4-4-2014

Improving Gait And Function In Children With Cerebral Palsy; A Comparison Of Supported Speed Treadmill Training To Therapeutic Exercise

Brianna Palmer
University of New England

Critically Appraised Topic (CAT)

Title: Improving Gait and Function in Children with Cerebral Palsy; A Comparison of Supported Speed Treadmill Training to Therapeutic Exercise

Author: Brianna Palmer

Date CAT Completed: 4/14/14

Clinical Question: Is supported speed treadmill training more effective than therapeutic exercise in improving gait performance for children with spastic cerebral palsy (CP) classified as level 2, 3 or 4 by the Gross Motor Function Classification Scale (GMFCS)?

Patient/Problem – Children with GMFCS level 2, 3 or 4 spastic CP (diplegic, triplegic or quadriplegic)
Intervention – Supported Speed Treadmill Training Exercise Program (SSTTEP)
Comparison – Therapeutic Exercise/Strengthening Program
Outcome – Improved gait as measured by gait speed, cadence and Pediatric Outcomes Data Collection Instrument (PODCI) global scores

Search History:

Databases/Sites Searched	Search Terms	Limits Used
PubMed - Medline	MESH terms: "Cerebral Palsy AND "Gait Disorders, Neurologic/ rehabilitation" AND "Exercise Therapy" AND "treadmill"	- Clinical Trial or Meta-Analysis or Randomized Controlled Trial or Journal Article or Case Report - Humans - Child: birth - 18years - English

Citations:

Johnston TE, Watson KE, Ross SA, et al. Effects of a supported speed treadmill training exercise program on impairment and function for children with cerebral palsy. Dev Med Child Neurol. 2011;53(8):742-50

Schindl MR, Forstner C, Kern H, Hesse S. Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy. Arch Phys Med Rehabil. 2000;81(3):301-6.

Summary of Study:

Study Design: Randomized Controlled Clinical Trail with two active treatment groups

Setting: Department of Physical Therapy, University of the Sciences, Philadelphia PA; Department of Physical Therapy, Shriners Hospitals for Children, Philadelphia PA; School of Health Professions, Maryville University, St. Louis MO; Medical Staff, Shriners Hospitals for Children, Shreveport LA; Department of Physiology, Temple University, Philadelphia PA; Department of Physical Therapy, Temple University, Philadelphia PA; School of Medicine, Washington University, St. Louis MO

Participants: Thirty-eight children were recruited from three outpatient physical therapy clinics in different regions of the US. These children were screened for eligibility using the following criteria: spastic CP, marginal ambulatory function[1], able to take eight steps independently with or without assistive device, body weight less than 150 pounds, age 6-13 years, and ability to follow multi-step commands during training and data collection. Children were excluded if they had a medical condition that would be negatively affected by exercise, athetoid or mixed CP, lower extremity orthopedic surgery in the previous year, botulinum toxin A in the previous 6 months, dorsal rhizotomy in the previous 2 years, intrathecal baclofen, or flexion contractures $>30^{O}$ at the hip, $>20^{O}$ at the knee or $>15^{O}$ of plantarflexion during knee extension. From the original 38 children, 34 were deemed eligible, and 26 completed the study. All participants aged 7 and up completed assent forms, and one parent per child completed a consent form and authorization required by HIPAA.

The final SSTTEP group had fourteen participants, mean age 9years 7months; there were seven females and seven males, of which eight children had spastic diplegic CP and six children had spastic quadplegic CP. One child in the SSTTEP group was classified as GMFCS Level II, nine were classified as GMFCS Level III and four were classified as GMFCS Level IV. The final exercise group had twelve participants, mean age 9years 6months; there were five females and seven males, of which four children had spastic diplegic CP, two children had spastic triplegic CP, and six children had spastic quadplegic CP. One child in the SSTTEP group was classified as GMFCS Level II, six were classified as GMFCS Level III and five were classified as GMFCS Level IV.

Intervention: An intensive training induction period of two weeks preceded a ten week intervention program. A study period of twelve total weeks was used due to known neurophysiological training effects, as well as evidence in previous research on functional ambulation and gross motor function improvements in non-ambulatory children with CP[2]. The intensive training weeks involved two 30minute sessions 5days/week to establish the child's program and to train parents. A physical therapist (PT) oversaw these sessions, and administered them either in the clinic or in the patient's home. An induction program was used due to preliminary, unpublished work by the same researchers, which suggested that such a program yielded better outcomes than a program without an intensive induction phase[3]. After the induction period the parents were capable of conducting the intervention for the child. All necessary equipment was sent home and interventions were performed for 30minutes 5days/week for ten weeks. Both groups were monitored via weekly phone calls with the PT, to ensure that the protocol was being followed correctly, and to allow for decision making regarding increasing the speed for the SSTTEP group and advancing the interventions for the exercise group. Parents also had to keep weekly logs to record sessions.

