TREADMILL TRAINING FOR SCHOOL AGED CHILDREN WITH CEREBRAL PALSY

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STATEMENT OF AUTHORSHIP

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All substantive contributions by others to the work presented, including jointly authored publications, is clearly acknowledged.

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ABSTRACT

Despite treadmill training being increasingly used in clinical practice to habilitate walking in children with cerebral palsy, research investigating potential benefits for these children is in its infancy. This thesis describes three studies undertaken to examine the current evidence for treadmill training in cerebral palsy, add to this body of evidence by conducting the first known randomised controlled trial in the area, along with investigating the feasibility and potential benefits of a body weight supported treadmill training program conducted in an accessible special school environment.

The first study is a systematic review of current literature that has investigated the effectiveness of treadmill training for young people with cerebral palsy. Of 125 papers initially identified, five met the criteria for review. Methodological quality of the studies was low with a median PEDro rating score of 4 out of 10. The trial designs were predominantly pre-post intervention studies, with one study utilising a matched-pairs design. At the time of the review, no randomised controlled trial had been undertaken in this area. Treadmill training had been investigated for children aged between 3 and 14 years and studies included children with gross motor function classified across many levels of the Gross Motor Function Classification System (GMFCS); mostly GMFCS level III and IV. A variety of treadmill training protocols have been investigated. Training was typically conducted two or three times a week for around 30 minutes each session, however there was large variation in the length of the programs with training duration of between 2 and 12 weeks. The review indicated that treadmill training with body weight support is safe and feasible for children with cerebral palsy across a wide range of ages and functional abilities and that this type of training may be beneficial for improving

walking speed, endurance and gross motor skill performance. The review suggested that treadmill training may be particularly beneficial for children with more severe walking difficulty (GMFCS III or IV) with these children demonstrating significant increases in walking speed (d=1.48, 95% CI: 0.49–2.40) and gross motor performance (d=1.5, 95% CI: 0.50–2.50) after training. The results also indicated that treadmill speed and length of training sessions might need to be specifically matched to the desired intervention goals such as increasing walking speed or endurance.

The second study describes a randomized controlled trial that investigated the effectiveness of a 9 week, school based, body weight supported treadmill training program for children with cerebral palsy compared with an equivalent duration of overground walking training. As in the studies included in the literature review, the study found treadmill training with body weight support to be safe and feasible for children with cerebral palsy and moderate to severe walking difficulty. Contrary to expectations however, children in the treadmill training group did not improve their overground walking endurance or their self-selected walking speed after training. A small, non-statistically significant trend (F=3.004, p=0.097) for an increase in walking endurance was found for the children who completed overground walking training. Despite significant increases in session duration and treadmill walking speed for the children who completed treadmill training, a decrease in walking endurance was measured in this group. This suggests that there may have been benefits from training on a treadmill that did not carryover to overground walking. Potential explanations for these finding are discussed.

The third study used a qualitative methodology to explore the perceived benefits of body weight supported treadmill training from the perspectives of the children involved in the treadmill training program and of the school staff supporting them. Potential barriers and facilitators to conducting treadmill training in the school environment were also investigated. The results revealed physical and psychosocial benefits of treadmill training that were meaningful to the participants. These included improved walking endurance and balance along with a sense of pride and enjoyment. Important factors for clinicians to consider if contemplating treadmill training for young people with cerebral palsy, such as equipment and maintaining the child's motivation during training, are discussed.

This series of studies suggests that, while there is some evidence that children with cerebral palsy may experience changes in walking endurance after treadmill training, there are important aspects of training protocols, such as progressive reduction of body weight support and inclusion of concurrent overground walking practice, which may need to be considered for training to be maximally effective and for benefits to carryover to overground walking. Results of the studies also suggest that overground walking practice may be of benefit to children with cerebral palsy. These studies highlight that the specific groups of children who might respond best to this training, along with elements of treadmill training such as training intensity and systematic reduction of body weight support, must be further explored and rigorously investigated before firm conclusions can be made about the effectiveness of treadmill training for children with cerebral palsy.

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SYMBOLS & ABBREVIATIONS

10MWT	Ten metre walk test
95% CI	Ninety five percent confidence interval
Asymm	Asymmetrical
CD	Compact Disc
cm	Centimetres
CP	Cerebral Palsy
d	Effect size index
DGO	Driven Gait Orthosis
DVD	Digital video disc
EEI	Energy expenditure index
F	Test statistic for analysis of variance
FAC	Functional Assessment Questionnaire
GMFCS	Gross Motor Function Classification System
GMFM	Gross Motor Function Measure
I/P	Inpatient
k	Cohen's Kappa coefficient
kg	Kilogram
kph	Kilometres per hour
m	Metres
Min	Minutes
mo	Months
m/s	Metres per second

n	Number of participants
O/P	Outpatient
p	Probability (of Type I error associated with a test of significance)
PBWS	Partial body weight support
(P)BWSTT	(Partial) body weight supported treadmill training
PEDro	Physiotherapy Evidence Database
Quad	Quadriplegia
RCT	Randomised Controlled Trial
r	Pearson's correlation coefficient
SD	Standard deviation
SFA (travel)	School Function Assessment Travel Scale
y	years

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PREFACE

This thesis contains chapters that are designed to be read independently. Some of these chapters contain studies that have been published in peer reviewed journals and will be presented in their published format:

- Chapter 1 published as:

  Willoughby, K.L., Dodd, K.J., Shields, N. (2009). A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disability and Rehabilitation, 31*, 1971-1979.

- Chapter 2 published as:

  Willoughby, K.L., Dodd, K.J., Shields, N., Foley, S. (2010). Efficacy of partial body weight–supported treadmill training compared with overground walking practice for children with cerebral palsy: A randomized controlled trial. *Archives of Physical Medicine and Rehabilitation, 91*, 333-339.

- Chapter 3 comprises the manuscript:

  Willoughby, K.L., Shields, N., Dodd, K.J. School based treadmill training for young people with cerebral palsy: a qualitative study".

  This manuscript is currently under review by the journal *Disability and Rehabilitation*.

CHAPTER 1

Introduction

For children in developed countries, cerebral palsy is the most common cause of physical disability, with 2-2.5 per 1000 children affected (Reddihough and Collins 2003; Stanley, Blair, and Alberman, 2000; Surveillance of Cerebral Palsy in Europe [SCPE], 2000). In Australia, one child is born with cerebral palsy every 15 hours (Australian Cerebral Palsy Registers [ACPR] Group, 2009) equating to approximately 600 new diagnoses each year (Stanley et al., 2000; ACPR Group, 2009). A clear and appropriate definition of cerebral palsy has been widely debated over many years (Bax, 1964; Bax, Goldstein, Rosenbaum, Leviton, and Paneth, 2005; Mutch, Alberman, Hagberg, Kodama, and Velickovic, 1992) but it is currently accepted that the term describes “a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing foetal or infant brain” (Rosenbaum et al., 2007)

While the motor component of the disorder is a fundamental feature of cerebral palsy, the clinical presentations are varied and children diagnosed with cerebral palsy can experience a variety of challenges including deficits in vision and hearing, fine motor skills, speech, communication and learning difficulties, along with medical issues such as epilepsy (Wake, Salmon and Reddihough, 2003). The clinical signs of cerebral palsy vary depending on the location and the size of the primary lesion to the central nervous system. However, the movement difficulties that are the hallmark of cerebral palsy can be classified in three ways: 1) by the type of movement disorder experienced by the individual i.e. spasticity, dyskinesia, ataxia, 2) by the topographical distribution i.e. diplegia, hemiplegia, quadriplegia and 3) by the extent to which the individual’s gross motor function is affected e.g. by the Gross Motor Function Classification System (Palisano et al., 1997).

Many of the disorders of movement and posture that are associated with cerebral palsy can be related to the upper motor neurone syndrome (Kandel, Schwartz, and Jessel, 2000) which is described as having both positive and negative features. The positive features include spasticity, increased reflexes and muscle co-contraction, while the negative features are weakness, loss of selective motor control and deficits in balance and coordination (Bache, Selber, and Graham, 2003). These features are commonly associated with delays in the onset of walking and the abnormal gait patterns that are often observed in children with cerebral palsy (Bache et al., 2003; Bell, Ounpuu, DeLuca, and Romness, 2002). Over 28% of Australian children with cerebral palsy cannot walk and another 11% require a walking frame or sticks to walk. (ACPR group, 2009)

Many of the secondary deficits associated with cerebral palsy can significantly limit the child's activity level and societal participation, including achievement at school and development of social relationships (Liptak and Accardo, 2004). In particular, the walking ability of children with cerebral palsy has been shown to be predictive of a their capacity for activity, participation and social interaction (Bjornson, Belza, Kartin, Logsdon, and McLaughlin, 2007). It has been found that children with cerebral palsy who experience reduced motor function, as classified by the Gross Motor Function Classification System (Palisano et al., 1997), exhibit higher energy costs during walking than their typically developing peers (Johnston, Moore, Quinn, and Smith, 2004; Unnithan, Clifford, and Bar-Or, 1998). Improving walking function for these children may have the capacity to increase their activity and participation at home, school and their wider community, and influence their development of friendships and social relationships.

While the currently accepted definition of CP describes a non-progressive injury to the brain, secondary musculoskeletal changes can occur as children age. Abnormalities such as bony torsion, joint dysplasia and muscle contracture can then be exacerbated further by tertiary abnormalities arising from the compensations that children use in an attempt to overcome the impact of primary and secondary impairments (Gage and Novacheck, 2001). It has been shown that, as children with cerebral palsy approach adulthood, around 30% experience deterioration in their ability to walk either independently or with an assistive device, and up to 45% of those who were independently ambulant in their teenage years lose their ability to walk independently. (Bottos, Feliciangeli, Sciuto, Gericke, and Vianello, 2001). Adults with cerebral palsy also experience loss of mobility much earlier than their unaffected peers, with 70% losing their ability to walk between the ages of 20 and 40 years. (Bottos et al., 2001).

Because of the impact walking function can have on activity and societal participation of children with cerebral palsy, and the deterioration in gait that occurs at an early age in this population, improving the efficiency of walking and developing maximally independent gait is often the focus of therapeutic interventions for children with cerebral palsy. A combination of both conservative approaches – therapy, orthotic bracing – and pharmacological and surgical interventions are often used to address gait abnormalities (Damiano, Alter, and Chambers, 2009). These approaches are usually complementary as they each address some, but not all, of the deficits that a child may experience. For example, orthopaedic surgery to address bony malalignment or muscle contracture does not have an impact on selective motor control or weakness (Gage & Novacheck, 2001). Therefore intervention approaches offered by physiotherapists become important in complementing and maximising the benefits gained through pharmacological options to reduce spasticity, such as Botox ® and oral or intrathecal baclofen, and after orthopaedic surgery.

Historically, therapeutic interventions have been based on assumptions that improving a person's primary impairments, such as spasticity or muscle contracture, will result in improved function, however this is not necessarily true in all cases (Abel et al., 2003). For example, it has been demonstrated that passive motion is not directly correlated with an improvement in active motion and so alleviating a child's muscle contracture may not result in improved joint range or lead to increased motor function (McMulkin, Gulliford, Williamson, and Ferguson, 2000; Thompson, Baker, Cosgrove, Saunders, and Taylor, 2001). In some cases, passive interventions such as stretching have been demonstrated to be ineffective for improving muscle length people for people with cerebral palsy (Pin, Dyke, and Chan, 2006; Wiart, Darrah, and Kembhavi, 2008). Therapists have begun to move away from passive interventions where the physio is 'doing to' the child toward activity focussed interventions that reflect more recent views of motor learning theory. The importance of activity focussed interventions is now increasing in focus (Damiano, 2006).

From a motor learning perspective it has been argued that opportunities for repetitive practice of a motor skill within the context of the functional activity should be for a person to develop and improve motor tasks (Shumway-Cook and Woollacott, 2007). Neuronal group selection theory suggests that when encountering a new motor skill or when adapting a motor behaviour to a specific situation, a group of strongly interconnected neurons is selected from a primary neuronal repertoire based on prior experience of the task (Hadders-Algra, 2000). The movement patterns and postural adjustments that are generated from the task are then refined via afferent feedback. This suggests that without any therapeutic intervention many children with cerebral palsy may have difficulty in adapting their motor behaviours successfully due to a compound effect of each of these factors: due to decreased prior experience of the task they can only select movement patterns from a limited repertoire, and limited refinement of movement patterns is achieved due to abnormal sensorineural feedback. It is suggested that children with cerebral palsy require active, repetitive practice of the skill which will "enhance the processes of selection and thereby the production of better adapted motor behaviour" (Hadders-Algra 2000).

For this reason use of a mechanical treadmill may improve walking in children with cerebral because it provides an increased opportunity to repetitively train the whole gait cycle, facilitate an improved gait pattern and, when a body weight support system is used, reduce the impact of decreased balance on the child's ability to maintain active weight bearing during walking.

The effect of treadmill training on the recovery of gait or improvement in gait pattern for people with movement disorders has been investigated over some time in a variety of adult patient populations (Hesse, 2008; Shumway-Cook and Woollacott, 2007). Hesse and colleagues (1995 and 1999) have investigated the effectiveness of treadmill training with body weight support for adults following stroke. They found that gait velocity, cadence, step and stride length all significantly increased during the treadmill training sessions compared to interventions based on neurofacilitation (Hesse, Bertelt, and Jahnke, 1995). They suggested that, for improving walking speed and independence, the opportunity to train the whole gait cycle during treadmill training was more effective than part-practice of individual components of the cycle (Hesse et al., 1995). They have also found that, compared with overground walking, adults retraining walking following stroke walk with a more favourable gait pattern when walking with body weight support on a treadmill (Hesse, Konrad, and Uhlenbroch, 1999). Larger hip extension was noted on the treadmill than during overground walking and this was thought to assist the person with initiation of swing phase. A decrease in the length of double limb support phase was suggested as evidence that the person was able to initiate swing more quickly. They found that these adults walked more symmetrically on the treadmill than during overground walking, regardless of the level of body weight support that was provided. (Hesse et al., 1999)

Over more recent years, researchers in the field of cerebral palsy have begun to turn their attention to the possibility that treadmill training may be effective in improving walking for these children. Some preliminary work has suggested that body weight supported treadmill training is feasible in children as young as 15 months and can be used with children who are not yet walking independently (Richards et al., 1997). Improved walking has the potential to increase the mobility and therefore the societal participation of children with CP at home, at school and in the wider community.

Accordingly, a decision was made to devise a research program to investigate the effectiveness of treadmill training for children and adolescents with cerebral palsy. The aims of the current research program were to:

1) identify and critically examine the current evidence investigating the effectiveness of treadmill training programs for young people with cerebral palsy;
2) investigate the benefits of a school based program of body weight supported treadmill training for school-aged children with cerebral palsy who have moderate to severe walking difficulties; and,
3) evaluate the feasibility of a school based treadmill training program and identify the possible benefits, barriers and facilitators to the program from the perspectives of the children and school staff who were involved.

This thesis describes a literature review (Chapter 2), a randomised controlled trial (Chapter 3) and a qualitative study (Chapter 4) that were undertaken to achieve these aims.

CHAPTER 2

Systematic review of treadmill training for children with cerebral palsy

2.1 Preface

This chapter is based on a systematic literature review which investigated current evidence for the effectiveness and efficacy of treadmill training for children and adolescents with cerebral palsy. The review aimed to examine current evidence, describe the training protocols reported in the reviewed studies and to summarise the influence of age and severity of physical disability on the effectiveness of this type of training.

The review reported in this chapter is presented in its published form:

> **Willoughby KL,** Dodd KJ, Shields N. (2009) A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil*, *31*, 1971-1979. (See Appendix A for the co-authorship contribution statement)

This review was presented at the Australasian Academy for Cerebral Palsy and Developmental Medicine conference, Christchurch, New Zealand, February 2010:

> **Willoughby KL,** Dodd KJ, Shields N. A systematic review of the effectiveness of Treadmill training for children with cerebral palsy. *Developmental Medicine and Child Neurology, 52* (*Suppl s2),* 27

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REVIEW

A systematic review of the effectiveness of treadmill training for children with cerebral palsy

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Abstract

Purpose. The development of efficient and independent walking is an important therapeutic goal for many children with cerebral palsy (CP). Consequently, there has been growing interest in determining the effects of treadmill training programs for these children.

Method. A systematic review of the literature was conducted to evaluate the effectiveness of treadmill training for children with CP. Relevant trials were identified by searching electronic databases and by citation tracking.

Results. Of 125 papers initially identified, five met the criteria for review. Results showed that treadmill training is safe and feasible for children with CP across a wide range of ages and functional abilities. Children with more severely affected walking ability significantly increased their walking speed ($d = 1.48$, 95% CI: 0.49–2.40) and gross motor performance ($d = 1.5$, 95% CI: 0.50–2.50) after training. However, the results also suggested that treadmill speed and length of training sessions might need to be set to specifically match desired intervention goals such as increasing walking speed or endurance.

Conclusions. The review suggests that treadmill training is safe and feasible for children with CP and indicates that there may be some positive benefits in walking speed over short distances and in general gross motor skills. The provision of PBWS may be particularly beneficial for children with more severe walking disability (GMFCS III and IV). Further research is necessary before it can be concluded that treadmill training is beneficial for children with CP.

Keywords: *Cerebral palsy, children, treadmill training*

Introduction

With an incidence of around 1 in 400 children affected, cerebral palsy (CP) is the most common cause of physical disability in children [1]. Impairments such as muscle weakness, altered muscle tone and sensory function can result in abnormal motor control, associated delay in the onset of walking and the abnormal gait patterns that are common in CP [2]. It has been found that children with poorer locomotor function, as classified by the Gross Motor Function Classification System (GMFCS) [3], exhibit a higher energy cost during walking than their typically developing peers [4]. Decreased locomotor function has also been shown to be predictive of reduced capacity for activity, participation and social interaction [5].

Efficiency of walking and the development of independent gait are often the focus of therapeutic interventions for children with CP. Motor learning theory suggests that when encountering a new motor skill or adapting a motor skill to a specific situation, a group of interconnected neurons is selected from a primary neuronal repertoire based on prior experience of the task. Generated movement patterns and postural adjustments are then refined via afferent feedback [6]. Therefore, it has been argued that to develop and improve a motor skill such as walking, opportunities for repetitive practice of the skill need to be offered [7].

For this reason use of a mechanical treadmill may improve walking in children with CP. Treadmill walking provides increased opportunity to repetitively train the whole gait cycle, facilitate an

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improved gait pattern and, when a body weight support system is used, reduce the impact of poor balance on the child's ability to maintain weight bearing during walking. Some preliminary work suggests partial body weight supported treadmill training (PBWSTT) is feasible in children with CP as young as 15 months and can be used with children who are not yet walking independently [8]. Improved walking has the potential to increase the mobility and positively influence the societal participation of children with CP at home, at school and in the wider community [9]. Accordingly, this systematic review aimed to investigate if treadmill training with or without body weight support was effective in improving the gross motor function and societal participation of children with CP

Method

Identification and selection of studies

A search of the following electronic databases was conducted to identify relevant articles: the Cochrane Library, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register (July 2008), PEDro (July 2008), Medline (1950–July 2008), CINAHL (1982–July 2008), Embase (1988–July 2008), ERIC (1966–July 2008) PsychINFO (1985–July 2008), PubMed (1950–July 2008), AMED (1985–July 2008), Ausport Medical (1989–July 2008) and SPORT Discus (1930–July 2008). Keywords for the concepts 'cerebral palsy', 'child' and 'treadmill training' were identified using MeSH headings and synonyms. Additional articles were identified through a manual search of the reference lists of relevant articles and through citation tracking and key author searches completed using the Web of Science.

Two reviewers independently applied the inclusion and exclusion criteria to the titles and abstracts of identified articles. Disagreements about the eligibility of articles were resolved by discussion between the two reviewers. Articles were included if (1) participants were less than 18 years of age, (2) greater than 80% of participants had a diagnosis of CP and (3) treadmill training comprised greater than 80% of the total intervention where multiple, concurrent interventions were described. Articles were excluded if (1) participants had a concurrent physical or cardiorespiratory disorder that may have impacted on their ability to participate in training, (2) where a treadmill was used for assessment purposes only, for example, to examine fitness in a single test session, (3) if articles scored less than 3 on the PEDro quality assessment scale [10] and (4) if only an abstract was available. Where eligibility could not be determined from the title and abstract alone, the full text of the article was obtained.

Quality assessment

The methodological quality of the included studies was assessed using the PEDro scale which has demonstrated evidence of reliability [10]. This scale consists of 11 items, 10 of which are scored. Internal validity of each article is assessed by rating criteria relating to random allocation, concealment of allocation, comparability of groups at baseline, blinding of participants, therapists and assessors, measurement of key outcomes, intention to treat analysis, adequacy of follow-up and statistical reporting. For each item, a point was awarded when the specific criteria were met, with a maximum possible score of 10. Two reviewers independently rated the articles and any difference in their scoring was resolved by discussion until consensus was reached. Inter-observer agreement was calculated using a weighted κ statistic that rated the degree of disagreement between the final quality assessment scores of the reviewers using quadratic weights.

