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**An Intensive Virtual Reality Program Improves Balance and Functional Mobility of Adolescents with
Cerebral Palsy**

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AN INTENSIVE VIRTUAL REALITY PROGRAM IMPROVES BALANCE AND
FUNCTIONAL MOBILITY OF ADOLESCENTS WITH CEREBRAL PALSY

BY

MARIE BRIEN

THESIS

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I dedicate my thesis to my 2 dear sons, Erik and Oliver, as an inspiration for the pursuit of life-long learning.

ABSTRACT

This study examined the effect of an intensive virtual reality (VR) intervention on balance and functional mobility in four adolescent males (mean age 16 years, range 13 years 9 months to 18 years 9 months) with cerebral palsy (CP) in a Gross Motor Classification System (GMFCS) level I.

A single-subject multiple baseline experimental design (ABA) was used. Outcome measures were the Community Balance and Mobility Scale (CB&M), the Six-minute Walk Test (6MWT), the Timed Up and Down Stairs Test (TUDS) and the Gross Motor Function Measure (GMFM)-Dimension E. The participants were evaluated between three and six times in the baseline phase, five times in the intervention phase, and four times in the follow-up phase. The intervention consisted of an intensive 90-minute virtual reality-based balance training program for five consecutive days.

Analysis consisted of visual and statistical analyses of graphed data as well as analyses of clinical significance. All adolescents demonstrated statistically significant improvements on the CB&M and the 6MWT during the intervention phase and these improvements were maintained the week following the intervention as well as at one month follow-up. Statistically significant improvements on TUDS scores were present in one adolescent at intervention and follow-up.

One adolescent showed statistically significant improvements on the GMFM-dimension E and reached a ceiling effect on the GMFM-Dimension E at intervention and follow-up.

For the CB&M, reliable changes in mean scores were recorded in three out of four adolescents in the intervention phase and in all adolescents in the follow-up phase. For the 6MWT, one adolescent reached the minimal detectable change (MDC) value in the intervention phase that demonstrates significance for the mean distance walked. Three adolescents reached the MDC value in the follow-phase.

This study supports two major findings in adolescents with CP in GMFCS Level I. First, our data suggest that functional balance and mobility of these 13 to 18 year old adolescents with CP can improve with an intense, short duration VR intervention. Second, our data indicate that changes are maintained for at least one month following the VR training. For all participants, a causal relationship was established between the VR intervention and the significant improvements on the CB&M and the 6MWT. This relationship was maintained in the follow-up phase. The study provides evidence that balance and functional mobility are modifiable in ambulatory adolescents with CP in GMFCS Level I and that these adolescents have the potential to enhance their repertoire of complex movement strategies.

RÉSUMÉ

Ce projet de recherche a étudié l'effet d'un programme d'intervention intensif de réalité virtuelle sur l'équilibre et la mobilité fonctionnelle de quatre adolescents (âge moyen de 16 ans, entre 13 ans 9 mois et 18 ans 9 mois) avec la paralysie cérébrale (PC) classifiés au niveau I du Système de classification de la fonction motrice globale de la paralysie cérébrale (GMFCS).

Un protocole expérimental de cas uniques à niveaux de base multiples (A-B-A) a été utilisé. Les mesures de résultats ont été le *Community Balance and Mobility Scale* (CB&M), le *6-minute Walk Test* (6MWT), le *Timed Up and Down Stairs Test* (TUDS) et la dimension E du *Gross Motor Function Measure* (GMFM). Les participants ont été évalués entre trois et six fois dans la phase de base, cinq fois dans la phase d'intervention et quatre fois dans la phase suivant l'intervention. L'intervention a consisté d'un programme de réalité virtuelle intensif de 90 minutes visant l'entraînement à l'équilibre pour cinq jours consécutifs.

L'analyse a inclus les analyses visuelles et statistiques ainsi que l'analyse de signification clinique. Tous les adolescents ont démontré des améliorations statistiquement significatives sur le CB&M et le 6MWT qui étaient encore présentes la semaine après l'intervention ainsi qu'à un mois suivant l'intervention. Des améliorations significatives ont été démontrées sur le TUDS par un adolescent pendant la période de l'intervention et pendant la phase suivant

l'intervention. Un autre adolescent a démontré des améliorations significatives sur la dimension E du GMFM et a atteint un effet de plafond pendant la période de l'intervention et pendant la phase suivant l'intervention. Pour le CB&M, des changements fiables dans les résultats moyens ont été démontrés chez trois des quatre adolescents dans la phase d'intervention et chez tous les adolescents dans la phase suivant l'intervention. Pour le 6MWT, un adolescent a atteint la valeur du changement détectable minimale pendant la phase d'intervention et a démontré une différence significative pour la distance moyenne marchée. Trois adolescents ont atteint la valeur du changement détectable minimale pendant la phase suivant l'intervention.

Cette étude appuie deux constatations importantes chez les adolescents atteints de la PC au niveau I du GMFCS. D'abord, nos résultats suggèrent que l'équilibre et la mobilité fonctionnelle de ces adolescents de 13 à 18 ans peuvent s'améliorer avec une intervention intensive et de courte durée de réalité virtuelle. En deuxième lieu, nos résultats indiquent que les changements ont été maintenus au moins un mois suivant l'intervention de réalité virtuelle. Chez tous les participants, une relation causale a été établie entre l'intervention de réalité virtuelle et les améliorations significatives sur le CB&M et le 6MWT. Cette relation a été maintenue pendant la phase suivant l'intervention. Cette étude fournit l'évidence que l'équilibre et la mobilité fonctionnelle est modifiable chez les adolescents ambulants atteints de la PC au niveau I du GMFCS et que ces adolescents ont le potentiel d'améliorer leur répertoire de stratégies de mouvements complexes.

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LIST OF ABBREVIATIONS

6MWT: Six-Minute Walk Test

ABI: Acquired brain injury

CB&M: Community Balance and Mobility Scale

COP: Center of pressure

CP: Cerebral Palsy

GMFM: Gross Motor Function Measure

GMFCS: Gross Motor Function Classification System

ICF: International Classification of Functioning

MDC: Minimal detectable change

TBI: Traumatic brain injury

TD: Typically developing

TUDS: Timed Up and Down Stairs

SD: Standard deviation

VE: Virtual environment

VR: Virtual reality

WS: weight shift

CHAPTER 1

INTRODUCTION

Children and youth with cerebral palsy with high level motor skills continue to demonstrate deficits in balance and mobility as they reach adolescence. Despite the impact these deficits have on quality of life and integration into activities with peers, these children and youth are often not provided with rehabilitation programs as their motor function is thought to have attained its maximum potential. Although recent studies suggest that certain interventions may lead to improvements on specific components of balance (Woollacott & Shumway-Cook, 2005) and/or mobility (Provost et al., 2007), the type, intensity and duration of intervention required for improvement are not well defined. This thesis addresses the topic of intervention options aimed at balance and functional mobility impairments in ambulatory adolescents with cerebral palsy (CP). A single subject research design was used to investigate the effects of a virtual-reality (VR) based balance training program on four clinical outcome measures.

Statement of Purpose

The purpose of this study was to examine the effect of an intensive VR training program on balance and functional mobility in four 13 to 18 year old adolescents with CP in Gross Motor Function Classification System (GMFCS) level I.

Justification for the study

Cerebral palsy is a well-recognized neurodevelopmental condition beginning in early childhood and persisting through the lifespan. In 2004, an international symposium attended by selected leaders in the field was held to review and update the definition and classification of CP in light of emerging understanding of developmental neurobiology and changing concepts about impairment, functional status and participation. The updated definition describes CP as “a group of disorders of the development of movement and posture, causing activity limitation that are attributed to non-progressive disturbances in the developing fetal or infant brain. Individuals with CP may also have disturbances of sensation, cognition, communication, perception, and/or behaviour, and/or a seizure disorder” (Rosenbaum et al., 2007). While the underlying neuropathology is non-progressive, the clinical manifestations of CP are widely believed to change through the lifespan (Dan, 2007).

The Gross Motor Function Classification System (GMFCS) is the most widely used objective functional scale to group individuals with CP into one of five levels of severity based on movement abilities and limitations (Palisano et al., 2000). Classification of children with CP into a GMFCS level is based on the child’s self-initiated movements and functional mobility as observed or reported by clinicians or parents. The GMFCS takes into consideration everyday performance in home, school and community settings, rather than best capacity. The scale was designed primarily to help clinicians

prognosticate about the motor function of individuals with CP. The initial GMFCS consisted of four age bands with descriptors for children between 0 to 2 years, 2 to 4 years, 4 to 6 years, and 6 to 12 years of age. An expanded and revised version of the GMFCS (GMFCS-E&R) was developed to include an age band for youth 12 to 18 years of age (Palisano, Hanna, Rosenbaum, Bartlett, & Livingston, 2008).

According to the GMFCS, children in level I are relatively functional in their mobility by the time they reach 6 years old. Youth with CP in GMFCS Level I have been reported to possess motor skills necessary for successful function within their homes, schools, and communities (Palisano et al., 2008). They are able to walk indoors and outdoors, walk up and down stairs without the use of a railing and can run and jump to some extent. However, despite being able to ambulate independently without assistive devices, they present with a limited movement repertoire resulting in restricted variation of movement strategies within given environments or activities (Damiano, 2009). For example, children in this level show difficulties with balance (Woollacott & Shumway-Cook, 2005; Burtner, Qualls, & Woollacott, 1998), speed (Thompson et al., 2008), and coordination (Crenna, 1998 but c.f. Palisano et al., 2000). Important factors leading to participation limitations include difficulties with walking on uneven surfaces and inclines, walking in crowds or confined spaces, lack of endurance, reduced speed, balance, and coordination (Voorman et al., 2006).

Physiotherapy services for children and adolescents with CP in GMFCS level I are usually quite limited as they are thought to have reached a plateau in terms of their motor skills based on the Gross Motor Function Measure (GMFM), the standardized outcome measure most commonly used for youth with CP (Hanna et al., 2009). Rather than developing specific balance and functional mobility training for this cohort, children and adolescents in GMFCS level I are encouraged to participate in community recreational programs and activities with their peers. This approach has some limitations since participation in physical activities and sports has been shown to depend on personal choices and environmental factors (Palisano et al., 2008). For example, school-aged children with CP who have higher levels of fundamental balance and functional mobility skills report greater performance and participation in sports and physical activity with peers than children with lower levels of balance and mobility (Voorman et al., 2006). Moreover, rather than being integrated into activity, adolescents with CP may experience limitations to participation and have been reported to be less physically active (Maher, Williams, & Olds, 2008) and walk less than peers without CP (Bjornson, Belza, Kartin, Logsdon, & McLaughlin, 2007).

Adolescence and early adulthood has been recognized as an important time of transition particularly for individuals with CP (Dan, 2007). It remains unclear whether balance and functional mobility naturally stabilize, improve or deteriorate over this period. In a prospective longitudinal study from adolescence to early adulthood, the

gross motor development curve for GMFCS Level I followed a Stable Limit model. This pattern was based on the Gross Motor Function Measure (GMFM-66) with 657 study participants who showed no evidence of functional decline or improvement during adolescence (Hanna et al., 2009). In contrast, a retrospective data analysis on 7550 children with CP initially aged 10 years and 5721 adults with CP aged 25 years who had varying levels of ambulatory ability (initial GMFCS Levels I-IV), documented that children with CP who walked and climbed stairs without difficulty at age 10 demonstrated a 23% probability of performance loss. By 25 years of age, this initial group of 10 year-olds required a handrail to manage stairs (Day, Wu, Strauss, Shavelle, & Reynold, 2007). In an another retrospective study, Sandstrom, Alinder and Oberg (2004) showed deterioration of motor function in adults in all GMFCS levels with deterioration seen predominantly in adults in level I. For this group, structured interviews and functional assessments revealed decreases in walking ability that resulted in GMFCS level changes from level I to II. The deterioration in the functional status of adults with CP and the secondary impairments leading to the reduction or loss of ambulatory capacity in people with CP have underscored the important role of physical therapy in the period of adolescence (Bottos, Feliciangeli, Sciuto, Gericke, & Vianello, 2001). Despite this evidence demonstrating loss of function in youth with CP in GMFCS level I documented from adolescence to adulthood, there are limited data supporting the effectiveness of interventions aimed specifically at improving balance and functional mobility of adolescents in GMFCS Level I.

A novel intervention approach, VR-based intervention, is beginning to be used to optimize motor rehabilitation through task-oriented practice (see Holden, 2005 for review). The VR-based interventions use virtual environments (VEs) to provide unique multidimensional medium involving multimodal sensory processes to elicit movements from the user (Sveistrup, 2004). In the VE, the individual interacts with virtual objects and scenarios consistent with real life situations providing ecological validity to the movements that are elicited. The level of task difficulty may be modified to provide optimal and motivating challenges for individual clients. In the VE, intensive repetition can be automated to deliver specific stimuli under very controlled conditions (Weiss, Rand, Katz, & Kizony, 2004). Early intervention studies in adults with traumatic brain injury (TBI) have demonstrated the effectiveness of training using VEs when compared to real world based interventions. Improvements have been shown on community-level functional mobility (Thornton et al., 2004) as well as confidence and independence (Thornton et al., 2005). The literature in pediatric motor rehabilitation supporting the use and effectiveness of VR-based interventions with children with CP is scarce and based on reports of small numbers of individuals. Among those studies, results showed improvements in reaching kinematics in three out of four children (Chen et al., 2007), increased upper extremity control in a small group of 4 children (Reid, 2002b) as well as improved ankle selective motor control and participant motivation in a group of 10 children (Bryanton et al., 2006). These previous findings along with theorized advantages of VR (i.e., motivation, controlled stimulus delivery, ability to individualize

intervention, ecological validity) suggest that there is potential for using VR as a means to deliver effective intervention for youth with CP.

This study addresses the need for effective balance intervention programs for ambulatory adolescents with CP in GMFCS Level I. A multiple baseline single subject research design was used to evaluate the clinical impact of an intensive, short duration VR-based balance intervention.

Hypotheses

We hypothesized that a five day 90-minute per day VR-based balance training program would result in improvements on four outcome measures: the Community Balance and Mobility Scale (CB&M), the Six-Minute Walk Test (6MWT), the Timed Up and Down Stairs (TUDS) and the Gross Motor Function Measure (GMFM) Dimension E. We also hypothesized that these improvements would be maintained the week after the intervention as well as one month later.

Limitations

In this multiple baseline design (MBD), concurrency was not possible due to the intensive nature of the study and the availability of the virtual reality system. However, despite the non-concurrency of the design, participants' baseline and intervention phases overlapped and all occurred during the summer period when adolescents were not involved in a school program. Finally, we chose to observe changes following a five day

intervention. Subsequent work will examine the effect of longer periods of treatment as well as longer term retention of improvements in balance and functional mobility.

Delimitations

Participants were 13 to 18 years of age and the findings cannot be generalized to younger children or to the adult population. As well, the adolescent participants had CP in GMFCS level I so the results cannot be generalized to individuals in other GMFCS levels.

Functional balance and mobility were assessed in the adolescent participants using the CB&M which, although validated for the adult traumatic brain injury survivors, has not been validated for the adolescent cerebral palsy population.

CHAPTER 2

REVIEW OF THE LITERATURE

General Overview

A multiple baseline single subject research design was used to examine the effects of a virtual reality intervention on balance and functional mobility in adolescents with CP in GMFCS Level I. The following review of the literature will highlight the different areas of knowledge which have merged together to develop the research question for this study. The first section addresses the World Health Organization's International Classification of Functioning, Disability and Health (ICF) model (WHO, 2001) as a conceptual framework applied to CP. Specifically, the current study intends to intervene at the activity level using an intervention which targets balance and functional mobility with intent to improve participation. The second section examines the motor control theories which have informed the design of the intervention program used in the study. The third section addresses balance and mobility in CP using background knowledge of balance development in the typically developing child. The fourth section of the literature review examines the use of virtual reality in physical rehabilitation. Lastly, the fifth section addresses the topic of single subject research design and its use in clinical practice.

The ICF Model Applied to Cerebral Palsy

The ICF is a conceptual framework for description of all health and health-related aspects of well-being. This model of human functioning and disability was developed to reflect the interactive relationship between health conditions and contextual factors. It is a biopsychosocial model which was designed to provide a coherent view human functioning and disability from body, individual and societal perspectives. The ICF is organized in two parts which describe health and well-being with interrelated dimensions. Part 1, functioning and disability, consists of three components: body functions and structures, activities and participation. Part 2, contextual factors, consists of two components: environmental or extrinsic factors and personal or intrinsic factors (WHO, 2001).

Rather than a biomedical model of illness and treatment, the ICF provides a framework to understand the process of disablement as an interaction between the individual and the environment. In CP, problems with the integrity of body functions and structures are reflected by impairments such as muscle spasticity, range of motion limitations and muscle weakness. The activity component of the model is reflected by the performance of tasks or actions such as gross motor skills, mobility and basic functional skills. Participation refers to the involvement of the individual in life situations (i.e., the person-environment interaction) and is reflected by involvement in daily activities at home, school and in the community with family and peers (Wright, Rosenbaum,

Goldsmith, Law, & Fehlings, 2008). For children and adolescents, participation relates to active engagement in typical activities available to and/or expected of peers in the same context (Goldstein, Cohn, & Coster, 2004). Problems within an ICF dimension lead to disability and may be described as impairment in body functions and structures, limitation of activity and participation restriction (WHO, 2001).

It is recognized that an individual's functioning or disability in a specific dimension represents an interaction between the health condition and contextual factors. In contrast to a biomedical model of illness and treatment, this framework changes from a deficit perspective to a focus on what the child wants and can do within his or her personal context (Goldstein et al., 2004). The GMFCS-Expanded and Revised (E&R), used to classify youth with CP, is designed to emphasize concepts of the ICF by reflecting the potential impact of environmental and personal factors on activity and participation (Palisano et al., 2008). For example, important mobility considerations in daily life participation by these youth have been reported to relate to safety and efficiency in ambulation (i.e., body function and activity dimensions) as well as the influence of environmental and personal factors (i.e., contextual factors) (Palisano et al., 2009).

For many decades, there was an implicit assumption that impairment-based approaches to treatment led to functional results (Rosenbaum & Stewart, 2004). For example, an impairment-based approach would address problems at the body function and structures levels (i.e. muscle tone, range of motion, muscle strength) which are

thought to be the cause of functional limitations. Thus, a therapist may have approached a clinical problem of lower extremity weakness with the following question. “If hip and knee strength increases (body functions and structures), to what extent can the youth’s walking ability improve (activity) and what impact might this have on his ability to go to the park or the mall with his peers (participation)?”

One clear example of the complex multilevel and multifactorial contributors to function and disability addressed the effectiveness of a common pharmaceutical agent on different levels of the ICF (Wright et al., 2008). In a pre-post experimental study, 35 ambulatory children with CP were given botulinum toxin type-A injections (BOTOX) with the goal of decreasing spasticity in injected muscles. Despite the known changes produced by BOTOX intervention on body functions and structures, results showed weak associations in the relationships between changes in outcome measures of impairment (body functions and structures) and outcome measures of activity and participation. Combinations of predictors including baseline scores, GMFCS levels and age accounted for 10% to 69% of the variation in activity and participation change scores (Wright et al., 2008).

