
Dayna Pool

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ABSTRACT

Aims

This thesis investigated the effects of daily, community-applied functional electrical stimulation (FES) to the ankle dorsiflexors during the swing phase of gait in children and adolescents with unilateral spastic cerebral palsy (USCP).

Methods/Results

Two studies were conducted that investigated the effect of FES in children between 5 and 18 years of age with USCP and a Gross Motor Function Classification System (GMFCS) and Winters Gage and Hicks classification of I or II. The first was a single subject ABA pilot study (n=12) designed to determine the acceptability and effect of FES on impairments of body structure and function, gait, pilot outcome measures and to establish sample size for an adequately powered randomised controlled trial (RCT). Results indicated that intermittent, short-term use of FES applied in the community was potentially effective for addressing ankle related impairments in body structure and function affecting gait in children with USCP. The pilot study highlighted the need for comprehensive measurements, particularly for the effects of FES on activity and participation. Hence the RCT was adequately powered and designed to address the limitations that were highlighted in the pilot study. Thirty-two children were matched by age and GMFCS level and then randomly assigned to the FES group (n=16, eight weeks of daily FES) and control group (n=16 usual treatments). Outcome measurements represented the domains across the International Classification of Functioning, Child and Youth Version (ICF-CY), assessed at baseline (week 0), post treatment (week 8) and follow-up (week 14). The primary outcome measures at the level of body structure and function: tibialis anterior strength and muscle volume. At the activity level: lower limb mechanics during gait, community mobility and high-level balance skills. Finally, at the participation level: performance and satisfaction in participant/parent identified performance problems. The secondary outcome measures included selective motor control, antagonist gastrocnemius strength and muscle volume, ankle and knee passive and dynamic range of motion and foot sensation. The results supported the efficacy of FES in gait in children with USCP in
addressing individual mobility related performance problems with clinically meaningful improvements in performance and satisfaction scores. FES in gait improved gait mechanics with elevated ankle dorsiflexion during swing to enable toe clearance that functionally reduced toe drag when walking. The high dosage of stimulation over the eight weeks (mean 6.2 hours SD 3.2 hours) increased muscle strength and volume of the ankle dorsiflexors. With the FES device removed, there was evidence of clinically meaningful improvements in spasticity, community mobility and high-level balance skills. These improvements were maintained by up to six weeks post treatment with participants remaining satisfied with the residual carry-over effects.

**Conclusion**

FES as an activity-based intervention improves ankle impairments in body structure and function, activity and participation when it is applied within a family centred, environmentally relevant context in children with USCP. The effects of FES on muscle strength and volume and ankle kinematics in gait are use-dependent. However once FES is removed, the improvement in spasticity, community mobility and balance skills are maintained for up to six weeks post treatment, suggesting the role of motor learning. This research provides NHMRC Level II evidence (Appendix A) supporting clinicians and families in choosing evidence-based interventions.
PUBLICATIONS AND PRESENTATIONS DURING DOCTORAL CANDIDATURE

Publications


**Presentations**

Free paper presentation based on Paper 4 at the World Congress International Society of Prosthetics and Orthotics, Lyon, 2015. **Winner for Best Paper in Advancing Technology**

Novel treatments in Rehabilitation: Cerebral Palsy Symposium 2015, Pathways to Possibilities *Perth*, 2015. **Invited Speaker.**


Free paper presentation based on Paper 1 at the Australasian Academy of Cerebral Palsy and Developmental Medicine, *Hunter Valley*, 2014. **Note:** Abstract was accepted but presentation withdrawn due to unforseen personal circumstances.

Activity Based Rehabilitation Lecture in children with neurological injuries, at the Training Centre in Subacute Care (or TRACS) conference, *Princess Margaret Hospital, Perth*, 2014. **Invited Speaker.**

Activity Based Rehabilitation Case Presentation on the use of Functional Electrical Stimulation using cloud reporting for a teenager with Transverse Myelitis at the Australian Faculty of Rehabilitation Medicine Conference *Sydney*, 2013. **Invited Speaker.**

Functional Electrical Stimulation: Theoretical Concepts and Applications in the paediatric setting. Graduate Diploma in Neurological Rehabilitation (Paediatrics), The University of Western Australia *Perth* 2012. **Invited Speaker.**
The physiotherapy management of dyskinetic cerebral palsy. Graduate Diploma in Neurological Rehabilitation (Paediatrics), The University of Western Australia 

*Perth 2012 and 2013 Invited Speaker.*

FES: To do or not to do? That is the question. Australian Physiotherapy Association Symposium *Perth 2012. Invited Speaker.*

**Workshop/Seminar Presentations**


Activity Based Rehabilitation Workshop (six workshops in total) on the application of Functional Electrical Stimulation in children with neurological injuries, at the TRACS conference, *Princess Margaret Hospital, Perth, 2013. Invited Speaker.*

STATEMENT OF CANDIDATE CONTRIBUTION

This is to certify that:

1. This thesis comprises only my original work towards the PhD.

2. Due acknowledgement has been made in the text to all other material used.

3. The thesis is less than 100,000 words in length, exclusion of tables, bibliographies and appendices.

4. The thesis reflects work done during the period of candidature.

5. I have used no part of this work for the award of another degree.

6. This thesis was conducted according to the Code of Conduct for Research.

7. The work involved in designing and conducting the studies described in this thesis was conducted principally by Dayna Pool. The outline and experimental design of the studies contained in the thesis were developed and planned by the candidate, in consultation with the supervisors. The candidate was responsible for all participant recruitment, along with the organisation and implementation of all data collection sessions.

8. The candidate was responsible for all data analysis and original drafting of all chapters contained within this thesis, as well as papers that have been published or are prepared for future publication arising from this thesis. All authors of papers that have been prepared for submission have been prepared for submission have given permission for works to be included within this thesis, acknowledging principle contribution of the candidate.

Dayna Pool

February 2016
The four papers from this PhD dissertation have been published in internationally recognised journals. These papers will be presented in this thesis in the same style and format found in the journal.
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This list is extensive but it is the only way it can be because I have had the privilege of being surrounded by the most outstanding and amazing people. This is my opportunity to thank you in print.

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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>2SD</td>
<td>Two standard deviation</td>
</tr>
<tr>
<td>4SST</td>
<td>Four Square Step Test</td>
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<tr>
<td>AAFO</td>
<td>Articulated ankle foot orthoses</td>
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<tr>
<td>ABR</td>
<td>Activity Based Rehabilitation</td>
</tr>
<tr>
<td>ACTRN</td>
<td>Australian clinical trials registration number</td>
</tr>
<tr>
<td>AFO</td>
<td>Ankle foot orthoses</td>
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<tr>
<td>ANCOVA</td>
<td>Analysis of covariance</td>
</tr>
<tr>
<td>ANOVA</td>
<td>Analysis of variance</td>
</tr>
<tr>
<td>ANZCTR</td>
<td>Australian and New Zealand Clinical Trials Register</td>
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<tr>
<td>ASAS</td>
<td>Australian Spasticity Assessment Scale</td>
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<tr>
<td>BoNTA</td>
<td>Botulinum Toxin Type A</td>
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<tr>
<td>CBMS</td>
<td>Community Balance Mobility Scale</td>
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<tr>
<td>CI</td>
<td>Confidence Intervals</td>
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<tr>
<td>Con</td>
<td>Control</td>
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<tr>
<td>CONSORT</td>
<td>Consolidated standards of reporting trials</td>
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<tr>
<td>COPM</td>
<td>Canadian Occupational Performance Measure</td>
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<tr>
<td>CP</td>
<td>Cerebral palsy</td>
</tr>
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<td>DP</td>
<td>Dayna Pool</td>
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<tr>
<td>ES</td>
<td>Electrical stimulation</td>
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<tr>
<td>FAFO</td>
<td>Fixed ankle foot orthoses</td>
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<tr>
<td>FES</td>
<td>Functional Electrical Stimulation</td>
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<tr>
<td>GMFCS</td>
<td>Gross motor function classification system</td>
</tr>
<tr>
<td>Hz</td>
<td>Hertz</td>
</tr>
<tr>
<td>ICC</td>
<td>Intraclass correlation co-efficient</td>
</tr>
<tr>
<td>ICF-CY</td>
<td>International Classification of Functioning Child and Youth Version</td>
</tr>
<tr>
<td>Kg</td>
<td>Kilograms</td>
</tr>
<tr>
<td>mA</td>
<td>Milliamps</td>
</tr>
<tr>
<td>MVPA</td>
<td>Moderate to vigorous physical activity</td>
</tr>
<tr>
<td>NC</td>
<td>No change</td>
</tr>
<tr>
<td>NGST</td>
<td>Neuronal group selection theory</td>
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<tr>
<td>NHMRC</td>
<td>National Health Medical Research Council</td>
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<tr>
<td>NMES</td>
<td>Neuromuscular electrical stimulation</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td>NS</td>
<td>Non significant</td>
</tr>
<tr>
<td>OGS</td>
<td>Observational Gait Scale</td>
</tr>
<tr>
<td>PMH</td>
<td>Princess Margaret Hospital for Children</td>
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<tr>
<td>PND</td>
<td>Percentage of non-overlapping data</td>
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<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
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<tr>
<td>ROM</td>
<td>Range of motion</td>
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<tr>
<td>Rx</td>
<td>Treatment</td>
</tr>
<tr>
<td>SCALE</td>
<td>Selective Control Assessment of the Lower Extremity</td>
</tr>
<tr>
<td>SE</td>
<td>Standard error</td>
</tr>
<tr>
<td>SMC</td>
<td>Selective motor control</td>
</tr>
<tr>
<td>TCCP</td>
<td>The Centre for Cerebral Palsy</td>
</tr>
<tr>
<td>TES</td>
<td>Therapeutic Electrical Stimulation</td>
</tr>
<tr>
<td>μs</td>
<td>microseconds</td>
</tr>
<tr>
<td>USCP</td>
<td>Unilateral spastic cerebral palsy</td>
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<tr>
<td>WGH</td>
<td>Winters Gage and Hicks</td>
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1  PREFACE

The challenge and responsibility for clinicians is to implement effective best practice treatments by critically evaluating the available evidence (Novak et al., 2013). This is important not only because services are often limited in terms of intensity to deliver the required dosage, but also limited across the lifespan with less services delivered with increasing age (Moll & Cott, 2013). Of even greater importance, and at the centre of this pursuit to implement better research and clinical practices, are the children and families who are faced with the burden of making decisions on effective treatments within the context of a lifelong condition.