Data extraction

Data extraction was conducted independently by two reviewers using a standardised form developed for this review. Data were extracted under the following headings: study objective, study type, population details, participant details (including number, gender, age and classification of CP), intervention undertaken (including details of specific treadmill training protocol used), outcome measures used and results.

Data analysis

To enable comparisons of the reported outcomes in each trial, effect sizes with 95% confidence intervals were calculated where sufficient data were reported. Effect sizes for controlled trials were calculated by subtracting the mean of the control group post-intervention from the mean of the experimental group post-intervention and dividing the result by the standard deviation of the control group [11]. Where studies had a single group, effect size was calculated by dividing the difference in the means (pre and post intervention) by the standard deviation of the difference scores. Where sufficient data were not reported to enable calculation of effect sizes, the relevant author was contacted and required data requested. Consistent with Cohen's convention,

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effect sizes of d less than 0.20 were considered small, d between 0.20 and 0.80 were considered medium, and effect sizes greater than 0.80 were considered large [12]. There was significant variation in the outcomes assessed by each trial and in clinically relevant characteristics, such as the participant characteristics and the intensity and duration of training programs. Because of this clinical heterogeneity between the trials a meta-analysis was not performed.

Results

The initial search identified 125 potentially relevant articles. After application of the inclusion criteria to the titles and abstracts, 15 articles remained. Of these, 10 were excluded. Three articles were excluded as they were only available as abstracts [13–15]. A further three articles were excluded because a combination of interventions was used and treadmill training comprised less than 80% of the intervention [8,16,17]. One article was excluded because only the physiologic response to a single walking trial was being investigated [18], and another because the participant did not have a diagnosis of CP [19]. Two articles were excluded as they scored less than 3 on the PEDro scale [20,21]. This left a total of five articles for review [22–26].

Table I summarises the PEDro rating score, participant characteristics, training schedule and outcome measures for each included trial. The methodological quality of these studies was low, ranging from 3 to 6 of 10, with a median score of 4. The trial designs were a matched pairs, clinical controlled design [23] and four pre-post intervention designs [22,24–26]. Two of the studies included a control or comparative group but did not conceal group allocation [22,23]. One other study included two groups, both participating in training but at separate venues (an inpatient and an outpatient group). However, only results for the outpatient group were included in this review as the inpatient group was of mixed diagnoses and participated in an intensive rehabilitation programme concurrently with treadmill training. Only one study reported blinding of the assessors [22]. The inter-observer reliability of assessing the methodological quality of the articles was $\kappa = 0.58$.

The sample size in each study was small (6–19 participants, total of 48 across the studies included in the review), and the demographics of the participants varied considerably (Table I). Most participants were male, with a mean age ranging from 4.5 to 11.5 years. The classification of the participants' movement disorders (type and severity) varied both within individual studies and between studies.

Training protocols

The training protocols implemented across the studies varied in intensity and duration (Table I). Training was typically conducted two or three times a week, for around 30 minutes each session, for a duration of between 2 and 12 weeks. In each study, at least one physiotherapist supervised all training sessions, with some studies employing two [26] or three [25] personnel. Each study incorporated gait facilitation during training. Gait facilitation was described by all studies, including assistance with initiation of swing, facilitation of heel contact, attention to knee extension, prevention of hyper-extension during stance and prolonging stance phase. One study was unique, using a Driven Gait Orthoses (DGO) to facilitate gait on the treadmill [24]. The DGO comprised two leg orthoses, with hip and knee joints, connected to the frame of a body weight support system and fastened to the legs of participants. Two linear drivers, controlled by a computer system, moved the orthoses synchronously with the treadmill speed.

Body weight support systems

All studies used partial body weight support (PBWS) as part of the training protocol. The LiteGait body weight support system and harness was used in two studies [22,25]. Other BWS systems used were a mobile hoist and a sling designed by the researcher [23], the WalkAble system with Walkable harness [23], a harness suspended by a rope and pulley system [26] and a counterweight system that was part of the DGO [24]. Three studies attempted to quantify the amount of body weight support provided during training. One of these used a Bisym attachment as part of the PBWS apparatus to set the weight support at 30% [25]. Another study used a harness suspended by a rope and pulley system connected to an adjustable counterweight of 2 kg increments [26], and the third study set the initial body weight support provided by the DGO at 50% [24]. In the remaining studies, clinical observation of the participant's standing posture was used to set a level of body weight support that was sufficient to maintain foot contact with the treadmill, but avoid knee collapse or excessive hip flexion [22,23].

Progression of training parameters

Training intensity was increased either by decreasing the amount of body weight support provided or by increasing the treadmill speed or the time spent walking, or through a combination of both. Three studies reported a

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Table I. Summary of the quality assessment, participant and intervention characteristics of the articles included in the review.

Author	PEDro Score	Sample size	Mean age and range (years)	Gender	Type of CP distribution	GMFCS/FAC	Training schedule: frequency, session duration, length	Setting	Outcome measures
Cherng et al. [22]	6	8	4.5 and 3.5–6.3	6 boys, 2 girls	Spastic diplegia $n=8$	GMFCS III $n=6$, GMFCS I $n=2$	2–3 per week 20 minutes 12 weeks	Not stated	Walking speed, cadence, stride length, double limb support, GMFM, Muscle tone and selective motor control
Dodd and Foley [23]	5	14	8.8 and 5–14	10 Boys, 4 girls	Athetoid quad $n=8$, Spastic diplegia $n=2$, Spastic quad $n=4$	GMFCS III $n=4$, GMFCS IV $n=10$	Twice per week 30 min max 6 weeks	School gym	10 MWT, 10 minute walk
Meyer-Heim et al. [24]	4	10	8.17 and 5.17–14.33	6 Boys, 4 girls	Bilateral spastic CP $n=10$	GMFCS I $n=1$, GMFCS II $n=3$, GMFCS III $n=4$, GMFCS IV $n=2$	3–4 per week 25–45 minutes 3–5 weeks (10–13 sessions)	Tertiary paediatric hospital outpatient department	10 MWT, 6 minute walk, GMFM, FAC
Provost, et al. [25]	3	6	10.5 and 6–14	4 Boys, 2 girls	Hemiplegia $n=4$, Asymm diplegia $n=2$	GMFCS I $n=6$	2 times/day 30 minutes 2 weeks	Not stated	10 MWT, 6 minute walk, EEI, GMFM, single leg stance
Schindl, et al. [26]	3	10	11.5 and 6–11	4 Boys, 6 girls	Spastic quad $n=7$, Spastic diplegia $n=3$	FAC 0 $n=6$, FAC 2 $n=2$, FAC 3 $n=1$, FAC 4 $n=1$	3 per week 30 min max 3 months (36 sessions)	Out-patient rehab clinic	FAC, GMFM

CP, cerebral palsy; Quad, quadriplegia; Asymm, asymmetrical; GMFCS, gross motor function classification system; FAC, functional ambulation category; GMFM, gross motor function measure; EEI, energy expenditure index; 10 MWT, 10 metre walk test; I/P, inpatient; O/P, outpatient.

gradual decrease in the amount of body weight support for each participant over the course of training [24–26]. Three studies reported progression of treadmill speed with mean increases ranging from 50 to 58%: from 0.11 to 0.17 m/s [23], from 0.23 to 0.34 m/s [26] and from 0.67 and 0.85 m/s to 1.03 and 1.65 m/s [25]. An increase in mean walking time was reported by two studies with mean increases of 76% (12.07–21.25 min) [23] and 46% (12.8–18.8 min) [26].

Setting and motivating tools

Three studies described the setting for intervention. One study was completed in a school gymnasium within school hours [23], and another was completed in an outpatient rehabilitation setting [26]. The third study had an outpatient group training in the rehabilitation unit of a tertiary paediatric hospital [24].

Only one study described using motivational tools such as games, activities or incentives to encourage the children to continue training [24]. In that study, children were encouraged to bring a favourite CD or DVD to watch during training. The DGO also incorporated a biofeedback system, providing real time graphical representation using data from force sensors, but it was reported that children were only able to focus on this for a short period of time.

Effect on walking

The results from the included trials suggest that treadmill training can increase the speed of over ground walking. Four studies investigated the effects of treadmill training on walking speed over short distances over ground [22–25]. Two of these studies reported large effect sizes for increased self-selected walking speed over 10 metres (Figure 1) [23,25]. The other two studies provided insufficient data to enable calculation of effect sizes and the authors of these studies were not able to be contacted. For these two studies a significant increase in walking speed

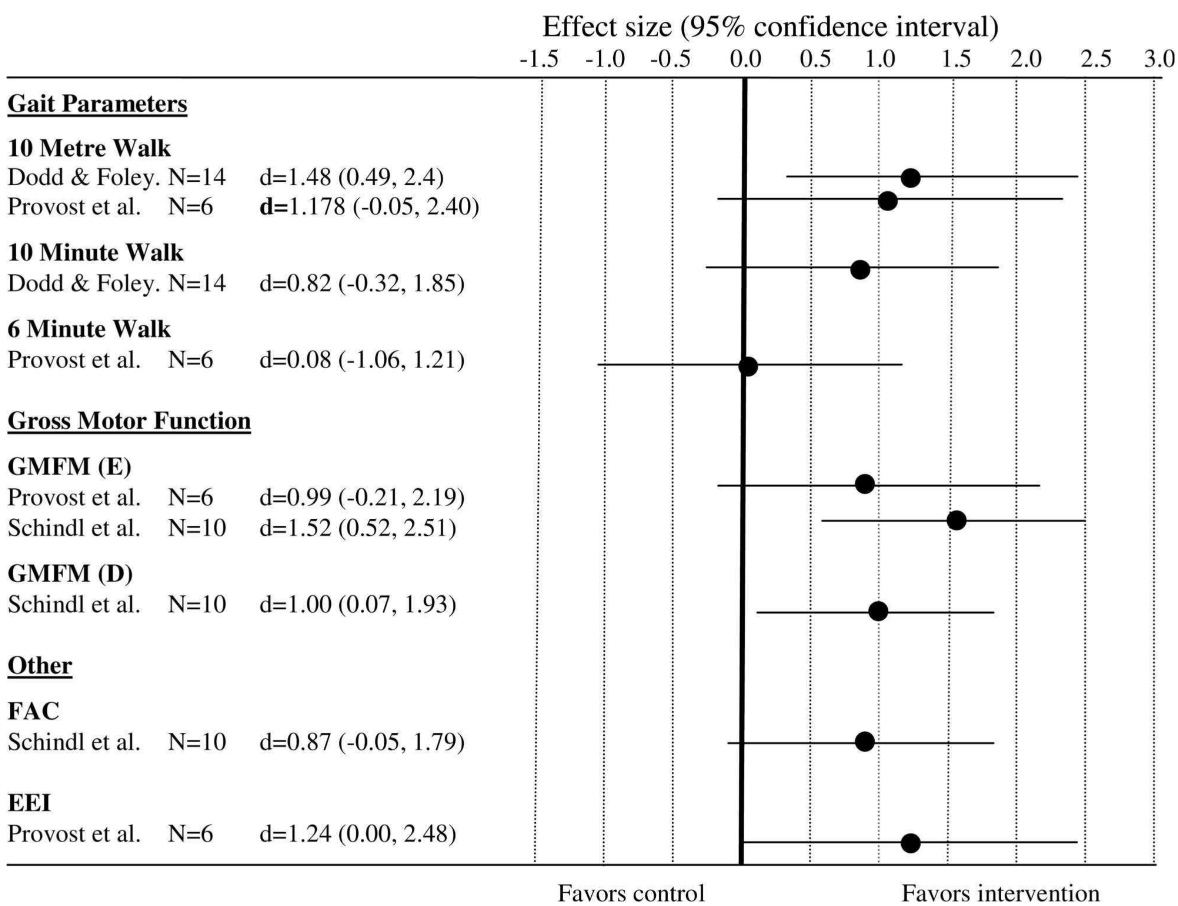

Figure 1. Effect sizes with 95% confidence intervals able to be calculated for outcome measures of the articles included in the review. GMFM (E), Gross Motor Function Measure Dimension E; GMFM (D), Gross Motor Function Measure Dimension D; FAC, Functional Ambulation Category; EEI, Energy Expenditure Index.

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over 10 m was reported for the group training with the DGO, with a mean increase of 0.22 m/s [24], and the second study reported no significant change in walking speed for a group of participants of GMFCS level I, as measured with a GAITRite electronic walkway system [22].

The results suggested that treadmill training had no effect on walking endurance or on the amount of physical support required. Two studies measured the effects of treadmill training on walking endurance. One used the 6 min walk test and found a non-statistically significant effect in a group of participants of GMFCS level I [25] (Figure 1). The remaining study used the 10 min walk test and found a large, but not statistically significant, effect size in a group of participants with more severely affected walking abilities and classified as GMFCS III or IV [23] (Figure 1). Two studies investigated the effect of treadmill training on the amount of physical support required by the child to achieve functional ambulation [24,26]. This was measured by the Functional Ambulation Categories (FAC), which describes six levels of physical support provided by another person that is required to achieve ambulation [27,28]. As seen in Figure 1, one study demonstrated a trend for change in FAC [26]. For the group training on the DGO, mean score remained unchanged.

Effect on gross motor skills

Treadmill training appeared to be effective in improving general gross motor skills. Four studies assessed the effects of treadmill training on general gross motor skills [22,24–26]. All reported significant changes in Dimension E (walking, running, jumping) of the Gross Motor Function Measure (GMFM) [22,24–26] with large effect sizes found in two groups [25,26] (Figure 1).

Three studies investigated change in Dimension D (standing), with a large effect size found in one (Figure 1) [26]. A second study found no statistically significant difference following training [24], and the third reported a statistically significant change in Dimension D ($F = 8.4$, $p = 0.03$) and in the total GMFM score ($F = 52.74$, $p = 0.01$) [22]. In the latter study, it was reported that the improvements in the total GMFM score were retained for at least 12 weeks after training was completed [22].

Effects on body structure and function

One study investigated the effects of treadmill training on Energy Expenditure Index (EEI) which assesses energy cost of walking [25]. A large effect size was found for change in EEI (Figure 1) with improvements noted for all participants.

The effects of treadmill training on muscle tone and on selective motor control was investigated by another study [22] in which change in muscle tone was measured with the Modified Ashworth Scale [29]. Selective motor control was measured by clinical observation of the participants ability to dorsiflex their foot to a target. A rating of 1–4 was awarded dependent on recruitment of other muscle groups to assist dorsiflexion. No statistically significant change was found for either outcome measure.

Effect on societal participation

None of the included studies investigated the effects that treadmill training might have on the societal participation of children with CP.

Adverse events from training

No study reported unexplained withdrawals, and all studies reported that the training was well tolerated by participants. One study reported two participants who found the treatment ‘exhausting’ and were unable to increase the length of time spent walking during treatment sessions [26]. There were no reports of muscles soreness or joint pain during or after training, and no injuries due to trips or falls were reported.

Discussion

The results of this review demonstrate that investigation of the effects of treadmill training for children with CP is only in its early stages. The absence of adverse events heterogeneity across participants suggests that treadmill training with body weight support is a safe and feasible intervention for children with CP across a wide range of ages and functional abilities. It has also demonstrated that treadmill training might offer some positive benefits for children with CP with a range of gross motor abilities and differing movement disorders. However, with such a small number of studies identified by this review, low methodological quality demonstrated in most of the trials, and largely heterogeneous populations as their focus, caution must be taken when drawing conclusions from the results of the studies and applying these to clinical practice.

PBWSTT appears to be effective in increasing the self-selected walking speed of children with CP over short distances, reflecting results found for adults after stroke and spinal cord injury [30–33]. This is a potentially important clinical finding because slower walking speeds have been found to restrict a child’s

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ability to function in their community and so it can impact on their societal participation [9]. However, the results of this review also suggest that the greatest benefits may be for children with more severe functional involvement (GMFCS III and IV). For children with more severe functional involvement, improving walking speed over short distances may be functionally important because this has the potential to influence their ability to use walking for indoor mobility, either at home or in the classroom, and may decrease their reliance on bulkier and less manoeuvrable wheeled mobility in these settings.

The results also suggest that treadmill training can improve other gross motor skills such as static and dynamic balance in standing and negotiating stairs. Again the largest effect was found for a group of children with full body involvement and greater walking disability. In contrast, no significant effects were found in a group of children with hemiplegia or diplegia who were able to walk independently. This difference in findings may be explained by the fact that the more functionally able children attained close to the maximum possible score for Dimension E of the GMFM before they began their training and so they may have been very close to or have already reached their own maximal potential in this area. The influence of the partial body weight support systems used during training may also have provided an environment in which children with more severe walking disability could develop balance and weight shift in standing, leading to improvements in other gross motor skill areas.

For clinicians, progression of training parameters is an important aspect to consider when setting up a treadmill program. The results of this review indicate studies that found improvements in overground walking speed also reporting increases in treadmill belt speed during training [23,25]. Specificity of training is a guiding principle of motor learning theories. This principle suggests that to improve a motor task, the specific task needs to be practiced and this is better done within a functional context. Therefore, if the aim of therapy is for a child to walk faster, then it is important that the child practices walking faster. This concept is supported by research in adult populations that has demonstrated that specificity of training directly relates to re-training walking with adults after stroke [34]. Results have shown that structured, speed-dependent treadmill training is more effective in improving walking speed than training without significant speed increases [34]. This suggests that when clinicians set the training parameters of treadmill training they should carefully consider matching these parameters with the goals of treatment.

Although this review suggests that treadmill training may be effective in improving walking speed over short distances and improving other areas of gross motor function for children with CP, a number of clinically important questions remain. For example, the most effective level of body weight support remains unclear. Of the three studies in this review that attempted to measure the level of body weight support, between 14% and 50% of body weight support was provided. No study provided evidence for the chosen level of support. The effect of different amounts of PBWS on the gait of normal adults during treadmill walking demonstrates that PBWS of greater than 30% results in significant distortion to normal gait patterns. This research suggests that support levels of between 10 and 30% produce the least distortion to gait and may be the optimum level of support if the goal of training is for improvement in gait pattern [35]. The incorporation of PBWS in treadmill training programs also appears to be important due to the support that it provides children with more severe walking disabilities to enable them to participate in treadmill training. Further investigation of the optimum level of body weight support needed during treadmill training to improve walking for children with CP is required to guide clinicians.

Another characteristic of treadmill training that has not been addressed clearly, even in adult populations, is the optimum intensity and duration of training. A systematic review of the effects of treadmill training after stroke in adult populations found a variety of training dosages ranging from 20 to 60 minutes per day, 3 to 5 days per week for between 2 and 10 weeks [33]. No study has directly compared different training dosages, but it has been hypothesised that treatment effects may be highly dependent on the intensity of the training protocol used [33]. The training dosage of studies in the current review varied in intensity and duration and contrasting training protocols were found in studies that reported positive benefits. For example, of the two studies that produced large effect sizes for change in over-ground walking speed, one included an intense training protocol with participants training twice a day for 2 weeks. In the second study, participants trained twice weekly for 6 weeks. It seems that varying protocols can each result in positive changes for the participant, however when establishing a training protocol, clinicians must consider its feasibility for participants and their families. High intensity training programs of short duration have been reported as effective [36,37] and may be more accessible to some children and their families, where a less intense program may be more easily implemented in a school or other community setting.

Only a handful of outcome measures were investigated in the studies included in this review.

Most measures focussed on changes in activity, and no study investigated change in societal participation for this group of children. Few changes to body structure and function (e.g. muscle tone, energy expenditure, muscle strength, bone density) were investigated by the five studies. These may be important areas of outcome to address because while it may not be expected that PBWSTT may result in a large change in the functional abilities of children with severe walking impairment (GMFCS IV), there may be other potential benefits for these children. For example, it is possible that increased walking might impact on body mass index, growth, nutritional status and bone health, all factors which can have an enormous impact on the child's general health and well-being.

Although this review included an extensive and comprehensive search of relevant databases and available literature, limitations exist that need to be considered. First, included studies were limited to full studies published in English, resulting in possible exclusion of relevant articles written in other languages. Second, no attempts were made to locate and access theses or other unpublished materials due to the difficulties in identifying and locating such studies. Because of this, publication bias cannot be ruled out. Although calculation of effect sizes demonstrated large effects for some outcomes, such small and heterogenous samples create a subsequent lack of power in the majority of the studies. The results of this review highlight the paucity of research into the effects of treadmill training for children with CP and the weaknesses identified in the existing literature should guide the development of future studies. Further, high-quality research needs to address examining children of specific levels of walking disability and with larger sample sizes to increase study power.

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Conclusions

The results of this systematic review support the safety and feasibility of PBWSTT for children with CP across a range of ages and functional abilities. The review also indicates that there may be some positive benefits in walking speed over short distances and in general gross motor skills. The provision of PBWS may be particularly beneficial for children with more severe walking disability (GMFCS III and IV). However, the specificity of the training protocol must be addressed with parameters of the training protocol (e.g. treadmill speed and length of time on treadmill) progressed according to the aspect of gait that the clinician is targeting e.g. walking speed, endurance, balance during walking. Because of the relatively small amount of literature in this area and the low methodological quality of existing studies, further high-quality research needs to be completed before it can confidently be concluded that PBWSTT has a beneficial effect on the activity and participation of children with CP.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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CHAPTER 3

Efficacy of partial body weight–supported treadmill training compared with overground walking practice for children with cerebral palsy: A randomised controlled trial

3.1 Preface

This chapter describes a randomised controlled trial which investigated the efficacy of a nine week, school based program of partial body weight supported treadmill training for young people with cerebral palsy. In this study, the potential benefits of body weight-supported treadmill training were directly compared with an equivalent intensity of overground walking practice.