Current conceptualization of rehabilitation with the ICF model illustrates the multidirectionality of relationships where changes at the different ICF dimensions are complex. Over the past few years, physiotherapists have begun to incorporate the ICF into their clinical practice as it provides a standard language for communication about

functional status assessment, goal setting, treatment planning and monitoring, as well as about functional outcomes measurement and research. In research and in clinical practice, the ICF model guides the selection of intervention and measurement tools to inform goal setting and determine meaningful outcomes (Rosenbaum & Stewart, 2004). Although outcome relationships between the different levels of the ICF however are not yet clear (Wright, 2008), the outcomes measured need to be multidimensional to encompass the impact of treatment at different levels of body function and structures, activity and participation. Interventions aimed at skills at the activity level such as gross motor skills and mobility which take into account the impact of personal and environmental factors are more likely to produce functional changes than those addressing the body function and structure (impairment) levels. It is important to consider approaches which bridge the gap between acquisition of basic skills and the performance higher-level daily activities in different environments (Wright et al., 2008).

Motor Control Applied to Rehabilitation

The following section presents an overview of motor control theories that have shaped our present understanding of motor learning and its application to functional skill development. These theories have informed the development of the intervention protocol used in the current study.

While early theories of motor control were based on the view that the CNS was a reactive system, as explained by the reflex (Sherrington, 1947 as c.f. Shumway-Cook &

Woollacott, 2007, p. 9) and hierarchical (Foerster 1977 as c.f. Shumway-Cook & Woollacott, 2007, p.10) theories, more recent theories have emerged to take into account the characteristics of the system and the impact of internal and external forces on the body. The systems theory gave rise to a distributed model of motor control. The body was described as a mechanical unit with many degrees of freedom to be controlled and the model argued that synergies created from clustering components played an important role in the timing and grading of movement. The systems theory takes into account both the contributions of the musculoskeletal system and the nervous system to action as well as the forces of gravity and inertia. However, a limitation of this theory is that the interaction of the organism with the environment is not an important focus ((Bernstein, 1967 but c.f. Shumway-Cook & Woollacott, 2007, p.11-13).

Early dynamic systems theorists proposed that motor development reflected a complex interplay of factors beyond the maturation of the baby's brain and nervous system and included the baby's changing body and the environment (Thelen & Cooke, 1987). The dynamic action theory suggests that a new movement emerges due to critical changes in one of the systems or 'control parameter', a variable that regulates change in the behaviour of the entire system without need for specific command from the CNS. One of the major implications of the dynamic action theory is that movement emerges from multiple elements which self-organize based on their dynamic properties. The emergence of movement is thus explained by physical principles rather than neural

structures. The dynamic action theory was later modified to incorporate many of Bernstein's concepts from the systems theory, resulting in the dynamic systems model which integrates both physical and neural components (Shumway-Cook & Woollacott, 2007, p.14-15).

The dynamical systems perspective on motor control incorporates the interactions between the individual, the task and the environment and is thus consistent with the ICF model (Rosenbaum & Stewart, 2004). These three components interact with each other to influence the outcome of movement and may be enablers or limiters to motor control and learning. The dynamical systems model has major implications as a foundation for intervention in physiotherapy and in clinical research. The individual's component systems, along with the task requirements and the environmental context may be altered to facilitate change (Carr & Shepherd, 2000). In the present study, these components of motor control will be manipulated within the VE to facilitate skill acquisition.

As summarized above, in the past 20 years, there have been significant advances in our understanding of the neural bases of movement with a shift from anatomical and physiological bases for motor control to a task-oriented approach or functional perspective that is more consistent with the ICF framework. Damiano (2006) proposed that physiotherapy management of cerebral palsy needs to shift from traditional approaches such as impairment-based therapy to a more focused and proactive approach of promoting activity. According to this approach, effective lower-extremity training

should involve activity-based strategies which require the common functions of lower extremities. These gross motor activities involve repetitive, reciprocal or bilateral, coordinated motions of both lower extremities. Training programs which can focus on various aspects of motor performance such as balance, coordination, strength, endurance and coordination are likely to produce better functional outcomes (Damiano, 2009). An example of this approach is the high intensity training intervention using a treadmill which has been shown to be effective in the treatment of CP (Provost et al., 2007).

Although the benefits of higher intensity strength or resistance training are becoming increasingly recognized to promote neural and functional recovery, the carryover of strength gains to functional activities may not be immediate. Mockford & Caulton (2008) conducted a systematic review of 13 articles examining the effect of progressive strength training in ambulatory children and adolescents with CP aged 4 to 20 years. Findings showed that function and gait improvements were greatest in preadolescents and specifically with isokinetic training. The benefits of intense and task-related exercise programs such as strength training show the strongest level of evidence (Damiano, 2009). However, key factors such as optimal practice level, type of feedback and practice conditions remain unknown and further research in pediatric neurological rehabilitation for decision making is required.

Finally, training transfer to a new task or to a new environment is also a critical issue in rehabilitation (Carr & Shepherd, 2000). The ability to generalize learning to novel

situations is a crucial variable in motor learning and research has shown that repetition and variable practice increases the ability to adapt and generalize learning (Lee, Swanson, & Hall, 1991). Variable practice may be essential when learning tasks that are likely to be performed in the real world which has variable conditions. In fact, it has been suggested that the most effective transfers occur when the processing demands in the practice environment most closely resemble those experienced in the real world environment (Carr & Shepherd).

Key aspects from the current theories of motor control and motor learning were used to develop this VR intervention study. Specifically, the intervention was developed taking into account the literature demonstrating benefits from functional, activity-based activity delivered at high intensity (Shepherd and Carr 2000; Damiano, 2009). In addition, the intervention included variable practice at difficulty levels set for individual participants as well as the opportunity to set tasks in practice environments resembling real world situations to allow for transfer of skill into every life.

Balance and Mobility in Cerebral Palsy

Functional balance consists of the elements of postural control that allow a child to safely perform everyday tasks. A typically developing (TD) school-aged child with functional balance is expected to be independent within his/her home and school environment when performing basic activities of daily living, mobility, and gross motor activities, including recreational activities and play (Franjoine, Gunther, & Taylor, 2003).

The ability to adapt balance responses to increasing balance threats is not yet present in new standers and new walkers. Specifically, organized postural muscle activation patterns to induced losses of balance during independent stance are not produced until the infants are able to pull themselves into a standing position (Sveistrup & Woollacott, 1996) while compensatory stepping responses during balance recovery are refined by six months of walking experience (Roncesvalles, Woollacott, & Jensen, 2000). By 7 to 10 years of age, TD children have acquired adult-like patterns of balance control and locomotion (Woollacott et al., 1998) and show adult-like gait characteristics including proactive strategies for obstacle avoidance (McFadyen, Malouin, & Dumas, 2001), articulated versus “en bloc” control of the head in space during locomotion (Assaiante, Mallau, Viel, Jover, & Schmitz, 2005) and backward shift of center of pressure (COP) in gait initiation (Ledebt, Bril, & Breniere, 1998). In contrast, children and adolescents with CP demonstrate impaired acquisition of postural responses to perturbations with inappropriate delays and inappropriate muscle activation (Burtner et al., 1998; Shumway-Cook, Hutchinson, Kartin, Price, & Woollacott, 2003). Similar neuromuscular constraints are reported on balance and gait in children with CP suggesting that they may have a common origin (Crenna, 1998).

Early work has shown that massed practice of reactive postural responses to externally induced balance threats improved the organization and efficiency of postural responses in TD infants (Sveistrup & Woollacott, 1997). Infants between the ages of 36 and 48 weeks

and able to stand with support were given extensive balance training on a moveable platform consisting of 100 perturbations per day over five days. Significant improvements in directional specificity of postural responses were recorded. Specifically, the tibialis anterior, the quadriceps and the abdominal muscles were activated with greater frequency in response to induced backward sway while the gastrocnemius muscles were activated with greater frequency in response to induced forward sway. A greater number of functionally appropriate postural muscles were activated in a distal-to-proximal order. These findings suggest that, in normal motor development, specific muscle activation parameters of the automatic postural response respond to experience with the postural task.

Two of the more commonly used training approaches for balance and mobility in children with CP are the moveable platform and treadmill training. Studies using a moveable platform have primarily focused on the underlying control mechanisms of reactive postural muscle responses to discrete perturbations and the effects of reactive balance training (Burtner et al., 1998; Shumway-Cook et al., 2003; Woollacott et al., 2005). The second training method, body-weight-supported treadmill training (BWSTT), addresses balance and mobility in a task-related context specifically aimed at locomotion (Provost et al., 2007).

A series of studies has characterized postural responses to externally induced balance loss following perturbation of the support surface. Muscle recruitment patterns of seven

children with spastic CP, between the ages of 1.7 years and 14 years, were compared to those of TD children with the same level of walking experience (Burtner et al., 1998). Functional walking skills were used as criteria to divide the children with CP and the TD children into three groups: (a) prewalkers (PW) with no emergence of independent walking; (b) young walkers (YW) who had 2 to 4 years of independent walking experience; and (c) experienced walkers (EW) who had a history of 8 to 14 years of walking independently. The children stood on a moveable platform that translated forward or backward at 20 cm/s for 2.8 cm for PW children, 25 cm/s for 3.3 cm for YW children and 25 cm/s for 3.8 cm for the EW CP and control groups. Compared to TD children with the same level of walking experience, children with spastic CP demonstrated increased antagonist leg and thigh muscle recruitment, decreased trunk muscle activation and longer onset latencies in leg and thigh muscles. The children with spastic CP were shown to exhibit many constraints on posture including a crouched posture which contributed to increased sway and longer time to recover balance, delayed responses to the balance perturbations in the ankle muscles, inappropriate proximal to distal muscle sequencing; and increased co-contraction of agonist and antagonist muscles. These findings suggested that balance differences in children with spastic CP may be a result of the underlying pathology in the neural mechanisms as well as the mechanical differences in their crouched posture (Burtner et al.).

To determine if it was possible to influence and improve the postural muscle responses to externally induced balance loss, Shumway-Cook et al. (2003) examined the effect of massed practice on reactive balance control in six children between the ages of 7 to 12 years with spastic CP in GMFCS level I and II. The training paradigm mimicked that used by Sveistrup and Woollacott (1997) and consisted of five days of intensive training using 100 perturbations per day on a moveable platform. A force platform was used to obtain kinetic data including the total center of pressure path (COP) defined by the mean area of center of pressure movement per second during balance recovery and the amount of time to recover stability following a balance threat. After training, all children showed a significant improvement in their ability to recover a stable balance posture. These changes were still present 30 days following the completion of training. Specifically, they demonstrated a reduction in both the total COP path used during balance recovery and in the time to restabilize balance following a perturbation. These findings suggest that reactive postural control mechanisms in children between the ages of 7 to 12 years with CP in GMFCS level I and II are modifiable with intense practice in balance recovery of stability.

Using a similar training program, Woollacott and Shumway-Cook (2005) studied the possible neural mechanisms that contribute to improvements in balance control produced by reactive balance training in children with CP. They demonstrated that the efficiency of balance recovery could be improved in children with CP. Specifically, they found that

muscle response characteristics changed following training and suggested that these changes contributed to improved recovery of balance. These changes included reductions in the time of leg and thigh muscle contraction onset, improved leg, thigh and trunk muscle response organization, and reduced co-contraction of agonist and antagonist muscles in the leg and thigh. Additional changes included improvements in directional specificity of muscle responses. These changes resulted in muscle activation patterns that were more comparable to those seen in TD children. These important findings showed functional implications. Faster activation of muscle contractions, the emergence of appropriate distal-to-proximal muscle sequencing and improvements in the ability to modulate muscle activity amplitudes with reductions in agonist-antagonist co-contractions resulted in faster recovery of stability (Woollacott et al., 2005).

In contrast to platform training for balance control, the effects of a two-week high intensity body-weight-supported treadmill training (BWSTT) program (30 minutes twice daily) on balance and gait was studied with six children between the ages of 6 to 14 years with CP in GMFCS Level I (Provost et al., 2007). This task-related training addressed some of the components needed for functional locomotion including speed, single leg balance, endurance and energy expenditure. Improvements were noted in measures of energy expenditure and walking velocity although only half of the children showed improvements in walking endurance and in single leg balance. This study suggests that a short, intensive course of BWSTT can improve measures of endurance and speed

although there may be limited improvements on other important components of functional gait and balance in children and adolescents with CP in GMFCS level I. Although both the platform and treadmill training programs reported some success in improving specific dependant measures, the training methods are relatively limited in the types of movements the children perform or are exposed to. Treadmill training involves producing constant alternating stepping mimicking forward overground progression at specific speeds. Platform training involves responding to forward and/or backward perturbations of the support surface that result in balance threats. In summary, the platform and treadmill training methods result in specific changes to function, however neither incorporate motor planning or complex movement strategies which are necessary for optimal functional outcomes (Damiano, 2009).

Virtual Reality in Physical Rehabilitation

Virtual environments provide a unique multidimensional medium involving multimodal processes to optimize motor rehabilitation through task-oriented practice (see Sveistrup, 2004 for review). Intervention programs using VR offer the capacity to individualize treatment needs while providing standardized task-oriented training within an ecologically valid context. Virtual scenarios reproduce conditions consistent with real life situations without the practical concerns of safety issues such as falling. Applications using virtual reality allow the users to interact with images and virtual objects in real-time through multiple sensory modalities. In addition, the level of difficulty of a VR program

may be modified to continuously provide an optimal challenge and motivation to the participant (Sveistrup). Furthermore, intensive repetition can be automated to deliver specific stimuli under very controlled conditions without unintentional variations between task repetitions, therefore providing increased practice opportunity as compared to real-world therapy (Penn et al., 2009).

Evidence suggests that VR can be used to provide unique VEs that embed therapy in motivating, purposeful and functional contexts while supporting both grading of the task and documentation of the user's progress (Sveistrup et al., 2004). Individuals with motor impairments including those with CP present with deficits in multiple motor, sensory and cognitive components necessary for typical movement, including tone, strength, range of motion, sensation, visual-perception, motivation, cognition (Valvano, 2004). Each of these impairments may impact an individuals' ability to interact with the task and the environment. A virtual environment however provides a means by which the interaction between the impairments, the task and the environment can be manipulated.

Weiss et al. (2004) proposed a conceptual model within the context of the ICF (WHO, 2001) framework for the use of VR in rehabilitation. The model consists of three nested circles: the inner 'Interaction Space', the intermediate 'Transfer Space', and the outer 'Real World'. Within the 'Interaction Space', two primary sets of characteristics influence the interaction between the user and the VE: user characteristics and the characteristics of the virtual environment. The user characteristics include: the

demographic factors (e.g., age, gender, and cultural background), body functions (e.g., cognitive, sensory, motor) and structures (e.g., arms, legs). The characteristics of the VE, which may be enablers or barriers to activity and participation, include the type of VR platform, its underlying technology and the nature of the task and the demand. The therapist manipulates the VE to optimize the environmental factors to facilitate the individual's interaction with the VE. It is within this inner 'Interaction Space' that the sensations and perceptions related to the virtual experience occur. Thus, the "Interaction Space" encompasses establishing the user's sense of presence, the process of assigning meaning to the virtual experience and the actual performance of the virtual tasks or skills. The intermediate circle, the 'Transfer Space' involves transfer of the trained skill as well as the environmental modifications to the real-world. This may be done by the individuals themselves or may require guidance from the clinician. The time frame for the accomplishment of this goal varies across users and across tasks. Finally, the outer circle represents the real world environment and represents the transfer of the trained skill into functional skills and abilities of everyday life activities through the potential of VR as a rehabilitation tool.

VR-based tasks have been used effectively to challenge the user's postural control system and balance. One study required study participants to reach sideways at increasing distances in order to touch a defined object (Lott, Bisson, Lajoie, McComas, & Sveistrup, 2003). The lateral reach resulted in lateral shifts of the center of pressure (COP) within

the base of support. Three experimental conditions were used to study movements in healthy adults: continuous lateral reach to a physical object, flatscreen third-person VR to a virtual object seen on a TV monitor and head-mounted display third-person VR requiring reaching to a virtual object. The flatscreen VE resulted in significantly larger lateral COP movements than those recorded in the other environments. The authors suggest that this is in part due to the maintenance of an exocentric frame of reference in combination with the gaming atmosphere established in the flatscreen VE (Lott et al., 2003). These results indicate that postural control requires the interaction of the three major sensory systems, the visual, vestibular and somatosensory systems to create relevant frames of reference which the flatscreen VE provides to the users.

Several studies have compared the effectiveness of VR-based motor rehabilitation interventions to real world interventions for training functional balance and mobility with healthy older adults as well as with adults following TBI. Bisson, Constant, Sveistrup and Lajoie (2007) compared the impact of a visual biofeedback and a VR training program on a measure of community balance, the CB&M, as well as on a measure of reaction time during stance. Each 10-week training program consisted of two 30-min sessions per week. Participants in the visual biofeedback group stood on a force platform and saw a cursor representing their centre of pressure (CP) on a monitor. The participants were required to move the cursor to the four corners of the monitor in a controlled manner by leaning forward and backward as well as left and right. Participants in the VR condition

juggled a virtual ball that fell to the side of the body at different distances. Participants in both groups showed significant improvements, both one week and one month later, in their functional balance and mobility as measured with the CB&M as well as decreased reaction time during standing. These findings suggest that both training paradigms are beneficial in automating postural control, likely due to allocating less attention to the postural task of standing because of the concordance of the visual and the proprioceptive information from the environment during training (Bisson et al.).

In a separate study, Thornton et al. (2005) compared a physical world activity-based (AB) program to a virtual reality based (VR) program for balance retraining. Study participants included adults with moderate to severe TBI who were at least six months post-injury. Participants completed three 50-minute exercise sessions per week for six weeks and changes in the ability to access the community were recorded. Following intervention, participants in the VR group showed greater improvements than participants in the AB group on community-level functional mobility as measured by the CB&M. Importantly, the participants in the VR-based intervention group provided more comments than participants in the AB group expressing enjoyment and improved confidence and independence. These two studies indicate that both community dwelling older adults and adult TBI survivors can improve functional balance and mobility skills as measured by the CB&M following interventions delivered using virtual reality. Virtual reality interventions have also been shown to facilitate motor learning with the functional

relevance of a specific environmental context as well as skill transfer and integration into real life situations (Penn, Rose, & Johnson, 2009).

Paediatric motor rehabilitation is one of the newest fields to benefit from advances in VR technology. A review of the literature shows that data supporting the use and effectiveness of VR-based interventions for motor rehabilitation with children with CP is scarce and limited to single case studies, small group pre-test post-test designs and a few studies using single-subject research designs.

One of the first applications of VR with a pediatric population used Mandala Gesture Xtreme (Vivid Group Inc., Toronto, Canada) technology and developed a play-based intervention to study intervention effectiveness on upper extremity function (Reid, 2002b). The authors reported results of single cases with pre-test-post-test design with four children aged 8 to 12 years with CP in GMFCS levels III and IV. The intervention required that the children reach laterally into the full reach space to create virtual paintings and to touch virtual objects that changed shape and made sounds on virtual contact. There were clinically significant changes on the Quality of Upper Extremity Skills Test (QUEST) in two of the four children. Qualitative comments from the participants revealed a high degree of motivation, interest and pleasure, and opportunity for play not previously engaged in (Reid, 2002b). A separate series of single case studies with pre-test-post-test design reported the benefits of virtual play on perceptions of self-efficacy as measured by the Canadian Occupational Performance Measure (COPM) in

three children. Positive changes in perceived performance abilities and satisfaction with performance with task specific areas were recorded in two children (Reid, 2002a). In a subsequent study, Harris and Reid (2005) explored the degree of motivation shown by 16 children aged 8 to 12 years with CP in GMFCS Level I to V during therapeutic play in different VEs. The Pediatric Volitional Questionnaire (PVQ) revealed that the use of a VE for play had a positive impact on their level of motivation. Taken together these studies demonstrate that VR play provides relevant and optimal environment conditions for fostering engagement and motivation by providing variable yet challenging and rewarding games to meet each child's needs.