The availability of social media support networks, personal blogs and Facebook® pages documenting personal experiences, successes and therapy sessions, provide a wealth of information and support for many families. However, amongst all of this information is also the potential for misinformation. Families who engage in their own research need guidance and support from their therapy team to select the most appropriate, safe, evidence based treatments with cost effective services for their child. This in part describes a family centred approach that is based on family set priorities through the facilitation of honest and evidence based discussions (Novak et al, 2013).

Using functional electrical stimulation (FES) whilst walking is not particularly new or original. It was first reported in 1961 by Liberson and colleagues who identified that FES during gait in persons with stroke was effective to improve toe clearance when walking (producing what is known as an orthotic effect) and even demonstrated an ongoing effect (known as a therapeutic effect) when the device was removed (Liberson et al., 1961). Implementing this in children with CP has not been an easy process. There have been many factors to consider and questions to ask along the way. Firstly, muscle electrical stimulation may be quite uncomfortable and therefore not tolerated by many children – so how could this be used in a paediatric population? Secondly, CP is a heterogeneous condition affecting multiple body segments, so which muscles are the most appropriate to stimulate to provide the best outcome? Finally, the parameters of treatment need to be defined and this includes identifying the length of treatment, the setting i.e.
home or during therapy and whether it should be incorporated into function or used more as a strength-training aide (Caurough et al., 2010).

To address these questions, equipment appropriate for use with children is essential. In the past, strategies were needed to manage the wires that connect the electrodes with the main device. These wires were often secured in a pocket or on a belt (Durham et al., 2004; van der Linden et al., 2008) and were described to be cumbersome, limiting regular use. The method of securing electrodes on the leg was also difficult. As such, protocols required children to be placed in a standardized position so that the electrodes could be safely secured. The trigger for the onset of electrical stimulation was also challenging and therapists described protocols to manually trigger the required timing (Carmick, 1995; Comeaux et al., 1997). Some clinicians trialled the use of surgically implanted electrodes to address many of these issues (Johnston et al., 2004; Merrill, 2009; Pierce et al., 2004; Stackhouse et al., 2007). However, this approach is not readily available and therefore not a viable option for many children and clinical practices. Consequently surface applied electrical stimulation remains the best option for many clinicians. Though there have been many questions and limitations since 1961, paediatric researchers have continued to explore this area because of its potential for functional and therapeutic benefit.

Fortunately, new technologies and equipment have emerged onto the commercial market. At present, there are two readily available Therapeutic Goods Act approved devices on the market in Australia. One such device has surface electrical stimulation activated or triggered by a heel sensor. However this device was not chosen for our studies because of the prevalence of equinus gait patterns in children with CP limiting the effectiveness of the heel sensor. The Walk Aide® is another device that is currently available that delivers surface electrical stimulation during gait. A patented tilt sensor triggers the stimulation to occur just after toe-off and ceases just after heel strike. The wires are hidden and encased within a cuff that is secured onto the leg just under the knee. The Walk Aide® first came onto the market in 2006 and was originally designed for addressing drop foot in adults with neurological injuries. For this population, studies have since confirmed the efficacy of its use as an orthosis, with evidence of central cortical
changes and continued improvement even with the Walk Aide® removed (Everaert et al., 2010; Stein et al., 2010; Thompson et al., 2006).

The origin of this thesis was based on my clinical experience as a physiotherapist at The Centre for Cerebral Palsy - a community non-government organisation in Perth, Australia. In 2010, an assessment kit and several Walk Aides® were purchased and over a two year period, this device was used with 10 children having either unilateral or bilateral presentations of CP. We observed clinical evidence of its effectiveness. Children and their families were also pleased with the outcome and children were fascinated with seeing their foot move even when the Walk Aide® was removed. In some cases, children did not tolerate the sensation and this led us to explore methods of introducing the stimulation and our responsibility in understanding the parameters that were needed to increase comfort, tolerability and compliance. Teenagers provided valuable feedback about what they felt and what they thought the Walk Aide® was doing. They even described the elimination of pain in their legs and back – a problem they had thought was non-negotiable and simply, just part of having CP.

As families began to pursue avenues of fundraising to purchase this device, it became increasingly clear that best quality research to support evidence based practice was required to substantiate these reports and clinical observations to ensure responsible use of limited funds. If FES proves to be beneficial, then it needs to be quantified with protocols in place for use in clinical practice. However, if FES proves to be ineffective, then this also needs to be documented so that the possibility of newer and more effective interventions can be pursued.
INTRODUCTION

2.1 The Problem: Is Functional Electrical Stimulation an effective treatment for children with unilateral spastic cerebral palsy?

Cerebral palsy (CP) is the most common life long physical disability of childhood, caused by non-progressive damage to the developing brain (ACPR, 2009). Unilateral spastic CP (USCP) indicates that one side of the body is mainly affected and is the most common presentation of CP (ACPR, 2009). Children with USCP are able to walk without restrictions but typically have problems with equinus during gait. As such, children may have limitations walking on uneven surfaces or crowded spaces, along with limitations in high-level gross motor skills (Palisano et al., 2008). These limitations are attributed to common impairments in body structure and function, which include a combination of muscle weakness, muscle atrophy, spasticity, contracture and poor selective motor control (SMC) (Graham and Selber, 2003). To alleviate or manage these problems as well as to improve the capacity to participate in daily life situations, evidence-based treatments are essential.

Functional electrical stimulation (FES) applied during gait is a treatment technique that has the potential to address the common problems associated with equinus gait patterns in children with USCP. It refers to the electrical stimulation of muscles that cannot be activated effectively by the patient when performing a functional motor task (Merrill, 2009). FES has been implemented in the adult stroke population with documented improvements in toe clearance during gait (known as an orthotic effect) as well as evidence of an ongoing effect even with the removal of FES (known as the therapeutic effect) (Stein et al., 2010). Evidence supporting the use of FES in CP has so far been quite varied. In fact, it is not conclusively clear whether or not it is actually effective in improving outcomes. From what we have so far, FES as a treatment is promising with some studies reporting improvements in strength, muscle size, range of motion and gait (Damiano et al., 2013; Hazlewood et al., 1994; Nunes, et al., 2008; Seifart et al, 2010). However, most studies have either been inadequately powered, without control groups or have focused largely on the effect on body structure and function impairments rather than in the execution of tasks or participation in life situations. As such, FES as a treatment...
applied during gait is only cautiously advocated for children with CP and labelled as a “yellow light” intervention (Cauraugh et al., 2010; Chiu & Ada, 2014; Kerr et al., 2004; Seifart et al., 2010; Wright et al., 2012; Novak et al., 2013)

2.2 Significance and Purpose of the Thesis

The “yellow light” (Novak et al., 2013) indicates inconclusive evidence for the use of FES in children with CP putting forward the need for rigorous controlled studies with homogenous samples and comprehensive outcome measures. Such studies would likely impact the confidence in the estimate of effect of this intervention to provide the evidence required for informed practice (Novak et al., 2013). The proposed series of papers aims to substantiate and advance the knowledge concerning the orthotic and therapeutic effects of surface lower limb FES on all levels of the International Classification of Functioning – Child and Youth (ICF-CY) version in children with USCP. The thesis will explore and examine the effect of community, daily-applied FES by building on current recommendations on the use of FES in children with an activity-based approach. Results from these studies will support evidence-based practices for clinicians and families to ultimately provide best practice guidelines.

The essential questions to be addressed are:

1. What are the orthotic effects of FES on impairments in body structure and function, activities and participation?

2. What are the therapeutic effects of FES on impairments in body structure and function, activities and participation?

2.3 Synopsis of the Thesis

A synopsis of the thesis is outlined in the concept map (Figure 1). Two studies will be conducted to answer the essential questions. The first will be a pilot study that will enable a better understanding of the FES in terms of the practical application in the community, parameters, length of treatment and tolerability in this population. It will also provide an opportunity to pilot key clinical measures and enable a power calculation for a more comprehensive randomised controlled trial.
The second will be a randomised controlled trial that will determine if FES treatment significantly improves outcomes on a comprehensive set of outcome measures across the ICF-CY when compared to usual or conventional treatments. The key theme throughout the papers will be the translation to community clinical practice. Hence, most of the measures will be those that are easily accessible for clinicians in the community.

