I. Title: The Development Of A Partial Weight Bearing Gait And Balance Training Device Which Can Safely And Effectively Be Used In The Home Therapy Environment By Parents, In Long Term Therapy Sessions With Children Diagnosed With Cerebral Palsy.

II. Purpose: It is the primary purpose of this study to determine if it is feasible to develop a partial weight bearing gait and balance training device that can be safely and effectively used in the home therapy environment by parents, in therapy sessions with their CP children. It is the secondary purpose of this study to develop a training program to prepare the parents to safely and effective accomplish gait and balance training session in the home, with the device.

III. Introduction: The development of cerebral palsy can have an devastating effect on the families and the children involved.

IV. Background:

A. Cerebral Palsy: The United Cerebral Palsy Association estimates that 500,000-700,000 children and adults have been diagnosed with CP, with approximately 4,500 American babies diagnosed each year. One in every 1,000 babies born in the US will develop cerebral palsy (NINDS, 1997; United Cerebral Palsy Association of Washington, 1997). According to the National institute of Neurological Disorders and Stroke, in the 1860s, William Little documented a startling disorder occurring in children. Dr. Little noted that during the first year of life, children afflicted by this disorder displayed stiffness and spasticity in the muscles of there legs, and to a lesser extent, the muscles in their arms. This strange disorder seemed to interfere with the child's ability to grasp objects, to crawl and later, to walk, but it did not seem to be progressive. It was noted that children born from complicated deliveries often manifested symptoms of this disorder, then know as "Little's Disease". Dr. Little surmised that the disorder was a result of the disruption of adequate oxygen supply to the infants brain during a difficult delivery, causing brain damage to a certain extent. In 1897, however, Dr. Sigmund Freud noted that children with Little's Disease often displayed other significant developmental problems such as mental retardation, visual impairments and seizures. Dr. Freud suggested that Little's Disease did not occur solely from a lack of oxygen, but stemmed from some cause during the earliest development of the brain in the mother's womb. In spite of Dr. Freud's insights, Dr. Little's theory of oxygen deprivation was viewed by physicians and researchers as the primary causal mechanism for what we now call cerebral palsy (NINDS, 1997).

According to NINDS, cerebral palsy (CP) "is an umbrella-like term used to describe a group of chronic disorders impairing control of movement that appear in the first few years of life and generally do not worsen over time". By definition, cerebral refers to the "cerebrum of the brain" (Barron's Medical Guide, 1994) and palsy refers to "any disorder that impairs control of body movement" (NINDS, 1997). Individuals diagnosed with CP often display spasticity, athetosis (purposeless movement), rigidity, a loss of muscle control, difficulty walking, poor balance and coordination, vision, hearing and speech impairments, difficulty in swallowing, drooling, abnormal sensation and perception and mental retardation. (Barron's Medical Guide, 1994; NINDS, 1997; United Cerebral Palsy Association of Washington, 1997). Seizures and epilepsy are also common occurrences, with as many as 50% of all CP children experiencing either one or the other (NINDS, 1997). According to the NINDS, 33% of all children diagnosed with CP are mildly intellectually impaired and 33% are mildly to severely intellectually impaired (1997). Children suffering from CP also experience long term growth problems manifested by too little weight gain, poor development of skeletal muscle, lack of sexual development (NINDS, 1997).

CP occurs in several forms and has been classified according to the type of movement disorder it creates; spastic, athetoid, ataxic and mixed forms. Spastic CP occurs in 70–80 percent of all individuals diagnosed with cerebral palsy. Spastic CP is characterized by excessively stiff muscles, with permanent contractures, often resulting in a characteristic scissors gait. Some individuals may also experience hemiparetic tremors, or an uncontrollable shaking on one side of the body (NINDS, 1997).

Athetoid cerebral palsy occurs in 10-20 percent of the CP population, and is characterized by slow, writhing movements affecting not only the muscles of the arms and legs, but also the face and tongue. Facial contortion, drooling, and speech impediments often accompany athetoid CP (NINDS, 1997).

