LEARNING TO WALK AFTER STROKE: A THEORY-FRAMED APPROACH

LEARNING TO WALK AGAIN:

USE OF MOTOR LEARNING PRINCIPLES AS A THEORETICAL FRAMEWORK FOR WALKING-SKILL TRAINING IN COMMUNITY-DWELLING INDIVIDUALS FOLLOWING STROKE

By

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A Thesis

Submitted to the School of Graduate Studies

in partial fulfillment of the requirements

for the degree

Doctor of Philosophy

McMaster University

Doctor of Philosophy (2013) McMaster University

(Rehabilitation Science) Hamilton, Ontario, Canada

TITLE: **Learning to walk again: Use of motor learning principles as a theoretical framework for walking-skill training in community-dwelling individuals following stroke**

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Number of pages: xv, 201

Abstract

Learning to walk again: Use of motor learning principles as a theoretical framework for walking-skill training in community dwelling individuals following stroke

Introduction: Walking is a complex motor skill embedded in numerous basic and instrumental activities of daily living. Walking dysfunction is one of the most disabling and persistent of stroke-related sequela. Physiotherapists are challenged to provide effective interventions to help patients recover optimal walking-skill after stroke. Theory- and research-derived motor learning principles (MLPs) offer an ideal theoretical framework for the development and evaluation of walking-skill focused interventions.

Purpose: To: 1) appraise the degree of adherence to motor learning principles (MLPs) in current post-stroke walking-skill training research; 2) describe the Motor Learning Walking Program (MLWP), a novel, MLPs-framed walking training program; and 3) compare the MLWP to an alternate theory-framed walking-focused intervention in community-dwelling individuals within one year of stroke.

Methods: A scoping review methodology was used to identify the prevalent theoretical frameworks in current post-stroke walking training literature, and to appraise the adherence to selected MLPs in walking-focused interventions. A randomized controlled trial (n=71) was conducted to compare the MLWP to a body-weight-supported treadmill training (BWSTT) intervention.

Results: In the scoping review of 27 walking-focused studies, a minority of investigators explicitly stated a theoretical-framework. Application of MLPs was inconsistent across interventions. In the randomized controlled trial, both intervention groups improved walking function after 5 weeks of training however, there were no significant between-group differences in the primary and secondary outcomes. Interventions were also equal in the number of treatment sessions attended, and mean amount of walking-specific practice per session.

Conclusions: To date, there has been limited integration of MLPs into post-stroke walking-skill training literature. This randomized controlled trial is unique in its comparison of two theoretically divergent, yet equally intense, walking-training interventions. While the results were equivocal, future research should continue to explore the impact of application of MLPs on walking-skill recovery after stroke.

Acknowledgements

I would like to thank the following individuals for their unique and essential contributions to my graduate studies.

To Dr. Laurie Wishart, my supervisor, for her constant guidance, wisdom, patience, and generosity. At all times, Laurie treated me as a research colleague, even before I earned this status. She reminded me of the strengths I bring to this field, while continuously challenging me to expand my skills and knowledge. Without her support this work would not have been possible.

I have been very fortunate to work with, and learn from every member of my committee, all excellent mentors in their own right. To Dr. Tim Lee for his constant support and ability to ask the pertinent question, or make a simple suggestion that helped me to see my work in a new light. To Dr. Julie Richardson for her encouragement and interest in my work and career, and her ability to help me see the bigger picture and implications of this work. To Dr. Lehana Thabane for providing the expertise, guidance, and practical advice I needed to successfully conduct the randomized controlled trial.

I want to thank my family who have accompanied me through this entire journey. To my wife, Karen, who patiently accepted this abnormal life as somewhat normal, gave unsolicited advice at just the right times, fielded the inevitable “when is Vince going to be finished” questions from family and friends, and was always there to encourage and support me. To my children, Claire, Gabriel and Samuel, who shared the dining room table as we did our homework together and tolerated my frequent periods of absence (mental and physical) with little complaint. To my parents, Ray and Aileen DePaul, for their constant interest in my work and willingness to support me in so many different ways.

Thank you to my fellow graduate students, particularly Danielle Levac who through friendship, encouragement, and example helped me to keep moving forward. I look forward to working together again.

I want to recognize the contributions of the participants in the randomized controlled trial, without whom this work would not have been possible. Thank you to the Physiotherapists, Physiotherapy assistants, and administrative staff who worked on the trial. Special thanks to Ruthanne Cameron, Karen Henderson, and Taffina Marley who were indispensible to the successful completion of the RCT.

I would like to acknowledge the support of my colleagues at St. Joseph's Healthcare Hamilton, and in particular Julie Moreland and Beverley Cole. Thanks also to the faculty at McMaster, particularly Dr. Patty Solomon, Dr. Paul Stratford, and Dr. Liliana Coman, who have instructed, encouraged me, and followed my progress with sincere interest.

I am very grateful for the funding that I have received during my doctoral studies. The randomized controlled trial was funded by a grant received from the Ontario Stroke System, Ministry of Health and Long Term Care, and a Novice Researcher Award grant from the Father Sean O'Sullivan Research Centre, Hamilton, Ontario. I appreciate the financial support that I received from the CIHR's Banting and Best Canada Graduate Scholarship and the CIHR's Strategic Training Program in Rehabilitation Research, McMaster University.

Declaration of Academic Achievement

The following summary details all author contributions to each of the manuscripts in this thesis.

For the manuscript in Chapter 2, entitled "Use of theory and motor learning principles in outpatient-based post-stroke walking-training research: A scoping review", Vincent DePaul developed the research question, and selected the research design, conducted the literature search, summarized the themes, and wrote the manuscript. Dr. Laurie Wishart collaborated with V. DePaul on the literature search, data extraction, and summary of themes. Dr. Wishart, Dr. Julie Richardson, Dr. Timothy D. Lee, and Dr. Lehana Thabane provided editorial assistance with manuscript preparation.

Chapter 3 and Chapter 4 contain the manuscripts entitled, "Varied overground walking-task practice versus body-weight-supported treadmill training in ambulatory adults within one year of stroke: a randomized controlled trial protocol", and "A comparison of two active, task-related walking training interventions in community dwelling adults within one year of stroke: a randomized controlled trial". These manuscripts describe the rationale, methods, results and implications of the major research component of this thesis work. Vincent DePaul conceived of the study, drafted the grant application, submitted ethics applications for the trial, acted as the principal investigator and wrote the protocol and results manuscripts. Dr. L. Wishart assisted with preparation of the grant application, refined the study design, and assisted with the management of the conduct of the trial. Dr. L. Wishart, Dr. J. Richardson, Dr. T.D. Lee and Dr. L. Thabane contributed to the study design, were grant holders, contributed to the editing of the manuscript, and approved the final manuscript. Dr. Lehana Thabane provided statistical expertise in clinical trial design and final analysis. Dr. Jinhui Ma provided assistance with running statistical analysis for the results manuscript.

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Chapter 1: Introduction

Background

Walking recovery after stroke: a persistent problem

Every year, approximately 50 000 new stroke events are documented in Canada (Heart and Stroke Foundation of Canada, 2012). With over 300 000 Canadians living with its residual effects, stroke is a leading cause of adult disability in this country. Walking dysfunction is one of the most common, and disabling symptoms associated with stroke.

Almost two thirds of hospitalized stroke survivors are unable to walk without assistance in the first week after stroke onset (Jorgensen, Nakayama, Raaschou, & Olsen, 1995). While the majority of people regain basic walking ability, many experience persistent impairments, and activity limitations. When assessed months, or years, after stroke onset, ambulatory community-dwelling individuals frequently present with impaired gait coordination (Krasovsky & Levin, 2010), gait asymmetry (Olney & Richards, 1996; Patterson et al., 2008), decreased walking speed (Olney & Richards, 1996), decreased walking endurance (Muren, Hutler, & Hooper, 2008), and impaired balance (Michael, Allen, & Macko 2005). In addition, this group faces persistent reduced walking-related self-efficacy (Yiu, Miller, Eng & Liu, 2012), increased risk of falls (Weerdesteyn, Niet, van Duijnhoven, & Guerts, 2008), and reduced walking activity (Michael, et al., 2005).

Considering the global impact of stroke on walking ability, it is not surprising that recovery of walking function is one of the most common rehabilitation goals identified by patients (Bohannon, Williams, & Smith, 1988). In particular, individuals express the desire to return to walking in their community (Lord, McPherson, Rochester, & Weatherall, 2008). In a recent longitudinal study, (DePaul, Moreland, & deHueck, in press), the self-reported needs of individuals with recent stroke were tracked over the first year after discharge from hospital. At the one-year assessment, approximately 30% of participants considered to have had a mild stroke (i.e. acute FIM score >80), reported ongoing difficulties with activities related to community mobility (i.e. walking outdoors, walking in crowds, stairs, and walking fast), and 10% reported some difficulty walking in their own home. In patients with moderate stroke severity (i.e. acute FIM score 40-80), up to 75% reported difficulty with community mobility activities, and 35% had difficulties with walking in their home. Once discharged from hospital, a significant proportion of patients with stroke find themselves limited to walking within their home, and unable to return to the meaningful, walking-related activities and roles within the community (Mayo, Wood-Dauphinee, Côté, Durcan, & Carlton, 2002).

It is clear from these data that there remains a significant gap between the outcomes that patients aspire to, and the outcomes patients actually attain. It is essential that researchers and clinicians work toward narrowing this gap through the development and application of optimally effective walking-focused rehabilitation interventions. Achievement of this goal requires a shift in how we approach the rehabilitation of walking after stroke.

This chapter will introduce the perspective of post-stroke walking rehabilitation as a motor-skill acquisition problem; will consider walking as a complex skill to be learned; discuss the potential role of motor learning science as a framework for walking rehabilitation; and review the evidence of current application of motor-learning science based principles in practice and research. At the end of this chapter, the goals and objectives of this thesis work will be described, and each manuscript will be briefly outlined.

Post-stroke walking training as a motor-skill acquisition problem

Physiotherapists working in stroke rehabilitation are primarily concerned with helping patients achieve optimal recovery of functional mobility. While this goal may involve some treatment at the impairment level (e.g. walking training to improve aerobic capacity and strength), therapists spend much of their time and energy helping patients acquire mobility-related motor skills. A motor skill is a movement that is dependent on practice and experience for its execution, as opposed to being genetically defined (Schmidt & Lee, 2011, p.499). Although there is some evidence that humans are born with certain innate abilities relevant to walking (Dietz, 2003), when we consider the enormous amount of experience required before children can walk independently (Adolph et al., 2012), there is little doubt that walking is a motor skill that needs to be learned or relearned through practice or experience.

Walking as a complex motor skill

As we plan a research program that focuses on the development and evaluation of effective walking-skill training interventions, it is important that we establish what the skill, or task, of walking entails. We may start with a classic, biomechanical definition, where at it's most basic; walking is "a cyclic pattern of bodily movements that is repeated over and over, step after step." (Inman, Ralston & Todd, 1981, p. 2). Although accurate, this definition is limited in scope, and ability to inform the development of walking-skill training programs.

The work in this thesis is based on a broader definition of the skill of walking. While it is strictly correct that walking involves the repetition of the complete gait cycle, the gait cycle is almost always embedded in meaningful activities of daily living. The complex nature of the walking task is highlighted in the important work of Shumway-Cook et al. (2002). In this study, a group of older adults were observed on three trips into their communities. During these outings, participants were required to walk under a variety of environmental and task conditions. Challenges included walking long distances (> 300 m per bout), walking fast, carrying bags or packages, opening heavy doors (35% of trips), going up and down slopes, curbs and stairs (40-68% of trips), managing uneven surfaces (61% of trips), walking in distracting environments (62% of trips), reaching up and down, stopping and starting, and changing directions while walking.

If the goal of physiotherapy treatment is to have patients *learn*, or relearn the motor skill of walking, then our interventions must reflect the day-to-day demands of typical walking, and be informed by the most current understanding of motor skill learning.

Motor learning science: a framework for post-stroke walking-skill rehabilitation

Motor learning science encompasses a large body of theory-based, and experimentally derived knowledge related to the acquisition of motor skills. Decades of research in healthy populations has informed a set of rules, or motor learning principles (MLPs), that can be used to predict the impact of certain experiences, or practice conditions on learning outcomes (Schmidt and Lee, 2011). For example, some of these MLPs predict that: 1) increased amount of practice will lead to increased learning; 2) motor tasks that have no recognizable beginning or end (*continuous skills*) are best learned when practiced as a whole-task; 3) excessive guidance and augmented feedback typically degrades learning; and 4) practice of a task under a variety of conditions typically improves retention and transfer of that skill to other conditions.

Although originally developed in laboratory environments, these principles have been validated in sports, work, and increasingly in rehabilitation settings. (Schmidt and Lee, 2011) While a number of authors have recommended MLPs as an ideal theoretical framework for stroke rehabilitation (Schmidt, 1991; Sabari, J.S., 1991; Gilmore & Spaulding, 2001), application of these principles into walking training research and practice has been limited.

Evidence of limited uptake of MLPs in current practice

While it is impossible to describe practice of all physiotherapists, there is evidence to indicate limited uptake of MLPs in stroke rehabilitation. Clinical practice continues to be heavily influenced by neurophysiological treatment approaches (i.e. Bobath/Neurodevelopmental Treatment) (Menon, Korner-Bitensky, & Straus, 2010). Although, these interventions have undoubtedly evolved to include contemporary concepts, including MLPs (Lennon & Ashburn, 2000), therapist practice continues to reflect traditional, often discredited, ideas (Tyson, Connell, Busse, & Lennon, 2009a). Observational studies of physiotherapy treatments reveal frequent use of hands-on guidance and movement error correction, part-practice of mobility tasks, and non-informational, motivation-focused verbal feedback (Tyson, Connell, Busse, & Lennon, 2009b; Talvitie, 2000). In addition, despite overwhelming support for the MLP related to amount of practice (Schmidt & Lee, 2011), studies repeatedly demonstrate that amount of actual walking-related practice remains low in inpatient and outpatient stroke rehabilitation settings (Lang, et al., 2009; West & Bernhardt, 2012). Based on this evidence, it seems that the call for application of MLPs in stroke rehabilitation has yet to have a significant impact on the practice patterns of physiotherapists or the experiences of patients.

Intervention variability and application of MLPs in walking-focused research

Considering the apparently limited influence of motor learning science on current practice, one would hope for better integration of these MLPs into stroke rehabilitation research. In the last decade, the concept of task-specific practice has emerged in post-stroke walking intervention research. This terminology has been used to describe a diverse, seemingly dissimilar set of treatments. Some investigators utilize task-specific training (or the related terms task-related, task-oriented, and task-orientated training) in reference to over-ground focused, circuit training interventions (Salbach, 2004, van de Port, 2007), while others use the term to describe treadmill-focused interventions (Hesse, Werner, Bardeleben, & Barbeau, 2001; Macko, et al., 2005), including body-weight supported treadmill training (BWSTT), and robotic-assisted treadmill training. Beyond, this emphasis on the repetition of the complete gait cycle, these interventions vary significantly in practice environment, practice content, role of the therapist, and role of the patient. This treatment variability raises important questions about the theoretical rationale, and degree of integration of MLPs in the content of these different interventions.

While the concept of task-specific training, resembles the MLPs related to specificity of practice, and whole task practice, the broader integration of motor learning theory and research is not yet clear. With the exception BWSTT and robotic-assisted BWSTT, it is noteworthy that these different approaches have followed independent paths in their development, and seemingly different theoretical frameworks. In addition, effectiveness studies have typically compared the specific variety of walking training to a non-walking intervention. The literature lacks direct comparisons of these different interpretations of task-specific walking training after stroke.

In summary, there is a need for a comprehensive review of the theoretical underpinnings of current post-stroke walking training interventions. Specifically, it is important that current approaches are appraised against best practices in motor skill learning, as represented by MLPs. Lastly, in order to provide clear direction to clinicians regarding the optimal approach to walking-skill training, a head-to-head comparison of an MLP-framed intervention against an alternate walking-focused intervention is required.

Goal Of Thesis Research

The overall goal of this thesis work is to inform the development of theory-driven, optimally effective, walking-focused rehabilitation interventions for individuals with history of stroke. This work is framed in motor learning science.

The research objectives of this thesis are:

1. To identify the prevalent theoretical frameworks in current, post-stroke, outpatient-based walking-focused intervention literature;
2. To appraise the nature and extent of integration of motor learning science and MLPs in outpatient walking training research;
3. To introduce a novel, motor learning science-framed, post-stroke walking-training intervention designed to adhere to key MLPs;
4. To evaluate the effectiveness of this intervention on walking-function in community-dwelling, adults within one year of stroke.

This work will contribute to a broader research program that is focused on the development, evaluation, and dissemination of motor learning science-framed, mobility-focused rehabilitation interventions that target individuals who present with mobility dysfunction related to stroke, other neurological conditions, and aging.

Description Of Manuscripts

This dissertation is organized as a sandwich thesis. As such, it includes 3 manuscripts that have been prepared for publication in peer-reviewed journals.

The manuscripts in this sandwich thesis represent a component of an overall research program related to the development and evaluation of motor-learning-science informed walking-focused rehabilitation interventions. The first manuscript (Chapter 2) is a scoping review of the use of theory and MLPs in current walking-retraining literature. In the second manuscript (Chapter 3), a new motor-learning-science framed intervention is introduced, along with the detailed description of the methods for the randomized controlled trial completed for this thesis. In the third manuscript (Chapter 4), the results of this RCT are presented and implications are discussed in the context of current theory and research. The contents of each manuscript are described in more detailed in the following section.

Chapter 2: Use of theory and motor learning principles in outpatient-based post-stroke walking training research: A scoping review

A scoping review is a systematic method of describing, or mapping key concepts and practices within a specific field of study (Arksey & O'Malley, 2005). This scoping review was based on 2 basic proposals; first, the study, and practice of post-stroke walking-training would benefit from a clear theoretical framework, and second, that motor learning science offers the ideal framework for this field. As such, the purpose of this scoping review was to: 1) describe the use of theory in current, outpatient-based, post-stroke walking training literature, and 2) to appraise the degree, and nature of application of MLPs in this literature. In this manuscript, the methods for study selection, data extraction, and data summary are described. The major themes are summarized, and implications of the findings to research and practice are discussed.

This review identifies the current state of the literature, identifies strengths, and limitations of the research in relation to use of theory and application of MLPs. Implications of these findings on the future development, evaluation and application of motor learning-science-based walking interventions will be discussed.

Chapter 3: Varied overground walking-task practice versus body-weight-supported treadmill training in ambulatory adults within one year of stroke: a randomized controlled trial protocol

This manuscript provides a detailed description of the theoretical rationale and research methods of the randomized controlled trial completed as the major research component of this thesis. In this protocol paper, a novel theory-framed, walking-focused intervention is described in detail. The Motor Learning Walking Program (MLWP) is a varied, overground, walking-training program, designed to be consistent with MLPs related to practice content, practice variability, practice order, provision of feedback, and provision of physical guidance. The comparison intervention, body-weight supported treadmill training (BWSTT), is rooted in the central pattern generator theory of gait control and recovery (Dietz, 2009). This intervention was selected for use as a comparison treatment as it is was judged to provide an equally intense walking activity, however, is delivered in a manner inconsistent with key MLPs related to specificity of practice, variability of practice, feedback and guidance. In addition to presenting the rationale and intervention descriptions, this manuscript outlines the research methodology including participant selection, outcome measurement and statistical analysis. This paper provides the background, theoretical framework, and methodology necessary for interpretation of the final manuscript.

Chapter 4: A comparison of two, active, task-related walking training interventions in community dwelling adults within one year of stroke: a randomized controlled trial

The focus of the third manuscript is to present the results of the randomized controlled trial. The primary hypothesis of this study was that following 5 weeks of training, participants assigned to the MLWP would have demonstrate better walking function (i.e. comfortable overground walking speed), than participants randomized to the BWSTT intervention. Over a 3 ½ year period, a total of 71 participants were recruited and randomized to receive one of the two study interventions. Results of this study will be presented, and findings discussed in the context of current theory and research. Implications for future research and rehabilitation practice will be outlined.

Chapter 5: Discussion

Chapter 5 will include a overview of the main findings of the thesis studies, and a discussion of the implications of this research work to clinical practice, research and theory. Limitations of the research will be discussed and future recommendations for research will be made.

Content overlap between manuscripts

This thesis has been formatted as a sandwich thesis and includes one manuscript that has been published (Chapter 3), and 2 manuscripts (Chapters 2 and 4) that have been prepared for submission to peer-review journals. As each manuscript was written for publication as a stand-alone document, there is some necessary content overlap between manuscripts. For example, each paper pulls from the same theory, concepts and literature to provide background and rationale for the remaining content of the paper. Despite this overlap, each manuscript provides a unique contribution to the overall thesis document, and to the literature as a whole.

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Chapter 2

Use of theory and motor learning principles in outpatient-based post-stroke walking training research: A scoping review

Authors: Vincent G. DePaul, Laurie R. Wishart, Julie Richardson, Lehana Thabane, Timothy D. Lee

Publication Status: This manuscript has been prepared for, but not yet submitted to the journal *Archives of Physical Medicine and Rehabilitation*.

Summary: This manuscript describes a scoping review of post-stroke, outpatient-based, walking training literature. The aim of this review was to describe the use of theory, and in particular, motor learning theory and research, in current walking-focused stroke rehabilitation literature. The results of this review highlight current deficiencies, and introduce the need for theory-driven research, and the utilization of Motor Learning Principles as a framework for walking-skill training after stroke.

ABSTRACT

Objectives: 1) To describe the current use of theory in outpatient-based, walking-focused stroke rehabilitation research, and 2) to appraise the degree and nature of application of motor learning science-derived principles (MLPs) in this literature.

Data Sources: Electronic data bases (Medline, EMBASE, PubMed, AMED, PsychInfo and CINAHL) (January 1996 - March, 2011); and hand search of reference lists.

Study Selection: Two investigators independently reviewed titles, abstracts and full articles that met the following criteria: 1) controlled and uncontrolled study design; 2) community-dwelling, ambulatory, adults with stroke; 3) walking-focused interventions (i.e. overground, treadmill [with and without support], robotics, and virtual reality); 4) walking-focused outcomes. Twenty-seven studies were selected for final data extraction.

Data Extraction: A standardized data extraction form was used to review selected papers; data was summarized, and themes identified.

Data Synthesis: In the majority of studies, a theoretical framework was not stated. In particular, very few studies were explicitly informed by motor learning science; and adherence to MLPs was inconsistent. MLPs related to specificity, and intensity of practice were partially, or fully adhered to; adherence to MLPs related variability of practice, and guidance varied across treatment modalities; and feedback and order of practice was rarely described.

Conclusions: In this review of post-stroke walking training literature, a minority of studies were explicitly organized around any theoretical framework. In particular, very few studies were explicitly informed by motor learning science, and adherence to MLPs was inconsistent. Future research should evaluate the effectiveness of interventions framed in motor learning science-derived principles.

BACKGROUND

Immediately following a stroke, approximately two thirds of individuals admitted to hospital are unable to walk independently.[1] For many, walking limitations persist long after stroke onset.[2] Researchers and clinicians are challenged to develop, test and apply rehabilitation interventions that optimize walking recovery in this population. Repetitive, task-specific walking training has been recommended as an effective treatment approach following stroke.[3, 4] By definition, task-specific walking training includes goal-oriented, repetitive practice of functional walking, and walking-related tasks.[5, 6] In the literature, overground walking, circuit training, treadmill training, body-weight-supported treadmill training (BWSTT), and robotic-assisted training have all been classified as task-specific treatments. In meta-analyses of effectiveness studies, task-specific training has been shown to be associated with improved walking outcomes after stroke.[6-9] Unfortunately, variation in the interventions tested in these different studies makes clinical translation a challenge. While all interventions include some form of walking, it is not clear that the practice of walking is the sole, or even principal, active ingredient of these complex interventions. In order to design better walking-focused treatments, we must not only ask if task-specific interventions improve walking outcomes after stroke, but also attempt to understand how and why these improvements occur.

A theory is a set of interrelated constructs, formed into propositions that specify the relationship among specific variables, with the overall purpose of explaining a particular phenomena.[10] In the research evaluation of complex interventions, theory can act as an organizing framework for the study; including hypotheses generation, identification of target population, selection of outcomes, and interpretation of results. [10-12] A clear theoretical framework would help plan coherent, post-stroke walking-related rehabilitation studies. Given the fact that stroke rehabilitation is largely focused on the recovery of motor skills, the science of motor learning has been proposed as an ideal theoretical framework for this field of study and practice.[13-15] Motor learning science encompasses a large body of theoretically-related, and experimentally-derived knowledge that can be used to predict the effects of specific practice, instruction, and feedback conditions on motor skill learning.[16] We argue that framing research in motor learning principles (MLPs) will facilitate improved research design and allow for the identification of the essential components of effective walking-focused interventions.

The purpose of this scoping review is to describe the current use of theory in outpatient-based walking-focused stroke rehabilitation research, and in particular, to appraise the degree and nature of application of MLPs in this literature.

METHODS

In this study, scoping review methodology was utilized.[17] A scoping review is a systematic method of mapping key concepts within an area of research by assembling multiple sources and types of evidence. It provides an overview and critical analysis of the existing literature that can be used to identify gaps and direct future research directions.[18] As is typical for scoping reviews, this review does not involve formal critical appraisal of the quality of the included studies, or an assessment of the overall effectiveness of specific interventions. We utilized the scoping review framework originally described by Arksey and O'Malley,[17] and elaborated on by Levac et al.. [19] According to this framework, there are 5 main steps in a scoping review; 1) Identifying the research question, 2) identifying relevant studies, 3) selecting studies, 4) charting the data, and 5) collating, summarizing, and reporting the results of the review.[17, 19]

Step 1: Identifying the research question

This scoping review was guided by the following research questions: 1) "What theoretical frameworks have been used in post-stroke, outpatient-based walking rehabilitation interventions in the literature?" and 2) "How does motor learning science inform current post-stroke walking rehabilitation research."

Step 2 and 3: Identifying Relevant Studies and Study Selection

A search of the literature was conducted using the EMBASE, MEDLINE, PubMed, AMED, and CINAHL databases. As the intention of this review was to describe current thinking in the literature, the search was limited to studies published since January 1st, 1996, until March 11, 2011. Search terms included; gait, stroke, rehabilitation, body weight supported treadmill training, treadmill training, walk training, circuit training, mechanical gait trainers, robotic, virtual reality. The search was limited to English language, adults (≥18 years), and human research. Publications were included if they met the following criteria: 1) were focused on physical practice of walking, 2) interventions targeted walking outcomes, 3) interventions were delivered in an outpatient or community setting, 4) intervention lasted more than one session, and 5) study was published as a full article within a peer reviewed journal. Papers were excluded if the experimental intervention included motor or mental imagery, action observation, or functional electrical stimulation; if the intervention and outcome assessment were completed within a single session; or if the primary outcome involved neuroimaging or brain mapping technology. Two investigators (VD, LW) conducted all steps of the search and study selection process. The reference lists of relevant original research and review articles were hand searched for literature missed in the original search strategy.

Step 4: Charting the Data

Each investigator independently reviewed and summarized 3 papers using a standardized data extraction form. Results were compared and discussed prior to proceeding with independent data extraction of the remaining papers.

Data extraction questions included:

Did the authors explicitly identify a theoretical framework for their specific intervention?

If not explicit, was there evidence of an implicit theoretical framework?

Did the authors explicitly discuss motor learning principles as rationale for their intervention?

Was the intervention described in enough detail to determine a level of adherence to specific motor learning principles?

If able, rate the level of adherence to the specific motor learning principles (Rating Scale: Not described = 0, Low = 1, Moderate = 2, High = 3)

Each paper was reviewed and rated for motor learning principles related to specificity of practice, intensity of practice, variability of practice, practice order, feedback and guidance. If a paper was deemed to be contrary to the stated principle, it was given a low rating (+); a moderate rating (++) was given for partial adherence; and a high rating

(+++) was given if we judged the intervention to adhere fully to the MLP. An intervention was given a ND (not described) rating if there was inadequate description provided to judge adherence. For each paper, the two investigators (VD, LW) discussed any discrepancies in their data extraction and ratings, and came to a consensus on the final data and MLP rating.

Results

Step 5: Collating, summarizing and reporting the results

From the search, 464 titles were identified, and 66 citations were selected for abstract review. On review of abstracts, studies were excluded where the primary aim of the intervention was not to improve walking ability (n=15), training took place in an inpatient setting (n=5), the intervention did not include walking (n=7), participants were not exclusively patients with stroke (n=3), participants were non-ambulatory (n=2), or the intervention was limited to a single day (n=1). 30 papers were included for full data extraction. On review, two papers were excluded as they were found to be take place in inpatient settings, [20, 21] and one case-study was excluded as the target outcome was balance rather than walking.[22] The final review included 14 randomized controlled trials (RCT), 3 RCT protocols, 1 cross-over trial, 1 controlled pilot trial, 7 uncontrolled before-after trials, and 1 case-series paper. All 27 studies focused on ambulatory participants, and the majority (n=21) targeted individuals with chronic stroke (typically greater than one year post-stroke). Interventions included varied-overground-focused walking task practice,[23-30] treadmill training,[31-33] BWSTT,[34-37] treadmill training (with and without body weight support) combined with over ground training,[38-43] robotic-assisted walking training,[44-47] and treadmill training with virtual reality.[48, 49] A description of the studies can be found in Table 1.

Explicit or implicit use of theory

Of the 27 studies that met the criteria for final review, 8 studies [24, 31-33, 36,42, 43, 45] explicitly stated their theoretical framework, or referenced a theory or hypothesis to explain the proposed mechanism of effect of their particular walking-focused intervention. In 17 papers, [23, 25, 26, 28-30, 34, 35, 37-41, 46-49] a framework was implied through the citation of literature or presentation of ideas. In the remaining papers,[27, 44] authors seemed to rely exclusively on empirical evidence of previous effectiveness of the tested interventions, and made no attempt to explain the mechanism underlying the proposed treatment effect.

Investigators utilized one or more of the following theoretical frameworks to justify their walking-focused intervention; exercise science (n=12); use-dependent neuroplasticity (n=11); systems model of walking control (n=6); central pattern generator (CPG) theory of gait control and recovery (n=6); and motor learning science (n=6). Eleven of the 27 papers cited concepts from more than one theoretical framework.

1. Exercise Science

Twelve papers utilized exercise science-related concepts and/or literature as the framework for their interventions and study design.[23, 26, 28-33, 35, 37, 38, 41] In an exercise science framework, post–stroke walking dysfunction is assumed to be partly, or entirely related to limitations in the structure and function of the musculoskeletal, cardiovascular, and/or respiratory systems. This view is rooted in evidence that individuals with stroke exhibit changes in muscle biology, structure and function,[50] and limited cardiorespiratory fitness;[51] and that these impairments are associated with walking performance.[52] This rationale assumes that resolution of these impairments will lead to improved walking ability, performance and participation. As an example, Sullivan et al.[37] built an exercise science informed case around the impact of decreased muscle strength on walking ability after stroke and the proposed benefit of combined walking and strength training on walking outcomes.

