Dec 2, 1010

Dear _____

Thank-you for the opportunity to address your concerns in approving a gait trainer for _____. _____ is a 14 month old girl with diatomic tetraplegic cerebral palsy Gross Motor Functional Classification Level V. Her highest gross motor skill is that she can clear her airway in prone. She enjoys fully supported sitting and standing and is able to lift her head, turn her head and bat at toys. She has access to a supported stander at her child care center and will continue to have access to this equipment throughout her elementary school years. Her family, childcare providers, and early intervention team feel that a mobility device is in _____ best interest at this time and is medically necessary.

I have recently (last month) published my dissertation on supported standing (http://iospress.metapress.com/content/ln51p1tn131l67q2/) (see reference 1) and have documented the benefits of this intervention. She has demonstrated her eagerness to control her environment through the use of switch toys. While her cognition is difficult to measure due to her limitations in movement, vision and hearing, she is able to communicate her basic needs and appears to understand cause and effect. She has reciprocal movements in her lower extremities (central pattern generator can be elicited 75% of trials when the hip flexor is stretched) (MacKay-Lyons [2]). I believe that the evidence supports, with continued facilitation, that Sophia can learn to move about her environment and access the benefits of self propelled mobility in a device that fully supports her trunk and un-weights her legs (Bodkin[3]). Damiano's[4] (2010) systematic review of body weight support literature supports this premise. Recently(Willoughby[5], 2010) a study out of Australia has shown that using a gait trainer can be as effective as body weight support treadmill training for children with cerebral palsy. Furthermore, Paleg [6](1997), van der Putten[7] (2005), and Low[8] (2005) have all shown that children can be taught to move gait trainers when when they cannot sit, stand or walk independently. Bjornson[8] (2007)has shown that a child with tetraplegia is physically active for only 20 minutes a day compared with almost 6 hours in a typical child. Adolph[9] (2007) has shown that the average child her age takes 2,000 steps per day. _____ takes none; this can adversely affect her body structures and function as well as her participation. Adolph[10] has also shown that it is through repetition and practice that toddlers of _____ age learn self mobility. Kermoian[11] has published two studies suggesting that allowing _____ to explore her environment even while her trunk is supported can result in improvements in her cognition (visual spatial skills). Bodkin[3] reported an unexpected outcome and was able to shift an infant predicted to have a GMFCS Level 3/4 to a 2.

A dynamic gait trainer is preferable to static one because of her dyskinesia. A study from Italy[12] (Cimolin, 2009) showed that dynamic seating decreased dykinesia in the upper extremities in 10 children with spastic tetraplegic cerebral palsy GMFCS Level 5 (just like _____!). When _____ stands in a static supported standing device, every dyskinetic movement results in a forceful collision with the apparatus. Even a static gait trainer causes her discomfort. The KidWalk from Prime Engineering allows for supported movement in all 3 planes of motion. The spring action gently returns her to mid-line when her dystonic movement stops. The Italian study showed that a dynamic system can statically significantly reduce the amount of force that the children exert against the device. These same findings, although not with statistical significance, were published by Hahn[13] (2009).

In summary I hope I have addressed your concerns with evidence based medicine.

1) "Beneficiary is unable to effectively and safely use this equipment". She is currently using this piece of equipment, on loan, and has done so effectively and safely for 3 weeks. She is able to stand, bear weight through her lower extremities, hold up her head, turn her head and bat at toys. Most importantly, she is more active, engaged and vocal when upright and fully weight bearing. She has taken up to 5 consecutive steps with moderate facilitation (quick stretch) of the hip flexors.

2) "_____ will never be able to ambulate" While our best data at this point supports that she will never attain GMFCS Level 2 (independent ambulation without any assistive device for long distances), she is still predicted to be able to take steps when fully supported and un-weighted and will most likely learn to move around her classroom. This should improve her spatial awareness and may also encourage language development[14] (Ulrich, 2008)

3) "Why is a gait trainer requested rather than a stander?" _____ will benefit more from dynamic supported standing with the option for mobility, then static standing alone. Using a stander has not been shown to improve gross motor skill attainment in children like _____. While it does offer certain benefits (ROM, Spasticity, Bowel, and Bone Mineral Density), this can be accomplished with existing equipment at the child care center and continue in her school setting. Being upright, the ability to bounce (load and unload) and begin to explore her environment are age appropriate skills.