A VR exercise program using an IREX system (GestureTek, Toronto, Canada) was compared to a conventional physiotherapy exercise program in 10 children with CP in GMFCS level I and II, aged 7 to 17 years (Bryanton et al., 2006). The exercise programs were designed to elicit selective motor control of ankle dorsiflexion. Ankle joint range of motion was recorded bilaterally. Sessions consisted of two conventional exercises and two VR-based exercises in an ABBA design with order counterbalanced between children. Results showed that movements performed under the VR conditions were executed through a greater range of motion and the endpoint positions were held for longer periods as compared to movements executed during conventional exercises. These results suggest increased selective motor control under the VR conditions. As well, participant self-reported interest and motivation as well as parental perception of their

child's interest and motivation to perform the exercises was highest when the children participated in the VR exercise program. These findings are particularly important for these school-aged children with CP who have often lost interest in performing any conventional exercise and in particular, the program of home exercises often prescribed for rehabilitation. A limitation of this study is that retention and functional carryover of the intervention effects were not determined.

You and colleagues (2005) reported on central nervous system changes following VR intervention. This single case study of an eight year old child with hemiparetic CP examined the effects of an IREX exercise program that consisted of five-60 minute sessions per week for a four week period. Cortical reorganization was recorded with functional magnetic resonance imaging (fMRI) and showed evidence of increased activation of the contralateral sensorimotor cortex (SMC) and disappearance of altered activation in other areas following the intervention period. The cortical changes were consistent with significant changes on functional motor testing of the affected upper extremity including reaching, dressing and self-feeding. Furthermore, the efficacy of enriched environments to promote neuronal plasticity and functional recovery following pediatric TBI has been suggested in recent literature and has indicated that rehabilitation conditions must be conducive to harnessing this neural plasticity (Penn et al., 2009). The changes documented with functional magnetic resonance imaging (fMRI) support the

argument that training in a VE offers potential for long-term learning as evidenced by functional cerebral reorganization and adaptive cerebral plasticity.

Further research is needed to validate and support the development of new clinical applications for VR in rehabilitation particularly in field of pediatric neurology. While studies have been done examining the effects of VR on functional balance and mobility of older adults and adults post-TBI, the effectiveness of a VR-based intervention program on balance and mobility of ambulatory adolescents with CP is unknown. Furthermore, no research has been done on the effectiveness of a VR-based motor rehabilitation program of high intensity and short duration. A single-subject research design will provide a quasi-experimental approach to evaluate clinical change and treatment effectiveness for this study.

Single-Subject Research Design

The single-subject research design (SSRD) has become increasingly recognized in rehabilitation literature as a valuable tool that can inform and guide clinical practice by demonstrating individual differences while demonstrating treatment effectiveness (Romeiser Logan, Hickman, Harris, & Heriza, 2008; Portney & Walkins, 2000; Backman & Harris, 1999). Within-subject methods, such as SSRD, are advantageous in clinical research where heterogeneity of subjects lead to difficulty in obtaining power for a group study (Ottenbacher, 1986).

The traditional experimental model requires large numbers of subjects and control groups which are often barriers to clinical studies. Experimental group designs deal with group averages and generalizations across individuals, often hide factors or cancel their effect and do not allow the clinician to differentiate characteristics of patients who respond to treatment and those who do not improve. Despite generalization being important in understanding outcomes to treatment, clinicians view group outcome as relevant if it can be used to understand and predict individual outcomes (Portney & Watkins, 2000).

The process of single-subject research consists of systematic, repeated measurement of target behaviour (dependant variable) through one or more baseline and intervention phases (Backman & Harris, 1999). These repeated assessments or observations are required to observe trends or patterns in the data and to evaluate the variability of the response over time. This type of variability in the data across time cannot be observed in group studies where data are collected only before and after treatment.

External validity or generalizability of single-subject research is established using replication and, in fact, there are compelling arguments regarding the superiority of the SSRD as compared to group designs (Portney & Watkins, 2000). For example, generalization can be demonstrated in different settings or by different clinicians and the target behaviour could be monitored after the intervention has stopped by incorporating a follow-up or maintenance phase in the SSRD. Direct replication in SSRD involves repeating the original study with a series of subjects with similar characteristics (i.e.,

same diagnoses, impairments or functions). Reliability in SSRD, as in other forms of clinical inquiry, is usually assessed concurrently with the data collection rather than as a separate pilot study (Portney & Watkins). Interrater reliability may be reported using a measure of agreement between observers with reliability checks performed by having two testers observe the target behaviour at several sessions across each phase.

Using a conventional notation, the baseline phase is represented by the letter A and the intervention period by the letter B. The baseline refers to a period of time in which the target behaviour or dependent variable is observed and recorded as it occurs without introduction of an intervention (independent variable). Baseline data is gathered for a minimum of three to four sessions or observations to establish stability in the dependent variable where possible (Portney & Watkins, 2000). The baseline behaviour reflects the natural state of the individual or control condition and provides the frame of reference for comparison with future behavior or behavior during and following intervention. It is assumed that the baseline period reflects the effects of ongoing background variables such as personal characteristics, daily activities, and other treatments on the target behaviour. The collection of baseline data distinguishes SSRD from group designs, case studies, and clinical practice. In these other designs, treatment is initiated most often following a single assessment. The baseline phase of the study needs to be long enough to achieve stability in the target behavior. Once the baseline data set is complete, only one

independent variable should be changed as the subject moves from the baseline to the treatment conditions. This minimizes the introduction of confounding variables.

The treatment phase, B, is a period of time during which the experimental manipulation is introduced. During this period, target behaviour continues to be observed and recorded. Continued repeated measures of the dependent variable are taken through the baseline and the intervention phase allowing for comparison between the two phases and cause-effect inference to be made (Romeiser Logan et al., 2008).

Numerous types of SSRD exist including *N*-of-1 randomized controlled trials, alternating treatment designs, randomized concurrent or nonconcurrent multiple baseline design (MBD), replicated basic designs with at least 3 phases e.g. ABA or ABC, where C is a second intervention, and AB or simple baseline designs.

The AB design

The AB design which includes one baseline phase (A) and one intervention phase (B) is the weakest design for controlling threats to internal validity such as history or maturation. It is impossible to conclude that the treatment was the causative factor in changes in the dependant variable because contributing factors, such as the natural recovery process, are not controlled in the AB design (Backman, Harris, Chisholm, & Monette, 1997). The control in this design can be strengthened if the effects are replicated across multiple subjects, conditions or behaviours.

The ABA design

The ABA design replicates one baseline phase following the intervention phase and is the strongest of the single subject designs (Backman et al., 1997). Internal validity is controlled as it is quite unlikely that confounding factors would be present before and after the intervention. It is designed to show that changes are evident only in presence of the intervention. At times, the withdrawal of treatment may present ethical and feasibility problems or there may be a learning effect which has occurred. One limitation of the ABA design involves irreversibility of the behaviour, such as learning and the natural recovery process; once a change in the independent variable occurs, a change affected in the dependent variable cannot be undone by simply removing the independent variable. An example of irreversibility would be where children are tested on their ability to kick a ball, an intervention (teaching period) is instituted to teach ball kicking, and then, the children are again tested on their ability to kick a ball. In this situation, what the children learned cannot be reversed. For the ABA design to be effective, the behaviour should be reversible (Portney & Walkins, 2000). An example of reversibility would be where subjects are tested on the pressure distribution under their feet while they walk overground. The subjects are provided with an in-sole orthotic and tested while walking with the orthotic. In the second baseline phase, the orthotic is removed and subjects walk again without the intervention. If the orthotic is responsible for the change in behaviour, the effect of the in-sole disappears since the effects are only due to the presence of the

orthotic. An ABAB (or ABBA) design can strengthen the experimental control and clinical relevance by having two baseline and two interventions periods.

Multiple baseline design

The multiple baseline design (MBD) is used to replicate effects either across subjects, across treatment conditions, or across multiple target behaviours. The MBD ensures experimental control by initially requiring the concurrent collection of baseline data across a minimum of three data series, for example, where baseline data on balance is recorded simultaneously from at least three study participants. The MBD allows for the use of AB or ABA designs (Portney & Walkins, 2000).

The MBD across subjects is replicated across three or more subjects in a staggered manner, each of whom is assigned a baseline phase of different length. When the baseline data show a stable pattern, the intervention is applied only to the first series and the other baselines are continued. The interventions in the other participants begin once a stable response to the intervention has been observed or at a predetermined interval of time (Ottenbacher, 1986). The analysis then compares trends across subjects as well as between the phases of each subject (Backman & Harris, 1999).

Strengths of the MBD include its effectiveness for controlling extraneous variables of the environment. Internal validity is strengthened by demonstrating that the baselines are independent and that change is observed only in the subjects when the intervention is applied and that no change occurs in the other subjects as they continue in the baseline

phase. By allowing each baseline to run for a different period, systematic changes in the target behaviour correlated with the onset of the intervention phase can be attributed to the intervention. In fact, each subject, behaviour, or setting provides replication of the effects found in the previous subject, behaviour, or setting. The built-in replication of the MBD ensures a degree of generalizability which the other SSRD do not have (Ottenbacher, 1986).

The non-concurrent MBD is a recent, clinically feasible, alternative to the concurrent MBD and allows the researcher to arbitrarily determine the length of several baselines (Portney & Watkins, 2000). Subjects are randomly assigned to different baseline lengths often based on their availability for participation in a study and treatment is introduced at the appropriate time. This nonconcurrent design may be weaker than the concurrent MBD if external factors related to the passage of time are different for each baseline. For example, studies examining community mobility in children using walkers to ambulate may be influenced by seasonal variation and results may differ across children as a function of weather conditions and time of year.

Guidelines for SSRD

Important guidelines which must be adhered to when designing a SSRD include reliable and repeated measurement, description of baseline and treatment conditions where a single variable is changed, and identification of appropriate analysis techniques (Romeiser Logan et al., 2008). Since these designs involve multiple measures of

behavior, it is important for the instrumentation to be reliable. Conditions for data collection such as time of day and location of testing should be standardized and observers need to be trained. Consistency in measurement is especially crucial in the transition before and after the treatment. Since the same behavior is measured on multiple occasions, repeated measures are needed to obtain a clear pattern or consistency in the behavior over time and to control for the normal variation of behavior that is expected within short time intervals. Clear, detailed descriptions of the conditions of measurement and the nature of the treatment are needed to strengthen internal and external validity (Portney & Watkins, 2000).

The strengths of the individual designs have been summarized in a set of five evidence levels (Romeiser Logan et al. 2008; see Appendix 7 for full table). The most rigorous level of evidence for SSRD or level I is the randomized controlled *N*-of-1 (RCT), alternating treatment, and concurrent or non-concurrent MBD with clear-cut results. The level I SSRD has generalizability if replicated across 3 or more subjects and the MBD consists of a minimum of 3 subjects, behaviours, or settings and can provide causal inferences. The current study is classified as a level III design as it is a non-randomized, non-concurrent, controlled MBD with clear-cut results. This design demonstrates generalizability if it consists of at least 3 subjects, and it provides limited causal inferences. The lowest level of evidence or level V is the non-randomized controlled AB design.

In addition to levels of evidence assessing rigour of research design, a series of 14 rigor questions have been produced and are the recommended guidelines for clinicians planning to conduct and review pediatric single subject research (Romeiser Logan et al. 2008; see Appendix 8 for full list). The questions are based on similar questions or criteria used for evaluating group designs and rigorously review all aspects of the study including the description of participants and settings, the independent variables, the dependent variables, the design and the analyses.

Serial dependency

Before visual and statistical analyses can be achieved, it is essential that baseline data from each participant in a single subject design be analyzed for presence of serial dependency. Serial dependency or autocorrelation refers to the fact that sequential measures or responses from the same individual are correlated with previous measures allowing for prediction of subsequent performance. Serial dependency is an issue for any research design that uses repeated measures as it violates the assumption of independence. The presence or absence of serial dependency will dictate which statistical tests are appropriate for analysis of single subject data (Backman & Harris, 1999).

Serial dependency is calculated using the autocorrelation coefficient which indicates to what extent measures at one point in a series are predictive of subsequent measures in the same series. The lag-1 autocorrelation is the resultant coefficient of differences between scores in pairs formed from adjacent points. Serial dependency may be calculated for

baseline data alone, baseline and intervention separately or the entire data series. If the intervention is effective, it would obviously contribute to serial dependency between the data points in the intervention phase that may not exist in the baseline phase as a progressive change in behaviour at each assessment is expected. Ottenbacher (1986) recommends calculating serial dependency for each phase separately but, if any given phase has a small number of points (i.e. 5 or less), the entire data set is to be used. Bartlett's Test is used to determine statistical significance of the autocorrelation coefficient (Ottenbacher, 1986).

When data are not autocorrelated, visual and statistical analyses can be applied to the raw data. However, if present, serial dependency must be removed using either first difference transformation or moving average transformation before further visual or statistical analysis of the data is performed. The first difference transformation is used with a data series showing a linear trend while the moving average transformation is used when the data appear to be highly variable. Once data have been transformed, serial dependency is again computed to confirm that the autocorrelation coefficient is no longer significant. Transformation of data results in the loss of one data point and changes the nature of the data series resulting in a loss of clinical information when data are graphed for visual analysis. A constant value may be added to the each data point in the series to remove negative values or to make the graphical representation of the data conform to the traditional standard for the specific outcome measure or behaviour (Ottenbacher, 1986).

Once autocorrelation is removed, visual analysis can be achieved and inferential statistical analysis can quantify and strengthen the visual findings (Romeiser Logan et al., 2008).

Visual analysis

Visual analysis of graphed data is the foundation of analysis in SSRDs and is typically the first level of analysis used for data interpretation. Visual analysis involves assessment of variability, trends and levels between adjacent phases to describe the results (Backman & Harris, 1999).

Analysis of level is described as a change in the value or magnitude of the dependent variable after intervention. It is judged by comparing the value of the target behaviour at the last point in one phase with its value at the first data point of the next adjacent phase. It can also be described as the change in the mean or the average value of the dependent variable from one phase to the subsequent phase (Portney & Watkins, 2000).

Analysis of trend refers to examination of the direction of change within a phase and is described as accelerating, decelerating, stable or variable. Trends can be linear or curvilinear. A trend in baseline data does not represent a problem when it reflects changes in the opposite direction to that expected in the intervention phase. However, a baseline trend in the direction of that expected at intervention would make it difficult to assess the effects of the intervention. When trends occur in the baseline phase, it is

recommended to extend this phase to achieve stability in the data and to attempt to identify the causative factors (Ottenbacher, 1986; Portney & Watkins, 2000).

A celeration line or trend line, sometimes used to estimate trend within a data series, demonstrates whether the data are showing an accelerating, decelerating, or stationary trend. A 'best-fit' trend line is computed using data points in the baseline phase with the line then extended to the treatment phase (Portney & Watkins, 2000). The treatment effect is determined by comparing the proportion of data points above and below the line across the two phases. A minimum number of six data points in baseline has been recommended for application of this technique (Noubakhsh & Ottenbacher, 1994). The slope of the celeration line can be calculated to estimate the rate of change in the behaviour.

There are several advantages of visual analysis. Most importantly, it is insensitive to a weak treatment effect thereby only large treatment effects with obvious clinical significance are reported in the literature (Noubakhsh & Ottenbacher, 1994). Furthermore, it does not require mathematical operations, is intuitively meaningful and researchers with basic information can accurately describe outcomes using this method (Portney & Watkins, 2000). Disadvantages of visual analysis include the lack of formal decision rules for data interpretation as well as poor interrater reliability and unreliable interpretation of time-series data (Noubakhsh & Ottenbacher).

Statistical analysis

Statistical analysis is the second level of analysis in SSRD. The three most commonly used statistical methods are the two-standard deviation band method, the split-middle line and the C statistic (Nourbakhsh & Ottenbacher, 1994). Although analysis of variance (ANOVA) may be appropriate where there is no serial dependency, it requires a larger number of data points than that usually found in SSRD. Moreover, analysis of variance is designed to evaluate differences in means of data between experimental conditions whereas trends in data are the primary concern in single-subject research (Wolery & Harris, 1982).

There are clear advantages of the statistical methods used in SSRD. Specifically, they are essential where there is failure to establish a stable baseline and also in presence of unstable data. Statistical methods are sensitive to the detection of small effects, variability and trend which may be ignored in visual analysis. Moreover, they may be used when data are serially dependant. Statistical analyses provide objective, quantifiable conclusions regarding treatment effects and they produce consistent results that are independent of the person performing the computations. Statistical procedures control for extraneous factors in the natural environments where clinical research takes place (Nourbakhsh & Ottenbacher, 1994).

Two standard deviation band method

The two standard deviation (2SD) band method is based on the computation of the standard deviation of the baseline data and assumes that the data are normally distributed. Two horizontal lines, the 2SD band, are drawn on the graph at ± 2 SD from the mean of the baseline data. If at least two consecutive data points in the intervention phase fall outside the 2SD band, the intervention phase behaviour is determined to be statistically different from that of the baseline (Backman & Harris, 1999).

The split-middle line

While the celeration line estimates the trend within a data series, a test of statistical significance using the split-middle method of trend estimation represents a measure of the central tendency (Nourbakhsh & Ottenbacher, 1994). It involves computations based on the medians of the two halves of the data series for which the trend line is being determined. While the split-middle line is a useful estimate of trend, its interpretation is limited to describing clinical change because it is relatively insensitive to extreme scores. A binomial test is used when data points are either above or below the split middle line to determine the probability that the treatment did effect a change (Portney & Watkins, 2000).

The C statistic

The C statistic, also called a time-series analysis, produces a z value which is interpreted using the normal probability table for z scores (Tryon, 1982). It uses the same

logic underlying visual analysis in that variability in successive data points is evaluated relative to change in slope from one phase to the next. The C statistic is used to evaluate the baseline data first, and if it is found to contain a nonsignificant trend, both baseline and intervention phases are combined and the C statistic is recomputed to determine if a statistically significant change has occurred.

The primary advantage of the C statistic is that it can be used with data which has serial dependency. However, the statistic requires data sets with at least eight observations per experimental phase in order to evaluate the intervention effects (Tryon, 1982).

Clinical significance

The third level of analysis in SSRD is the evaluation of clinical significance of change and involves determination of whether the changes in performance are clinically important, useful and meaningful to the subject or perceived by others as being worthwhile in the real-world setting. Clinical significance has also been called social validity (Wolery & Harris, 1982). Statistical significance and clinical significance are not necessarily concurrent. A change in data may be statistical significant but not of clinical significance. Conversely, clinically significant changes may not be statistically significant.

The minimal detectable change (MDC), also called the reliable change index, is one of the more common distribution-based change indexes. The MDC is based on the standard

error of measurement (SEM) and is considered the minimal amount of change that is not likely to be due to chance variation or random measurement error (Haley & Fragala-Pinkham, 2006). Although an MDC at a 90% confidence interval (CI) is the most common standard used in the literature, it is not available for all outcome measures. In addition, other confidence intervals such as 95% or 80% may be used depending on the precision needed for the score estimate. When clinical significance can be evaluated, this analysis completes the visual and statistical analyses used for SSRDs by providing valuable information to the clinician and researcher.

This study will use a multiple baseline single subject research design to evaluate the clinical impact of an intensive, short duration VR-based intervention on balance and functional mobility of adolescents with CP in GMFCS Level I.

We hypothesized that a five day 90-minute per day VR-based balance training program would result in improvements on four outcome measures: the Community Balance and Mobility Scale (CB&M), the Six-Minute Walk Test (6MWT), the Timed Up and Down Stairs (TUDS) and the Gross Motor Function Measure (GMFM) Dimension E. We also hypothesized that these improvements would be maintained the week after the intervention as well as one month later.

