the record form.	<u>Recruitment</u> 52 children were recruited from eight rehabilitation centres. Initially, 28 children were allocated to mCIMT-BiT and 24 to UC; however, 2 children withdrew from the UC arm after allocation due to family circumstances. <u>Randomisation</u> Within 48 hours of inclusion, each child was randomised to mCIMT-BiT or UC by throwing a dice with equal probabilities. <u>Assessment</u> All children underwent a comprehensive upper limb evaluation before the start of the intervention period (week 0), at the end of the intervention period (week 8), and at the end of the study protocol (week 17). After the end of the study protocol, those allocated to the UC group were offered the chance to participate in a mCIMT-BiT group. All assessments were	<u>ROM active wrist extension</u> <u>a. Score at each assessment point (mean ± SD)</u> - Baseline mCIMT-BiT: 127.9 ± 21.2 UC: 117.5 ± 36.7 - Week 9 mCIMT-BiT: 133.8 ± 21.0 UC: 118.9 ± 39.4 - Week 17 mCIMT-BiT: 128.2 ± 22.0 UC: 114.8 ± 38.7 mCIMT-BiT: p = 0.062 UC: p = 0.393 <u>b. Change scores (mean ± SD)</u> - At week 9 compared to baseline mCIMT-BiT: 5.9 ± 13.5 UC: 1.4 ± 17.3 - At week 17 compared to baseline mCIMT-BiT: 0.4 ± 17.5 UC: -2.7 ± 29.1 Mean group difference of change score (95% CI)*: 5.4 (-3.41 - 14.29) Effect size: 0.25	**Limitations** Small sample size (N=50) Power calculation not reported in this paper (however, reported in Aarts et al., 2010, but for another outcome) 2 withdrawals following randomisation **Other information** The authors report that the mCIMT-BiT group received an average of 9 hours per week of therapy, and an additional 3.3 hours of stimulation at home (total stimulation time of 12.3 ± 1.9 hours). The UC group received an average of 1.5 hours per week of therapy and an additional 11.2 hours of stimulation at home or school (total stimulation time of 12.7 ± 2.1 hours).

modified Constraint-Induced Movement Therapy followed by Bimanual Training (cIMT-BiT) were established. **Study dates** Not reported **Source of funding** Grant from the Johanna Children Fund	II: 10 III: 5 AWE: 1: 7 2: 9 3: 6 There were no significant differences between the two arms. **Inclusion criteria** Cerebral palsy with a unilateral or severely asymmetric, bilateral spastic movement impairment Age 2.5 - 8 years MACS scores I, II or III **Exclusion criteria** Intellectual disability such that simple tasks could not be understood or executed (i.e. developmental age below 2 years) Inability to combine the study protocol with the regular school programme Inability to walk independently without a walking aid	-Setting: Rehabilitation centre and home -Who delivered: OT, PT and parents - **Comparison** <u>UC (n=22)</u> -Type of intervention, frequency and duration: Children received a regular rehabilitation programme for eight weeks. This included individual OT or PT given twice a week in 0.5 - 1 hour sessions (total of 1.5 hours per week). Another 7.5 hours per week stimulation of bimanual hand use was given at home or in (pre)school groups, according to predetermined instructions. Parents and teachers were asked to register the duration of specific stimulation on the daily record form. -Setting: Rehabilitation centre, school and home -Who delivered: OT, PT, parents and teachers	performed by one blinded OT. It was not possible to blind either participants or therapists to the treatment allocation, due to the nature of the intervention. <u>Outcomes assessed</u> The active (aROM) and passive (pROM) range of extension motion at the affected wrist and elbow were measured simultaneously by two therapists, using a standard goniometer. The child was in a seated position, and the aROM was measured first, followed by the pROM. a. Wrist extension Measurements were started with the elbow 90° flexed, the forearm fully pronated and the upper arm alongside the trunk b. Elbow extension Measurements started with the shoulder in 90° anteflexion, the elbow in full flexion with the fingertips on or near the ipsilateral shoulder and the elbow supported by	*corrected for difference at baseline <u>ROM passive wrist extension</u> <u>a. Score at each assessment point (mean ± SD)</u> - Baseline mCIMT-BiT: 177.7 ± 7.0 UC: 178.2 ± 6.6 - Week 9 mCIMT-BiT: 180.4 ± 7.6 UC: 177.3 ± 10.7 - Week 17 mCIMT-BiT: 179.8 ± 7.9 UC: 176.4 ± 13.2 mCIMT-BiT: p = 0.725 UC: p = 0.623 <u>b. Change scores (mean ± SD)</u> - At week 9 compared to baseline mCIMT-BiT: 2.7 ± 8.7 UC: -0.9 ± 5.9 - At week 17 compared to baseline mCIMT-BiT: 2.1 ± 6.7 UC: -1.8 ± 8.9	