If you have any further questions or would like to discuss how I arrived at these conclusions, please feel free to email me at _____ or call me at _____. Below are the abstracts of the articles I have referenced. I have most of the full text versions electronically and can provide hem upon request.

Sincerely,

_____

REFRENCES:

1.Glickman, L, Geigle P and , Paleg G. A systematic review of supported standing programs Journal of Pediatric Rehabilitation Medicine Volume 3, Number 3 / 2010 p197-213

Objective: The routine clinical use of supported standing in hospitals, schools and homes currently exists. Questions arise as to the nature of the evidence used to justify this practice. This systematic review investigated the available

evidence underlying supported standing use based on the Center for Evidence-Based Medicine (CEBM) Levels of Evidence framework.

Design: The database search included MEDLINE, CINAHL, GoogleScholar, HighWire Press, PEDro, Cochrane Library databases, and APTAs Hooked on Evidence from January 1980 to October 2009 for studies that included supported standing devices for individuals of all ages, with a neuromuscular diagnosis. We identified 112 unique studies from which 39 met the inclusion criteria, 29 with adult and 10 with pediatric participants. In each group of studies were user and therapist survey responses in addition to results of clinical interventions.

Results: The results are organized and reported by The International Classification of Function (ICF) framework in the following categories: b4: Functions of the cardiovascular, haematological, immunological, and respiratory systems; b5: Functions of the digestive, metabolic, and endocrine systems; b7: Neuromusculoskeletal and movement related functions; Combination of d4: Mobility, d8: Major life areas and other activity and participation. The peer review journal studies mainly explored using supported standers for improving bone mineral density (BMD), cardiopulmonary function, muscle strength/function, and range of motion (ROM). The data were moderately strong for the use of supported standing for BMD increase, showed some support for decreasing hypertonicity (including spasticity) and improving ROM, and were inconclusive for other benefits of using supported standers for children and adults with neuromuscular disorders. The addition of whole body vibration (WBV) to supported standing activities appeared a promising trend but empirical data were inconclusive. The survey data from physical therapists (PTs) and participant users attributed numerous improved outcomes to supported standing: ROM, bowel/bladder, psychological, hypertonicity and pressure relief/bedsores. BMD was not a reported benefit according to the user group.

Conclusion: There exists a need for empirical mechanistic evidence to guide clinical supported standing programs across practice settings and with various-aged participants, particularly when considering a life-span approach to practice.

2. MacKay-Lyons M Central pattern generation of locomotion: a review of the evidence.

Phys Ther. 2002 Jan;82(1):69-83.

Abstract
Neural networks in the spinal cord referred to as "central pattern generators" (CPGs), are capable of producing rhythmic movements, such as swimming, walking, and hopping, even when isolated from the brain and sensory inputs. This article reviews the evidence for CPGs governing locomotion and addresses other factors, including supraspinal, sensory, and neuromodulatory influences, that interact with CPGs to shape the final motor output. Supraspinal inputs play a major role not only in initiating locomotion but also in adapting the locomotor pattern to environmental and motivational conditions. Sensory afferents involved in muscle and cutaneous reflexes have important regulatory functions in preserving balance and ensuring stable phase transitions in the locomotor cycle. Neuromodulators evoke changes in cellular and synaptic properties of CPG neurons, conferring flexibility to CPG circuits. Briefly addressed is the interaction of CPG networks to produce intersegmental coordination for locomotion. Evidence for CPGs in humans is reviewed, and although a comprehensive clinical review is not an objective, examples are provided of animal and human studies that apply knowledge of CPG mechanisms to improve locomotion. The final section deals with future directions in CPG research.

3. Bodkin AW, Baxter RS, Heriza CB. Treadmill training for an infant born preterm with a grade III intraventricular hemorrhage. Phys Ther. 2003 Dec; 83(12):1107-18.

Abstract
BACKGROUND AND PURPOSE: Research has documented the feasibility and benefit of treadmill training in children with cerebral palsy and Down syndrome. The purposes of this case report are: (1) to determine the feasibility of treadmill training in an infant at high risk for neuromotor dysfunction and (2) to describe the child's treadmill stepping patterns following treadmill training.

CASE DESCRIPTION: The male infant, who had a grade III intraventricular hemorrhage following premature birth, began physical therapy and treadmill training at 51/4 months corrected age. Treadmill training was conducted 3 times weekly and videotaped weekly. Videotape analysis determined number of steps, step type, and foot position.