The SSTTEP intervention consisted of treadmill walking on a home folding treadmill with a pediatric suspension walker fitted on top of the treadmill. Each child wore a harness for the walker, and their leg was guided by a PT or parent if needed. Children were allowed to wear ankle-foot orthoses (AFOs) if needed. Gait speed was determined by gait analysis and was adjusted to the child's response. During the induction period, aims were set to decrease body-weight support to 30%, and to increase speed to

[1] Defined as decreased gait velocity <80% of age-expected value regardless of GMFCS level, or GMFCS level III or IV
[2] Research by Schindl et al – see citations
[3] As referenced in the Johnston et al paper: Page 743, column 2, paragraph 3

normal values. These adjustments were based on whether the child used a foot-flat or heel-toe gait pattern, on the child's ability to initiate swing and achieve knee extension, and on consistency of foot placement.

The exercise intervention consisted primarily of strengthening and standing-weight-bearing activities that addressed functional task impairments. The program was 30minutes long and designed for each child individually, considering standing abilities, overall strength, and endurance. Interventions included forward step-ups, squats, upper and lower extremity progressive resistive exercise, and core strengthening. Assistance was allowed and provided as needed by either the PT or parent. Assistive devices were also allowed for weight-bearing exercises. Interventions were progressed by first increasing repetitions and then by increasing resistance (via cuff weights).

Outcome Measures: Measurements were taken for spasticity, strength, motor control, gait speed, cadence, stride length, physical function and gross motor skills. Gait speed was regarded as the primary outcome measure, and values were considered to be clinically meaningful if the increase was 0.10m/s or more. Gait speed, cadence and stride length were measured via three-dimensional motion analysis as children walked at their preferred gait speed and with assistive devices if needed.

Strength, spasticity & motor control were measured using a computerized dynamometer called a "KinCom." This device was used in place of the Ashworth Scale because it has better validity in quantifying spasticity. In measuring strength, children applied isometric force while the KinCom moved through a 10^{o}/sec range of motion. Values were then corrected for gravity and divided by the body mass of the child tested. The greatest of three trials was considered the child's strength. Motor control was determined by setting the KinCom to the isokinetic mode, with an angular velocity of 10^{o}⁄s. The 'target' force was set as 20% of the child's previously determined max strength, and was displayed on the computer monitor as a horizontal line on a force–angle diagram. The knee was then moved from end range flexion to end range extension, while the child attempted to match the force of his/her knee to the line on the computer. The outcome measure for motor control was thus the standard deviation of the force-angle data.

The primary measures for physical function were the PODCI global function scores and the PODCI transfers & mobility scores. The primary measure for gross motor skills was the dimensions A to E on the GMFM

Data Analysis: A priori data analysis determined that the study would require 54 participants in order to have an 80% power in a two tailed test (α=0.05). Data was collected at baseline (week 0), at the end of the study (week 12), and 4 weeks after the study (week 16) for post-hoc analysis. Data was collected by the same evaluator and was done in the child's primary site. Inter- and intra-rater reliability was not tested, though selected evaluators had experience in the measures being taken.

For all of variables measured (see above), the mean, sum and standard deviation was calculated. Data was tested for normality via the Shapiro-Wilk test, and a normalized rank transformation was applied before completing an ANOVA. Two-tailed testing was also performed to determine if the null hypothesis[4] could be rejected (α=0.05). Minimally clinically important difference (MCID) was used to

[4] Null Hypothesis "There [is] no difference in the measured parameters among the treatment groups or between time periods (0, 12, 16)."

establish clinical meaningfulness of any changes, as they may not always be statistically significant. The MCID values for relevant outcomes were obtained from previous, outside research, and were regarded as secondary measures. Finally, post-hoc testing was completed for weeks 12 through 16.

Summary of Evidence:

There was significant variability in the means and standard deviations for the 13 measures (plantarflexor spasticity, knee flexor spasticity, knee extension strength, knee flexion strength, dorsiflexion strength, plantarflexion strength, motor control, GMFM, PODCI scores (global and transfers & mobility), gait speed, cadence, stride length) and thus there were no statistically significant differences between nor within groups (See Table I). Considering the within-group standardized effects of the interventions over time, gait speed and cadence had a statistically significant increase for both groups; and stride length was significantly decreased in the SSTTEP group[5]. Finally, the MCID scores also had mixed results, with children improving in certain areas while declining or remaining the same in other areas. These changes were inconsistent between children as well. It could be suggested that there were improvements in the GMFM for the exercise group, and improvements in the PODCI and in gait speed for children in the SSTTEP group. Considering the variability across participants and the small sample size these results should be scrutinized[6].