2. Use-dependent neuroplasticity

The second most common framework, *use-dependent neuroplasticity*, was cited or implied in eleven papers to explain the proposed link between task-specific walking training and improved walking outcomes.[24, 31-33, 35, 36, 39, 40, 42, 43] In this framework, post-stroke walking dysfunction is assumed to directly result from stroke-related brain tissue damage. Functional recovery is driven by post-injury experiences, including therapy.[53] Based in both animal and human studies, current understanding of the brain's response to experience, training, injury and rehabilitation have been summarized as principles to guide optimal stroke rehabilitation interventions.[54] Some studies cited the related concepts of learned non-use and forced use.[24, 31, 42, 43, 55] Although these concepts have primarily been used in upper-extremity, constraint induced movement therapy,[56] a number of investigators extend this framework to walking-focused training.[24, 31, 42, 43]

3. Central Pattern Generator Theory of Walking Control

Another group of papers utilized the CPG theory of stepping control in walking.[45, 47] According to this theory, a set of neurons (CPGs), located in the spinal cord and subcortical brain areas, are largely responsible for the rhythmic stepping pattern observed in locomotion.[57] This theory is rooted in basic science experiments where stepping behavior was elicited in animals with severed spinal cords. In stroke, it is assumed that the repetitive, specific afferent input elicited through passive or active-assisted, repetitive limb movements, with some weight bearing and specific trunk positioning, will activate these CPG's, elicit stepping movements, and ultimately improve overground walking ability.[57, 58] In our review, this theory was most commonly cited in studies that included BWSTT,[34, 36, 42, 43] and robotic–assisted walking training.[45, 47]

4. Systems model of walking control

A number of the studies utilized a systems model of motor control as a basis for their intervention.[23, 24, 28, 42, 43, 48] Rather than crediting a single anatomical structure or system, the systems model proposes that motor skills, including walking, arise from the contribution of many different systems, internal and external to the person.[59] A hallmark of the systems model is the proposition that motor skills arise from an interaction of the person, characteristics of the task, and features of the environment. How a person walks is influenced by the specific context of the walking task, and the environment in which the person is walking. Although a systems model does not specifically describe how a person will learn, or relearn walking skill, it encourages the consideration of task and environmental context observed during typical, everyday walking when developing a walking intervention. All but one of the interventions that utilized a systems model of walking control included overground walking practice. [23, 25, 28, 42, 43]

5. Influence of motor learning science and adherence to MLPs

Although a major goal of post-stroke walking training is to improve motor skill, a relatively small number of studies (n=6) referred to concepts derived from motor learning science.[34, 36, 39, 43, 46, 49] Despite this lack of explicit reference to motor learning literature, many articles provided adequate description of their interventions for us to assess adherence to specific MLPs related to: a) specificity of practice and whole- task practice, b) intensity, c) practice variability, d) practice order, e) provision of feedback and guidance. In Table 2, we provide a summary of adherence to these MLPs by treatment category. As described in the methods section, adherence was rated low (+), moderate (++), high (+++), or not described (ND).

5 a) Specificity of practice and whole-task practice

Principles: *Motor skill retention is typically enhanced when practice conditions resemble the conditions of later performance (or testing).*[16] *As a continuous task, walking should be practiced as a whole-task.*[16, 60]

According to the motor learning principle of specificity of practice, learning is optimized when the sensory, motor, contextual, and informational processing conditions of practice resemble the conditions of retention and transfer testing.[16] According to a related motor learning concept, continuous tasks, such as walking, are best learned under whole-task, rather than part-task conditions.[16, 60] Interpreted together, post-stroke walking training should include the whole-task of walking, ensuring practice conditions resemble the conditions in which patients will be walking in their daily life. In our review, the majority of papers described their interventions as task-specific, task-related or task-oriented practice, however only one paper cited the MLP related to specificity of practice,[36] and only two papers cited the whole-task practice MLP.[25, 38] On assessment of intervention content, varied overground walking, outdoor walking and virtual reality interventions were deemed to be most adherent to these MLPs, as participants were required to walk under a variety of real or virtual task and environmental contexts. In treadmill and BWSTT interventions, adherence was suboptimal as walking training was not specific to overground environments. For some over-ground focused interventions, time spent practicing the whole task of walking was sacrificed by the inclusion of many non-walking tasks (e.g. sitting), or part-task practice (e.g. weight shift, step-ups) in circuit training stations.[23, 26, 29]

<u>5 b) Intensity</u>

Principle: *Practice should be abundant, progressive and challenging*.[61]

When learning a motor skill, intensity of practice matters.[16, 61] Practice must be sufficiently abundant, progressive and challenging. In a motor learning science framework, challenging practice is that which requires the learner to problem solve, and exert cognitive effort.[62] In this review, all papers provided some description of intensity, however, the description typically focused on exercise prescription concepts, that is, the number of sessions, session duration, and for some interventions, physical effort as measured by heart rate, or blood pressure.[26, 31, 35, 41] A smaller group of studies, including overground and virtual reality interventions, described intensity from a motor learning perspective, with the inclusion of more challenging tasks such as dual task or environmental challenges,[24, 28, 38, 39, 48, 49] or a marker of the amount of task-specific practice (distance or time spent walking, or number of steps taken).[31, 33-35, 38]

5 c) Variable practice

Principle*: The practice of motor skills under a variety of task and environmental conditions typically improves skill retention and transfer to real life activities.* [16]

This motor learning principle arises from the Schema theory of motor skill acquisition. [63, 64] A key prediction of this theory is that the schema, or memory representation of a movement or skill, becomes stronger and more versatile when it is practiced under a variety of conditions. In this review, overground-focused interventions,[23-30] and combined interventions [38-43] consistently included a variety of walking and walking-related tasks within a single session. Almost all treadmill training, BWSTT and robotic training practiced the single task of walking on a treadmill in a constant manner.[31-37, 43-47] In one BWSTT trial,[36] the authors explicitly refer to the MLP of variable practice and assigned one of the treatment groups to practice treadmill walking under variable speed conditions. In virtual reality interventions,[48, 49] participants walked on a treadmill but were required to vary such things as speed, step length, and focus of attention focus, in response to virtual obstacles and environments.

5 d) Order of practice:

Principle: *The effect of variable practice is usually enhanced when tasks are practiced in a non-repetitive (random or serial) order.* [16]

According to Nikolai Bernstein, a pioneer in the fields of motor control and learning, the essence of successful motor skills practice is repeating the *solving* of a movement problem, rather than repeating the *solution* of the problem.[65] Non-repetitive (random or serial) practice of tasks has been proposed to require the learner to engage in repeated motor skill problem solving, strengthening the learning (retention) and transfer of the skill learned.[16] In the majority of papers in our review, practice order was either poorly described, or inconsistent with this MLP. In treadmill, BWSTT and robotic training, practice was constant, and therefore, blocked. For overground circuit training interventions order of practice stations was not clearly described.[23, 24, 26-30] It seemed that participants spent a *block* of time practicing a single task, for example stepping up and down a step, and then moved to the next task, never to return to the stepping station. In the one paper that was explicit about organizing practice in a random order,[49] participants walked through a virtual neighbourhood with other pedestrians, cars driving past them, and a random configuration of buildings. Despite apparent consistency with the principle, the authors did not specifically cite motor learning literature as rationale for the structure of their virtual environment.

5 e) Feedback and guidance:

Principle: *When provided, augmented feedback should be informational.[16] Augmented feedback and physical guidance should be provided in a manner that allows the learner to experience and attempt to correct errors during practice. Excessive guidance can degrade learning.[16, 66]*

In motor learning studies, augmented feedback is most beneficial when it includes information that can be used to improve subsequent performances.[16, 66] While feedback can facilitate learning, low frequency feedback and limited physical guidance typically results in better learning outcomes than high frequency feedback and constant guidance.[16] According to the guidance hypothesis, excessive feedback and physical guidance can prevent individuals from learning to evaluate and correct their own performances once feedback and guidance are withdrawn.[66, 67]

Of the 27 studies in our review, more than half of the papers [25-33, 36, 37, 40, 44, 48] failed to describe how feedback was provided. For the remaining papers, adherence with the MLP was variable. In some BWSTT and robotic interventions, participants received intermittent, knowledge-of-results feedback on walking speed,[38, 39, 41] while others provided frequent and concurrent knowledge of performance feedback related to gait pattern using computer displays and mirrors.[34, 42, 45, 47] Only one study was explicit in the application MLP related to feedback, resulting in a well-described protocol of weaning feedback frequency and encouraging self-evaluation of performance.[43]

Description of the frequency, amount, and timing of physical guidance was treatment modality dependent. For studies that included BWSTT and robotic interventions, guidance was an integral component of the intervention and described in some detail. [34-37, 40-47] In the majority of these papers, the apparent aim of guidance was to facilitate high repetitions of a more normal, gait pattern. Despite this tendency toward a ‘perfect practice’ approach, the guidance hypothesis, and the importance of variability during practice, was cited as rationale for the superiority of therapist-assisted BWSTT over robotic-assisted training,[34, 47] and as support for the development of an assist-as-needed robotic device.[46] Of the papers in our review, the overground interventions, particularly group circuit training, were most consistent with the guidance principle. Despite their apparent adherence to this principle, these papers failed to cite the guidance literature as rationale for their interventions.

Discussion:

An explicit theoretical framework can be helpful as a guide to research design, and to allow hypothesis development and testing regarding the essential elements of effective rehabilitation interventions.[12, 68] We submit that the principles derived from motor learning science are ideally suited for use as the theoretical framework for post-stroke walking-skill training research. We undertook this scoping review to identify which theoretical frameworks, if any, have been used to explain the apparent effects of task-specific walking training after stroke, and to specifically assess the current application of MLPs in this field.

Lack of a clear theoretical framework impacts interpretation of research

In this review, we found that a minority of investigators were explicit in their statement of a theoretical framework. For most studies, a framework was inferred based on ideas presented and papers cited. Whether explicit or implicit, task-specific walking training seemed to be informed by a diverse range of theories, concepts and research-based knowledge related to the normal control of walking, the underlying causes of post-stroke walking dysfunction, and the conditions required for walking recovery after stroke.

A number of authors incorporated concepts from two, or even three different theoretical frameworks. For example, treadmill papers cited concepts related to both exercise science and use-dependent neuroplasticity.[31-33] These papers represent an explicit theory-driven program of research rooted in a multi-systems model of post-stroke walking dysfunction in which treadmill training is proposed to improve walking function by promoting central neural, peripheral muscle and cardiovascular adaptations.[31] In this case, the chosen frameworks are synergistic in how they inform the development of a repetitive, task-specific, prolonged and intense intervention. In other papers, the concepts and theories cited may have had a conflicting influence on intervention design. For example, a number of studies cited the CPG theory of gait control as well as MLPs related to guidance,[34] feedback,[43] and variable practice.[36] According to CPG theory, the repetition of the symmetrical gait cycle in BWSTT allows for very specific sensory input, and subsequent activation of the spinal and subcortical neurons and the expression of the stepping pattern.[58] In this model, cognitive engagement during practice is unnecessary and perhaps counter productive. On the contrary, an underlying principle of motor learning is that learning requires, and is enhanced by cognitive effort on the part of the learner.[62] The impact of limiting guidance, delaying or decreasing feedback, and to some degree, varying practice,[64] all take advantage of the proposed benefit of cognitive effort on learning.

In general, careful consideration of the implications of selected theoretical framework would improve the design and evaluation of interventions, making interpretation of study results easier for clinicians and other researchers.

Limited impact of motor learning science on walking-training research

In our review, we found that very few studies cited motor-learning science-derived principles as a framework for the content and structure of their interventions. Given the presumed walking-focused nature of the interventions selected for this review, it is not surprising that specificity of practice was the most consistently adhered to MLP, however, degree of adherence seemed to depend on the investigators' definition of the task of walking. Authors that defined walking in terms related to the repetition of the normal gait cycle were more likely to include treadmill walking or repetitive, robotic-assisted stepping as the sole, or primary walking task within their intervention.[34, 43, 44, 46, 47] Investigators who defined walking in relation to the typical task and environmental demands associated with everyday walking, were more likely to include practice of walking under different conditions.[25, 26, 28, 30, 38-40, 42, 48]

The terms task-specific, task-related and task-oriented are frequently used interchangeably in the literature. We would recommend that task-specific be reserved for practice that includes actual overground walking, ideally in a variety of realistic settings. Treadmill, robotic, or circuit training that emphasize walking-related exercises over actual walking, would be more accurately described as task-related or task-oriented training.

Despite an acknowledgement in the broader literature of the importance of the MLP of abundant practice in rehabilitation,[69, 70] description of practice intensity was frequently limited to exercise prescription parameters. Only one study reported the number of steps taken during sessions.[35] The availability of step activity monitors and other remote monitoring technology make it feasible to quantify supervised and unsupervised walking practice.[71] This data would allow investigators to more accurately describe the components of interventions, and comment on the relative impact of ingredients, such as amount of task-specific practice, on treatment outcomes.

Although few papers in our review gave explicit consideration to the MLPs related to feedback, guidance and error experience, there has been increase attention to this topic in engineer-driven field of rehabilitation robotics.[46, 72] In the experimental, guidance-as-needed paradigm, a certain bandwidth of performance error is allowed before the robot assists the patient in the completion of the desired movement or task.[46, 73] This acceptance of some degree of variability and error during training seems to represent a re-evaluation of the previously held assumption that more perfect-practice of the gait cycle would lead to better outcomes.[74]

In a number of cases, interventions were deemed to be consistent with MLPs however adherence seemed to be unintentional. For example, as a result of higher patient-to-therapist ratios, group-based circuit training interventions were assumed to provide limited, if any, hands-on guidance, and require participants to experience error and solve motor problems independently. Despite relatively high adherence, there was no explicit consideration of this MLP in these papers. Similarly, in overground interventions, practice of a variety of walking related tasks was integral to the intervention, however there was no evidence that such practice was based in MLPs.

Facilitating interpretation of complex rehabilitation intervention trials

The results of this scoping review confirmed the complex-nature of task-specific walking training interventions. The process of reviewing each study and treatment through the lens of MLPs highlighted the presence of between-intervention similarities and differences in practice content, practice schedule, intensity and challenge level, and tolerance for movement errors. In addition to informing the development and organization of interventions and research, a clear theoretical framework, such as motor learning science, can facilitate better interpretation of study results, and plan follow-up studies.[75] For example, in the recently published LEAPS (Locomotor Experience Applied Post-Stroke) trial,[76] investigators found no significant difference in the effect of an early-BWSTT program, a late-BWSTT program, and a supervised home exercise program. While the no-difference result is an important finding, the meaning and implications of this finding are not clear. Did these two seemingly different interventions improve walking function through similar or different treatment mechanisms? Was there a common, essential element in both interventions that led to the improvements? In a follow-up commentary, LEAPS investigators emphasized the need to better describe the components of task-specific training in order to judge their relative contribution to outcomes. [77] We would argue that motor learning science provides an ideal theoretical framework for identifying and evaluating the individual and combined contributions of the multiple, potentially active variables within complex walking training interventions after stroke.

Limitations

The most significant limitations of this review relate to the chosen methodology, including our approach to theory identification. If not explicitly stated, we were forced to either assume that no theoretical framework was used, or to attempt to deduce what framework was utilized. These conclusions may have been erroneous. Absence of an explicit presentation of a theoretical framework does not necessarily mean that theory was not used in the study development stage. Limited discussion of theory may be more representative of a space-allocation issue rather than lack of investigator utilization of theory in the research process. We would argue that the identification of a theoretical framework, and explanation of how that framework drove intervention development and research design decisions, should be considered a priority by authors and editors.[75] The increasing practice of publishing rehabilitation trial protocols provides an opportunity to state theoretical framework, as well as allowing space to describe experimental and control interventions in adequate detail to allow interpretation and duplication. At the outset of this paper, we indicated that the intention of this review was to focus on the rationale and content of the studies in the field, and not to make comment on the effectiveness of the interventions under examination. As such, we are unable to conclude that the application of theory and MLPs would result in more effective interventions without evidence from experimental and pragmatic clinical studies.

Conclusion

This scoping review of post-stroke walking rehabilitation has highlighted the variability that exists within the literature. Variability in approach to training seem to reflect differences in explicit or implicit understanding of the mechanisms of the motor-control of walking, post-stroke walking dysfunction, and the relationship between walking training and walking recovery. In our assessment, the most coherent interventions and study designs included a clear statement of theoretical framework. It is possible that the gap between current and optimal post-stroke walking recovery outcomes could be narrowed through a greater understanding of, and control over, the active ingredients of task-specific interventions. We propose that motor learning science provides an ideal framework for exploration and evaluation of these active ingredients. In our review, explicit consideration, and adherence to these principles was atypical in the walking training literature. In order to assist clinicians in making informed clinical decisions, it is important that future laboratory-based experiments and randomized clinical trials evaluate the impact of motor-learning-science informed interventions on post-stroke walking outcomes.

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Table 1: Description of studies by intervention category

Study	Design	Participants	Experimental Intervention	Control Intervention	Outcomes
Overground training					
Dean (2000)	RCT n=12	Chronic ≥ 3months	Group circuit, 5 walking, 7 walking-related tasks; 12 sessions in 4 weeks	Seated, upper-extremity group circuit training	Gait speed, endurance, gait quality, exercise tolerance, mobility
Fritz (2007)	Case series n=8	Chronic ≥ 6months Berg ≤45/56	Varied task practice; Walking, standing, and sitting activities x 3 hours, 10 sessions over 2 weeks	N/A	Gait quality, balance, falls efficacy, mobility
Lord (2008)	RCT n=36	Subacute; Limited outdoor ambulator	Whole-task, community walking with PT assistant, Progressive, challenging; 14 sessions/7 weeks	Clinic-based "Motor Relearning Program"; part + whole-task	Gait speed, endurance, self-efficacy Health related Quality of Life
Michael (2009)	Before-after n=10	Chronic (mean 7.5 years) asymmetric gait	Circuit, group; 2 walking, 15 walking-related Progression: intensity, duration, complexity; 72 sessions over 6 months	N/A	Balance, mobility, gait endurance, exercise tolerance, falls efficacy, step activity monitor
Mudge (2009)	RCT n=60	Chronic ≥ 6months walking deficit	Group circuit – 15 stations (3 walking + 12 walking-related); Progressive; 12 x 50 min/ 4 weeks	Group social and education sessions – 8 x 90 min. sessions	Step activity, gait speed, endurance, self-efficacy, self-reported mobility and global function
Salbach (2004)	RCT n=91	≤ 1 year of stroke	Circuit – 9 walking + 1 walking-related stations – Progression: complexity, reps; 18 sessions / 6 weeks	Seated upper extremity task circuit training (18 sessions)	Gait endurance, gait speed, balance, balance self-efficacy
Scianni (2010)	RCT n=40	≤ 6 months since hospital discharge, gait speed 0.4 to 0.8 m/s, weakness	Circuit training- 3 whole task + 7 part-task stations, with strength training; Progressive 30 sessions/ 10 weeks	Circuit training walking-related stations without strength training	Strength, coordination, Gait speed, gait quality, quality of life
Van de Port (2009)	RCT(p) n=220	Sub-acute; FAC ≥ 3	Group Circuit – 4 walking + 4 walking- related stations; Progress complexity, repetitions, work; 24 x 90 min/12 weeks	Usual care one-to-one physiotherapy	Self-reported mobility, quality of life, strength, endurance, speed, falls, cost, efficacy, fatigue, anxiety, depression
Virtual Reality					
Yang (2008)	RCT n=24	Chronic ≥ 6 months, FAC 2-3	Treadmill training with virtual reality; 9 x 20 min. sessions over 3 weeks Progression: task complexity, speed	Treadmill training, without virtual reality (9 sessions)	Gait speed, community walking test, self-reported walking ability, balance self-efficacy
Walker (2010)	Before-after n=7	Post-rehab, < 1 year post-stroke	BWSTT with virtual reality 12 sessions over 6 weeks Progressed duration, speed	N/A	Functional gait assessment including gait speed, balance, treadmill speed
Treadmill					
Macko (2005)	RCT n=61	Chronic > 6months	TT, progressed aerobic demand 3x/week x 6 months; 72 sessions Aerobic intensity 60-70% HRR	Stretching with 5 minutes of low-intensity treadmill (72 sessions)	Exercise capacity - VO_2 peak, gait speed, endurance, self-reported mobility
Patterson (2008)	Before-after n=39	Chronic, > 6 months	TT, progressed aerobic demand 3x/week x 6 months (72 sessions) Aerobic intensity 60-70% HRR	N/A	Exercise tolerance, gait speed, endurance, gait quality
Silver (2000)	Before-after n=5	Chronic > 6months	TT, progressed aerobic demand 3x/week x 3 months (36 sessions) Aerobic intensity 60-70% HRR	N/A	Functional mobility, gait speed, gait quality

RCT = randomized controlled trial, RCT(p)=RCT protocol, Before-after = Before-after study design, BWS = body weight support, TT = treadmill training, m/s = metres per second, min.= minutes, m=metres, mph = miles per hour, HRR=heart rate reserve, PT = physical therapist, FAC = Functional Ambulation Classification

Table 1: Description of studies by Intervention category (cont'd)

Study	Design	Participants	Experimental Intervention	Control Intervention	Outcomes
BWSTT					
Hornby (2008)	RCT n=48	Chronic, > 6months, gait speed ≤ 0.8 m/s MMSE > 23/30	BWSTT, 12 x 30 min. session/ 4 weeks; Progression: BWS, speed	BWSTT with mechanical gait trainer for leg movements	Gait speed, quality, + endurance, balance, self-report mobility + participation, strength, tone, depression
Moore (2010)	Cross-over trial n=20	Chronic, ≥ 6 months, gait speed ≤ 0.9 m/s	BWSTT, 2 – 5 sessions/week x 4 weeks, PT assist to increase intensity not to correct stepping pattern	Period of no-treatment used as control	Gait speed, endurance, efficiency balance, exercise tolerance, treadmill speed, functional mobility
Sullivan (2007)	RCT, n=80	Chronic, ≤ 5 years, gait speed ≤ 1.0 m/s	BWSTT, with arm or leg ergometer, or strengthening, 24 sessions; Progress: BWS, speed	Arm Ergometer with Strength Training	Gait speed, endurance, motor recovery, balance, quality of life, strength
Sullivan (2002)	RCT n=24	Chronic > 6 months	BWSTT, Fast speed (≥ 2 mph); 12 sessions over 5 weeks, Progress: BWS, speed;	BWSTT-variable speed, (0.5-2.0 mph), BWSTT–slow (0.5 mph)	Gait speed
Robotics					
Dias (2007)	RCT n=40	Chronic > 12 months	Mechanical gait trainer + BWS + Therapist assist; 40 min. sessions x 25 over 5 weeks	Balance and gait training (Bobath) 25 sessions	Motor control, balance, gait speed, endurance, mobility, global function
Westlake (2009)	RCT n=16	Chronic, > 6 months, gait speed ≥ 0.3 m/s	Robotic gait training with BWS; 12 sessions over 4 weeks; Progress: speed, BWS	BWSTT with therapist assist, 12 sessions Similar progression protocol	Gait speed, gait quality, endurance, balance, motor control, functional mobility, quality of life
Banala (2009)	Before-after n=2	Chronic >2 years,	BWSTT with robotic assist + visual FB Assist as needed program; 15 sessions over 6 weeks	N/A	Biomechanical measures of gait pattern, foot trajectory, lower extremity joint angles during training,
Hilder (2009)	RCT n=63	Rehab ≤ 6 months, gait speed 0.1 – 0.6m/s	Robotic gait training with BWS: Progress: speed, BWS, assist; 24+ sessions over 10 weeks	Traditional over-ground gait and pre-gait training, with up to 15 minutes of treadmill training	Gait speed, endurance, cadence, balance, functional mobility, motor control, quality of life and participation
Combined					
Ada (2009)	RCT (p) n=210	Chronic, < 5 years, gait speed ≤ 1m/s	TT and overground. 24 sessions over 2 months. Progress: speed, incline, dual task, increased overground. Metronome + FB to increase step length	Same Treadmill and Overground intervention however 48 sessions in 4 months.	Gait endurance, speed, gait quality, quality of life, falls efficacy, self-reported functional mobility and participation
Ada (2003)	RCT n=29	Chronic 6 months-5 y, gait speed ≤1.2 m/s	TT and overground. 12 sessions over 4 months. Progress: as for Ada (2009)	Low intensity unsupervised home exercise with telephone check-up	Gait speed, endurance, quality of life, gait quality
Duncan (2007)	RCT (p) n=400 3 groups	Subacute – ≤ 30 days, Speed < 0.8 m/s	BWSTT with overground. 36 x 90 min. over 12 weeks. Initiated at 2, or 6 months. Progress: speed, BWS, dual task	PT Supervised Home exercise – flexibility, strength, 36 x 90 min. sessions, 2 months post-stroke	Gait speed, endurance, step activity, motor control, FAC, quality of life and participation, self-efficacy, depression
Jorgensen (2010)	Before-after n=14	Subacute ≤ 3months, Able to perform 6MWT	Combined intervention - BWSTT, aerobic ergometer, Strength training, Functional training	N/A	Cardiac vital signs, gait speed, endurance, aerobic capacity
Plummer (2007)	Before-after n=7	3 – 7 months post-stroke, Gait speed ≤ 0.8 m/s	BWSTT with overground. 36 x 30 min.in 12 weeks Progress: speed, BWS, dual task.	N/A	Gait speed, gait quality, step activity, endurance, motor control, balance self-efficacy, quality of life, participation
Trueblood (2001)	Pilot studies n = 13	Chronic-mean 9.8 months	BWSTT progressing to overground walking. 24 x over 8 weeks. BWS ≥ 40%. Progress: speed, BWS	Not described	Gait quality and muscle activation and timing during gait

RCT = randomized controlled trial, BWS = body weight support, TT = treadmill training, m/s = metres per second, min.= minutes, m=metres, mph = miles per hour, HRR=heart rate reserve, PT = physical therapist, FAC = Functional Ambulation Classification

Table 2: Theoretical framework and adherence to motor learning principles

Study	Theoretical Framework	Theory Explicit or Implied	Specificity	Intensity	Variable practice	Order of Practice	Feedback	Guidance
Overground								
Dean (2000)	Systems model, Exercise science	Implied	++	++	+++	ND	++	ND
Fritz (2007)	Neuroplasticity, (Forced use)	Explicit	++	+++	+++	ND	+	ND
Lord (2008)	Systems model	Explicit	+++	++	+++	ND	ND	ND
Michael (2009)	Exercise science	Implied	++	+++	+++	+	ND	++
Mudge (2009)	No recognizable theory	No theory	++	+	+++	ND	ND	++
Salbach (2004)	Systems model, Exercise science	Implied	+++	+++	+++	ND	ND	ND
Scianni (2010)	Exercise science	Implied	++	++	+++	ND	ND	ND
Van de Port (2009)	Exercise science	Implied	+++	+++	+++	ND	ND	++
Virtual Reality								
Yang (2008)	Systems model	Implied	+++	++	+++	ND	ND	++
Walker (2010)	Neuroplasticity, Motor Learning (cognitive effort)	Implied	+++	+++	+++	+++	++	++
Treadmill								
Macko (2005)	Exercise science, Neuroplasticity	Explicit	++	+++	+	+	ND	++
Patterson (2008)	Neuroplasticity, Exercise science	Explicit	++	+++	+	+	ND	++
Silver (2000)	Exercise Science, Neuroplasticity	Explicit	++	++	+	+	ND	++
BWSTT								
Hornby (2008)	CPG theory Motor learning (Guidance)	Explicit	++	++	+	+	+	++
Moore (2010)	Neuroplasticity; Exercise science	Implied	++	+++	+	+	ND	++
Sullivan (2007)	Exercise science	Implied	++	++	+	+	ND	+
Sullivan (2002)	CPG theory, Neuroplasticity, Motor learning (variability)	Explicit	++	++	+	+	ND	+

Motor learning principle rating scale: ND = not adequately described, + = low adherence, ++ = moderate adherence, +++ = high adherence; CPG = Central pattern generator; FB = Feedback

Table 2: Theoretic framework and adherence to motor learning principles (cont'd)

Study	Theoretical framework	Theory Explicit or Implied	Specificity	Intensity	Variable practice	Order of Practice	Feedback	Guidance
Robotic								
Dias (2007)	No recognizable theory	No theory	++	++	++	+	ND	+
Westlake (2009)	CPG theory	Explicit	++	++	+	+	+	+
Banala (2009)	Motor learning (Guidance)	Implied	++	++	+	+	++	++
Hilder (2009)	CPG theory	Implied	++	++	+	+	+	+
Combined								
Ada (2009)	Exercise science	Implied	+++	+++	+++	ND	++	++
Ada (2003)	Motor Learning (whole-task), Neuroplasticity (Forced-use)	Explicit	+++	++	+++	ND	++	++
Duncan (2007)	Neuroplasticity	Implied	+++	+++	+++	ND	ND	++
Jorgensen (2010)	Exercise science	Implied	++	+++	++	+	+++	+
Plummer (2007)	CPG theory, Systems model, Neuroplasticity (Forced-use)	Explicit	+++	+++	+++	ND	+	+
Trueblood (2001)	CPG theory, Systems model, Neuroplasticity (Forced-use), Motor learning (FB + Guidance)	Explicit	++	++	++	+	+++	++

Motor learning principle rating scale: ND = not adequately described, + = low adherence, ++ = moderate adherence, +++ = high adherence; CPG = Central pattern generator; FB = Feedback

Chapter 3

Varied overground walking-task practice versus body-weight-supported treadmill training in ambulatory adults within one year of stroke: a randomized controlled trial protocol

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Publication status: This manuscript has been published in BMC Neurology.

Citation: DePaul VG, Wishart LR, Richardson J, Lee TD, Thabane L. Varied overground walking-task practice versus body-weight-supported treadmill training in ambulatory adults within one year of stroke: a randomized controlled trial protocol. BMC Neurology 2011, 11:129. http://www.biomedcentral.com/1471-2377/11/129

Summary: In this manuscript, the randomized controlled trial protocol is presented. In the previous manuscript, the scoping review highlighted the need for theoretically-framed research trials and specifically recommended use of the motor learning principles as a framework for intervention development. This protocol paper describes work that begins to fill this gap in research and practice. The manuscript outlines the rationale and methodology for a unique trial in which two interventions, based in different theoretical-frameworks, are compared. A detailed description of the experimental intervention, the Motor Learning Walking Program is also provided.