OUTCOMES: Except for foot position, trends in treadmill stepping were similar to those of studies with infants not at high risk for neuromotor disabilities.

DISCUSSION: This case report shows that treadmill training is feasible for an infant at high risk for neuromotor disabilities and may be associated with more mature stepping characteristics. Future research should evaluate optimum treadmill training parameters and long-term developmental outcomes.

4. Damiano DL, DeJong SL.A systematic review of the effectiveness of treadmill training and body weight support in pediatric rehabilitation. J Neurol Phys Ther. 2009 Mar; 33(1):27-44.

Abstract
BACKGROUND AND PURPOSE: Given the extensive literature on body weight-supported treadmill training (BWSTT) in adult rehabilitation, a systematic review was undertaken to explore the strength, quality, and conclusiveness of evidence supporting use of treadmill training and body weight support in those with pediatric motor disabilities. A secondary goal was to ascertain whether protocol guidelines for BWSTT are available to guide pediatric physical therapy practice.

METHODS: The database search included MEDLINE, EMBASE, CINAHL Plus, PEDRO, Cochrane Library databases, and ERIC from January 1, 1980 to May 31, 2008 for articles that included treadmill training and body weight support for individuals less than 21 years of age, with or at risk for a motor disability. We identified 277 unique articles from which 29 met all inclusion criteria.

RESULTS: Efficacy of treadmill training in accelerating walking development in Down syndrome has been well demonstrated. Evidence supporting efficacy or effectiveness of BWSTT in pediatric practice for improving gait impairments and level of activity and participation in those with cerebral palsy, spinal cord injury, and other central nervous system disorders remains insufficient, although many studies noted positive effects.

DISCUSSION AND CONCLUSION: The original evidence demonstrates efficacy of BWSTT in children with Down syndrome, but large-scale controlled trials are needed to support the use of BWSTT in other pediatric subgroups. Increased use of randomized designs, studies with treadmill training-only groups, and dosage studies are needed before practice guidelines can be formulated. Neural changes in response to training warrant exploration, especially given the capacity for change in developing nervous systems.

5. Willoughby KL, Dodd KJ, Shields N, Foley S. Efficacy of partial body weight-supported treadmill training compared with over ground walking practice for children with cerebral palsy: a randomized controlled trial. Arch Phys Med Rehabil. 2010 Mar; 91(3):333-9.

Abstract
OBJECTIVE: To evaluate the efficacy of 9 weeks of twice-weekly partial body weight-supported treadmill training (PBWSTT) for children with cerebral palsy (CP) and moderate to severe walking difficulty compared with over ground walking.

DESIGN: Randomized controlled trial.

SETTING: Metropolitan Specialist School for children with moderate to severe physical and/or intellectual disabilities.

PARTICIPANTS: Thirty-four children classified level III or IV by the Gross Motor Function Classification System were recruited and randomly allocated to experimental or control groups. Of these, 26 (15 girls, 11 boys; mean age 10 y, 10 mo +/- 3 y, 11 mo [range, 5-18 y]) completed training and testing.

INTERVENTIONS: Both groups completed 9 weeks of twice-weekly walking training. The experimental group completed PBWSTT, and the control group completed over ground walking practice.

MAIN OUTCOME MEASURES: Ten-meter walk test (self-selected walking speed), 10-minute walk (walking endurance), School Function Assessment.

RESULTS: The over ground walking group showed a trend for an increase in the distance walked over 10 minutes (F=3.004, P=.097). There was no statistically significant difference in self-selected walking speed over 10 meters or in walking function in the school environment as measured by the School Function Assessment.

CONCLUSIONS: PBWSTT is safe and feasible to implement in a special school setting; however, it may be no more effective than over ground walking for improving walking speed and endurance for children with CP. Continued emphasis on progressive reduction of body weight support along with adding concurrent over ground walking practice to a treadmill training protocol may increase the intensity of training and assist with carryover of improvements to over ground walking. Treadmill training programs that include concurrent over ground walking as an additional key feature of the training protocol need to be rigorously evaluated for children with CP.

6. Paleg, G. Teaching Older Children with CP to Sit, Stand and Walk. Dev Med & Child Neuro. Abstract C:3 1997. 19 subjects mean age of 6 years (range 2-14), primary diagnoses of cerebral palsy and were not yet able to independently sit, stand and walk. MOVE Top-Down Motor Milestone Test on day one (beginning) and day five (conclusion) of a one week intensive (40 hrs therapy) in-patient stay. 95% of the children learned to walk, 58% learned to sit and 47% of the children learned to stand during the five day study.