This thesis is presented as a series of papers. A literature review will provide an overview of the topic (Chapter 3) followed by four papers that will be presented in Chapters 4 through to 8. Chapter 9 will bring together the results from the studies and provide recommendations for clinicians and directions for future research.

2.4 Aims and Hypothesis

Pilot Study: Single Subject Design


Aims

1. To investigate the acceptability of FES in children with USCP.

2. To estimate the magnitude of change of FES on ankle selective motor control, range of motion, strength, gastrocnemius spasticity, gait patterns and balance during the eight week intervention and six week follow-up period when compared to baseline.

3. To investigate if FES reduces the incidence of tripping or toe-drag and falling during the eight weeks of intervention as well as during the six week follow-up.

4. To pilot the outcome measures to be used in the randomised controlled trial.

5. To collect data for a power calculation to establish sample size for the randomised controlled trial.
Hypotheses

1. Eight weeks of FES will improve ankle dorsiflexion strength, selective motor control, range of motion, gastrocnemius spasticity, balance and gait with a reduction in toe drag and falls in children with USCP.

2. Improvements in ankle dorsiflexion strength, selective motor control, range of motion, gastrocnemius spasticity, balance and gait with a reduction in toe drag and falls will be maintained in the 6-week follow-up period compared to baseline.

Randomised Controlled Trial

Paper 2: Daily functional electrical stimulation during everyday walking activities improves performance and satisfaction in children with unilateral spastic cerebral palsy: a randomized controlled trial

Aims

1. To determine whether FES is effective in improving individually identified mobility performance problems in children with USCP.

2. To explore the mobility performance of children with USCP employing the International Classification of Functioning Child and Youth version (ICF-CY) framework.

Hypotheses

1. Eight weeks of FES treatment will address individually identified priorities with higher performance and satisfaction scores on the Canadian occupational performance measure (COPM) in the children receiving FES treatment compared with controls not receiving FES.

2. Children who received FES treatment will continue to have higher performance and satisfaction scores at follow-up compared with controls not receiving FES.
**Paper 3:** Community-based Neuromuscular Electrical Stimulation assisted gait increases muscle strength and volume in children with unilateral spastic cerebral palsy: a randomized controlled trial.

**Aims**

1. To determine the effect of daily community applied FES to the ankle dorsiflexors during gait in children with USCP on muscle volume and strength.

**Hypotheses**

1. Children who received eight weeks of FES treatment will demonstrate greater increase in ankle dorsiflexion strength and muscle volume compared to controls without FES.

2. Children who received eight weeks of FES treatment will maintain the muscle hypertrophy and strength improvements at the six-week follow-up compared to controls without FES.

**Paper 4:** The orthotic and therapeutic effect following daily community applied functional electrical stimulation in children with unilateral spastic cerebral palsy: a randomised controlled trial.

**Aims**

1. To determine the orthotic and therapeutic effect of daily community applied FES to the ankle dorsiflexors on gait (ankle kinematics and temporal-spatial parameters) and community mobility.

**Hypotheses**

1. Children who received eight weeks of FES treatment will demonstrate an orthotic effect in gait with improved lower limb kinematics (elevated dorsiflexion during the swing phase of gait) during the gait cycle compared to controls without FES.
2. After the removal of FES, children who were in the FES treatment group will demonstrate a therapeutic effect with improved lower limb mechanics and better community mobility and balance scores compared to controls without FES.

2.5 Delimitations

Both studies will be delimited by the inclusion of children aged five to 18 with USCP, GMFCS level and Winters Gage and Hicks classification of I and II who have not had orthopaedic surgery in the past 12 months. For those who do receive botulinum toxin type A (BoNTA), timing of FES commencement will be dictated by current clinical care i.e. six monthly injections. Baseline measures will commence at three months post injections. By doing so, the effect of spasticity reduction from BoNTA will be at it’s lowest (De Paiva et al., 1999; Love et al, 2001) so that the response to FES treatment can be better isolated. Further, the 14-week study period will not significantly delay the next round of injections. The Walk Aide® is a single channel stimulator so it only stimulates the common peroneal nerve for ankle dorsiflexion activation. The effect therefore of the applied intervention will be equally assessed for all participants in the treatment group.

2.6 Limitations

The heterogeneous presentation of CP requires an individualised approach for FES parameters to ensure accurate muscle stimulation and tolerance to stimulation so the intervention cannot be completely standardized. Protecting foot integrity particularly the foot prepositioning for initial contact will be carefully considered. Hence each patient will have a different degree of dorsiflexion generated by FES to ensure that the foot is not brought into an everted position prior to heel contact. Generalizability of results assumes a similar degree of professional assistance in setting up the device. Each individual however, will be affected by his or her own individualised environmental and personal factors and this may not be quantifiable. These studies will be community based so although participants will be asked not to participate in new sporting activities over the study period we will not however, be able to control the school curriculum for physical education.
2.7 Ethics

Ethics approval was obtained from the Human Research Ethics committee of Princess Margaret Hospital and The University of Western Australia (Appendix B). Both Study 1 and Study 2 were registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR) (Appendix B).

2.8 Funding Support

The Cerebral Palsy Foundation supported Study 1 and The Princess Margaret Hospital Foundation supported Study 2. Orthopedic Appliances Pty Ltd (OAPL) donated ten Walk Aides® to The Centre for Cerebral Palsy that were subsequently used for both studies. OAPL had no input or role in data collection, analysis and presentation.
Figure 1. Concept map of thesis structure, main aims and conclusions derived from studies.
3 LITERATURE REVIEW

3.1 Cerebral Palsy

Cerebral palsy (CP) is the most common cause of physical disability in children, affecting between 2.0 and 2.5 per 1000 live births (Reddihough & Collins, 2003). Put simply, one child is born with CP every 15 hours in Australia (ACPR 2009). CP does not describe a single entity; rather it is an umbrella term that is used to describe a group of motor dysfunctions caused by non-progressive damage to the developing brain (Rosenbaum et al. 2007). The known causes of CP refer to the timing of the brain lesion, that being, prenatal, perinatal or post-natal.

The common prenatal causes typically involve congenital malformations, maternal infections and vascular events. Perinatal causes commonly involve problems during labour or delivery whilst post-natal causes are acquired, usually because of infection or accidental injuries such as motor vehicle accidents or near-drowning events (Colver et al., 2014; Reddihough & Collins, 2003). Cranial magnetic resonance imaging (MRI) is a standard imaging diagnostic procedure for CP. These images show that in 42.5% of known cases, brain lesions involve white matter damage. Other lesions involve the basal ganglia (12.8%), cortical and subcortical areas (9.4%), malformations (9.1%) and focal infarcts (7.4%). Normal MRI findings are also reported in children with CP (Bax et al., 2006). The causes in many cases are unknown but there is an associated increased risk with premature babies, multiple births and low birth weight (ACPR 2009).

The latest definition reflects the increasing understanding that CP is not merely limited to just a motor disorder. Non-motor disturbances are also usually present and can influence the ability to perform tasks of daily living. Hence the international consensus for the definition of CP is as follows:
“Cerebral palsy 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 fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, perception, cognition, communication, and behaviour, by epilepsy, and by secondary musculoskeletal problems”

(Rosenbaum et al. 2007 Pg 9)

This definition highlights the complexity and the heterogeneity of CP and as a term itself, it is not particularly useful. As such, CP can be classified using multiple methods in an attempt to better describe the clinical presentation as well as to provide a common language amongst clinicians.

3.2 Classification of USCP by Movement Disorder

CP is the most common cause of upper motor neurone syndrome in children. Consequently the clinical features that are observed can be described as having both positive and negative signs (Graham & Selber, 2003; Love et al., 2010). Sanger et al. (2006) defined positive signs as “those that lead to involuntary increased frequency or magnitude of muscle activity, movement or movement patterns” (pg 2160). Positive signs include hypertonia (this encompasses spasticity, dystonia and rigidity) dyskinesias, hyper-reflexia, clonus and co-contraction (Graham & Selber, 2003). Spasticity is one form of hypertonia (Sanger et al., 2003) and is the most common presentation accounting for nearly 86% of known CP cases between 1993 and 2003 in Australia (ACPR, 2009). Other positive signs may co-exist with spasticity but do account for a smaller proportion of the population with CP. Distinguishing between the different forms of hypertonia can be challenging but it is clinically important to do so as treatments may vary. The main distinguishing element of spasticity from other forms of hypertonia is that it occurs when “resistance to externally imposed movement increases with increasing speed of stretch and varies with the direction of joint movement” and/or when “resistance to externally imposed movement rises rapidly above a threshold speed or joint angle” (Sanger et al., 2003 pg e91). Hence, it has a significant impact on functional
mobility. Spasticity is usually present with the negative signs and this combination will determine an individual’s capacity for functional mobility (Sanger et al., 2006).

Negative signs describe poor muscle activity and control. They are clinically observed as weakness, poor balance, loss of selective motor control and sensory deficits (Graham & Selber, 2003; Sanger et al., 2006). Negative signs can greatly impact motor function because they cannot be managed by pharmacological or medical interventions. The combination and the extent to which both positive and negative signs coexist will not only determine functional mobility capacity but also the musculoskeletal presentation (Rodda et al., 2004). The musculoskeletal presentation represents the progressive aspect to CP. This includes muscle shortening and contracture, bony torsion, joint instability and degenerative arthritis (Graham & Selber, 2003).