ABSTRACT

Background: Although task-oriented training has been shown to improve walking outcomes after stroke, it is not yet clear whether one task-oriented approach is superior to another. The purpose of this study is to compare the effectiveness of the Motor Learning Walking Program (MLWP), a varied overground walking task program consistent with key motor learning principles, to body-weight-supported treadmill training (BWSTT) in community-dwelling, ambulatory, adults within 1 year of stroke.

Methods/Design: A parallel, randomized controlled trial with stratification by baseline gait speed will be conducted. Allocation will be controlled by a central randomization service and participants will be allocated to the two active intervention groups (1:1) using a permuted block randomization process. Seventy participants will be assigned to one of two 15-session training programs. In MLWP, one physiotherapist will supervise practice of various overground walking tasks. Instructions, feedback, and guidance will be provided in a manner that facilitates self-evaluation and problem solving. In BWSTT, training will emphasize repetition of the normal gait cycle while supported over a treadmill, assisted by up to three physiotherapists. Outcomes will be assessed by a blinded assessor at baseline, post-intervention and at 2-month follow-up. The primary outcome will be post-intervention comfortable gait speed. Secondary outcomes include fast gait speed, walking endurance, balance self-efficacy, participation in community mobility, health-related quality of life, and goal attainment. Groups will be compared using analysis of covariance with baseline gait speed strata as the single covariate. Intention-to-treat analysis will be used.

Discussion: In order to direct clinicians, patients, and other health decision-makers, there is a need for a head-to-head comparison of different approaches to active, task-related walking training after stroke. We hypothesize that outcomes will be optimized through the application of a task-related training program that is consistent with key motor learning principles related to practice, guidance and feedback.

Trial Registration: ClinicalTrials.gov # NCT00561405

Funding: Ontario Stroke System/MOHLTC Grant #06356

BACKGROUND

Every year an estimated 9 million new stroke events occur globally, and an additional 30.7 million individuals live with the ongoing effects of stroke [1]. Decreased ability to walk is one of the most common and debilitating functional limitations following stroke [2-4]. Although the majority of adults with history of stroke recover some ability to ambulate independently following rehabilitation [2], many individuals experience long term residual limitations in walking speed [5,6], endurance [6] and walking-related self-efficacy [7,8]. Between 27% and 50% of community dwelling individuals report difficulty walking outside of their homes for months and years following stroke onset [6,9-11]. In the face of these difficulties, independent walking remains one of the most frequently-stated goals of stroke rehabilitation [12], with 75% of individuals identifying the ability to walk in the community as a priority in living at home [10]. Given these challenges, stroke-rehabilitation clinicians and researchers are compelled to apply and evaluate interventions that optimize the recovery of walking skill and participation in community mobility related activities.

According to recent stroke-rehabilitation reviews and practice guidelines, optimal walking recovery may be realized through the application of a task-related walking training approach [13-15]. In the literature, the term task-related walking practice generally refers to any intervention where walking or walking-related tasks are practiced using a functional approach [16]. Alternate terms include task-specific [13,17], task-oriented [18,19], and task practice [14,20,21]. Although the specific content of interventions varies, they are all based on the premise that in order to optimally improve walking skill, one must practice walking. Training protocols include walking tasks performed overground, on a treadmill, or both. Two of the most common interventions described in the stroke-rehabilitation literature include practice of a variety of primarily overground walking-related tasks [16], and body-weight-supported treadmill training (BWSTT) [22].

Varied Overground Walking-task Training

Rooted in movement science, including motor learning research, Carr and Shepherd were early advocates of task-related walking practice after stroke [23]. They emphasized the importance of patient engagement in abundant, active practice of the whole task of walking. In addition, they promoted the practice of varied walking-related tasks organized in a circuit of stations. A small number of controlled studies have evaluated the effectiveness of this varied task practice approach in community-dwelling adults with stroke history [19,24,25]. These studies differ in quality, intervention content and effect on walking performance. In a small-sample pilot study by Dean and colleagues [24], 12 individuals with chronic stroke were randomized to a varied task-related training protocol, including overground walking, treadmill walking, and walking-related tasks (e.g. heel raises, step-ups, narrow base standing), or to a control intervention (upper-extremity task training). The experimental group improved walking endurance and speed more than the control group, however, the authors failed to discuss the implications of the relatively high proportion of participants who did not complete the study (n=3). In a larger trial, 91 individuals within one year of stroke were randomized to receive 18 sessions of varied walking-related task practice, or upper-extremity task practice performed in sitting [19]. The experimental intervention included practice of walking tasks (i.e. stand up and walk, walking along a balance beam, walking backwards, walking while carrying, walking with speed, stairs and walking on a treadmill) and walking-related tasks (i.e. step-ups, kicking a ball). Following treatment, the walking group demonstrated significantly greater changes on the 6-minute walk test [35 m more than control, 95% confidence interval (CI) 7, 64], gait speed (0.11 m/s more than control, 95% CI 0.03, 0.19) and walking-related self-efficacy. In a more recent trial, 58 adults with chronic stroke were assigned to a 12-session walking-related task training protocol or to a non-exercise control intervention [25]. In this study, only 4 of the 15 stations involved walking while the remaining stations focused on strength and balance tasks in standing or sitting. The authors reported that the experimental group demonstrated modest, but statistically greater gains on the 6-minute walk test (19 m, p=0.03) compared to the control group.

Based on this literature, variable practice of walking and walking-related activities in a circuit format is associated with greater improvements in gait speed, endurance and walking self-efficacy than a non-walking control intervention such as upper-extremity task practice. To date we do not know if this approach is superior to an alternate walking-focused treatment.

Body Weight Supported Treadmill Training

BWSTT is rooted in the central pattern generator (CPG) theory of gait control and recovery [26]. The theory proposes that gait is largely controlled by a set of neurons located primarily at the spinal level [27], and these CPG's can be activated through the afferent input associated with typical gait through passive or assisted limb movements, weight shift, and postural alignment [26-28]. Mass repetition of these movements is thought to result in neural reorganization and subsequently improve capacity for overground walking in individuals with history of stroke [29,30]. As described in the literature, BWSTT requires the use of specialized body weight support equipment, a treadmill and the assistance of one to three trainers [22]. While recommended in opinion papers and reviews [31,32], when planning our study we found only 3 controlled trials that have evaluated the effectiveness of BWSTT in community dwelling individuals post-stroke [17,33,34]. In 2002, Sullivan randomized 24 individuals with chronic stroke to one of three BWSTT protocols; fast speed, variable speed and slower speed [33]. After 12 sessions, participants who trained at fast speeds improved overground velocity by 0.08m/s more than those who trained at slow speeds ($p=0.04$). In a larger RCT, 80 individuals with chronic stroke were assigned to one of the four combined treatment protocols; BWSTT and arm ergometer, cycling and arm ergometer, BWSTT and lower extremity strength training, and BWSTT and cycling [34]. The group that received alternating sessions of BWSTT and arm-ergometer exercise (12 sessions each over 6 weeks) improved overground gait speed by 0.12 m/s ($p<0.01$) more than those who received the cycling and arm-ergometer program. There were no significant differences between the change scores of the different BWSTT interventions. Finally, in a recent repeated-measures, randomized crossover study [17], 20 adults with chronic stroke and recently discharged from physical therapy were assigned to receive either 12 sessions of BWSTT followed by 4 weeks of no treatment, or 4 weeks of no treatment then 12 sessions of BWSTT. Improvements in gait speed, gait efficiency (O_2 cost) and daily stepping activity were observed after BWSTT treatment periods and not following the no-treatment periods. Based on these small-sample controlled trials, approximately 12 sessions of BWSTT seems to be more effective than a no-treatment control intervention or a non-walking intervention such as cycling. In addition, improvements seem to be optimized when participants train at speeds greater than their typical overground walking speeds. To date the effectiveness of BWSTT has not been evaluated against an alternate program of overground walking-focused training in community dwelling adults with history of stroke.

In summary, varied overground-focused walking practice and BWSTT have been shown to result in greater improvements in walking speed, endurance and/or self-efficacy when compared to non-walking interventions (i.e. arm and hand exercises, cycling). These two walking task-related interventions are different in theoretical rationale as well as in content. In the case of BWSTT, the rationale is clear - repetition of the normal stepping pattern of gait activates the locomotor CPG's and results in improved overground walking. Practice is constant and blocked, guidance is provided liberally, and the use of the treadmill environment allows for the repetition of a more normal gait pattern thought to be necessary to activating the CPG's [17,33,34]. In varied overground-focused walking practice, the theoretical premises for learning are less defined. While all studies implicitly apply the motor learning principle of specificity of practice, these overground-focused walking task training interventions fail to take full advantage of decades of behavioral motor learning research that have identified optimal learning conditions in healthy adult and rehabilitation populations [35]. For example, based on this research, retention and transfer of learned skills are typically enhanced if practice is abundant, variable, and organized in a random rather than blocked order. Learning is typically optimized if augmented feedback is delayed and intermittent rather than immediate and continuous and if physical guidance is not excessive but allows learners to experience and attempt to correct their own errors. Although the overground-focused task-related training interventions include variable practice of walking tasks that resemble typical walking conditions, order of practice is blocked, and feedback schedule is not described [19,24,25]. We suggest that the impact of task-related walking training will be more fully realized if the content and structure of interventions are consistent with these key motor learning principles.

The purpose of this randomized controlled trial is to compare the impact of the Motor Learning Walking Program (MLWP), a 15-session program of varied overground walking-task training consistent with key motor learning principles related to practice, guidance and feedback, to 15 sessions of BWSTT on walking performance in community-dwelling, ambulatory adults within 12 months of stroke onset.

It is our hypothesis that participants assigned to the MLWP group will demonstrate greater scores in comfortable gait speed and secondary outcome measures at post intervention and follow-up assessments.

METHODS/DESIGN

Design Outline

This study is a prospective, randomized, single blind, balanced parallel-group (1:1) superiority trial with stratification by baseline comfortable gait speed (<0.5 m/s and ≥ 0.5 m/s). The design includes concealed allocation during recruitment and screening, blinded outcome assessment and intention to treat analysis. Refer to Figure 1 for study design diagram.

Ethics

All study activities have been approved by the Research Ethics Boards of St. Joseph's Healthcare Hamilton (#6-2753), the Hamilton Health Sciences/Faculty of Health Sciences McMaster University (#07-054), and Joseph Brant Memorial Hospital, Burlington, Ontario.

Participants

The target population of this trial is community-dwelling, ambulatory older adults with mild to moderate stroke-related walking dysfunction within twelve months of most recent stroke onset. In contrast to most previous trials [17,24,25,33,34], time since onset was limited to less than one year as it represents the period when patients are most likely to access community-based rehabilitation interventions. Seventy participants will be recruited from clients about to be discharged from inpatient acute and rehabilitation units and outpatient programs at two teaching hospitals in Hamilton, Ontario, Canada (St. Joseph's Healthcare Hamilton and Hamilton Health Sciences) and one community hospital, Joseph Brant Memorial Hospital, in the neighbouring community of Burlington. We expect that treating physiotherapists and other clinicians will refer the majority of potential participants; however, some individuals may self-refer in response to community advertisements. Following screening, individuals will be invited to participate if they meet the following criteria: 1) living in the community at time of entry into study, 2) at least 40 years old, 3) within 12 months of onset of a physician diagnosed ischemic or hemorrhagic stroke in any brain location (with or without evidence from diagnostic imaging), 4) able to walk 10 m without assistance with self-selected gait speed < 1.0 m/s (or typically use a walking aid), 5) able to follow a 2-step verbal command, 6) independent with community ambulation prior to most recent stroke, and 7) receive physician approval to participate in the study. Individuals with history of more than one stroke who meet all other inclusion criteria will be included in the study. Individuals will be excluded if they present with: 1) marked cognitive impairment (i.e. Mini Mental Status Exam < 24/30 or score less than predicted according to age and education level) [36], 2) severe visual impairment, 3) lower extremity amputation, 4) presence of serious unstable cardiac, medical or musculoskeletal conditions that would limit safe participation in walking exercise (as determined by physician screening and baseline assessment interview).

Randomization

Participants will be randomly allocated to the two active intervention groups using a fixed allocation ratio of 1:1. Consistent with previous studies in this area [19,33], we anticipate the response to both training programs to be associated with pre-treatment walking ability and participants will be stratified by baseline comfortable gait speed (slow < 0.5 m/s and fast ≥ 0.5 m/) to minimize group imbalances on this variable [37]. In order to maintain recruitment balance between groups throughout the trial, a permuted block randomization process will be used within each strata using block sizes of at least 2 with all blocks divisible by 2 [38]. The randomization creation process (including block sizes) and resulting schedule will be set, held and managed by a central randomization service (Biostatistics Unit at St. Joseph's Healthcare Hamilton). Group assignment will be communicated by email to the research coordinator on a single participant basis after screening, written informed consent, and baseline assessments have been completed.

Interventions

Experimental Intervention: Motor Learning Walking Program (MLWP)

The Motor Learning Walking Program is a program of varied overground walking-task practice based on theory and research from the fields of motor control, motor learning, neuroplasticity, and stroke rehabilitation. The following statements will be used to guide the implementation of the MLWP:

1. ***Motor skill is the product of multiple systems, internal and external to the individual*** [39]. Skilled human walking arises from the distributed contribution of both internal (e.g., musculoskeletal, cardiovascular and central nervous system) and external systems (e.g. the environment). The characteristics of walking will vary depending on the specific task and environmental context in which it is performed. A comprehensive rehabilitation program must address the known demands of community walking [40].
2. ***Learning is defined as a relatively permanent change in skill level (retention) and the ability to perform skill under varied conditions (transfer)*** [35]. ***Motor learning is typically specific to the conditions of practice.*** Practice conditions should resemble the conditions of expected typical performance, including task characteristics, sensory motor conditions and information processing demands [35]. Repetitive task-related practice of walking results in improved walking outcomes after stroke [20]. Training-induced neuroplasticity is specific to the trained movement or skill [41,42].
3. ***Practice should be sufficiently intense.*** Increased amounts of practice (repetitions) are typically associated with increased learning [35,42]. Increased practice of lower

extremity focused activities is associated with improved recovery of walking after stroke [43].

4. ***Practice must be sufficiently challenging and engaging.*** Motor learning is enhanced when the learner is cognitively challenged during practice or training [44,45]. Cognitive effort may be facilitated through non-repetitive (random or serial) practice schedule, opportunity for self-evaluation and error correction through reduced augmented feedback presentation and minimal physical guidance, and increased task complexity [44-46]. Motor learning rather than simple motor activity or movement repetition is required to induce cortical and sub-cortical reorganization [42,46]. Practice must be interesting, meaningful, with the learner/client actively engaged in order to induce desired neuroplastic changes [42].
5. ***Variable practice optimizes learning***. Practice of a skill under a variety of environmental and task conditions usually leads to improved retention and transfer of skill to novel performance conditions [35].
6. ***The effect of variable practice is usually enhanced when practiced in a non-repetitive order*** [35].

Content of the MLWP

At the first session, the therapist will spend 15 minutes to establish walking-related goals with the client. These goals will help inform the content and emphasis of the walking training program. Training will be organized to promote engagement in intense, repetitive practice of a variety of challenging, walking tasks. Practice will be cognitively effortful, encouraging participants to solve and re-solve the problems of walking in a variety of environmental and task conditions. Refer to Figure 2 for a graphic representation of the MLWP.

Core Tasks: Participants will practice all walking tasks overground. At every session, the therapist will incorporate the following seven core tasks that reflect the typical demands of home and community ambulation [40,47]: 1) walk short distances, 2) walk prolonged distances or times (>50 m or > 5 minutes), 3) steps, curbs and slopes, 4) obstacle avoidance, 5) transitional movements (e.g. sit to stand and walk), 6) changes in centre of gravity (e.g. pick up object from floor while walking) and,7) changing direction/turning while walking.

Increasing Complexity of Walking Task Practice: Using the concepts described by Gentile in her Taxonomy of Task Analysis [48] the training therapist will make each of the core tasks more complex through the addition of concurrent mental, verbal or physical tasks, adding a time restraint, altered terrain and/or lighting, increased duration, reduced predictability and/or performance of walking in a mobile environment. The therapist will adjust the difficulty of practice tasks based on their assessment of the participant's ability to perform the task safely without maximum physical assistance.

Tasks will be practiced in a serial or random order, moving from task to task, avoiding repetition of one station more than two times in a row. Feedback will be delayed and participants will be asked to self-evaluate their performance on a task and develop strategies to improve performance. When feedback is given, it will include either knowledge of results (e.g. time taken to complete a specific task) or knowledge of performance (e.g. step length, stance time) types of feedback [49]. The therapist will only provide hands-on guidance or assistance when required for safety, or for initial completion of the basic task. Specific handling or facilitation techniques will not be used to affect quality of gait. Participants will practice walking tasks with and without their preferred gait aid. Tasks will be practiced in the physiotherapy gym and/or more natural settings inside and outside the hospital (e.g. courtyard, sidewalks, hospital lobby). The tasks will be designed to encourage inclusion of both lower limbs during practice (e.g. reciprocal stepping up stairs). Each session will last 45 minutes including intermittent rest periods as required. Participants will practice three times a week for five weeks for fifteen sessions. Refer to Figure 2 for a graphic representation of the Motor Learning Walking Program.

Comparison Intervention: Body Weight Supported Treadmill Training

Participants in the control group will practice walking on a treadmill according to a protocol based on an intervention described by Sullivan et al. [33] and Duncan et al. [50]. Based in the CPG theory of stepping control and recovery [51], the focus of this intervention is to provide participants with an opportunity to practice many repetitions of the normal gait cycle. Within a 45-minute session, participants will practice walking for up to 30 minutes at a time on the treadmill. Participants will train using the LiteGait system (harness and mechanical overhead suspension) and the GaitKeeper treadmill (Mobility Research Inc.: Tempe, AZ). All participants will initiate training with 30% of their total body weight supported. A maximum of 40% body weight support will be provided during training. As recommended in the literature [33,52], participants will practice walking on the treadmill at speeds above their preferred overground walking speeds, preferably at or above 0.89 m/s (or 2.0 mph). Physical guidance will be provided by 1 to 3 therapists at the participant's pelvis, and/or their limbs to increase gait symmetry, facilitate weight shift, increase hip extension during stance, and to correct foot placement. Verbal feedback related to the participants gait pattern (knowledge of performance) will be provided frequently and concurrent to participants walking on the treadmill. Continuous visual feedback will also be provided via a full-length mirror. Participants will be discouraged from placing their hands on the LiteGait or treadmill handles during training. Body weight support, feedback, and guidance will be weaned, and treadmill speed adjusted according to a clinical decision making algorithm modified from a training algorithm described for individuals with spinal cord injury by Behrman et al. [53]. A comparison of key elements of the MLWP and BWSTT are provided in Table 1.

For experimental and control interventions, blood pressure (BP), heart rate (HR) and rating of perceived exertion (RPE) will be measured at the beginning, during rest periods and at the end of every treatment session. During training, exercise intensity will be reduced if HR exceeds 70% of age predicted maximal heart rate (220 – age) or RPE is greater than 13 on the Borg RPE scale. If resting BP exceeds 180 mmHg systolic and/or 100 mmHg diastolic, the exercise session will be stopped and their physician notified. This information will be recorded allowing comparison between groups. Patients will also wear the StepWatch 3© step activity monitor during training sessions, and mean number of steps taken during the sessions recorded as a measure of amount of task-related practice.

In the event of missed sessions, participants will be allowed a maximum of seven consecutive weeks to complete as many of the fifteen sessions as possible. Considering that previous studies have demonstrated changes in walking skill following 12 [24,25,33,34] and 18 sessions [19] over 4 [24,25,33,35] to 6 [19,34] weeks, we expect that a training frequency of 2 to 3 sessions per week for a total of 15 sessions will be result in improved walking skill in our participants.

To minimize the risk of contamination, separate training physiotherapists will deliver the Motor Learning Walking Program and the BWSTT program. All therapists will undergo a standardized training program prior to treating study participants on their own. The principal investigator will monitor ongoing competence and adherence through session observation, case discussions and documentation reviews. In order to minimize the impact of expectation bias, training therapists and participants will be blinded to the hypotheses of the investigators regarding which of the two interventions is expected to result in superior outcomes. To avoid co-intervention, participants will be asked to refrain from attending physiotherapy for their balance or walking limitations during the study intervention period. Participants will be questioned at post-intervention and follow up measures regarding their participation in physiotherapy outside of the study.

Outcomes

Efficacy of the interventions will be determined by comparing change scores (baseline to post treatment) on a variety of standardized outcome measures taken at baseline, post-treatment and 8 weeks post-intervention. The primary outcome measure is comfortable gait speed as measured by the five-metre walk test [54]. Following stroke, gait speed is frequently reduced compared to age matched normals [5,55,56]. Gait speed has been shown to be reliable (r=0.94)[57], responsive to change (SRM = 1.22; effect size = 0.83) [54], and significantly related to independent community ambulation [11].

Secondary outcome assessment will include measures of maximal gait speed, walking endurance (Six Minute Walk Test), dynamic balance (Functional Balance Test) [58], balance and walking related self-efficacy (Activities- specific Balance Confidence Scale) [59], walking function (modified Functional Ambulation Categories) [60], walking participation (5-day daily step activity - StepWatch 3 step activity monitor) [61,62], community reintegration (Life Space Questionnaire) [63,64], health related quality of life (Stroke Impact Scale 3.0) [65], goal attainment (Patient Specific Functional Scale) [66] and mean number of trainers per training session.

In addition, the baseline assessment will include the collection of demographic information, assessment of cognitive function (Mini Mental Status Exam) [36], presence of depression (Geriatric Depression Scale –15) [67], and the Chedoke-McMaster Stroke Assessment Leg and Foot stages of motor recovery [68]. At follow-up, information will be collected regarding participation in physiotherapy and any change in health status. This information will be used to describe the groups and interpret the results of the interventions.

Training and assessor therapists will record any of the following adverse events that occur during or between sessions: 1) falls (unintentionally landing on the ground), 2) any injury during session, 3) myocardial infarction (confirmed by physician and/or health records), 4) new stroke or transient ischemic attack (confirmed by physician and/or health records), 5) hospitalization for any cause, 6) death of any cause.

Physiotherapists trained to perform the standardized outcome measures will measure outcomes. Assessors will be blinded to the participant's intervention assignment and study hypotheses, limiting the potential for expectation bias. Participants will be instructed not to reveal their group assignment to the assessor.

Outcome assessment domains, tools and timing are summarized in Table 2.

Sample size

Seventy participants will be recruited. The sample size has been calculated to reliably detect a 0.14 m/s between-group difference in gait speed change (assuming a standard deviation of 0.19 m/s) with 80 % power at a 2-tail significance level of 0.05. Using self-selected gait speed as the primary outcome, this sample size has been estimated based on a range of change scores and standard deviation values reported in the literature. Reported differences in change scores between experimental and control interventions range from 0.9 m/s to 0.14 m/s and standard deviation in change scores range from 0.14 to 0.19 m/s [19,33,34,69,70]. Using a conservative estimate of standard deviation of change score of 0.19 and a difference between group change scores of 0.14 m/s, the minimal number of participants required for each treatment group is 29 participants. Dropout rates in previous studies have ranged from 7 to 20% [19,33]. Allowing for a 17% loss to follow up rate, the study will need to recruit approximately 35 participants into each group for a total of 70.

Statistical Analysis

The trial results will be reported in accordance with the CONSORT criteria [www.consort-statement.org]. The flow of patients in the trial will be summarized using a flow-diagram. The baseline characteristics and outcomes scores of the patients will be analyzed using descriptive statistics reported by group as mean (standard deviation [SD]) or median (first quartile [Q1], third quartile [Q3]) for continuous variables depending on the distribution and count (percent) for categorical variables. Intention to treat analysis technique will be used for the primary analysis [71]. Missing data will be handled through multiple imputation technique [72]. All statistical tests will be performed using two-sided tests at the 0.05 level of significance. The Bonferroni method will be used to adjust the level of significance for testing for secondary outcomes. For all models, the results will be expressed as estimate of mean difference (or odds ratios for binary outcomes), standard errors, corresponding two-sided 95% confidence intervals and associated p-values. P-values will be reported to three decimal places with values less than 0.001 reported as <0.001. Adjusted analyses will be performed using regression techniques to investigate the residual impact of key baseline characteristics on the outcomes (i.e. age, time since stroke onset, comfortable gait speed, and training site). Goodness-of-fit will be assessed by examining the residuals for model assumptions and chi-squared test of goodness-of-fit. All analyses will be performed using SPSS version 16.0 for Windows or SAS 9.2 (Cary, NC).

Primary Analysis

The post-intervention (T2) self-selected overground walking speed for the MLWP and BWSTT groups will be compared using analysis of covariance. The two factors will be intervention group (intervention or control) and baseline speed stratum (i.e. slow or fast).

Secondary Analysis

Mixed design analysis of variance will be used to compare the two groups' baseline, post-intervention and follow-up scores on all other secondary measures. The two factors will be time and group. Descriptive statistics (i.e. means, or frequencies) will be used to present data related to adverse and serious adverse events by groups. Any apparently significant differences between groups will be analysed for significance using chi square statistics. In an effort to describe the two interventions, the mean number of steps taken per session will be counted in a convenient sub-sample of participants using the step activity monitors. Independent samples t-test statistic will be used to compare the mean number of steps taken per session by the two groups during treatment sessions.

Sensitivity Analyses:

Sensitivity analyses will be performed to assess the robustness of the results. First, there is likely to be high inter-correlations among all outcomes. We will use multivariate analysis of variance (MANOVA) approach to analyze all outcomes simultaneously. This method accounts for possible correlations among all outcomes and provides for a global assessment of differences between groups with an indication of where differences exist. Second, we will use generalized estimating equations (GEE) [73] to account for possible serial correlation of measurements within a patient overtime. Unlike ordinary linear regression, GEE allows accounting possible correlation of outcome scores for the same patient over time. We will use sensitivity analysis to explore potential clustering of measurements/outcomes from the same patient. The clustering effect, measured by intra-class correlation coefficient, will be assumed to be equal across patients. Sensitivity analysis will also include a between-group comparison of post-intervention comfortable gait speed in participants who completed at least 12 of the 15 training sessions using analysis of variance. Refer to Table 3 for a summary of the planned analyses.

DISCUSSION

To date, a number of controlled trials have tested the effectiveness of intensive, task-related walking training interventions against a non-walking focused control treatment.

A head-to-head comparison of two different active walking-focused interventions will help answer the question whether it matters *how* individuals practice walking after stroke. As with most rehabilitation interventions, task-related walking training can be complex and multifaceted. A sound theory-base can help focus an intervention on the proposed, relevant active ingredients [74]. In our study, the experimental and comparison intervention were designed based on two different theoretical frameworks. While both interventions emphasize walking practice, their respective theory bases dictate what type of walking is practiced, the practice environment, tolerance for error and variability during practice, the role of the therapist, and the role of the participant during practice. As a result, this study provides a direct comparison of the effectiveness of two quite different task-related walking training protocols with different resource requirements. The results of this study takes an important step toward informing clinicians, patients, caregivers and administrators of the essential components of an optimally effective task-related walking training intervention following stroke.

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

VGD conceived of the study, acted as the principal investigator and drafted the manuscript. LT provided statistical expertise in clinical trial design. All authors contributed to the study design, are grant holders, contributed to the editing of the manuscript, and read and approved the final manuscript.

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ACKNOWLEDGEMENTS AND FUNDING

This study has received funding from the Ontario Stroke System, Ministry of Health and Long Term Care (MOHLTC) (Grant #06356) and the Father Sean O'Sullivan Research Centre, Hamilton, Ontario, Canada. Work completed related to this study was a component of VGD's doctoral studies at McMaster University. VGD received financial support from the Canadian Institutes of Health Research's Fredrick Banting and Charles

Best Canada Graduate Scholarship Doctoral Award and the Canadian Institutes of Health Research Strategic Training Program in Rehabilitation Research, McMaster University.

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Figure Legends

Figure 1: **Study design and timelines**

Figure 2: Motor Learning Walking Program. Every session includes all seven core tasks described in the centre circle. During or between sessions, the training physiotherapist may adjust the level of challenge of each core task by adding or removing one or more of the task complexity factors described in the outside circles.