The study reported in this chapter is presented in its published form:

> **Willoughby KL**, Dodd KJ, Shields N, Foley S. (2010) Efficacy of partial body weight–supported treadmill training compared with overground walking practice for children with cerebral palsy: a randomized controlled trial. *Archives of Physical Medicine and Rehabilitation,.91,* 333-339.
>
> (See Appendix G for the co-authorship contribution statement)

Following publication, a letter to the editor was received by the journal and a response to these comments was accepted for publication. The letter and an author response were published in *Archives of Physical Medicine and Rehabilitation* in September 2010 and are included in Appendix H.

This paper was presented at the International Cerebral Palsy Conference, Sydney, Australia, February 2009:

> **Willoughby KL**, Dodd KJ, Shields N, Foley S. (2009) The effectiveness and efficacy of treadmill training for children with cerebral palsy: a randomized controlled trial. *Developmental Medicine and Child Neurology. 51 (Suppl.S2),* 9.

This paper was nominated as one of the top ten papers of the year in the field of Developmental Disabilities by senior members of the American Academy of Cerebral Palsy and Developmental Medicine at the annual meeting in Washington, DC, September, 2010.

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ORIGINAL ARTICLE

Efficacy of Partial Body Weight–Supported Treadmill Training Compared With Overground Walking Practice for Children With Cerebral Palsy: A Randomized Controlled Trial

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

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

Design: Randomized controlled trial.

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

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

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

Main Outcome Measures: Ten-meter walk test (self-selected walking speed), 10-minute walk (walking endurance), School Function Assessment.

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

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

Key Words: Cerebral palsy; Child; Exercise therapy; Gait; Rehabilitation; Walking.

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THE DEVELOPMENT OF independent walking and efficient gait is often a primary focus of physiotherapy interventions for children with CP. Decreased locomotor function is predictive of reduced capacity for activity, participation, and social interaction for children with CP.[1] Their walking energy expenditure is increased up to 3 times that of typically developing children,[2] particularly for children with poorer locomotor function, classified as level III (reliant on a hand-held mobility device for ambulation) or IV (can walk only short distances with a body support walker) by the GMFCS[3,4] (appendix 1). Improving walking function for children with moderate to severe walking difficulty is particularly important because it has the potential to increase their mobility and positively influence their societal participation at home, at school, and in the wider community.[5]

With a growing body of research evaluating the efficacy of treadmill training for adults with neurologic disorders, most notably after spinal cord injury, clinicians and researchers in the field of pediatric CP have begun to turn their attention to the potential benefits of treadmill training for improving walking in children with CP. This interest is based on the principle that task-specific and repetitive practice is required to develop and improve a motor skill such as walking.[6-9]

Use of a mechanical treadmill, with or without body weight support, may improve walking in children with CP because it provides an opportunity to repetitively and intensively train the whole gait cycle and facilitate an improved gait pattern during walking. Preliminary work suggests that PBWSTT is feasible in children with CP and may improve their walking speed, walking endurance, and general gross motor skills.[10-14] However, it is difficult to draw strong conclusions from existing

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List of Abbreviations

CI	confidence interval
CP	cerebral palsy
GMFCS	Gross Motor Function Classification System
PBWSTT	partial body weight–supported treadmill training
10MWT	ten minute walk test

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studies or determine guidelines for clinicians because of limitations within existing studies. These limitations include small heterogeneous samples, lack of control or comparison groups, no randomization of participants or allocation concealment, and assessors not blinded to group allocation. Although the results reported in previous studies and systematic reviews are promising, the potential benefits of treadmill training for children with CP need to be investigated for children with specific levels of disability and through rigorously designed trials with large sample sizes that ensure greater statistical power.

Thus, the aims of this single-blind randomized controlled trial were to (1) determine the safety and feasibility of a PBWSTT program held in a special school environment and (2) investigate if PBWSTT can increase the walking endurance, walking speed, and walking function at school of children and adolescents with CP and moderate to severe walking difficulty (GMFCS III and IV) compared with overground walking practice.

METHODS

Participants

Participants were recruited from a metropolitan specialist school for children with moderate to severe physical and intellectual disabilities. Participants were included if (1) they were aged between 5 and 18 years, (2) they had a diagnosis of CP, (3) their gross motor function was categorized III or IV by the GMFCS,[4] and (4) they were able to understand simple instructions and reliably indicate yes and no. Children were excluded if they (1) needed physical assistance from another person to walk with their assistive device, (2) had a concurrent medical condition such as severe cardiorespiratory disease or uncontrolled epilepsy that posed a risk to their safety during training, or (3) had lower limb orthopedic surgery or botulinum toxin injections in the 6 months prior to their participation, because these factors may confound results.

Ethical approval was granted by University Ethics Committee and the Department of Education. Informed consent was gained from the parents or guardians of each participant and from participants over 16 years with sufficient cognitive capacity.

Apparatus

A motorized treadmill (Proteus MTM 4500[a]) with a minimum speed of 0.1km/h was used for the treadmill training sessions. Partial body weight support was provided by a walking harness (Kilparrin[b]) that provided full contact at the pelvis and trunk without limiting hip movement. The harness was attached to either a mobile hoist (Elf Hoist[c]) or ceiling hoist (Bravo hoist[d]). The ceiling hoist was used for children over 150cm, because the mobile hoist was unable to elevate them sufficiently to provide body weight support.

Procedure

Participants were randomly allocated to the experimental (treadmill training) or control (practice of overground walking) group by a block randomization method. Randomization was stratified according to GMFCS level (GMFCS level III or IV) and age (5–12y or 13–18y). For each stratum, the allocation sequence was generated from a random numbers table with assignments sealed in sequentially numbered opaque envelopes. Following enrollment, a participant was assigned to a group by opening the next envelope. This process was administered by a team member not known to any of the participants and not involved in recruitment or the training programs.

Treadmill Training Protocol

The treadmill training protocol implemented in this study was developed from recent systematic reviews of literature examining the effects of treadmill training for children with CP.[15-17] Positive effects have been reported from training protocols consisting of 2 or 3 training sessions each week for between 6 and 12 weeks,[10-12] and where body weight support was systematically reduced and walking speed was systematically increased over the training period. The training protocol for the current study consisted of 2 training sessions per week for 9 weeks. Nine weeks was chosen because the program was conducted at the children's school and within the academic school year, and the minimum length of a school term was 9 weeks. Key features of the protocol were to (1) systematically reduce body weight support, (2) progressively increase treadmill speed, and (3) emphasize upright standing posture and facilitate the normal kinematic components of the gait cycle.

Body weight support was decreased systematically throughout the training period. To do this, the amount of body weight support was assessed at the beginning of each training session, monitored throughout the session, and reduced when possible. Support was reduced if the physiotherapist observed improved upright trunk posture, increased hip extension during mid stance, and/or slackening of the supportive harness indicating the children were taking greater body weight through their lower limbs. Walking speed was increased as tolerated, with the aim being to increase walking speed at each training session. Treadmill speed was set at the point at which the child was able to maintain a fluid stepping action without a need to increase the level of body weight support required to maintain lower limb loading. Emphasis was also placed on optimizing walking kinematics and the sensory cues for walking through facilitation of the key components of the gait cycle: to initiate swing, achieve full hip extension in stance, assist with weight shift, guide foot progression, and achieve heel strike.

Training Session Procedure

Training was conducted at school within school hours and was overseen by the participant's physiotherapist. Training sessions were supervised by the physiotherapist or a trained assistant. For the treadmill group, each child was fitted with a harness, which was then attached to the hoist. The hoist was moved into position over the treadmill with the child's feet positioned centrally on the belt. The child was asked or assisted to stand upright and the hoist lowered to reduce body weight support until flexion at the hips or knees was observed. The treadmill speed at the first session was determined by starting the treadmill at the lowest speed and gradually increasing to a speed at which the child stepped forward comfortably (0.1kph increments). Treadmill speed was increased during each walking session as tolerated, and at subsequent sessions the child began walking at the maximum speed recorded at the previous session. The trainer provided assistance with components of the gait cycle as described previously (see Treadmill Training Protocol). A mirror was positioned in front of the treadmill to provide the child with feedback on postural alignment and to assist motivation.

Participants in the control group practiced overground walking using their usual walking assistance device. At each session the children were assisted into their walking device, and they then practiced walking in the school corridors or on the grounds. Where necessary, the trainer provided facilitation of components of the gait cycle as described for the treadmill group. At each training session, children were encouraged to walk faster and for a longer duration than the previous training

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session. The control group did not participate in any treadmill training.

Both groups walked for a maximum of 30 minutes. Sessions ceased earlier if the children indicated a desire to stop or when they stopped actively stepping. All children wore their usual footwear and orthoses during training. A log book was used to record the duration of training, distance walked, treadmill speed (experimental group), use of orthoses, and details of any adverse events.

Throughout the program, participants continued with their usual physiotherapy, which consisted mostly of group-based sessions. These included gross motor, bike riding, and aquatics programs. Each participant's program remained constant prior to, during, and after the training period. Parents and guardians were requested not to initiate any additional interventions, not to have the children perform any treadmill walking on their own, and not to increase the usual intensity of the children's walking practice during the trial.

Outcome Measures

To evaluate change in walking performance, measures of preferred self-selected walking speed (10-meter walk test),[18,19] walking endurance (10MWT),[5] and walking function in the school environment (School Function Assessment)[20] were recorded. Assessments were completed at baseline (week 0), immediately after training (week 10), and 14 weeks after completion of training (week 24).

The 10MWT was chosen because it has been shown to reflect the walking performance of children with neurologic disorders in a community setting.[5] It has good retest reliability in children with CP (intraclass correlation coefficient .91, 95% CI .77–.99).[5] The test was conducted on a 20-m oval track, with markings at 1-m intervals. Each child walked around the track for 10 minutes. One assessor walked beside the children and verbally encouraged them to continue walking. A second assessor used a stopwatch to record the time taken to complete each lap. The total distance walked in 10 minutes was recorded.

The 10-meter walk test measured self-selected walking speed. It is representative of the distances children commonly need to walk between classrooms, to the toilet, or within the home.[5] The 10-meter walk test has high retest reliability ($r>.95$) for people with neurologic disorders.[18,19] The test was conducted on a marked 14-m walkway. Two meters at the start and end allowed for acceleration and deceleration. One assessor stood at the end of the walkway to indicate the endpoint, another walked beside the children and verbally encouraged them to continue walking. Each child was instructed to walk at his/her usual speed. A stopwatch recorded the time it took to walk the middle 10 meters.

Two physiotherapists, blind to group allocation, completed the assessments. Children wore their usual footwear and orthoses and completed the walking tasks with their usual walking assistive device.

The Travel subscale of the School Function Assessment[21] was chosen to measure walking function at school because it has been shown to be a valid tool for documenting a child's function in this environment.[22] The retest reliability of its 3 domains range from intraclass correlation coefficient .80 to .98, with the highest being for part III, Activity Performance, which includes the Travel subscale.[20,23] This measure was completed by the children's usual physiotherapist, who also supervised their walking training so were not blinded to group allocation. This was required to maximize reliability of the measure because it needs to be completed by a school staff member familiar with the student's typical performance rather than a single isolated performance.[21]

Statistical Analysis

Data from a pilot study[11] including similar participants and outcome measure to those in the current trial were used to calculate the sample size. A power analysis using the most conservative effect size (Cohen $d=1.02$) suggested 30 participants (15 per group) were required for an 80% power to detect a between-group difference at $P<.05$.

To determine if baseline differences existed between the groups, independent t tests were completed. To determine the effects of training at week 10 and week 24, analyses of covariance were performed. Where baseline variables were significantly different, they were entered as covariates.

To determine the efficacy of training, (ie, the extent to which a treatment achieves its intended effect under ideal circumstances[24]), participants who were withdrawn from the study because of unexpected surgery or as a result of secondary conditions *and* who completed less than 30% of training sessions were excluded from the analysis. Intention-to-treat analysis was used to manage any missing data for participants who completed the full intervention. Where data were missing, the carry forward technique was used, which assumes missing data remain constant.[25,26] Effect sizes and 95% CIs were calculated for any comparisons approaching statistical significance. Consistent with Cohen's convention, effect sizes of d less than .20 were considered small, d between .20 and .50 were considered medium, and effect sizes greater than .80 were considered large.[27]

To determine if there were any significant within-group changes between baseline and 10 weeks, group results were analyzed using paired t tests. All analyses were performed using SPSS software[e] (version 14.0).

RESULTS

Thirty-four children were recruited, and their progression through the trial is shown in figure 1. Of the 33 participants assessed at baseline, 5 in the experimental group and 2 in the control group withdrew after completing only 3 to 5 training sessions. Five of these children (4 experimental, 1 control) had unexpected surgery or botulinum toxin treatment, 1 child developed brain cysts, impacting on ability to participate, and 1 child experienced back pain when walking in the walking assistive device and could not participate. No adverse events or safety issues were reported for any of the participants in the treadmill or overground training groups. Nobody experienced muscle or joint soreness or any injuries resulting from trips or falls either during or after any training session.

Demographic details for the 26 participants who progressed to training are summarized in table 1. A significant difference was found between the groups at baseline for the 10-meter walk test, with the control group walking at slower speeds over 10 meters.

Adherence to training was similar between groups. Of a total of 18 sessions, the control group attended a mean of 14.21 ± 2.19 sessions (range, 10–17) and the experimental group attended a mean of 13.33 ± 2.02 sessions (range, 11–17). Nonattendance was mostly because of illness (50 sessions), participation in school excursions (14 sessions) or public holidays (6 sessions). No session was missed because of adverse events related to training. Training intensity increased in both groups during the program, with a larger increase in session duration and walking distance in the experimental group (table 2), who demonstrated a significant within-group increase in session duration ($t_{11}=-3.356$, $P=.006$) and overall distance walked each session ($t_{11}=-3.222$, $P=.008$).

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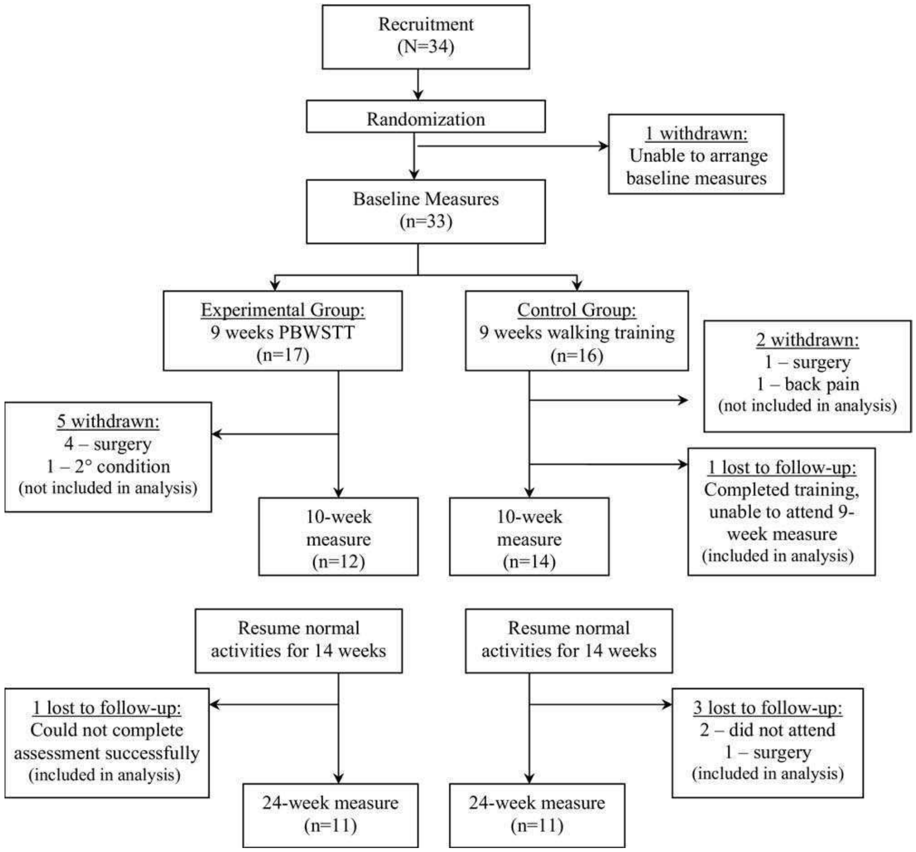

Fig 1. Progression of participants through the trial.

Analysis revealed a statistically nonsignificant but small trend for a difference in walking endurance (10MWT) between the groups at 10 weeks (F=3.004, P=.097), and at 24 weeks (F=2.992, P=.098) favoring the control group (tables 3, 4). A medium between-group effect size was found at 9 weeks (d=.76 ; 95% CI −.06 to 1.54).[27] Power analysis revealed that if this effect size was maintained, a sample size of 25 in each group would be required to detect a significant difference between the groups for the 10MWT. No significant difference was found between the groups for increase in 10-meter walk test (F=1.797, P=.194) or the Travel subsection of the School Function Assessment (F=1.932, P=.133).

Table 1: Participant Characteristics

Characteristic	Experimental Group n=12	Control Group n=14
Age (y)	10.35±3.14	11.24±4.17
Height (cm)	132.45±23.94	133.39±21.45
Weight (kg)	33.44±16.72	32.14±19.23
GMFCS level		
III	5	3
IV	7	11
Sex (boys/girls)	6/6	9/5

NOTE. Values are mean ± SD or n. Level IV indicates greater disability.

As shown in table 3 and figure 2, the control group showed a mean within-group increase in distance walked over 10 minutes of 17.46m (a 14.75% increase), although it did not reach statistical significance (t_{13}=1.341, P=.20). A statistically nonsignificant but small within-group trend (t_{11}=1.831, P=.09) was found for children who had completed the treadmill training program to walk shorter distances overground in the 10MWT with a mean decrease of 24.96m (a 10.21% decrease) and a medium effect size (d=.53; 95% CI, −2.65 to 3.71).

DISCUSSION

This randomized controlled study demonstrated that, for children with moderate to severe walking disability, PBWSTT under supervision is safe and feasible to conduct in a special school setting. However, with no statistically significant difference between the two training groups, PBWSTT was found to be no more effective for improving walking speed, endurance, and walking function at school than practicing overground walking.

This finding would appear to contrast with findings from recently published systematic reviews,[15-17] which suggest that many PBWSTT programs designed to improve walking in children with CP have large positive effects for improving walking performance. The treadmill training protocol in our study was similar to those used in previous studies reporting positive results for children with CP.[10-14] The apparent discrepancy in findings may be because previous trials have overestimated the effect size of PBWSTT on children with CP. Previous trials are generally of

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Table 2: Change in Training Intensity From First to Last Training Session

Training Characteristic	First Session		Last Session		Mean Difference (95% CI)	
	Experimental n=12	Control n=14	Experimental n=12	Control n=14	Experimental	Control
Time spent walking (min)	15.40±5.86	26.13±5.20	22.53±7.26	29.64±1.34	7.13 (1.54 to 12.72)	3.51 (0.56 to 6.46)
Distance (m)	351.66±198.58	300.64±254.36	772.50±471.94	407.54±337.60	420.84 (114.31 to 727.34)	106.9 (−125.31 to 339.11)
Walking speed (m/s)	0.38±0.18	0.18±0.15	0.59±0.23	0.24±0.17	0.21 (0.04 to 0.38)	0.06 (−0.06 to 0.18)

NOTE. Values are mean ± SD except where otherwise noted.

poor quality, with small sample sizes and a lack of randomization, concealed allocation, and blinded assessment, potentially leading to an overestimation of their effect.

There are a number of other possible explanations for why the treadmill training protocol used in this study may be no more effective than overground training for children with CP. It is possible that, unless the opportunity for direct carryover of skills to the overground walking environment is provided, PBWSTT does not provide an entirely task-specific approach to training overground walking. The experimental group increased their endurance when walking on the treadmill, as evidenced by the significant within-group increase in session duration (48% increase) and total distance walked within a session (119% increase) observed from week 1 to week 9 of the training program. However, these improvements did not carry over to overground walking at reassessment. This observation is consistent with locomotor training algorithms reported when rehabilitating adults after spinal cord injury, where the importance of concurrent overground walking practice, providing opportunity for direct carryover of skills to overground walking, has also been highlighted.[28-30] We decided to examine the effects of a conventional PBWSTT program in the current study because a number of previous studies focusing on children with CP and using similar programs to that implemented in this current study have reported positive effects. However, our results suggest that in clinical practice, just as found in adults with spinal cord injuries, maximum efficacy for children with CP may be achieved by providing opportunities to practice treadmill and overground walking concurrently.