3.3 Classification of Cerebral Palsy by Topography

Topographic descriptions of CP indicate the anatomical distribution of the neurological signs. Standardising a classification system continues to be challenging due to the complexity and heterogeneity of CP and though children may be broadly categorized by topography, variability continues to exist (Rosenbaum et al., 2007). The most common descriptions of anatomical distributions include hemiplegia, diplegia and quadriplegia. Hemiplegia indicates that one side of the body (including the upper limb, lower limb and trunk) is involved. Diplegia refers to bilateral lower limbs being predominantly involved with the possible mild inclusion of the upper limbs. Quadriplegia or “whole body” refers to involvement of all limbs and trunk (Rosenbaum et al., 2007). Whilst these terms broadly describe the areas of the body that are most affected, it remains somewhat subjective as the distinction between diplegia and quadriplegia for example, is dependent on how “severe” the upper limb involvement is (Gorter et al., 2004; Rosenbaum et al., 2007). For this reason, another hierarchical system for classifying topography has been proposed.

The Surveillance of Cerebral Palsy in Europe classification system offers an alternative method to standardise these clinical descriptions. With this classification system, spasticity limb distribution is noted as being either unilateral
or bilateral (SCPE, 2000). Other CP sub-types in this classification system include dyskinetic CP (either dystonic or choreo-athetotic), ataxic and non-classifiable. The CP sub—types are identified through a clinical decision tree as demonstrated in Figure 2.

![Clinical Decision Tree](image)

**Figure 2.** Cerebral sub-types clinical decision tree from SCPE (SCPE, 2007). Figure used with permission.

Spastic hemiplegia or USCP is the most common topographical presentation and accounts for 38% of cases in Australia (ACPR, 2009). White matter damage of immaturity occurs in over a third of children with USCP with other common MRI findings including focal infarcts and malformations (Bax et al., 2006). It is also acknowledged that unilateral presentations may not be purely unilateral and motor signs may also be observed on the “unaffected” side (Wiley & Damiano, 1998). It has therefore been recommended that neurological signs and topographical distribution descriptions also include a functional motor classification system (Rosenbaum et al., 2007).
3.4 **Classification of CP by Gross Motor Function**

The Gross Motor Function Classification System (GMFCS) developed in 1997 (and then expanded and revised in 2008) is a clinically valid five level grading system that describes the functional motor abilities for children aged over two years with CP (Palisano et al., 2008). A detailed description can be found in Appendix C. However, a brief description of each of the levels is as follows:

**Table 1.** Gross Motor Function Classification System levels described in brief (Palisano et al., 2008)

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Walks without restrictions, limitations in more advanced gross motor skills</td>
</tr>
<tr>
<td>II</td>
<td>Walks without restrictions, limitations walking outdoors and in the community</td>
</tr>
<tr>
<td>III</td>
<td>Walks with assistive mobility devices, limitations walking outdoors and in the community</td>
</tr>
<tr>
<td>IV</td>
<td>Self mobility with limitations, children are transported or use power mobility outdoors and in the community</td>
</tr>
<tr>
<td>V</td>
<td>Self mobility is severely limited, even with the use of assistive technology</td>
</tr>
</tbody>
</table>

The GMFCS in conjunction with topographical and predominant neurological descriptions provides a comprehensive clinical picture for clinicians facilitating inter-profession communication, research and intervention. Nearly 90% of children with USCP have high functional mobility with gross motor skills close to that of age matched typically developing children (Beckung et al., 2007; Gorter et al., 2004). The key feature here is that despite independent walking, there are limitations with activity skills such as running, jumping and safe community ambulation. Within the gross motor function classification for children with USCP, variability regarding gait patterns is still present because of differences in the extent of which spasticity, contracture, weakness, poor selective motor control and sensation that are simultaneously present. Gait pattern classification in children with USCP provides clinically meaningful information particularly regarding the impairments in body structure and function that affect mobility.

3.5 **Classification of USCP by Gait Patterns**

Gait is an efficient, controlled and coordinated process that moves the body forwards through a series of repetitive limb movements (Gage & Schwartz, 2009).
Normal walking has five main attributes which are (i) stability in stance, (ii) foot clearance in swing, (iii) prepositioning of the foot for initial contact, (iv) adequate step length and (v) conservation of energy (Gage & Schwartz, 2009). Meeting these requirements occurs through practice and refinement of skills through feedback and maturation of the central nervous system and musculoskeletal system (Koop, 2009). These attributes are impaired in children with USCP and can give the appearance of a limp whilst walking. Opportunities to practice and develop these skills are hindered in children with CP because of the influence of both positive and negative signs.

Altered gait patterns for people with USCP was first described by the Winters, Gage and Hicks (WGH) classification (Winters, Gage, & Hicks, 1987). The classifications highlight the main impairments on body structure and function. Hence distinguishing between the different gait patterns is useful to direct therapeutic intervention and medical management strategies. Four distinct patterns are identified ranging from sagittal involvement at the ankle only (Type 1) to sagittal involvement affecting the ankle, knee and hip (Type 4) (Winters et al., 1987). Children with Type I demonstrate excessive plantarflexion during the swing phase of gait or drop foot that is mainly due to weakness and poor activation of the ankle dorsiflexors (Rodda & Graham, 2001). Type II patterns are the most common gait presentation, characterised by excessive plantarflexion in stance (equinus) because of a combination of impairments including gastrocnemius spasticity and plantarflexion contracture (McDowell et al., 2008; Rodda & Graham, 2001; Winters et al., 1987). Stability in stance is reduced and the rocker motion in late stance is disrupted resulting in poor ankle power generation. Consequently, gait is inefficient largely because of the compensatory hip extensor moment that is required for limb progression (Riad et al., 2008). Clearance of the foot in swing and pre-positioning of the foot in terminal swing is also hindered because of poor ankle dorsiflexion selective motor control and muscle weakness (Riad et al. 2008, Winters et al., 1987). Type II gait patterns can be further categorized into 2 groups (Type IIa and Type IIb as shown in Figure 3) with the main distinguishing features occurring in mid to late stance (Rodda & Graham, 2001). Type IIa indicates that in mid to late stance, the knee is neutral with the hip extended. Type IIb indicates that the knee is hyperextended with the hip in extension in mid to late stance. This
distinction mainly accounts for the degree of gastrocnemius spasticity and contracture that is present (Rodda & Graham, 2001). Type III and IV gait patterns not only involve the characteristic features of Type II but also more proximal features with limited range of motion at the knee (Type III) and at the hip and pelvis (Type IV).

Common compensatory strategies are adopted usually to assist with limb clearance and prepositioning of the foot for stance. They include excessive hip flexion, knee flexion and anterior pelvic tilt (Winters et al, 1987). The consequences of these compensatory strategies are not well documented but may well contribute toward the deterioration in gait as well as pain reports in early adult years (Opheim et al., 2009).

The selection of management strategies adopted in each of the different gait patterns aim to address the problems associated with the body structure and function impairments (both the positive and negative signs) as well as the resultant compensatory strategies. This includes the use of AFO, pharmacological interventions and physiotherapy interventions.

Figure 3. Common gait patterns in USCP (spastic hemiplegia) according to Rodda and Graham (2001). Figure used with permission.

So far, the classification systems have been able to broadly describe topographical distribution of neurological signs, gross motor function and gait patterns. To summarise, spastic hemiplegia or USCP is the most common presentation of CP.
These children function at a GMFCS level of I or II and commonly have a Winters Gage and Hicks gait classification of Type IIa or IIb, indicating mainly ankle involvement. This information still does not reflect the heterogeneity even within these classifications and most importantly, the extent they impact on activity and life situations. The contributing factors toward the limitations in activity skills and participation in life situations for children with USCP is multifactorial and can extend beyond the body structure and function impairments. Contextual factors are also influential and this can be in either a positive or negative way. These influences are individually specific and include personal or environmental factors such physical terrains or environments, social support networks either at home, school or community and attitudinal factors such as self-esteem, self-consciousness or confidence. Any combination of these factors will influence a person’s capacity to execute tasks or participate in their community (World Health Organisation, 2007). For this reason, classification systems are also accompanied by more detailed analysis of the clinical presentation. This theoretical framework is known as the International Classification of Functioning, Child and Youth version (World Health Organisation, 2007)

3.6 Theoretical Framework on the Levels of Functioning for Children and Youth

The International Classification of Functioning, Disability and Health, Child and Youth Version (ICF-CY) provides a framework to facilitate a universal language to describe the effects of impairments on body structure and function, of activity limitations on tasks or actions, and their impact on participation restrictions in life situations (World Health Organisation, 2007; Jeglinsky et al., 2012; Stanger & Oresic, 2003). This framework suits clinical practice as it can also be used to set goals and direct intervention within the context of environmental and personal factors that affect activity and participation (World Health Organisation, 2007). The ICF-CY is currently considered to be the optimal framework for assessment, treatment and research for children with CP (Jeglinsky et al., 2012).

This framework (shown in Figure 4) will form the basis of the analysis of strength and difficulties that affect children with USCP with a GMFCS level of I and II and Winters Gage and Hicks gait classification of Type I and II and will now be
discussed in more detail. The ICF-CY will also provide a framework to determine how the intervention that will be investigated in this thesis affects each domain.

