Quantifying Energetic Demands of Walking for People with Cerebral Palsy

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STUDY PROTOCOL

Background

Walking promotes independence, participation, fitness, and exploration in daily life. Like other activities, walking requires metabolic energy. That energy is obtained from the food we eat and the air we breathe, ultimately being used by our muscles to power movement. Experimentally, we can measure the energy being used by our muscles using indirect calorimetry, which monitors oxygen consumption and carbon dioxide generation as the body converts stored energy into the form used by muscles during activities of daily living. Decades of energetics research has demonstrated that human walking is incredibly efficient. However, for people with cerebral palsy, the energetic cost of walking is significantly increased, on average over two times higher than for typically-developing individuals. This means that for people with cerebral palsy, walking is as demanding as jogging or climbing stairs. Energetic costs of this magnitude restrict activities of daily living and causes exhaustion. While our team and many others have sought to reduce these costs through surgical interventions, rehabilitation, orthotics, or other assistive devices, these strategies have not resulted in meaningful reductions in energy. To design strategies that successfully reduce walking costs, we must first understand the underlying mechanisms contributing to elevated cost in people with cerebral palsy. This clinical trial seeks to fill this knowledge gap by examining biomechanical factors that contribute to elevated energetic costs of walking for people with cerebral palsy. Specifically, we will evaluate the energetic cost of vertical and lateral support of the body during walking for children with cerebral palsy, and compare these costs to typically-developing peers. Supporting and stabilizing the body require very little energy during unimpaired walking, accounting for less than ten percent of the total walking cost. However, the relative costs of these tasks remain unknown for people with cerebral palsy, which is problematic as they can have direct implications for treatment decisions and assistive device design. This research uses a mechatronic device to provide precise support and stabilization assistance during walking, so that we can quantify the impact of this assistance on walking cost. This research provides the foundation to create evidence-based strategies to decrease energy costs, minimize fatigue, and increase quality of life for people with cerebral palsy and other neurologic injuries.

Human Subjects Involvement, Characteristics, and Design

Aims 1 and 2 will use the same set of individuals to evaluate if energetic cost changes with varying levels of support. We aimed to recruit at least 21 individuals with cerebral palsy and 7 age- and sex-matched typically-developing peers (3:1 allocation ratio) to participate in the proposed research at Gillette Children's Specialty Healthcare. The age range of 8 to 17 years will allow us to examine costs during the period most children receive treatment and evaluate potential differences due to age. Our inclusion criteria are age between 8 and 17 years, diagnosis of spastic bilateral cerebral palsy, classification as Gross Motor Function Classification System Level II, absence of dystonia or ataxia or athetosis, no surgical procedures within the preceding 12 months, no pharmacological spasticity treatments such as botulinum toxin or baclofen within two months prior to testing, no current pharmacological agents that impact neuromuscular control, capacity to follow instructions and provide informed assent, ability to walk on a treadmill for six minutes, and absence of acute or chronic pain in lower extremities. Individuals will not be excluded on the basis of ethnic background, race, sex, or socioeconomic factors.

Each individual will perform a protocol that consists of walking on a treadmill with varying levels of support while energy cost is measured by indirect calorimetry. An experienced pediatric physical therapist will collect physical exam data including strength, selective motor control, spasticity, and joint range of motion. We will place wireless electromyography sensors on each leg to monitor the seven large superficial muscle groups that have previously been shown to be important contributors to walking biomechanics. The electromyography data will be collected at 2000 Hertz, band-pass filtered at 20 to 450 Hertz, rectified, and low-pass filtered at 20 Hertz to compare between levels of support or stabilization. We will employ a standard clinical marker set and model to calculate kinematics using the Vicon plug-in-gait model, including functional calibration of knee and hip joints. Participants will wear shoes without orthoses during all trials.