Another possible reason for why the treadmill training protocol was no more effective than overground walking practice may be that the body weight support used to prevent flexion in the treadmill training group meant the treadmill training intervention was less intense compared with practicing walking overground. Seventeen of the 26 children who completed the treadmill training program had a GMFCS classification of IV and were thus heavily reliant on body weight support to be able to ambulate. This greatly limited how much body weight support could be reduced over the training period. Systematic reduction of body weight support and maximizing load bearing by the lower extremities have been identified as key components of a successful training protocol in treadmill training for adults with spinal cord injury.[28] In our study, body weight support was systematically reduced at each session where possible; however, the severity of disability of most participants greatly limited the extent to which body weight support could be reduced, and this potentially decreased the overall intensity of the intervention.

Training intensity may have also been reduced because of the relatively small total number of hours over which training was completed. The training protocol prescribed 9 hours of training over a 9-week period; however, because of absences from school, the total amount of walking training per group was less than 7 hours. While a pilot study in a population of children demonstrated improvements in walking endurance after only 6 hours of intervention over 6 weeks,[11] less than 7 hours of walking training may have been insufficient to show significant change in our study, particularly where the experimental group training protocol was potentially less intense.

After treadmill training, the group demonstrated an apparent deterioration in the distance walked over 10 minutes (see fig 2). The reasons for this are not clear. For children with severe walking disabilities, manipulating a walking assistive device and propelling themselves forward are challenging aspects of overground walking. In comparison, walking on a treadmill may have been less challenging because of the relatively high amount of body weight support provided by the harness and because each step was facilitated by the moving treadmill belt. This made treadmill walking comparatively easier for the children. During the immediate posttraining period and at the reassessment, it was observed that a number of children who had completed the treadmill training program stopped walking more often during the 10MWT and seemed to experience greater difficulty propelling their walker forward compared with their baseline performance. This may have been the children's reaction to the difficulty of overground walking compared with the relative ease of walking they had experienced on the treadmill. This further supports the potential importance

Table 3: Results of Walking Assessments at Baseline to 10 Weeks

Outcome Measure	Baseline		10 Weeks		Mean Within Group Difference (95% CI)	
	Experimental n=12	Control n=14	Experimental n=12	Control n=14	Experimental	Control
10MWT (m)	244.33±115.41	118.36±88.89	219.38±123.71	135.82±95.65	−24.96 (−54.95 to 5.04)	17.46 (−10.66 to 45.59)
10-m walk test (m/s)	0.56±0.34	0.30±0.23	0.56±0.39	0.34±0.27	0.01 (−0.12 to 0.14)	0.04 (−0.04 to 0.13)
SFA (Travel)	39.17±14.41	42.07±15.04	40.00±13.28	47.64±17.29	0.83 (−4.78 to 6.44)	5.57 (−.072 to 11.87)

NOTE. Values are mean ± SD.
Abbreviation: SFA (Travel), School Function Assessment Travel scale.

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Table 4: Results of Walking Assessments at Baseline to 24 Weeks

Outcome Measure	Baseline		24 Weeks		Mean Difference (95% CI)	
	Experimental n=12	Control n=14	Experimental n=12	Control n=14	Experimental	Control
10 MWT (m)	244.33±115.41	118.36±88.89	215.67±142.99	148.43±103.52	−28.67 (−78.10 to 21.66)	30.07 (−6.54 to 66.68)
10m walk (m/s)	0.56±0.34	0.30±0.23	0.49±0.41	0.35±0.26	−0.07 (−0.25 to 0.11)	0.05 (−0.03 to 0.14)
SFA (Travel)	39.17±14.41	42.07±15.04	39.00±12.90	44.50±15.04	0.16 (−7.17 to 6.83)	2.43 (−6.28 to 11.14)

NOTE. Values are mean ± SD.
Abbreviation: SFA (Travel), School Function Assessment Travel scale.

that concurrent treadmill and overground walking practice may have for these children. A combined treadmill and overground walking protocol might provide the children with the opportunity to maintain their ability to propel forward overground, in addition to providing carryover of improvements in walking kinematics and lower-limb loading.

A strength of this study was that training was performed at the children's school. This enhances the accessibility and feasibility of the intervention for the children and their families. There was no direct burden on parents in terms of time or transport costs. Almost all previous studies have been conducted in rehabilitation hospitals or outpatient centers, with the use of expensive equipment and high therapist resources.[12-14] This may limit ongoing accessibility for some families. The equipment used in this study was relatively inexpensive and readily available. A low level of staffing was required, with a single therapist or trained assistant implementing the training without incident.

Study Limitations

A limitation of this study was that only a small number of outcomes that focused on walking function were measured. Subtle changes to the child's walking kinematics may have been achieved after intervention, but these could not be measured by the outcome measures used in this study. There may also have been other potentially important benefits to treadmill training that were not measured, such as changes to the child's quality of life and self-confidence, as well as changes to physiologic outcomes such as cardiovascular fitness and bone density. Another limitation is that only children classified as GMFCS III and IV, with moderate to severe walking difficulty, were included in this study and so the results cannot be generalized to other GMFCS groups. This trial was also limited by a relatively small sample size. The target sample of 30 participants was met during initial recruitment, but dropouts because of surgery and secondary medical conditions meant only 26 children proceeded to training.

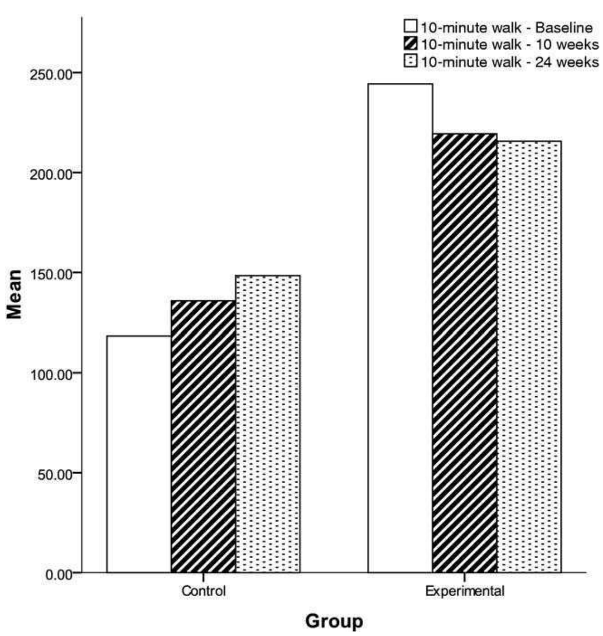

Fig 2. Group means for 10-minute walk (m) at baseline, 10 weeks, and 24 weeks.

CONCLUSIONS

It has been proposed that treadmill training might improve the walking of children with CP[10-14]; however, improvements to walking speed and endurance made during PBWSTT may not be directly transferable to overground walking without the addition of concurrent overground walking practice to enable direct carryover of improvements. While PBWSTT is safe and feasible for children with CP and moderates the severe walking difficulty, our results suggest that, for this group of children, a conventional PBWSTT protocol may only be as effective as practicing overground walking. Treadmill training protocols that include concurrent overground walking practice as an additional key feature of the training protocol such as those demonstrated to be effective for adults after spinal cord injury[28-30] need to be rigorously evaluated for their efficacy for children with CP.

Acknowledgements: We thank Yooralla, the Victorian Department of Education and Early Childhood Development, school staff involved in the project, and Physiotherapists Jane Sever, Samuel Wills, Robyn Hateley, Kari Steer, and Alexandra Gargett for their support and assistance with training and data collection.

APPENDIX 1: GROSS MOTOR FUNCTION CLASSIFICATION SYSTEM—DESCRIPTORS

Level III	Children walk using a hand-held mobility device in most indoor settings. Standing transfers require physical assistance of a person or support surface. When traveling long distances, children use wheeled mobility. Children may walk up and down stairs with a rail or physical assistance.
Level IV	Children use methods of mobility that require physical assistance or powered mobility. Children require adaptive seating for trunk and pelvic control. Children require physical assistance for transfers. When positioned, children may use a body support walker at home or school. At school, outdoors, and in the community children are transported in a manual wheelchair or use powered mobility.

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Suppliers

a. PMB Fitness, 6B Hazelwood Dr, Morwell, Victoria, Australia 3840.
b. Polley and Bailey, 43 Flinders St, Edwardstown, South Australia, Australia 5039.
c. ProMed, 12/260 Wickham Rd, Highett, Victoria, Australia 3190.
d. Arjo Hospital Equipment, Unit 2 Lord St, Botany, New South Wales, Australia 2019.
e. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

CHAPTER 4

School based treadmill training for young people with cerebral palsy: A qualitative study

4.1 Preface

This chapter is based on a qualitative study that investigated the perceived benefits and experiences of young people with cerebral palsy who completed a school based treadmill training program. Benefits perceived by the teachers and physiotherapists who supported the young people were also investigated along with factors which may have acted as barriers or facilitators to conducting a program of treadmill training in the special school environment.

The study reported in this chapter was submitted to the journal *Disability and Rehabilitation* on 1st November 2010 for consideration for publication.
(See Appendix P for the co-authorship contribution statement)

The paper is presented here in the format required for submission of a manuscript to this journal.

4.2 Introduction

Preliminary evidence suggests that treadmill training may be beneficial for young people with cerebral palsy (CP).[1-4] However, the small number of published studies available investigating the effects of treadmill training for these young people have been limited to measuring a small number of quantitative physical outcomes such as changes in walking speed, walking endurance and general gross motor skills (e.g. standing, squatting, jumping, hopping). These measures have been chosen by the researchers based on changes they anticipate may be observed in young people with cerebral palsy after treadmill training. No previous study has reported the participant's experience or views about the benefits of treadmill training, and few have explored the potential barriers and facilitators to implementing treadmill training programs.[2, 5-8]

Qualitative studies can provide information about treadmill training from the perspective of the young person participating and their support people. These types of studies allow us to highlight outcomes that may be meaningful to the young person with CP, not just the researcher, and they create the potential to identify outcomes that may not have been considered previously.

In addition to effectiveness of the intervention, qualitative studies can help identify factors that may act as barriers or facilitators to participation in the intervention from the perspective if participants. To date, no study investigating treadmill training has specifically reported on the feasibility, barriers or facilitators of training in the chosen environment. One potentially important factor is accessibility. Accessibility is an important aspect of a successful training program because an intervention that is demonstrated to be beneficial has little value if it is not accessible. Information about accessibility would be valuable to clinicians wanting to implement treadmill training for their clients. Most previous studies investigating the benefits of treadmill training have taken place within tertiary hospitals or rehabilitation centres.[5-8] Only a small number of single case studies have reported on home-based training[9] and one larger study has reported on a training program conducted at the child's school.[2] Training programs within the home or school have potential to be more easily accessed by young people and their families as they are more likely to fit within the young person's daily routine. Training within a special school setting may also have the advantage of easier access to specialised equipment and support people.

Qualitative studies can also provide clinicians with valuable information about factors that are important to successfully undertake and implement a specific intervention. Elements of interventions such as the equipment used, the ease of physical support to be provided to the participant and the capacity to conduct the intervention within different working environments are important considerations. Qualitative studies provide the opportunity to explore these factors from the perspective of clinicians who have experienced that particular intervention or training program.

Therefore, the current study aimed to explore the experiences of young people with CP who completed a school based treadmill training program and the staff who supported them. We wanted to investigate the young people's thoughts and feelings about participating in the training and identify any benefits that they, or their teachers and physiotherapists, perceived they had gained from the training. Another aim was to explore the factors that acted as barriers or facilitators to implementing the program from the perspectives of the young people completing the training and of the school staff who supported them. To achieve these aims, young people with CP who had completed a treadmill training program were interviewed about their experiences, along with their teachers and physiotherapists involved in the program.

4.3 Method

4.3.1 Participants

The young people with CP who were interviewed were participants in a randomised controlled trial (RCT) investigating the effectiveness of treadmill training with partial body weight support compared with over-ground walking.[10] Participants in the RCT were recruited from a metropolitan Specialist School for children and adolescents with moderate to severe physical disabilities. Each young person's teacher and physiotherapists who supervised the treadmill training program were also invited to participate.

Ethical approval for the study was granted by University Ethics Committee and the Department of Education and Early Childhood Development. Written, informed consent was gained from each participant and from each school staff member interviewed.

4.3.2 Treadmill Training Program

Training was conducted at the school, within school hours and was overseen by the young person's usual physiotherapist. Training sessions were completed twice a week for 9 weeks. Young people with moderate to severe walking difficulty (gross motor function classified as GMFCS[11] level III or IV) usually require the use of a body weight support system to enable them to participate in treadmill training programs. In the RCT, a mobile or ceiling-mounted hoist and a harness system was used to provide body weight support during training. During training sessions, the trainer provided the young person with assistance (if necessary) to initiate swing, assist with weight shift, guide foot progression and/or achieve heel strike. Each session lasted a maximum of 30 minutes and a logbook was kept to record walking speed, distance and duration of each training session. Full details of the training protocol are described elsewhere.[10]

4.3.3 Data Collection

In-depth interviews were conducted using a semi-structured schedule of questions which encouraged the interviewees to talk freely about their experiences. Two sets of questions were developed for two different participant groups: 1) young people who completed treadmill training, and 2) teachers and physiotherapists. The schedule of questions is shown in table 1.

The interviews were conducted by a member of the research team (NS) who was not involved in supervising the training sessions, had no prior relationship with any of the participants, and was experienced in conducting interviews with young people with cerebral palsy. All interviews were completed in a quiet and private room at the school with only the interviewer and interviewee present. Interviews were recorded using a digital recorder.

4.3.4 Data Analysis

Data were analysed through thematic analysis using a grounded theory approach.[12] Grounded theory emphasises generation of theory from data that is collected, rather than using data to test a preconceived hypothesis.[12] To do this, current knowledge of treadmill training and preconceived ideas about its benefits and potential barriers and facilitators to training were set aside and only the participant’s subjective experiences were considered with the aim of eliciting a new understanding of various aspects of treadmill training programs. To add to the rigour of the study, the digital recording of each interview was transcribed verbatim. A copy of the interview transcript was sent to each participant for them to review the accuracy of content.

Thematic analysis was completed by two researchers: the first (NS) is a physiotherapist and University lecturer. Her area of research interest is increasing engagement in physical activity among children with disability. The other (KW) is a doctoral student and registered physiotherapist with 10 years experience working in community settings with young people with cerebral palsy. Each transcript was independently read by the two researchers (NS and KW) and common themes were coded. One researcher with access to NVivo software (Version 7, QSR international) used it to code the content of the transcripts. The second researcher completed coding manually. To ensure credibility of emerging themes, and to minimise potential researcher

Table I: Schedule of questions for semi-structured interview

Young people who participated in the program:	
1	Tell me what you thought about the walking on the treadmill
2	What did you like about walking on the treadmill?
3	What didn't you like about walking on the treadmill?
	Can you tell me about the effort of getting on and off the treadmill?
	How hard was it walking on the treadmill?
	Tell me about walking on the treadmill at school?
4	Have you noticed any differences in yourself since you've been practising your walking on the treadmill?
	Did it do anything or change anything for you?
	Have you noticed any differences in your legs?
	Have you noticed any differences in how you get about?
5	Is there anything you would change about the treadmill walking?

Physiotherapists and Teachers:	
1	Tell me what you think about the treadmill training
2	What are the advantages of this programme?
3	What are the disadvantages of this programme?
4	Is there anything you would change about the programme?

bias the two researchers met once coding was completed to compare codes. Similar codes were then grouped under similar concepts so that coding was refined and major themes were identified.[12] Confirmability was achieved through the elimination of potential bias from the researchers by including a third researcher (KD) in peer review and discussion of the emerging themes. Trustworthiness of data was enhanced by using direct quotes to support identified themes. Pseudonyms are used where direct quotes are reported to maintain participant's privacy.

4.4 Results

Of the participants in the RCT who completed the treadmill training program (n=17), those able to engage verbally in a semi-structured interview were invited to participate in the current qualitative study. Of these participants, only 2 were able to engage verbally in an interview and, following invitation, both young people gave their consent to participate and their characteristics are detailed in table 2. All physiotherapists (n=3) and teachers (n=7) accepted the invitation to be interviewed and their characteristics are detailed in table 3.

Table II: Participant characteristics – Young people with cerebral palsy

Participant	*Age*	*Sex*	*GMFCS*	*Motor type/Distribution*
Peter	15	M	III	Spastic Diplegia
Jenny	15	F	III	Dystonia, quadriplegia

GMFCS, Gross Motor Function Classification System

4.4.1 Perceived benefits

Two main themes emerged from participant's comments about benefits that were experienced or observed from the training. Each of the participant groups noted changes that were either physical or psychosocial in nature.

Table III: Participant characteristics – Physiotherapists and teachers

Participant	*Sex*	*Role at school*	*Years in Special Education*
Julie	F	Physiotherapist	6
Bridget	F	Physiotherapist	1
John	M	Physiotherapist	6
Mary	F	Teacher	34
Janice	F	Teacher	20
Rachel	F	Teacher	25
Helen	F	Teacher	2
Joanne	F	Teacher	2
Eileen	F	Teacher	33
Sarah	F	Teacher	2

4.4.1.1 Physical Changes

The young people talked about an increase in walking endurance after training.

> "I can walk longer than I used to be able to…. [before training] I could only walk a little bit and then I was very tired. (Jenny)

The physiotherapists and teachers confirmed the observed improvements "mainly in [the young people's] endurance" (Julie, physio) and also described an increase in their energy level after training,

> "her stamina, strength and endurance definitely improved. She went from being fairly unwilling to walk…whereas after [the training] she would tend to go much longer distances" (Helen, teacher)

One teacher also talked about how observing this increase in the young people's energy was opposite to her initial expectations.

That part of it surprised me at bit, that they actually came back from a really energetic session and, although they were tired, they could still work.” (Janice, teacher)

As well as noticing changes in the young people’s walking endurance, the physiotherapist’s also made specific observations that were related to changes in the young people’s gait patterns

> “[there were] changes, as well, in the accuracy of his gait and his stepping…he improved his control with his gait [on the treadmill]” (Bridget, physiotherapist)

The physiotherapists also remarked that the gains some young people made while walking on the treadmill did not carryover to their overground walking:

> “Some of the students seemed to do really well on the treadmill but...the skill is so different that they weren’t often able to transfer it back [to overground walking]...because the treadmill goes for them…they still hadn’t practiced that skill of getting the walker moving.” (Julie, Physio)
>
> “They’re literally just picking their feet up and walking on the [treadmill] which is great for practicing that but…you could see that he doesn’t get the concept of pushing like during his transfers…and this didn’t carryover to his transfers” (Bridget, Physio)

Changes in activity performance were reported by the young people, their teachers and physiotherapists. One child perceived an improvement in his balance and in functional activities:

> "I'm able to stand by myself like for a lot longer, just not leaning against anything… and being able to take a few steps on my own without my frame or my crutches" (Peter, young person with CP)
>
> "like being able to carry stuff and being able to walk with one stick instead of two…so that's been real good, cause I never thought I'd be able to do that." (Peter)

The functional implication that these changes had on the young people's daily school activities was discussed by their teachers:

> "…his ability to stand and make contact [with his feet] on the ground…now when we are doing sit to stand transfer with him he can push through the ground and maintain [standing] a few seconds longer" (Joanne, teacher)
>
> "She's walking around furniture a lot more now. [The Physio] actually had her taking independent steps" (Eileen, teacher)

4.4.1.2 Psychosocial Changes

All participant groups spoke about the opportunity the training gave the young people to build a closer relationship with their physiotherapist.

> "They seemed to form fairly close relationships and that might be a positive thing for [their] communication" (Amy, teacher).
>
> "I liked doing it because I got to talk to people like [the physio]" (Jenny, participant)
>
> "[I was] really happy spending more one on one time with the kids because we don't get to spend a lot of one on one time with [them]" (John, Physio)

Two teachers also thought the training motivated the students including motivating them to walk independently.

> "They would remind me that they had to go [to training], so that in itself you know, is quite an intrinsic motivator" (Eileen, teacher).
>
> "She's certainly motivated to be walking independently… She'll leave the frame and push furniture around or do anything other than use the frame." (Eileen, teacher)

The physiotherapists also spoke of how the age appropriate aspects of training on a treadmill acted as an intrinsic motivator for the young people.

> "It was like going to the gym and using a treadmill…especially for the older students… their older brothers and sisters go to the gym and get to use a treadmill, so it was an activity that others do that they could join in." (Julie, Physio)

The participants described a strong sense of pride:

> "It raised my independence level and I was just thinking 'Yeah, I can do this'.....It's been real good, cause I never thought I'd be able to [walk on a treadmill]". (Peter, child with cerebral palsy)
>
> "It was good. Every time I did it I went home and told my mum about it and my mum was really excited about me doing it" (Jenny, child with cerebral palsy).

Teachers and Physiotherapists also noted this sense of pride and a strong feeling of enjoyment from the young people:

> "They all came back [to the classroom] with smiles on their faces and the physio reinforced that and said that they had a good time and they had enjoyed doing it" (Mary, teacher).

> "She came back [to class] with a sense that she'd achieved something…it was just really good to physically be able to do something where normally they rely on their sticks" (Janice, teacher)
>
> "He absolutely loved it …you could see that it was, I suppose, almost a sense of like freedom." (Bridget, Physio)

Not all the staff noticed a change in the young people after training. One physiotherapist spoke of observing minimal change in the young people he supported, describing that "[They] didn't seem any stronger or fitter, or happier or sadder" (John, Physio).