**Figure 4.** The International Classification of Functioning Child and Youth version domains (World Health Organisation, 2007)

### 3.7 Impairments in Body Structure and Function

#### 3.7.1 Selective Motor Control

Selective motor control (SMC) is one of the negative signs observed in CP. Recently, the impact of reduced SMC in children with CP has gained more recognition in the literature as a significant contributor to impaired motor function. The ankle joint is typically most affected in the lower limb (Fowler et al., 2010; Ostensjø et al., 2004; Zwaan et al., 2012). Poor SMC refers to an “impaired ability to isolate the activation of muscles in a selected pattern in response to demands of a voluntary posture or movement” (Sanger et al. 2006, pg 2162). Poor SMC coupled with under-activity of tibialis anterior – the prime ankle dorsiflexor, contributes to drop foot in the swing phase of gait (Boyd & Hays, 2001; Rodda & Graham, 2001; Wakeling et al., 2007) and can functionally result in tripping or falling whilst walking. Poor ankle dorsiflexion SMC may also directly influence stability of the leg whilst in the stance phase of gait affecting the contralateral limb during swing (Fowler et al., 2009).

The mechanism for poor SMC can be due to reduced central drive to tibialis anterior, relating to the corticospinal involvement in the periventricular white
matter area as observed in diagnostic imaging (Fowler et al., 2010; Galea, 2014; Petersen et al., 2013). Problems with co-activation or co-contraction can also contribute to poor SMC, particularly at the ankle joint where the agonist ankle dorsiflexors and antagonist ankle plantarflexors are activated at the same time (Wakeling et al., 2007). Co-contraction may become particularly evident when there is a clear intent to move the ankle into dorsiflexion but is hindered because of excessive antagonist activity during voluntary agonist contraction (Bandholm et al., 2009a; Bayle & Gracies, 2014; Stackhouse et al., 2005). This is attributed to impaired reciprocal inhibition and represents a very disabling form of muscle overactivity. Impaired reciprocal inhibition occurs when the antagonist muscle is not proportionately inhibited because of abnormal spinal and supraspinal circuitry (in particular the presynaptic mechanisms) (Bandholm et al., 2009a; Leonard et al., 2006; Mukherjee & Chakravarty, 2010). Failure to modulate inhibition to antagonist muscles reduces agonist force production and this is may be clinically observed as poor SMC and muscle weakness (Bandholm et al., 2009a; Mockford & Caulton, 2010).

Conservatively, problems with inhibition to the antagonist can be addressed or modulated through therapeutic interventions that involve repetitive and voluntary movements that move the joint through its available range of motion (Leonard et al., 2006). Pharmacological interventions to alleviate the over-activity of the antagonists through the use of BoNTA can also improve SMC (Boyd & Graham, 1999). Whilst the use of BoNTA may reveal a better ability to isolate movement, it does not fundamentally address the difficulties with generating adequate power and force for the movement to be functionally meaningful. Thus active treatments need to be implemented alongside BoNTA if problems with SMC are to be addressed.

3.7.2 Sensation and the impact on SMC

The impact of sensory deficits on motor function is now better recognised (Auld et al., 2012a; Cooper et al., 1995; McLaughlin et al., 2005), with neuroimaging demonstrating sensory tract dysfunction co-located with spasticity in some children (Hoon et al., 2002). Sensory impairments such as tactile deficits, poor proprioception, directionality and stereognosis have been reported for the upper
limb in children with USCP (Auld, 2012b; Cooper et al., 1995). Lower limb sensory impairments are rarely documented, limited to a few reports identifying sensory impairment in children with CP (McLaughlin et al., 2005; Tedroff et al., 2006). Sensation particularly relating to poor tactile sensation, proprioception and directionality can affect the ability to isolate joint movement and must therefore also be considered in children with CP. The importance of sensation was highlighted in a study that implemented a sensory stimulation program to the ankle dorsiflexors in a group of children with spastic CP. The results of the study revealed significant improvements in active movement of the foot, reinforcing the importance of sensation to mobility (Mäenpää et al., 2004). Physiotherapy treatments to address problems with SMC should also evaluate the role of sensation.

3.7.3 Muscle Dysfunction in Children with USCP

The mechanism for muscle weakness and impaired muscle growth in children with CP is multifactorial. Muscle dysfunction can be attributed to a combination of alterations or changes in normal muscle activation physiology including both neural and musculoskeletal components. The normal physiology will first be reviewed in brief.

3.7.3.1 Physiological Muscle Activation

The process of neural activation coupled with a muscle contraction is collectively called excitation-contraction coupling (Lieber, 2010). An action potential is the first stage of the excitation-contraction couple. It is induced by the exchange of sodium ions that enter the peripheral nerve whilst potassium ions leave. The action potential propagates orthodromically, in other words, the action potential is conducted in the normal direction down the peripheral nerve to arrive at the neuromuscular junction (Smith et al., 2013). The neuromuscular junction is composed of the presynaptic motor neuron and the postsynaptic muscle membrane and is the site of exchange involving the neurotransmitter acetylcholine and calcium. The acetylcholine that is released from the motor nerve diffuses and attaches to the postsynaptic muscle membrane through proteins known as SNAP and SNARE (Dolly & Aoki, 2006). Vesicular fusion of acetylcholine binding to the
muscle membrane results in depolarisation of the muscle fibre where an exchange of sodium and potassium ions occurs. The exchange of ions occurs once again causing an action potential to propagate but this time, through the muscle (Lieber & Smith, 2014). Muscles contain sarcomeres, which form the basic functional units of a muscle contraction. Each sarcomere is composed of interdigitating actin and myosin filaments. When the action potential propagates through the muscle, these filaments interact to form a cross-bridge (Lieber et al., 2014, Alhusaini, 2014). The cross-bridge is the active force generating structure in a muscle so the more these filaments overlap, the greater the force generation of the sarcomere (Alhusaini, 2014). This refers to the length tension relationship where achieving optimal sarcomere length enables the production of adequate muscular force. If a sarcomere is too long, then less overlap is possible - effectively reducing muscle force generation. Alternatively if the sarcomere is too short then the filaments are already overlapped making it mechanically impossible to overlap any further and this would also reduce muscle force generation (Lieber & Smith, 2014).

Relaxation of the muscle is equally as important and this occurs with a drop in calcium when neural activation ceases to block actin-myosin interaction (Lieber, 2010). This series of events occurs repeatedly and is timed so that impulses overlap with the summation of impulses generated to produce a greater muscular force. This is known as temporal summation and is responsible for regulating when the muscle fibres are active and relaxed (Lieber & Smith, 2014). A tetanic muscle contraction occurs when a motor unit is maximally stimulated by its motor neuron at a sufficient frequency to produce a smooth sustained contraction (Lieber, 2010). The individual muscle fibre activation is asynchronous in that they are not all switched on at the same time, rather they are timed through a complex series of commands by the central nervous system (Dean et al., 2007; Lieber, 2010). Normal physiological recruitment patterns are characterized by asynchronous recruitment of small fatigue resistant type I motor units followed by type II motor units – this sequence of recruitment is referred to as the Henneman’s size principle (Bergquist et al., 2011; Reed, 1997). Asynchronous recruitment ensures optimal efficiency by enabling motor units to cycle through periods of rest and activity to ensure that the muscle contraction is held for the desired task.
Physiological muscle activation is therefore a co-ordinated interaction between centrally driven commands and peripheral mechanical muscle properties.

### 3.7.3.2 Muscle Weakness in Children with USCP and its Influence on Activity Performance

Muscle weakness, in tibialis anterior and gastrocnemius are well documented features in CP (Rose & McGill, 2005; Stackhouse et al., 2005; Wiley & Damiano, 1998). It is defined as “the inability to generate normal voluntary force in a muscle or normal voluntary torque about a joint” (Sanger et al. 2006 pg 2161). As described in the Winters Gage and Hicks Type I and II classification, difficulties in foot clearance in swing suggest in part, ankle dorsiflexion weakness and poor push-off in stance indicating ankle plantarflexion weakness (Rose & McGill, 2005). Muscle weakness is usually also accompanied with reduced muscle volume in children with USCP (Barber et al., 2011; Bland et al., 2011; Lampe et al., 2006; Malaiya et al., 2007; Riad et al., 2012; Wiley & Damiano, 1998). Muscle weakness is clinically observed as impaired movement with reduced force production capacity that is largely influenced by reduced muscle volume, which is indicative of impaired muscle growth (Barrett & Lichtwark, 2010). The development of both volume and strength is activity dependent but this can be problematic for children with CP because activity is often reduced when compared to their age matched peers (Gough & Shortland, 2014).

Tibialis anterior in children with USCP produces only 22% of force when compared to their typically developing peers (Wiley & Damiano, 1998) with its cross sectional area reduced by nearly 40% (Damiano et al., 2013). The reported reductions in volume and strength impacts gait velocity and the degree of ankle dorsiflexion needed to avoid drop foot or equinus (Bandholm et al., 2009; Bland et al., 2011). It has also been determined to be the most important factor for gait speed, endurance and symmetry in adults recovering from a stroke (Ng et al 2012). Similarly, gastrocnemius is weak in children with USCP producing only 58% of the force when compared to their typically developing peers, with medial gastrocnemius volumes reduced by 22% to 35% (Barber et al., 2011; Malaiya et al., 2007; Wiley & Damiano, 1998). Gastrocnemius weakness and impaired growth affects the stance phase of gait by hindering how the limb prepares the body to
push off the ground in pre-swing in order to advance the foot forwards (McNee et al., 2009; Riad et al., 2008). Dynamically, the gastrocnemius and soleus ankle plantar flexor combination are needed for activities such as running and jumping, both of which may be limited if these muscles are not able to generate sufficient force. Weakness in the muscles that control the ankle during gait accounts for the compensatory strategies discussed previously for foot clearance (excessive hip, knee flexion and anterior pelvic tilt) and power generation (occurring at the hip instead of the ankle for forward progression) (Riad et al., 2008; Winters et al., 1987).