CHAPTER 3

METHODS

This study was approved by the University of Ottawa Research Ethics Board and the Ottawa Children's Treatment Center (OCTC) Research Review Committee.

Participants

Participants were recruited from the OCTC's patient database and met the following inclusion criteria: (1) between the ages of 13 and 18 years; (2) CP in GMFCS Level I; and (3) able to follow directions in English or French on standardized testing. Exclusion criteria were: (1) orthopedic surgery within the past 12 months and (2) Botulinum toxin type A injections within the past 6 months. Written informed consent or assent was obtained as appropriate from the participant and/or parent(s) of each participant. On the first day of the study, participants completed the participant questionnaire (appendix 9) and parents completed the parent questionnaire (appendix 10).

Study Design

A single-subject multiple baseline design (MBD) using ABA with one month follow-up was used. One licensed physiotherapist who was independent from the research team completed all assessments during the three study phases: (1) baseline phase: between three and six assessments in the the week prior to the intervention phase; (2) intervention phase: assessments prior to training on days two through five to avoid possible fatigue

effect from training; and (3) follow-up phase: three assessments in the week following the intervention phase and at one month post-intervention. In this MBD, the number of assessments in the baseline phase was pre-determined for each participant. The study design followed the guidelines recommended by Romeiser Logan et al. (2008) for a level III controlled MBD. This level of design is defined as a non-randomized, non-concurrent, controlled MBD with clear-cut results. A minimum of three subjects allows for generalizability of the results. The baseline, intervention and follow-up phases were arranged to support a decision of causality and generalizability. Standardized measurement conditions were ensured for repeated participant testing with consistency in both location and time of day. Separate data collection forms were used for each session and for each clinical measure to eliminate scoring bias from knowledge of prior results. There was no participant attrition or loss of data points during the study.

Outcome Measures

Four outcome measures were used to identify changes in balance and functional mobility. The Community Balance and Mobility Scale (CB&M) was used as the primary outcome measure for all participants as it evaluates high level balance abilities while addressing the coordination and speed components required for everyday function in the community (Howe, Inness, Venturini, Williams, & Verrier, 2006). The Six-Minute Walk Test (6MWT), an endurance measure, was used to assess functional long distance mobility (Maher et al., 2008). The Timed Up and Down Stairs Test (TUDS) was used to

assess the speed of stair climbing and descent. Negotiating stairs involves greater demands in balance, coordination, strength, and muscle control than walking (Zaino, Marchese, & Westcott, 2004). Finally, the Gross Motor Function Measure (GMFM)-Dimension E was used to assess high level gross motor function (Russell, 2002).

Community balance and mobility scale (CB&M)

The CB&M is a clinically meaningful performance-based measure which evaluates high level balance abilities and addresses the coordination and speed components required for everyday function in the community (Howe et al., 2006). This 13-item measure with a maximum score of 96 points assesses postural instability in high-functioning ambulatory individuals. The CB&M was developed for use with community-living adults who have sustained a mild to moderate traumatic brain injury (TBI) and who have higher level balance abilities. A change in score of greater than 5 points is considered clinically significant and corresponds to a change in community integration and confidence in community mobility (JA Howe, personal communication, 2009).

The CB&M is a valid and reliable outcome measure for the ambulatory individual with traumatic brain injury. Test content and construct validity, test-retest, high inter- and intra-rater reliability and internal consistency have been reported in individuals with TBI who present with high level balance abilities. Content validity was demonstrated by the involvement of individuals with TBI (n=7) and clinicians (n=17) in the process of item generation and by physical therapists' ratings of item relevance (Howe et al., 2006).

Further support for content validity is the correlation between CB&M scores and global balance ratings of individuals with TBI as scored by a physical therapist ($r=0.62$) (Howe et al.). Construct validity was supported by the ability of the measure to differentiate between patients along the continuum of care and also by comparisons of scale score with maximal walking velocity ($r=0.64$) (Howe et al.). Individuals with TBI who scored greater than or less than 50 on the balance measure demonstrated significantly different Community Integration Questionnaire scores ($P=0.004$) (Howe et al.). The CB&M demonstrated intraclass correlation coefficients (ICCs) of 0.977, 0.977, 0.975 and Cronbach's alpha of 0.96 for intra-, inter-, test-retest reliability and internal consistency, respectively (Howe et al., 2006). More recently, the psychometric properties of the CB&M were investigated in youth aged 8 to 17 years with acquired brain injuries (ABI). The scale was shown to have excellent inter-rater reliability ($ICC= 0.93$) and test-retest reliability ($ICC= 0.92$) (Wright & Brewer, 2009). However, the CB&M has not yet been validated in adolescents with cerebral palsy.

The six-minute walk test (6MWT)

The 6MWT, a sub-maximal test performed at a self-selected speed, evaluates functional capacity for walking over a prolonged distance. Guidelines recommended by the American Thoracic Society (ATS) (ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories, 2002) were followed with the exception of a practice trial, as no significant learning effect were found when adults with spasticity did

two 6MWT trials (Thompson et al., 2008). Orange cones marked the beginning and the end of the course as well as designated turning points. Standardized encouragement was provided during the walk at every minute. The subjects stopped when the stopwatch showed six-minutes and the distance covered was measured and reported in meters.

The 6MWT has been shown to have excellent test-retest reliability with ambulatory adults with CP (Andersson, Asztalos, & Mattsson, 2006) as well as with ambulatory children with CP (Maher et al., 2008). In adolescents with CP, the 6MWT demonstrated excellent test-retest reliability with a narrow 95% confidence interval (CI) in a sample of 31 children with cerebral palsy across GMFCS Levels I, II and III subgroups. The test-retest ICC in adolescents with CP in GMFCS level I was 0.93 (Thompson et al., 2008).

These data support the use of the 6MWT among community ambulators since walking for longer durations at a self-selected walking speed is typically needed for mobility in the community. The 6MWT, with its reliance on endurance rather than achievement of a maximal short-burst of speed, is robust to assessor error in measurement (Thompson et al., 2008).

When using the 6MWT for evaluative purposes, a score change greater than the estimated minimal detectable change (MDC) is required for evidence of true change. For example, Andersson et al. (2006) showed that adults with CP who walked without aids needed to walk 37m further in the six-minute period in order to demonstrate true improvements. Thompson et al. (2008) observed differences in 6MWT MDCs ranging

from 47 to 64m in children in GMFCS levels I through III. The differences among children in different GMFCS levels suggest that a level-specific MDC should be used when interpreting change scores. A MDC at 95% CI of 61.9 m was determined for children with CP in GMFCS Level I (Thompson et al., 2008).

Timed up and down stairs test (TUDS)

The timed up and down stairs test (TUDS) assesses functional mobility by requiring participants to quickly ascend an 11-step flight of stairs, turn around, and descend to the starting point (Zaino et al., 2004). It is a quick, low-cost, reliable test for children with and without CP aged eight to 14 years. The TUDS was developed as a functional mobility outcome measure that would potentially reflect improvements in the musculoskeletal and neuromuscular systems that contribute to the control of posture. This measure is associated with the ability to be active in the community, at home and during recreational activities. Ascending and descending stairs demands more balance, coordination, strength, and muscle control than overground walking (Zaino et al.). The TUDS is scored in seconds and each data point reflects the mean of two trials.

The TUDS has demonstrated excellent reliability with a group of 20 school-aged children with CP. The TUDS has excellent intrarater and interrater reliability (ICC=0.99 for both) and excellent test-retest reliability (ICC=0.94) for both typically developing (TD) children and children with CP (Zaino et al., 2004). The TUDS accounts for variation in developmental and functional abilities and shows differences in scores across

age and GMFCS levels. A group of 27 TD children aged 8 to 14 years scored on average 0.58 sec/step for ascending/descending stairs. This was almost half of the 1.11 sec/step used by children with CP in GMFCS Level I and one third of the 1.75 sec/step used by children with CP in GMFCS Level II/III (Zaino et al.). An estimated minimal detectable change (MDC) value, required for evidence of true change, is not available for the TUDS.

Gross motor function measure (GMFM)-Dimension E

The GMFM is a valid and reliable clinical measure of gross motor function in children with CP and has been shown to measure change over time (Russell, 2002). The GMFM has been shown to be responsive to change in gross motor function in children with CP and has been used extensively in research to assess the effect of different interventions. The complete GMFM contains 88-items of gross motor function distributed over 5 dimensions: A) lying and rolling, B) sitting, C) crawling and kneeling, D) standing, and E) walking, running and jumping. Each item is scored on a 4-point scale (0 to 3) with specific descriptors for scoring items (Russell, 2002). The dimension E subscale of the GMFM (Walking, Running and Jumping) has 24 items and has been reported to have an appropriate minimum set of items for assessment of functional outcome in children with ambulatory CP (Oeffinger et al., 2007). This dimension has a possible total point score of 72 and allows a dimension percentage to be calculated.

The GMFM-88 was validated for use in CP with a sample of 111 children under 20 years of age (Russell et al., 1989). The participants were characterized with CP of different levels of severity (mild/moderate/severe). At the time of the validation study, the GMFCS did not exist to classify levels of severity in CP, therefore, the 29 children who were classified as mild would have been those who could perform items in dimension E. Psychometric data for the GMFM-dimension E subscale were reported for intra-rater reliability (ICC= 0.99), inter-rater reliability (ICC= 0.99), and reliability of judgement of change by a therapist (ICC= 0.96) (Russell et al.). Clinically important change scores for the GMFM-88 have been reported for different age groups and different GMFCS levels however, a percentage change score is not available for a specific dimension of the GMFM.

Balance and Functional Mobility Intervention

The balance and functional mobility intervention was designed to provide intensive and short duration training to the participants. The intervention phase consisted of 90 minutes of VR-based balance and functional mobility training on 5 consecutive days. Daily interventions were delivered in two 45-minute sessions with a 30 minute rest break. During the rest period, participants were engaged a seated quiet activity of their choice such as reading a book, watching a DVD or listening to their MP3 player.

The VR-based program was delivered at the Ottawa Children's Treatment Center using a commercially available system consisting of a 32" widescreen LCD display, a

high performance computer, a video camera and a green screen as background for computer generated imaging (GestureTek Health, Toronto, Canada). Participants stood approximately 2.7m from the screen display and had the ability to move within a room 2.2m in width.

GestureTek's Interactive Rehabilitation and Exercise System software (IREX®, version 1.4) immersed real-time video images of the participant into a 2D virtual world. The participants interacted with virtual objects to achieve tasks that had difficulty levels specifically set for each individual. Study participants were trained using four consecutive modules of five IREX applications in each of the two 45-minute daily training sessions. Applications lasted two minutes each and were separated by a 10 second rest interval. Training modules consisted of different combinations of applications requiring similar types of movements and of comparable difficulty levels. Verbal guidance was provided if necessary to help participants understand the task goals. As participants showed moderate degrees of successes in movement abilities and application scores, modules including applications with progressively greater difficulty levels and speed were introduced. For example, the level of difficulty was increased for the soccer application once a participant was able to block 50% of the soccer balls. Participants continued with lower level modules while more difficult challenges were added. The VR-based balance and functional mobility program involved a replicable protocol with

defined sequences of applications and progressive increases in their levels of difficulty (see Appendix 11).

The primary applications used were Soccer, Snowboard, Sharkbait, Zebra Crossing and Gravball. These applications challenged dynamic standing balance and coordination requiring participants to perform weight shifting in standing, single leg stance, reaching away from the center of gravity, squats and jumps, side-lunges, side steps and gallops. Repeated, at times sustained, and unpredictable patterns of movement were elicited from the participants at increasing speed. The description of the virtual reality applications and movements elicited are explained in Table 1.

Data Analysis

Guidelines recommended for rigorous analysis of single subject research design (SSRD) were used (Romeiser Logan et al., 2008). Prior to visual and statistical analyses, serial dependency was determined for each outcome measure for each participant using a lag-1 autocorrelation (Ottenbacher, 1986). The autocorrelation coefficient was computed across the entire data series as there were six or fewer data points in each phase. Serial dependency was found for the TUDS for participants 1, 3 and 4 (P1, P3 and P4) and for the GMFM-Dimension E for Participant 2 (P2). For these datasets, the first difference transformation procedure was applied to transform the raw data (Ottenbacher, 1986). The autocorrelation coefficient was recalculated on the transformed data sets and confirmed elimination of the serial dependency. No serial dependency was found in the data from any of the participants for the CB&M or for the 6MWT.

Raw or, where appropriate, transformed data points for the CB&M, 6MWT, TUDS and GMFM-Dimension E were plotted for visual inspection on graphs using the same scale for all participants. For the transformed data, a constant of eight was added to the data for the TUDS and a constant of 93 was added to the GMFM-Dimension E to allow the graphs to conform to traditional standards (Ottenbacher, 1986). Visual analysis of graphed data from adjacent phases was achieved by summarizing patterns of data based on trend, level and variability.

Statistical analyses of single-subject data were achieved to complement the visual analysis using the two standard deviation (2SD) band method. This method was chosen as the number of data points in the baseline phase was not sufficient to apply methods such as the C statistic (i.e., eight points) (Tryon, 1982) or the celeration line (i.e., six points) (Noubakhsh & Ottenbacher, 1994). With the 2SD band method, statistically significant differences between phases were determined when two consecutive data points occurred outside the 2SD band. If the values for the test scores in the follow-up phase remained outside of the 2SD band, the change was defined as being maintained (Portney & Watkins, 2000).

The clinical significance of change scores from baseline was determined for the CB&M and 6MWT by computing the differences between the mean scores at baseline and the mean scores at intervention and follow-up. For the CB&M, a minimum change score of 5 points was used and is considered to correspond to true change in community

integration and confidence in community mobility (JA Howe, personal communication, 2009). For the analysis of the 6MWT, mean differences were analyzed with respect to the minimum detectable change (MDC) for GMFCS Level I at 80% confidence interval (CI) as per Thompson et al. (2008). The calculated MDC80 is 40.45m. The calculation of 6MWT MDC80 for GMFCS level I is explained in Appendix 12.

CHAPTER 4

RESULTS

Participant Characteristics

Four adolescents with CP in GMFCS Level I were recruited (4 males; mean age 16 years, SD 2.25 years, range 13 years 9 months to 18 years 9 months). Individual participant characteristics including past medical history are presented in Table 2.

Participant 1 (P1)

P1 was 17 years 8 months of age and had a diagnosis of spastic diplegia with the left side more involved than the right side (L>R). He had not participated in any sports or physical activity during the past school year and this did not change during the course of the study. He worked part-time as a cashier in a coffee shop.

He reported that he did not usually get tired of standing for long periods but rather when walking over long distances. He occasionally used a railing when walking up the stairs and reported that his main difficulty at school was that he was slower than his peers when walking up the stairs. His main difficulty when outdoors was maintaining his balance when walking over icy surfaces. His main goal was to improve his running ability as he reported feeling unbalanced when he ran.

Participant 2 (P2)

P 2 was 13 years 9 months of age with a diagnosis of choreoathetosis. During the past school year, he participated in gym class twice weekly. During the course of the study, he was not involved in any organized sports although he played ball games with his siblings who adjusted game speeds to meet his needs. His favourite quiet activity in sitting was playing with his hand-held Nintendo DS gaming system.

He felt at ease walking in crowded areas, reported fatigue when walking up hills and slowed his pace when walking down hills in order to maintain his balance. He reported getting tired when standing for long periods and tended to slump over or lean onto a support as he had difficulty standing still. He reported getting fatigued when walking over prolonged distances although he was able to keep up with his friends. He occasionally tripped and caught his left foot on the ground as it “turned in”. He walked up the stairs well but walked down more slowly and preferred to hold onto the railing for safety. He expressed frustration at the way his body moved as he had involuntary movements which he had trouble controlling.

He reported that his main difficulty when at home was trying to steady his body while performing activities of daily living (ADL) such as dressing (e.g., putting on socks and shoes). His primary difficulty at school was when his body moved involuntarily and his arms jerked causing objects to get knocked over. His main difficulty outdoors was tiredness when walking on trails or when riding his 3-wheeler bike around the

neighbourhood. He reported that his arms jerked on the handlebars causing the bike to veer. His main goal was to learn to control and maintain his overall posture. He reported wanting to be able to hit a ball with a bat while playing baseball.

Participant 3 (P3)

P3 was 18 years 9 months of age with a diagnosis of spastic diplegia with symmetrical involvement of both lower extremities. His regular school year routine included attending a gym (3 times per week) where he worked mainly on his upper body, playing tennis (1x/wk) and jogging around the neighbourhood (1x/wk). He did regular stretching exercises at home with emphasis on hamstrings and hip adductors. During the course of the study, he worked part-time as a store cashier. His main areas of self-reported difficulty were walking down hills, getting tired when standing for long periods or when walking over prolonged distances and occasional tripping and falling when walking outdoors on unpaved surfaces or on ice. He occasionally used a railing when walking up and down the stairs.

He reported that his main difficulty when at home or indoors involved walking while carrying a plate of food and a full glass and trying not to spill their contents. His primary area of difficulty at school and in the community was getting in or out of aisles in his university auditorium or in movie theatres while people are seated and where there is little space to manoeuvre. He reported trying to find a seat at the end of an aisle whenever possible. His main difficulty when outdoors was maintaining his balance when

standing on the wet floor of the city bus in the winter time with his “heavy backpack and heavy clothing” and “reacting” to the stop and go of the bus. His main frustration was that because he “does not look handicapped”, people riding the bus do not give him the seat reserved at the front of the bus. His main goals were to improve his ability to move quickly from sitting to standing and to improve his overall stability in standing and walking over various surfaces.

Participant 4 (P4)

P4 was 14 years of age with a diagnosis of spastic diplegia (R>L). In the past school year, he participated in a daily physical education program in his private school (soccer, ball hockey, basketball, rugby, badminton, volleyball). During the course of the study, he did not participate in any sport or physical activity.

He reported that he would sometimes get tired when standing for long periods or when walking over prolonged distances or up a hill. He used the railing at times to walk up the stairs and usually used the railing to walk down. His main difficulty at home was carrying large and heavy objects while walking down the stairs as this often “threw him off balance”. His primary area of difficulty at school was playing singles badminton in physical education class as he had difficulty moving rapidly to cover the whole court on his own. His main difficulty outdoors was his slow running speed which was often inadequate to keep up with his friends who would have to slow down for him. His main goal was to improve his overall balance abilities for everyday activities.

Outcome Measures

The four participants completed all study phases and fully complied with the intervention. Baseline data stability was achieved for the CB&M and the 6MWT in all participants, for the TUDS in P2 and for the GMFM-Dimension E in all participants except in P2. When baseline stability was not achieved, serial dependency was removed by data transformation. Data are graphed for each participant (Figures 1, 2, 3, and 4). Visual analyses, statistical analyses using the 2 SD band method and clinical significance of changes where appropriate are reported for each outcome measure separately.

Community Balance and Mobility Scale

Visual analysis

P1 and P2 did not show changes in level from the baseline phase to the intervention phase but demonstrated accelerating trends in the intervention phase. Both P3 and P4 showed increases in level as well as accelerating trends in the intervention phase compared to the baseline phase. Scores on the CB&M remained stable in the follow-up phase for all participants.

Statistical analysis

Based on the 2 SD band method, all participants showed statistically significant improvements in scores on the CB&M in the intervention phase when compared to the baseline phase. These improvements were maintained in the follow-up phase.

Clinical significance

A true change in mean differences in scores from the baseline phase to the intervention phase was achieved by three participants (P1: mean 7.5, P2: mean 5.5, P3: mean 9.1). For P4, the change in mean score from baseline to intervention approached significant change (mean 4.6). In the follow-up phase, true change mean differences were maintained or continued to improve and were present in all participants (P1: mean 12, P2: mean 10, P3: mean 8.6, P4: mean 7.1).