4.4.2 Barriers and Facilitators

Teachers, physiotherapists and young people described factors that created challenges that needed to be overcome (barriers) and things that made it easier to conduct or participate in the training (facilitators).

The physiotherapist's experience of the training was shaped by the opportunities that it provided them to work intensively with the young people and to focus on specific elements of walking training:

> "It was an opportunity to really have a good, solid workout…an opportunity to have that experience of walking and the reciprocal gait pattern. The students don't have an opportunity to do much cardiovascular work…so it was an opportunity for that to happen" (Bridget, Physio)

The physiotherapists found it challenging to motivate the young people to walk on the treadmill for extended periods and they each used similar strategies to motivate them to keep walking:

> "They were very difficult to motivate on a treadmill...you have to really entertain them the whole time or they just stop and drop down [in the harness]".," (John, Physio)

> "With younger students who didn't understand it as well, just using things like playing games, stepping on things…using something that they had to reach for" (Bridget, Physio)

> "We had a bucket of soft teddy turtles that we'd throw under their feet and get them to stamp on them…we'd get them looking in a mirror… It was hard work." (John, Physio)

The older students with higher cognitive capacity could be motivated through direct feedback about the speed or distance they had walked:

> "Because of the way the treadmill is set up, you could see how far you've walked and how fast and that was quite motivating for students" (Julie, Physio)

Generally, staff indicated that the school environment was an enabling factor:

> "[The students] are here, the equipment is here, it's easy for them whereas if the had to come in separately or travel to another physio centre it might be more difficult for some of the parents I think, especially if they've got other kids and they're busy and they're working...." (Helen, teacher)

While the structure of timetabled walking training sessions was a positive thing for some, the physiotherapists and teachers talked about the challenge of coordinating time for the training to occur within the child's school day:

> "Timetabling can be a bit of a nightmare," (Joanne, Teacher)

> "It was a big commitment. It was often difficult to coordinate the times… sometimes it didn't work in with the sessions where we would normally see

them...sometimes we had to pull them out of other classes which was difficult" (Julie, Physio)

Despite the challenge of timetabling the training sessions, teachers expressed positive feelings about the young people needing to leave class programs to go to their training sessions.

"Because we saw it as a priority, it didn't matter [that children were removed from class]" (Janice, teacher)

"I'm used to having kids go off to different programs, so it was fine. We worked out a roster at the start, so I knew that they'd be going [during] certain classes" (Helen, teacher)

"It's still part of their education, part of their mobility program…so personally I didn't mind at all" (Mary, teacher)

The fact that the program occurred within the context of research was reported by some staff as helping make the program happen at school;

"I think that things like this don't come along very often and we make the most of it…it was a priority" (Janice, teacher)

"I guess because it was part of [a research project] people were more motivated so that it makes it all happen." (Bridget, PT)

but staff also discussed doubts about being able to sustain the training in the everyday school situation:

"It's hard within a school to carry on with that program...so it was mixed feelings I suppose. 'This is really good, but it's not sustainable'" (Bridget, Physio)

The equipment used in training presented both a barrier and a facilitator. One young person described the positive aspects of the partial body weight support system:

> "If I walked on the treadmill [without the sling] I would get tired very quickly, but in the sling I could walk at least 20 minutes" (Jenny, child with cerebral palsy).

She also described that "On the treadmill I can concentrate on my feet, where they're going". Peter recalled the sensation of being supported over the treadmill by the harness and hoist:

> "The weird part was just being hoisted into the air a little bit…it didn't feel like you were actually on the treadmill, it felt like you were just walking in air." (Peter, child with cerebral palsy)

The body weight support system was described as being advantageous by the physiotherapists "because it allows you time to really get in and work on some of the finer details of their gait". (Bridget, Physio). John (Physio) described that "the moving treadmill is great because some kids have trouble initiating stepping so [on the treadmill] it's done for them". However, the harness and hoist system also created some challenges for some physiotherapists. They indicated it as "a little bit tedious at the start to get them in the hoist and get them up and positioned over the treadmill" (Bridget, Physio). It was reported that the harness was specifically problematic for one young person with gross motor function classified as GMFCS IV:

> "It was more the walking harness becoming uncomfortable. It would actually sting…it would ride up and then we'd have to lower it and readjust it" (Julie, Physio)

The challenges imposed by the equipment led one physio to comment that "walking [over ground] is more likely to be able to continue than the treadmill 'cause it's not so dependent on specialised equipment" (Bridget, Physio)

4.4.3 Recommendations for future programs

Suggested changes that may improve future programs were made by some of the teachers and physiotherapists. Teachers suggested that it would be valuable to have more information about the purpose of the training, how the students were actually walking on the treadmills and feedback regarding their progress:

> "I didn't receive any feedback as to what they did when they were away…I probably would have liked to have been informed about what they were doing when they were [training]" (Mary, teacher)

Sarah (teacher) commented that "I couldn't imagine him on a treadmill until I saw him" and suggested that it would be valuable to have "a video of a student who has done it…just so in your mind you've got a visual [perspective] of what they're doing"

Both teachers and physiotherapists talked about important aspects of the child's school week that needed to be considered for timetabling training sessions to have a minimal impact on their school work:

> "Looking at generally what other programs that child is doing on the day and how tired they are going to be, as long as those things are considered" (Amy, teacher)

> "I think, especially over a longer period, if they had missed the same class every week, then they really would have missed a big chunk of their learning" (Julie, Physio)

Physiotherapists described improvements to the use of equipment that might overcome the initial difficulties of setting up the training scenario:

> "I guess I'd get wider treadmills for the kids because some of them stepped wider and it was tricky" (John, Physio)

> "Getting a comfier harness [would be an improvement]" (Julie, Physio)

> "It took a while to sort out how the [equipment] would work…so maybe a teething period…to get used to it before you start [the formal program]" (Bridget, Physio)

4.5 Discussion

All the participant groups perceived that there were physical benefits gained by the young people after participation in the treadmill training program. This is particularly interesting as it is in contrast to the findings of the quantitative study[10] which found a deterioration in overground walking speed and endurance following treadmill training. Some of the gains were anticipated by the young people and their support staff, such as improvement in walking endurance, gait patterns, balance and performance of standing transfers. Others, such as an increase in energy and ability to concentrate in the classroom were unexpected. Overall, the training was feasible to conduct in a school environment but there were challenges to be overcome to successfully run the program. These included careful timetabling, a comfortable body weight support harness and the challenge of motivating the child during training. Concerns were raised that it may be difficult to sustain the intensity of the training outside of a research study.

This qualitative study revealed benefits from treadmill training that have not been reported in previous studies. A number of positive psychosocial outcomes were identified including increased confidence, a sense of achievement, increased motivation and the opportunity to build closer relationships with people in their community. This suggests that perhaps psychosocial outcomes should be included in future studies of treadmill training for young people with CP.

Overall, the participants agreed that it was feasible to conduct a PBWSTT program within a school environment and that aspects of the structured school environment, such as the availability and ease of access to required equipment, enabled the training program. The school provides an environment where therapy is integrated into the child's day, staff are already aware of the importance of physiotherapy interventions for the development and maintenance of physical skills, and appropriate staff numbers are available. At the school where the training program was conducted, each child was transported to and from school each day by bus, and this eliminated the need for a family to travel to a hospital or specialist therapy centre multiple times each week to access the intervention.

Maintaining the young people's motivation during training was described as a significant challenge. Motivation is important to ensure that the training is sufficiently active and repetitive. Without active engagement in the training, the opportunity for refining performance of the task through neural feedback is lost.[13, 14] There are a number of possible strategies to engage both adolescents and younger children during treadmill walking. The display console of the treadmill provides a visual record of the time and total distance walked, along with walking speed. This can act as an intrinsic motivator for adolescents who can be encouraged to challenge themselves to walk faster and for longer at each training session. In this study, simple logbooks were used as a record of the young person's achievement at each training session and may have provided motivation for them to increase their walking speed and duration at subsequent sessions. For younger children, play-based interventions are commonly successful and this same principle could be transferred to the treadmill environment. Physiotherapists in this study suggested counting games and soft beanbags to 'stomp' on as strategies to assist in maintaining the motivation of younger children in this study.

One of the few negative aspects of the program identified was the discomfort the harness caused for some young people. Peter (GMFCS III) described the need to accommodate to the sensation of the body weight-support system and recommended that other young people trying treadmill training for the first time should “just try not to think too much about [the harness].” In clinical practice, physiotherapists should be aware of the potential for harness related discomfort and ensure that the body weight-support system chosen for their client facilitates a comfortable and enjoyable treadmill walking experience.

An important theme which may be important for clinicians to consider was a concern about possibly not being able to continue with such an intense training program in the long-term. Support staff identified four factors which they thought were important to ensure the smooth implementation and running of such training: 1) careful timetabling to ensure that the training does not impact on the young person’s classroom learning, 2) provision of information for teachers about the purpose of the training, potential benefits and logistics of assisting the young people to walk on a treadmill, 3) regular feedback for teachers about their student’s performance throughout the training period, and 4) training of other staff to enable them to supervise training under consultation from the school’s physiotherapists.

This is the first known published study to undertake qualitative analysis of the experiences of people involved in a treadmill training program for young people with cerebral palsy. It provides valuable information not only from the perspective of those young people who took part on the training, but also the staff who supported them. The main limitation of this study was that only two young people who participated in the training program were interviewed. As the RCT included young people with gross motor function classified as GMFCS III or IV and attending a specialist school setting, most participants had cognitive delays or expressive communication difficulties which prevented us from being able to interview them about their experiences of the training. It is also important to note that because only young people with gross motor function classified GMFCS III or IV participated the results of this study may not be generalized to young people with milder walking difficulties (GMFCS I or II).

The results of this study indicate that all young people, teachers and all but one physiotherapist involved in the program felt that it offered physical benefits to the young people who were participating in the training. All of the people involved in the training felt that it resulted in psychosocial benefits to the young people and, despite some specific challenges which can be overcome, the training was feasible and could be successfully run in a specialist school setting. These results support further, rigorous investigation of the impact of this type of training on a range of outcomes for young people with cerebral palsy, including both physical and psychosocial outcomes.

4.6 References

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CHAPTER 5

Extended Discussion

5.1 OVERVIEW OF MAIN FINDINGS

The series of studies presented in this thesis make an important contribution to the growing body of evidence about the effects of treadmill training for children and adolescents with cerebral palsy. A thorough review of existing literature (Chapter 2) indicated promising potential for the benefit of body weight supported treadmill training for improving walking in young people with cerebral palsy. The review also guided the design of a randomised, controlled trial (Chapter 3) to directly compare body weight supported treadmill training with overground walking practice. This trial was the first known study to make a direct comparison between treadmill training and overground walking for this group of children. The results indicated that treadmill training may not be as effective as overground walking practice for improving overground walking speed and endurance. There was also an indication that treadmill training may have a deleterious effect on overground walking performance. The RCT also highlighted some of the challenges associated with treadmill training with body weight support, potential limitations of this form of training for improving overground walking and possible strategies to maximise the effectiveness of training. A qualitative study (Chapter 4) complemented the quantitative findings of the RCT and revealed potential benefits of this training for children with cerebral palsy that may not have been previously considered or investigated by researchers. The qualitative nature of the study also facilitated exploration of the suitability of a special school as a training environment and highlighted barriers and facilitators to conducting such a training program in this environment.

Treadmill training, both with and without body weight support, continues to be a growing area of interest for clinicians working with children with cerebral palsy. Since the publication of the systematic review presented in this thesis, a number of other reviews have been published (Daminao & DeJong, 2009; Mattern-Baxter, 2009; Mutlu, Krosschell and Gaebler-Spira, 2009); Zwicker & Mason, 2010). Each review has concluded that, while treadmill training is a safe and feasible intervention for children with cerebral palsy and that results are encouraging for body structure and function and activity outcomes, there is currently insufficient evidence for clinicians to be confident that treadmill training has significantly positive effects for children with cerebral palsy.

In particular, subsequent reviews have continued to highlight the low levels of evidence presented in published studies, the heterogeneous gross motor abilities of children included within the studies (GMFCS I through to IV) and the wide variability in training parameters used in training protocols across the studies. These heterogeneous characteristics of published studies have precluded a meta-analysis from being conducted, however Zwicker and Mayson (2010) effectively synthesised the findings of 5 systematic reviews. They highlight that, due to the wide variability in training parameters used in studies published to date, it is not possible to deduce which particular training parameters (e.g. treadmill speed, body weight support, session time, frequency and duration of training) might primarily be responsible for any positive effects observed in children after treadmill training.

In the wake of an increasing number of systematic reviews of existing studies, a number of new studies of the effects of treadmill training for children with cerebral palsy have been published (Borggraefe et al., 2010; Dieruf, Burtner, Provost, Phillips, Bernitsky-Beddingfield, & Sullivan, 2009; Johnston et al., 2011; Kurz, Corr, Stuberg, Volkman &

Smith, 2011; Kurz, Stuberg, & DeJong, 2011; Mattern-Baxter, Bellamy & Mansoor, 2009). Many of these studies have reported encouraging results but, despite the findings of published systematic reviews, the majority of studies have continued to include small sample sizes (Dieruf, Burtner, Provost, Phillips, Bernitsky-Beddingfield, & Sullivan, 2009; Kurz, Corr, Stuberg, Volkman & Smith, 2011; Kurz, Stuberg, & DeJong, 2011; Mattern-Baxter, Bellamy & Mansoor, 2009) and all but one study (Dieruf, Burtner, Provost, Phillips, Bernitsky-Beddingfield, & Sullivan, 2009) included samples of children with heterogenous gross motor abilities classified from GMFCS levels II through to IV. Two of the studies used specialised and expensive treadmill and body weight support systems: a robotic assisted driven gait orthoses (Borggraefe et al., 2010) and a treadmill enclosed in a lower body positive pressure support system (Kurz, Corr, Stuberg, Volkman & Smith, 2011). Despite encouraging results being demonstrated with these training systems, they remain implausibly accessible to the majority of children with cerebral palsy.

Theoretic context for treadmill training programs

Theories underpinning motor learning, such as Neuronal Group Selection Theory (Hadders-Algra, 2000) and Dynamic Systems Theory (Darrah & Bartlett, 1995; Thelen, 1989) highlight that for practice of a motor task to be effective it must be task specific, repetitive and performed in a functional context. It was therefore expected that a program of body weight supported treadmill training that adhered to these principles and was combined with a study methodology that addressed many of the weaknesses in previous studies, would improve overground walking ability of children with cerebral palsy. The opposite was found; immediately after finishing the 9 week program children in the treadmill training group demonstrated reduced walking speed and endurance.

There are a number of possible explanations for an apparent deterioration in overground walking ability following treadmill training. The amount of walking practice that the children usually participated in at school may have reduced during their participation in the study. This may have led to an overall decline in the amount of walking practice they completed. Participants in the treadmill training group, their families, physiotherapists and school staff were all advised to not make any changes to the amount of walking they would usually do during their participation in the study. Review of each child's school therapy program revealed that walking practice outside of the training program was changed for only one participant: her walking practice sessions were reduced from three to two sessions per week during her participation in the trial. However, one walking practice session was replaced with one of her twice weekly treadmill training sessions and therefore her the overall amount of walking practice still increased during her participation in the study.

Lack of opportunity to practice forward propulsion during treadmill walking may also be responsible for the decrease in walking speed and endurance found in the children who completed treadmill training. Treadmill walking generates passive forward momentum which can result in less muscle power being required for forward prolusion on a treadmill when compared with overground walking (Savelberg, Vorstenbosch, Kamman, van de Weijer, and Schambardt, 1998). It may be especially prudent to consider the impact of this aspect of treadmill walking for children with gross motor function classified GMFCS IV who can experience significant difficulty with forward propulsion when walking overground. For these children, it is possible that forward propulsion may be a feature of gait which must be specifically trained in order for their over ground walking speed and endurance to improve. As found in adult populations, (Behrman & Harkema, 2000 &

2007; Behrman et al., 2005; Dobkin et al., 2006) concurrent overground walking practice as part of a treadmill training program might assist in maximising carryover of improvements into overground walking.

Interestingly, while a decrease in overground walking speed and endurance was observed in the treadmill training group these children did improve their endurance for walking on the treadmill, demonstrated by a large progressive increase in treadmill speed and session duration recorded over the training period. While the children appeared to improve their ability to walk on a treadmill, these improvements were not reflected by improvements in overground walking.

This result is in opposition to findings of previous studies of treadmill training with body weight support that have reported large, positive effectives for improving overground walking speed, walking endurance and gross motor skills in children with cerebral palsy. The literature review highlighted some limitations in the methodology of these previous studies that may have resulted in an overestimation of the effect sizes that were reported, such as lack of assessor blinding or a control group. In studies that compared treadmill training to 'usual physiotherapy' it is not clear what types of intervention constituted the 'usual therapy'. For example, it was unclear if 'usual therapy' was of an equivalent intensity to the treadmill training program and if differences in training intensity may have influenced the results. The absence of a control group in many of the studies makes it difficult for clinicians to be confident that any changes observed in walking ability were due to the treadmill training program.

Transferring benefits gained from treadmill training to overground walking

While it may be that limitations in methodology of previous studies has resulted in over-estimation of the effects of treadmill training for children with cerebral palsy, the methodology of our study created the opportunity to directly compare treadmill walking with an equivalent amount of overground walking and has provided some insight into the effect of the intervention for children of different levels of walking ability. Careful consideration of the differences in kinematics and joint moments between treadmill and overground walking, and the secondary influences that are added when body weight support is provided to children of different walking abilities, may also account for the reverse training effect observed in our study.

In a paper discussing the mechanical differences between treadmill and overground walking, Van Ingen Schenau (1980) illustrates that differences which have been observed in the biomechanics of these two methods of walking can be attributed to the use of a fixed coordinate system as a point of reference for measurement. From a theoretical physics perspective and using calculations of energy change between the person and the treadmill system, Van Ingen Schenau concluded that as long as belt speed is constant and a coordinate system that moves with the belt is used for measurement, treadmill and overground walking are mechanically equivalent. This would suggest that treadmill walking provides an opportunity for walking training that is very task specific to overground walking.

However, the use of a body weight support system may render treadmill walking different mechanically to over ground walking and this may help explain why the improvements in speed and endurance observed during treadmill training were not transferred to overground walking. Van Ingen Schenau's theory of the mechanical equivalency between treadmill and overground walking is underpinned by the use of a moving system of coordinates as a reference point for measurement of gait mechanics. The introduction of a system of body weight support to the treadmill may alter this environment by introducing a fixed point of reference with the person suspended over the treadmill belt from a single point. If incorrectly using fixed coordinates for measurement results in differences in walking mechanics between treadmill and overground walking, provision of body weight support from a single point of fixation may have the potential to truly alter walking mechanics on the treadmill, thus creating differences between treadmill and overground walking.

Changes in walking mechanics have been reported in adults with neurological impairment when they walk on a treadmill with body weight support. Changes in gait kinematics, decreases in walking speed and decreases in postural sway have all been observed in adults participating in body weight supported treadmill training after stroke (Threlkeld, Cooper, Monger, Craven, and Haupt, 2003). Differences between treadmill and overground walking for children with cerebral palsy are less well established (McNevin, Caraci, and Schafer, 2000). If walking on a treadmill with bodyweight support does impose influences on these children that are different to overground walking, then it appears likely that body weight support must be reduced systematically and as much as possible over the course of the training period for the training to best match overground walking. This might capitalise on the task specific nature of the training environment and thus maximise carryover of benefits to overground walking.

Maximal reduction of body weight support, along with the inclusion of overground walking practice immediately following a treadmill training session, has been identified as a key component of treadmill training protocols for adults following spinal cord injury (Behrman & Harkema, 2000 & 2007; Behrman et al., 2005; Dobkin et al., 2006). It is possible that minimising body weight support is important for ensuring specificity of the training by maximising the similarity between the two walking environments. When maximal task specificity has been achieved on the treadmill, concurrent overground walking practice provides the person with the immediate opportunity to transfer any improvements they have made on the treadmill to overground walking. (Behrman et al., 2005; Behrman & Harkema, 2007). This has led to the development of algorithms that guide decision making about reduction of body weight support and introduction of concurrent overground walking during a treadmill training program. (Behrman et al., 2005). Based on the lack of carryover to overground walking measured in our study, it appears that these training components might also be as important for children with cerebral palsy as they have shown to be in adult populations.

Defining training protocols

If reduction of body weight support, and reducing this support to zero whenever possible, is an important aspect of effective treadmill training protocols, this may have consequences when targeting specific sub-populations of children with cerebral palsy. Due to the varying levels of body weight support that these children require to achieve independent walking overground, this might mean that treadmill training has the potential to be more effective for improving overground walking speed and endurance for those with gross motor function classified as GMFCS I, II or III who require minimal body weight support for walking. It may be less effective for improving walking endurance and increasing the speed of children's overground walking over short distances for those who are reliant on body weight support (GMFCS IV) where the capacity to reduce body weight support during treadmill walking may be limited.