			the assisting PT. The active movements were demonstrated by the assessing OT, after which the child performed the elbow or wrist extension. The assisting PT maintained the maximally reached joint position, while the OT recorded the aROM joint angle in 5° increments. The PT then moved the joint towards the maximum passive position and the OT recorded pROM joint angle, in 5° increments. <u>Statistical analysis</u> The two groups were compared with regarded to functional changes between pre and post treatment (week 0 and week 9 respectively) using ANCOVA in which differences at baseline were used as covariates. Cohen's d-values were used to calculate a pre-post intervention effect size, with the following values: small d=0.2, moderate d=0.5, and large d=0.8. Student t-tests were used to	Mean group difference of change score (95% CI)*: 3.5 (-0.82 - 7.76) Effect size: 0.33 *corrected for difference at baseline <u>ROM active elbow extension</u> <u>a. Score at each assessment point (mean ± SD)</u> - Baseline mCIMT-BiT: 170.2 ± 15.4 UC: 172.1 ± 14.9 - Week 9 mCIMT-BiT: 172.1 ± 10.3 UC: 171.1 ± 14.1 - Week 17 mCIMT-BiT: 173.6 ± 10.4 UC: 170.2 ± 17.6 mCIMT-BiT: p = 0.434 UC: p = 0.611 <u>b. Change scores (mean ± SD)</u> - At week 9 compared to baseline mCIMT-BiT: 2.0 ± 12.6	

			compare results at week 9 with those at week 17, to see whether the effect remained constant. The statistician was independent and blinded to group allocation.	UC: -0.9 ± 7.5 - At week 17 compared to baseline mCIMT-BiT: 3.4 ± 12.1 UC: -1.8 ± 8.5 Mean group difference of change score (95% CI)*: 2.1 (-2.85 - 6.99) Effect size: 0.17 *corrected for difference at baseline <u>ROM passive elbow extension</u> <u>a. Score at each assessment point (mean ± SD)</u> - Baseline mCIMT-BiT: 179.8 ± 7.9 UC: 180.9 ± 10.2 - Week 9 mCIMT-BiT: 179.8 ± 7.5 UC: 179.6 ± 11.4 - Week 17 mCIMT-BiT: 180.9 ± 6.4 UC: 178.4 ± 12.5 mCIMT-BiT: p = 0.297 UC: p = 0.397	

				b. Change scores (mean ± SD) - - At week 9 compared to baseline mCIMT-BiT: 0.0 ± 6.2 UC: -1.4 ± 5.2 - At week 17 compared to baseline mCIMT-BiT: 1.1 ± 4.8 UC: -2.5 ± 5.3 Mean group difference of change score (95% CI)*: 1.2 (-2.07 - 4.46) Effect size: 0.15 *corrected for difference at baseline	