The rarest form of CP, ataxic cerebral palsy, affects 5–10% of the CP population. Ataxic CP is characterized by a loss of the sense of balance and depth perception with an accompanying loss of coordination. These individuals often walk with a very wide based gait, are not able to execute quick or precise movements, and experience tremors when attempting voluntary tasks. Individuals that manifest symptoms from several of the categories of cerebral palsy are characterized as mixed form cerebral palsy. While the combination of spastic and athetoid CP are the most common, any combination is possible (NINDS, 1997).

The causal mechanisms of cerebral palsy are not as easily explained, as are the categories of CP. Until the 1980's causal theories on cerebral palsy were strongly rooted in the early observation and documentation of English surgeon, William Little. Dr. Little noted that children involved in difficult deliveries, at which time adequate oxygen was not supplied to the brain, displayed a disorder known as Little's Disease (later renamed cerebral palsy). Delivery room procedures were altered to address ways to prevent "distress" by the fetus, in efforts to decrease the instance of cerebral palsy. However, in the 1980's, scientists began to analyze the data produced by the change in delivery room protocol, only to find that, in fact, the instance of cerebral palsy had not been improved (Mayo Health Oasis, 1997)). This analysis revealed that up to 3-13% of all CP diagnoses are attributed to events that occurred during labor and delivery (congenital CP). While, 10% of all CP diagnoses are attributed to incidents during infancy and early childhood (acquired CP), and 80% of the CP diagnoses stem from unknown causes (Mayo Health Oasis, 1997; and NINDS, 1997). There are, however, certain conditions that are known causes of cerebral palsy.

ADD KNOWN CAUSES..

B. Current Cost of Physical Therapy: Wake Forest University recently completed an investigation of the financial ramifications of having a child with cerebral palsy. While a regional study, the results brought to light some interesting issues. It was established that the primary care giver was the mother (94%) and that 15.7% of the families operated as single parent households. It was also established that 67% of the, 20% of which also have a special health care need. In an attempt to better care for their special needs children, 13% of the parents reduced the number of hours worked and 34% we forced to terminate their employment. When looking at the therapy received by the child, 84% saw a physical therapist approximately 6 times per month, 50% saw an occupational therapy approximately 5 times per month and 37% of the children saw a speech therapist 5 times per month. 36% of the parents has concerns about the quality of the physical therapy that their child was receiving. The average annual household income of the families in the study was $30,000. While 63% of the child's medical bills were covered by Medicaid, 30% of the parents reported having significant concerns about the cost of physical therapy for their child. (UCP Research & Educational Foundation, 1997)……. **Need other cost statistics ……**

C. Partial Weight Bearing Gait Training: Brown et al conducted the first notable gait training research in the early 1900's. Brown spinalized cats to eliminate the animal's ability to support its own body weight, maintain proper posture or coordination and to walk unassisted. Using a tabletop treadmill, Brown proceeded to provide postural support for the hind limbs and provide the coordination for the stepping patterns with his own hands. Through a series of training sessions, Brown retrained the cat to step independently. Brown theorized that the forward stepping was a result of a reflex prompted by stretch on the hind limbs created by the moving treadmill belt. Research has since proven that Brown's reflex theory was not entirely correct and that central pattern generators (CPG) are actually responsible for the independent stepping patterns. Brown's early research, however provided the foundation for partial weight bearing gait training, producing very strong evidence that there are several interrelated components which must be present to accomplish the retraining of stepping patterns in spinalized cats. These factors are 1). posture; 2). coordination; 3). partial weight bearing; and 4). a slow rhythmic stimuli. Brown et al demonstrated that by relieving the body weight from the affected hind limbs, providing postural support and providing the coordination or step timing with his own hands, the spinalized cat could be taught to step. The stepping patterns, however, only occurred when postural and body weight support was provided by some outside force.