We will use indirect calorimetry to calculate net dimensionless walking cost. Energetic cost is defined as the energy consumed per unit time. We will measure resting cost while the participant is supine in a recliner for five minutes. Walking cost will be measured while walking at each level of support or stabilization assistance. Resting and walking costs are evaluated by measuring the volume of oxygen consumed and carbon dioxide produced over the last three minutes of each five minute walking trial.

We will familiarize each participant to walking on the instrumented treadmill before beginning the walking trials. In our extensive experience with treadmill testing, we find this usually takes less than five minutes for children with cerebral palsy. Participants will then complete the walking trials to quantify support or stabilization costs, with order randomized between levels of assistance and a minimum twenty-minute break between support and stabilization trials. All participants will walk at a fixed dimensionless speed of 0.26 to account for differences in size between participants. We selected this dimensionless speed to provide a common and achievable speed based on prior trials of children classified as Gross Motor Function Classification System Level II who have completed energetic testing at Gillette. There will be a rest between trials. We will ask participants to report perceived exertion after each trial.

For both aims, we will use a custom mechatronic system with forces generated by a Humotech system that enables control of vertical or lateral forces to the body during walking. The mechatronic system allows us to precisely generate and monitor desired forces while minimizing undesired forces throughout the trial. For Aim 1 we control the direction of the applied vertical force using a low friction and low inertia 2 degree-of-freedom ceiling-mounted gantry. For Aim 2,

we apply lateral forces when the pelvis deviates from the middle line of the treadmill using a custom-designed frame that allows for free movement of the pelvis in the fore/aft direction.

a. Potential risks:

There are minor risks associated with completing motion analysis and indirect calorimetry while walking on a treadmill with the mechatronic system. The potential risks associated with the proposed research include risk of tripping or falling while standing and walking on a treadmill, risk of skin discomfort from sensors attached to the skin to monitor muscle activity with electromyography sensors and motion with reflective markers, risk of fatigue and soreness from the exercise activity of walking, risk from applied assistance as the Humotech system applies force to a safety harness to provide vertical and lateral forces, and risk of privacy breach. Tripping and falling are possibilities and we will take numerous precautions to prevent such risk as described below. Fatigue and muscle soreness are also potential risks and we will provide adequate time to rest and recover for all tasks. Forces from the Humotech system are also a potential risk and physical hardware and software back-up safety mechanisms were built into the system to reduce the risk of excessive forces.

b. Recruitment and informed consent:

Children with cerebral palsy will be recruited from Gillette Children's Specialty Healthcare using brochures designed to describe the research and involvement. An experienced research coordinator will assist with recruiting and contacting potential participants. Before participation, each child and their parent or guardian will receive a thorough explanation of the protocols from a member of the research team. We will obtain informed permission from the parent or guardian and assent from the child. Children that do not voluntarily communicate their assent and understand the procedures will not be included in the study. Information will be provided verbally and in writing. Individuals will be reassured of their right to withdraw at any time from the study.

c. Protection against risks:

We take numerous precautions to protect against risks associated with using motion capture to analyze human movement. To prevent tripping and falling we ensure that the floor of the facility and treadmill is free from wires or other obstructions and a safety harness is used while walking on the treadmill. Electromyography sensors and motion analysis markers are also safe and have been tested and used extensively during similar tasks for research and clinical applications. For the Humotech system, to avoid accidents due to applying external assistance, the connections to the harness include automatic releases if the force from the system exceeds a threshold or if the position of the actuator exceeds normal operating limits. Emergency stop buttons are provided to the participant and research staff that will immediately stop the treadmill and force actuator. We will inspect all wires, equipment, and connections before every experiment. Participants will be given frequent breaks during all experiments to avoid fatigue. For all experiments, individuals can terminate the experiment at any time. To protect against any breach in confidentiality, data collected for this study will be stored securely on password-protected computers. Codes instead of names of individuals will be used on all data files and reports. Any data used for publication or presentations will be de-identified.

This research involves children who represent a vulnerable population. According to age, assent or consent will be provided by each child in addition to consent from the parent or guardian.