While the results were not statistically significant and were somewhat inconclusive, this study does bring hope to children with CP in improving function via either an SSTTEP or a simple exercise program. Both groups did show improvements in gait speed, cadence, and PODCI scores despite their statistical insignificance. In the post-hoc analysis, it was discovered that only the SSTTEP group maintained the gains they had made (gait speed and PODCI scores) 4 weeks after the intervention had been discontinued, so there may be some benefit to that therapy after all.

Table I. *For outcome measures, the Means and Standard Deviations are presented as "mean(SD)" for the 14 children in the SSTTEP group and the 12 children in the exercise group*

	BASELINE		**12 WEEKS**		**WASHOUT**	
	SSTTEP	**Exercise**	**SSTTEP**	**Exercise**	**SSTTEP**	**Exercise**
Plantarflexor Spasticity (J/deg/s)	0.0013 (0.0012)	0.0030 (0.0024)	0.0016 (0.0024)	0.0030 (0.0021)	0.0012 (0.0018)	0.0026 (0.0013)
Knee Flexor Spasticity (J/deg/s)	0.0088 (0.0114)	0.0032 (0.0044)	0.0074 (0.0133)	0.0072 (0.0137)	0.0083 (0.0139)	0.0053 (0.0044)
Knee Extension Strength (N/kg)	3.90 (3.09)	3.09 (3.15)	3.58 (2.82)	3.80 (4.22)	3.66 (3.25)	3.69 (3.66)
Knee Flexion Strength (N/kg)	2.47 (1.45)	2.35 (2.04)	2.43 (1.54)	2.98 (3.26)	2.57 (1.65)	2.54 (2.09)
Dorsiflexion Strength (N/kg)	0.86 (1.21)	0.62 (0.75)	0.69 (0.78)	0.77 (0.66)	1.02 (1.54)	0.62 (0.53)
Plantarflexion Strength (N/kg)	3.44 (1.91)	3.06 (3.62)	3.23 (1.45)	3.14 (3.32)	3.65 (2.13)	3.35 (3.17)
Motor Control (N)	28.3 (14.9)	27.5 (16.4)	22.1 (9.0)	27.8 (5.6)	26.8 (11.6)	24.4 (8.7)
GMFM	62.7 (17.5)	58.4 (26.9)	63.3 (16.2)	60.1 (25.1)	65.3 (16.5)	60.6 (26.7)

[5] Depicted on Figure 3 of the original article
[6] Depicted on Table III of the original article

PODCI Global	50.4 (11.2)	50.9 (14.9)	59.1 (11.4)	52.0 (22.6)	60.0 (10.0)	55.4 (21.7)
PODCI Transfers & Mobility	46.4 (23.0)	60.6 (26.7)	55.0 (22.9)	55.4 (21.7)	56.9 (20.7)	49.9 (36.2)
Gait Speed (m/s)	0.50 (0.26)	0.44 (0.35)	0.62 (0.31)	0.50 (0.39)	0.63 (0.28)	0.44 (0.34)
Cadence (Steps/Min)	76.9 (33.9)	53.3 (24.0)	82.2 (38.2)	60.7 (26.8)	81.2 (38.6)	55.5 (24.8)
Stride Length (m)	0.71 (0.27)	0.61 (0.29)	0.68 (0.29)	0.55 (0.29)	0.78 (0.28)	0.64 (0.31)

Additional Comments:

- This study has a small sample size so results may not be as meaningful as they would have been with a larger sample
- This study's level of evidence is a 1b according to the Centre for Evidence Based Medicine, as it is an individual RCT that is prospective and validates the study with good reference standards.
- As participants were not randomly selected, external validity is not particularly high. Further, the internal validity is decent though a control group without intervention could have strengthened this.
- Strengths:
    - Thorough data analysis
    - Post hoc analysis
    - Clear descriptions and definitions
    - Represented a wide range of ages and types of CP
    - Intervention took place in child's least restrictive environment and families were heavily involved in the intervention; weekly phone calls ensured compliance and accuracy
- Weaknesses:
    - A priori data analysis was done to determine the appropriate sample size for a two-tailed test with =0.05 and a power of 80%. It was determined that 54 participants would be needed though the study only had 26
        - One site was unable to conduct the spasticity measurements thus the sample size for that variable was even smaller
    - Treadmill speed was adjusted for each individual child. This may have made the intervention more beneficial for that child, but compromised the study's ability to keep the independent variables constant
    - MCID values were taken from previously done research that was not validated for children in level IV of the GMFCS, so this study had to use the MCID codes for children in level III
    - No statistics on inter- or intra- rater reliability on measurement error
- This CAT was submitted as part of the course requirements for *PTH 604: Physical Therapy Management of Children with Special Health Needs* under the instruction of Eileen Ricci PT, DPT, MS, PCS