It is not conclusively clear why children with CP exhibit muscle weakness and reduced muscle volume. However, it seems likely to be due to a combination of primary central and maladaptive activity dependent changes affecting both peripheral and central mechanisms of normal muscle physiology (Gough et al., 2014). The first possible mechanism is reduced neural drive or input from the corticospinal tract to the spinal cord. This reduced neural drive decreases the necessary motor output that is required for maximal muscle activation that is required for ambulation (Galea, 2014). In other words, the motor neuron pool is not able to drive the required muscle activation for both tibialis anterior and gastrocnemius (Mockford & Caulton, 2010; Petersen et al., 2013; Rose & McGill, 2005). Secondly, motor unit recruitment patterns may be disorganised making muscle contractions inefficient and functionally less effective (Mockford & Caulton, 2010). Early onset fatigue is inevitable because a disordered pattern of recruitment is inefficient and will consequently reduce muscle force production. Finally, alterations in fibre type distribution as well as spastic fibre atrophy may also contribute to muscle weakness (Friden & Lieber, 2003; Rose & McGill, 2005; Rose et al., 1994). Although this remains controversial, alterations in muscle activation patterns may in part suggest muscle fibre transformation. Muscle fibre alteration or transformation is thought to occur in response to changes in the habitual use of muscles. Preliminary evidence suggested that gastrocnemius, which should be composed mainly of type II muscle fibres because it is needed for power in push-off in gait and running transforms to mainly type I muscles fibres in people with CP (Ito et al., 1996). This activity dependent fibre type transformation may be further compounded by fibrosis and adipose tissue within the muscle, effectively
reducing the volume of active contractile muscle (Johnson et al., 2009; Lieber & Smith, 2014). In summary, the combination of reduced central muscle activation drive, fibre type transformation, disorganised firing patterns, persistent antagonist co-contraction and impaired SMC reflect activity dependent changes that limit the ability for the agonist to generate sufficient torque and this is clinically observed as weakness (Gough & Shortland, 2014).

3.7.3.3 Muscle length contracture and its influence on muscle weakness

The combination of positive and negative signs result in muscle contracture or stiff muscles, limiting joint range of motion (Smith et al., 2011). Clinically, contracture is measured as reduced passive range of movement but it is not possible to know whether it is because of muscle or tendon properties. Muscle contracture presents as a significant functional issue as it impairs SMC, muscle strength and functional mobility (Barrett & Lichtwark, 2010). Gastrocnemius contracture is of particular significance in children with USCP and contributes to the problems with foot clearance during the swing phase of gait as well as the stability in the stance phase of gait (Winters et al., 1987). Contractures also limit the ability to absorb the elastic energy that is required for dynamic activities such as running and jumping (Hof et al., 2002; Sawicki et al., 2009).

The underlying mechanisms for muscle contracture in CP are also not well understood but it is clear that spastic muscles do undergo some structural related changes (Lieber et al., 2004). So far, research suggests that the main changes could be due to a complex interaction between increased sarcomere length and tension, muscle fibre stiffness and extracellular matrix stiffness (Lieber & Smith, 2014). These changes not only impact muscle length but also the ability to generate muscle force. These relationships are summarised in Figure 5.
Figure 5. Summary of the relationship between selective motor control, weakness and contracture.

In persons with CP, increased sarcomere length in spastic muscles have been documented without muscle fibre length changes despite the muscle being shortened and contracted (Lieber & Friden, 2002; Smith et al., 2011). This seemingly counter-intuitive finding suggests that there may be fewer “in-series” sarcomeres that are over-lengthened and placed under greater strain. The loss of “in-series” sarcomeres placed under tension may not only contribute to the poor capacity for force generation as noted earlier, but also contracture by creating a short normalised muscle fibre length. The role of muscle fibre alterations in contractures is not yet well understood with conflicting evidence reported in the literature. While one study documented that muscle fibres were twice as stiff in children with CP when compared to typically developing controls (Friden & Lieber, 2003) other authors have documented no alterations to muscle fibre stiffness (Smith et al., 2011).
The role and pathology of the extracellular matrix is also not well understood, however there have been some documented changes that demonstrate its influence on muscle contracture (Smith et al., 2011). The extracellular matrix is composed of connective tissue made up by endomysium (surrounding individual muscle fibres or cells), perimysium (surrounding muscle fascicles both along and across muscle fibres) and epimysium (surrounding the muscle). This connective tissue forms a fascia that connects the muscle to the bone and is responsible for force transmission from the muscle to the joint (Gillies & Lieber, 2011). The extracellular matrix in children with CP appear to have excessive collagen content and this could potentially contribute toward increased stiffness and perhaps also limiting muscle force transmission as a result (Booth et al., 2001; Smith et al., 2011).

Conservative management of range of motion is a large component of paediatric physiotherapy practice and the challenge is often in obtaining adequate dosage of treatments to reduce the persistent plantarflexion. It is likely that the management of muscle contracture is also activity dependent in that it needs to be addressed concurrently with muscle weakness and SMC.

3.8 Participation for Children with USCP

Participation, defined as involvement in a life situation (World Health Organisation, 2007), is increasingly recognized as one of the main focuses of rehabilitation as it seems to be intrinsically related to well-being and quality of life (Colver, 2009; Shikako-Thomas et al., 2012). Participation is often restricted due to environmental factors as well as mobility related issues even if children are classified as independent community ambulators (Livingston et al., 2007; Calley et al., 2012; Chiarello et al., 2010; Donkervoort et al., 2007; Pollock et al., 2014). These participation restrictions are apparent in children as well as in adults with CP especially when compared to the general population (Hilberink et al., 2007; Michelsen et al., 2009; World Health Organisation, 2007). Given that children with USCP mostly attend mainstream schools, the disparity between participation levels may be particularly evident as there is more potential to be compared to their peers in order to “keep up.” In fact regardless of severity, children with CP experience psychosocial consequences including lower self-esteem and self-
consciousness because of the visible nature of an altered gait appearance when compared with their peers (Wake et al., 2003). There is a growing body of literature describing priority areas of need in terms of participation restrictions in children with CP as a whole but there are no clear indicators on what is specifically important for school aged children with USCP. It is important for physiotherapists to understand the impact of these mobility related performance problems on participation. The specific participation needs of children with USCP can be easily overlooked due to their classification of independent community ambulators (Imms, 2008a; Michelsen et al., 2009). Recognition of each child’s participation goals will enable therapists to provide targeted intervention in an effort to close the gap between the known disparities in participation of children with CP compared with their peers (Imms, 2008b).

3.9 Common Treatments for Children with USCP

3.9.1 Physiotherapy

The challenge in clinical practice is to provide the optimal treatment at the optimal intensity dosage at the right time and to the right child (Franki et al., 2012; Scholtes et al., 2010). Gait retraining, treadmill training, task specific training, neurodevelopmental therapy, stretching, serial casting, neuromuscular electrical stimulation and strengthening are all therapies directed at improving body and structure functioning and activity performance (Gibson et al. 2007; Dodd et al. 2003; Scholtes et al. 2010; Pin et al. 2006; McNee et al. 2009; Novak et al. 2013; Cauraugh et al. 2010). Recent reviews have concluded that interventions targeting a specific domain of the ICF-CY may be effective at that domain but will have limited overflow into other domains – in other words, these interventions do not have an effect on more than one domain in the ICF-CY (Franki et al., 2012; Novak et al., 2013). This was the case with strength training; a foundation of physiotherapy practice where strength improvements have been found to not necessarily translate into functional mobility improvements (Scholtes et al., 2010; Taylor et al., 2013). These studies do not undermine the value of strength training, rather they highlight that strengthening represents just one component of physical rehabilitation. The term - Activity Based Rehabilitation (ABR) has come to the forefront recently forming the new direction of contemporary therapeutic
Interventions for children with CP. ABR or sometimes referred to as activity-dependent plasticity describes an intensive motor learning program that has been largely referenced in spinal cord injury literature (Dunlop, 2008; Sadowsky et al., 2013). It is often used to describe the use of patterned locomotor training such as gait training or cycling and non-patterned motor activation including task specific training and sensory stimulation to influence reorganisation and functional connectivity of the central nervous system. The principles of ABR imply a changeable central nervous system through targeted physical activity and graded sensory input (Dunlop, 2008) addressing aspects of motor performance that involve repetitious movements to develop and maintain neural structures and pathways (Damiano, 2006). When reviewing the literature for effective therapeutic approaches in CP it is not difficult to realize that these approaches actually describe ABR where therapists hope to influence movement patterns through activities that enable repetition and graded sensory input that is contextually specific and relevant (Franki et al., 2012; Novak et al., 2013). ABR reflects the basic mechanisms of motor learning, which can be simply described as first a stage of acquisition of skill followed by repetition that is both varied and intensive (Shepherd, 2014). Occupational Therapy interventions have led the way in establishing the efficacy of ABR for children with USCP in particular. These upper limb interventions include goal directed and functional therapies, bimanual training, context-focused therapy and constraint induced movement therapy (Novak et al., 2013). To note, these approaches involve cognitive engagement and are individually experience dependent processes (Damiano, 2006; Galea, 2014). It is often difficult to incorporate similar levels of cognitive engagement into repetitious lower limb movements that are cyclical in nature because they require minimal conscious effort (Damiano, 2006). Hence interventions that are focused on activity in real life situations and environments are more likely to be engaging and may possibly be an effective approach for children who are already ambulant. Exploring how the principles of ABR can be implemented to address mobility related performance problems specific to children with USCP is essential in the field of physiotherapy intervention and thus forms the basis of intervention that will be investigated in this thesis.
3.9.2 Botulinum Toxin Type A in the Management of Spasticity