Table 1: Description of experimental and comparison interventions

Learning Variable/Principle	Motor Learning Walking Program	Body Weight Supported Treadmill Training
Amount of Practice/Intensity	Up to 40 minutes of walking activity per session 15 sessions over 5 weeks	Up to 30 minutes treadmill walking per session 15 sessions over 5 weeks
Specificity Of Practice	Reflects task and environmental demands of community walking	High repetitions of near normal gait cycle on treadmill
Variable Practice	Variable practice of different overground walking tasks	Single task practice – walking on treadmill
Practice Order	Random or serial order, moving through different tasks returning to each task at least once.	Blocked or mass practice of single task of walking on treadmill
Augmented Feedback	Encourage self-evaluation through delayed, intermittent and summary feedback KP and results KR provided	Continuous, immediate visual (mirror) and/or verbal feedback. Focus on KP, specifically related to posture and gait pattern
Instructions	Instructions provided related to the goals of the task. Emphasis on problem solving, discovery of alternate ways to complete walking tasks.	Instructions regarding performance of near normal gait pattern
Physical Guidance	Physical guidance provided for safety, or initial completion of basic task early in learning. Emphasis on allowing participants to make and attempt to correct errors.	Frequent guidance of one to three trainers at pelvis, hemi and non-hemi-limb to guide position and timing Up to 40% body weight support provided through harness - weaned according to performance Handle use discouraged Errors prevented or minimized
Training Personnel	Physiotherapist x 1	Physiotherapist x 1 plus 1 to 2 other physiotherapists or physiotherapy assistants
Training Setting	In hospital physiotherapy department, other parts of hospital and outdoors	In hospital outpatient department on treadmill
Training Speed	Practice of comfortable and fast walking	Will train at, or above target speed 2.0 mph (0.89 m/s) as soon as participant is able
Use Of Walking Aid/Orthoses	Practice with and without orthoses and walking aid	Practice without walking aid, may use orthoses if necessary

KP = knowledge of performance, KR = knowledge of results

Table 2: Outcome domains, measures and timing of assessments

ICF	*Domain*	*Instrument*	*Screening/ Baseline*	*Post - Intervention*	*Follow-up*
Personal and Environmental Factors	Stroke details	Interview, health record review	X		
	Comorbidities		X		
	Living situation		X		
	Gait aid		X	X	X
	Physiotherapy		X	X	X
	Fall history		X	X	X
	Adverse events		X	X	X
Body Structures /Function	Motor recovery	Chedoke-McMaster Stroke Assessment	X		
	Cognition	Mini Mental Status Examination	X		
	Depression	Geriatric Depression Scale Short form-15	X		
Activity	Walking speed	5 metre walk test	X	X	X
	Walking endurance	Six Minute Walk Test	X	X	X
	Dynamic balance	Functional Balance Test	X	X	X
	Balance self-efficacy	Activities-specific Balance Confidence Scale	X	X	X
	Goal attainment	Patient Specific Functional Scale	X	X	X
Participation	Walking independence	Modified Functional Ambulation Categories	X	X	X
	Daily walking activity	Step Watch 3.0 step activity monitor	X	X	X
	Mobility participation	Life Space Questionnaire	X	X	X
	Health related quality of life	Stroke Impact Scale 3.0	X	X	X

ICF = International Classification of Function domains

Table 3: Summary of planned primary, secondary and sensitivity analyses

Objective/Variable	*Hypothesis*	*Outcome measure (type) [continuous (c), binary (b)]*	*Method of Analysis*
1) Primary			
Walking speed at post-intervention (T2)	MLWP > BWSTT	Comfortable gait speed (c)	ANCOVA
2) Secondary (T2, T3)			
Secondary outcomes			
a) Fast walking speed	MLWP > BWSTT	Fast Gait Speed (c)	ANCOVA
b) Walking endurance	MLWP > BWSTT	Six minute walk test(c)	ANCOVA
c) Balance and walking related self-efficacy	MLWP > BWSTT	Activities-specific Balance Confidence Scale (c)	ANCOVA
d) Dynamic balance	MLWP > BWSTT	Functional Balance Test(c)	ANCOVA
e) Mobility participation	MLWP > BWSTT	Life Space Questionnaire (c)	ANCOVA
f) Health-related quality of life	MLWP > BWSTT	Stroke Impact Scale 3.0 (c)	ANCOVA
g) Goal attainment	MLWP > BWSTT	Patient Specific Function Scale(c)	ANCOVA
h) Walking participation	MLWP < BWSTT	Mean daily step activity	ANCOVA
i) Training staff requirement	MLWP < BWSTT	Total number of trainers / number of training sessions (c)	T-test
j) Meaningful change in gait speed of ≥ 0.14 m/s	MLWP > BWSTT	Comfortable gait speed change score T2-T1 ≥ 0.14 m/s[1])(b)	Chi-square test
Adverse events (count)			
a) Falls during session		Therapist report (b)	Chi-square test
b) Injury during session		Therapist report (b)	Chi-square test
c) Falls between session		Patient report (b)	Chi-square test
d) Myocardial Infarction		Patient report/health record (b)	Chi-square test
e) New stroke		Patient report/health record (b)	Chi-square test
f) Hospitalization		Patient report/health record (b)	Chi-square test
g) Death (all causes)		Health record/Physician (b)	Chi-square test
3) Sensitivity Analysis			
a) All outcomes analysed simultaneously to account for correlation among them		Primary and secondary outcomes	MANOVA
b) Serial correlation of all outcomes at baseline, T2, T3		Primary and secondary outcomes	GEE
c) Completers ($\geq$12 sessions)	MLWP>BWSTT	Comfortable Gait speed	ANCOVA

IMPORTANT REMARKS:
The GEE[2] is a technique that allows to specify the correlation structure between patients within a hospital and this approach produces unbiased estimates under the assumption that missing observations will be missing at random. An amended approach of weighted GEE will be employed if missingness is found not to be at random[3].
In all analyses results will be expressed as coefficient, standard errors, corresponding 95% and associated p-values. Goodness-of-fit will be assessed by examining the residuals for model assumptions and chi-squared test of goodness-of-fit. Bonferroni method will be used to adjust the overall level of significance for multiple secondary outcomes.

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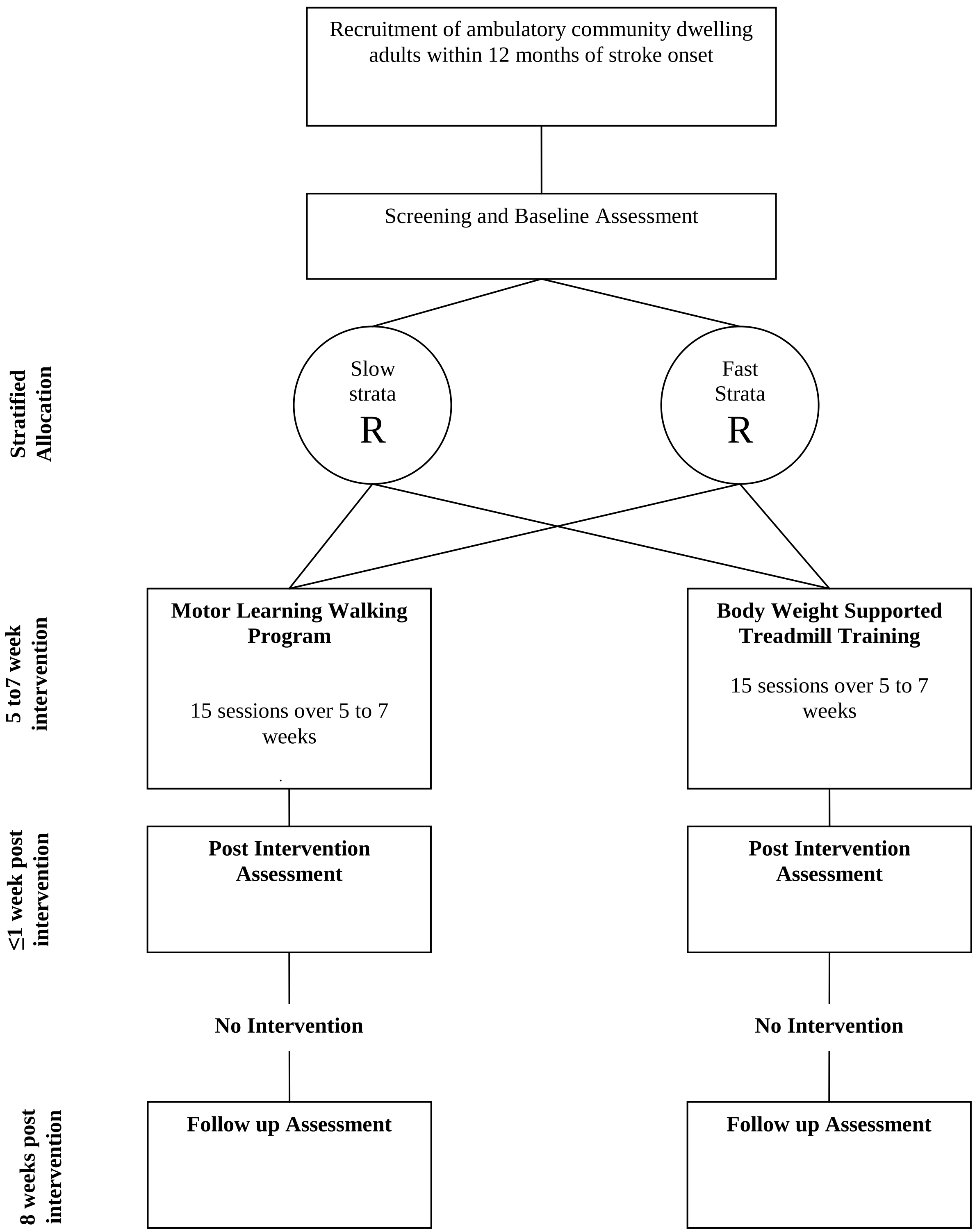

Figure 1: Study design and timelines

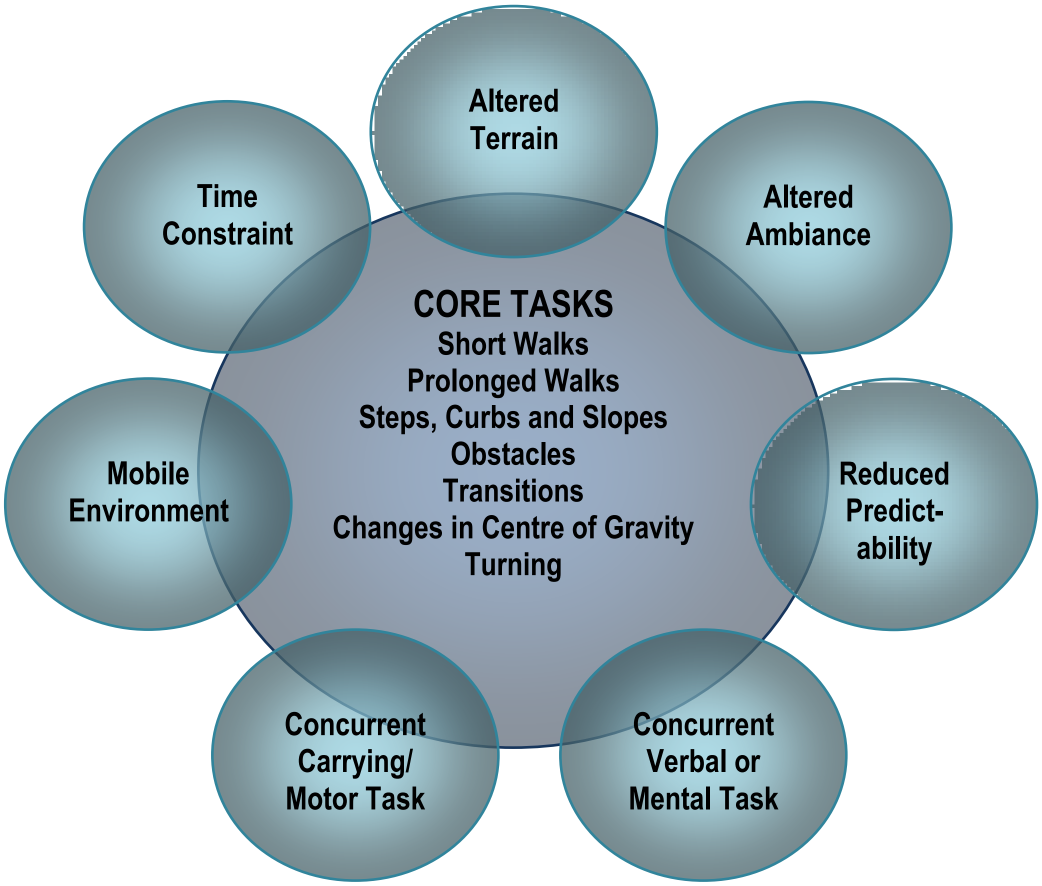

Figure 2: Motor Learning Walking Program
Every session includes all seven core tasks described in the centre circle. During or between sessions, the training physiotherapist may adjust the level of challenge of each core task by adding or removing one or more of the task complexity factors described in the outside circles.

Chapter 4

A comparison of two active, task-related walking training interventions in community dwelling adults within one year of stroke: a randomized controlled trial

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Publication status: This manuscript has been prepared for, but not yet submitted to the journal, *Neurorehabilitation and Neural Repair*.

Summary: This manuscript presents the primary and key secondary results of the randomized controlled trial conducted for this thesis. These results will be discussed in the context of recent clinical research trials, as well as from the perspective of motor learning science. The implications for the application of motor learning principles as a framework for future research and practice will be examined.

ABSTRACT

BACKGROUND: Following a stroke, individuals frequently experience significant walking dysfunction. We propose that the science of motor learning provides an ideal framework for an optimally effective outpatient-based, walking-skill training program.

OBJECTIVE: To compare the impact of varied, overground, walking-skill training based in motor learning principles (MLWP), to a body-weight-supported treadmill training (BWSTT) program in ambulatory, community-dwelling adults (≥ 40 years) within 1 year of stroke onset.

Methods:

In this 1:1 parallel randomized controlled trial, participants were stratification by baseline gait speed. In the experimental group (MLWP), participants practised a variety of overground walking tasks under the supervision of one physiotherapist. Cognitive effort was encouraged through random practice and limited provision of feedback and guidance. The control intervention (BWSTT) emphasized constant, guided, repetition of the normal gait cycle while being assisted by one to 3 therapy staff. The primary outcome was self-selected gait speed at post-intervention assessment (T2). Outcomes assessors were blinded to treatment allocation.

Results: 71 individuals (mean age 67.3 [S.D. 11.6] years) with stroke (mean onset 20.9 [14.1] weeks) were randomized (MLWP n=35, BWSTT n=36). Groups were equal in the mean number of treatment sessions and steps taken per session. There was no significant between-group difference in gait speed at T2 (0.002 m/s [95% confidence interval (CI) = -0.112, 0.117] $p > 0.05$). The MLWP group improved by 0.14 m/s (95% CI = 0.09, 0.19) and the BWSTT group improved by 0.14 m/s (95% CI = 0.08, 0.20).

Conclusions: In this group of community dwelling adults within one year of stroke, a task-related walking training intervention based in MLPs was not shown to be superior to an equally intensive, BWSTT program. MLP-framed research should continue to explore the key elements of optimally effective walking-focused interventions after stroke.

Trial Registration: ClinicalTrials.gov # NCT00561405

Funding: Ontario Stroke System/MOHLTC Grant #06356

Key words: stroke, walking, motor skill, learning, physical therapy

INTRODUCTION

Stroke is a leading cause of long-term disability in North America.[1, 2] Walking dysfunction is one the most common, disabling, and persistent consequences of stroke[3-5]. It is not surprising that the recovery of walking function is a priority rehabilitation goal for many individuals [6, 7].

Task-related walking training has been recommended as a key component of stroke rehabilitation for community-dwelling individuals. [8, 9]. Despite these recommendations, there is significant variability in the theoretical rationale, treatment content, and outcomes achieved with task-related walking training interventions. [10-14] Given the fact that post-stroke physical therapy is primarily concerned with the reacquisition of motor skills, we propose that motor-learning science offers a sound theoretical framework to develop a more coherent and effective task-related walking training intervention.

The goal of motor-learning science is to understand how people acquire motor skills through practice or experience.[15] From this literature, we know that individuals learn motor skills optimally under specific conditions. In recent years, the same conditions shown to elicit behavior changes have also been associated with changes in the activity and structure of the brain.[16] According to these motor learning principles (MLPs), learning is optimized when practice is abundant, engaging, challenging and progressive.[17] We also know that learning is typically improved when: practice is variable and random in order; practice conditions resemble the expected performance conditions (specificity of learning); continuous tasks such as walking are practiced as a whole-task; and feedback and guidance are provided in a manner that encourages error experience, self-evaluation and self-correction.[15-17]

In a recent scoping review, we found inconsistent application of these principles within the community-based, task-related training literature.[10] While most investigators incorporated some whole-task walking practice, adherence to other principles was uneven. Circuit-training interventions included variable-task practice however stations frequently focused on part-task practice (e.g. heel raises, step-ups), were blocked in order, and authors failed to describe feedback provision.[18-22] In studies rooted in a central pattern generator (CPG) theory of gait control and recovery, participants typically underwent whole-task practice of the gait cycle through body-weight-supported treadmill training (BWSTT), where practice was constant, heavily guided, and usually had limited inclusion of overground walking.[23-26]

In addition to an incomplete application of MLPs, most studies failed to compare the experimental task-oriented intervention to an alternative approach of repetitive, task-oriented training. For example, varied walking task practice interventions have been shown to be more effective than seated activities,[18, 19] and standard physical therapy care.[21] In BWSTT studies, one BWSTT intervention has been compared to another BWSTT protocol,[24, 25] or a non-walking-activity.[25] Recognizing this limitation in the literature, investigators of the recently published LEAPS trial, compared BWSTT to an active, balance, strength and flexibility-focused home-exercise program.[27] The experimental intervention was found to improve gait speed more than standard care, however the BWSTT and the home exercise program were equally effective. On the surface this study seems to indicate that the task-oriented BWSTT program is not better than a non-task-oriented intervention. However, the inclusion of walking-specific goal setting,[28] instructions to walk daily, supervision, and the context-specific home environment,[29] may have led to a substantial amount of walking-specific practice by the comparison intervention group. As the home exercise intervention was not based in any particular theoretical framework, nor intentionally designed to include task-related practice, interpretation of these results is challenging.

In summary, the literature is still not clear whether one approach to task-oriented walking-skill training is superior to another task-oriented approach. More research is required to identify the essential ingredients of an optimally effective, post-stroke walking-skill training intervention for individuals living in the community. We propose that a systematic, motor-learning science-framed research approach would lead to an increased understanding of treatment mechanisms, and subsequently result in improved patient outcomes.

The purpose of this randomized controlled trial was to evaluate the impact of the Motor Learning Walking Program (MLWP) in community dwelling individuals within one year of stroke onset. The MLWP is an intensive, varied, task-specific, overground walking-skill training program organized to be consistent with key MLPs. In an effort to assess the relative value of motor-learning science as a theoretical framework, the MLWP was compared with body-weight-supported treadmill training (BWSTT), a very different approach to walking-skill training that has been informed, and influenced by an alternate theory of walking control and recovery.

METHODS

All study activities were approved by the Research Ethics Boards of St. Joseph's Healthcare Hamilton (SJHH) (#6- 2753), the Hamilton Health Sciences/Faculty of Health Sciences McMaster University (#07-054), Hamilton, Ontario, and Joseph Brant Memorial Hospital, Burlington, Ontario. The study was registered at ClinicalTrials.gov, trial # NCT00561405.

This study was a randomized, parallel-group (1:1) trial with stratification by baseline comfortable gait speed (< 0.5 m/s and ≥ 0.5 m/s). The design included concealed allocation during screening and randomization, rater-blinded outcome assessment, and intention to treat analysis.

Between January 1, 2007 and August 31, 2010, participants were recruited through clinician referrals from inpatient acute and rehabilitation units, and outpatient rehabilitation programs at two hospitals in Hamilton, ON and one in Burlington, ON. Some participants were recruited through community-based marketing. Written physician clearance was obtained prior to initiation of study activities.

The research coordinator screened patients for eligibility and obtained written, informed consent. Eligible and consenting participants underwent baseline assessment on primary and secondary outcome measures. A permuted block, randomization schedule was created and administered by a central randomization service (SJHH Biostatistics Unit). On completion of the screening, consent and baseline assessment process, group assignment was communicated by e-mail to the research coordinator. The outcome assessor and data analyst were blinded to treatment group assignment. In an effort to minimize expectation bias, all participants and therapists in both groups received information that promoted the rationale and potential benefits of their assigned intervention, and were blinded to the study hypotheses.

Participants

Inclusion criteria were as follows: 1) living in the community, 2) ≥ 40 years old, 3) < 12 months of onset of a physician diagnosed ischemic or hemorrhagic stroke, 4) able to walk 10 m without assistance, 5) able to follow a 2-step verbal command, and 6) independent with community ambulation prior to stroke. Individuals were excluded if they presented with: 1) cognitive impairment (i.e. Mini Mental Status Exam score less than age and education norms),[30] 2) severe visual impairment, 3) lower extremity amputation, 4) unstable cardiac, medical or musculoskeletal conditions that would limit safe participation in walking exercise (as determined by physician screening and baseline assessment interview), or 5) comfortable gait speed > 1.0 m/s without a gait aid.

Interventions

Participants in the experimental group were assigned to the MLWP intervention. The MLWP is a program of varied overground walking-task practice based on theory and research from the fields of motor learning, neuroscience, and stroke rehabilitation. The aim of this program was to engage and challenge participants as they practiced a variety of walking-related tasks relevant to community mobility.[31] At every training session, participants practised seven core walking activities; 1) short distance, 2) longer distance, 3) steps, curbs, and slopes, 4) obstacle avoidance, 5) transitions (e.g. sit to stand and walk), 6) changes in centre of gravity (e.g. picking up an object off floor), and 7) changes in direction. The challenge level associated with tasks was adjusted through the addition or removal of concurrent verbal or physical tasks, time constraint, altered terrain and/or lighting, increased duration, reduced predictability or performance in a mobile environment. In addition to variable practice, and task-related practice, sessions were organized in a manner consistent with motor learning principles related to guidance, feedback, and order of practice.[15]

Participants in the control intervention were assigned to BWSTT. The BWSTT protocol was structured to provide participants with the opportunity to practice high repetitions of a near normal gait pattern while supported over a treadmill and assisted by one or more therapists. This approach to training is rooted in the CPG theory of gait control and recovery,[32] and based on protocols described in the literature.[24, 33] A detailed description of the study methods including rationale and content of the MLWP and BWSTT interventions can be found in the previously published trial protocol paper.[34]

Both intervention groups were offered 15 sessions over 5 weeks in an outpatient physical therapy clinic setting. Sessions were one hour long, including set up, vital sign assessment, and rest periods. Refer to Table 1 for a comparison of the two interventions.

Outcomes

The primary outcome for this study was comfortable gait speed measured approximately one week following the completion of treatment (T2). Gait speed, measured using the 5 m walk test,[35] has been shown to be reliable ($r = 0.94$),[36] responsive to change,[35] and significantly related to independent community ambulation in individuals with stroke.[37] Secondary outcomes included measures of maximal gait speed (5m walk test),[35] walking endurance (Six Minute Walk Test),[38] higher level balance and walking control,[39] balance and walking-related self-efficacy (Activities-specific Balance Confidence Scale),[40] walking function (modified Functional Ambulation Categories),[41] community mobility participation (Life Space Questionnaire),[42] and the self-reported mobility, activities of daily living, participation and global recovery subscales of the Stroke Impact Scale 3.0.[43] Step activity data during treatment sessions was collected using StepWatch™ step activity monitors[44] (Orthocare Innovations, Oklahoma City, OK) in a convenient sample of participants from both intervention groups.

Analysis

Descriptive statistics were performed for baseline characteristics and outcomes scores (means with standard deviation [SD] or median with first [Q1] and third quartile [Q3]), for continuous variables, and count (percent) for categorical variables. Intention to treat analysis with multiple imputation technique for missing values [45] was used for between-group comparisons for primary and secondary outcomes. For primary outcome analysis, post-intervention (T2) comfortable walking speeds for the intervention groups were compared using analysis of covariance with group (MLWP or BWSTT) and baseline speed stratum (i.e. slow or fast) as factors. Secondary analysis included between-group comparisons of gait speed at 2-month follow-up (T3), and all other outcomes at T2 and T3 using analysis of covariance. For each outcome, two covariates were used; baseline comfortable gait speed and the baseline value of the outcome of interest. All statistical tests were two-sided with a 0.05 level of significance. The Bonferroni correction method was used to adjust the level of significance for testing for secondary outcomes. Poisson logistic regression analysis was used to compare the mean number of steps taken per session by the two groups during treatment sessions. Descriptive statistical analyses were performed using IBM SPSS Statistics 20.0 for

Windows (Somers, NY). Primary and secondary analysis was performed using SAS 9.2 (Cary, NC).

In order to reliably detect a 0.14 m/s between-group difference in gait speed (assuming a standard deviation of 0.19 m/s), with 80% power at a 2-tail significance level of 0.05, sample size was calculated to be 29 participants per treatment group. Considering loss to follow up rates reported in the field ranged from 7 %[19] to 20%,[24] we allowed for 17% loss to follow up, and aimed to recruit a total of 70 participants.

RESULTS

Study recruitment was initiated in January 2007 and the final participant's follow-up assessment was completed in December 2010. A total of 186 ambulatory, community-dwelling individuals within one year of stroke were referred for screening. Of these, 71 participants met inclusion and exclusion criteria, consented, and were randomized (MLWP n=35, BWSTT n=36). The mean age of participants was 67.3 (SD 11.6) years with a mean of 20.9 (SD 14.1) weeks since stroke onset. One participant from each group withdrew for personal reasons after baseline assessment and before beginning training. A total of 64 participants were assessed at post-treatment (T2) (MLWP = 30; BWSTT = 34). Fifty-eight participants were assessed at follow-up (T3) (MLWP = 26; BWSTT = 32). Participant flow is presented in Figure 1.

The 69 participants who undertook at least one treatment completed an average of 13 sessions (MLWP 13.29 [SD 4.33]; BWSTT 13.50 [SD 3.87]). In a sample of convenience, there was no significant between-group difference for number of steps-per-treatment session (p=0.61), with 1620 (SD 624) steps taken during MLWP (n=19), and 1712 (S.D. 487) steps taken during BWSTT (n=21).

Groups were balanced on most baseline characteristics (see Table 2). As baseline assessments were collected prior to randomization, apparent imbalances in gait speed are attributable to chance alone. In Table 3, the observed data has been summarized using mean scores for primary and secondary outcomes at baseline, post-intervention and follow up. In Table 4, the differential effects of the MLWP over BWSTT for primary and secondary outcomes at T2 and T3 are presented for intention to treat and adjusted analysis. Performances on selected outcomes across the three assessment periods are presented by group in Figures 2 a - f.

Primary Outcome

There was no significant between-group difference in comfortable gait speed at T2. Mean between-group difference was 0.002 m/s (95% CI = -0.112, 0.117; $p > 0.05$). Both groups improved comfortable gait speed following treatment. The change in gait speed at T2 in the MLWP group was 0.14 m/s (95% CI = 0.09, 0.19), and 0.14 m/s (95% CI = 0.08, 0.20) for the BWSTT group.

Secondary Outcomes

There were no significant between-group differences in any of the secondary outcome measures at T2 or at follow-up (T3). Although effect sizes did not reach statistical significance, participants in the MLWP group tended to perform the Functional Balance Test, a test of higher level balance and walking,[39] more quickly than participants in the BWSTT group (between group difference = - 6.01 seconds [95% CI -15.97, 3.95]), and T3 (between group difference = -12.15 seconds [95% CI -26.17, 1.89]). In addition, there was a trend for the scores in the MLWP group to be higher on the Life Space Assessment,[42] at T2 (between group difference = 6.81 points [95% CI - 1.09, 14.71]).

Participants in both groups demonstrated gains in all functional performance outcome measures (gait speed, six minute walk test, Functional Balance Test) from T1 to T2. From T2 to T3, scores in both groups improved or were maintained on all outcomes, except the Functional Balance Test in BWSTT group, where performance deteriorated between T2 and T3.

When gait speed data was dichotomized, at T2, 50% (15 of 30) of MLWP participants improved their gait speed by 0.14 m/s or more between T1 and T2, compared to 32% (n=11 of 34) of the BWSTT group. With an odds ratio of 2.10 (95% CI -0.58, 3.98) individuals in the MLWP group tended to be more likely to improve gait speed by a clinically meaningful amount, than the BWSTT. The between-group difference for odds ratios was not statistically significant (p=0.143).

There was no significant difference between fall rates in the two groups (MLWP 11/30 [36.7%], BWSTT 10/32 [31.2%]). A total of 12 individuals (18.2%) reported at least one fall at T2, and 14 (22.2%) at follow up (T3). A total of 3 patients (4.5%) (2 [6.2%] in MLWP, 1 [2.7%] in BWSTT) reported a new onset stroke or transient ischemic attack over the study period. Two participants had cardiac events requiring hospitalization, both in the BWSTT group. A total of 4 participants died during the study period. One person in the MLWP group died following a new stroke event one week after completing the 15 intervention sessions and just prior to their post-intervention assessment (T2). Three participants died between assessment at T2 and T3 (1 in MLWP, 2 in BWSTT). No participants died, had a cardiac event, or stroke during or between treatment sessions.

DISCUSSION

The intention of this randomized controlled trial was to compare the impact of two different approaches to task-related walking training in ambulatory, community-dwelling individuals within one year of stroke. We hypothesized that the MLWP, a walking training intervention designed to adhere to key motor learning principles, would be more effective than BWSTT, an intervention based in a CPG theory of gait control. The failure to detect a significant difference between these two interventions challenges us to re-evaluate our original assumptions.

The principal assumption underlying this trial was that consistent adherence to motor learning principles would increase the effectiveness of task-related walking training. Borrowing Whyte's analogy of a recipe,[46] each of these motor learning 'ingredients' (i.e. intensity, specificity, whole-task practice, variability, order, feedback and guidance) were assumed to be active, potent factors to improving walking skill. On reflection, it is likely that some motor learning ingredients are more active, or important, than others, particularly so for this patient cohort. When in-treatment step-activity was measured in a sample of participants, both MLWP and BWSTT groups took more than three times the mean number of steps (507 [S.D.64]) observed by Lang et al.[47] during standard outpatient stroke physical therapy sessions. These findings are consistent with previous studies that have demonstrated the benefits of increased walking-related practice after stroke.[48, 49] Perhaps, as long as an individual practices walking in some manner, amount or intensity of practice becomes the most potent treatment ingredient.

Although our primary results indicate that the two interventions were equally effective, results on some secondary measures indicated a trend in favour of the MLWP program. The Functional Balance Test (FBT)[39] is a measure of higher-level balance and walking skill. During the test, participants are timed while they perform a circuit of walking-related tasks (i.e. stand up from a chair and walk, walk up and down a step, pick up an object off floor while walking, turn and walk back to chair). We found a clinically meaningful difference between groups in favour of the MLWP group on this test. As the demands of this test more closely resemble the practice items within the MLWP, this result may be interpreted as support for the motor learning principle of specificity of practice.[15] Alternatively, they may reflect a beneficial effect of the variable practice within the MLWP. According to the Schema theory of motor control,[50] variable practice of a particular skill helps the learner develop a stronger, more flexible, schema for that skill, leading to an increased ability to perform that skill in different environments and task conditions. It is likely that the 5-metre walk test was not optimally suited to detect such a benefit. The trend observed in the Functional Balance Test times as well as increased mobility participation represented by the adjusted Life Space Assessment score in the MLWP group may reflect the transfer advantage of variable task practice. As this study was not powered to detect differences on the secondary outcomes, these hypotheses need to be tested in controlled experimental studies, and eventually in larger sample pragmatic trials.

Based in motor learning science, the MLWP was specifically designed to encourage cognitive effort and problem solving during training.[17] Practice tasks were random or serial in order, and feedback and guidance was delayed or limited in frequency to allow self-evaluation and correction of movement errors. Although these strategies have been associated with improved outcomes after stroke,[51-53] there is evidence that the degree of benefit is influenced by the complexity of the skill being learned, and the experience of the learner.[54-56] In their Challenge-Point framework, Guadagnoli and Lee propose a task- and person-specific approach to structuring practice.[57] When a person practices a motor skill they receive a certain amount of information about their performance from their own feedback systems or from external sources such as a therapist. This information represents challenge, where too little or too much information can limit learning. Task practice that is too difficult will represent more information than is valuable to the learner, whereas task practice that is too easy or simple will provide insufficient information to promote learning. The optimal information level or *challenge point* depends on the skill and experience of the learner/patient, combined with the difficulty level of the task. The role of the therapist is to adjust the task challenge level by not only changing the task difficulty, but also by adjusting such variables as practice order, frequency of feedback, and provision of guidance, ultimately finding the optimal challenge point for a particular patient.