Six Minute Walk Test

Visual analysis

P1 showed a decelerating trend for the first 2 days of the intervention phase, followed by an accelerating trend for the remainder of the intervention phase. For P2 and P4, the 6MWT was characterized by an increase in level and an accelerating trend in the intervention phase. These characteristics were most evident in the first few days and levelled off in the second half of the intervention phase. P3 showed an increase in level and an accelerating trend in the first half of the intervention phase, however showed a decelerating trend in the second half of the intervention phase as had a respiratory illness at sessions 8 to 10 which may have had an impact on this endurance measure. In the follow-up phase, the scores for P1 and P2 levelled off, P3 regained a significant accelerating trend to a level higher than at intervention phase, and P4 continued an accelerating trend on the 6MWT.

Statistical analysis

Based on the 2SD band method, all participants showed statistically significant improvements on the 6MWT in the intervention phase compared to the baseline phase. Moreover, the improvements seen in all participants were maintained at follow-up.

Clinical significance

Based on the 6MWT MDC80 of 40.45m, P3 (mean 46.55m) showed true change in mean differences from baseline while the change demonstrated by P2 (mean 40.22m) approached significance. Continued improvements on the 6MWT in the follow-up phase led to true change in mean differences being achieved in three participants (P2: mean 46.58m; P3; mean 46.55m, P4: mean 43.46m). The improvement shown by P1 (mean 39.96m) approached clinical significance.

Timed Up and Down Stairs

Visual analysis

Serial dependency was found for the TUDS in three participants, P1, P3 and P4. Once the data were transformed, serial dependency disappeared. There were no changes in level and trend of the data for P1, P3 and P4. However, P2, whose baseline data did not show serial dependency, showed a change in level and a decelerating trend in the intervention phase compared to the baseline phase. In P2, the scores on the TUDS levelled off at a lower level in the follow-up phase compared to the baseline phase.

Statistical analysis

Compared to the baseline phase, P2 demonstrated significant improvements on the TUDS during the intervention phase (mean change 1.3s) as well as in the follow-up phase (mean change 2.61s). No statistically significant changes from baseline were found in P1, P3 and P4.

Gross Motor Function Measure-Dimension E

Visual analysis

No change in level from the baseline to either the intervention or follow-up phase was seen in any participant. An accelerating trend was demonstrated in P1 and P2 in the intervention phase when compared to the baseline phase. Compared to the baseline phase, P3 and P4 showed stable data in both intervention and follow-up phases.

Statistical analysis

P1 demonstrated a small yet significant increase on the GMFM-Dimension E in the intervention phase which was maintained at follow-up. The limited increase may have been the result of a ceiling effect since P1 scored close to the maximum on the Dimension E in the baseline phase. The change recorded for P2 also reached statistical significance with a small increase in the Dimension E score from the baseline to the intervention phase yet these gains were not maintained at follow-up.

Summary of Results

All participants showed statistically significant improvements on the CB&M and the 6MWT with changes continuing beyond the intervention period into the follow-up phase. Clinically significant improvements on the CB&M were shown in P1, P2, and P3 in the intervention phase while the improvement recorded for P4 approached clinical significance. All participants showed clinically significant improvements on the CB&M in the follow-up phase. A clinically significant improvement on the 6MWT was recorded in P3 in the intervention phase while the improvement seen in P2 approached clinical significance. P2, P3, P4 showed clinically significant improvements on the 6MWT in the follow-up phase while the changes in P1 approached clinical significance.

Changes from baseline TUDS scores were statistically significant in P2, the only participant for whom the data were not autocorrelated. Statistical significance was reached for the GMFM-Dimension E in P1 at both intervention and follow-up, with a ceiling effect being shown on this measure.

Participant Study Anecdotes

During the course of the study, participants spontaneously expressed themselves regarding their movement abilities and their experience with the VR. As well, some parents reported on motor changes seen in their adolescent. Comments were documented to provide this qualitative information.

Participant 1

P1 was very pleased with improvements specifically on the 6MWT as he had expressed repeatedly during the baseline phase that he thought he “could never be able to walk faster”. By the end of the study, he expressed the desire to become more physically active in his everyday life as he realized his potential for improving his balance, his walking speed and his overall fitness level. His parents were runners and had also been providing him with much encouragement regarding the benefit of physical activity.

Participant 2

P2’s mother reported that she saw her son be “completely transformed” during the course of the five days of the intervention. While shopping with her son following the VR intervention, she noted that he was able to stand up straight, walk more upright and control his jerky movements caused by the choreoathetosis. She spoke about his increased display of self-satisfaction when with his peers as he told them about all the games and sports he was able to play using virtual reality.

At the end of the last intervention session, P2’s mother attended to view her son using the VR training. While in the VE, this participant was totally immersed in the games. His mother was amazed at his ability to regulate his movements as required by the task using slow controlled movements (Tai-Chi like at times), graded movements in and out of mid-amplitude positions as well as quick and accurate bursts of movement as needed. His mother noted that the slow controlled movements were most notable while using the

Sharkbait and Gravball applications where he was able to maintain positions with good alignment, both in standing and in 1/2-squat positions while performing independent arm or leg movements. Most of all, he expressed that he “had fun”!

Participant 3

During the VR intervention, P3 performed complex sequences of movements at increasingly higher speeds. Towards the end of the intervention phase, he reported that he spontaneously leapt up and forward from a seated position to get his cell phone from a friend, moving from sit to stand and lunging forward in the same movement in the presence of a group of friends. His friends expressed that they had “never seen him move so fast”. His friends commented: “that thing (VR) you’re doing must really be working!” Furthermore, he learned the next day from another group of friends that his new spontaneous and rapid movement abilities were being talked about among other acquaintances as if “something miraculous” had happened!

Participant 4

At the end of the final intervention day, P4’s able-bodied twin brother and his best friend were provided with the opportunity to trial the VR-soccer application at level 5. P4 successfully and proudly beat them both with the rapidity of his movements and skill at blocking the balls from the net. He scored better than both able-bodied adolescents. His sense of self-satisfaction was evident!

CHAPTER 5

DISCUSSION AND CONCLUSIONS

The purpose of this study was to examine the effect of an intensive five-day VR intervention on the balance and functional mobility of adolescents with CP in GMFCS Level I. We hypothesized that complex balance and coordination skills in walking performance (CB&M and GMFM-Dimension E), walking speed and endurance (6MWT), and stair climbing and descent (TUDS) would be improved in these children and that these improvements would be maintained at one week and one month following the end of training.

Functional Improvements in Cerebral Palsy

Results from our study support two major findings in adolescents with CP in GMFCS Level I. First, our data suggest that functional balance and mobility of these 13 to 18 year old adolescents with CP can improve with an intense, short duration VR intervention. Second, our data indicate that changes are maintained for at least one month following the VR training. For all participants, a causal relationship was established between the VR intervention and the significant improvements on the CB&M and the 6MWT that was maintained in the follow-up phase.

This study has important clinical implications as it provides evidence that balance and functional mobility are modifiable in adolescents with CP in GMFCS level I and that they

respond to a short and intense balance training using VR intervention. This study demonstrates that adolescents between the ages of 13 to 18 years with CP in GMFCS levels I have the potential to enhance their repertoire of movement strategies following an intensive five-day VR intervention program. Improvement of these abilities at the activity level of the ICF as identified through changes on the CB&M may contribute to positive changes on performance of these adolescents at the participation level of the ICF (Wright et al., 2008). Children in GMFCS Level I are reported to have achieved 90% of their expected limit of gross motor skill acquisition by 4.8 years of age (50% range 4.0-5.8 years) (Rosenbaum et al., 2002) and, based on the GMFM-66, follow a Stable Limit model into adolescence (Hanna et al., 2009). However, our findings demonstrate that it may be possible to stimulate motor and balance skills in youth in GMFCS Level I and alter the natural history of CP in these adolescents.

Functional balance and mobility are necessary for safe performance of everyday tasks. Adolescents with CP demonstrate difficulties with both of these skills which result in significant problems that contribute to participation restrictions. A large body of literature reports specific underlying impairments that contribute to difficulties with balance and mobility including inappropriate timing and organization of muscle activation (Burtner et al., 1998; Shumway-Cook et al., 2003), decreased muscle strength and joint range of motion (Crenna, 1998). These underlying impairments result in specific activity limitations in home and community such as stair climbing and descent

and walking for long distance mobility (Palisano et al., 2009) as well as in stability during rapid changes in movement direction (Woollacott & Shumway-Cook, 2005). Many of these activities are assessed using clinical outcome measures such as the CB&M, the 6MWT, the TUDS and the GMFM which provide information on an individual's function within the context of the activity domain of the ICF (Howe et al., 2006; Thompson et al., 2008; Zaino et al., 2004; Russell et al., 2002). Specific individual differences on outcomes measures in the participants may also be related to the type of tonal involvement (impairment) of each participant as well as personal factors.

In the clinical setting, the focus of therapeutic intervention is on improving function as it relates to the activity domain of the ICF with the ultimate goal of impacting participation (Wright et al., 2008). Intervention programs in youth with CP need to address impaired balance as a contributor to functional limitations since improvements have been shown to enable greater performance and participation in sports and physical activity with peers (Voorman et al., 2006). The changes recorded on performance outcome measures such as the CB&M and the 6MWT indicate changes in refinement of balance skills and functional mobility needed for community participation (Howe et al., 2006; Thompson et al., 2008)

The clinical changes found in the CB&M demonstrate that improvements in complex balance skills along with coordination and speed components in ambulation were acquired. This measure represents tasks or components of tasks which underlie functional

skills required in the community. Specific untimed coordination tasks in the CB&M include tandem walking, tandem pivoting, hopping forward, lateral foot scooting and performance on stairs (Howe et al., 2006). Timed tasks of the CB&M include unilateral stance, crouch and walk, lateral dodging involving repeated cycles of foot crossovers, running with controlled stop, forward to backward walking, walking while looking at a target and repeated cycles of stepping up and down a step (Howe et al., 2006). The baseline scores on the CB&M identified functional balance and mobility issues in each of this study's adolescent participants. Moreover, the scale was responsive to behaviour change in the study participants.

Although anecdotal, the higher level balance and mobility skills acquired in training appear to have been integrated into everyday life during the intervention and follow-up phases as documented by the comments made by the parents, friends and participants following the study. By the end of the study, P1 was becoming more physically active in his everyday life as he realized his potential for improving his balance, his walking speed and his overall fitness level, P3's friends commented on his novel movement level as he spontaneously moved from sit-to-stand to leap forward in one rapid transition and P2's mother reported that her son was completely transformed as he was able to participate in community outings with less apparent fatigue as evidenced by his significant reduction in involuntary movements, and ability to stand up straight and to walk more upright for long distances.

Three adolescents did not show significant changes in gross motor function based on the GMFM- dimension E, one adolescent showed statistically significant changes and demonstrated a ceiling effect on this dimension. While it has been shown that gross motor development curve for GMFCS Level I follow a Stable Limit model into adolescence, it may be based on an erroneous assumption that the GMFM-66 is sensitive enough to detect changes in youth with CP in GMFCS level I. Some of the most difficult items on the Dimension E such as walking up and down four steps without a rail, jumping off a step or jumping forward and walking along a straight line were nearly all achieved by participants in the baseline phase. Hopping on one foot (10 times), the most difficult skill on the GMFM, showed improvement in all participants and was fully achieved by P1 who reached a ceiling effect. A Challenge Module for the GMFM is being developed to evaluate change in high level ambulatory skills in youth with CP in GMFCS Level I (Wright et al., 2009). Pilot testing for the Challenge Module has identified 22 ambulatory skills, which include walking backward on a line, hopping on a hopscotch grid, doing a shuttle run, and carrying a lunch tray along a path (Wright et al., 2009). It is hypothesized that the Challenge Module will address the ceiling effect found on the dimension E for youth in GMFCS level I and will likely detect change in these adolescents by paralleling some of the outcome measures used in the current study.

Our study builds on findings from Shumway-Cook et al. (2003) who showed significant improvements in recovery of stability in children with CP in GMFCS Levels I

and II following a five-day massed practice intervention on a moveable platform. Specifically, they demonstrated a reduction in the total COP path used during balance recovery and in the time to restabilize balance following a perturbation. Contributing neural mechanisms involved in improvements in balance control produced by reactive balance training in children with CP included faster activation of postural muscles, the emergence of appropriate distal-to-proximal muscle sequencing and improvements in the ability to modulate muscle activity amplitudes with reductions in agonist-antagonist co-contractions (Woollacott & Shumway-Cook, 2005).

Body-weight support treadmill training, a high intensity lower extremity task, has shown improvements on short distance walking speed as shown by the Ten-Meter Walking Velocity in children with CP in GMFCS Level I (Provost et al., 2007). However, in contrast to our study, only half of the children studied showed improvements in performance on the 6MWT and single leg balance. Lee & Hidler (2008) have reported biomechanical differences in overground and treadmill walking. These differences, specifically in joint range of motion and speed of limb travel may explain the lack of training effect seen in children on specific outcome measures. While the treadmill training facilitated a limited motor behaviour of forward progression, our intensive VR program focused on the multiple contributing factors of motor performance by addressing balance, coordination, strength, endurance and perceptual-motor skill to produce the best functional outcomes (Carr & Shepherd, 2000).

It is unknown to what extent the specificity of training balance in response to an externally generated loss of stability or gait in response to treadmill training can generalize to other types of training or to functional balance challenges. There have been no reports of balance training using a platform paradigm and limited reports of treadmill training with adolescents with CP. How these types of training relate to clinical assessments or functional balance measures remains to be determined.

Training Requirements for Rehabilitation

Burtner, Woollacott, Craft, & Roncesvalles (2007) reported that in both a laboratory and clinical setting, it is necessary to truly challenge the balance abilities of children with CP to determine their motor capacity for recovery. Critical factors for motor training are the intensity, repetition, specificity, and enriched environments. Our data demonstrate that the training experienced using our program of GestureTek's IREX applications results in changes on outcome measures that relate to changes in community integration and mobility. The VR program developed for this study required the participants to practice different movement sequences repeatedly with the tasks requiring unexpected changes in movement direction, speed and context within the virtual environment. Our intensive protocol progressively increased the size and velocity of movement demands with the increases individualized to each participant. Training programs using this type of activity to develop balance have resulted in changes in balance however much of the intervention work has been done with the adult (Thornton et al., 2004) or aging

population (Bisson et al., 2007). A study using a moving platform to challenge balance was designed to determine the influence of different sensory contributions to training (Hu & Woollacott, 1994a; Hu & Woollacott, 1994b). Older adults completed a 10-hour balance training program over 15 days with subject groups receiving different manipulations of sensory inputs from the visual, vestibular, and somatosensory systems. Subjects showed significantly improved stability (anteroposterior platform torque) after training in five of the eight training conditions and demonstrated changes in muscle and movement characteristics of postural responses. When tested four weeks after completion of training, subjects fell less frequently when the ankle/foot somatosensory inputs were minimized and stood longer on one leg than subjects in the control group (Hu & Woollacott, 1994a). Results from this study suggest that a multisensory balance training program designed to improve sensory interaction could effectively improve balance performance and optimize muscle and movement characteristics of postural response in older adults (Hu & Woollacott, 1994b).

Gatts and Woollacott (2006) reported on the use of a Tai Chi (TC) balance exercise training model to improve motor control in the older adult population. They reported significant improvements on four clinical measures including the Timed Up and Go, Functional Reach, One leg Stance and Tandem Stance. Overall TC training transferred to significantly faster and better coordinated neuromuscular responses controlling the ankle joint during gait perturbations in the balance impaired seniors. A parallel may be drawn

between the TC training and our IREX VR-training with results on functional balance outcome measures in individual with impaired balance. These two training protocols have many similarities in the intensity and repetition of movement as well as in the types of positions, transitions and sequences of movements elicited during the training period. However, TC lacks the immersive multi-dimensional and multisensory interaction experience that IREX offers to its users.

In recent years, popular video gaming systems, such as the Wii Fit (Nintendo), have become increasingly popular. Deutsch and colleagues (2008) studied the effect of training with the Wii system's Wii Sports games on visual-perceptual processing, postural control and functional mobility in a 13-year old adolescent with CP in GMFCS level III. The subject completed 11 training sessions lasting between 60 and 90 minutes each, using games in sitting and supported standing. The adolescent showed improvements in postural control, defined in relation to stance and amount of sway, and in functional mobility, defined in terms of the ability to see and process the surroundings. While promising, the results require replication due to the sample size. Of significant concern with the Deutsch et al. (2008) study is that some baseline data were extracted through chart review and not included in the assessment period.

Advantages of IREX over other Training Approaches

A major advantage of VR balance training using the IREX system is its ability to elicit specific movements for complex dynamic balance skill sequences required for successful

interaction with real-life environments. The tasks generated in the VR applications required the participants to use complex movement strategies across the width of a 2.2 m room to achieve success. Moreover, the ability to set the parameters on an individual level to challenge each participant's capacity was clearly a benefit. Our participants ranged in mean baseline score on the CB&M from 44.0 to 66.3 indicating the need for distinct challenge levels during training.

Intense, task-related and complex training strategies have shown the strongest level of evidence for functional change and are gradually replacing traditional physical therapy approaches. Current trends in rehabilitation involve increased intensity in the amount of practice or the physiological demands of exercise and increased task or functionally-based training (Damiano, 2009). Task repetition is crucial for improving performance as repetitive practice enables the nervous system to build on previous attempts and coordinate new muscular synergies to accomplish the task goal (Carr & Shepherd, 2000). The IREX system meets these requirements for training by facilitating repetition within its VR applications without loss of motivation and interest as often seen in real world conventional exercises (Weiss et al., 2004). Studies have compared real-world exercise programs to VR-based IREX programs and have reported higher motivation in performing the VR-based activities which provide repetition with greater variability of practice (Thornton et al., 2005; Bryanton et al., 2006).

Virtual reality may offer an innovative tool for intervention in paediatric neurological rehabilitation allowing the youth to interact in with the VE in a safe, motivating, functional and goal-directed context. Evidence suggests that motivation, challenge, and the ability to distract or augment the user's attention are some of the most important aspects of this therapeutic intervention (Weiss et al., 2004). Repetition and intensity of task-practice may be graded to meet specific therapeutic objectives. It allows for stimulus control and consistency, as well as stimulus and response modifications that are contingent on the user's physical abilities. This modality is an ecologically-valid opportunity with real-time performance feedback for paediatric physiotherapists to use an enriched environment which is known to promote neuronal plasticity and functional recovery (Penn et al., 2009). Documented changes on functional magnetic resonance imaging have shown that training in a VE offers potential for long-term learning in CP as evidenced by adaptive cerebral plasticity consistent with significant functional motor improvements (You et al., 2005). The findings of this present study suggest that VR is effective at refining balance skills and functional mobility needed for community participation in ambulatory youth with CP.

The Single-Subject Research Design: A Scientific Inquiry for Clinicians

A multiple baseline single subject research design (ABA) was chosen as an alternative to the traditional two group experimental study as it could best inform and guide clinical practice by showing individual differences and demonstrating treatment

effectiveness with a small group of adolescents with CP while ensuring the rigorous guidelines of this quasi-experimental study. The MBD was used to strengthen internal validity. The participants were exposed to standardized experimental conditions in every phase of the design. The intervention was initiated once stability of the data in the baseline phase was reached. The VR-based balance and functional mobility program involved a replicable protocol with defined sequences of applications and progressive increases in the level of difficulty (see Appendix 11). The effects of the intervention were replicated across all participants. Strengths of this study include none of the adolescents participating in this study received any concurrent therapy or alternative intervention. As well, due to the short intensive nature of this study, external factors that could have influenced the changes seen were limited. The same independent physiotherapist administered the outcome measures to each participant on every visit and at the same time of the day to ensure consistency and assessment reliability. Separate data sheets were used at each evaluation session to eliminate bias from knowledge of previous results. The study results were analysed rigorously using visual analysis, statistical analysis and, where possible, with determination of clinical significance using the MDC.