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Full citation Sakzewski,L., Ziviani,J., Abbott,D.F., Macdonell,R.A., Jackson,G.D., Boyd,R.N., Randomized trial of constraint-induced movement therapy and bimanual training on activity outcomes for children with congenital hemiplegia, Developmental Medicine and Child Neurology, 53, 313-320, 2011 **Ref ID** 158781 **Country/ies where the study was carried out** Australia **Study type** Randomised controlled trial **Aim of the study** To determine if constraint-induced movement therapy (CIMT) is more effective than bimanual training (BIM) in improving upper limb activity outcomes for children with	**Sample size** N = 64 children CIMT n=32 BIM n=32 Results were presented for a total of 62 children at 3 weeks CIMT n = 31 BIM n = 31 Results were presented for a total of 58 children at 26 weeks CIMT n = 28 BIM n = 30 **Characteristics** Age of participants : mean (95% CI) CIMT = 10y, 1m (9y, 1m – 11y) BIM = 10y, 2m (9y, 2m – 11y, 1m) Male CIMT = 17/32 BIM = 16/31 GMFCS n CIMT = Level 1 : 8, Level 2 : 24 BIM = Level 1 : 8, Level 2 : 23 MACS classification n CIMT = Level 1 : 8, Level 2 : 23, Level 3 : 1 BIM = Level 1 : 8, Level 2 : 23, Level 3 : 0 House scale n CIMT Spontaneous use : 3 Active assist : 24 Passive assist : 5	**Interventions** Both interventions were delivered in groups of 9-13 children for 6 hours/day for 10 days (i.e. 60 hours of physical therapy). An intensive day-camp model was chosen and 6 camps were run in community sports facilities in Melbourne and Brisbane, Australia. A circus theme was used to encourage the children's motivation, engagement and participation. Children attending at pairs of camps (one CIMT, one BIM) were grouped by age to ensure activities were tailored to developmental stages. Interventions in both groups used a goal directed, activity based framework. Principles of motor learning (including specific task practice, fostering problem solving (individually and within the group)) were included as well as modifying task and environmental constraints to support goal attainment. Specifically this involved fine motor activities, functional goals identified prior to camp, 2 hour circus training, mealtimes, gross motor upper	Recruitment: potential participants were identified through public and private medical specialists in Queensland and Victoria Australia Sample size calculation: Based on a t-test comparison of changes using a SD of 9 units for both groups, a significance (alpha) level of 0.05 and 80% power, a minimum of 26 children in each group was required (total 52 children) Randomisation and allocation concealment: Children were matched in pairs according to age, sex, side of hemiplegia, and MAUULF scores (function). Once matched the children were randomised to pairs using a computer generated list of random numbers and concealed envelopes opened by non-study personnel. Occupational and physical therapists (who were aware of treatment allocation) measured the outcomes at baseline, 3 and 26 weeks. MUUL and	AHA Mean Difference (95% CI) compared to baseline at 3 weeks CIMT = 3.1 (1.4 to 4.7) BIM = 1.9 (0.2 to 3.6) MD Comparison across groups = 1.2 (-1.2 to 3.5) Mean Difference compared to baseline at 26 weeks CIMT = 1.6 (-0.1 to 3.4) BIM = 2.3 (0.6 to 4.0) MD Comparison across groups = -0.7 (-3.1 to 1.7) MUUL Mean Difference (95% CI) compared to baseline at 3 weeks CIMT = 2.8 (1.2 to 4.3) BIM = 0.9 (-0.6 to 2.5) MD Comparison across groups = 1.8 (-0.3 to 4.0) Mean Difference compared to baseline at 26 weeks CIMT = 4.5 (2.9 to 6.1) BIM = 0.0 (-1.5 to 1.6) MD Comparison across groups = 4.4 (2.2 to 6.7)	**Limitations** Study is adequately powered according to sample size calculation **Other information** Ethics approval : The Children's Hospital Melbourne, La Trobe University, The Royal Children's Hospital and Health Services District Brisbane, University of Queensland Consent Written informed consent was obtained from parents and young people aged 12 years or older and verbal assent from younger participants