7. van der Putten A, Vlaskamp C, Reynders K, Nakken H. Children with profound intellectual and multiple disabilities: the effects of functional movement activities.Clin Rehabil. 2005 Sep; 19(6):613-20.
OBJECTIVE: To determine the effect of functional movement activities within the MOVE (Mobility Opportunities Via Education) curriculum on the independence of children with profound intellectual and multiple disabilities.

SUBJECTS: Forty-four children with profound intellectual and multiple disabilities.

SETTING: Centers for special education.

DESIGN: A quasi-experimental pretest-posttest with control group design.

INTERVENTION: The children in the control group (n=12) participated in the regular programme at the centre of special education. The children within the experimental group (n=32) were additionally supported by the MOVE curriculum.

METHOD: Both group comparisons and individual analyses were conducted.

RESULTS: The level of independence of the experimental group increased significantly in performing movement skills; the control group did not increase significantly. At an individual level, 20 children (63%) of the experimental group improved in comparison with the control group, in which four children (33%) improved.

CONCLUSION: Results showed that the children receiving functionally focused activities achieved the greatest improvements in independence when performing movement activities.

8. Low SA. "Effects of the MOVE Curriculum on ROM, Motor Skills, and Functional Mobility of Children with Severe Multiple Disabilities: A Pilot Program." 2005. *Pediatric Physical Therapy* Spring 17:1

39 kids age 3.5-13 yrs, Progress over 1 year w/ MOVE & no direct PT

79% gained FM, 28% improved developmental level (Gesell), Majority made gains w/o PT

8. Bjornson KF, Belza B, Kartin D, Logsdon R, McLaughlin JF. Ambulatory physical activity performance in youth with cerebral palsy and youth who are developing typically. Phys Ther. 2007 Mar; 87(3):248-57.

Background and Purpose Assessment of walking activity in youth with cerebral palsy (CP) has traditionally been "capacity-based." The purpose of this study was to describe the day-to-day ambulatory activity "performance" of youth with CP compared with youth who were developing typically.

Subjects Eighty-one youth with CP, aged 10 to 13 years, who were categorized as being in Gross Motor Function Classification System (GMFCS) levels I to III and 30 age-matched youth who were developing typically were recruited.

Methods using a cross-sectional design, participants wore the StepWatch monitor for 7 days while documenting average daily total step counts, percentage of time they were active, ratio of medium to low activity levels, and percentage of time at high activity levels.

Results The youth with CP demonstrated significantly lower levels of all outcomes than the comparison group.

Discussion and Conclusion Daily walking activity and variability decreased as functional walking level (GMFCS level) decreased. Ambulatory activity performance within the context of the daily life for youth with CP appears valid and feasible as an outcome for mobility interventions in CP.

9. Adolph KE. Learning to Move.
Curr Dir Psychol Sci. 2008 Jun 28; 17(3):213-218.
"according to a recent estimate (Adolph, Badaly, Garciaguirre, & Sotsky, 2008), each hour, 14-month-olds take more than 2,000 walking steps, travel an accumulated distance of 7 football fields, and incur 15 (usually inconsequential) falls."

10. Berger SE, Adolph KELearning and development in infant locomotion.Prog Brain Res. 2007;164:237-55.

Abstract
The traditional study of infant locomotion focuses on what movements look like at various points in development, and how infants acquire sufficient strength and balance to move. We describe a new view of locomotor development that focuses on infants' ability to adapt their locomotor decisions to variations in the environment and changes in their bodily propensities. In the first section of the chapter, we argue that perception of affordances lies at the heart of adaptive locomotion. Perceiving affordances for balance and locomotion allows infants to select and modify their ongoing movements appropriately. In the second section, we describe alternative solutions that infants devise for coping with challenging locomotor situations, and various ways that new strategies enter their repertoire of behaviors. In the third section, we document the reciprocal developmental relationship between adaptive locomotion and cognition. Limits and advances in means-ends problem solving and cognitive capacity affect infants' ability to navigate a cluttered environment, while locomotor development offers infants new opportunities for learning.