Recommendations

This study has important clinical implications for therapists, families and adolescents with CP. The study provides evidence that balance and functional mobility are modifiable in ambulatory adolescents with CP in GMFCS Level I and that they respond

to short duration and high intensity VR training. These youth in GMFCS Level I have the ability to enhance their repertoire of movement strategies and this new intervention tool may promote adaptive changes which facilitate functional neuroplasticity.

The present study observed changes following a five-day intervention with a follow-up phase at one week and one month following the end of the intervention. Subsequent work will examine the effect of longer periods of treatment and will also explore whether the retention of improvements in balance and functional mobility continues longer than one month post intervention.

Further investigation is necessary to examine the effectiveness of VR intervention in a younger age group of children with CP in GMFCS level II. Additional work will explore variations in training protocol requirements for different types of CP and GMFCS levels. Moreover, additional research is needed to determine the intensity, frequency and duration of the VR intervention required to best impact balance and functional mobility in adolescents with CP.

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APPENDIX 1

STATEMENT OF CONTRIBUTION OF COLLABORATORS

The research for this thesis and article was performed by Marie Brien. The research question and the hypothesis were selected by Marie Brien in collaboration Dr. Heidi Sveistrup.

The data collection and coding was done by Veronica Patterson. The data processing and analysis was done by Marie Brien with guidance from Dr. Heidi Sveistrup.

Finally, the thesis was written by Marie Brien and was edited by Dr. Heidi Sveistrup, Dr. Rose Martini and Dr. Yves Lajoie.



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Recruitment letter

STUDY TITLE: The Effect of an Intensive Virtual Reality Intervention Program on Balance and Functional Mobility of Children with Cerebral Palsy

Dear Sir or Madam,

Dr. Heidi Sveistrup from the University of Ottawa and Marie Brien from the Ottawa Children's Treatment Center are undertaking a study to examine the effect of an intensive virtual reality based intervention program on balance and functional mobility, in school-aged children and adolescents with cerebral palsy who are able to walk on their own without walking aids. This study is being completed as part of thesis requirements for an MSc in Human Kinetics for Marie Brien. **This study will take place at the Ottawa Children's Treatment Center during the summer of 2009. In order to accommodate family summer plans, we will schedule as soon as families indicate interest.**

Your child is invited to participate in the study. If you agree to participate, your child will be asked to:

1. Take part in balance training sessions of computer virtual reality games aimed at training standing balance for 5 consecutive days (morning or afternoon). The balance activities will be delivered using novel virtual reality technology using computer-based games during which your child will be involved in reaching and moving his/her body in a standing position.

2. Attend test sessions with a physiotherapist who will assess the standing balance and movement skills of your child. Your child will be asked to do tasks such as standing on one foot, jumping up and down, walking up and down a short set of stairs, and walking as fast as possible over a short distance. The test sessions with a physiotherapist will occur in the 4 study phases: Phase 1: up to six times during the week before starting balance training; Phase 2: on each day of balance training right after the training session; Phase 3: three times during the week after balance training; and Phase 4: one time at one month following balance training. The test sessions with a physiotherapist will last approximately 40 minutes each and the same tasks will be repeated at each session.

Your child has the right to withdraw from the study anytime without consequences.

Copies of the information and consent form for study participation have been included in this mailing. **If you have any questions regarding the study or if you wish to participate, please contact Marie Brien, co-investigator**

We thank you in advance for your collaboration in this research initiative.

Sincerely,

Heidi Sveistrup, Faculty of Health Sciences, School of Rehabilitation Sciences,
University of Ottawa,

Marie Brien BSc (PT) MSc Candidate, Ottawa Children's Treatment Center.

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Lettre de recrutement

Titre du projet: L'effet d'un programme d'intervention intensif de réalité virtuelle sur l'équilibre et la mobilité fonctionnelle des enfants avec la paralysie cérébrale

Madame,
Monsieur,

Heidi Sveistrup de l'Université d'Ottawa et Marie Brien du Centre de Traitement pour enfants d'Ottawa entreprennent une étude ayant pour but d'évaluer l'effet d'un programme d'intervention intensif de réalité virtuelle sur l'équilibre et la mobilité fonctionnelle d'enfants d'âge scolaire et d'adolescents qui ont la paralysie cérébrale et qui marchent seuls. Cette étude est entreprise pour la thèse de maîtrise en sciences de l'activité physique pour Marie Brien. L'étude aura lieu au Centre de Traitement pour enfants d'Ottawa.

Nous invitons votre enfant à participer. Si vous acceptez de participer, on demandera à votre enfant de :

1. Participer à des séances d'entraînement de l'équilibre debout avec des jeux d'ordinateur en réalité virtuelle pour 5 jours consécutifs (matin ou après-midi). Les activités seront fournies en utilisant une nouvelle technologie de réalité virtuelle utilisant des jeux informatiques qui demanderont des mouvements du corps en positions debout.
2. Participer à des séances d'évaluation où une physiothérapeute évaluera l'équilibre debout et les habiletés de mouvement de votre enfant. Nous demanderons à votre enfant de faire des activités telles que se tenir sur un pied, sauter, monter et descendre un court escalier et marcher aussi vite que possible sur une courte distance. Les séances d'évaluations avec une physiothérapeute auront lieu pendant les 4 phases de l'étude :
Phase 1 : jusqu'à six fois pendant la semaine avant de commencer les séances d'entraînement de l'équilibre; Phase 2 : chaque jour des séances d'entraînement de l'équilibre immédiatement après la séance d'entraînement; Phase 3 : trois fois pendant la semaine après les séances d'entraînement; et Phase 4 : une fois à un mois après l'entraînement de l'équilibre. Les sessions d'évaluation avec une physiothérapeute seront d'une durée approximative de 40 minutes chacune et les mêmes activités seront répétées à chaque séance.



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Votre enfant peut se retirer de l'étude en tout temps sans conséquences.

Vous trouverez ci-joint une copie de la lettre d'information et du formulaire de consentement pour la participation à l'étude. Si vous avez des questions au sujet de l'étude ou si vous désirez y participer, veuillez communiquer avec Marie Brien, investigatrice secondaire, au

Nous vous remercions à l'avance de votre collaboration à cette initiative de recherche.

Bien à vous,

Heidi Sveistrup, Faculté des sciences de la santé, École des sciences de la réadaptation, Université d'Ottawa.

Marie Brien BSc (PT) MSc Candidate, Centre de traitement pour enfants d'Ottawa

APPENDIX 3 a.



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Consent Form

Title of the study: The Effect of an Intensive Virtual Reality Intervention Program on Balance and Functional Mobility of Children with Cerebral Palsy

Heidi Sveistrup PhD Faculty of Health Sciences, School of Rehabilitation Sciences, University of Ottawa,

Marie Brien BSc (PT) MSc Candidate, Ottawa Children's Treatment Center,

Invitation to Participate: My child is being invited to participate in the abovementioned research study conducted by Marie Brien and Heidi Sveistrup. This project is being funded by a clinical research grant from the Ottawa Children's Treatment Center. This study is being completed as part of a thesis requirement for an MSc in Human Kinetics for Marie Brien.

Purpose of the Study: The main purpose of the study is to examine the immediate and short-term effects of an intensive virtual reality based intervention program on balance and functional mobility, in school-aged children and adolescents with cerebral palsy who are able to walk on their own without walking aids. We also want to gather information to allow us to develop an innovative virtual reality intervention program geared toward improving balance for these children.

Participation: My child will participate in balance testing sessions and balance training sessions.

Balance training: My child's participation will consist essentially in participating in 45-minute intensive balance training sessions twice daily (45 min. rest period between sessions) for 5 consecutive days. The sessions will be scheduled either in the morning or in the afternoon and will take place at the Ottawa Children's Treatment Center. The balance activities will be delivered using novel virtual reality technology using computer-based games during which my child will be involved in reaching and moving his/her body in a standing position.

Balance testing: My child's balance abilities, gross motor function and mobility will be assessed by a physiotherapist during 4 study phases: Phase 1: up to six times during the week before starting balance training; Phase 2: on each day of balance training immediately following the training sessions; Phase 3: three times during the week after balance training; and Phase 4: one time at one month following balance training.

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These testing sessions will last approximately 40 minutes each. During the testing sessions, my child will be asked to complete different tasks that are part of a set of clinical measurement scales. These include tasks such as walking as fast as possible over 6 m, standing and turning, walking up and down stairs, standing on one foot. These tasks will be repeated at each of the testing sessions.

Risks: My child's participation in this study will entail that he/she participate in a balance training program using computer games and this may cause my child to feel tired. I have received assurance from the researcher that every effort will be made to minimize this risk. There will be daily 45 minute rest periods of 'quiet activities' between the two intervention sessions.

Benefits: My child's participation in this study will contribute to the advancement of knowledge as it relates to the use of virtual reality computer-based games to develop balance in children with CP. Upon completion of the study, a summary of the study results will be provided.

Confidentiality and anonymity: I have received assurance from the researcher that the information I/my child will share will remain strictly confidential. My child's identity will be kept confidential by the use of a code or number instead of my personal information. Only the members of the research team will have access to the data which will be kept in a locked filing cabinet in Marie Brien's office at the Ottawa Children's Treatment Center. Anonymity will be ensured at all times. The results of this study (including mine) will be presented during a scientific conference and will be submitted for publication in a scientific journal. Confidentiality of the data will be ensured during the conduct of the study and in the release of the findings. The identity of the participants will be not be revealed in publications.

Conservation of data: The data collected including written records, paper test sheets will be kept securely in the co-investigator's office in a locked filing cabinet. Electronic data will be stored on a password-protected lab computer. My child's data will be conserved for a maximum period of 5 years. At the end of the 5 year period, the data will be destroyed. Paper data will be sent for shredding and electronic data will be erased.

Compensation: I will be compensated \$20 for each visit I make or my child makes to the OCTC for the purpose of the study.

Voluntary Participation: My child's participation in this study is voluntary and if he/she chooses to participate, he/she can withdraw or I may withdraw my child from the study at any time and/or refuse to

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answer any questions, without suffering any negative consequences. If he/she chooses to withdraw or if I withdraw my child from the study, all data gathered until the time of withdrawal will be destroyed.

Acceptance: I, _____ (*name of parent/guardian*), agree that my child participate in the above research study conducted by Marie Brien of the School of Human Kinetics, Faculty of Health Sciences, University of Ottawa, under the supervision of Dr. Heidi Sveistrup, University of Ottawa.

If I have any questions about the study, I may contact the investigators.

If I have any questions regarding the ethical conduct of this study, I may contact the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 159, Ottawa, ON K1N 6N5

Tel.: (613) 562-5841

Email: ethics@uottawa.ca

There are two copies of the consent form, one of which is mine to keep.

Parent/guardian's signature: _____ Date: _____

Parent/guardian's signature: _____ Date: _____

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Formulaire de consentement

TITRE DE L'ÉTUDE : L'effet d'un programme d'intervention intensif de réalité virtuelle sur l'équilibre et la mobilité fonctionnelle des enfants avec la paralysie cérébrale

Heidi Sveistrup, Faculté des sciences de la santé, École des sciences de la réadaptation, Université d'Ottawa

Marie Brien, B.Sc. (PT), MSc (candidate)

Invitation à participer: Mon enfant est invité(e) à participer à la recherche nommée ci haut qui est menée par Marie Brien and Heidi Sveistrup. Ce projet de recherche est subventionné par des fonds de recherche clinique du Centre de traitement pour enfants d'Ottawa. Cette étude est entreprise pour la thèse de M.Sc. en activité physique pour Marie Brien.

But de l'étude: Le but de l'étude est d'évaluer les effets immédiats et à court terme d'un programme d'intervention intensif de réalité virtuelle sur l'équilibre et la mobilité fonctionnelle d'enfants d'âge scolaire et d'adolescents atteints de paralysie cérébrale marchant seuls sans aide technique. Nous voulons aussi recueillir de l'information nous permettant de développer un programme d'intervention de réalité virtuelle visant à améliorer l'équilibre de ces enfants.

Participation: Mon enfant participera à des séances d'évaluation de l'équilibre et des séances d'intervention visant l'entraînement de l'équilibre.

L'entraînement de l'équilibre : La participation de mon enfant consistera essentiellement à participer dans des séances de 45 minutes chacune, à raison de 2 séances par jour avec 45 minutes de repos entre chaque séances, et ce, pour 5 jours consécutifs. Les séances seront cédulées le matin ou l'après-midi et auront lieu au Centre de Traitement pour enfants d'Ottawa. Les activités d'entraînement à l'équilibre seront fournies en utilisant une nouvelle technologie de réalité virtuelle utilisant des jeux informatiques qui demanderont des mouvements du corps en positions debout.

L'évaluation de l'équilibre : Les habiletés d'équilibre, la motricité globale et la mobilité de mon enfant seront évaluées par une physiothérapeute pendant les 4 phases de l'étude : Phase 1 : jusqu'à six fois pendant la semaine avant de commencer les séances d'entraînement de l'équilibre; Phase 2 : chaque jour des séances d'entraînement, immédiatement après la fin des séances d'entraînement, Phase 3 : trois fois pendant la semaine après les séances d'entraînement; et Phase 4 : un mois après l'entraînement de l'équilibre. Ces sessions d'évaluation seront d'une durée de 40 minutes chacune.



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Pendant les séances d'évaluation, on demandera à mon enfant de faire des activités qui font partie de différents tests d'évaluation clinique. Ceux-ci incluent des activités telles que marcher aussi vite que possible sur une distance de 6 m, se tenir debout et se tourner, monter et descendre les escaliers et se tenir debout sur un pied. Ces activités seront répétées à chaque séance d'évaluation.

Risques: Je comprends que la participation de mon enfant à cette recherche demandera qu'il participe à un programme d'entraînement de l'équilibre utilisant des jeux d'ordinateur et il est possible que ceci entraîne de la fatigue chez mon enfant. J'ai reçu l'assurance du chercheur que tout se fait en vue de minimiser ces risques. Il y aura des périodes de repos avec activités tranquilles pendant 45 minutes à tous les jours entre les deux sessions d'intervention.

Bienfaits: La participation de mon enfant à cette recherche aura pour effet de contribuer à l'avancement du savoir dans le domaine de l'utilisation de jeux d'ordinateur de réalité virtuelle pour le développement de l'équilibre chez les enfants atteints de paralysie cérébrale. Lorsque l'étude sera terminée, vous recevrez un résumé des résultats de l'étude.

Confidentialité et anonymat: J'ai l'assurance de la chercheuse que l'information que mon enfant partagera avec celle-ci restera strictement confidentielle. L'identité de mon enfant sera gardée confidentielle par l'utilisation d'un code ou d'un numéro au lieu son information personnelle. Seuls les membres de l'équipe de recherche auront accès aux données recueillies lesquelles seront gardées dans un classeur verrouillé dans le bureau de Marie Brien au Centre de Traitement pour enfants d'Ottawa. L'anonymat sera garanti en tout temps. Les résultats de l'étude (y compris ceux de mon enfant) seront présentés à une conférence scientifique et sera soumise pour être publié dans une revue scientifique. L'identité des participants ne sera pas révélée dans des publications.

Conservation des données: Les données recueillies incluant information écrite, formulaires de tests seront conservées de façon sécuritaire dans le bureau de l'investigatrice secondaire dans un classeur verrouillé. Les données électroniques seront conservées dans un ordinateur protégé par un mot de passe. Les données de mon enfant seront conservées pour une période maximale de 5 ans. A la fin de la période de 5 ans, les données seront détruites. Les données sous forme de papier seront envoyées pour être déchetées et les données électroniques seront effacées.

Compensation:

Je recevrai un montant de \$20 pour chaque visite que mon enfant et moi-même faisons au Centre de traitement pour enfants d'Ottawa pour les fins de cette étude.



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Participation volontaire: La participation de mon enfant à la recherche est volontaire et mon enfant et moi-même sommes libres de se retirer en tout temps, et/ou de refuser de répondre à certaines questions, sans subir de conséquences négatives. Si mon enfant ou moi-même choisissons de se retirer de l'étude, les données recueillies jusqu'à ce moment seront détruites.

Acceptation: Je, _____ (*nom du participant*), accepte de participer à cette recherche menée par Marie Brien de l'École des sciences de l'activité physique, Faculté des sciences de la santé, laquelle recherche est supervisée par Dr. Heidi Sveistrup, Université d'Ottawa.

Pour tout renseignement additionnel concernant cette étude, je peux communiquer avec le chercheur ou son superviseur.

Pour tout renseignement sur les aspects éthiques de cette recherche, je peux m'adresser au Responsable de l'éthique en recherche, Université d'Ottawa, Pavillon Tabaret, 550, rue Cumberland, salle 159, Ottawa, ON K1N 6N5
Tél.: (613) 562-5841
Courriel : ethics@uottawa.ca

Il y a deux copies du formulaire de consentement, dont une copie que je peux garder.

Signature du parent/tuteur: _____ Date: _____

Signature du parent/tuteur: _____ Date: _____



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Assent Form for Child

Study Title:

The Effect of an Intensive Virtual Reality Intervention Program on Balance and Functional Mobility of Children with Cerebral Palsy

Researchers:

Heidi Sveistrup, University of Ottawa,

Marie Brien, Ottawa Children's Treatment Center.

Heidi Sveistrup and Marie Brien are studying standing balance and movement abilities in children with cerebral palsy who are able to walk on their own. They want to see if playing different computer games while you're standing up will change the way you move around and walk. This study is being completed as part of Marie Brien's graduate studies.

Here is what we will ask you to do:

First Step

If you would like to do these activities, you will visit the Ottawa Children's Treatment Center up to six times during the week before the virtual reality computer balance program. During these visits, a physiotherapist will look at your balance and movement abilities. The therapist will ask you to do movements such as walking up and down stairs, jumping, standing on one foot and walking fast for a short distance. These visits will last about 40 minutes each and you will be asked to do the same things at each of the visits.

Second Step

You will come to the Treatment Center for 5 days in a row, either in the morning or in the afternoon, to do the virtual reality balance training program. You will do these activities, standing up, for 45 minutes twice each day. There will be a rest period of 45 minutes between the 2 sessions of balance activities. During that time you will do quiet activities (games while sitting at a table, watching a DVD...) and eat a snack.

On those 5 days, after the balance training sessions, a physiotherapist will also look at your balance and movement abilities. This will take about 40 minutes.



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Third Step

You will come back to Treatment Center, for 3 visits the week after finishing the balance activities. On those visits, a physiotherapist will look your balance and movement abilities. Those visits will last about 40 minutes.

Fourth Step

You will come back to Treatment Center for a last visit one month later, when a physiotherapist will look your balance and movement abilities. This visit will last about 40 minutes.

You may get tired when you do the activities. You will have rest breaks, and if you want more rest break times, or for longer periods, you just have to tell your parents or the researchers. You may feel as if you had been playing in the playground with your friends. If you don't want to do the activities anymore, you can tell the researcher or your mom and dad, and they can be changed or you can stop.

If you or your mom or dad have any questions, you or your mom/dad can call Marie Brien at the Ottawa Children's Treatment Center. Her e-mail is

Your mom\dad can also contact the Protocol Officer for Ethics in Research at any time with questions about your rights when you participate in research. She is located at the University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 159, Ottawa, ON K1N 6N5. Her phone number is (613) 562-5841 and her e-mail: ethics@uottawa.ca.