congenital hemiplegia **Study dates** Not reported **Source of funding** National Health and Medical Research Council and a Career Development Grant	BIM Spontaneous use : 4 Active assist : 25 Passive assist : 2 **Inclusion criteria** - aged between 5 and 16 years - the ability to follow instructions (determined during a screening assessment and in consultation with caregivers) - predominant spasticity with MAS grades of between 1 and 3 for wrist flexors, forearm pronators, and/or thumb adductors interfering with upper limb function **Exclusion criteria** - predominant dystonia/muscle contracture (MAS>3) - previous upper limb orthopaedic surgery - serial casting or botulinum toxin injections in the upper limb within 6 months of the study intervention starting	limb games and debriefing. For both CIMT and BIM training the focus was on completing all the activities. BIM camps were run immediately before CIMT camps. Tasks undertaken by the BIM training group were modified for the CIMT group to accommodate the unimanual nature of the intervention. Each group received a similar amount of training with similar content delivered in the same environment 1. CIMT n= 32 children Participants wore a tailor made glove on their unimpaired limb. When the glove was removed (for circus activities) fingers of the unimpaired hand were taped together to simulate the glove. Children could use their hand as a support but as the glove was less intrusive than a full arm cast or sling, it was thought to be safer because children could use their hand for safety 2) BIM n= 32 children HABIT strategy was used whereby children were provided with specific instructions on how each	AHA were assessed using videotapes by a trained occupational therapist unaware of treatment allocation. Analysis Intention to treat analysis was performed. Continuous data were compared between groups by fitting a regression model using General Estimating Equations to baseline, 3 week and 26 week results with an interaction term between intervention group and 3-level factor indicating time of measurement. Matching characteristics of age, sex and side of hemiplegia were used as covariates Outcomes assessed 1. Assisting Hand Assessment (AHA) 2. Melbourne Assessment of Unilateral Upper Limb Function (MAUULF)		

		hand should be used before each activity **Comparison** CIMT vs BIM			

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Full citation Law,M.C., Darrah,J., Pollock,N., Wilson,B., Russell,D.J., Walter,S.D., Rosenbaum,P., Galuppi,B., Focus on function: a cluster, randomized controlled trial comparing child-versus context-focused intervention for young children with cerebral palsy, Developmental Medicine and Child Neurology, 53, 621-629, 2011 **Ref ID** 158780 **Country/ies where the study was carried out** Canada **Study type** Cluster randomised controlled trial **Aim of the study** To evaluate the efficacy of a child focused intervention compared to a context focused intervention in improving performance of functional tasks and	**Sample size** 91 therapists were trained and randomised to an intervention group 79 therapists treated children in the study Of the children treated : 73/79 children allocated to the child focused intervention, received treatment and a further 2 were lost to follow up 63/67 children allocated to the context focused intervention, received treatment and a further 6 were lost to follow up Results were presented for a total of 128 children Child focused group n = 71 Context focused group n = 57 **Characteristics** Male Child focused group = 50/71 Context focused group = 29/57 Female Child focused group = 21/71 Context focused group = 28/57 p=0.03 using Pearson's chi squared test with Yates' continuity correction GMFCS Child focused group = Level 1 : 24, Level 2 : 11, Level 3 : 11, Level 4 : 8, Level 5 : 17 Context focused group = Level 1 : 13, Level 2 : 12, Level 3 : 10, Level 4 : 13, Level 5 : 9 Age at baseline mean (SD) Child focused group = 3.53 (1.43)	**Interventions** Therapists received 1.5 days' training and ongoing expert consultation throughout the study. A classification of intervention strategies was developed for each intervention approach. Both interventions were delivered over a 6 month period with a frequency of 18-24 sessions. Children returned to their regular therapy between assessments at 6 and 9 months. Parents received general education and information about their child's disability. They also received specified strategies to practice at home that would complement the intervention that their child received from the therapist. 1. Child focused intervention n= 71 children The aim of the intervention was to use a combination of therapeutic strategies to focus on remediation of impairments and to build the children's skills and abilities by practising functional activities. Therapists identified motor, cognitive or sensory	Recruitment: potential participants were identified as children from consenting families under the care of occupational and physical therapists from 19 children's rehabilitation centres in Ontario and Alberta in Canada Sample size calculation: Estimated at 104 children per treatment group to detect a difference of 3 points on the PEDI with a two-sided alpha value of 0.05 and power of 80. This calculation assumed a cluster size (number of children per therapist) of three and an intraclass correlation coefficient (ICC) of 0.1, leading to a variance inflation factor (design effect) associated with therapists of 1.2. Randomisation and allocation concealment: Therapists from 19 children's rehabilitation centres were stratified according to specialty (occupational or physical therapy) and were block randomised by a study coordinator into a	PEDI Functional Skill scale - self-care At Baseline Child focused group = 47.34 (17.00) Context focused group = 46.09 (14.80) At 6 months Child focused group = 51.54 (18.20) Context focused group = 49.05 (14.96) At 9 months Child focused group = 51.88 (18.65) Context focused group = 51.77 (17.75) PEDI Functional Skill scale - mobility At Baseline Child focused group = 49.46 (25.87) Context focused group = 47.64 (22.87) At 6 months Child focused group = 55.02 (26.37) Context focused group = 53.85 (22.34) At 9 months	**Limitations** Unit of analysis error: Therapists were randomised to treatment group. Results are presented by the children in each treatment group. Cluster effects were addressed in the analysis. **Other information** The content of the two interventions differed, as did the person who delivered them