Participants will be reminded throughout the research that they can stop participation. Additional protections include minimal use of adhesives for placing markers on the skin, size adjustable safety harnesses, and the use of exertion scales to monitor participant comfort and energy throughout the experimental protocol. The parent or guardian will be allowed to stay with the child throughout all testing procedures.

d. Potential benefits of the proposed research to human subjects and others:

There are no immediate potential benefits to the participants in this study.

e. Importance of the knowledge to be obtained:

The potential risks associated with this study are reasonable in the context of the knowledge and advancement in our understanding of cerebral palsy that will be gained. We anticipate that the proposed experiments will provide fundamental insight into the mechanisms underlying elevated energetic cost during walking for children with cerebral palsy relative to typically-developing peers. This research will test the generalizability of our current theory for understanding how humans efficiently move and explore the world, which are critical for activity and participation. Understanding the generalizability of this theory is critical to enhance our ability to support life-long participation and support human performance across the range of human health and ability. This basic-science proposal will provide the foundation for future research that can support novel strategies to manage the energetic costs of walking and enable participation across the lifespan for individuals with or without cerebral palsy. The results from this work will also be extendable to other clinical populations such as stroke, traumatic brain injury, spinal cord injury, and multiple sclerosis, which also exhibit similar pathology and elevated energetic costs of movement.

STATISTICAL ANALYSIS

We will recruit children with bilateral cerebral palsy who are classified as Gross Motor Function Classification System Level II and typically-developing peers. Our sample size was designed to test the primary hypotheses that support and stabilization costs are elevated for children with cerebral palsy relative to typically-developing peers. Independent sample t-tests will be used to compare the support and stabilization costs between groups. Given the novelty of this work, we have based these estimates of our effect size on our retrospective studies and literature, where available. We estimated an effect size of 1.5 based on three comparisons. First, Unnithan et al., (2006) observed support costs in children with cerebral palsy more than two times that reported in unimpaired individuals, although the amount of assistance was not reported nor systematically controlled[1]. Second, prior experiments with unilateral amputees and stroke survivors, who generally have reduced energetic costs compared to children with cerebral palsy, showed elevated support and stabilization costs. Third, the difference in fixed cost between children with cerebral palsy and typically-developing peers from our retrospective analyses supports this effect size. To detect an effect size of 1.5 with alpha equal to 0.05 and an allocation ratio of cerebral palsy to typically-developing of three to one would require 21 children with cerebral palsy and seven typically-developing peers. We used G-Power software for all estimates with power of 0.9.

Our primary hypotheses are that support and stabilization costs are elevated in children with cerebral palsy compared to typically-developing peers. To test these hypotheses, for each participant we will calculate the walking energy in each condition. We then test the impact of vertical and lateral support using linear regression models, comparing how the walking energy changes with support. In this model, walking energy is the net dimensionless walking cost, and support assistance represents the levels of either vertical or lateral support. Secondarily, we will use linear multiple regression models to evaluate the impact of participant characteristics on support and stabilization costs. In this model, cost is the net dimensionless walking cost, assistance represents the four levels of either vertical or lateral support assistance, group represents the cerebral palsy and typically-developing cohorts, and characteristics include participant characteristics. We will evaluate whether the coefficient for group is significant, indicating the effect of support is different between groups. Participant characteristics for the regression model will include age, sex, body mass index, and minimum knee flexion during stance.

Table 1: Variable definitions

Variable	Description
Net Dimensionless Walking Cost	The energy consumed per unit time during walking, normalized for body size, calculated as the difference between walking cost and resting cost.
Support Cost:	The change in net dimensionless walking cost at maximum vertical support assistance compared to no assistance condition.
Stabilization Cost	The reduction in net dimensionless walking cost at maximum lateral stabilization assistance compared to no assistance condition.

REFERENCES

1. Unnithan VB, Kenne EM, Logan L, Collier S, Turk M. The effect of partial body weight support on the oxygen cost of walking in children and adolescents with spastic cerebral palsy. Pediatr Exerc Sci. 2006;18(1):11–21.