My Assent:

I understand that I can stop being part of this study and I understand the part that I will do in the study and I agree to participate.

Dated the.....day of.....200...

Name: _____

Signature: _____

Signature of researcher: _____



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la réadaptation

University of Ottawa
Faculty of Health
Sciences

School of Rehabilitation
Sciences

Documentation d'assentiment de l'enfant

Titre de l'étude :

L'effet d'un programme d'intervention intensif de réalité virtuelle sur l'équilibre et la mobilité fonctionnelle des enfants avec la paralysie cérébrale

Chercheurs:

Heidi Sveistrup, Université d' Ottawa

Marie Brien, Centre de traitement pour enfants d'Ottawa

Heidi Sveistrup and Marie Brien étudient l'équilibre debout et les habiletés de mouvement chez les enfants qui ont la paralysie cérébrale et qui peuvent marcher par eux-mêmes. Elles veulent voir si le fait de jouer debout à différents jeux d'ordinateur en réalité virtuelle peut améliorer comment tu bouges et comment tu marches. Cette étude est entreprise pour un travail de thèse de Marie Brien.

Ce qu'on te demandera de faire :

Première étape

Si tu veux faire ces activités, tu viendras au Centre de traitement pour enfants d'Ottawa jusqu'à six fois pendant la semaine avant le début du programme d'équilibre avec ordinateur en réalité virtuelle. Pendant ces visites, une physiothérapeute regardera ton équilibre et tes mouvements. La thérapeute te demandera de faire des mouvements tels que monter et descendre les escaliers, sauter, te tenir sur un pied et marcher vite sur une courte distance. Ces visites dureront environ 40 minutes chacune et on te demandera de faire les mêmes choses à chacune des visites.

Deuxième étape

Tu viendras au Centre de traitement pendant 5 jours de suite, soit le matin ou l'après-midi, afin de participer au programme d'équilibre avec ordinateur en réalité virtuelle. Tu joueras ces jeux d'ordinateur, debout, pour 45 minutes deux fois par jour. Il y aura une période de repos de 45 minutes entre les deux périodes de jeu d'ordinateur. Pendant ce temps, tu feras des activités tranquilles (jeux assis à une table, regarder un DVD...) et tu auras une collation.



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Pendant ces 5 jours, après avoir fini les programmes d'équilibre, une physiothérapeute regardera ton équilibre et tes mouvements. Ceci durera environ 40 minutes.

Troisième étape

Tu reviendras au Centre de traitement 3 fois la semaine après avoir terminé les jeux d'ordinateur. Une thérapeute regardera ton équilibre et tes mouvements. Ces visites dureront environ 40 minutes chacune.

Quatrième étape

Tu reviendras au Centre de traitement une dernière fois un mois plus tard afin qu'une thérapeute regarde ton équilibre et tes mouvements. Cette visite durera environ 40 minutes.

Il se peut que tu sois fatigué lorsque tu feras ces activités. Tu auras des périodes de repos, et si tu veux plus de périodes de repos, ou pour de plus longues périodes, tu n'as qu'à le dire à tes parents ou aux chercheurs. Tu ne te sentiras probablement pas plus fatigué que si tu jouais au parc avec tes amis. Si tu ne veux plus faire les activités, tu peux le dire au chercheur et ils peuvent changer les activités ou les arrêter.

Si toi ou ta mère ou ton père avez des questions, ta mère ou ton père peuvent appeler Marie Brien au Centre de traitement pour enfants d'Ottawa Son adresse courriel est:

Ta mère ou ton père peuvent aussi s'adresser au Responsable de l'éthique en recherche en tout temps s'ils ont des questions concernant tes droits lorsque tu participe à de la recherche. Il se trouve à l'Université d'Ottawa, Pavillon Tabaret, 550, rue Cumberland, salle 159, Ottawa, ON K1N 6N5
Tél.: (613) 562-5841 Courriel : ethics@uottawa.ca

Mon assentiment :

Je comprends que je peux arrêter de participer à cette étude et je comprends ce que je dois faire dans cette étude et j'accepte de participer.

Daté le.....jour de200.....

Nom : _____

Signature: _____

Signature du chercheur: _____

APPENDIX 5



Université d'Ottawa University of Ottawa

Service de subventions de recherche et déontologie Research Grants and Ethics Services

May 23, 2008

RE: The Effect of an Intensive Virtual Reality Intervention Program on Balance and Functional Mobility of Children with Cerebral Palsy (H 04-08-05)

Dear Professor Svestrup and Mrs. Brien,

You will find enclosed the Health Sciences and Science REB ethical clearance for the abovementioned study.

During the course of the study, any modifications to the protocol or forms may not be initiated without prior written approval from the REB. You must also promptly notify the REB of any adverse events that may occur.

This certificate of ethical clearance is valid until May 23, 2009. Please submit an annual status report to the Protocol Officer in May 2009 to either close the file or request a renewal of ethics approval. This document can be found at:

http://web9.uottawa.ca/services/rgessrd/ethics/application_dwn.asp

A copy of this approval will be sent to research services, if necessary.

If you have any questions, you may contact the undersigned at the number

Sincerely yours,

Germain Zongo
Protocol Officer for Ethics in Research
For Dr. Daniel Lagarec, Chair of the Health Sciences and Science REB

550, rue Cumberland 550 Cumberland Street
Ottawa (Ontario) K1N 6N5 Canada Ottawa, Ontario K1N 6N5 Canada

(613) 562-5841 • Téléc./Fax (613) 562-5338
<http://www.uottawa.ca/services/research/rge/index.html>



Université d'Ottawa University of Ottawa

Service de subventions de recherche et déontologie Research Grants and Ethics Services

HEALTH SCIENCES AND SCIENCE RESEARCH ETHICS BOARD

CERTIFICATE OF ETHICAL APPROVAL

This is to certify that the University of Ottawa Health Sciences and Science Research Ethics Board has examined the application for ethical approval of the research project entitled **The Effect of an Intensive Virtual Reality Intervention Program on Balance and Functional Mobility of Children with Cerebral Palsy (H 04-08-05)** submitted by Pr. Heidi Svestrup of the School of Rehabilitation Sciences at the University of Ottawa and Mrs. Marie Brien of the Ottawa Children Treatment Centre.

The Board found that this research project met appropriate ethical standards as outlined in the Tri-Council Policy Statement and in the Procedures of the University of Ottawa Research Ethics Boards, and accordingly gave it a Category 1a (approval). This certification is valid one year from the date indicated below.

May 23, 2008

Date

Germain Zongo
Protocol Officer for Ethics in Research
For Dr. Daniel Lagarec, Chair of the
Health Sciences and Science REB

550, rue Cumberland 550 Cumberland Street
Ottawa (Ontario) K1N 6N5 Canada Ottawa, Ontario K1N 6N5 Canada

(613) 562-5841 • Téléc./Fax (613) 562-5338
<http://www.uottawa.ca/services/research/rge/index.html>



Ottawa Children's Treatment Centre
Centre de traitement pour enfants d'Ottawa
Founded in 1951 Fondé en 1951

APPENDIX 6

October 29, 2008

Heidi Sveistrup
School of Rehabilitation Sciences
Faculty of Health Sciences
University of Ottawa

Marie Brien
Physical Therapist
Ottawa Children's Treatment Centre

RE: The effect of an intensive virtual reality intervention program on balance and functional mobility of children with cerebral palsy (#2008-02)

Dear Dr. Sveistrup and Ms. Brien,

I am pleased to inform you that your research project entitled *The effect of an intensive virtual reality intervention program on balance and functional mobility of children with cerebral palsy* has received approval by the Research Review Committee.

At the completion or termination of your project, Principal Investigators are required to submit a report to outline progress on the project. Any modifications to the protocol or adverse events must be reported to the Chair of the Research Review Committee. This approval will expire when your Research Ethics Board approval expires, on May 23, 2009.

We wish you good luck with your project!

Sincerely,

Antoinette Megens
Chair
Research Review Committee
Ottawa Children's Treatment Centre

395 ch. Smyth Road
Ottawa ON K1H 8L2
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Toll Free/sans frais: 1-800-565-4839
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Fax/télé: (613) 932-5688



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with multiple
disabilities*

*La voix des enfants
atteints d'incapacités
multiples*

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Appendix 7

Level of Evidence for Single Subject Research Designs (Romeiser Logan et al., 2008)

| <u>Level</u> | <u>Evidence</u> |
|--------------|--|
| I | Randomized controlled N-of-1 (RCT), alternating treatment (ATD), and concurrent or non-concurrent multiple baseline designs (MBDs) ¹ with clear-cut results; generalizability if the ATD is replicated across three or more subjects and the MBD design consists of a minimum of three subjects, behaviors, or settings. These designs can provide causal inferences. |
| II | Non-randomized, controlled, concurrent MBD ^a with clear-cut results; generalizability if design consists of a minimum of three subjects, behaviors, or settings; limited causal inferences. |
| III | Non-randomized, non-concurrent, controlled MBD ^a with clear-cut results; generalizability if design consists of a minimum of three subjects, behaviors, or settings; limited causal inferences. |
| IV | Non-randomized, controlled SSRDs with at least three phases (ABA, ABAB, BAB, etc.) with clear-cut results; generalizability if replicated across five or more different subjects; only hints at causal inferences. |
| V | Non-randomized controlled AB single-subject research design with clear-cut results; generalizability if replicated across three or more different subjects; suggests causal inferences allowing for testing ideas. |

¹ If the intervention(s) is known to be successful, a baseline or control phase is not required.

Appendix 8

Quality Rating Questions for Single-Subject Research Designs (Romeiser Logan, 2008)

Description of participants and settings

1. Was/were the participant(s) sufficiently well described to allow comparison with other studies or with the reader's own patient population?

Independent variable

2. Were the independent variables operationally defined to allow replication?
3. Were intervention conditions operationally defined to allow replication?

Dependent variable

4. Were the dependent variable operationally defined as dependent measures?
5. Was interrater or intrarater reliability of the dependent measures assessed before and during each phase of the study?
6. Was the outcome assessor unaware of the phase of the study (intervention vs control) in which the participant was involved?
7. Was stability of the data demonstrated in baseline, namely lack of variability or a trend opposite to the direction one would expect after application of the intervention?

Design

8. Was the type of SSRD clearly and correctly stated, for example A-B, multiple baselines across subjects?
9. Were there an adequate number of data points in each phase (minimum of five) for each participant?
10. Were the effects of the intervention replicated across three or more subjects?

Analysis

11. Did the authors conduct and report appropriate visual analysis, for example, level, trend, and variability?
12. Did the graphs used for visual analysis follow standard conventions, for example *x*- and *y*-axes labeled clearly and logically, phases clearly labeled (A, B, etc.) and delineated with vertical lines, data paths separated between phases, consistency of scales?
13. Did the authors report tests of statistical analysis, for example celeration line approach, two-standard deviation band method, C-statistic, or other?
14. Were all criteria met for the statistical analyses used?

Appendix 9

Participant number: _____

Date: _____

Virtual Reality Study- Participant Questionnaire

You have agreed to participate in the Virtual Reality Study. Your answers are important to us, as they will help us find out about what physical activities you are involved in and how you feel you move around.

All the information is confidential

Please circle one answer.

1. I know some different exercises and activities that are good for me.

Yes Yes-sometimes No

2. I do exercises at home

Yes Yes-sometimes No

3. I participate in sports or physical activities during the school year

Yes-regularly scheduled Yes-sometimes No

If yes- Which one(s) ? _____

How often ? _____

4. I am currently participating in sports or physical activities.

Yes-regularly scheduled Yes-sometimes No

If yes- Which one(s) ? _____

How often ? _____

5. I am happy with how I am doing in physical education class (gym)

Yes Yes-sometimes No Not Applicable

Participant number: _____

5. I feel comfortable walking in crowded areas (e.g.: school hallways, shopping malls)

Yes Yes-sometimes No

6a. I feel comfortable walking up a hill

Yes Yes-sometimes No

6b. I feel comfortable walking down a hill

Yes Yes-sometimes No

7a. I often get tired of standing

Yes Yes-sometimes No

7b. I often get tired of walking

Yes Yes-sometimes No

8. I have to be careful not trip or fall.

Yes Yes-sometimes No

If yes- when?_____

9. I am able to walk down a long hallway at school or at a mall at the same speed as my friends .

Yes Yes-sometimes No

10. I am able to safely walk outdoors with my friends or by myself

Yes Yes-sometimes No

Participant number: _____

11. I am able to easily walk up a flight of stairs

Yes Yes-sometimes No

12. I am able to easily walk down a flight of stairs

Yes Yes-sometimes No

13. I use a railing when using the stairs

Yes Yes-sometimes No

If yes- To walk up? _____ To walk down? _____

14. I am able to play sports where I have to throw and catch a ball.

Yes Yes-sometimes No

Which ones? _____

15. I am able to play sports where I have to run and kick a ball

Yes Yes-sometimes No

Which ones? _____

16. Do you play any games on video gaming or computer at home?

Please check which one:

Computer _____ Playstation _____ X-box _____ Wii _____

Other: _____

Participant number: _____

Please rate yourself on the following questions using the following scale:

| | | | | |
|------------------------------|-----------------|------------------|--------------|---------------------------|
| 1 | 2 | 3 | 4 | 5 |
| Strongly Disagree | Disagree | Undecided | Agree | Strongly Agree |

1. I am satisfied (OK) with the way I walk.

| | | | | |
|----------|----------|----------|----------|----------|
| 1 | 2 | 3 | 4 | 5 |
|----------|----------|----------|----------|----------|

2. I am satisfied (OK) with the way I move my arms.

| | | | | |
|----------|----------|----------|----------|----------|
| 1 | 2 | 3 | 4 | 5 |
|----------|----------|----------|----------|----------|

3. I am satisfied (OK) with the way I move my legs.

| | | | | |
|----------|----------|----------|----------|----------|
| 1 | 2 | 3 | 4 | 5 |
|----------|----------|----------|----------|----------|

4. I am satisfied (OK) with the way I move my body.

| | | | | |
|----------|----------|----------|----------|----------|
| 1 | 2 | 3 | 4 | 5 |
|----------|----------|----------|----------|----------|

5. I am satisfied (OK) with how fast I can walk.

| | | | | |
|----------|----------|----------|----------|----------|
| 1 | 2 | 3 | 4 | 5 |
|----------|----------|----------|----------|----------|

6. I am satisfied (OK) with my balance.

| | | | | |
|----------|----------|----------|----------|----------|
| 1 | 2 | 3 | 4 | 5 |
|----------|----------|----------|----------|----------|

Participant number: _____

When you think about getting around.....

1. What is the hardest physical thing for you to do at home?

How difficult is this?

| | | | | |
|-------------------|-----------|-----------|--------------------|-----------------------|
| 1 | 2 | 3 | 4 | 5 |
| Very Difficult | Difficult | Undecided | A little difficult | Not very Difficult |

2. What is the hardest physical thing for you to do at school?

How difficult is this?

| | | | | |
|-------------------|-----------|-----------|--------------------|-----------------------|
| 1 | 2 | 3 | 4 | 5 |
| Very Difficult | Difficult | Undecided | A little difficult | Not very Difficult |

3. What is the hardest physical thing for you to do outdoors in the community?

How difficult is this?

| | | | | |
|-------------------|-----------|-----------|--------------------|-----------------------|
| 1 | 2 | 3 | 4 | 5 |
| Very Difficult | Difficult | Undecided | A little difficult | Not very Difficult |

4. What do you think would be the most important physical thing for you to get better at?

How important is this to you?

| | | | | |
|----------|----------|----------|----------|----------|
| 1 | 2 | 3 | 4 | 5 |
|----------|----------|----------|----------|----------|

Appendix 10

Participant number: _____

Date: _____

Virtual Reality Study- Parent Questionnaire

You and your child have accepted to participate in the virtual reality study. In order to better describe your child's characteristics, we would appreciate if you could answer the following questions.

All answers will be kept confidential.

1. Has your child had any orthopedic surgery? If so, what type and when?

2. Has your child had tone management intervention such as BOTOX injections?
If so, in which muscles and when?

3. Has your child had any neurosurgery such as selective dorsal rhizotomy?
If so, when?

4. Does your child presently wear AFO(s)' (Ankle Foot Orthoses)?
If so, on which foot and when?

Thank you!

Appendix 11

Virtual Reality Programs

The following are the modules created for the study. The module titles refer to the primary goal. Numbers in brackets refer to the level of difficulty of the applications based on IREX levels.

Initiation to VR (1)

ID#: Date: Intervention Day: Session #:

| Application | Score | Comments |
|-----------------------------------|--------------|-----------------|
| Drums 120 sec. | | |
| Soccer 120 sec.- Level 1 | | |
| Formula Racing 120 sec. | | |
| Airbourne 120 sec.-Level 1 | | |
| Birds and Balls 120 sec. | | |

Rest time between applications:

Total session time:

Initiation to VR (2)

ID# : Date: Intervention Day #: Session#:

| Application | Score | Comments |
|--|--------------|-----------------|
| Shark Bait 120 sec.- Level 2 | | |
| Zebra Crossing 120 sec.-Level 2 | | |
| Gravball 120 sec. | | |
| Snowboard 120 sec.- Level 2 | | |
| Volleyball 120 sec. | | |

Rest time between applications:

Total session time:

ID# : **Date:** **Intervention Day #:** **Session#:**

Full Body Weight Shift (3)

| Application | Score | Comments |
|--|--------------|-----------------|
| Formula Racing 120 sec. | | |
| Snowboard 120 sec.- Level 3 | | |
| Soccer 120 sec.-Level 3 | | |
| Zebra Crossing 120 sec.-Level 3 | | |
| Shark Bait 120 sec.- Level 3 | | |

Rest time between applications:

Total session time:

ID# : **Date:** **Intervention Day #:** **Session#:**

Full Body Weight Shift (5)

| Application | Score | Comments |
|--|--------------|-----------------|
| Formula Racing 120 sec. | | |
| Snowboard 120 sec.-Level 5 | | |
| Gravball 120 sec. | | |
| Zebra Crossing 120 sec.-Level 5 | | |
| Shark Bait 120 sec.- Level 5 | | |

Rest time between applications:

Total session time:

ID# : **Date:** **Intervention Day #:** **Session#:**

Sports

| Application | Score | Comments |
|-----------------------------------|--------------|-----------------|
| Formula Racing 120 sec. | | |
| Snowboard 120 sec.-Level 5 | | |
| Volleyball 120 sec. | | |
| Gravball 120 sec. | | |
| Soccer 120 sec.-Level 5 | | |

Rest time between applications:

Total session time:

ID# : **Date:** **Intervention Day #:** **Session#:**

Full Body Weight Shift (7)

| Application | Score | Comments |
|--|--------------|-----------------|
| Formula Racing 120 sec. | | |
| Snowboard 120 sec.-Level 7 | | |
| Soccer 120 sec.-Level 7 | | |
| Zebra Crossing 120 sec.-Level 7 | | |
| Shark Bait 120 sec.- Level 7 | | |

Rest time between applications:

Total session time:

ID# : **Date:** **Intervention Day #:** **Session#:**

Full Body Weight Shift (8)

| Application | Score | Comments |
|---|--------------|-----------------|
| Snowboard 120 sec. -Level 8 | | |
| Zebra Crossing 120 sec. -Level 8 | | |
| Soccer 120 sec. -Level 8 | | |
| Shark Bait 120 sec. -Level 8 | | |
| Drums 120 sec. | | |

Rest time between applications:

Total session time:

ID# : **Date:** **Intervention Day #:** **Session#:**

Full Body Weight Shift (9)

| Application | Score | Comments |
|---|--------------|-----------------|
| Snowboard 120 sec.- Level 9 | | |
| Zebra Crossing 120 sec. -Level 9 | | |
| Soccer 120 sec.- Level 9 | | |
| Shark Bait 120 sec.- Level 9 | | |
| Drums 120 sec. | | |

Rest time between applications:

Total session time:

ID# : **Date:** **Intervention Day #:** **Session#:**

Full Body Weight Shift (10)

| Application | Score | Comments |
|--|--------------|-----------------|
| Snowboard 120 sec.- Level 10 | | |
| Zebra Crossing 120 sec. -Level 10 | | |
| Soccer 120 sec.- Level 10 | | |
| Shark Bait 120 sec.- Level 10 | | |
| Drums 120 sec. | | |

Rest time between applications:

Total session time:

Appendix 12

Calculation of Minimal Detectable Change for Six-Minute Walk Test

Legend:

ICC: intraclass correlation

CI: Confidence interval

SDB: Standard deviation of baseline scores

SEM: Standard error of measurement

Reliability Data for GMFCS level I from Thompson et al., 2008:

6MWT SDB = 84.4, ICC = 0.93, MDC95 = 61.9 meters

Calculation:

$$SEM = SDB * (\sqrt{1 - ICC})$$

$$= 84.4 * (\sqrt{1 - 0.93})$$

$$= 84.4 * \sqrt{0.07}$$

$$= 22.35$$

$$MDC = z\text{-score (level of confidence)} * SEM$$

$$MDC_{80} (80\% CI) = 1.28 * \sqrt{2} * SEM = 1.28 * \sqrt{2} * 22.35$$

$$= 40.45 \text{ meters}$$

Table 1

Description of Virtual Reality Applications and Movements Elicited

| IREX Applications | Description | Movements Elicited |
|-------------------|---|---|
| Soccer | <p>The participant is a goalkeeper and must stop the balls from entering the net. Any body part can stop the balls coming from different directions at increasing speed.</p> <p><i>Scoring:</i> “saves” and “goals” (against) are counted</p> | <p>Full body application-lateral weight shifting over wide base of support with lateral reaching, side-stepping, lateral crossovers, side-lunges, upward jumps, rapid changes of direction of side-stepping to alternate sides, trunk rotation/extension and side flexion</p> |
| Snowboard | <p>The participant is snowboarding down a narrow slope and must go over as many jumps as possible while avoiding all the other objects (rocks, tree stumps, trees and snowmen).</p> <p><i>Scoring:</i> “jumps” and “slams” are counted</p> | <p>Full body application- lateral weight shifting over wide base of support, consecutive lateral stepping, wide side-lunges, rapid changes of direction of side-stepping to alternate sides, trunk rotation/ extension and side flexion</p> |
| Shark Bait | <p>The participant is deep sea diving and must navigate to capture stars and touch dolphins while avoiding shark and eels.</p> <p><i>Scoring:</i> “score” and “traumas” are counted</p> | <p>Full body application requiring side-stepping, lateral weight shifting, graded squats/rises or jumps, sustained squats, raising arms</p> |
| Gravball | <p>The participant is in a zero gravity spaceship and must prevent launched balls from falling into the hole on his side by using any body part.</p> <p><i>Scoring:</i> goals “for” and “against” are counted</p> | <p>Full body application requiring side-stepping, graded squat/ rises, sustained squats, raising arms</p> |
| Zebra Crossing | <p>The participant must move sideways along a brick path and up zebra street crossings to catch as many stars as possible.</p> <p><i>Scoring:</i> total score is counted</p> | <p>Full body application, consecutive lateral stepping, single to repeated upward jumps with arms reaching up</p> |
| Volleyball | <p>The participant is playing a volleyball match against a robot. He must bump the ball with any part of the body in order to get it into the opponent’s court.</p> <p><i>Scoring:</i> goals “for” and “against” are counted.</p> | <p>Full body application- anterior-posterior weight shifting in a step position, lateral stepping, trunk rotation/extension and side flexion</p> |

Table 2

Participant Characteristics

| Participant | Age (y: mo) | Diagnosis | Prior medical intervention |
|-------------|----------------|------------------------------|--|
| 1 | 17:8 | Spastic diplegia (L > R) | Lengthening left tendoachilles (2001) Botox of left gastrosolei (1999) |
| 2 | 13:9 | Choreoathetosis | none |
| 3 | 18:9 | Spastic diplegia | Botox hamstrings, gastrosolei (2001) Botox bilateral gastrosolei (1999) Gastrocnemius re-lengthening (1998) Triple level releases (1995) |
| 4 | 14:0 | Spastic triplegia (R > L) | Botox right gastroc-soleus (2001) Selective dorsal rhizotomy (2000) Botox bilateral gastrosolei (1999) |

FIGURE CAPTION

Figure 1: Community Balance and Mobility Scale scores at baseline, intervention and follow-up phases for participants 1, 2, 3, and 4 (P1 to P4). The number of sessions in the baseline phase differs by participant ranging from three sessions for P1 to six sessions for P4. Note that the fourth session in the follow-up phase is one month following the intervention period. The horizontal lines indicate +/- 2 standard deviations from the mean of the baseline data.

Figure 1

Community Balance and Mobility Scale

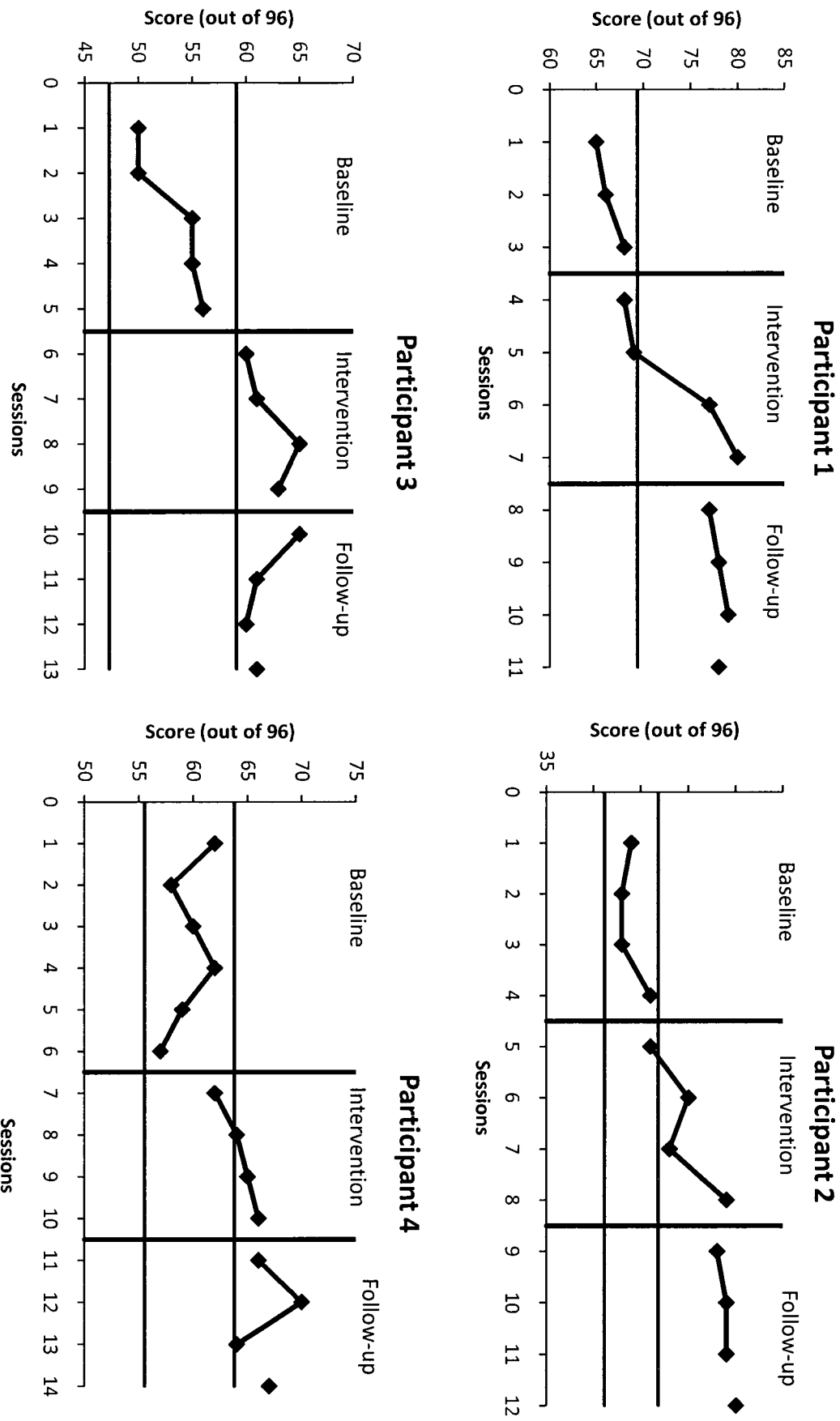


FIGURE CAPTION

Figure 2: Six-Minute Walk Test scores at baseline, intervention and follow-up phases for participants 1, 2, 3, and 4 (P1 to P4). The number of sessions in the baseline phase differs by participant ranging from three sessions for P1 to six sessions for P4. Note that the fourth session in the follow-up phase is one month following the intervention period. The horizontal lines indicate ± 2 standard deviations from the mean of the baseline data.

Figure 2

Six-Minute Walk Test

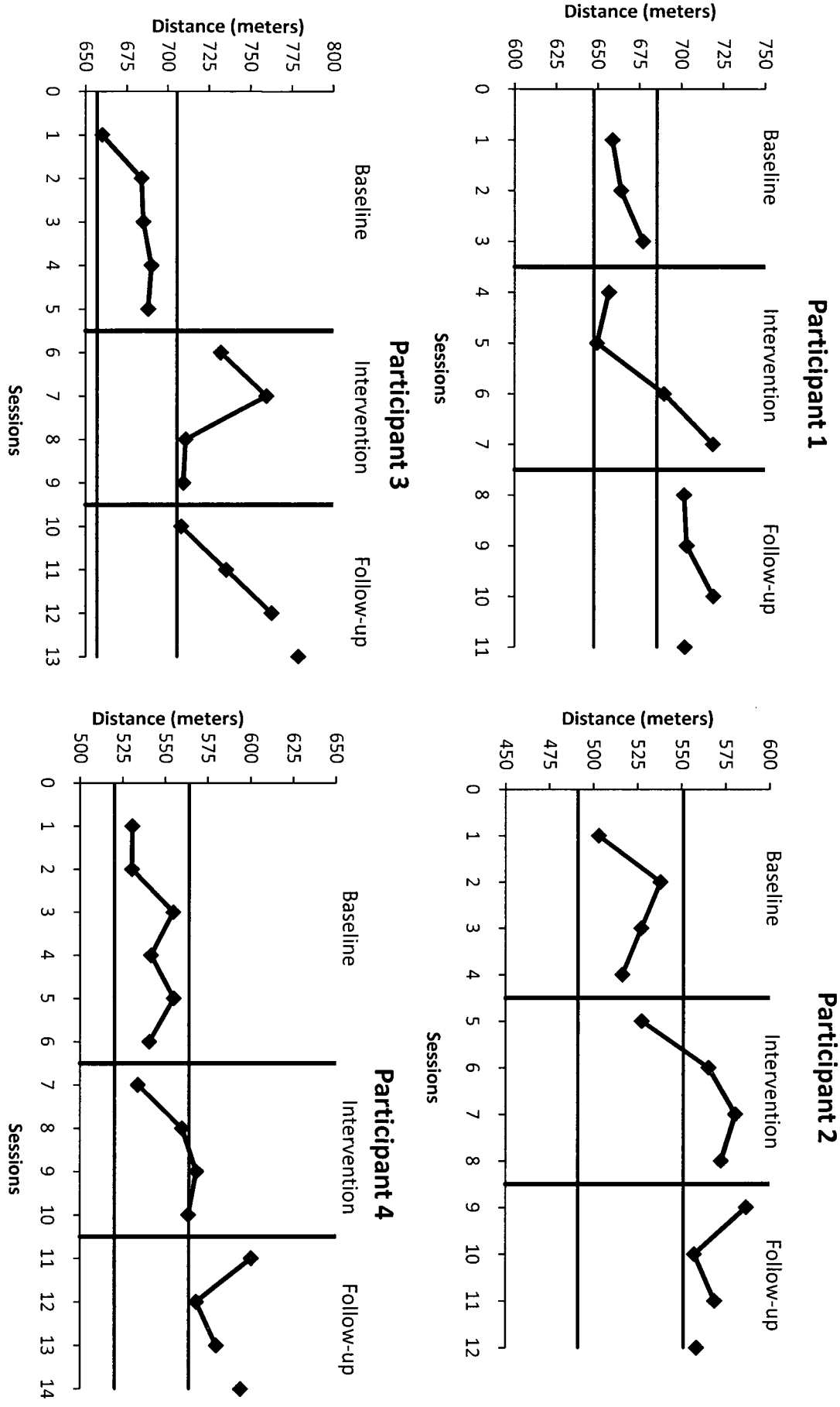


FIGURE CAPTION

Figure 3: Timed Up and Down Stairs scores at baseline, intervention and follow-up phases for participants 1, 2, 3, and 4 (P1 to P4). The number of sessions in the baseline phase differs by participant ranging from three sessions for P1 to six sessions for P4. Note that the fourth session in the follow-up phase is one month following the intervention period. The baseline data showed serially dependency in P1, P3, and P4. For these participants, the data were transformed and a constant of 8 points was added for the graphical representation to conform to traditional standard for the TUDS. The horizontal lines indicate +/- 2 standard deviations from the mean of the baseline data.

Figure 3 Timed Up and Down Stairs

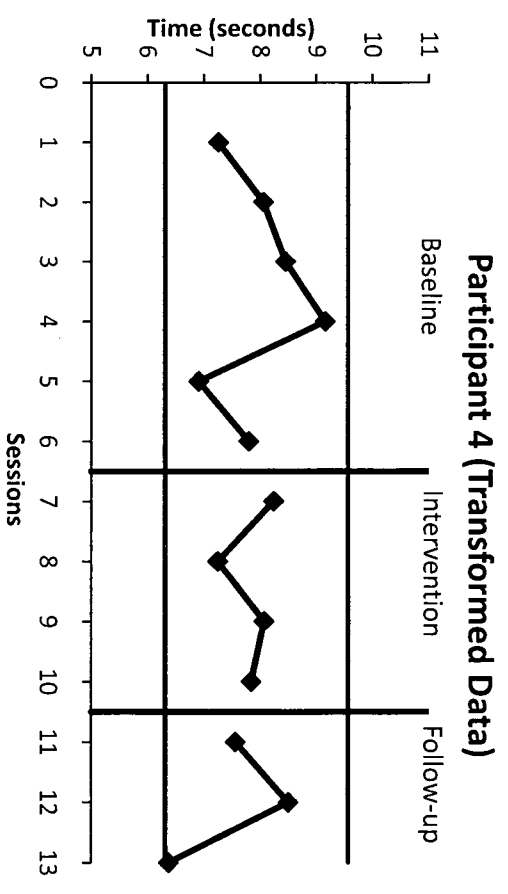
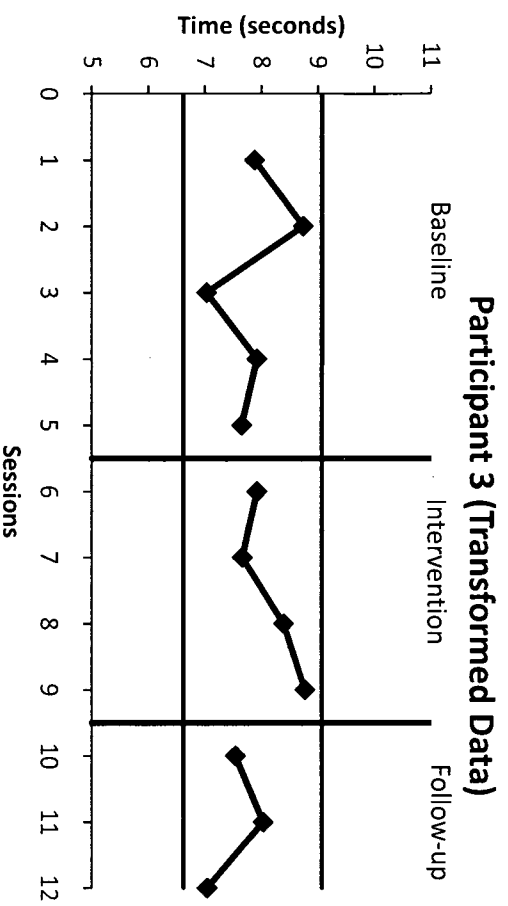
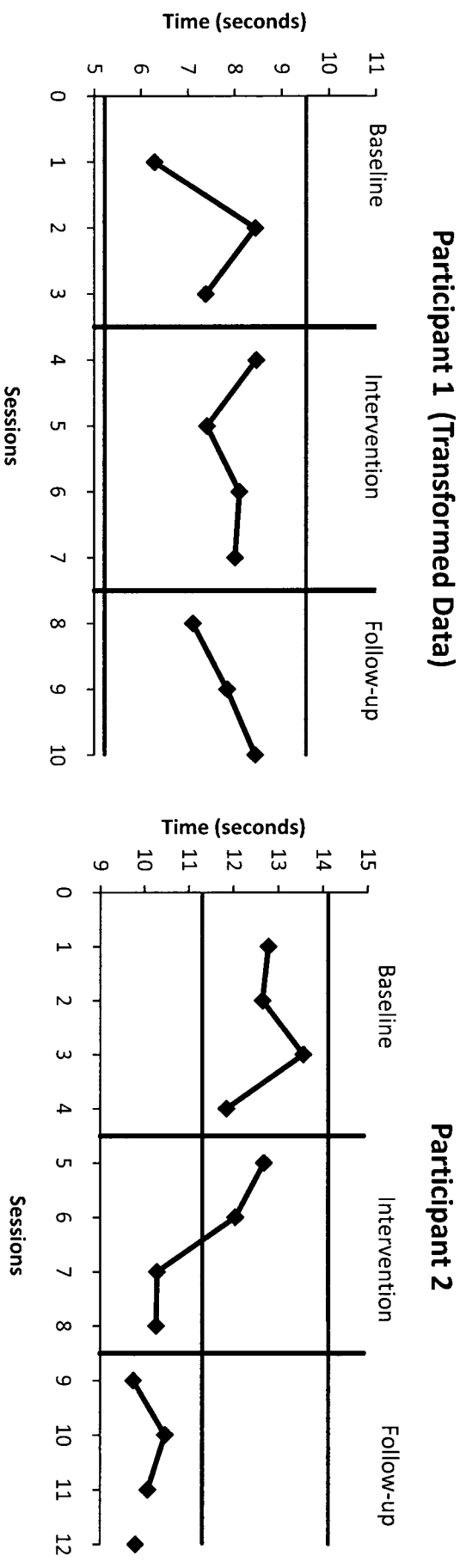


FIGURE CAPTION

Figure 4: GMFM-Dimension E scores at baseline, intervention and follow-up phases for participants 1, 2, 3, and 4 (P1 to P4). The number of sessions in the baseline phase differs by participant ranging from three sessions for P1 to six sessions for P4. Note that the fourth session in the follow-up phase is one month following the intervention period. The baseline data showed serially dependency in P2. For this participant, the data were transformed and a constant of 93 points was added for the graphical representation to conform to traditional standard for the GMFM-Dimension E. The horizontal lines indicate ± 2 standard deviations from the mean of the baseline data.

Figure 4

GMFM-Dimension E