D. Benefits of PWB Techniques to Children with CP: While children with cerebral palsy are typically born with normal hip structures, they are prone to a variety of hip problems. The development of spasticity, specifically in the musculature of the hip, evokes structural changes in the hip joint. The muscle imbalance and bone deformities that result play a significant causal role in subluxation and dislocation of the hip joint. The instance and severity of the hip disorder tend to increase in the non-ambulatory children, and correlate strongly with the degree of spasticity (Atar et al, 1995; and Gamble et al, 1990). When investigating the relationship between hip stability and ambulatory status, a very strong correlation was found (Gamble et al., 1990; and Scrutton, 1989). Evidence suggests that 50% - 70% of quadriplegic patients requiring bed care experience dislocations of the hip joint. In comparison, hip dislocations in ambulatory patients is uncommon (Cooperman et al., 1987; Bleck 1987; and Lonstein and Beck, 1984).

V. Research Plan:

A. Equipment Design Requirements: In order for WalkAble™, the partial weight bearing gait and balance therapy device, to be effective and functional in the home therapy environment, it must be designed to maximize control of balance, posture, coordination, weight bearing load and rhythmic stimuli. The unit must also be versatile, in that it allows for gait and balance training in conjunction with a rhythmic stimuli (slow moving treadmill), as well as for gait and balance training over ground. The unit must move easily and be maneuverable through doors and around the home environment. The construction must be such that the unit is portable and collapsible, made of lightweight but exceptionally durable materials. The WalkAble™ must also clean easily and be convenient to use, all the while being enjoyable for both the parents and the child. Finally, the device design must be such that it is easily shipped and affordable to parents.

When designing a partial weight bearing gait and balance training device, one must first look at the components of gait. There are three primary components which function together to facilitate safe and efficient walking patterns. Posture, balance and coordination can all be adversely affected by cerebral palsy, making independent ambulation very difficult for the child. Proper upright posture is the cornerstone for safe and efficient gait. Because contracture is a very real problem for the cerebral palsy patient, often proper upright posture cannot be achieved and/or maintained independently. Gait, if at all possible, becomes unstable and inefficient because of the shortening of the muscles and tendons. It is, therefore, paramount that the WalkAble™ partial weight bearing gait and balance training device accomplish three postural goals. First, the device must support the child from two points above the shoulders facilitating proper upright posture. Second, the devise must also have a harness system that acts as a pair of hands, supporting the trunk and hip region. The harness must be flexible and comfortable for the child, but rigid enough to eliminate the “seated” posture at the hip joint and enable full hip extension during gait training. Third, the device must allow for adjustments to be made specific to each child’s postural issues.

Along with posture, balance is a key issue in ambulation. Poor balance can cause slow, asymmetrical walking patterns which are both extremely inefficient and very unstable. Poor balance can also lead to “fear of falling” for both the child and the parent, making independent ambulation even more stressful and difficult. The WalkAble™ device must, therefore, address the issue of balance by creating a safely supported environment that is free from the potential of falling. The harness system must be designed to comfortably and securely “grab” onto the soft tissue of the abdomen, while a padded groin piece keeps the harness in place on the child. The child is safely and comfortably supported in a fall free environment, now freeing the parent to manually manipulate weight shifts, foot placement, heel strike and other important components of coordinated walking patterns.

Coordination, or the ability of the child to walk in a symmetric gait pattern is greatly inhibited by the spasticity and contractures related to the CP disease state. The WalkAble™ device must not only address the posture and balance issues, it must also facilitate the development of new, more efficient stepping patterns. The research has shown that the repetitive and rhythmic stimuli of a slow moving treadmill is a key to the stimulation of the (CPG) responsible for initiating the stepping pattern (sources). The WalkAble™, therefore, must enable the parent to attach the child to the device from either a seated or standing position, and move the child onto a treadmill for gait training. Once over the treadmill, the parent can make adjustments in posture and/or the amount of weight bearing load supported by the device. The child is safely supported in a fall free environment, freeing the parent to observe current gait and posture, as well as manually manipulate weight shifting, foot placement, step timing and any other important components of proper gait.