If we consider a patient who may be practicing stairs for the first time after a stroke, their optimal challenge point may be met with more frequent feedback, hands-on guidance and blocked practice. Whereas a patient who has attempted this task a number of times may require less frequent feedback, no guidance, and random practice in order to continue to maximize learning. There is evidence to support the application of a challenge point framework in arm and hand rehabilitation in Parkinson's disease.[58] Future research should explore the application of this framework in walking retraining post-stroke.

Despite a lack of between-group difference on the primary outcome, it is important to note that both interventions resulted in a clinically meaningful change (0.14

m/s) in comfortable gait speed[58] and most secondary measures. In addition, the magnitude of change in this study was comparable to the change previously reported for patients of similar functional status and stroke chronicity undergoing task-related training. [18, 19, 27] Although participants in the LEAPS study[27] made larger gains in gait speed (0.25 m/s versus 0.14 m/s), interventions began almost 3 months earlier, and magnitude of change has been shown to diminish with time post-stroke onset.[60] In addition, the interventions in our study were only 15 sessions compared to the 36 sessions in the LEAP protocol. It is possible that that the effect size of the MLWP and the BWSTT programs would be greater if these interventions were initiated sooner after stroke, and for a longer duration. Use of repeated measures design over an extended training period could help identify optimal timing, duration and frequency of walking training in this population.

Interestingly, a significant proportion of the participants in our study were recruited after being discharged from other physiotherapy programs. This is consistent with a recent crossover study where individuals deemed to have maximized their recovery were observed to make further improvements with additional walking-focused training.[61] It is possible that in some patients, an apparent recovery “plateau” may be an indicator of need for a re-evaluation and change of treatment approach, rather than a true marker of prognosis for further improvement.[62] It is also important to note that the concept of a recovery ‘plateau’ is not consistent with motor learning research. While the rate of change may slow over time, even individuals considered to be experts at a particular motor skill continue to improve proficiency after years of practice.[15]

Without definitive evidence in support of MLWP over BWSTT, clinicians may base treatment decisions on practical considerations such as patient preference, treatment setting, and equipment and human resources availability. The BWSTT intervention required an average of 1.4 (range 1 to 3) therapy staff per session compared to 1 therapist for the MLWP. In the United States, the median hourly rates for a Physical Therapist is $37.00/hour, and $25.00/hour for a Physical Therapy Assistants (PTA).[65] At these rates, 15 one-hour sessions of MLWP supervised by one therapist would cost $ 555.00. On the other hand, 15 one-hour sessions of BWSTT supervised by one therapist and assisted by a PTA (on 40% of the sessions), would cost $ 705.00. In addition, BWSTT requires specialized, costly equipment whereas the MLWP incorporates objects found in any therapy department, or home, and could be delivered in a community or clinical setting. While this trial did not include a formal economic analysis, clinicians and administrators may consider MLWP a more cost-effective, flexible treatment option than BWSTT intervention for ambulatory, community dwelling individuals with history of stroke.

LIMITATIONS

Unfortunately, 2 participants withdrew from the study prior to training (MLWP =1, BWSTT=1), 5 participants were lost to follow-up at T2 (MLWP = 4, BWSTT=1), and 11 participants were lost to follow-up at T3 (MLWP=8, BWSTT=3) (see Figure 1). Participants in the MLWP group were more likely to be lost for reasons other than death. As session attendance was equal between groups, and treatment was typically completed before the loss, it is unlikely that this imbalance reflects a specific intolerance to the MLWP intervention. Despite this loss, we reached the target sample size. In addition, lost data was imputed to retain the benefits of random allocation. In this study, we intentionally compared two intense, task-related walking interventions. As neither of these interventions represents standard practice, we cannot be certain that the observed changes were greater than expected with active, standard physical therapy care. We expect that the increased focus on walking would lead to better outcomes; however this needs to be confirmed through further research. In order to exaggerate the difference between interventions, the MLWP did not include a treadmill walking, and BWSTT did not include overground training. Combined interventions maybe more typical of clinical practice and have been associated with some positive outcomes.[63, 64] The field would benefit from further evaluation of novel treatment combinations that target walking skill reacquisition.

CONCLUSION

In this randomized controlled trial, we compared two, intensive, task-related walking-skill training programs that were different in theoretical rationale and level of adherence to specific motor learning principles. Both interventions were associated with a clinically meaningful improvement in walking performance in this group of community dwelling individuals within one year of stroke. There were no significant between-group differences on primary outcome of comfortable gait speed. Clinical decisions may be informed by pragmatic considerations such as equipment and staff availability, and patient preference. Further experimental and clinical research is required to determine the individual impact of, and interactions between, specific motor learning variables on walking retraining outcomes after stroke.

Sources of funding: This study was completed through funds received by the Ontario Stroke Network, Ministry of Health and Long Term Care, Ontario (Grant #06356), and from the Father Sean O'Sullivan Research Centre, Hamilton Ontario.

Conflicts of Interest/Disclosures: The authors have no conflicts of interest/disclosures to report.

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Table 1: Description of experimental and comparison interventions

Learning Variable/Principle	Motor Learning Walking Program	Body Weight Supported Treadmill Training
Amount of Practice/Intensity	Up to 40 minutes of walking activity per session 15 sessions over 5 weeks	Up to 30 minutes treadmill walking per session 15 sessions over 5 weeks
Specificity Of Practice	Reflects task and environmental demands of community walking	High repetitions of near normal gait cycle on treadmill
Variable Practice	Variable practice of different overground walking tasks	Single task practice – walking on treadmill
Practice Order	Random or serial order, moving through different tasks returning to each task at least once.	Blocked or mass practice of single task of walking on treadmill
Augmented Feedback	Encourage self-evaluation through delayed, intermittent and summary feedback KP and results KR provided	Continuous, immediate visual (mirror) and/or verbal feedback. Focus on KP, specifically related to posture and gait pattern
Instructions	Instructions provided related to the goals of the task. Emphasis on problem solving, discovery of alternate ways to complete walking tasks.	Instructions regarding performance of near normal gait pattern
Physical Guidance	Physical guidance provided for safety, or initial completion of basic task early in learning. Emphasis on allowing participants to make and attempt to correct errors.	Frequent guidance of one to three trainers at pelvis, hemi and non-hemi-limb to guide position and timing Up to 40% body weight support provided through harness - weaned according to performance Handle use discouraged Errors prevented or minimized
Training Personnel	Physiotherapist x 1	Physiotherapist x 1 plus 1 to 2 other physiotherapists or physiotherapy assistants
Training Setting	In hospital physiotherapy department, other parts of hospital and outdoors	In hospital outpatient department on treadmill
Training Speed	Practice of comfortable and fast walking	Will train at, or above target speed 2.0 mph (0.89 m/s) as soon as participant is able
Use Of Walking Aid/Orthoses	Practice with and without orthoses and walking aid	Practice without walking aid, may use orthoses if necessary

KP = knowledge of performance, KR = knowledge of results

Table 2: Baseline characteristics of study participants

Characteristics	MLWP n=35	BWSTT n =36
Age (in years): mean (SD)	66.4 (10.98)	69.03 (12.26)
Sex: male (%)	21(60%)	22 (61%)
Time from stroke onset (weeks): median (Q_1, Q_3)	18.00 (10.00,30.00)	18.5 (7.25,34.00)
Stroke Characteristics		
Type of stroke		
Ischemic	27	29
Lacunar	2	2
Hemorrhagic	5	3
Stroke location		
Anterior Cerebral Artery	1	1
Middle Cerebral Artery	23	18
Posterior Circulation	0	2
Brainstem/cerebellum	6	5
Undefined	5	10
Side of hemiparesis		
Right	20	17
Left	12	18
Bilateral	3	1
Comorbidities		
Diabetes	7	7
Chronic cardiac condition	14	10
Previous stroke	3	5
Hypertension	21	27
Lower limb orthopedic condition	12	13
Peripheral vascular disease (with claudication)	5	3
Pre-stroke Modified Functional Walking Category (/6) : mean(SD)	5.89 (0.32)	5.92 (0.28)
Post-Stroke Modified Functional Walking Category (Baseline) / 6: mean(SD)	4.54 (1.34)	4.31 (1.19)
Mini Mental Status Examination /30: mean(SD)	28.00 (2.04)	27.44(2.09)
Chedoke-McMaster Stroke Assessment: mean(SD)		
Leg /7		
Foot /7	5.10 (1.06)	4.88 (1.43)
	4.27 (1.68)	4.28 (1.63)
Comfortable Walking Speed (metres/second): mean(SD)		
	0.58 (0.24)	0.63 (0.29)

MLWP = motor learning walking program, BWSTT= body weight supported treadmill training, SD = standard deviation, Q=quartile

Table 3: Primary and secondary outcomes at baseline (T1), post-Intervention (T2) and 2-month follow up (T3)

Outcomes	**Groups mean (SD)**					
	Baseline (T1)		Post Treatment (T2)		Follow up (T3)	
	MLWP	BWSTT	MLWP	BWSTT	MLWP	BWSTT
Self Selected Gait speed (metres/sec)	0.58 (0.24)	0.63 (0.29)	0.69 (0.31)	0.77 (0.35)	0.74 (0.29)	0.78 (0.38)
Fast Gait speed (metres/sec)	0.76 (0.33)	0.85 (0.42)	0.89 (0.40)	1.10 (0.48)	0.99 (0.40)	1.01 (0.51)
Six Minute Walk Test (metres)	209.90 (109.64)	204.60 (102.82)	238.56 (120.11)	267.50 (135.26)	268.52 (117.40)	271.28 (136.63)
Functional Balance Test - Score (/20)	16.50 (2.55)	16.26 (2.47)	17.76 (2.71)	17.53 (2.23)	17.77 (2.30)	17.56 (2.44)
Functional Balance Test - Time (seconds)	71.43 (44.79)	72.85 (57.43)	60.29 (41.60)	60.91 (50.01)	54.12 (41.25)	66.88 (67.70)
Activities-specific Balance Confidence Scale (/100)	61.74 (18.07)	54.58 (22.60)	70.10 (17.44)	63.62 (20.02)	71.18 (21.14)	67.60 (20.34)
Life Space Assessment (/120)	46.19 (17.48)	46.23 (16.16)	53.15 (18.37)	53.47 (22.69)	59.08 (21.41)	58.03 (21.11)
SIS Global Recovery (/100)	55.09 (16.35)	59.81 (16.87)	65.08 (18.76)	65.74 (20.05)	71.73 (20.69)	67.31 (19.02)
SIS ADL (/50)	37.37 (8.07)	35.78 (6.85)	40.10 (7.04)	39.24 (6.77)	41.19 (7.18)	41.09 (6.46)
SIS Mobility (/45)	36.03 (5.93)	34.47 (6.02)	38.67 (4.55)	38.12 (5.03)	39.00 (5.52)	38.78 (5.20)
SIS Participation (/40)	26.31 (6.72)	24.61 (7.40)	29.93 (7.23)	28.59 (7.23)	31.96 (6.40)	30.97 (7.36)

SD = standard deviation SD), SIS = Stroke Impact Scale, MLWP=motor learning walking program, BWSTT=body weight supported treadmill training

Table 4: Differential effect of MLWP over BWSTT for primary and secondary outcomes at post-intervention and follow-up using intention-to-treat statistical analysis methods

Outcome	Differential effect of MLWP over BWSTT ($X_{MLWP} – X_{BWSTT}$) (95% CI)	p-value	Covariate(s)
Primary Analysis			
Comfortable Gait Speed at T2 (m/s)	- 0.00 (- 0.11; 0.11)	0.98	gait speed strata (binary)
Secondary Analysis			
Comfortable Gait speed at T3 (m/s)	0.00 (- 0.10; 0.10)	0.97	Self-selected gait speed T1
Fast gait speed T2 (m/s)	0.02 (- 0.10; 0.14)	0.79	Self-selected gait speed T1 Fast gait speed T1
Fast Gait Speed T3 (m/s)	0.05 (- 0.08; 0.19)	0.44	Self-selected gait speed T1 Fast gait speed T1
Six minute walk Test T2 (seconds)	- 7.38 (- 43.46; 28.71)	0.69	Self-selected gait speed T1 SMWT T1
Six Minute Walk Test T3	5.53 (-30.39; 41.44)	0.76	Self-selected gait speed T1 SMWT T1
ABC scale T2	4.85 (2.32; 12.03)	0.18	Self-selected gait speed T1 ABCscale T1
ABC scale T3	1.46 (-6.12; 9.04)	0.70	Self-selected gait speed T1 ABCscale T1
FBT – score T2	0.54 (- 0.18; 1.25)	0.14	Self-selected gait speed T1 FBTscore T1
FBT – score T3	0.53 (- 0.32; 1.37)	0.22	Self-selected gait speed T1 FBT score T1
FBT - time T2	- 6.01 (-15.97: 3.95)	0.23	Self-selected gait speed T1 FBT time T1
FBT – time T3	- 12.15 (-26.17; 1.89)	0.09	Self-selected gait speed T1 FBT time T1
Life Space Assessment T2	6.81 (- 1.09; 14.71)	0.09	Self-selected gait speed T1 LSQ T1
Life Space Assessment T3	5.08 (-3.73; 13.88)	0.26	Self-selected gait speed T1 LSQ T1
SIS ADL T2	1.68 (-0.72; 4.09)	0.17	Self-selected gait speed T1 SIS ADL T1
SIS ADL T3	0.68 (-1.57; 2.93)	0.55	Self-selected gait speed T1 SIS ADL T1
SIS Mobility T2	0.10 (-1.85; 2.06)	0.92	Self-selected gait speed T1 SIS Mob T1
SIS Mobility T3	0.07 (- 2.24; 2.38)	0.95	Self-selected gait speed T1 SIS Mob T1
SIS Participation T2	1.35 (-1.61; 4.30)	0.37	Self-selected gait speed T1 SIS Part T1
SIS Participation T3	0.96 (-1.94; 3.87)	0.52	Self-selected gait speed T1 SIS Part T1
SIS Global recovery T2	2.01 (-6.34; 10.36)	0.64	Self-selected gait speed T1 SIS Global Recovery T1
SIS Global Recovery T3	6.00 (-3.43; 15.42)	0.21	Self-selected gait speed T1 SIS Global Recovery T1

Bonferroni adjustment: alpha = 0.05/21=0.002

CONSORT Flow Diagram

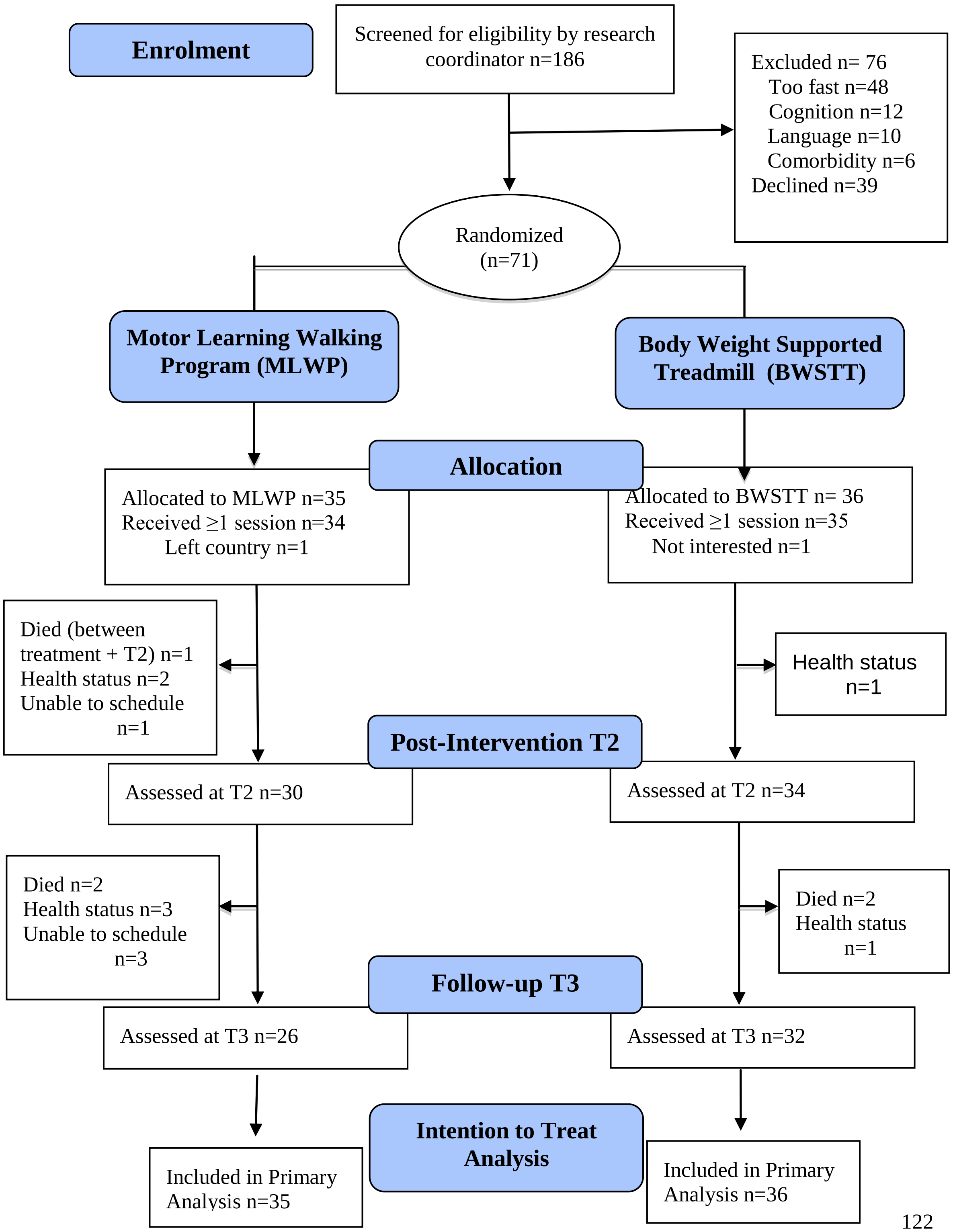

Figure 2 (a – f): Line graphs comparing intervention group scores on selected outcome measures at baseline (T1), post-intervention (T2), and follow-up(T3)

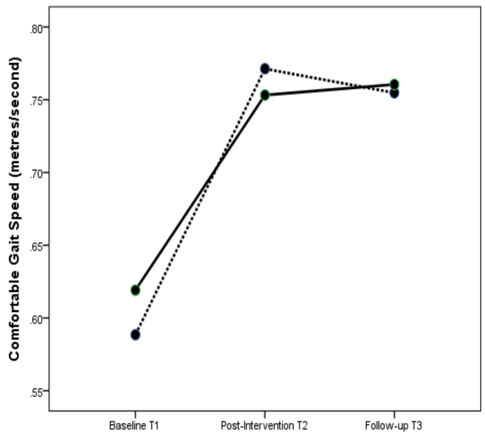

Figure 2a: Comfortable gait speed by intervention group over time

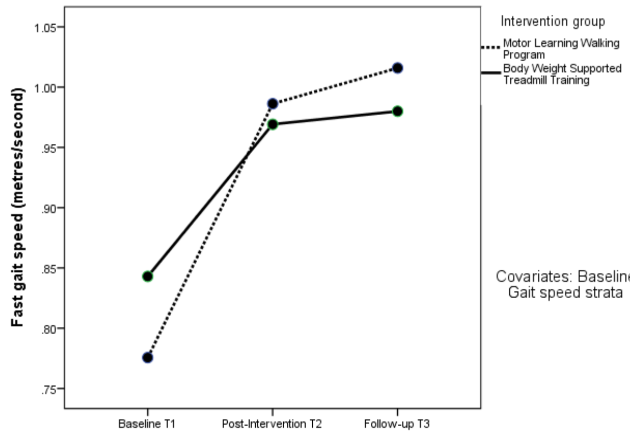

Figure 2b: Fast gait speed by intervention group over time

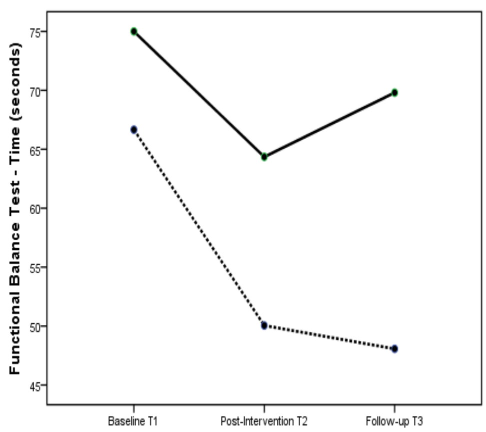

Figure 2c: Functional Balance Test - time by Intervention Group over time

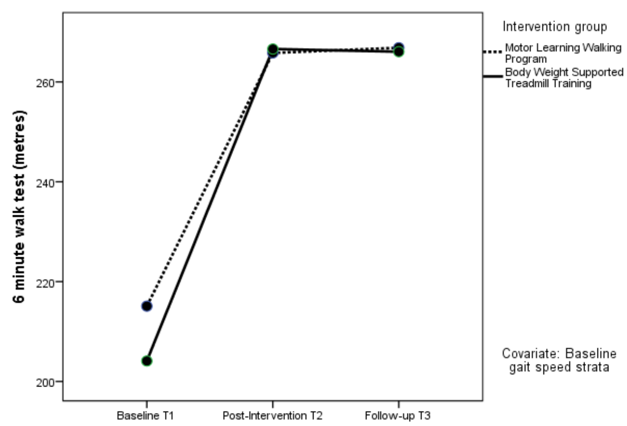

Figure 2d: Six minute walk test by intervention group over time

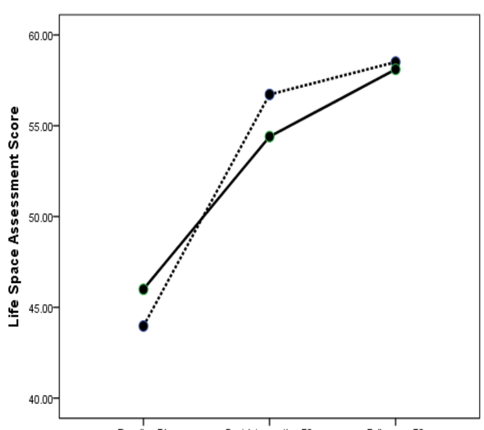

Figure 2e: Life Space Assessment by intervention group over time

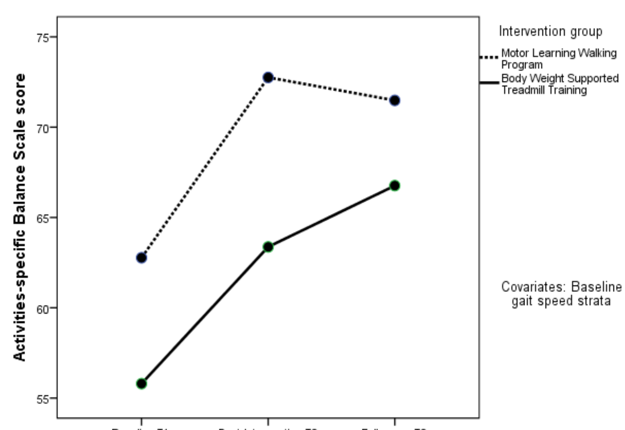

Figure 2f: Activities-specific Balance Scale score by intervention group over time

Chapter 5 – Discussion

INTRODUCTION

Following a stroke, as many as one in three people will report significant, persistent, walking dysfunction (Mayo, Wood-Dauphinee, Côté, Durcan, & Carlton, 2002). Physiotherapists working in inpatient, outpatient and community-based stroke rehabilitation settings are charged with helping these patients recover walking function and return to meaningful walking-related activities and roles. The manuscripts within this thesis represent a component of an overall research program dedicated to the development, evaluation, and implementation of optimally effective walking training interventions. This work is framed in the theory and research related to motor skill learning.

This discussion chapter includes a brief summary of the results of the studies in this thesis, discussion of the implications on practice, research and theory, potential limitations, recommendations for future research, and a brief conclusion.

SUMMARY OF THESIS RESULTS

Scoping Review

The first manuscript describes the methods, results and implications of a scoping review of the literature. The aim of this scoping review was to provide an overview of the general use of theory in outpatient-based walking-focused stroke rehabilitation research; and in particular, to appraise the degree and nature of the application of motor learning principles (MLPs) in this literature. Using a standardized data extraction process, twenty-seven papers were reviewed, data was collated, and themes summarized. In the majority of studies, investigators did not explicitly state a theoretical framework for their intervention and research. Research interventions tended to be based on one or more of the following theories, concepts, or fields of study (in order of frequency): 1) exercise science, 2) use-dependent neuroplasticity, 3) systems model of walking control, 4) central pattern generator theory of gait control and recovery, and 5) motor learning science. Given the required focus on walking-skill outcomes, surprisingly few papers (n= 6) cited motor learning science (or MLPs) as a rationale for the intervention content. Despite a lack of explicit reference to MLPs, the majority of described interventions were at least partially consistent with whole-task practice, and intensity of practice principles. Overground and virtual reality interventions were more likely to adhere to the MLPs related to specificity of practice, and variability of practice. Body-weight-supported treadmill training (BWSTT) and robotic interventions were typically inconsistent with the MLP related to guidance. Most authors failed to adequately describe practice order and feedback provision of their interventions. Overall, adherence to key MLPs was variable across walking-training interventions, and study interventions were rarely explicitly informed by motor-learning science.

Randomized controlled trial (RCT)

The major component of this thesis involved the planning, implementation, and analysis of a randomized controlled trial. The purpose of this trial was to evaluate the efficacy of the Motor Learning Walking Program (MLWP), in a group of ambulatory, community-dwelling, individuals within one year of stroke onset. The MLWP is an intense, task-specific walking training intervention designed to be consistent with MLPs related to practice, feedback and guidance. In this study, MLWP was compared to

BWSTT, a task-oriented walking intervention selected for its relative inconsistency with specific MLPs related to practice, feedback and guidance. A total of 71 participants were randomized to receive either 15 sessions of MLWP (n=35), or 15 sessions of BWSTT (n=36). Following training, there were no significant between-group differences on the primary outcome, post-intervention (T2) comfortable gait speed, or secondary outcome measures at T2 and T3 (2-month follow-up). Mean change in comfortable gait speed was 0.14 m/s for both intervention groups, a clinically meaningful change on this measure (Perera, Mody, Woodman, Studenski, 2006). Both interventions were observed to be equally intense with regards to treatment duration, number of sessions attended, and number of steps taken during each session (as represented by a step-counts on a sub-set of participants).

IMPLICATIONS OF THESIS WORK

This work represents a novel theory-framed approach to post-stroke walking-skill training research. The methods and results of both the scoping review and the randomized controlled trial have important implications to this field. In the following section, work presented in this thesis will be discussed in terms of potential implications and contributions to physiotherapy practice, the conduct of future research, and the interpretation and application of motor learning principles and theory in this area.

Implications And Contributions To Practice

This next section outlines the implications and contributions of this research on physiotherapy practice. Specifically the research will be discussed in terms of its potential use in the facilitation of increased clinical application of MLPs, and the feasibility of delivering an effective, high-intensity, walking-skill specific intervention in the clinical setting.

Scoping review as a reference for clinicians

Staying current with the latest evidence can be a challenge for frontline clinicians. Physiotherapists working in stroke-rehabilitation settings identify a lack of time, and limited confidence in their ability to read and appraise the literature, as barriers to keeping up-to-date with walking-intervention research (Salbach et al., 2009). Therapists who do find the time to read, tend to select review papers and clinical practice guidelines over original research (Salbach et al., 2009). While these literature summaries may be preferred, their availability does not necessarily lead to change in practice (Bayley et al., 2012). Vague descriptions and insufficient detail of interventions can make it difficult for therapists to apply recommendations. For example, task-related (also referred to as task-oriented, and task-specific) walking training has been recommended as the rehabilitation treatment of choice for patients with stroke, however, as outlined in Chapter 2 of this thesis, it can be difficult for clinicians to interpret what task-related walking training actually entails.

The scoping review component of this thesis provides therapists with a digestible description of walking-focused interventions from the perspective of treatment content and adherence to motor learning principles. This comparison of interventions from six task-related treatment categories [1) overground-focused, 2) treadmill, 3) BWSTT, 4) robotic-assisted treadmill training, 5) combined treadmill and overground, and 6) treadmill training in virtual environments], should assist clinicians with treatment selection and implementation. This review also provides a summary of key MLPs, and an example of how they can be used as a framework to appraise the content of other interventions within the literature, or to assess their own treatment sessions. Although a similar approach has been used to describe paediatric rehabilitation, (Zwicker & Harris 2009; Levac, Wishart, Missiuna, & Wright, 2010; Levac, Rivard, & Missiuna, 2012), and post-stroke arm and hand rehabilitation (Timmermans, Spooren, Kingma & Seelen, 2010), to our knowledge, this is the first scoping review that examines the post-stroke walking training literature through the lens of MLPs.

Modeling the application of MLPs in stroke rehabilitation

The underlying premise of this thesis is that motor learning science, and the associated MLP's, are a suitable theoretical framework for the study and practice of stroke rehabilitation. The directive for increased application of MLPs is not new (Carr & Shepherd, 1982; Gilmore & Spaulding, 1991; Wishart, Lee, Ezekiel, Marley, & Lehto, 2000), however, as evident in the results of the scoping review, integration of these principles into walking training literature and practice remains limited. Although the results of the RCT do not indicate the superiority of MLWP over BWSTT, we maintain that motor learning science can serve as an appropriate framework by which clinicians can evaluate and structure their treatments. The MLWP treatment model described in the protocol paper provides a detailed example of how treatment maybe organized, and modified based on the manipulation of one or more motor learning principles to potentially improve the acquisition of walking skills.

Intensive, high repetition walking practice is feasible

There has been much attention given in the stroke literature to the importance of training intensity during rehabilitation. We know that the addition of as little as 16 hours of task-oriented lower extremity training within the first 6 months after stroke can improve functional outcomes (Kwakkel et al., 2004). While the amount of time spent on walking-related activities is important, the number of repetitions of steps taken during training may be a more relevant indicator of treatment intensity. The minimal dose of stepping practice required to induce neuroplastic adaptation has yet to be determined in humans, however animal experiments suggest that it will likely require thousands of steps per day to achieve functional recovery (Lang, et al. 2009, MacLellan, et al., 2011). Unfortunately, when typical outpatient physiotherapy has been observed, patients took only 500 steps per session (Lang, et al., 2009). In our RCT, participants from both interventions took an average of more than 1600 steps in a single 45-minute treatment session. If therapists prioritize the practice of walking, it is feasible to significantly increase the amount of task-specific walking practice without the addition of specialized equipment, or extra-therapist assistance.