11. Kermoian R, Campos JJ. Locomotor experience: a facilitator of spatial cognitive development.
Child Dev. 1988 Aug;59(4):908-17.
2 studies were designed to test the prediction that spatial search strategies (i.e., "object permanence") may be influenced by locomotor experience. Infants were assigned to 3 groups based on loco motor history: prelocomotor, prelocomotor with walker-assisted experience, and hands-and-knees creeping. Infants in all groups were 8.5 months of age. Results showed that hands-and-knees and walker-assisted loco motor experience facilitated spatial search performance. The longer those infants had been moving, the higher their scores. Furthermore, there were no differences between the hands-and-knees and prelocomotor/walker-assisted groups, suggesting that the relation between loco motor experience and spatial search performance was not merely a function of the maturation of prone progression. A third study found that the quality of locomotion affected object permanence performance: Belly crawlers performed differently than infants with hands-and-knees or walker experience, insofar as they performed at prelocomotor levels regardless of weeks of loco motor experience. Taken together, the pattern of findings suggests that infants with more efficient modes of locomotion are more likely to profit from the experiences generated by locomotion.

12. Cimolin V, Piccinini L, Avellis M, Cazzaniga A, Turconi AC, Crivellini M, Galli M.
3D-Quantitative evaluation of a rigid seating system and dynamic seating system using 3D movement analysis in individuals with dystonic tetraparesis. Disabil Rehabil Assist Technol. 2009 Nov;4(6):422-8.

To improve postural stability in individuals with dystonic cerebral palsy, the concept of a dynamic seat has been suggested as a potential solution. An experimental set-up for the acquisition of movement during extensor thrusts while sitting on a seating system was defined and applied on a group of dystonic individuals, to compare a dynamic versus a rigid seat system, using quantitative movement analysis. The seating system in dynamic configuration is able to reduce the extensor thrust experienced by the consumers, as well as to increase range of motion in the anterior-posterior direction, limiting the sliding down of trunk and showing better upper limb smoothness during extensor thrusts. The procedures used in this study appear to provide a useful tool for better understanding how the concept of a dynamic back in a seat system may affect and influence position and stability of individuals with dystonia on the seat system

13. Hahn, ME, Simkins, SL, and Gardner, JK, Kaushik, G. A DYNAMIC SEATING SYSTEM FOR CHILDREN WITH CEREBRAL PALSY. Journal of Musculoskeletal Research, Vol. 12, No. 1 (2009) 21–30

The study's aim was to determine the initial effects of a dynamic seating system as a therapeutic intervention in children with cerebral palsy. A two-factor, repeated-measures design was used. Twelve children with neuromuscular dysfunction (mean age 6.0, SD 2.7 years) were included in the study, randomly assigned to an experimental or a control group. At study initiation the experimental group received a wheelchair with dynamic seating components that allows limited range of motion in the hip and knee, and the control group received a static setting wheelchair. Participants were evaluated for range of motion, muscle spasticity (Modified Ashworth Scale), motor function (Gross Motor Function Measure), and level of disability (Pediatric Evaluation of Disability Inventory) at study initiation, 3-months, and 6-months post intervention. Both groups improved in motor function over time, particularly in the categories of Sitting and Crawl/Kneel. Measures of disability improved in both groups for the categories of self-care, mobility, and social function. A larger, more homogeneous sample would likely show significant group differences in measures of muscle spasticity, gross motor function and disability.

14. Ulrich DA, Lloyd MC, Tiernan CW, Looper JE, Angulo-Barroso RM.
Effects of intensity of treadmill training on developmental outcomes and stepping in infants with Down syndrome: a randomized trial. Phys Ther. 2008 Jan;88(1):114-22

BACKGROUND AND PURPOSE: Infants with Down syndrome (DS) are consistently late walkers. The purpose of this investigation was to test the effects of individualized, progressively more intense treadmill training on developmental outcomes in infants with DS.
SUBJECTS: Thirty infants born with DS were randomly assigned to receive lower-intensity, generalized treadmill training or higher-intensity, individualized training implemented by their parents in their homes.
METHODS: Research staff members monitored implementation of training, physical growth, and onset of motor milestones of all infants on a monthly basis.
RESULTS: Infants in the higher-intensity, individualized training group increased their stepping more dramatically over the course of training. Infants in the higher-intensity training group attained most of the motor milestones at an earlier mean age.
DISCUSSION AND CONCLUSION: Treadmill training of infants with DS is an excellent supplement to regularly scheduled physical therapy intervention for the purpose of reducing the delay in the onset of walking.