When addressing the provision of body weight support during training, it is also possible that children with gross motor function classified at different levels of the GMFCS may require different levels of body weight support, and specific protocols for the systematic reduction of that support. For example, children with gross motor function classified as GMFCS III do not typically need high levels of bodyweight support when walking over ground, and instead they rely on upper limb support using crutches or a walking frame (Palisano et al., 1997). These children may be capable of achieving progressively faster walking speeds on the treadmill if they are offered body weight support. If this support is not progressively reduced over the course of training, the child may not be able to transfer the improvements made to their walking speed on the treadmill and achieve the same speed overground where they do not have the benefit of body weight support. Progressively reducing body weight support with concurrent increases in treadmill walking speed may be an integral component aspect of training protocols for these children.

In contrast, a child whose gross motor function is classified as GMFCS IV is unable to walk overground without significant body weight support (Palisano et al., 1997). For these children, a large focus on reducing bodyweight support during treadmill training is likely to challenge them beyond their weight bearing ability. Too much reduction in body weight support may result in them needing to sit their weight heavily in the body weight support system to maintain the speed of their stepping to match the speed of the treadmill belt, discouraging them from actively loading their lower limbs. It may be that the amount by which body weight-support can be reduced might be limited for these children so that maximal load bearing through the lower limbs is achieved, but concurrent overground walking practice might be the important component of training protocols for these children to ensure that they have the opportunity to practice forward propulsion overground. This serves as an important reminder to clinicians to carefully consider their treatment goals when considering treadmill training as an intervention for children with gross motor function of differing GMFCS levels.

The small number of studies that have investigated the effectiveness of treadmill training for children with cerebral palsy have also investigated a wide range of training protocols. Therefore, current literature does not provide clinicians with conclusive evidence to guide them to the most effective training protocol for children in their care. While the literature review indicated that the typical treadmill programs investigated for children with cerebral palsy were thirty minute sessions conducted two or three times weekly, the duration of the programs that were investigated ranged from two to twelve weeks. There was an indication that improvements in walking speed might be achieved for children who are able to walk independently [GMFCS I] following intense training of a short duration [two weeks, twice daily] (Provost et al., 2007) while a less intense training program over a longer duration [6 weeks, twice weekly] training achieved similar results for children with more severe walking difficulty (GMFCS III and IV) (Dodd and Foley, 2007). Gross motor skills were reported to improve for children able to walk independently [GMFCS I] after completing two weeks of twice daily training (Provost et al., 2007) while training 3 times per week for 12 weeks resulted in similar changes in gross motor function for a group of children who predominantly required significant support to walk (Schindl, Forstner, Kern and Hesse, 2000). These examples indicate that training protocols of differing intensity and duration might suit children with different levels of walking ability, however current research does not enable direct comparison of different training intensity and duration within discrete GMFCS levels. Further research is needed to conclusively establish the intensity and duration of training that may be most effective for children with different levels of walking ability.

Optimal treadmill training protocols and algorithms to guide decision making about progression of training parameters have been developed in adult populations over many years. While it could be assumed that these protocols can be directly applied to treadmill training for children with cerebral palsy, differences in the mechanism and consequences of the primary brain injury between adults who have had a stroke or spinal cord injury and children with cerebral palsy could make these assumptions problematic. An extensive body of knowledge has been generated over many years regarding the effectiveness of treadmill training in populations of adults following both stroke and spinal cord injury (Behrman & Harkema, 2007; Dobkin et al., 2006; Harkema et al., 2001; Hesse et al., 1995, 1999 & 2001; Moseley, Stark, Cameron, and Pollock, 2005) and researchers in the area of paediatrics began to apply this knowledge to children with cerebral palsy. The use of a treadmill to improve walking was first considered for adults with spinal cord injury and was based on learning from studies which observed walking ability in spinalised cats. (Belanger, Drew, Provencher and Rossignol, 1996; Edgerton, Griller, Sjostrom and Zangger, 1976; Grillner, 1985). This led to theories of the existence of 'central pattern generators' located within the spinal cord and their role in initiating and maintaining stepping and these theories were subsequently applied to the re-training of walking following spinal cord injury (Calancie et al.,1994; Harkema, 2001; Kandel et al., 2000).

The mechanism and consequences of the neurological injury in cerebral palsy is different to that of spinal cord injury and stroke in adults and may result in a different response to treadmill training. After a stroke or spinal cord injury, adults are effectively 're-learning' the ability to walk. They have already laid down the primary and secondary neuronal pathways and networks required to develop smooth and efficient gait. The mechanism by which adults 're-learn' the ability to walk is through neural plasticity and the potential for repair or 're-wiring'of pathways (Harkema, 2001; Kandel et al., 2000). Treadmill training provides an environment in which elements of gait can be practiced repetitively and the therapist can focus on ensuring that feedback via afferent pathways is as accurate as possible to help refine the task (Hadders-Algra, 2000). Children with cerebral palsy, whose neurological injury occurs very early in life, often prior to birth, have a limited primary neuronal repertoire and have not had the opportunity to refine these and lay down neural pathways for smooth and efficient gait. They are 'learning' walking from the very beginning; habilitating rather than re-habilitating their walking. While we may take valuable information from the body of evidence that exists in support of treadmill training in adult populations, it is important that researchers in the area of cerebral palsy continue to address this group as a discrete population and rigorously investigate the efficacy and effectiveness of treadmill training specifically for these children.

5.2 STRENGTHS AND LIMITATIONS

To date, this is the largest study to investigate treadmill training for children with cerebral palsy. The randomized controlled trial addressed weaknesses in existing literature by limiting the heterogeneity of the participant group, including a control group, by blinding assessors and by investigating the potential for lasting benefits of training by including a follow-up assessment period 14 weeks after cessation of training.

This is the first study in the area of cerebral palsy to directly compare treadmill training with overground walking practice. This is of clinical significance due to the potentially extensive equipment and staff resources required to conduct a body weight supported treadmill training program. Interventions that are cost effective and use readily available resources may potentially be more feasible in smaller workplaces such as those frequently attended in the community by children with cerebral palsy.

The study had a strong focus on being clinically meaningful. All previous studies, with one exception, have been conducted outside of the child's natural environment - in rehabilitation or outpatients centres - and using expensive equipment and intensive staff support. By conducting the training program at the child's school, using readily accessible and inexpensive equipment and by relying on a minimum level of staff resources, the feasibility of the intervention was enhanced and accessibility for the children and their families was maximised.

The inclusion of a qualitative aspect to the study was unique and important in highlighting potential benefits of training from the point of view of the children who completed the training and of the staff who supported them. This has the potential to guide future research and ensure that researchers consider investigating outcomes that are meaningful to children with cerebral palsy. While the children who completed treadmill training in our study did not demonstrate improvements in their walking speed and endurance, the qualitative indicated other benefits that may have been gained such as improved standing or walking balance and an increase in energy level and arousal. Other benefits such as a sense of achievement, motivation and the developmental of social relationships were also reported and these benefits of training may hold as much value for young people with cerebral palsy as improvements in their walking ability.

This is the first known study to report specifically on factors related to the feasibility of a treadmill training program in a special school environment. Knowledge of potential barriers and facilitators to treadmill training is valuable to clinicians considering this type of intervention for use with children they support. In the state of Victoria, in Australia, many children with cerebral palsy who have significant physical disabilities (GMFCS III and IV) receive most of their physiotherapy intervention through their school enrolment, either at a special school or their local primary school. Knowledge of the barriers and facilitators that may be encountered when implementing treadmill training in a school environment will be valuable to the physiotherapists supporting these children.

A limitation of this study was the use of a small number of outcome measures that focused on walking function. This was highlighted by the qualitative study which identified potential benefits of training that had not been specifically measured. Another limitation was that only children with gross motor function classified as GMFCS III and IV, with moderate to severe walking difficulty, were included. This allowed investigation of treadmill training for a discrete group of children, but limits the result being generalised to other GMFCS classifications.

It must also be highlighted that the small sample size of the quantitative study meant that it was underpowered which may have introduced the potential for a Type II error to have occurred (a difference was not detected where it did occur). As described in Chapter 3, calculations based on the results of a pilot study indicated that a sample of 30 participants (15 per group) would be required for an 80% power to detect a between-group difference at p<05. While 35 participants were recruited to the study, dropouts due to surgery and secondary medical conditions resulted in only 26 children proceeding to training. The reduced power of the study, and potential for Type II error, means that caution must be taken in interpreting the results.

The main limitation of the qualitative study was that it was only possible to interview two of the seventeen young people who participated in the training program. The level of cognitive disability or expressive communication difficulties of the children who took part in the study meant that was not possible for all of the children to take part in an interview.

5.3 DIRECTIONS FOR FUTURE RESEARCH

While this study makes a valuable contribution to the body of information about treadmill training in cerebral palsy, it highlights questions that remain unanswered.

While the focus of this series of studies was to investigate treadmill training with body weight support as an intervention to improve walking for children with cerebral palsy, the direct comparison with overground walking training created by the randomised controlled trial design has highlighted that overground walking may be of potential benefit to these children. This has important clinical implications as treadmill training relies on significant resources, including potentially expensive equipment. While the treadmill and bodyweight support systems used in this study were relatively inexpensive, the equipment had to be specifically sourced and purchased to enable the training to occur. Overground walking practice using the child's usual gait aid may be established with little additional expense and it may be more feasible to undertake in the child's natural environments: walking at home, around the neighbourhood or at the local shopping centre, for example. This may lead to the training being more readily accessible to children and more sustainable over time.

The apparent deterioration in overground walking ability of children who completed treadmill training in this study should not deter researchers from further investigation of the potential benefits of treadmill training for children with CP. Whilst they should be cautious of the potential for a negative impact on overground walking as found in our study, future studies investigating the most effective training protocol for children with cerebral palsy are warranted. The findings of this study, together with previous findings from studies investigating treadmill training for adults following stroke, suggest that the effect of adding concurrent overground walking practice to treadmill training protocols for children with CP should be investigated.

Another aspect of treadmill training protocols which requires further investigation is the provision of body weight support. One of the current challenges in establishing protocols for the systematic reduction of bodyweight support is the limited use of reliable systems for measuring bodyweight support in studies that have been conducted to date. For training protocols to be easily translated into the clinical setting, clinicians need to know the most effective levels of body weight support to provide to children during training and have access to a valid and reliable method for measuring that support. They require equipment that is not prohibitively expensive, or that requires specialised therapist training to use which limits its use to a laboratory environment rather than a clinical environment. Once a measurement method such as this is established, clinicians will require clear guidelines about the progressive and systematic reduction of body weight support.

Further research into the potential benefits of treadmill training for outcomes other than walking function is warranted. Existing studies have primarily investigated outcomes within the International Classification of Function, Disability and Health (World Health Organization, 2001) domain of ‘Activity’ with most outcomes focussing on changes to walking ability. Notably, no study to date has investigated measures within the ICF domain of ‘Participation’. The absence of outcomes from this domain of the ICF is striking given that a direct correlation between level of walking difficulty and capacity for activity, participation and social interaction has been demonstrated for children with cerebral palsy (Bjornson, Belza, Kartin, Logsdon, and McLaughlin, 2007). If changes in a child’s walking speed and endurance following a long and intense period of treadmill training are small and do not impact on the child’s participation within their family, school or local community, one might question the value of participating in the training. It will be important for future studies to investigate whether completion of a treadmill training program might influence a child’s level of participation.

There is also a paucity of data in previous studies related to outcomes in the domain of ‘Body Structure and Function’. Apart from those that measured change in general walking endurance, the literature review found only one study that included a specific measure of cardiovascular fitness in their investigation of the benefits of treadmill training (Provost et al., 2007). Given this, and recently reported evidence of the benefits of cardiovascular fitness training in cerebral palsy (Anttila, Autti-Ramo, Suoranta, Makela, and Malmivaara, 2008; Verschuren, Ketelaar, Takken, Helders, and Gorter, 2008), the inclusion of cardiovascular fitness outcome measures would be justified in future studies of treadmill training.

Future studies could also include measures of outcomes other than physical benefits. Even if change at the ‘activity’ level following treadmill training is only small, the changes in self-confidence and the sense of achievement reported by participants after treadmill training may result in increased 'participation' within their school and wider community. With reports of changes in self-confidence and a sense of achievement, the findings of the qualitative study support further investigation of the benefits of treadmill training on a range of outcomes for children with cerebral palsy, including both physical and psychosocial outcomes. Quality of life measures such as the CPCHILD and the CP QOL-Child (Carlon et al., 2010; Narayanan, Fehlings, Weir, Knights, and Campbell, 2006; Waters et al., 2007) could be considered for use in future studies. Results of a pilot study investigating changes in quality of life of children with cerebral palsy following treadmill training (Dieruf et al., 2009) encourage reporting of potential change in quality of life by both children participating in the training and by their parents.

5.4 CONCLUSIONS

The series of studies presented in this thesis has made important contributions to the body of knowledge regarding treadmill training for children with cerebral palsy. Evidence from the randomised controlled trial suggests that treadmill training with body weight support may not be as effective for improving walking speed over short distances and walking endurance for children with CP and gross motor function classified GMFCS level III or IV as evidence from previous studies has reported. As an intervention to improve overground walking speed and endurance, this study reveals that treadmill training may be no more effective than overground walking practice performed with the child's usual gait aid and that overground walking may be an effective, accessible and cost-effective intervention for improving walking endurance for children with cerebral palsy who experience moderate to severe walking difficulty.

The RCT has supported the findings of previous studies that treadmill training with body weight support is a safe intervention for children with cerebral palsy, and has also demonstrated that it is feasible to conduct this type of training program in a special school environment. Despite finding an apparent deterioration in walking ability following treadmill training, the study highlights several important elements of training which might be important for maximising the effectiveness of treadmill training programs and maximising carryover of benefits to overground walking.

The inclusion of a qualitative aspect to the study highlighted psychosocial benefits that have not previously been investigated but that may be gained by children with cerebral palsy by participating in treadmill training. These included a sense of achievement, increased self-confidence and a sense of motivation. While changes in walking speed and endurance were limited following treadmill training in this study, treadmill training programs may offer other benefits that are of value to young people with cerebral palsy.

In conclusion, this study provides a comprehensive evaluation of efficacy of body weight supported treadmill training for children with cerebral palsy. While it does not provide conclusive evidence for the effectiveness of treadmill training in improving overground walking for these children, it supports the investigation of overground walking practice as a very feasible, accessible and potentially effective intervention for improving walking function in children with cerebral palsy. It also it importantly highlights specific elements of treadmill training which must be further explored and rigorously investigated before firm conclusions can be made by clinicians about whether or not they might add this form intervention to the ‘toolkit’ they can use to assist children with cerebral palsy to improve their walking.

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APPENDIX A - Statement from co-authors confirming the authorship contribution of the doctoral candidate (systematic review)

As co-authors of the paper:

> **Willoughby KL,** Dodd KJ, Shields N. A systematic review of the effectiveness of treadmill training for children with cerebral palsy. *Disabil Rehabil*. 2009;31:1971-1979

we confirm that Kate Willoughby has made the following contributions:

- Development of the key systematic review question and key concepts
- Development of search strategies
- Conducting the literature search and screening publications
- Application of the inclusion and exclusion criterion
- Quality assessment of studies
- Data extraction
- Identification of main literature findings and themes
- Leading the development and review of manuscript

Prof Karen Dodd Signed Karen Dodd Date 28/9/11

Dr Nora Shields Signed Nora Shields Date 28/9/11

APPENDIX B - Example Search Strategy

Medline Search

		Results
1	exp Child/ or exp Adolescent/ or exp Pediatrics/	181899
2	(adolescen$ or child$ or disab$ child$ or youth$ or teen$ or paediatric$ or pediatric$).ti,ab.	106650
3	1 or 2	203314
4	exp Cerebral Palsy/	2400
5	(cerebral palsy or developmental disabilit$ or disabled child$ or handicapped child$ or physical disabilit$ or motor disorder$ or spastic diplegi$ or spastic quadriplegi$).ti,ab.	4385
6	4 or 5	5049
7	treadmill.mp.	1675
8	(treadmill$ or gait or walking or ambulation or locomot$ or mobility or body weight support).ti,ab.	12229
9	7 and 8	1671
10	3 and 6 and 9	29
11	limit 10 to english language	28

APPENDIX C - Application of inclusion and exclusion criterion to articles yielded from search

Author	Title	Journal	Year	Included	Comment
Abel, M. F. et al	Motor adaptation to treadmill walking in children with cerebral palsy. (ABSTRACT)	Jnl of sport & exercise psych	2003	✘	Abstract only
Bar-Or, et al	Repeated treadmill walks affect physiologic responses in children with cerebral palsy	Med & Science in Sports & Ex	2003	✘	Primary outcome measure was O2 uptake Change in gait function was not an outcome measure
Baxter, R. S. et al	Treadmill training for an infant born preterm with a grade III intraventricular hemorrhage	Physical Therapy	2003	✘	Diagnosis – not CP Description of gait on treadmill only No statistical analysis 2 or less on PEDro
Begnoche, D. M. et al	Effects of traditional treatment and partial body weight treadmill training on the motor skills of children with spastic cerebral palsy	Pediatric Physical Therapy	2007	✘	Treadmill not 80% of intervention – unable to tell Treadmill only one of 5-6 stations described Does not report on TT effect alone
Blundell, S. W. et al	Functional strength training in cerebral palsy: a pilot study of a group circuit training class for children aged 4-8 years	Clinical Rehabilitation	2003	✘	Treadmill not 80% of intervention Describe circuit – treadmill one of 5-6 stations described
Bodkin, A. W. et al	Home-based treadmill training in ambulatory children with hemiplegic cerebral palsy	Dev Medicine & Child Neurology	2006	✘	Abstract only
Burtner, P. A. et al	An intensive program of body weight supported treadmill training (BWSTT): clinical changes in children with cerebral palsy (ABSTRACT)	Developmental Medicine & Child Neurology	2006	✘	Abstract only

Cherng, Rj	Effect of treadmill training with body weight support on gait and gross motor function in children with spastic cerebral palsy	Am Jnl of Phys Med & Rehab	2007	✓	
Day, Ja et al	Locomotor Training with Partial Body Weight Support on a Treadmill in a Nonambulatory Child with Spastic Tetraplegic Cerebral Palsy: A Case Report	Pediatric Physical Therapy	2004	✓	May be out on Pedro during QA
Dodd, Kj & Foley, S	Partial body-weight-supported treadmill training can improve walking in children with cerebral palsy: a clinical controlled trial	Dev Medicine & Child Neurology	2007	✓	
Schindl et al	Treadmill training with partial body weight support in nonambulatory patients with cerebral palsy	Archives of Physical Medicine & Rehabilitation	2000	✓	
Josphic, K. et al	Supported speed treadmill training exercise program for children with cerebral palsy (ABSTRACT)	Dev Medicine & Child Neurology	2006	✗	Abstract only
Phillips, John P.	Ankle dorsiflexion fMRI in children with cerebral palsy undergoing intensive body-weight-supported treadmill training: a pilot study	Dev Medicine & Child Neurology	2007	✓	May be out on Pedro during QA
Provost, B et al	Endurance and Gait in Children with Cerebral Palsy After Intensive Body Weight-Supported Treadmill Training	Pediatric Physical Therapy	2007	✓	
Richards, Cl et al	Early and intensive treadmill locomotor training for young children with cerebral palsy: a feasibility study	Pediatric Physical Therapy	1997	✗	Combination of intervention ? % of Treadmill training? No statistical analysis (only means) Less than 2 on PEDro

APPENDIX D - Quality assessment tool

PEDro Rating Scale and scoring rules

Taken from: http://www.pedro.fhs.usyd.edu.au/scale_item.html 25/01/08

All Criteria	Points are only awarded when a criterion is clearly satisfied. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
1. Eligibility criteria were specified.	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received).	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomised allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
3. Allocation was concealed.	Concealed allocation means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
4. The groups were similar at baseline regarding the most important prognostic indicators.	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
	Key outcomes are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
5. There was blinding of all subjects.	Blinding means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied

	to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
6. There was blinding of all therapists who administered the therapy.	Blinding means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
7. There was blinding of all assessors who measured at least one key outcome.	Blinding means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
	Key outcomes are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups.	This criterion is only satisfied if the report explicitly states both the number of subjects initially allocated to groups and the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
	Key outcomes are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat".	An intention to treat analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
	Key outcomes are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.

10. The results of between-group statistical comparisons are reported for at least one key outcome.	A between-group statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group x time interaction). The comparison may be in the form of hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
	Key outcomes are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
11. The study provides both point measures and measures of variability for at least one key outcome.	A point measure is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. Measures of variability include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.
	Key outcomes are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.

APPENDIX E - Quality assessment of articles

* = disagreement, agreement reached by consensus

Author	Pedro Rating Scale											
	1	2	3	4	5	6	7	8	9	10	11	TOTAL
Cherng et al. (2007)		✓ *	✗	✓ *	✗	✗	✓	✓	✗	✓	✓	6
Day et al. (2004)		✗	✗	✗	✗	✗	✗	✓	✓	✗	✓ *	3
Dodd & Foley (2007)		✗	✗	✓	✗	✗	✗	✓	✓	✓	✓	5
Meyer-Heim et al. (2007)		✗	✗	✗	✗	✗	✗	✓	✓	✓	✓	4
Schindl et al. (2000)		✗	✗	✗	✗	✗	✗ *	✓	✓ *	✗	✓ *	3
Phillips et al. (2007)		✗	✗	✗ *	✗	✗	✗	✗ *	✓ *	✗	✗	1
Provost et al. (2007		✗	✗	✗	✗	✗	✗	✓	✓ *	✗ *	✓ *	3

DATA EXTRACTION FORM

The effect of treadmill training on the body structure and function, activity and participation restrictions of children and adolescents with Cerebral Palsy

Date of extraction: ___ / ___ / ___ Reviewer: ________________________

Included ☐ **Excluded** ☐

FULL REFERENCE: (author, title, source)

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STUDY OBJECTIVE:

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STUDY DESIGN: (e.g RCT, clinical controlled trial, case-control, case series, single case control)

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POPULATION DETAILS:

Target population:

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…………………………………………………………………………………………

% of population with diagnosis if CP:…………………………………………………...