WalkAble™ must also allow for the adjustment of the amount of weight bearing load supported by the device. Poor skeletal muscle development, muscle atrophy from lack of use, spasticity, contractures, bone deformities all contribute to the CP child's inability to walk safely and efficiently. For many CP, bearing their total body weight to even stand becomes impossible as contractures intensify and muscle atrophy progresses. It is essential that the WalkAble™ enables the amount of weight bearing load supported by the device to be systematically manipulated to meet the every changing physical needs of the child. In accordance with partial weight bearing protocol (sources), the amount of weight bearing load supported by the device should be decreased as strength levels improve and proper stepping patterns begin to develop. The device must, therefore, allow for the adjustment of weight bearing loads from 0% - 100% of the child's body weight.

Also in line with current established PWB protocol is the need to move the child from over treadmill gait and balance training to over ground gait and balance training. The transition from over treadmill stepping to over ground walking is paramount in the reinforcement of stepping patterns learned in response to the rhythmic stimuli.

The WalkAble™ must have the capacity to progress a child from the earliest stages of gait and balance training, requiring slower treadmill speeds and a higher percentage of body weight supported by the device, to over ground walking at full body weight. The versatility of the device must not end with its ability to move a child from over treadmill to over ground training.

WalkAble™ must also accommodate other aspects of the child's therapy session including but not limited to: balance activities, reaching activities, standing activities, Swiss ball activities, muscles strengthening, cardiovascular endurance, social interaction and play.

B. Equipment Design Specification:

The stability of the overhead yoke puts the child in proper upright posture, while the harness and strap system supports and stabilizes the child. The straps securely connect into both the harness and the overhead yoke, suspending the child at any percentage of body weight desired.

The base of the WalkAble™ is equipped with locking casters which allow the unit to be easily moved from one setting to the next and then locked into place for safely during gait and balance training.

C. Training Program Design: Secondary to the design, but equally as important is the training of the parents. The training program must be easily understood and learned by the parents to facilitate a safe and effective gait and balance training home therapy program. The parental training program is composed of three interrelated phases.

Phase I of the training will focus on the safe and effective use of the WalkAble™ in the home environment. This training will be in the form of written and video taped instructional materials. The parents will also have phone access to a professional who will be trained to provide feedback specific to each individual situation.

Phase II of the training program will be video analysis of the each specific child in the home therapy environment. The parent will be instructed to video tape the child functioning in the natural home environment.. The video taping will include current home therapy, as well as gait and balance training using WalkAble™. A trained professional will then analyze the videotape, and a detailed training program will be designed based on the information provided. The training program will be in the form of videotape, including further instruction on the proper and effective use of the WalkAble™. The Phase II videotaping will occur every three months over the course of the first year (four times). A monthly newsletter outlining user tips, current literature, books of interest, support group information and various other information will also be a part of the phase two training program.

Phase III of the training program is in the form of continuing education seminars. Semiannual seminars will be conducted in various parts of the country, to facilitate the continued learning by the parent. The continuing education seminars will also serve as a support network for parents of CP children.

D. Develop a training program for the instruction of parents in the home environment.

1. Develop guidelines for the proper use of WalkAble™.

2. Develop proper gait training techniques for use with WalkAble™ by the parents.
3. Develop proper safety guidelines for the use of WalkAble™.
4. Develop a long-term gait training protocol designed for the home therapy environment.

E. Research Questions

1. Is WalkAble™ functional in the home environment?
2. Is WalkAble™ cost effective for the home environment?
3. Can parents be trained to provide long-term gait training for their CP children?
4. Is the protocol functional and understandable for the parents to execute it safely and effectively?
5. Does the protocol meet the needs of both the parent and the patient population?
6. Does the protocol produce improvement in the outlined parameters?

F. Test Perameters

1. Walking symmetry
2. Weight shift
3. Toe off
4. Heel strike
5. Knee lock
6. Maximal walking velocity over ground
7. Maximal walking velocity over treadmill
8. Maximal weight bearing capability
9. Functional skills assessment

VI. Materials/Equipment:

VII. Statistical Package:

VIII. Budget:

IX. Business Plan:

X. Administrative Plan:

XI. Primary Investigator:

XII. Testing Site (in home or at facility):

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