Improved walking outcomes achievable within existing resources

For clinicians and health managers, the most obvious implication of this research relates to our findings of no-difference between the two interventions. Considering that that both interventions facilitated intense practice, and improved walking function, therapists should feel comfortable using either intervention with their patients. As discussed in the manuscript, clinicians may base treatment decisions on issues related to patient preference, availability of equipment, and staff resources. For facilities without BWSTT equipment, it would be difficult to justify the devotion of limited healthcare funds on the purchase of this costly equipment. As implemented in our study, the MLWP can be applied with existing equipment and resources in any outpatient physiotherapy department or clinic. This intervention may also lend itself to application within the patient's home and community. Further research is required to confirm the effectiveness of this intervention in the home setting.

Implications And Contributions To Research

The research in this thesis has important implications to the conduct and interpretation of future post-stroke walking-skill focused research. In the following section we discuss the need to clarify terminology, the value of a model of a theory-driven research, and the challenges related to the application of motor learning research concepts and methods to clinically focused research trials.

Clarifying terminology in research

The clear, consistent use of terms can help with interpretation and application of research findings. One of the contributions of the scoping review was to highlight the variability of terminology used, the implications of specific terms, and to offer recommendations that will help clarify the following commonly used terms; *task-specific* training, *task-oriented or task-related* training; and *intensity* as it relates to training or practice.

Task-specific versus task-oriented, or task-related training

In rehabilitation literature, task-specific training is frequently used interchangeably with such terms as task-oriented, and task-related training. In a recent review of walking-focused treatments, task-oriented training refers to "the practice of functional tasks associated with walking rather than to the remediation of specific impairments or of individual components of the gait cycle" (Dickstein 2008, page 650). In their study of a robotic-assisted walking training intervention, Dias et al. (2007, p.500) describe task-specific training, as any intervention that "allows the practice of complete gait cycles with many repetitions instead of single elements or preparatory manoeuvres…" As argued in the scoping review, the variability of terms, and definitions could be a barrier to research interpretation and implementation.

In the scoping review, two motor learning concepts relevant to task-specific training are discussed; specificity of learning, and whole task practice of continuous motor skills. The specificity of learning, or practice, hypothesis states that learning is optimized when the *conditions of practice* closely resemble the conditions of later performance or testing (Schmidt & Lee, 2011). *Conditions of practice* can refer to the task and environmental conditions, feedback conditions, and the required cognitive processes during training. According to the principle of whole-task practice, continuous tasks (i.e. tasks that have no distinct beginning or end) are learned optimally when practiced as a whole, rather than in parts.

Based on these definitions and MLPs we suggest that terms should be defined in a way that is consistent with the literature. We recommend that the term *task-specific* walking training be reserved to describe interventions that include the whole-task practice of the entire gait cycle, *and* where task, environment, feedback and cognitive processing conditions are structured to resemble the expected conditions of typical daily walking. *Task-oriented* and *task-related* practice should be considered a broader umbrella category of treatments. Under this umbrella one could include any intervention that is intended to improving a person's overground walking skill, but may include practice activities that are not specifically overground walking. For example, a walking *task-related, or task-oriented* intervention may include walking on a treadmill, or repetitive standing from a chair, step ups, and heel raises, to target the muscle groups known to be involved in normal-walking performance (e.g. hip extensors, ankle plantar flexors), however these activities would not meet the criteria for overground walking task-specific training.

Intensity of practice

Another frequently used term in need of clarification is *intensity of practice*. As demonstrated in the scoping review, many investigators framed walking rehabilitation in concepts related to exercise science. In this framework, the primary aim of walking training is to build physical capacity (i.e. aerobic, strength), and these changes in capacity are assumed to improve walking function. Given the prevalence of this framework, it is not surprising that most studies describe training intensity using exercise-prescription concepts such as training frequency, duration, and amount of physical effort or workload exerted (e.g. heart rate, blood pressure and perceived physical exertion) (Michael et al., 2009; Macko et al., 2005, Moore, Roth, Killian, & Hornby, 2010, Jorgensen et al., 2010). While we support the inclusion of dose and workload under the broad umbrella of intensity, in the scoping review we recommend that the definition of intensity be expanded to better reflect the motor-skill-building nature of post-stroke walking training interventions.

One of the strongest, most consistent findings in field of motor learning is that learning increases with increased practice (Schmidt & Lee, 2011). As such we recommend that amount of practice (e.g. number steps taken, time spent walking specific activity) be included in research descriptions of training intensity. In addition, we also know that in order for motor learning to occur, practice must not only be abundant, but it also needs to be *challenging* (Kleim 2008, Schmidt & Lee, 2011). In motor-skill learning, this concept of challenge implies not just physical effort, but also emphasizes the need for cognitive effort (Lee, Swinnen, & Serrien, 2004; Schmidt & Lee, 2011). As outlined in the scoping review and the RCT protocol, cognitive effort during practice can be increased or decreased through the addition of concurrent mental or physical tasks, limiting guidance and feedback, and ordering practice tasks in random or serial manner. In order to differentiate walking-skill focused interventions from walking-capacity building interventions, we recommend that in future research, the *intensity and challenge* level of walking-skill training interventions be explicitly described in terms related to amount of walking specific practice, and the amount of cognitive effort during practice.

Modeling a theory-driven approach to walking rehabilitation research

In addition to clarifying the use of terms, this thesis provides researchers with an example of how theory can be used to frame a rehabilitation research program. The scoping review manuscript highlights the inconsistent use of theory within walking rehabilitation literature. By summarizing the influence of stated, and implied, theoretical frameworks into categories (i.e. exercise science, use-dependent neuroplasticity, CPG theory, systems model of motor control, and motor learning science), the scoping review provides a template for further discussion of theory in this field of study. In addition to enumerating the theoretical frameworks in use, the apparent, and potential implications of these theoretical frameworks on clinical and research intervention decisions were considered. This work supports previous calls (Whyte, 2006; Siemonsma, Schroder, Roorda & Lettinga 2010) for researchers and research consumers to be explicit in their thinking and writing not only about what treatments they are using with patients, but also how and why these treatments elicit change in their patients' function – in other words, provide a theoretical framework. The limited presence of theory in this literature may reflect a discomfort, or lack of confidence on the part of investigators on the use theory in research. The RCT in this thesis is unique as it represents an example of a comparison of two theoretically defined walking interventions. Together, the RCT protocol and the results paper provide a model of a theoretically framed intervention and research design that can be applied in future rehabilitation trials.

Theoretical Implications And Considerations

According to Creswell (2009, p.51), a theory is "an interrelated set of constructs (or variables) formed into propositions, or hypotheses, that specify the relationship among variables (typically in terms of magnitude or direction)." In motor learning science, the relationship between a specific learning condition or variable, and learning outcome (i.e. skill-acquisition), is specified by a particular MLP. In this RCT, we took a number of key MLPs related to practice, feedback and guidance, and applied them together to improve overall walking-skill learning after stroke. This combination of MLPs and application to walking training was grounded in a number of assumptions regarding the MLPs themselves, the relationship between these different motor learning variables, and the interaction of the variables with the learner and the learning environment. In this section, we will reconsider some of the assumptions made and discuss the contributions to future understanding of motor learning and walking-skill acquisition following stroke.

Motor learning variables on a continuous rather than dichotomous scale

One basic assumption underlying the design of this RCT was that walking-training interventions could be judged as being adherent, or non-adherent to a particular MLP. That is, application of these MLPs was viewed in a dichotomous, (or in our scoping review, a trichotomous) manner. On reflection, it is likely more appropriate to think about these interventions on a continuous scale, with degrees of adherence with a particular principle. For example, if we consider specificity of practice in walking-skill training, we may place an impairment-focused, seated, strength-training program at the far left end of the specificity scale (*non-specific*), and a task- and environment-specific community-based walking training program at the far right end of the specificity scale (*highly-specific*). BWSTT and the outpatient-based MLWP program would likely fall somewhere between these two anchors. It may be that the differential impact of one intervention over another is dependent on the distance between the two interventions on the adherence scale. In an effort to compare two active, walking-skill focused interventions, the relative benefit of the arguably more task-specific MLWP program may have been relatively subtle, and difficult to detect using clinical outcome measures. MLPs related to amount of practice, variability, order, guidance, and feedback are all suited for this continuous scale approach to appraisal and application. In future trials, consideration of the relative adherence to MLPs on a continuous scale could assist researchers as selecting comparison interventions, and interpretation of results. .

One rule may not fit all situations

A second underlying assumption of this study was that the application of a particular MLP, or set of principles, would enhance walking-skill equally in all patients, with all types of walking tasks. In fact, it is probable that one motor learning rule does not fit all situations. In our RCT, the MLWP was designed to adhere to targeted MLPs in a fairly rigid, and standardized manner in order to extenuate the differences between comparison interventions. Therapists were instructed to organize all practice in a serial or random order, ask patients to self-evaluate performances, provide reduced frequency and/or summary augmented feedback, and to only provide guidance for safety. While these instructions may have improved treatment fidelity, this approach overlooks evidence that response to motor learning conditions may not be uniform across all situations.

As discussed in Chapter 4, there is evidence in the motor learning literature that effect of practice conditions can depend on the complexity of the task, and the skill level of the learner. For example, contrary to the prediction of the guidance hypothesis, Wulf, Shea, and Whitacre (1998) found that individuals benefited from physical guidance during practice of a complex ski simulation task. This interaction between task complexity and learning response has also been demonstrated in relation to practice order, and feedback (Wulf & Shea, 2002). Similarly, there is evidence that learner experience and skill level may also impact the response to adjustments in practice order (Schmidt and Lee, 2011, Porter & Magill, 2010), feedback (Dornier, Guadagnoli & Tandy, 1996), and physical guidance (Schmidt & Lee 2011; Marchal-Crespo, McHughen, Cramer & Reinkensmeyer 2010). Future research should explore the impact of a more flexible approach to the application of MLPs. As discussed in Chapter 4, incorporation of the learner-, and task-specific concepts represented in the Challenge Point Framework (Guadagnoli & Lee 2004), may enhance the effect of the MLWP on walking outcomes.

Another example of "one rule may not fit all situations", relates to choosing the number of variables within an intervention. An underlying assumption of the scoping review and the RCT was that if learning could be enhanced by adherence to one of these MLPs, then the simultaneous application of 3, 4, or 5 of these MLPs would magnify the learning effect and improve recovery of walking function. Basic to this prediction is the assumption that *if* these ML variables interact with each other, the interaction will be positive. On reflection, this assumption needs further exploration. Because most learning experiments adjust one variable at a time, we know very little about how these variables may interact. If we return to the Challenge Point Framework (Guadagnoli & Lee, 2004), in certain situations, the addition of reduced frequency feedback, and minimal physical guidance, to an already challenging, randomly-ordered practice schedule, may actually impede rather than improve, learning. Future studies should explore the effects of application of single, versus multiple motor learning principles in learning of walking tasks.

LIMITATIONS OF THESIS WORK

There are a number of limitations of this thesis work that may impact the validity and generalizability of the findings. These limitations will be discussed as they relate to the scoping review manuscript, and the RCT.

Scoping Review Limitations

The intent of the scoping review within this thesis was to describe the state of the research from the perspective of the use of theory, and in particular, application of MLPs. These results represent the appraisal of a specific body of literature, from a specific time period. As such, the results cannot be directly generalized to other interventions, (e.g. functional electrical stimulation or biofeedback studies), and to literature published before 1996, and after 2011. While we do not expect that the direction, and content of the literature has changed significantly since 2011, the broadly disseminated results of the LEAPS trial, one of the largest RCT's published in rehabilitation, has generated interesting discussion regarding the use of theory, and particularly the need to examine the content of task-related walking interventions (Dobkin & Duncan, 2012). We are optimistic that the work within this thesis will contribute to this apparent change in the approach to post-stroke walking rehabilitation.

Randomized Controlled Trial Limitations

In the thesis RCT, there were a few issues related to participant recruitment, inclusion criteria, and outcome measurement that could have affected the overall validity, and generalizability of the results. Each of these limitations will be discussed briefly in the following section.

Participant recruitment challenges

One of the most important, and challenging, aspects of planning and running a RCT, is ensuring adequate and timely recruitment of participants. In this RCT, the projected recruitment rate was 3 participants per month over the 2-year funding period. At the end of 27 months, only 24 participants had been recruited, and a time extension was required. A review of recruitment processes revealed barriers related to patients (e.g. transportation, awareness), referring clinicians (e.g. awareness, misconceptions, and negative attitudes regarding study interventions), and the system (e.g. competition with existing clinical programs and other research studies.) These barriers are consistent with issues previously identified in rehabilitation research (Bell et al., 2008; Blanton et al., 2006; Lloyd, Dean, & Ada, 2010). In effort to improve recruitment rate, existing funds were reorganized to implement the following strategies; 1) hired a recruitment physiotherapist to meet with clinicians and patients, 2) opened a satellite treatment site, 3) organizing and paying for transportation, and 4) increased marketing through newspapers, flyers, and e-mail. Following the implementation of these strategies, recruitment rate increased from 1 participant-per-month, to 3 participants-per-month. In the final 16 months of the study, 47 participants were recruited and randomized. Recruitment patterns are presented in Figure 1.

Impact of recruitment challenges on participant characteristics

Although the target sample size (n=70) was achieved, an extended recruitment period and recruitment difficulties can threaten the validity, and generalizability of research (Bell et al., 2008). Post-hoc review of data revealed potentially important participant differences between recruitment periods. Participants recruited in the first 27 months (n=24) represented a younger, more able group from a smaller geographical area. Following changes in recruitment and intervention delivery strategies, an older, more disabled sample of participants from a broader area were recruited (n=47). While we believe that the improvements in recruitment strategy minimized the overall impact of our original slow, limited recruitment, it is important that in future research, recruitment issues are anticipated, planned for, and addressed earlier in the study process.

Potential impact of broad inclusion criteria

Broad inclusion criteria of the RCT increased generalizability of the results however may also have diluted the observed effects of the MLWP or the BWSTT on walking outcomes. It is possible that certain subgroups of patients are better suited for the cognitively demanding, varied practice approach of the MLWP, while others are more suited for the repetitive, assisted BWSTT approach. There is evidence that patients with reduced proprioception have been shown to benefit from more frequent feedback than those with intact proprioception (Vidoni & Boyd, 2009). In other research, location of stroke can influence response to practice (Boyd & Winstein 2006) and feedback (Saywell & Taylor, 2008). It is important that future exploratory research identify the differential effect of MLP-based walking interventions on different stroke sub-populations.

Lack of impairment-focused outcome measures

In the RCT in this thesis, impact of training was measured using clinical measures of walking function, and self-reported measures of self-efficacy, participation, and quality of life. While both interventions were associated with improvements in these clinical measures, the lack of an impairment-based measure of gait quality makes it impossible to determine whether these changes represent actual remediation of pre-stroke motor control, or rather, compensatory strategies that allow functional improvements (Krakauer, Carmichael, Corbett, & Wittenberg, 2012). In order to maximize our understanding of how different interventions affect similar changes in function, future explanatory research needs to include impairment as well as activity and participation based outcome measures.

In summary, a number of methodological issues in the scoping review and RCT may affect the validity and generalizability of this work. We expect that discussion of these limitations will future research design in this area of study.

FUTURE RESEARCH DIRECTIONS

Going forward, we recommend that post-stroke walking training research should be organized to include small, explanatory, theory testing experiments; small randomized controlled efficacy trials; and when appropriate, large pragmatic multicenter, effectiveness trials. While the *content* of this program is consistent with the modified phased approach to research (Whyte, 2009, Dobkin 2009), it is recommended that future research also be informed by the Medical Research Council (MRC) guidelines for the development and evaluation of complex interventions (Craig et al., 2008). By definition a complex intervention is one that is “built up from a number of components, which may act independently or interdependently although the ‘active ingredient’ is generally difficult to specify.” (Wells, Williams, Treweek, Coyle, & Taylor, 2012, p. 2). Walking-skill training would comfortably fit this definition. The MRC framework will benefit this research program for a number of reasons: 1) the iterative, bidirectional, flow of research, will allow the research program to move from the theory-driven, RCT described in this thesis, back to theory-testing experimental studies, and return to RCT’s again; 2) the framework’s emphasis on the need to include measures of intervention process and fidelity, for example, indicators of practice intensity such as step activity, and cognitive effort; and 3) the recognition that some variability of treatment delivery is inevitable, allowing for the MLWP to be delivered in a patient, task and environment-specific manner.

Based on the results of the scoping review, and the randomized controlled trial, the following future research activities are recommended.

Recommendation 1: Review study

Consistent with its objectives, the scoping review provided a comprehensive overview of the current use of theory, and in particular, the integration of MLPs in outpatient-based, post-stroke walking training research. While this research has highlighted current gaps and research directions, it would be valuable to follow up this work with a meta-analysis using MLPs as a framework. Timmermans et al. (2010) conducted a systematic review that assessed the impact of content of task-oriented arm and hand training interventions after stroke. In their study, a distributed practice schedule, provision of feedback, random practice, and goal setting, were all associated with greater treatment effect sizes. Notwithstanding some methodological limitations within this systematic review, it would interesting to use a similar approach to evaluate the impact of these MLPs on treatment effect size in walking studies.

Recommendation 2: Secondary Analysis of the RCT

As a follow-up to this RCT, we are interested in asking additional questions of the data. As there were no between-group differences on the primary and secondary outcome measures, and the study was not powered for subgroup analyses, data could be assessed as a single cohort. Secondary analyses could explore the factors that predict clinically meaningful change, and maintenance, on primary and secondary outcomes. We could also examine the strength of correlations between baselines and change scores on the different outcome measures.

In addition, data based on other measures could be analysed. For example, we plan to explore data collected in this trial using the Patient Specific Function Scale (Stratford, Gill, Westaway, & Binkley, 1995) at T1, T2, and T3. As this was the first time the PSFS has been used in a stroke rehabilitation trial, we are interested in describing the types of walking-related goals identified, the behaviour of PSFS scores over time, and the relationship between change scores on the PSFS and other performance-based, and self-report measures collected in this study.

Recommendation 3: Future experimental and clinical research activities

In order to confidently recommend the increased application of MLPs in post-stroke walking training practice, more research is required to evaluate the individual and combined effects of structuring practice and feedback according to motor learning science. There is a need for small, laboratory, and clinic-based experiments in individuals with stroke. For example, using a motor-learning-research paradigm, participants will practice standardized, novel, challenging walking tasks while the impact of adjustments to single motor learning variables are evaluated. We have already initiated this type of work. In an ongoing experiment (n=30), participants learn a modified-tandem walk task over 5 days, under one of three guidance conditions (no-, faded-, or constant-guidance) (DePaul, Wishart, Balasubramaniam, & Lee, 2012). Studies should progress to include stepwise evaluation of different combinations of motor-learning-variable adjustments on learning outcomes. It is also recommended that future studies evaluate the use of the Challenge Point Framework (Guadagnoli & Lee, 2004) as an approach to tailor walking training interventions to suit patient experience and skill level, and complexity of the walking task to be learned.

In addition to clinical measures of walking speed, these experimental studies, should include retention measures on the experimental walking task, transfer tests (e.g. performance of walking task over altered walking surface), and measures of temporo-spatial measures of gait. The inclusion of these measures will help differentiate remediation versus compensation-driven improvements in function, informing intervention content, target population (e.g. stroke chronicity), and outcome selection in Phase II and III type studies (Krakauer, et al., 2012).

Once the MLWP has been refined through explanatory, Phase I and II type studies, research should progress to a pragmatic evaluation of the relative effectiveness, and cost-effectiveness, of different methods of delivering the MLWP to patients. Future research should include a large, RCT to compare group-format, versus one-to-one MLWP delivery models. It would also be useful to evaluate clinic-based versus home-based models of a refined version of the MLWP.

Recommendation 4: Describing Interventions

As highlighted in the results of the scoping review, it is essential that future rehabilitation research adequately describes the content and fidelity of experimental and control interventions. Investigators should provide some description of what was practiced, the order of practice, what feedback was provided, and how much guidance was provided. We also recommend the use of step activity monitors, or other accelerometers (Gebruers, Vanroy, Truijen, Engelborghs, & De Deyn, 2010), to quantify the amount of walking activity performed during, and between treatment sessions. This will allow hypothesis generation regarding the relative contribution of practice intensity on treatment outcomes. Investigators may also consider including a measure of cognitive effort such as performance on a concurrent mental task, or a surrogate physiological marker (e.g. pupil dilatation [Schmidt & Lee, 2011], skin temperature [Cohen & Waters, 1985]) to allow comment on the importance of cognitive effort during practice on functional outcomes.

CONCLUSIONS

The overall goal of this thesis work was to inform the development of optimally effective, walking-skill focused, rehabilitation interventions for community-dwelling individuals with history of stroke. This research was unique in its explicit use of motor learning principles as a framework for the review and interpretation of literature, intervention development, and design of a randomized controlled trial. This theory-based approach highlights the limited, inconsistent application of MLPs in current literature, provides therapists with a novel treatment model for the integration of MLPs into post-stroke walking-skill training, and offers researchers an example of a theory-driven approach to rehabilitation research. The methods and results of this work offer a unique and significant contribution toward the development and evaluation of effective walking-skill focused interventions. This work represents important steps forward in a comprehensive program of motor learning science-framed clinical research.

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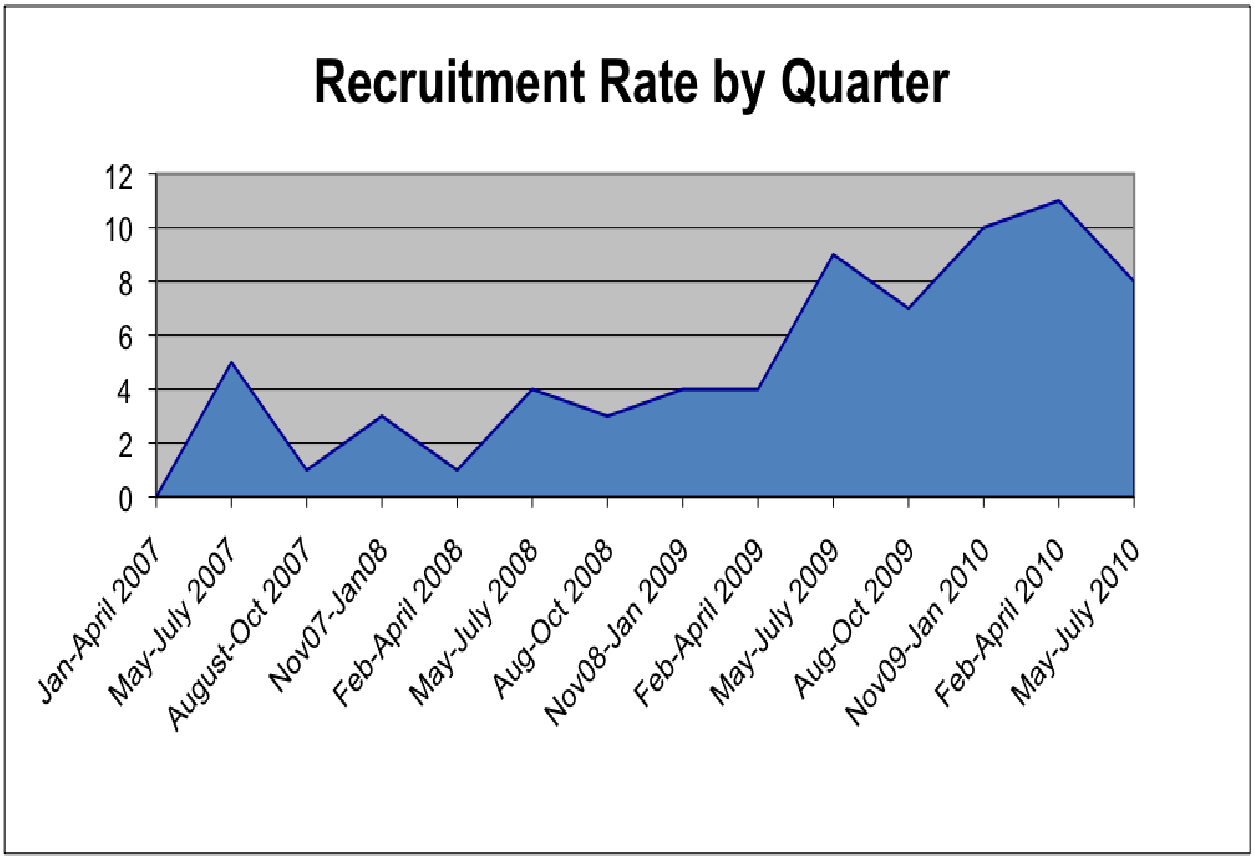

Figure 1: Participant recruitment rate per 3-month period for randomized controlled trial

Appendix A: Scoping review data extraction tool

Data Extraction Tool – Scoping Review

Author Year Journal	
Design	
Purpose	
Participants	
Experimental Intervention	
Intervention category	
Control Intervention	
Outcomes	
Theoretic Rationale 1	
Explicit or Implicit	
Theoretic Rationale 2	
Explicit or Implicit	
Definition of walking	
Description of Intervention	
Specificity of Task	
E vs I	
Practice intensity/Amount	
E vs I	
Variability/practice order	
E vs I	
Feedback/Instructions	
E vs I	
Physical Guidance	
E vs I	

Appendix B: Scoping review - Adherence to motor learning principles rating scale

Scoping Review

Adherence to Motor Learning Principles Rating Scale

Adherence Rating		**Definitions/Criteria**
Specificity of Training/Practice: *Practice conditions should resemble the expected conditions of typical performance*.		
3	High	Tasks practice are specific to walking Tasks resemble/consider environmental context and demands of community mobility Majority of tasks focus on walking
2	Moderate	Some task practice relates to walking/stepping May not consider environmental context/demands of community mobility
1	Low	Does not include actual walking Impairment focused practice Part-task practice
0	Not Reported	Inadequate information provided for us to rate level of adherence to principle
Variable Practice: *Practice of a skill under a variety of environmental and task conditions usually leads to improved skill retention and transfer.*		
3	High	Training includes practicing walking under a variety of task and environmental conditions – within a single practice session.
2	Moderate	Training includes walking – there is some evidence that the participant had a chance to walk under different conditions – yet not consistent or done with the purpose of benefiting from variable practice. Eg. for treadmill training, authors mention that treadmill speed may increase from training bout to training bout (with the same training session) depending on partipant performance).
1	Low	Training includes walking task – however there is no evidence that participant has the opportunity to practice the task under different conditions (task or environmental) during a single training session. E.g. walking on treadmill – with change in speed or amount of body weight support
0	Not Reported	Inadequate information provided for us to rate level of adherence to principle

<table>
<tr><td colspan="3">Intensity of practice

Practice should be abundant, progressive and challenging.</td></tr>
<tr><td>3</td><td>High</td><td>Emphasis on intense practice from exercise perspective and learning perspective

Explicit re. intensity of practice – re. frequency, duration, number of repetitions

Task practice is challenging, progressive – including adding such challenges as dual task, task complexity</td></tr>
<tr><td>2</td><td>Moderate</td><td>Describes frequency and duration

Not specific about progressing task difficulty/challenge level of training</td></tr>
<tr><td>1</td><td>Low</td><td>Relatively low intensity, no mention of challenging re. complexity of tasks, not progressive</td></tr>
<tr><td>0</td><td>Not Reported</td><td>Inadequate information provided for us to rate level of adherence to principle</td></tr>
<tr><td colspan="3">Practice Order

The effect of (variable) practice is usually enhanced when practice is organized in a non-repetitive order (ie. Random or serial).</td></tr>
<tr><td>3</td><td>High</td><td>Explicit about order of practice – random or serial – non-repetitive – learner returns to station/task after performing other stations/tasks

Consistent application of this principle</td></tr>
<tr><td>2</td><td>Moderate</td><td>Inconsistent use of random or serial practice order</td></tr>
<tr><td>1</td><td>Low</td><td>Blocked practice</td></tr>
<tr><td>0</td><td>Not Reported</td><td>Inadequate information provided for us to rate level of adherence to principle</td></tr>
<tr><td colspan="3">Feedback (FB)

Augmented FB should be given in a manner that encourages the learner to interpret their own internal FB mechanisms.</td></tr>
<tr><td>3</td><td>High</td><td>Augmented FB consistently given in manner that encourages learner to interpret own FB mechanisms –

Frequency is likely to be intermittent, delayed, or summary FB

Patient may be specifically asked to self evaluate their own performance

Content of FB is directed at helping participant learn or develop skill related to the task practiced.

May include motivational FB but not exclusively motivational/encouragement.</td></tr>
<tr><td>2</td><td>Moderate</td><td>Inconsistent application of the desired FB behaviours (as per rating high)

Evidence that FB provided in order to improve skill/learning</td></tr>
</table>

		Some evidence that participant allowed to interpret own FB mechanisms (through delayed FB, intermittent FB) May mix motivational FB and some evidence of allowing of self evaluation/time to interpret own FB
1	Low	FB is mostly motivational, encouragement May also report providing continuous verbal or visual FB with the intention to have patient correct movement errors , or prevent movement errors. Provided continuous FB with apparent goal to enhance performance
0	Not Reported	Inadequate information provided for us to rate level of adherence to principle
Physical Guidance *Excessive guidance can degrade learning. Guidance should be provided in a manner that allows one to commit and learn from errors.*		
3	High	Guidance, if any, provided in a manner that allows patient to learn from errors. Minimal physical guidance/handling during practice. Some mention of rationale for limited or no guidance based on learning.
2	Moderate	Some evidence that handling/guidance was minimal or not constant – however not explicit about the rationale for minimal guidance. If group or class format – likely low guidance but not specified.
1	Low	Constant or frequent guidance provided with the intention to prevent, minimize errors during practice.
0	Not Reported	Inadequate information provided for us to rate level of adherence to principle
Note: Explicit versus Implicit use of Motor Learning Principles **Explicit**: Authors refer to the motor learning priniciple by name and may cite the motor learning literature as rationale for designing their intervention as they did. **Implicit:** Authors *do not* refer to motor learning principles or cite motor learning literature. Judgement of level of adherence is based of review of the intervention description provided.		

Use of Theory as rationale for study and study design
Explicit Use of Theory: Authors explicitly refer to theory when describing the rationale for the study, the intervention or study design decisions. Ideally, authors actually use the term theory, principles, and/or model in their rationale. **Implicit use of Theory**: Authors may cite empirical evidence rather than a theoretic framework as rationale for study. If a theory is not explicitly described, a theoretic framework may be implied in, or deduced from, the authors' chosen background literature, use of terminology, outcomes selected, intervention content.