mobility in young children with cerebral palsy **Study dates** September 2006 to April 2009 **Source of funding** National Institutes of Health, USA	Context focused group = 3.92 (1.42) Number of therapy sessions Child focused group = 18.65 (2.94) Context focused group = 17.69 (3.36) Both groups included children who were regularly receiving botulinum toxin type A injections **Inclusion criteria** - aged between 12 months an d 5 years 11 months - diagnosis of cerebral palsy at any level of GMFCS **Exclusion criteria** - planned surgery or medication changes during the 6 month study intervention period that might have affected motor function - starting a botulinum toxin type A regime during the study intervention period	impairments that were due to a functional limitation and provided therapy a) to remediate the impairment and b) to practise specific movements and tasks. Treatment strategies were chosen by the therapist and included - maintaining range of motion and joint alignment by using stretching casting and splinting, strength training, sensorimotor training and stimulation, bilateral isokinematic training, weight bearing through the hands - facilitating normal movement patterns and postural control by physical handling and practice of functional activities 2) Context focused intervention n= 57 children A primary therapist model was used. Each child was assigned to either a physical or occupational therapist who conducted the intervention for that child (consultation was provided by the other therapy specialist)	treatment group. Children from consenting families received the treatment to which their therapist was randomised. Therapists and children and their parents were not blinded to the treatment group. Outcome assessors were blinded to the treatment group Analysis Intention to treat analysis performed and missing values were imputed Change from baseline scores were estimated for 6 and 9 month outcome measures Linear mixed effects models were fitted using time and treatment as fixed effects and participant as a random effect. Covariates were included in the model in the following order: GMFCS, age, sex and therapist specialty. Number of co-interventions was not used as a covariate. Maximum likelihood estimation was used to compare different models. Baseline and 6 month data were used to	Child focused group = 56.72 (26.81) Context focused group = 55.20 (23.81) PEDI Caregiver Assistance scale - self-care At Baseline Child focused group = 37.80 (24.92) Context focused group = 35.56 (22.16) At 6 months Child focused group = 42.31 (26.18) Context focused group = 42.89 (23.51) At 9 months Child focused group = 43.57 (27.22) Context focused group = 42.29 (24.98) PEDI Caregiver Assistance scale - mobility At Baseline Child focused group = 44.75 (29.60) Context focused group = 44.94 (25.55) At 6 months Child focused group = 52.11 (30.75) Context focused group = 51.69 (27.23)	