Inclusion criteria: ………………………… Exclusion criteria: …………………………

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Recruitment procedures:

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PARTICIPANT DETAILS:

	Control Subjects:	Experimental Subjects:
Number:	……………………………………	………………………………………
Gender:	……………………………………	………………………………………
Age (mean and range):	……………………	………………………………………
……………………………………………	..	………………………………………

Cerebral Palsy type: (GMFCS level, classification of movement disorder)

………………………………………………… ………………………………………
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Were experimental and control groups comparable?

……………………………………………………………………………………………

Were participants randomly allocated to experimental and control groups? YES / NO

INTERVENTION

Focus: (gait parameters, muscle strength, endurance)
………………………………………………………………………………………………
……………………………………………………………………………………………

PBWS : Yes ☐ No ☐

Equipment used:

Treadmill:…………………………………………………………………...

Sling: ………………………………………………………………………….

PWBS apparatus: ……………………………………………………………..

Frequency of training: ……………………………………………………………...

Session duration: ………………………………………………………………...

Duration of intervention: …………………………………………………………...

Who administered/supervised intervention?: ……………………………………………

Setting for intervention: ……………………………………………………………

Other: (e.g; assistance provided; progression of speed, ramping of treadmill, training provided for those administering intervention?).…………………………………….....................................

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……………………...…………………………………………………………………

Motivating factors utilised/concurrent activities to encourage participation (if described):
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……………………………………………………………………………………………

Outcome measures:

Impairment: …………………………………………………………………………
……………………………………………………………………………………………

Activity: …………………………………………………………………………………
……………………………………………………………………………………………

Participation: ………………………………………………………………………………
……………………………………………………………………………………………

Reliability/Validity of tools? How was this demonstrated?:

…………………………………………………………………………………………………
…………………………………………………………………………………………………

Who carried out measurement/assessment?:

…………………………………………………………………………………………………

Time interval between measurements:

…………………………………………………………………………………………………

<u>RESULTS</u>: (inc. statistical technique used, statistical results, effect size, attrition rates)

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<u>OTHER COMMENTS:</u> (adverse events, drop-outs and reasons)

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APPENDIX G - Statement from co-authors confirming the authorship contribution of the doctoral candidate (RCT)

As co-authors of the paper:

> **Willoughby KL**, Dodd KJ, Shields N, Foley S. Efficacy of Partial Body Weight–Supported Treadmill Training Compared With Overground Walking Practice for Children With Cerebral Palsy: A Randomized Controlled Trial. *Arch Phys Med Rehabil.* 2010; 91: 333-339.

we confirm that Kate Willoughby has made the following contributions:

- Collaboration with co-authors regarding research design
- Sole responsibility for participant recruitment
- Coordination of intervention phase for both the treadmill training and the overground walking interventions of study
- Coordination of data collection
- Data analysis and interpretation
- Leading the development and review of the final manuscript

Prof Karen Dodd	Signed	Karen Dodd	Date 28/9/11
Dr Nora Shields	Signed	Nora Shields	Date 28/9/11
Sarah Foley	Signed	Sarah Foley	Date 28/9/11

APPENDIX H – Letter to the editor and author response:

DEPARTMENTS

Letters to the Editor

The Trouble With "Body Weight Support" In Treadmill Training

Kate L. Willoughby and colleagues are to be congratulated on the work done recently with children with cerebral palsy on the treadmill.[1] Only those who have actually done it appreciate the amount of devotion necessary in training young children that way.

We are particularly interested in that part of their results showing a trend for better endurance achieved by the group trained overground versus (partial) body weight supported treadmill training (PBWSTT). Although being part of this name, body weight support (BWS) should in fact be avoided or kept as low as possible. This is particularly true for chronic patients who have had recent experience with full weight-bearing upright walking overground.[2-4]

Incidentally, to avoid overemphasizing BWS, we have proposed Laufband therapy as a name for locomotor training on the treadmill,[2] and one of our slogans has been: As little help (as little BWS) as possible, as much as necessary.[4]

Children like to sit in the harness, thereby increasing BWS up to 100%, and happily swing overground rather than perform tedious walking/stepping. This resembles the old robot problem: Why actively move your legs when they are set by a robot,[5] or why touch ground when the harness can be used as a helicopter? Again, compliments to the team for managing this problem, particularly present when children do not intend to or are not able to cooperate fully.

The overall recommendation given by the investigators to combine (adjustable) BWS on the treadmill with aided overground ambulation, continuously increasing the share of the latter, is also valid for adults and other neurologic diseases.[3,4] The advantages of initially using a treadmill with suspension are before all securing the patient and preventing falls. BWS may allow learning or relearning of locomotor movements with weak or partially paralysed/innervated muscles, also against or with help of spasticity.[3,4] Less load further allows easier handling of lower limbs by the therapists when, for example, counteracting the frequently present adductor spasticity or supporting knee extension with shift of body weight (see rules of spinal locomotion[2-4]). It is important that BWS is continually reduced (in accordance with the capability of the patient) and at least as an indicator, walking overground is regularly attempted from the very beginning.

When a sufficient amount of BWS is provided by 1 or 2 therapists to maintain an upright position, most patients can perform some stepping over firm ground with or without additional supporting devices like a walker. With such tedious although valid training, patients quite likely encounter more episodes of full weight-bearing than on the treadmill, especially when BWS on the treadmill is maintained high throughout the training period. Such differences in the application of BWS most likely are responsible for the somewhat better endurance achieved by the present control group.[1]

Anton Wernig, MD
Department of Physiology
University Bonn
Bonn, Germany
and Klinikum Karlsbad Langensteinbach
Karlsbad, Germany

Sabine Wernig, PT
Klinikum Karlsbad Langensteinbach
Karlsbad, Germany

Disclosure: No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

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1. Willoughby KL, Dodd KJ, Shields N, Foley S. Efficacy of partial body weight–supported treadmill training compared with overground walking practice for children with cerebral palsy: a randomized controlled trial. Arch Phys Med Rehabil 2010;91:333-9.
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doi:10.1016/j.apmr.2010.05.015

The authors respond

We thank Wernig and colleague for their comments and for generating important discussion around this topic. While treadmill training has been investigated in adult patient populations for some time, we have only recently begun to see rigorous investigation of the benefits of this intervention for children with cerebral palsy.

As discussed in our article and highlighted by Prof Wernig, the amount of body weight support provided to a person during treadmill training is potentially an important factor in the success of training. Of even greater importance is the focus on progressive reduction of body weight support over the course of the training period, encouraging the participant to increase active weight-bearing. Our other main point of discussion, that concurrent overground walking may be necessary for carryover of improvements achieved on the treadmill, is also supported by the findings of previous adult studies.[1]

The suggestion that body weight support be avoided altogether creates a specific challenge for the population of children who were the focus of our study. Children included in our study were classified as level III or IV by the Gross Motor Function Classification Scale.[2] Inherent within the definitions of this classification scale is the child's ability to ambulate independently. Children classified in levels I and II ambulate independently. For children classified in levels III and IV, their ability to stand or walk, whether overground or on a treadmill, is dependent on a certain level of body weight support. This support is offered either through upper-limb weight-bearing on a walking aid (III) or through the body weight support provided by the harness, chest, and/or pelvic support which forms part of their postural support walker (IV). While it was not possible for participants in our study to walk on the treadmill with no body weight support, our training protocol focused on providing as little support as possible, but enough to allow the child to maintain upright posture while stepping, to achieve an optimal gait pattern during training and also to afford the ease of handling of the lower limbs by the therapist to which Prof Wernig refers.

The training protocol for our current study was determined through consultation of published literature in the area of cerebral palsy[3-5] and certainly included the important elements of training that have been identified for adults after stroke or spinal cord injury. Prof Wernig rightfully highlights in his letter that treadmill training with minimal body weight support has been shown to be effective for adults with brain injury "who have had recent experience with full weight-bearing upright walking overground." We consider it important to bear in mind that, for young people with cerebral palsy, gait training is not so much a process of motor relearning, as learning the task from the very beginning and within a less than optimal neurologic and musculoskeletal system. Therefore, it cannot simply be assumed that motor relearning theories and the existing body of research supporting the benefits of treadmill training for adults with other mechanisms of brain injury can necessarily be generalized to children with cerebral palsy.

Whether the term "body weight support" or "Laufband therapy" is used to describe treadmill training with some level of support for weight-bearing, it is important that we focus on the discrete elements of the training protocol: training duration and intensity, progression of walking speed and, importantly, maximal reduction of body weight support wherever possible.

Kate L. Willoughby, BPhysio
Yooralla
Glenroy, Victoria, Australia
School of Physiotherapy
La Trobe University
Melbourne, Victoria, Australia

Karen J. Dodd, PhD, BAppSc (Physio)
Division of Allied Health and Musculoskeletal Research Centre
La Trobe University
Melbourne, Victoria, Australia

Nora Shields, PhD
School of Physiotherapy and Musculoskeletal Research Centre
La Trobe University
Melbourne, Victoria, Australia

Sarah Foley, BAppSc (Physio), GradDipHlthResMeth
Children's Therapy Services
Geelong, Victoria, Australia

Disclosure: No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

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1. Behrman A, Lawless-Dixon A, Davis S, et al. Locomotor training progression and outcomes after incomplete spinal cord injury. Phys Ther 2005;85:1356-71.
2. Palisano R, Rosenbaum P, Walter S, Russell D, Wood E, Galuppi B. Development and reliability of a system to classify gross motor function in children with cerebral palsy. Dev Med Child Neurol 1997;39:214-23.
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doi:10.1016/j.apmr.2010.06.008

RESEARCH AND GRADUATE STUDIES OFFICE

LA TROBE UNIVERSITY

MEMORANDUM

To: **Karen Dodd, School of Physiotherapy**
Nora Shields, School of Physiotherapy

From: **Secretary, La Trobe University Human Ethics Committee**

Subject: **Review of Human Ethics Committee Application No. 06-152**

Title: ***A randomized controlled trial to determine the effects of a treadmill training program for school aged children with cerebral palsy***

Date: **5 December 2006**

Thank you for submitting your correspondence of 30 November 2006 regarding your application for ethics approval to the La Trobe University Human Ethics Committee (HEC) for the project referred to above.

Your response was forwarded to the Chair of the HEC, who has assessed the project as complying with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* and with University *Human Research Ethics Guidelines.* Your project has been granted ethics approval. You may now commence the study.

The project has been approved to 31 January 2008.

Please note that your application has been reviewed by a sub-committee of the HEC in the interest of facilitating a decision on your application before the next committee meeting. The decision to approve your project will need to be ratified by the full HEC and consequently approval for your project may be withdrawn or conditions of approval altered. However, your project may commence prior to ratification of the approval decision. You will be notified if the approval status of your project is altered.

The following standard conditions apply to your project:

- **Complaints.** If any complaints are received or ethical issues arise during the course of the project, researchers should advise the Secretary of the HEC on telephone (03) 9479 1443;

- **Limit of Approval.** Approval is limited strictly to the research proposal as submitted in your application while taking into account the conditions and approval dates advised by the HEC;

- **Variation to Project.** As a consequence of the previous condition, any subsequent variations or modifications you may wish to make to your project must be notified formally to the HEC. This can be done using the appropriate form (*Application for Approval of Modification to Research Project)* which is available on the internet at http://*www.latrobe.edu.au/www/rgso/ethics/ethics.htm* or from the HEC Secretary in electronic or hard copy. If the HEC considers that the proposed changes are significant, you may be required to submit a new application form for approval of the revised project;

- **Progress Reports.** You are required to submit a *Progress Report* form annually (if your project continues for more than 12 months) and at the conclusion of your project. The form is also available on the internet (see above address) and can be collected in electronic or hard copy. When completed the form should be returned to the Secretary of the HEC. Failure to submit a progress report will mean approval for this project will lapse. An audit may be conducted by the HEC at any time.

A **Final Report** will be due by **31 July 2008**.

If you have any queries on the matters mentioned above or require any further clarification please contact me at the Research and Graduate Studies Office on telephone (03) 9479 1443, facsimile (03) 9479 1464 or e-mail address humanethics@latrobe.edu.au

Dr Cam Simpson
Secretary, La Trobe University Human Ethics Committee

APPENDIX J - Ethics Approval: Department of Education & Training

Department of Education & Training

Office of Learning and Teaching

SOS003384

Professor Karen Dodd
c/- the School of Physiotherapy
La Trobe University
BUNDOORA 3086

Dear Professor Dodd

Thank you for your application of 12 September 2006 in which you request permission to conduct a research study in government schools titled: *A randomised controlled trial to determine the effects of a treadmill training program for school aged children with cerebral palsy.*

I am pleased to advise that on the basis of the information you have provided your research proposal is approved in principle subject to the conditions detailed below.

1. Should your institution's ethics committee require changes or you decide to make changes, these changes must be submitted to the Department of Education & Training for its consideration before you proceed.

2. You obtain approval for the research to be conducted in each school directly from the principal. Details of your research, copies of this letter of approval and the letter of approval from the relevant ethics committee are to be provided to the principal. The final decision as to whether or not your research can proceed in a school rests with the principal.

3. No student is to participate in this research study unless they are willing to do so and parental permission is received. Sufficient information must be provided to enable parents to make an informed decision and their consent must be obtained in writing.

4. As a matter of courtesy, you should advise the relevant Regional Director of the schools you intend to approach. An outline of your research and a copy of this letter should be provided to the Regional Director.

2 Treasury Place
East Melbourne, Victoria 3002
Telephone: +61 3 9637 2000
DX 210083

GPO Box 4367
Melbourne, Victoria 3001

Victoria
The Place To Be

APPENDIX K - Proposal letter and executive summary to the principal of Glenroy Specialist School

LA TROBE UNIVERSITY
Opportunity for Excellence

YOORALLA
People Helping People Achieve

October 2006

Ms Raelene Kenny
Principal,
Glenroy Specialist School
48-50 Box Forest Road
Glenroy Victoria 3046

Dear Ms Kenny

Re research project titled: 'A randomised controlled trial to determine the effects of a treadmill training programme for school aged children with cerebral palsy'

I am writing to seek your permission as principal of the Glenroy Specialist School to conduct a research project on the premises of the Glenroy Specialist School, during normal school hours with students attending your school. It is anticipated that the study would be conducted within the normal school terms in 2007. It is hoped that a total of 30 children and adolescents with cerebral palsy will be recruited for this study.

The proposed study is being conducted as a collaboration between physiotherapists employed by Yooralla Society of Victoria and the School of Physiotherapy at La Trobe University. The Chief investigators are Professor Karen Dodd, who is the Head of the School of Physiotherapy at La Trobe University, Ms Kate Willoughby who is a physiotherapist with the Yooralla Society of Victoria who currently provides physiotherapy services and support to children at your school, and Dr Nora Shields who is the Paediatric Lecturer at the School of Physiotherapy at La Trobe University.

Please find attached a more detailed summary of the proposed study for your consideration.

If you have any questions or comments please feel free to contact me on telephone number 9479 5723 or email k.dodd@latrobe.edu.au.

Yours sincerely,

Karen Dodd

Karen Dodd. PhD
Professor and Head
School of Physiotherapy
La Trobe University

EXECUTIVE SUMMARY FOR SCHOOL PRINCIPAL

Title: A randomised controlled trial to determine the effects of a treadmill training programme for school aged children with cerebral palsy

This study will be the first ever scientifically rigorous randomised controlled trial comparing the effects of a 9-week treadmill and body weight support training programme compared to walking practice on the walking ability, quality of life and performance of physical activities of school aged children with cerebral palsy. As many as 90% of all children with cerebral palsy have difficulty walking because of the spasticity, muscle weakness and movement incoordination associated with this condition. More than 50% of these children have a moderate to severe walking disability. Thirty children from this latter group will be invited to take part in this study and will be randomly allocated to either the experimental or the control group (15 children in each group).

The experimental group will participate in a 9-week twice a week treadmill and body weight support training programme conducted at the Glenroy Specialist School. A motorized treadmill will be used and partial body weight support will be provided by either the WalkAble™ system or a custom-made harness. The control group will participate in a supervised walking practice programme, twice a week for 9 weeks. The children's walking ability will be measured by self-selected and fastest overground walking speed over 10m, and the distance walked over 10 minutes. Changes to the child's quality of life will be evaluated using the Cerebral Palsy Quality of Life measure, and changes in the performance of physical activities will be measured using the School Function Assessment. These measurements will be taken by a blinded assessor at three points; the start of the trial (week 0), after the intervention phase (week 10) and at follow-up (week 24). This treadmill training programme is novel because it will be run within the child's normal school environment, so that should it prove beneficial it would be a feasible, meaningful and realistic treatment option to help children with moderate to severe cerebral palsy walk independently.

Aims and significance of the project

The primary aim of this study is to determine if compared to a supervised overground walking practice programme, a 9-week, twice a week treadmill and body weight support training programme improves the walking ability (walking speed and walking endurance) of school aged children with cerebral palsy and moderate to severe walking difficulty.

The secondary aims are to (a) to determine if a 9-week, twice a week treadmill and body weight support training programme improves the quality of life and performance of physical activities compared to a supervised walking practice programme for school aged children with cerebral palsy and (b) to determine the safety and acceptance of treadmill and body weight support gait training within the children's normal school environment.

Participants

A total of 30 children will be recruited from the Glenroy Specialist School. The child's parents will be required to provide informed consent for their child to participate in the study, and if the school staff judge the child to be cognitively able, the children themselves will also be invited to provide consent. To be included, children will be (1) aged between 5 to 18 years, (2) have a diagnosis of cerebral palsy, (3) have a functional disability categorized as III or IV on the Gross Motor Function Classification System (GMFCS), and, (4) be able to understand simple instructions, and reliably indicate yes and no.

Ethical approval will be sought from the Human Ethics Committee of La Trobe University and approval will also be sought from the Victorian Department of Education and Training prior to the start of this trial.

To minimise disruption to the student's educational program all interventions will be provided within the child's normal school environment, and each child will participate in a maximum of only 18, 30 minute sessions over one consecutive 9-week period.

Expected Results of the project:

(a) The experimental group will show improved walking ability compared to the control group

(b) The experimental group will show improved quality of life compared to the control group

(c) The experimental group will show improved functional physical performance in the school environment compared to the control group

Who will benefit from the project?

Children with cerebral palsy who have moderate or severe walking disabilities will significantly improve their walking speed and also possibly their walking endurance enabling them to become more active members of their school and home communities. The particular advantage of the proposed programme is that it is non-invasive and can be undertaken in the child's usual school environment. Evidence to support this innovative approach to helping children with cerebral palsy walk better will also be beneficial for clinicians who work this group to help them develop feasible, relatively simple and possibly cost effective programmes that are easy to replicate in specialised schools.

When the project will start and the anticipated length of time to completion

The project is proposed to commence in January 2007 and will continue for 12 months (the trial will occur in all four terms of 2007). It is estimated that data collection will continue until March 2008.

APPENDIX L - Letter from Yooralla management confirming support from principal and school council

YOORALLA

People Helping People Achieve

1st August 2006

Karen Dodd PhD
Professor and Head
School of Physiotherapy
La Trobe University

Dear Karen,

As discussed with yourself and Norah, I took your treadmill research proposal to Glenroy School management. Raelene Kenny, School Principal in turn presented the proposal to the School Council.

They are happy to proceed, in principle, but have some concerns, which are in line with some of the issues that we discussed when we met.

Having discussed the project again with the Physiotherapy staff at Glenroy, I have outlined below the major points of concern from Glenroy School Management and Council, and the therapy staff. These issues require some assurance from you to enable the project to go ahead.

- The research protocols must be compatible with the current integrated approach to therapy in the school for both the experimental and control groups. Ie students withdrawn from classroom time minimally.
- Require multiple treadmills/hoist and slings located across several areas in the school
- Preference to run the project across a school year to facilitate consistency of staff and caseloads, classroom groupings etc
- Length of training program to match shortest school term. Ie 9 weeks in 2007.
- Protocols for treadmill training clearly documented after extensive consultation and collaboration with Glenroy therapy staff
- For February 2007 start, Allocation of Experimental and Control groups required by December 2006.
- Baseline measurements would be required prior to school term commencing in January 2007, which would require considerable coordination with families.
- To determine interest from potential students' families, a general letter with expressions of interest would need to be circulated ASAP. It is difficult to gauge the likely return rate from families – usually not great at Glenroy.
- Parents and Carers requiring more information or having queries should be directed in first instance to Karen or Norah.

- Formal acknowledgement of participation of individual therapists, Glenroy School and Yooralla Society of Victoria will be required.