BoNTA is often implemented alongside physiotherapy interventions to address lower limb focal spasticity in children with CP (Love et al., 2010). BoNTA reduces spasticity, co-contraction and improves range of motion and SMC to facilitate gross motor progression and quality of gait (Baird & Vargus-Adams, 2010; Boyd & Graham, 1999; Fazzi et al., 2005; Gibson et al., 2007; Love et al., 2001; Lukban et al., 2009; Yap et al., 2010). The efficacy of BoNTA to the gastrocnemius muscle is well established for the management of equinus to improve gait and is recommended for children with USCP with a Winters Gage and Hicks classification of Type II, III and IV (Graham & Selber, 2003; Love et al., 2010; Rodda & Graham, 2001). BoNTA induces a neuro-paralytic effect by blocking the binding of the acetylcholine vesicles to the plasma membrane of the motor endplate. This method of chemical denervation effectively blocks neurotransmission (Graham & Selber, 2003). The chemical effects of BoNTA are not sustained long term as original nerve endings are restored after around three months (De Paiva et al, 1999). BoNTA is hence a temporary treatment but the clinical effects may last anywhere between four and six months (Love et al., 2010). Repeat injections are recommended at six month intervals and clinically indicated with the return of spasticity (Love et al., 2010). Serial BoNTA needs to also be balanced with the known side effects that include muscle weakness and atrophy (Edgar, 2001; Schroeder et al., 2009; Williams et al., 2013). Therefore, it is recommended that BoNTA be used in conjunction with physiotherapy and orthotic intervention to ensure ongoing clinical and functional improvements (Love et al., 2010; Molenaers et al., 2010).

3.9.3 Orthotic Management for Children with USCP

Orthotic devices are externally applied devices that are commonly used for children with CP to improve standing and walking by modifying the structural and functional characteristics of the neuromuscular and skeletal systems (Brehm et al., 2011; Fatone, 2010; Wingstrand et al. 2014). For children with plantarflexor spasticity and contracture, AFO are used in conjunction with physiotherapy and BoNTA treatments to promote heel strike in the stance phase of gait, help with toe clearance during swing and to maintain ankle range of movement (Balaban et al., 2007; Buckon et al., 2001; Rodda & Graham, 2001; Romkes & Brunner, 2002;
The use of AFO to improve these gait parameters and prevent contracture needs to be balanced with concerns that AFO may impede power generation for effective push off (Buckon et al., 2001; Desloovere et al., 2006; Romkes & Brunner, 2002), limiting the ability to perform dynamic activities such as running and jumping. This is particularly relevant for high functioning children with CP as it may exacerbate the already reduced muscle volume and strength of the ankle plantarflexors (Lam et al. 2005; McNee et al. 2009; Barber et al. 2011; Autti-Ramo et al. 2006). Cosmesis and comfort also affect AFO acceptance in some individuals and this may be a contributor to reduced AFO use during adolescence (Beckung et al. 2007; Prosser et al. 2012; Woo 2001; Wingstrand et al. 2014). High quality evidence to support the use of orthoses is limited and whilst it appears to be effective on body structure and function, the long term effects as well as its effects on other domains of the ICF-CY remain unclear (Autti-Ramo et al., 2006; Figueiredo et al., 2008; Novak et al., 2013). Given the current state of evidence for orthoses and for children where AFO acceptance is of particular issue, alternate interventions that facilitate dorsiflexion during swing whilst allowing active plantarflexion at push-off need to be explored. The common treatments for children with USCP GMFCS and WGH I or II is summarised in Figure 6.

**Figure 6.** Summary of the ICF-CY and current treatments adopted for children with USCP
3.10 Motor Learning

Lesions to the developing brain result in substantial reorganisation and pruning of synaptic pathways. As a result, movement patterns are stereotyped and lack variation because they are practiced repeatedly (Shepherd, 2014). Children have a developing nervous system and there lies great potential for activity dependent cerebral plasticity thus offering a therapeutic window of opportunity (Eyre, 2007). To optimise motor performance, repetition and high activity are essential ingredients for strengthening synaptic transmission in a changeable brain (Johnston, 2009, Cramer et al., 2011). Opportunities to promote the acquisition and retention of new skills are also influenced by contextually driven factors. Therefore the role of family, school and peers within an activity-based rehabilitation paradigm are crucial to create an enriched environment to foster plastic changes (Law et al., 2011; Morgan et al., 2013).

The neuronal group selection theory (NGST) provides an essential framework for physiotherapists because it distinguishes between the development of primary and secondary repertoires of movement (Edelman, 1989). This theory forms the foundation to understanding the principles of motor learning and plasticity (Hadders-Algra, 2000a, 2000b). Primary repertoires represent motor behaviours derived from neuronal cortical and subcortical groups, selected by development and behaviour and reinforced by afferent/sensory information (Hadders-Algra, 2000a). With maturity, experience and practice, the strength of the synaptic connections between the neuronal groups is modified and selected to create secondary repertoires (Galea, 2014; Hadders-Algra, 2000a). The acquisition of secondary repertoires relies heavily on sensory input and experience of movement variation that is vital for the ability to adapt and respond to environmental cues (Hadders-Algra, 2000b). Therefore the context in which a new skill is learnt may be equally as important. This was highlighted in a study that investigated the effect of strength training versus motor skill training in 24 healthy adults. The results of the study suggested that strength training was effective for strength gains but it did not demonstrate corresponding plastic changes in the central nervous system when compared with skill or motor learning based interventions (Jensen et al,
According to the NGST, children with USCP already have many primary repertoires at their disposal but execution of the movement is often limited by impairments of body structure and function, that is, spasticity, poor SMC, muscle weakness, contracture and poor sensation as described earlier. Building on Figure 6, Figure 7 demonstrates this relationship as these impairments may limit the ability to practice, hindering synaptic modification and hence the development of secondary repertoires. As a result, children with USCP display limited adaptability and variability of movement and in doing so these habitual patterns are subsequently reinforced (Damiano, 2009; Galea, 2014). The deficit in movement adaptability consequently restricts the performance of activity and participation such as running, walking outdoors or walking on uneven surfaces due to the risk of tripping and falling.

**Figure 7.** Summary of the relationship between the ICF-CY and the NGST relevant to children with USCP.

In summary, children with USCP can develop secondary repertoires but require adequate practice, sensory input and an enriched environment (Hadders-Algra, 2000b; Morgan et al., 2013). The expansion of primary and secondary repertoires
requires the implementation of principles of motor learning. This means that treatments need to:

1. Be implemented as early as possible so that repertoires of movement can be expanded driving neuroplastic changes and not allowing maladaptive changes to occur (Hadders-Algra, 2000b; Yang et al., 2013, Damiano 2009).


3. Involve repetition with ample opportunities for active and incrementally challenging practice (Nielsen & Cohen, 2008; Sanes & Donoghue, 2000).

4. Be implemented in contextually relevant environments (Novak et al., 2013).

The integration of these principles within the ICF-CY model is essential. This ensures a family centred approach with specificity and targeted execution of treatment whilst mindful of the child’s environment, societal influences and family unit (Bamm & Rosenbaum, 2008; Jeglinsky et al., 2012; Löwing et al., 2011; Novak et al., 2013; Preston et al., 2011; Rauch et al., 2008; Stanger & Oresic, 2003).

The role of the paediatric physiotherapist is to set the stage to facilitate repetition with incremental challenges and the variability of movement that is required to develop these secondary repertoires (Fetters, 2010; Sanes & Donoghue, 2000). In order to achieve this, paediatric physiotherapists attempt to capitalize on the plasticity of the human body to promote activity and participation (Gannotti et al., 2014, Damiano, 2009). Dosing becomes important and this relies on ensuring adequate frequency, intensity, time and activity based therapies for both neuroplasticity and muscle plasticity (Gannotti et al., 2014).