Appendix C: Motor Learning Walking Program intervention description

Description of the Motor Learning Walking Program (MLWP) for the Stroke Walking Training Study

(Provided to MLWP training Physiotherapists)

December 20, 2006

Goal of the Motor Learning Walking Program

The goal of the Motor Learning Walking Program is to facilitate improvements in a participant's walking ability, walking self-efficacy and participation in community walking activities.
In order to achieve these goals, this intervention has been designed to maximally engage the learner/participant in the training program. This engagement is accomplished through manipulation of the following factors: 1) content of practice, 2) schedule of practice, 3) timing and content of augmented feedback, and 4) instructions provided.

Content of Practice

Variable Practice
In order to develop a level of skill that allows an individual to perform a task in a variety of different settings, in a variety of different circumstances, the training sessions must include variable practice. The basic task of walking over ground will be practiced in a variety of environments, under a variety of different situations. At times the tasks will be fairly similar – for example, walking over ceramic tiles versus walking over carpeted surface. Other tasks will be significantly different from one another. For example, walking over tiled floor to walking up and down stairs.

Core Tasks

It is essential that practice tasks resemble the demands of community mobility. It is also important that the tasks practiced are meaningful to the participant.
A core list of walking related tasks are to be practiced with all participants. These skills are seen to be essential to basic independent community ambulation. The core tasks include:
1) Walking over short distances;
2) Sustained walking over longer distances (>50m) or prolonged duration (> 5 minutes);
3) Walking up and down steps or slopes;
4) Obstacle avoidance while walking;
5) Transitional movements, eg. Getting up from chair and walking;
6) Changes in centre of gravity position during walking (e.g. walking then reaching to pick something off floor);
7) Walking and changing direction/turning;

Progressing or increasing complexity of core tasks

While the core tasks represent the basic demands of community mobility, the MLWP intervention has been designed to ensure participants are challenged by the tasks practiced. This element of challenge will require that these core tasks are made more complex.
Increasing the difficulty of these tasks is achieved in a number of ways: 1) dual or multiple task performance while walking (mental, or physical – including a carrying

task); 2) performance in altered environmental conditions (indoors, outdoors, uneven terrain, dim light, noisy room); 3) performance of task under time limited conditions (e.g. walking at a time crosswalk); 4) walking under predictable or unpredictable conditions – eg. Walking around stationary objects versus through a busy, crowded room.

It is important to note that one or more of these manipulations can be added to the core task concurrently. For example, a participant may be asked to walk 50 m on an uneven surface while carrying a weighted grocery bag.

The content of the Motor Learning Walking Program are based on the work of Anne Gentile (Taxonomy of Movement) (2000) as well as Shumway-Cook et al's (2002) work to describe the environmental demands of community mobility.

Examples of core task manipulations

Walking and perform a visual and cognitive task - add numbers off cards that are taped to walls around room

Manipulative/Carrying Demands
Carry grocery bag with light groceries – one hand
Carry empty cup
Carry cup with water
Carry small laundry basket
Carry tray with rolling ball on it
Carry tray with cup of water

Environmental Demands
Tile floor
Low pile carpet
Walking on soft mat
Walking on patio stones outside
Walking on grass or rough ground
Walking with lights dimmed – may also use
dark sunglasses to mimic change in lighting
Rising from seat of different heights

Time demands
Performance of task within a time limit – as may be required to walk across a street at a timed crosswalk, or rising from a chair and walking attempting to answer a phone before it stops ringing

Making practice meaningful through goal setting and task modification

During the first session, the training therapist will interview the participant regarding their activity goals of participation in walking retraining. From this interview, the therapist and the participant will choose specific tasks to add to the core list or modify core tasks to reflect participant activity goals.

For example, if a participant may identify a goal to return to their previous routine of shopping at the local farmer's market. In order to make the practice session more meaningful and goal related, the therapist may have the participant practice the core task of prolonged walking while pulling a shopping cart or carrying shopping bags through a crowded room. They may also add a reaching while walking or standing task to reflect the demands of shopping in the market.

While the number of different tasks and nature of tasks practiced will vary between participants, all participants will practice for 45 minutes (including rests).

The therapist, in consultation with the participant, can add, delete or modify tasks throughout the 15 sessions to ensure the participant is being challenged adequately. During each session, participants may practice a single task in a number of ways – eg. with, and without gait aid, on different surfaces, with and without a carrying task.

Practice Schedules

As previously stated, a primary objective of the MLWP is to cognitively engage the learner in the practice activity. A key method of cognitively engaging and challenging the learner is to organize the practice of tasks in a serial or random order.

In a serial practice schedule, participants practice a number of different tasks one after the other. If there are three tasks, task A, Task B, and Task C. The participant would practice Task A one time then Task B once, and Task C once. They would then return to Task A and repeat the cycle of practice.

In a random practice schedule, the tasks would be randomly organized. The order may be A, C, A, B, C, A, B, C.

A key element of both serial and random practice is the avoidance of multiple repetitions of practice of one task – referred to as Blocked Practice. A blocked schedule would look like A, A, A, B, B, B, C, C, C. Serial and random practice encourages the learner to re-problem solve the motor problem every time they are faced with the task. This phenomenon is referred to as contextual interference in motor learning literature. This is contrasted with the possible 'auto-pilot' effect of blocked practice – where participants solve the motor problem once and just repeat the solution over and over with minimal cognitive involvement.

It should be noted that the core tasks represent the tasks to be practiced in serial or random order. These tasks are considered different enough to demand a new strategy to accomplish the task. For example, walking on level ground versus walking up stairs, and stepping over obstacles, would be considered significantly different tasks. Tasks such as walking on the level over tiled floor versus walking on carpeted floor, are more subtle in their differences. The subtle difference is unlikely to maximally challenge the participant to re-solve the motor problem. Therefore, the practice of more similar tasks should be separated by a significantly different task.

The following is an example of a serial practice schedule:
Rise from an arm chair and walk to mark on floor (A)
Walking on level ground 30 m at comfortable pace (B)
Up and down 4 steps (C)
Walk over and pick up a 5 pound weight off floor (D)
Walk and carry weight over to a shelf (E)
Walk through a course of stationary obstacles – stepping over (F)
Sit down on a bench (G)
Rise from a bench and walk to mark on floor (A)
Walk on level ground 30 m at fast pace (B)
Up and down 4 steps (C)
Walk over an pick up an empty laundry basket off low table (D)
Walk and carry basket with two hands over to a high table (E)
Walk through a course of stationary obstacles (F)
Return to sit in a chair (G)
The therapist may decide to order the tasks in a serial or random manner. Both are acceptable, as long as similar or identical tasks are not practiced more than two times in a row.

Augmented Feedback

When performing a motor task, individuals utilize feedback mechanisms to judge the success of their attempt and/or the quality of the performance of the task. This feedback most often originates from internal mechanisms such as visual, kinaesthetic and proprioceptive systems. Feedback may also come from external sources. This information is referred to as augmented feedback – that is it augments the internal feedback systems.
The provision of augmented feedback has been shown to optimize learning of a motor skill when provided in a specific manner. In the Motor Learning Walking Program, augmented feedback will be provided the according to these motor learning principles. Participants will be encouraged to self evaluate their performance on a task, and problem solve ways to improve performance. Feedback will be delayed rather than concurrent to the task performance. For example, a participant may be allowed to attempt walking through a series of stationary obstacles as fast as they can without touching the obstacles. After two attempts they will be asked how they think they did. Once they have had an opportunity to self evaluate, the therapist may give them feedback on how long each

attempt took, or an average of the two attempts. They may also provide information on how many obstacles were touched. This type of feedback is referred to as knowledge of results (KR). The participant may also be asked if there was anything they think they could do differently to improve their performance. The participant may say – I should lift my toe higher when stepping over the obstacles. The therapist may agree and/or provide other such feedback about the movement to improve performance. This type of feedback is known as knowledge of performance (KP).
While augmented feedback may be both KR and KP, in the MLWP, an emphasis will be placed on provision of KR.

Physical Guidance and Walking Aids

The task can be made more or less difficult through the addition or removal of physical guidance. Physical guidance may refer to the guidance of therapists during a task performance or the use of adaptive devices such as a walker, cane, or railing on a stair case.
Use of walking aid – cane, 2 wheeled walker, 4 wheeled walker/rollator
Physical assistance of therapist/trainer – minimal, moderate, maximal
Use of one or two railings on stairs or step stool

In the Motor Learning Walking Program, an effort will be made to minimize the amount of physical guidance provided during training. Physical guidance may be provided for the purposes of safety or in the case that the task cannot be performed without some physical assistance. Regarding safety, therapist assistance will be provided to prevent a participant from falling. However, therapist assistance will not be provided to prevent a participant from making an error while walking – for example walking with unequal step length.
When a participant is attempting a task for the first time – the therapist may need to provide physical guidance to allow the performance of the task. This assistance should be weaned off as soon as possible.

Appendix D: Body-weight-supported Treadmill Training description

Description of the Body-weight-supported Treadmill Training (BWSTT) for the

Stroke Walking Training Study (Provided to BWSTT training Physiotherapists)

December 20, 2006

Body Weight Supported Treadmill training protocol
(Modified protocol – S.T.E.P.S. Trial K. Sullivan et al. as per email communication with Dr. K. Sullivan, July 24, 2006)

Preparatory steps

At the first session, prior to initiating BWSTT:
Obtain participants weight in pounds
Calculate body weight support value (in pounds) equivalents for 5% to 40% in 5% increments (eg. for 200 lb participant 5% = 10lbs, 10% = 20lbs….30% = 60lbs.)

At the beginning of each session perform the following:

Obtain and record resting blood pressure and heart rate in sitting.
Screen patient for any change in health status since last session (chest pain, change in neurological status)
Question patient regarding any adverse effects of last session

Warm up and cool down exercise

Every session should begin with a 2 minute warm up and end with a 2 minute cool down walk. These will be performed at 1.0 mph with 30% or more body weight support.

Manual Assistance of Trainers

During BWS treadmill training, manual assistance will be provided by one or two trainers to help facilitate a coordinated gait pattern.

Manual assistance may be provided at the pelvis and trunk or at the leg and foot.

Up to maximal assistance of two trainers may be provided to assist the participant in achievement of the following goals:
Erect and midline position of trunk and head
Symmetrical and coordinated weight shift between legs during gait
Appropriate and symmetrical lateral displacement and rotation of the pelvis
Appropriate limb kinematics including adequate hip extension in terminal stance, knee extension during mid stance, hip flexion during terminal swing, foot clearance during swing, and foot placement at initial contact
Inter-limb coordination – symmetry of step length and cadence

Specific techniques to achieve the desired gait pattern are presented below:

1. Hip Trainer
The hip trainer is responsible for establishing and maintaining proper participant position/alignment and control of the pelvis.

The head, shoulders, hips and feet should be aligned throughout stepping. This can be observed by the hip trainer by positioning a mirror beside the treadmill.
The trainer stands approximately eight inches behind the participant, and firmly grasps the participants pelvis or the harness straps.
In the different phases of gait, the hip trainer assists the participant's pelvis as necessary to achieve the pelvic movements that occur with normal gait kinematics.
1. During stance phase, the hip trainer may assist the participant in rotating the pelvis backward.
2. During stance to swing transition, the hip trainer may assist the participant in weight shifting to the contralateral leg.
3. During swing phase, the hip trainer may assist the participant in rotating the pelvis forward.
The hip trainer can also promote trunk extension in the participant.
Proper body mechanics for the hip trainer include having him/her keep his/her arms rigid and knees bent while rotating his/her own body simultaneously with the participant.
The participant is not permitted to lean back on the hip trainer. If the hip trainer is necessary in stepping, the only contact between the hip trainer and the participant should be the trainer's hands.

2. Leg Trainer
The leg trainer is responsible for appropriately assisting the participant's lower extremity to achieve normal gait kinematics throughout all phases of gait.

Hand Position:
The trainer's outside, upper hand, is positioned posteriorly at the participant's knee to facilitate flexion in pre-swing and initial swing, and then rotated anteriorly to the patellar tendon to facilitate knee extension in terminal swing and stance.
The trainer's inside, lower hand, is positioned on the dorsum of the participant's ankle to facilitate ankle dorsiflexion, heel strike, and provide medial/lateral stability.

Example of Hand Position:

STANCE PHASE (extension of hip and knee):
Upper hand: Facilitate knee extension by placing web of hand at anterior, proximal tibia on the patellar tendon. Provide just enough force to achieve knee extension, but NOT hyperextension.
Lower hand: Stabilize the dorsum of the foot, controlling eversion/inversion.

STANCE TO SWING TRANSITION:
Upper hand: Facilitate knee flexion by rotating your hand from the anterior tibia to the lateral hamstring tendon (laterally and upwardly). Press on the lateral hamstring tendon with two fingers.
Lower hand: Initially, provide some pressure through the dorsum of the foot to promote terminal stance. Then, either stay at the dorsum of the foot, and facilitate dorsiflexion for

toe clearance, or transition your hand to the client's heel and cue dorsiflexion. If at the heel, keep fingers open and AVOID grasping the achilles tendon.

SWING:
Upper hand: Guide the knee forward only using pressure at the back of the knee. Do not LIFT the leg or grab the calf. At terminal swing, start to rotate the hand to the front of the knee.
Lower hand: Maintain same position as stance to swing transition.

SWING TO STANCE TRANSITION
Upper hand: Finish rotating your hand to the front of the knee, and facilitate knee extension at heel strike by gently pressing on the proximal tibia at the patellar tendon.
Lower hand: Facilitate heel strike, then position hand on dorsum of foot for stance.

Verbal Instruction/Cueing provided by Trainers

In addition to manual assistance, the main trainer will provide frequent verbal instruction to the participant to facilitate achievement of the desired gait pattern.
Instructions will focus the participants attention on their body position and movements during gait.
Examples of appropriate instructions include:
Stand up tall
Look straight ahead
Straighten your knee
Pull your toes up
Bend your hip more as you step
Take a longer step
Try and hit the ground with your heel before your toe
Shift your weight toward your right/left side

Augmented Feedback

Verbal and visual feedback will be provided to participants during their walking session.

A mirror will be placed beside and in front of the participant to allow the participant to see their positioning during walking. If participants find this detrimental to their performance during the session, it will be removed.

Verbal feedback will be provided concurrently to the training session. Feedback regarding abnormal gait pattern or successful walking attempts will be provided immediately to the participants. As in the instructions, feedback will focus on the trunk, pelvis and limb position and movement during gait.

Initial Treatment Session Parameters and Progression

The ultimate goal of the body weight supported treadmill training intervention is that by the final 15th session, the subject will be walking on the treadmill at a minimum speed of 2.0 mph, with no body weight support or trainer assistance, for 20 minutes continuously.

This protocol will describe the training procedures and progression guidelines that will be made over the 15 sessions in attempt to reach this goal.

** It is very important to note that subject safety overrides any guidelines described in this protocol. If at ANY time a subject's safety is at risk at a certain treadmill speed or body weight support, then the treadmill is immediately stopped and adjustments in body weight support and/or treadmill speed are immediately made.
Operational Definitions:

Proper Gait Kinematics: operationally defined as upright posture, normal values of extension/flexion of hip/knee/ankle, and coordinating limb movement to achieve symmetrical limb cadence and equal step length.

Levels of Assistance
No Assistance = participant is able to achieve normal kinematics of the leg and trunk without manual assistance from the clinician. Verbal cueing is permissible.

Minimal Assistance = participant is able to achieve normal kinematics of the leg and trunk with manual assistance only during brief portions of the gait cycle. During the majority of the gait cycle, no manual assistance is given. (ie: manual assistance is given <50% of gait cycle).

Moderate Assistance = participant is able to achieve normal kinematics of the leg and trunk with manual assistance applied consistently throughout the majority of the gait cycle. (ie: manual assistance is given >50%, but less than 100%, of gait cycle).

Maximal Assistance = participant is able to achieve normal kinematics of the leg and trunk with manual assistance required to prevent the participant from tripping, falling, or collapsing. The clinician must provide manual assistance throughout the entire gait cycle (100%) to ensure subject safety.

Uncontrolled = participant is unable to achieve normal kinematics of the leg and trunk, despite the clinician's best efforts to provide manual assistance throughout the entire gait cycle.

1. BWSTT INTERVENTION SESSION 1

The optimal goal for the initial training session is for the subject to step at a treadmill speed of 2.0 mph, with up to maximum trainer assistance to enable proper gait kinematics, with a body weight support between 30-40% of the subject's weight, over four, 5 minute walking periods.

INITIAL BWSTT PARAMETERS
Body weight support = 30%
Treadmill speed = 2.0 mph
Trainer assistance = no assistance to maximum assistance
Use of Treadmill or Lite Gait handles for support
Proper gait kinematics

1. The purpose of this first session is to familiarize the subject with the treadmill training and the primary task goal of walking at 2.0 mph with proper gait kinematics.

Initial Body weight support (BWS) of 30% will be provided.
As the amount of BWS can vary during the gait cycle, the 30% BWS setting is based on that observed during stance phase on the more involved/hemiplegic leg.
The treadmill speed is started at 0.1 mph and increased in 0.1mph increments until 2.0 mph is reached.
Participants are instructed to hold handrails of the Lite Gait or the treadmill during first 5 minute walk during first session.
Up to maximal physical assistance of one or two trainers will be provided during walking to achieve a proper postural alignment, weight shift, gait kinematics (hip, knee and ankle flexion/extension, foot placement) and inter-limb coordination (step symmetry and timing)
The first continuous walking period will last a maximum of 5 minutes.

2. If the subject can not achieve a coordinated gait pattern at 2.0 mph treadmill speed, 30% BWS, with up to maximal trainer assistance, then:
BWS will be increased by 5% total body weight (TBW) to 35%. All other parameters will be maintained.
When BWS is being changed (increased), the trainer will reduce the treadmill speed temporarily and then increase it again by 0.1 mph increments to 2.0 mph.
If a coordinated gait pattern is still not demonstrated, BWS will be increased to 40%.
VERY IMPORTANT: The body weight support can never be increased above 40%.
The subject is given the opportunity to practice acquiring the skill of achieving proper limb kinematics at the speed and BWS that is challenging, yet successful. Therefore, if the subject can tolerate the activity at 2.0 mph and 40% BWS, then the subject will walk for the session under these practice conditions with emphasis on the subject acquiring proper limb kinematics. The trainer is to provide manual assistance and verbal cueing as necessary to achieve optimal training outcomes.
For this initial session, the progression would be to decrease the amount of manual assistance given to the subject before increasing the treadmill speed above 2.0mph or decreasing the body weight support.

3. If the subject can not obtain the 2.0 mph treadmill speed at 40% BWS, with up to maximal trainer assistance, then:
The treadmill speed is decreased from 2.0 mph in 0.1 increments until the maximum treadmill speed is obtained in which the subject can perform a coordinated gait pattern, with up to maximal trainer assistance.
Again, since the subject is learning a new skill, it is expected that the subject may not achieve proper gait kinematics in the first session. Therefore, every attempt should be made to obtain the fastest treadmill speed toward the 2.0 mph intensity goal.
The subject is given the opportunity to practice acquiring the skill of achieving proper limb kinematics at the treadmill speed that is challenging, yet successful.
Every attempt should be made by the trainer to have the treadmill speed for the subject ABOVE 1.5 mph. If the subject's safety is at risk, than the treadmill speed can be decreased below this threshold, with a supporting explanation in the comments section of the data form. Again, if the subject can tolerate 1.5mph, but only for 1 minute increments secondary to decreased endurance, then more rests breaks should be taken versus decreasing the treadmill speed.

4. If the participant is able to achieve a maintain a coordinated gait pattern for 5 minutes with 30% BWS at 2.0 mph,

During this first session, BWS will not be reduced or treadmill speed increased.
The protocol will be progressed by first asking the participant to walk without handrail support. If they achieve this then, the amount of manual assistance provided by the trainers will be reduced.

Rest Periods

The goal of the first session is to have participants to perform 4 sets of 5 minutes of continuous walking.
It is acknowledged that some participants will require a rest during the 5 minute sessions. The participant is permitted to rest as many times as necessary during the 5 minute period. During these rest periods – the treadmill will be stopped and participants can 'relax' within the walking harness. If necessary, participants will be allowed to sit back in their seats. The length of the rest is dependent upon the intervention therapist's clinical decision (based on heart rate and blood pressure parameters, participant report and clinical observation) of when the subject has physically recovered from the exercise and is able to start again.
On completion of 5 minutes walking time, participants are allowed to sit for 5 minutes and begin training again.
On the first day of walking practice, participants will optimally be able to complete 4 sets of 5 minute walking sessions (with or without rests). It is acknowledged that some participants will be unable to reach this goal on the first session.

2. BWSTT INTERVENTION SESSIONS 2 - 15

The goal for training sessions 2-15 is to re-train the subject's gait at a minimum treadmill speed of 2.0 mph*, with the minimum amount of body weight support and trainer assistance enable proper gait kinematics, for a total of 20 minutes**.

*Treadmill speed should not be increased above 2.0 mph until the subject's body weight support is less than or equal to 20% BWS and the minimum amount of trainer assistance is given for the subject to have proper gait kinematics over four, 5 minute walking bouts.
**Four, 5 minute walking bouts with as many rests as the subject requires during the 5 minute bout is the standard guideline for completing a body weight support intervention session. A progression in bout length is made if the subject's body weight support is less than or equal to 20%, and proper gait kinematics cannot be achieved with an increase in treadmill or a decrease in trainer assistance.

Each session is started at the maximum treadmill speed, minimum body weight support and minimum amount of trainer assistance that was achieved in the previous session. Evidence of progression in at least one of the training parameters (treadmill speed, body weight support, or trainer assistance) should be attempted in every training session.

PROGRESSIONS in treadmill training parameters should be made in the following order:

Treadmill speed:

<u>If the subject's treadmill speed is not at 2.0 mph:</u>
The first progression would be to increase the treadmill speed toward the target value of 2.0 mph.
If attempts over 1-2 treadmill training sessions have been made to increase the treadmill speed, and the subject has not been able to tolerate the increase (evident by uncontrolled level of assistance – see definition on page 1), then a progression in body weight support can be attempted. The body weight support would be decreased to the minimum amount where the treadmill speed at the previous body weight support can be maintained, and the trainer is providing up to maximum assistance.
At this decreased body weight support, progressions would then be made to increase the treadmill speed toward the target value of 2.0mph.
This progression guideline would continue until the subject reached 2.0 mph, or 20% body weight support.

<u>If the subject's treadmill speed is at 2.0 mph:</u>
The progression would be to decrease the body weight support to the minimum amount that enables proper gait kinematics, with up to maximum trainer assistance, over four, 5 minute walking bouts.
As long as the treadmill speed is being maintained at 2.0 mph, the body weight support can continue to be decreased to 20%, at which point other training parameters may be progressed.

Body weight support:

<u>If the subject is below 2.0 mph and above 20% body weight support:</u>
As stated under the progression of treadmill speed, some subjects may not reach the 2.0 mph treadmill speed, but they may make progression in their body weight support. Body weight support can continue to be decreased in this population toward the 20% target
If the subject reaches 20% body weight support, but all attempts to increase treadmill speed to 2.0 mph have been unsuccessful, then instead of decreasing body weight support, a progression in trainer assistance could be made (i.e.: decreasing assistance to obtain proper gait kinematics).

<u>If the subject is at 2.0 mph and above 20% body weight support:</u>

A progression is first made to decrease the body weight support to 20%, while keeping the treadmill speed at 2.0 mph.
If the subject can maintain 2.0 mph, at 20% body weight support, then a progression in trainer assistance (i.e.: decreasing manual assistance to the subject from the hip or leg trainer) is made.

Trainer Assistance:
Trainer assistance is decreased when the subject is at a minimum of 20% body weight support.
A decrease in trainer assistance is defined as the hip or leg trainer providing less manual assistance or verbal cueing to the subject to promote proper gait kinematics.

If the subject is stepping at 2.0 mph, with 20% body weight support and minimal assistance is given by the trainers to enable proper gait kinematics, then further progressions can be made in the following areas:
1. Increasing treadmill speed above 2.0 mph at 0.1 mph increments.
Decreasing body weight support at 5% BWS increments.
Decreasing trainer assistance at the leg and pelvis.
Increasing length of walking bouts in 5 minute increments (i.e.: decrease to 2, ten minute walking bouts.)

Overall, the progression of treadmill training parameters in <u>each session</u> should be toward the ultimate goal of having the subject step on the treadmill at a minimum speed of 2.0 mph, with no body weight support or trainer assistance, for 20 minutes continuously, by the 15th session.

Appendix E: Exercise safety guidelines

Stroke Walking Training Study
Exercise Safety Guidelines
PROCEDURE

<u>Description:</u> During walking retraining sessions participants should be appropriately monitored to ensure that their cardiovascular responses to activity are within normal limits. Specific monitoring guidelines are outlined for both intervention groups – Motor Learning Walking Program and the Treadmill Training Program.

<u>Equipment:</u> Automatic or manual blood pressure cuff, stethoscope if manual BP cuff, stopwatch if taking HR manually, Heart monitor (portable pulse oximeter or heart monitor).

<u>Session baseline assessment</u>

Interview
Prior to initiating walking retraining session, the trainer will interview the participant regarding any change in health status – specifically recent fall, new pain, new neurological symptoms (weakness, severe headache, balance deficit, dizziness, speech deficit) or cardio-respiratory symptoms (e.g. SOB, chest pain). The trainer will also enquire about any adverse effects of the previous training session.

Physical Assessment
Prior to initiating each walking retraining session, the trainer will assess and record the participant's resting blood pressure and heart rate.
Resting blood pressure should not be above 180 mmHg systolic and/or 100 mmHg diastolic prior to initiating any physical activity. Resting HR should not exceed 100 bpm at the beginning of the session.
If, at the beginning or during a session, a participant's blood pressure exceeds these values, identify any issues that might be the source of the problem (e.g. stress) and try to address those issues and allow period of time to pass for the person's blood pressure to drop to normal levels. If, after a period of rest and alleviation of external stressors, the participant's blood pressure is still greater than 180/100 mmHg (either number) or the HR is > 100 bpm, the session should be terminated. If a session is terminated due to blood pressure exceeding resting guidelines the primary investigator should be notified. The primary investigator will take necessary steps to communicate with the participant's physician.

<u>Monitoring during Walking retraining sessions</u>

Supervision
Trainers will be with participants at all times during training sessions. In this way, trainers will be able to monitor participants through observation throughout the session.

<u>Physical Assessment</u>

Motor Learning Walking Program - MLWP

Each session will last 45 minutes. Participants BP, HR and Report of Perceived Exertion (Borg Scale 6 – 20) will be assessed at the beginning of the session, after 20 minutes and at the end of the 45 minutes.
Trainers will obtain BP and HR more frequently if they observe any concerning symptoms (described in "Stopping Exercise Session).

Body Weight Supported Treadmill Training

Each session will last 45 minutes. Each session will consist of a 2 minute low speed warm up walk, four 5 minute training periods and a 2 minute low speed cool down period. After each 5 minute period, the participant will be allowed a sitting rest for 5 minutes. As the participant increases their exercise tolerance and walking ability, the trainer will extend the continuous exercise periods and reduce the number of rest periods.

The trainer will measure the patients BP and HR at the beginning of the session before exercise, at the beginning of each rest period and at the end of the last exercise period.

Participants will also be wearing a heart monitor that will allow continuous monitoring of heart rate during exercise. Rate of Perceived Exertion (RPE Borg scale 6 to 20) will also be obtained once during each exercise and at the end of each exercise period.

<u>Stopping Exercise Session</u>

Exercise will be stopped immediately with any signs of dizziness, decreased level of consciousness, sudden confusion, chest pain, respiratory distress, new neurological event, or excessive fatigue. At this point, the trainer will assess the participant further. In the case of symptoms of cardiac arrest or new onset stroke – the trainer will initiate the emergency response procedure – CODE BLUE hospital procedures.

Exercise will also be stopped if:
Participants **heart rate exceeds 70% of predicted maximum HR (220-age)** for any 60 second period during any phase of treadmill training.
Participants **RPE exceeds 14** on the Borg Scale (6 to 20)
In the case of HR above target HR or RPE above 14, the trainer will encourage a rest period and reassess HR at the end of the rest. If HR and RPE return to acceptable levels then the exercise session may continue with a reduced speed. Treadmill speed will be set at 0.2 mph less than the previous training period. HR and RPE will continue to be monitored and training intensity will be adjusted accordingly.

The following HR or BP responses are observed during or after exercise:
Systolic BP greater than 200 mmHg
Diastolic BP greater than 110 mmHg
Drop in systolic BP greater than 20 mmHg
Inappropriate bradycardia – drop in heart rate greater than 10 beats per minute (with exercise)

If a session is terminated due to HR or BP exceeding guidelines, the Principal Investigator should be notified, an adverse event will need to be reported, and the Principal Investigator will take necessary steps to communicate with the participant's physician.

Appendix F: Motor Learning Walking Program session record

Motor Learning Walking Program Session Record

Participant:

Date: **Session #**

Task Description	Reps/time	**Guidance**	**Attention demand**	**Environment**	**Comments (task and performance)**
Walk on straight path		Gait aid ☐N ☐ Y_______ Personal ☐ None ☐ Interm. ☐ Constant	☐ Single task ☐ Mental/verbal task ☐ Carrying task	☐ Flat tile ☐ Flat covered ☐ uneven ☐ Normal light ☐ Dim/Sunglasses	☐ comfortable pace ☐ fast walking pace
Sustained walking x 5min		Gait aid ☐N ☐ Y_______ Personal ☐ None ☐ Interm. ☐ Constant	☐ Single task ☐ Mental/verbal task ☐ Carrying task	☐ Flat tile ☐ Flat covered ☐ uneven ☐ Normal light ☐ Dim/Sunglasses	☐ comfortable pace ☐ fast walking pace
Walk up and down step or stairs		Gait aid ☐N ☐ Y_______ Personal ☐ None ☐ Interm. ☐ Constant	☐ Single task ☐ Mental/verbal task ☐ Carrying task	☐ Flat tile ☐ Flat covered ☐ uneven ☐ Normal light ☐ Dim/Sunglasses	Railing? ☐ N ☐ 1 ☐ 2 ☐Curb/single step ☐ Stairs # steps _______:

Obstacle Avoidance **Describe:**		Gait aid ☐N ☐ Y_______ Personal ☐ None ☐ Interm. ☐ Constant	☐ Single task ☐ Mental/verbal task ☐ Carrying task	☐ Flat tile ☐ Flat covered ☐ uneven ☐ Normal light ☐ Dim/Sunglasses	☐ stationary obstacles ☐ mobile obstacles ☐ predictable movement ☐ unpredictable
Transitional movements - **Sit to stand and walk**		Gait aid ☐N ☐ Y_______ Personal ☐ None ☐ Interm. ☐ Constant	☐ Single task ☐ Mental/verbal task ☐ Carrying task	☐ Flat tile ☐ Flat covered ☐ uneven ☐ Normal light ☐ Dim/Sunglasses	**Chair** ☐ standard ☐ low ☐ high ☐ no arms ☐ arms
Walking with changes in centre of gravity (eg. reaching to lower surfaces)		Gait aid ☐N ☐ Y_______ Personal guidance ☐ None ☐ Interm. ☐ Constant	☐ Single task ☐ Mental/verbal task ☐ Carrying task	☐ Flat tile ☐ Flat covered ☐ uneven ☐ Normal light ☐ Dim/Sunglasses	
Walking with multiple changes in direction		Gait aid ☐N ☐ Y _______ Personal guidance ☐ None ☐ Interm. ☐ Constant	☐ Single task ☐ Mental/verbal task ☐ Carrying task:	☐ Flat tile ☐ Flat covered ☐ uneven ☐ Normal light ☐ Dim/Sunglasses	

Appendix G: Body-weight-supported treadmill training session record

Body Weight Supported Treadmill Training Session Record

Participant Name: ___________________Age_________ Weight ______lbs Reference: **Max HR = .70(220-age) = _____**
Date: __________ Time Start: ___:___ Finish ___:___ Session # Therapist: _______________ Assistant: ______________

Pre-Exercise Assessment:
HR _____ bpm Resting HR within exercise parameters (<100) ☐ Y ☐ N
BP ____/____ mmHg Resting BP within exercise parameters (<180/100) ☐ Y ☐ N

Within 2 hours prior to training, did participant…smoke? ☐ Y ☐ N use caffeine? ☐ Y ☐ N use alcohol? ☐ Y ☐ N
Any change in status since last session?