		Using COPM, parents identified motor tasks that their children were initiating, trying to modify, or that they were showing an interest in performing but that they were having difficulty in accomplishing. Children were videotaped to record their performance of tasks identified for achieving goals. Task-related, child-related and environmental factors that hindered the child's performance were identified. Therapists analysed the constraints of the observed task performance working with the parents. Treatment focused on modifying identified constraints within the task and/or environment. Wherever feasible, practice of tasks was in the 'natural' environment (e.g. home or preschool). Children were encouraged to use compensatory strategies to achieve functional tasks. Therapists received instruction not to remediate the children's impairments. **Comparison**	fit models which did not include therapist cluster effects because the estimated intraclass correlation for PEDI outcomes were small, indicating a low cluster effect(ranged from 0.08 to 0.13) Outcomes assessed 1. PEDI Functional Skill scale - self-care and mobility and PEDI Caregiver Assistance scale - self-care and mobility When assessed: At baseline, at 6 months and at 9 months How assessed: At all assessments, by independently trained evaluators blinded to treatment allocation 2. GMFM-66 When assessed: At baseline, at 6 months and at 9 months How assessed: At all assessments, by independently trained evaluators blinded to treatment allocation	At 9 months Child focused group = 53.62 (31.54) Context focused group = 50.44 (28.57) GMFM-66 score At Baseline Child focused group = 53.31 (15.80) Context focused group = 52.14 (11.93) At 6 months Child focused group = 55.82 (15.45) Context focused group = 54.26 (11.99) At 9 months Child focused group = 56.84 (15.42) Context focused group = 54.11 (13.73) Right hip abduction - range of motion At Baseline Child focused group = 37.42 (13.08) Context focused group = 38.77 (14.56) At 6 months Child focused group = 38.33 (13.91) Context focused group = 39.31 (12.50)	

		At 6 month assessment: Child focused intervention vs context focused intervention At 9 month assessment: Child focused intervention for 6 months and usual therapy for 3 months vs context focused intervention for 6 months and usual therapy for 3 months	3. Range of motion of hip abduction, popliteal angle and ankle dorsiflexion When assessed: At baseline, at 3 months, at 6 months and at 9 months How assessed: At all assessments, by independently trained evaluators blinded to treatment allocation. The average of 2 consecutive measurements at the joint was used.	At 9 months Child focused group = 41.08 (13.69) Context focused group = 39.78 (11.55) Left hip abduction - range of motion At Baseline Child focused group = 36.61 (12.60) Context focused group = 38.31 (15.55) At 6 months Child focused group = 38.10 (12.50) Context focused group = 39.75 (12.88) At 9 months Child focused group = 40.03 (12.86) Context focused group = 38.61 (12.25) Right hip extension - range of motion At Baseline Child focused group = -0.43 (2.74) Context focused group = -0.35 (1.86) At 6 months Child focused group = -0.12 (0.70) Context focused group =	

				-0.51 (2.58) At 9 months Child focused group = -0.09 (0.66) Context focused group = -0.25 (1.10) Left hip extension - range of motion At Baseline Child focused group = -0.32 (1.69) Context focused group = -0.37 (1.85) At 6 months Child focused group = -0.06 (0.34) Context focused group = -0.68 (3.05) At 9 months Child focused group = -0.16 (0.83) Context focused group = -0.13 (0.79) Right popliteal angle - range of motion At Baseline Child focused group = 24.41 (18.11) Context focused group = 22.35 (17.63) At 6 months Child focused group = 22.55 (16.71)	

				Context focused group = 21.07 (17.13) At 9 months Child focused group = 25.34 (18.20) Context focused group = 25.63 (20.35) Left popliteal angle - range of motion At Baseline Child focused group = 24.80 (17.90) Context focused group = 21.85 (17.19) At 6 months Child focused group = 23.31 (17.94) Context focused group = 19.77 (17.61) At 9 months Child focused group = 26.33 (17.04) Context focused group = 23.66 (20.05) Right ankle dorsiflexion - range of motion At Baseline Child focused group = 14.23 (15.52) Context focused group = 17.88 (23.23) At 6 months	

				Child focused group = 14.53 (14.76) Context focused group = 15.11 (15.43) At 9 months Child focused group = 13.44 (13.47) Context focused group = 12.66 (18.61) Left ankle dorsiflexion - range of motion At Baseline Child focused group = 15.35 (15.72) Context focused group = 18.32 (22.97) At 6 months Child focused group = 13.60 (14.53) Context focused group = 13.92 (16.61) At 9 months Child focused group = 13.37 (12.79) Context focused group = 12.77 (17.50)	