- When presenting research results, we would like the opportunity for participating therapists to be involved.

- We require detailed information regarding financial assistance available from Latrobe University to cover additional staff hours and equipment.

While this list is quite extensive it is probably not exhaustive and I would expect that further concerns would surface as the process moves forward.

The staff at Glenroy School are enthusiastic about the project and will do everything possible to assist you to make it successful. Can you let me know what you feel the next step is? Do you require a response in writing from the School management?

I look forward to hearing from you.

Yours truly,

Tracy Larsen White
Group Manager
School and *e.quip* Services
Yooralla Society of Victoria.

APPENDIX M - RCT Information and invitation letter

LA TROBE UNIVERSITY
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YOORALLA
People Helping People Achieve

October 2006

Dear _______,

I am writing to provide you with information about a research trial that will be conducted with some students at the school during 2007.

For those of you who have not met me, I am a Physiotherapist working with Yooralla at Glenroy Specialist School. I am currently working with students in Junior Primary. The trial is a collaboration between Yooralla Society of Victoria and La Trobe University which is supported and endorsed by Glenroy Specialist School and the Department of Education.

The trial is being done to find out if a treadmill training program is better than normal walking practice with a walking frame in improving walking and the quality of life of students with Cerebral Palsy. We are contacting you as your son/daughter might be interested in taking part in this study.

The study is particularly exciting, as the walking training will be completed as part of the student's regular school program, within school hours. It would form part of the physiotherapy intervention that your child usually receives during the school week.

To be scientifically accurate, the study needs to compare walking training on a treadmill to normal walking training with a walking frame. Due to this, the 30 students who will eventually participate in the study will be *randomly* assigned to one of two groups: one group completing the walking training on a treadmill, and the other completing walking training with a walking frame. The students would train twice a week for 9 weeks during the school term.

If we do find out that treadmill training is more effective in improving students walking speed and endurance, this form of Physiotherapy intervention would become more widely available to all students who practice walking and we would know that we were being as effective and efficient as possible in improving your child's walking skills.

There is much more information to be shared with you before we ask you formally if you would like your child to participate in this study. For now, we are giving you the opportunity to express interest in participating in the study and to be able to speak with Dr Karen Dodd, Head researcher, to gain more information. Karen is a Physiotherapist and Professor and Head of the School of Physiotherapy at La Trobe University. She has completed extensive research into the best treatment options for both children and adults with Cerebral Palsy.

To express your interest in your child participating in the trial please complete and return the section below to me by …………………. . Dr Karen Dodd will then contact you to discuss the project and answer any questions you may have regarding your child's participation. If you have any questions regarding the project prior to this, you can contact Karen at La Trobe University on ………………

Kind Regards,

Kate Willoughby
Physiotherapist

……………………………………………………………………………………………

Expression of interest in Participating in Treadmill Training Trial

I, ………………………….., Parent/Guardian of ………………………….., would like to express interest in my child participating in the treadmill training trial to be held during 2007.

I give my permission for Dr Karen Dodd of La Trobe University to contact me to further discuss the trial and answer any questions I may have.

I would prefer to be contacted at this number: ……………………

Signed: …………………………… Date: ………………………

Please return this section to:
Kate Willoughby
Physiotherapist
Yooralla Society of Victoria
48-50 Box Forest Road
Glenroy VIC 3046

OR, via your child's communication book.

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Information and Consent Form: Participant

PROJECT TITLE: A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRAL PALSY.

INVESTIGATORS:

Professor Karen Dodd is a Professor and Head, School of Physiotherapy La Trobe University.

Ms Kate Willoughby is a physiotherapist with the Yooralla Society of Victoria

Dr Nora Shields is a lecturer in the school of Physiotherapy at La Trobe University

You are invited to participate in a project titled 'A randomised controlled trial to determine the effects of a treadmill training programme for school aged children with cerebral palsy'.

Description of investigation:

This study is being done to find out if a treadmill walking training programme is better than a normal walking programme in improving walking speed and endurance. Students with cerebral palsy who have difficulty walking, and who attend the Glenroy Specialist School are being asked if they would like to participate.

Investigation Procedures:

If you agree to participate in this study you will have your walking speed over 10m and your walking endurance over 10 minutes measured once at the beginning of the study, then 9 weeks later immediately after your walking programme, and then 3 months later. In addition, if you are aged 9 years or more you will be asked to complete a short questionnaire to measure what you think about your quality of life. These assessments will take about 45 minutes to complete. Each testing session will be done in a quiet area at the Glenroy Specialist School.

Following the first testing session, you will be randomly allocated to either the treadmill training or to the usual walking training group. This means that you will be allocated to one of these groups using a method that is out of the control of either the researchers or yourself.

People in the treadmill training group will be asked to attend two, 30 minute sessions of treadmill training a week for nine weeks under the supervision of a trained therapy assistant. The trainer will monitor your performance and record how long each session was, how fast you walked and how far you walked.

If you are allocated to the traditional walking training group you will also be asked to attend two, 30 minute sessions of walking practice a week for nine weeks under the supervision of a trained therapy assistant. If you are in this group you will not use the treadmill at all.

Possible risks of participating in this study:

The trainers will carefully supervise your program to reduce the risk of injury whichever group you are allocated to. As with any walking training program, there is a very small risk that you could fall during training. However, the risk is very small and if you are on the treadmill you will have the protection of a harness to help keep you standing up. If you experience distress due to the exercise you may choose to discontinue the program at anytime.

Possible benefits of participating in this study:

It is thought that participants who participate in this study will improve their walking speed and endurance, and that these changes might also improve your quality of life and your performance of physical activities. If the results show that walking was improved using the treadmill training programme, this regime will also be available for other students at the Glenroy Specialist School and might also become available for other school students with cerebral palsy in other schools.

Use of information obtained from this investigation:

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. Your information will be coded so that it can not be identified except by the principal researchers. For the duration of the research your information will be kept in a locked cabinet that can only be accessed by the researchers. Upon completion of the research, your data will be stored in a research archive for 15 years as required by the National Health and Medical Research Council. After 15 years your information will be destroyed using a confidential information disposal service. If you give us your permission by signing the Consent Form, we plan to publish the results of this investigation in an international journal and to share the results with health professionals and teaching staff in Australia by reporting the findings at an international conference. In any publication, information will be provided in such a way that you cannot be identified.

If you agree, upon completion of this research you will receive a written summary of the research findings and you will also be provided with your own results. The summary will include the contact details for the principal researchers if you should require further information about the investigation.

Participation is voluntary:

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your tuition at the Glenroy Specialist School. Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

You have the right to withdraw from active participation in this project at any time and, further, the right to require that all traces of your participation are removed from the project records provided that this right is exercised within four weeks of the completion of your participation in the project. You are asked to complete the "Withdrawal of Consent Form" or to notify the investigator by e-mail or telephone that you wish to withdraw your consent for your data to be used in this research project.

Questions regarding this investigation:
Any questions regarding this project may be directed to the senior investigator involved in the study: Professor Karen Dodd, School of Physiotherapy, La Trobe University Victoria 3086, telephone 03 94795793 or email K.Dodd@latrobe.edu.au.

Other issues:
If you have any complaints or queries that the senior investigator has not been able to answer to your satisfaction, you may contact Ms Barbara Doherty Secretary, Faculty Human Ethics Committee, La Trobe University, Victoria, 3086, (ph: 9479 1794, e-mail: b.doherty@latrobe.edu.au).

Consent Form: Participant

A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRLA PALSY.

I ____ have read (or, where appropriate, have had read to me) and understood the information above, and any questions I have asked have been answered to my satisfaction. I agree to participate in the project, realising that I may physically withdraw from the study at any time and may request that no data arising from my participation are used, up to four weeks following the completion of my participation in the research. I agree that research data provided by me or with my permission during the project may be presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used.

Name of Participant (block letters):______________________________

Signature:____Date:_____________

Name of Investigator (block letters):______________________________

Signature:____________________________________Date:________________

REVOCATION OF CONSENT FORM: Participant

A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRAL PALSY.

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the Glenroy Specialist School.

Participant's Name (block letters):_________________________________

Signature:_______________________________________ Date:________

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Information and Consent Form: Parents/guardians

PROJECT TITLE: A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRAL PALSY.

INVESTIGATORS:

Professor Karen Dodd is a Professor and Head, School of Physiotherapy La Trobe University.
Ms Kate Willoughby is a physiotherapist with the Yooralla Society of Victoria
Dr Nora Shields is a lecturer in the school of Physiotherapy at La Trobe University

You and your child are invited to participate in a project titled 'A randomised controlled trial to determine the effects of a treadmill training programme for school aged children with cerebral palsy'.

Description of investigation:

This study is being done to find out if a treadmill walking training programme is better than a normal walking programme in improving walking speed and endurance. The parents of students with cerebral palsy who have difficulty walking, and who attend the Glenroy Specialist School are being asked if they would give permission for their child to participate.

Investigation Procedures:

If you agree for your child to participate in this study they will have their walking speed over 10m and their walking endurance over 10 minutes measured once at the beginning of the study, then 9 weeks later immediately after their walking programme, and then 3 months later. In addition, if your child is aged 9 years or more and you think they could understand, your child will be asked to complete a short questionnaire to measure what they think about their quality of life. These assessments will take about 45 minutes to complete. Each testing session will be done in a quiet area at the Glenroy Specialist School. Also you will be asked to fill in a short written questionnaire about what you think your child's quality of life is, this will take about 15 minutes to complete and we will ask you to do this three times. We will send the questionnaire home to you and you can return it to us in the stamped self-addressed envelope we will provide you with. In addition, your child's school teacher and physiotherapist will fill in a short questionnaire about your child's physical activity level at school three times.

Following the first testing session, your child will be randomly allocated to either the treadmill training or to the usual walking training group. This means that your child will be allocated to one of these groups using a method that is out of the control of either the researchers or yourself.

Children in the treadmill training group will be asked to attend two, 30 minute sessions of treadmill training a week for nine weeks under the supervision of a trained therapy assistant. The trainer will monitor your child's performance and record how long each session was, how fast they walked and how far they walked.

If your child is allocated to the traditional walking training group they will also be asked to attend two, 30 minute sessions of walking practice a week for nine weeks under the supervision of a trained therapy assistant. If your child is in this group they will not use the treadmill at all.

Possible risks of participating in this study:
The trainers will carefully supervise your child's programme to reduce the risk of injury whichever group your child is allocated to. As with any walking training program, there is a very small risk that your child could fall during training. However, the risk is very small and if your child is on the treadmill they will have the protection of a harness to help keep them standing up.

Possible benefits of participating in this study:

It is thought that participants who participate in this study will improve their walking speed and endurance, and that these changes might also improve their quality of life and their performance of physical activities. If the results show that walking was improved using the treadmill training programme, this regime will also be available for other students at the Glenroy Specialist School and might also become available for other school students with cerebral palsy in other schools.

Use of information obtained from this investigation:

Any information obtained in connection with this project and that can identify your child will remain confidential. It will only be disclosed with your permission, except as required by law. Your child's information will be coded so that it can not be identified except by the principal researchers. For the duration of the research your child's information will be kept in a locked cabinet that can only be accessed by the researchers. Upon completion of the research, your child's data will be stored in a research archive for 15 years as required by the National Health and Medical Research Council. After 15 years your child's information will be destroyed using a confidential information disposal service. If you give us your permission by signing the Consent Form, we plan to publish the results of this investigation in an international journal and to share the results with health professionals and teaching staff in Australia by reporting the findings at an international conference. In any publication, information will be provided in such a way that your child cannot be identified.

If you agree, upon completion of this research you will receive a written summary of the research findings and you will also be provided with your child's results. The summary will include the contact details for the principal researchers if you should require further information about the investigation.

Participation is voluntary:

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your child's tuition at the Glenroy Specialist School. Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

You have the right to withdraw from active participation in this project at any time and, further, the right to require that all traces of your child's participation are removed from the project records provided that this right is exercised within four weeks of the completion of your participation in the project. You are asked to complete the "Withdrawal of Consent Form" or to notify the investigator by e-mail or telephone that you wish to withdraw your consent for your child's data to be used in this research project.

Questions regarding this investigation:

Any questions regarding this project may be directed to the senior investigator involved in the study: Professor Karen Dodd, School of Physiotherapy, La Trobe University Victoria 3086, telephone 03 94795793 or email K.Dodd@latrobe.edu.au.

Other issues:

If you have any complaints or queries that the senior investigator has not been able to answer to your satisfaction, you may contact Ms Barbara Doherty Secretary, Faculty Human Ethics Committee, La Trobe University, Victoria, 3086, (ph: 9479 1794, e-mail: b.doherty@latrobe.edu.au).

Consent Form: Parent/Guardian

A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRLA PALSY.

I ____ have read (or, where appropriate, have had read to me) and understood the information above, and any questions I have asked have been answered to my satisfaction. I agree for my child to participate in the project, realising that I may physically withdraw my child from the study at any time and may request that no data arising from my child's participation are used, up to four weeks following the completion of my child's participation in the research. I agree that research data provided by my child or with my permission during the project may be presented at conferences and published in journals on the condition that neither my child's name nor any other identifying information is used.

Name of Parent (block letters):______________________________

Signature:____Date:_____________

Name of Investigator (block letters):______________________________

Signature:____________________________________Date:________________

REVOCATION OF CONSENT FORM: Parent/guardian

A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRAL PALSY.

I hereby wish to WITHDRAW my consent for my child to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the Glenroy Specialist School.

Parents's Name (block letters):_________________________________

Signature:_______________________________________ Date:________

APPENDIX P - Statement from co-authors confirming the authorship contribution of the doctoral candidate (Qualitative Study)

As co-authors of the paper titled:

> **Willoughby KL**, Shields N, Dodd KJ. School based treadmill training for young people with cerebral palsy: a qualitative study

and submitted on 1st November 2010 for consideration for publication by the journal *Disability and Rehabilitation*, we confirm that Kate Willoughby has made the following contributions:

- Conceptual design of the study
- Ethics application
- Coordination of data collection
- Data analysis and interpretation
- Leading the development and review of the final manuscript

Dr Nora Shields Signed Nora Shields Date 28/9/11

Prof Karen Dodd Signed Karen Dodd Date 28/9/11

APPENDIX Q - Information and Consent Form – Participant (Qualitative Study)

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Information and Consent Form: Participant

PROJECT TITLE: A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRAL PALSY.

INVESTIGATORS:

Professor Karen Dodd is the Associate Dean of the Division of Allied Health at La Trobe University.
Ms Kate Willoughby is a physiotherapist with the Yooralla Society of Victoria
Dr Nora Shields is a senior lecturer in the school of Physiotherapy at La Trobe University

You took part in a project called 'A randomised controlled trial to determine the effects of a treadmill training programme for school aged children with cerebral palsy'. We would like to invite you to tell us about your experiences of our project.

What you would be asked to do?

If you agree to take part you will be asked to talk with one of the researchers and tell them how you felt about the training programme. What you say will be recorded using a digital recorder.

Possible risks of taking part:

If you get anxious or worried about speaking to the researchers you may choose to stop the conversation at anytime.

Possible benefits of taking part:

We will use the feedback we get from all the participants to make the programme better for other students at Glenroy Specialist School and other schools where the children with cerebral palsy practise their walking.

What will be done with the information you give us?

Any information you give us as part of this project and that can identify you will be kept confidential by us. It will only be given out with your permission, except as required by law. Your information will be given a code so that only the researchers who are working on the project will know who you are. For the duration of the project your information will be kept in a locked cabinet that can only be opened by the researchers. When the project is finished, your information will be stored in a research archive for 15 years as required by the National Health and Medical Research Council. After 15 years your information will be destroyed using a confidential information disposal service. If you give us your permission by signing the Consent Form, we plan to write a report on the results of this project for an international journal and to share the results with health professionals and teaching staff in Australia by speaking about the project at an international conference. In any report, information will be given in such a way that the reader will not know who you are.

Taking part in the project is voluntary:

Taking part in any research project is voluntary. If you do not wish to take part you do not have to. If you decide to take part and later change your mind, you are free to stop taking part in the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your lessons at the Glenroy Specialist School. Before you make your decision, one of the people involved in the project will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent

Form only after you have had a chance to ask your questions and have been given satisfactory answers.

You have the right to stop taking part in this project at any time and, also, you have the right to ask us to destroy any information you gave us, provided that you tell us you want to stop taking part in the project within four weeks of you finishing taking part in the project. You are asked to fill out the “Withdrawal of Consent Form” or to tell the people who are doing the project by e-mail or telephone that you wish to stop taking part in the project.

Questions regarding this project:

Any questions regarding this project may be directed to the senior person involved in the study: Professor Karen Dodd, School of Physiotherapy, La Trobe University Victoria 3086, telephone 03 94795793 or email K.Dodd@latrobe.edu.au.

Other issues:

If you have any complaints or questions that the senior investigator has not been able to answer to your satisfaction, you may contact the Secretary of the Faculty Human Ethics Committee, La Trobe University, Victoria, 3086, (ph: 9479 3573, e-mail: n.humphries@latrobe.edu.au).

Consent Form: Participant

A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRLA PALSY.

I ____have read (or, where appropriate, have had read to me) and understood the information above, and any questions I have asked have been answered to my satisfaction. I agree to participate in the project, realising that I may physically withdraw from the study at any time and may request that no data arising from my participation are used, up to four weeks following the completion of my participation in the research. I agree that research data provided by me or with my permission during the project may be presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used.

Name of Participant (block letters):______________________________

Signature:____Date:_____________

Name of Investigator (block letters):______________________________

Signature:____________________________________Date:________________

REVOCATION OF CONSENT FORM: Participant

A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRAL PALSY.

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the Glenroy Specialist School.

Participant's Name (block letters):_________________________________

Signature:_______________________________________ Date:________

APPENDIX R - Information and Consent Form – Parent/Teacher/Therapist (Qualitative Study)

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Information and Consent Form: Parents/Therapists/Teachers

PROJECT TITLE: A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRAL PALSY.

INVESTIGATORS:

Professor Karen Dodd is the Associate Dean of the Division of Allied Health at La Trobe University.
Ms Kate Willoughby is a physiotherapist with the Yooralla Society of Victoria
Dr Nora Shields is a senior lecturer in the school of Physiotherapy at La Trobe University

Your child/ a child in your classroom took part in a project called ‘A randomised controlled trial to determine the effects of a treadmill training programme for school aged children with cerebral palsy’. We are now inviting you to tell us about your experiences of our project.

What you will be asked to do?

If you agree to take part, you will be asked to speak with one of the researchers and tell them how you felt about the training programme. The conversation will be recorded using a digital recorder.

Possible benefits and risks of taking part:

We will use your feedback to improve the programme for students at Glenroy Specialist School and other schools where children with cerebral palsy practise their walking. You may choose to stop the conversation at anytime.

Use of information obtained from this investigation:

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. Your information will be coded so that it can not be identified except by the researchers. For the duration of the research your information will be kept in a locked cabinet that can only be accessed by the researchers. Upon completion of the research, your data will be stored in a research archive for 15 years as required by the National Health and Medical Research Council. After 15 years your information will be destroyed using a confidential information disposal service. If you give us your permission by signing the Consent Form, we plan to publish the results of this investigation in an international journal and to share the results with health professionals and teaching staff in Australia by reporting the findings at an international conference. In any publication, information will be provided in such a way that you cannot be identified.

Participation is voluntary:

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision to take part or not to take part, will not affect your relationship with Yooralla or Glenroy Specialist School. Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

You have the right to withdraw from this project at any time and, further, the right to require that all traces of your participation are removed from the project records provided that this right is exercised within four weeks of the completion of your participation in the project. You are asked to complete the "Withdrawal of Consent Form" or to notify the investigator by e-mail or telephone that you wish to withdraw your consent for your data to be used in this research project.

Questions regarding this investigation:

Any questions may be directed to: Professor Karen Dodd, School of Physiotherapy, La Trobe University Victoria 3086, telephone 03 94795793 or email K.Dodd@latrobe.edu.au.

Other issues:

If you have any complaints or queries that the investigators have not been able to answer to your satisfaction, you may contact the Secretary, Faculty Human Ethics Committee, La Trobe University, Victoria, 3086, (ph: 9479 9573, e-mail: n.humphries@latrobe.edu.au).

Consent Form: Parents, Therapists and Teachers

A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRLA PALSY.

I ____ have read (or, where appropriate, have had read to me) and understood the information above, and any questions I have asked have been answered to my satisfaction. I agree to participate in the project, realising that I may physically withdraw from the study at any time and may request that no data arising from my participation are used, up to four weeks following the completion of my participation in the research. I agree that research data provided by me during the project may be presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used.

Name of Therapist/ Teacher (block letters):______________________________

Signature:____Date:_____________

Name of Investigator (block letters):______________________________

Signature:_____________________________________Date:________________

REVOCATION OF CONSENT FORM: Parents, Therapists and Teachers

A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECTS OF A TREADMILL TRAINING PROGRAMME FOR SCHOOL AGED CHILDREN WITH CEREBRAL PALSY.

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise my relationship with the Yooralla or Glenroy Specialist School.

Parent/ Therapist/ Teacher's Name (block letters):_________________________________

Signature:_______________________________________ Date:________