Training Record * Assistance /cueing scale 0 = <25% assist/time, 1 = 25 – 50% assist/time, 2 = 50–75% assist/time, 3 = >75 % assist/time

Bout #	Walking time	BWS lbs - % (standing)	Max speed mph	Assistance Pelvis/Hip 0, 1, 2, 3*	Assist More Affected L/E 0, 1, 2, 3	Assist Less Affected L/E 0, 1, 2, 3	Verbal Cueing 0,1,2,3	Handle used Y/N	Rests (#)	HR	BP Systolic/ Diastolic	RPE 6-20	Comments/ Adverse Effects
1													
2													
3													
4													

Appendix H: Baseline outcome assessment form/data base RCT

Post-Stroke Walking Retraining Study

Participant Data Base

Baseline Assessment

Study ID #: _________________

Assessment Date:______________
dd/mm/yy

Time of Assessment: ____________

Assessor's Name:______________

Modified Functional Walking Categories (MFWC)

Category	Definition
1. Physiological walker	Walks for exercise only either at home or in parallel bars during physical therapy. Uses a wheelchair for both bathroom and bedroom mobility
2. Limited household walker	Relies on walking to some extent for home activities. Requires assistance for some walking activities, uses a wheelchair, or is unable to perform others. If a wheelchair is needed for either bedroom or bathroom mobility, the other activity can be performed with supervision only.
3. Unlimited household walker	Able to use walking for all household activities without any reliance on a wheelchair. Can perform bathroom mobility without assistance (may need supervision). If supervision is required for both bedroom and bathroom mobility, then can enter/exit the home without a wheelchair. Encounters difficulty with stairs and uneven terrain. Needs at least supervision for both entering and exiting the house and managing curbs.
4. Most-limited community walker	Independent (without supervision) in either entering/exiting the home or managing curbs. Can manage both entering/exiting the home and curbs without assistance. Requires some assistance in both local store and uncrowded shopping centers.
5. Least-limited community walker	Can perform all moderate community activities without use of wheelchair. Needs at least some assistance with a crowded shopping center. Can perform without assistance (but may need supervision) in one of the following: local stores or uncrowded shopping centers.
6. Community walker	Independent in all home and moderate community activities. Can accept uneven terrain. Can negotiate a crowded shopping center with supervision only.

Pre-Stroke FAC Score (Based on Interview) _____/6

Current Score (Based on interview and observation) ______/6

Activities-Specific Balance Confidence (ABC) Scale

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number form the following rating scale:

0%	10	20	30	40	50	60	70	80	90	100%
No confidence										Completely confident

"How confident are you that you will not lose your balance or become unsteady when you…

1…. walk around the house? _____%

2…walk up or down stairs? _____%

3…bend over and pick up a slipper from the front of a closet floor? _____%

4…reach for a small can off a shelf at eye level? _____%

5…stand on your tip toes and reach for something above your head? _____%

6…stand on a chair and reach for something? _____%

7…sweep the floor? _____%

8…walk outside the house to a car parked in the driveway? _____%

9…get into or out of a car? _____%

10… walk across a parking lot to the mall? _____%

11…walk up or down a ramp? _____%

12…walk in a crowded mall where people rapidly walk past you? _____%

13…are bumped into by people, as you walk through the mall? _____%

14…step onto or off of an escalator while you are holding onto a railing _____%

15…step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? _____%

16…walk outside on icy sidewalks? _____%

Total score = ____/1600 = ________%

Gait Speed - 5 metre walk test

Setting: Quiet hallway on level ground (Physiotherapy department hallway)

Participant will walk a total of 9 metres at a comfortable, self selected pace.
The assessment area will be marked with 4 lines on the ground, at starting position, 2 m, 7 m, and 9m. The rater will use a stop watch to record how long it takes to walk the middle 5 m of the 9 m track.
Participant stands just behind the first line. They begin walking when the rater says "Go". The rater begins timing as the participant crosses the 2nd line with their front foot, and stops the watch when they cross the 3rd line with their front foot. Participants continue to walk to the 4th line.

If participant can walk 10 m without human assistance and without a walking aid, then participant's gait speed should be tested without the walking aid.
If participant is unable to be tested without a walking aid – then test with patient's typical walking aid.
Participants will be tested at Self Selected speed as well as Fast speed.

Self Selected Speed

Instructions: "When I say go, begin walking at a comfortable pace. Continue walking until you cross the last line on the floor."

Time (seconds) to walk 5 m = _______________seconds = ________metres/second

☐ Without walking aid: Unable to test (i.e. participant unable to walk without human assistance without a walking aid)
OR
☐ With Walking Aid: (if unable to test without)
Walking aid used: ☐ cane ☐ quad cane ☐ 2 wheeled walker ☐ rollator

Maximal/Fast speed

Instructions: "When I say go, begin walking as fast as you are able while remaining safe. Continue walking until you cross the last line on the floor."

Time (seconds) to walk 5 m = _______________seconds = ________metres/second

☐ Without walking aid: Unable to test (ie participant unable to walk without human assistance without a walking aid)
OR
☐ With Walking Aid: (if unable to test without)
Walking aid used: ☐ cane ☐ quad cane ☐ 2 wheeled walker ☐ rollator

Functional Balance Test (FBT)

Starting position: Sitting in a standard height chair with arms with both feet on the floor.
Instructions to Participant: When I say go, you will

1) stand up from the chair,
2) walk to the step, step up onto the step one foot at a time, so you are standing with both feet on the step. Once on the step, then step down in front of the step,
3) walk to the bean bag on the floor. Carefully bend over and pick up the bean bag, stand up and then bend over and put the bean bag down again.
4) Walk to the marked area on the floor, turn around and walk straight back to the chair
5) Sit back down in the chair."

"I want you to walk as quickly as you can while remaining safe. I will help you if needed. If needed, you can use the arms of the chair to stand up and sit down."
(Note: Tester should demonstrate the test, then allow participant an opportunity to trial the test once before scored or timed.)

Functional Balance Test - Score sheet

1. Sit to stand ______/4
2. Step up onto then down a step ______/4
3. Pick up 2.5 kg weight off floor ______/4
4. Turn 180 degrees ______/4
5. Stand to sit ______/4

Total Score = ______/20
Total Time = ______seconds

Walking aid used ☐ None ☐ cane ☐ quad cane ☐ 2 wheeled walker ☐ rollator ______
Scoring Key
0 = Unable to complete task without maximal assistance (<50% work done by the participant)
1 = Moderate assist (>50% work done by the participant).
2 = Minimal assist (>75% work done by the client)
3 = Client requires supervision only (or dependent on hands to rise from/sit down in chair; or support of walking aid to pick up weight)
4 = Independent and safe in completing the task.
Timing: Start the stop watch on the word "Go" until the participant comes to rest in the chair.

---

* Participant should be tested without walking aid. If not possible, that is patient cannot walk without aid without human assistance, use the walking aid they would typically use most of their daily activities. If testing while using a walker or wheeled walker, the tester will have to assist the participant with the aid while they do the step. On subsequent tests (post intervention and follow up) use this walking aid for the testing in addition to attempting without aid again)

Life-Space Questionnaire

Life Space Level			Frequency				Independence	Score
During the past 2 weeks have you been to….			How often did you get there				Did you use aids or equipment? Did you need help from another person?	Level X Frequency X Independence
Life-Space Level 1 Other rooms of your home besides the room where you sleep?	Yes 1	No 0	Less than 1/wk 1	1-3 x per week 2	4-6 x per week 3	Daily 4	1 = personal assistance 1.5 = equipment only 2.0 = no equipment or personal assist	
Score ________ x ________________________x _______________ = /8								
Life space Level 2… An area outside your home such as your porch, patio, yard, apartment hallway, driveway	Yes 2	No 0	Less than 1/wk 1	1-3x per week 2	4-6 x per week 3	Daily 4	1 = personal assistance 1.5 = equipment only 2.0 = no equipment or personal assist	
Score ________ x ________________________x _______________ = /16								
Life space Level 3 Places in your neighborhood, other than your yard or apartment building	Yes 3	No 0	Less than 1/wk 1	1-3x per week 2	4-6 x per week 3	Daily 4	1 = personal assistance 1.5 = equipment only 2.0 = no equipment or personal assist	
Score ________ x ________________________x _______________ = /24								
Life-Space Level 4 Places outside your neighborhood, but within your town	Yes 4	No 0	Less than 1/wk 1	1-3x per week 2	4-6 x per week 3	Daily 4	1 = personal assistance 1.5 = equipment only 2.0 = no equipment or personal assist	
Score ________ x ________________________x _______________ = /32								
Life-space Level 5 Places outside your town?	Yes 5	No 0	Less than 1/wk 1	1-3x per week 2	4-6 x per week 3	Daily 4	1 = personal assistance 1.5 = equipment only 2.0 = no equipment or personal assist	
Score ________ x ________________________x _______________ = /40								
Total Score (Add Scores) = /120								

Stroke Impact Scale 3.0

Domain 1: Physical Problems

1. In the past week, how would you rate the strength of your....	**A lot of strength**	**Quite a bit of strength**	**Some strength**	**A little strength**	**No strength at all**
a. Arm that was most affected by your stroke?	5	4	3	2	1
b. Grip of your hand that was most affected by your stroke?	5	4	3	2	1
c. Leg that was most affected by your stroke?	5	4	3	2	1
d. Foot/ankle that was most affected by your stroke?	5	4	3	2	1

Domain total = __________________ /20

Domain 2: Memory and Thinking.

2. In the past week, how difficult was it for you to...	**Not difficult at all**	**A little difficult**	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
a. Remember things that people just told you?	5	4	3	2	1
b. Remember things that happened the day before?	5	4	3	2	1
c. Remember to do things (e.g. keep scheduled appointments or take medication)?	5	4	3	2	1
d. Remember the day of the week?	5	4	3	2	1
e. Concentrate?	5	4	3	2	1
f. Think quickly?	5	4	3	2	1
g. Solve everyday problems?	5	4	3	2	1

Domain total = __________________ /35

Domain 3: Emotions

3. In the past week, how often did you...	**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**
a. Feel sad?	5	4	3	2	1
b. Feel that there is nobody you are close to?	5	4	3	2	1
c. Feel that you are a burden to others?	5	4	3	2	1
d. Feel that you have nothing to look forward to?	5	4	3	2	1
e. Blame yourself for mistakes that you made?	5	4	3	2	1
f. Enjoy things as much as ever?	5	4	3	2	1
g. Feel quite nervous?	5	4	3	2	1

h. Feel that life is worth living?	5	4	3	2	1
i. Smile and laugh at least once a day?	5	4	3	2	1

Domain total = ________________ /45

Domain 4: Communication

4. In the past week, how difficult was it to...	**Not difficult at all**	**A little difficult**	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
a. Say the name of someone who was in front of you?	5	4	3	2	1
b. Understand what was being said to you in a conversation?	5	4	3	2	1
c. Reply to questions?	5	4	3	2	1
d. Correctly name objects?	5	4	3	2	1
e. Participate in a conversation with a group of people?	5	4	3	2	1
f. Have a conversation on the telephone?	5	4	3	2	1
g. Call another person on the telephone, including selecting the correct phone number and dialing?	5	4	3	2	1

Domain total = ________________ /35

Domain 5: Basic and instrumental activities of daily living

5. In the past 2 weeks, how difficult was it to...	**Not difficult at all**	**A little difficult**	**Somewhat difficult**	**Very difficult**	**Could not do at all**
a. Cut your food with a knife and fork?	5	4	3	2	1
b. Dress the top part of your body?	5	4	3	2	1
c. Bathe yourself?	5	4	3	2	1
d. Clip your toenails?	5	4	3	2	1
e. Get to the toilet on time?	5	4	3	2	1
f. Control your bladder (not have an accident)?	5	4	3	2	1
g. Control your bowels (not have an accident)?	5	4	3	2	1
h. Do light household tasks/chores	5	4	3	2	1
i. Go shopping?	5	4	3	2	1
j. Do heavy household chores?	5	4	3	2	1

Domain total = ________________ / 50

Domain 6: Mobility

6. In the past 2 weeks, how difficult was it to...	**Not difficult at all**	**A little difficult**	**Somewhat difficult**	**Very difficult**	**Could not do at all**
a. Stay sitting without losing your balance?	5	4	3	2	1
b. Stay standing without losing your balance?	5	4	3	2	1
c. Walk without losing your balance?	5	4	3	2	1
d. Move from a bed to a chair?	5	4	3	2	1
e. Walk one block?	5	4	3	2	1
f. Walk fast?	5	4	3	2	1
g. Climb one flight of stairs?	5	4	3	2	1
h. Climb several flights of stairs?	5	4	3	2	1
i. Get in and out of a car?	5	4	3	2	1

Domain total = ________________ /45

Domain 7: Hand function

7. In the past 2 weeks, how difficult was it to use your hand that was most affected by your stroke to...	**Not difficult at all**	**A little difficult**	**Somewhat difficult**	**Very difficult**	**Could not do at all**
a. Carry heavy objects (e.g. bag of groceries)?	5	4	3	2	1
b. Turn a doorknob?	5	4	3	2	1
c. Open a can or jar?	5	4	3	2	1
d. Tie a shoe lace?	5	4	3	2	1
e. Pick up a dime?	5	4	3	2	1

Domain total = ________________ /25

Domain 8: Participation

8. During the past 4 weeks, how much of the time have you been limited in...	**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**
a. Your work (paid, voluntary or other)	5	4	3	2	1
b. Your social activities?	5	4	3	2	1
c. Quiet recreation (crafts, reading)?	5	4	3	2	1

d. Active recreation (sports, outings, travel)?	5	4	3	2	1
e. Your role as a family member and/or friend?	5	4	3	2	1
f. Your participation in spiritual or religious activities?	5	4	3	2	1
g. Your ability to control your life as you wish?	5	4	3	2	1
h. Your ability to help others?	5	4	3	2	1

Domain total = ________________ /40

9. Stroke Recovery

On a scale of 0 to 100, with 100 representing full recovery and 0 representing no recovery, how much have you recovered from your stroke?

_______ Full Recovery
100
—
____
90
—
____
80
—
____
70
—
____
60
—
____
50
—
____
40
—
____
30
—
____
20
—
____
10
—
__ __0 No Recovery

Six Minute Walk Test

Setting: quiet marked hallway (Physiotherapy department)
Equipment: Stop watch, measuring wheel, pilons or markers to mark place for participant to turn, paper and pen to mark number of laps.

Instructions:
"The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able. You will be walking back and forth around the cones without stopping."
If possible, participant should be tested without using a walking aid. If participant unable to walk without a walking aid and without human assistance, test should be done using participants typical walking aid. Record the walking aid used. Subsequent tests should be performed using the same walking aid.
Demonstrate by walking one lap yourself. Walk and pivot around a cone briskly.
"Are you ready? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line. Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don't run or jog. Start now, or whenever you are ready."

1. Position the patient at the starting line. You should also stand near the starting line during the test. As soon as the patient starts to walk, start the timer.
2. Do not walk with the patient unless you are concerned that they may fall due to poor balance.
3. Use an even tone of voice when using the standard phrases of encouragement. Do not use other words of encouragement (or body language to speed up). Watch the patient. Each time the participant returns to the starting line, click the lap counter once (or mark the lap on the worksheet). Let the participant see you do it.

Standard phrases of encouragement:

After the first minute: "You are doing well. You have 5 minutes to go."

With 4 minutes remaining: "Keep up the good work. You have 4 minutes to go."

With 3 minutes remaining: "*You are doing well. You are halfway done*."
With 2 minutes remaining: "*Keep up the good work. You have only 2 minutes left*."
With 1 minute remaining: "*You are doing well. You have only 1 minute to go*."
With 15 seconds remaining: "*In a moment I'm going to tell you to stop. When I do, just stop right where you are and I will come to you.*"
Note: If the patient stops walking during the test and needs a rest, say this:
"*You can lean against the wall if you would like; then continue walking whenever you feel able*." Do not stop the timer. If the patient stops before the 6 minutes are up and refuses to continue (or you decide that they should not continue), wheel the chair over for the patient to sit on, discontinue the walk, and note on the worksheet the distance, the time stopped, and the reason for stopping prematurely.
When the six minutes are complete, say "*Stop!*" Walk over to the patient. Consider taking the chair if they look exhausted. Mark the spot where they stopped by placing a bean bag or a piece of tape on the floor. Record the number of laps from the counter (or tick marks on the worksheet). Record the additional distance covered (the number of meters in the final partial lap) using the measuring wheel. Calculate the total distance walked and record it on the worksheet. Congratulate the patient on good effort and offer a drink of water.

Six Minute Walk Test Record

Distance Walked: _________________metres

Walking aid used? ☐ None ☐ cane ☐ quad cane ☐ 2 wheeled walker ☐ rollator
____

Did patient walk for the entire 6 minutes? ☐ Yes ☐ No - Explain:

Did you need to walk with participant for safety reasons? ☐ No ☐ Yes - Explain:

Any adverse events? ☐ No ☐ Yes - Explain:

<u>Patient Specific Function Scale</u> (Stratford et al., 1995)

"Can you identify 3 important walking related activities that you are unable to do or have difficulty with as a result of your recent stroke?"
Using the following scale – can you rate your current ability to perform these activities.

0	1	2	3	4	5	6	7	8	9	10
Unable to perform activity										Fully Able to perform activity

Walking Related Activity	Pre	Post	FU
1.			
2.			
3.			
Total Score			

Chedoke-McMaster Stroke Assessment

Assess leg and foot recovery staging using the CMSA. Hemiplegic limb to be assessed. If bilateral involvement – assess both limbs.
Also assess Postural Control Staging.

	Right	Left	Comments
Leg			
Foot			
Postural Control			

Please indicate who was present at this assessment.

☐ **Participant alone** **or** ☐ **Participant and Family/Friend**

Did participant require a translator to answer questions?

☐ **Yes** ☐ **No**

Appendix I: Research Ethics Board approval letters

St. Joseph's Healthcare Hamilton

McMaster University

50 CHARLTON AVENUE EAST, HAMILTON, ONTARIO, CANADA L8N 4A6

RESEARCH ETHICS BOARD

Tel. (905) 522-4941 ext. 3537 Fax: (905) 521-6092

December 28, 2006

Mr. V. DePaul
Physiotherapy Dept.
St. Joseph's Healthcare Hamilton

Dear Mr. DePaul:

RE: R.P. #06-2753: A motor learning based walking program versus body weight supported treadmill training in community dwelling adults within six months of stroke onset: a randomized controlled trial - Protocol dated August 12, 2006, Information sheet/consent form dated 2006-12-18, Two Advertisement flyers, Ontario Budget Health Research Grants

The Research Ethics Board's Subcommittee reviewed R.P. #06-2753 at its meeting on November 20, 2006 and approved it with some conditions.

Those conditions have now been met. You have final approval to commence your research.

This approval will be for a one-year period **ending December 28, 2007.** We will request a progress report at that time.

If your project is terminated, it is your responsibility to notify the REB.
Any changes or amendments to the protocol or consent form must be approved by the Research Ethics Board prior to implementation.

Please ensure that all study personnel are familiar with the REB requirements on the appended page.

Please reference R.P. #06-2753 in any future correspondence.

We wish you well in the completion of this research.

Sincerely yours,

Raelene Rathbone

Raelene Rathbone, MB, BS, MD, PhD
Chairperson, Research Ethics Board
RR:lmm

cc: Marnie Fletcher - M.J. Sayles - Dr. Lisa Dolovich
Append.

4

St. Joseph's Healthcare
Hamilton

McMASTER UNIVERSITY

50 CHARLTON AVENUE EAST, HAMILTON, ONTARIO, CANADA L8N 4A6

RESEARCH ETHICS BOARD

Tel. (905) 522-4941 ext. 3537 Fax: (905) 521-6092

March 2, 2007

Mr. Vince DePaul
Physiotherapy Dept.
St. Joseph's Healthcare Hamilton

Dear Mr. DePaul:

RE: R.P. #06-2753: A motor learning based walking program versus body weight supported treadmill training in community dwelling adults within six months of stroke onset: a randomized controlled trial - **Therapist/Physician Advertisement Flyer, Physician Approval Form, Exclusion Criteria for participation in Stroke Walking Study, Physician Referral Form, Patient/Family Information Sheet – Amendment Request Jan 29/07, Memo received Jan 30 2007**

The Research Ethics Board's Subcommittee reviewed the amendments to the advertisement and recruitment materials for R.P. #06-2753 at its meeting on February 26, 2007 and approved them as submitted.

You have approval of Therapist/Physician Advertisement Flyer, Physician Approval Form, Exclusion Criteria for participation in Stroke Walking Study, Physician Referral Form, Patient/Family Information Sheet.

Please reference R.P. #06-2753 in any future correspondence.

Sincerely yours,

Raelene Rathbone

Raelene Rathbone, MB, BS, MD, PhD
Chairperson, Research Ethics Board

RR:ah

4

St. Joseph's Healthcare Hamilton

McMASTER UNIVERSITY

50 CHARLTON AVENUE EAST, HAMILTON, ONTARIO, CANADA L8N 4A6

RESEARCH ETHICS BOARD

Tel. (905) 522-4941 ext. 3537 Fax: (905) 521-6092

April 4, 2007

Mr. Vince DePaul
Physiotherapy
St. Joseph's Healthcare Hamilton

Dear Mr. DePaul

RE: R.P. #06-2753: A motor learning based walking program versus body weight supported treadmill training in community dwelling adults within six months of stroke onset: a randomized controlled trial – **Advertisement Flyer with REB stamp Apr 04 2007 – Amendment request March 29/07**

A designated member of the Research Ethics Board's Subcommittee reviewed the amendments to the advertisement and recruitment material for R.P. #06-2753 and approved them as submitted.

You have approval of the Advertisement Flyer.

Please reference R.P. #06-2753 in any future correspondence.

Sincerely yours,

Raelene L Rathbone

Raelene Rathbone, MB, BS, MD, PhD
Chairperson, Research Ethics Board

RR:ah

St. Joseph's Healthcare Hamilton

ANNUAL PROGRESS REPORT

Research Ethics Board Review of an Active Study
(to be completed by REB Chair only)

REB Project #:06-2753 **Principal Investigator:** **Mr. Vince DePaul**
Physiotherapy Dept.

Project Title: A motor learning based walking program versus body weight supported treadmill training in community dwelling adults within six months of stroke onset: a randomized controlled trial

[x] **Approved for continuation**

[ ] **Approved conditional on changes noted in "Conditions" section below**

Type of Approval:

[ ] **Full Board**
[x] **Subcommittee – NOVEMBER 29, 2007**

REB Approval Period: December 28, 2007 (from date) to December 28, 2008 (to date)

[ ] **New Enrolment Suspended**

[ ] **Suspended pending further review**

Conditions:

The St. Joseph's Healthcare, Hamilton, and the Hamilton Health Sciences/McMaster University Research Ethics Boards, operate in compliance with the ICH Good Clinical Practice Guidelines and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

Raelene A Rathbone
Signature of Research Ethics Board Chairperson

Raelene Rathbone, MB, BS, MD, PhD
Print or type name of REB Chairperson

November 29, 2007
Date

St. Joseph's Healthcare, Hamilton
Print or type name of REB

August 2002 *Page 3 of 3*

St. Joseph's Healthcare Hamilton

RESEARCH ETHICS BOARD

McMaster University

50 CHARLTON AVENUE EAST, HAMILTON, ONTARIO, CANADA L8N 4A6
Tel. (905) 522-4941 ext. 33537 Fax: (905) 521-6092

December 4, 2007

Mr. Vince DePaul
Physiotherapy Department
St. Joseph's Healthcare Hamilton

Dear Mr. DePaul:

RE: R.P. #06-2753: A motor learning based walking program versus body weight supported treadmill training in community dwelling adults with history of a stroke: a randomized controlled trial - **Protocol Version 3 November 23, 2007, Participant Information Sheet/Consent Form Version 2 dated 2007-12-03, Revised Study Information & Revised Therapists/MDs Advertisement Flyers – Amendment Request Nov 23/07**

A designated member of the Research Ethics Board reviewed the amendments for R.P. #06-2753 and approved them as submitted.

You have approval of the Protocol Version 3 November 23, 2007, Participant Information Sheet/Consent Form Version 2 dated 2007-12-03, Revised Study Information & Revised Therapists/MDs Advertisement Flyers.

Please reference R.P. #06-2753 in any future correspondence.

Sincerely yours,

Raelene Rathbone

Raelene Rathbone, MB, BS, MD, PhD
Chairperson, Research Ethics Board

RR:ah

St. Joseph's Healthcare Hamilton

Research Ethics Board

ANNUAL PROGRESS REPORT

McMaster University

Research Ethics Board Review of an Active Study
(to be completed by REB Chair or designate)

REB Project #:06-2753 **Principal Investigator: Mr. Vince DePaul**

Project Title: A motor learning based walking program versus body weight supported treadmill training in community dwelling adults with history of a stroke: a randomized controlled trial
Enclosure: Publication in Rehabilitation Magazine. P2.064

[X] **Approved for Continuation**

[ ] **Approved conditional on changes noted in "Conditions" section below**

Type of Approval:

[ ] Full Board
[X] Sub-Committee

REB Approval Period: 28 December, 2008 (from date) to 28 December, 2009 (to date)

[ ] **New Enrolment Suspended**

[ ] **Suspended pending further review**

Conditions:

The St. Joseph's Healthcare Hamilton Research Ethics Board operates in compliance with the ICH Good Clinical Practice Guidelines, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and Division 5 Health Canada Food and Drug Regulations.

Raelene L Rathbone
Signature of Research Ethics Board Chair

November 28, 2008
Date

Raelene Rathbone, MB, BS, MD, PhD
Print or type name of REB Chair

St. Joseph's Healthcare, Hamilton
Print or type name of REB

July 2008

St. Joseph's Healthcare Hamilton

RESEARCH ETHICS BOARD

McMaster University

50 CHARLTON AVENUE EAST, HAMILTON, ONTARIO, CANADA L8N 4A6
Tel. (905) 522-4941 ext. 33537 Fax: (905) 521-6092

March 31, 2009

Mr. Vince DePaul
St. Joseph's Healthcare Hamilton
Physiotherapy Dept.

R.P. #06-2753
Project Title: **A motor learning based walking program versus body weight supported treadmill training in community dwelling adults with history of a stroke: a randomized controlled trial**
Local Principal Investigator: Mr. Vince DePaul
Amendment Request received: **20 March, 2009**

Documents approved:
Recruitment Poster - Advertisement Poster
Recruitment Ad - Media Release
Other - Physician/Physiotherapy Reminder Card
Recruitment Material Other - Community Announcements

Dear Mr. DePaul:

A member of the Research Ethics Board Subcommittee has reviewed the Amendment Request for R.P. #06-2753 and approved it as submitted. You have approval of the amendment.

Please reference R.P. #06-2753 in any future correspondence.

Sincerely yours,

Raelene L Rathbone

Raelene Rathbone, MB, BS, MD, PhD
Chairperson, Research Ethics Board

RR:ah

Enclosures

St. Joseph's
Healthcare Hamilton

RESEARCH ETHICS BOARD

McMaster University

50 CHARLTON AVENUE EAST, HAMILTON, ONTARIO, CANADA L8N 4A6
Tel. (905) 522-4941 ext. 33537 Fax: (905) 521-6092

April 09, 2009

Mr. Vince DePaul
St. Joseph's Healthcare Hamilton
Physiotherapy Dept.

R.P. #06-2753
Project Title: A motor learning based walking program versus body weight supported treadmill training in community dwelling adults with history of a stroke: a randomized controlled trial
Local Principal Investigator: Mr. Vince DePaul
Amendment Request received: 08 April, 2009

Documents approved:
Recruitment Material Other - Executive Summary

Dear Mr. DePaul:

A member of the Research Ethics Board Subcommittee has reviewed the Amendment Request for R.P. #06-2753 and approved it as submitted. You have approval of the amendment.

Please reference R.P. #06-2753 in any future correspondence.

Sincerely yours,

Raelene Rathbone

Raelene Rathbone, MB, BS, MD, PhD
Chairperson, Research Ethics Board

RR:ah

Enclosure

St. Joseph's Healthcare Hamilton

Research Ethics Board

ANNUAL PROGRESS REPORT

McMaster University

Research Ethics Board Review of an Active Study
(to be completed by REB Chair or designate)

REB Project #:06-2753 **Principal Investigator: Mr. Vince DePaul**

Project Title: A motor learning based walking program versus body weight supported treadmill training in community dwelling adults with history of a stroke: a randomized controlled trial

[X] **Approved for Continuation**

[ ] **Approved conditional on changes noted in "Conditions" section below**

Type of Approval:

[ ] Full Board
[X] Sub-Committee

REB Approval Period: 29 December, 2009 (from date) to 28 December, 2010 (to date)

[ ] **New Enrolment Suspended**

[ ] **Suspended pending further review**

Conditions:

The St. Joseph's Healthcare Hamilton Research Ethics Board operates in compliance with the ICH Good Clinical Practice Guidelines, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and Division 5 Health Canada Food and Drug Regulations.

Raelene L Rathbone
Signature of Research Ethics Board Chair

27 November, 2009
Date

Raelene Rathbone, MB, BS, MD, PhD
Print or type name of REB Chair

St. Joseph's Healthcare, Hamilton
Print or type name of REB

July 2008