3.11 Muscle Plasticity

Muscles are highly adaptive tissues and will respond to activity with increases in strength and growth and likewise to ageing, immobilization and disuse to result in weakness and atrophy (Narici & Maganaris, 2007; Psatha et al., 2012). As already
discussed, children with USCP have significantly reduced muscle strength and volume. Although it is not yet known whether these changes are secondary to disuse with delayed acquisition of secondary repertoires or whether they are primarily related to the cerebral lesion, muscle plasticity in response to activity has been shown to be possible. Progressive resistance strength training appears to be effective in increasing strength and muscle volume of gastrocnemius in children with spasticity (McNee et al., 2009). This evidence pioneers our understanding of muscle plasticity in children with CP without any adverse increases in spasticity. The authors also bring forth the need to consider the effect of reduced muscle volume in view of aging and its possible relationship with early loss of mobility. However, without a control group it is more difficult to distinguish between the effects of natural development or growth and treatment. Muscle electrical stimulation is another intervention that has demonstrated evidence of muscular changes with alterations documented in muscle volume, strength, fibre size and fibre type transformation post treatment (Maffioletti et al., 2006; Schiaffino et al., 2007; Stackhouse et al., 2007). These changes are of particular interest in people with neurological injuries because as noted earlier, muscle weakness in CP could be influenced by fibre type transformation (Ito et al., 1996). Further, there is evidence that people with spinal cord lesions have a near complete loss of type 1 slow twitch muscle fibres in tibialis anterior, which is thought to be due to disuse as a result of changes in habitual levels of activity (Grimby et al., 1976). The tibialis anterior muscle in children with USCP may also be subject to these transformations because it is also disused and weak. Tibialis anterior is typically a “slow” muscle, made up of approximately 70% type I slow twitch muscle fibres (Gregory et al., 2001). Hence it is designed to be able to repetitively activate with minimal fatigue, but this feature may not be possible for children with USCP. Therefore the potential for activity dependent changes to induce fibre type transformation through muscle electrical stimulation presents as a plausible treatment modality because of the effect this could have on muscle strength and growth in children with USCP (Gordin et al., 2011; Schiaffino et al., 2007).

In summary, muscle contracture, weakness and impaired growth are intimately related and influence motor function as summarized in Figure 5. These impairments are at the body structure and function level but reflect activity
dependent changes. Hence activity and repetition are essential ingredients to facilitate the development of muscle activation to in turn, stimulate growth. Appropriate activity also facilitates the maturational process of the nervous system in the development of secondary repertoires reinforcing the desired neural circuits and preventing immature pruning (Damiano, 2006). These activity-dependent changes emphasize the potential for neuroplasticity and muscle plasticity in children with USCP, and form one of the fundamental goals of therapeutic intervention.

3.12 Muscle Electrical Stimulation

Muscle electrical stimulation is a treatment modality that is often incorporated in neurological rehabilitation approaches to induce both neuroplastic and muscular changes (Sadowsky & McDonald, 2009, Sadowsky et al., 2013). Outside of neurological rehabilitation, muscle electrical stimulation has been used in sports medicine for injury recovery and strength conditioning (Maffiuletti, 2006) as well as orthopaedic medicine following long periods of immobilization or post anterior cruciate ligament reconstruction (Kim et al., 2010). Muscle electrical stimulation presents as a plausible treatment modality in children with CP because it is based on the principles of:

1. ABR in that it can be implemented directly to weak muscles as part of repetitious, high dose locomotor training to facilitate muscular changes.

2. Motor learning theories of NGST in that it provides the opportunity for repetition in contextually relevant environments for the development of secondary repertoires.

3. The theoretical framework of the ICF-CY as it has the potential to influence all domains whilst considering the individually specific personal and environmental factors.

Muscle electrical stimulation acts through the application of an electrical current to motor nerves to activate motor units (Kerr et al., 2006; Reed, 1997). Action potentials are induced by a closed electrical circuit created by the placement of two electrodes over the skin on the target muscle (Reed, 1997). A muscle
contraction occurs when an alternating current is applied to stimulate an intact lower motor neuron (Wright et al., 2012). Given that CP is an upper motor neuron disorder, the lower motor neurons should be intact, hence muscle electrical stimulation can be applied.

The literature describes three methods of muscle electrical stimulation employed in neurorehabilitation in children with CP. This includes:

1. Therapeutic Electrical Stimulation;
2. Neuromuscular electrical stimulation and when applied functionally is
3. Functional Electrical Stimulation.

3.13 Therapeutic Electrical Stimulation

Pape (1997) was the first to describe the application of therapeutic electrical stimulation or TES in children with CP. This form of electrical stimulation is characterized by low currents that do not elicit an active muscle contraction. The low intensity sub contraction current aims to minimise the discomfort that is usually associated with electrical stimulation (Sommerfelt et al., 2001). TES is hypothesized to increase blood flow during a period of heightened trophic hormone secretion (i.e. at night) to increase muscle volume. This hypothesis was not supported in Dali and colleague’s 2002 randomized double blind placebo controlled clinical trial. In this study, TES was applied to the quadriceps and tibialis anterior for six hours a night, six nights a week for 12 months in 57 participants with spastic diplegia CP aged between 5 and 18 years. No statistically significant increases in muscle size were reported. Additionally, TES has demonstrated no clinically or statistically significant effects on range of motion, spasticity, muscle size, strength and motor abilities such as gait and balance (Dali et al., 2002; Sommerfelt et al., 2001). TES is not an activity-based intervention and robust studies do not provide support of its effectiveness.

3.14 Neuromuscular Electrical Stimulation

Neuromuscular electrical stimulation (NMES) is primarily employed for muscle strengthening in children with CP. NMES is applied in standardized positions
where the muscle is taken through its target range even if there are problems with SMC. It closely mimics strength training in that muscles are activated to contract with pre-set on and off (rest) times. The use of surface electrodes is the most accessible form of NMES and is commonly used clinically. The use of percutaneous or implanted electrodes has also been investigated to avoid issues with sensation and discomfort. Stackhouse et al. (2007) applied this to a group of children with spastic diplegia who underwent a low repetition, high force contraction program targeting the quadriceps femoris and tricep surae muscles. Improvements in quadriceps strength and cross sectional area improvements were documented, providing further support of muscle plasticity in children with CP (Stackhouse et al., 2007). Although these are promising results, percutaneous NMES is not readily available or accessible, hence the use of surface electrodes dominates the literature and clinical practice. The mechanisms for improving strength is based on the overload principle by increasing muscle cross sectional area and improving the synaptic efficiency of the target muscle (Reed, 1997). The literature describes NMES being applied to a variety of upper and lower limb muscles but with a wide range of different stimulation parameters comparisons and generalizations are more challenging. As such, results are varied but typically, improvements in range of movement, reduction in spasticity and improvements in strength have been documented (Kerr et al., 2004; Wright et al., 2012). Further, the literature is dominated by case reports and uncontrolled studies often with a limited selection of valid and reliable outcome measures. Recent systematic reviews have focused on the application of NMES on the lower limb only due to the scarcity of upper limb applications. These reviews have concluded that NMES could not be adequately supported nor discarded as a treatment option for children with CP. The reviews noted that many of the studies tested and applied NMES within gait laboratory conditions rather than at home or in the community. This limits the potential for NMES to be a viable treatment tool beyond standardised clinical conditions (Cauraugh et al., 2010; Kerr et al., 2004). Of the handful of controlled studies, the improvements in strength and range of motion following NMES did not translate to improvements in gait (Hazlewood et al., 1994; Kerr et al., 2006; van der Linden et al., 2003). This further supports the poor “over flow” effect from body structure and function improvements to activity functioning following therapeutic
interventions (Novak et al., 2013). NMES provides specificity of intervention to induce muscular changes, but it does not meet the motor learning needs because it is not activity based or context specific.

3.15 Functional Electrical Stimulation

The combination of NMES and task specific activity meets the requirements of an activity-based intervention and is referred to as Functional Electrical Stimulation (FES) (Alon, 2006; van der Linden et al., 2003; van der Linden et al., 2008). FES has long been utilised in rehabilitation to address drop foot in the adult stroke population (Liberson et al., 1961; Stein et al., 2010). There are a limited number of studies that have applied FES (synchronised application of NMES within a functional task) in children with CP. Synchronising NMES with functional movement is particularly challenging for the upper limb hence the settings are usually more cyclic in nature with pre-set on and off periods (i.e. as described earlier for NMES) (Wright & Granat, 2000; Wright et al., 2012). The application of FES is more feasible in gait due to the more predictable and repetitive nature of a gait pattern that can be triggered by predictable events such as a heel strike. Of the studies using FES in CP, FES is well tolerated (Meilahn, 2013; Prosser et al., 2012) with improvements in active and passive range of movement, (Carmick, 1993; Carmick, 1995) muscle strength, (Seifart et al., 2010) muscle volume, (Damiano et al., 2013) gait asymmetries (Durham et al., 2004) and ankle kinematics in gait (Comeaux et al., 1997; Durham et al., 2004; Galen et al., 2012; Meilahn, 2013; Pierce et al., 2012; Postans & Granat, 2005; Prosser et al., 2012; van der Linden et al., 2008). The effect of FES on ankle kinematics is referred to as the orthotic effect which occurs as a result of stimulation of tibialis anterior to clear the foot during swing (van der Linden et al., 2008). This raises the potential for FES to be an alternative to an AFO, which could be beneficial for some children to address issues with tolerability and compliance due to movement restriction, cosmesis and comfort (Autti-Ramo et al., 2006; Damiano et al., 2013; Prosser et al., 2012). As an orthotic effect, FES is of benefit for children with poor ankle SMC particularly when where efforts to strengthen the ankle dorsiflexors are limited. It is possible that synchronizing FES with gait can provide a consistent prompt for timing dorsiflexion in the gait cycle so assisting with motor learning. It has been
proposed that the repetitive nature of FES applied during gait can reduce joint co-
contraction by modulating the presynaptic inhibition to restore reciprocal
inhibition (Comeaux et al., 1997; Leonard et al., 2006; Postans & Granat, 2005).
Thus, FES as a treatment tool for children with CP appears promising.

It is worth noting that even within the application of FES, researchers have applied
it in a variety of contexts. Some studies applied FES throughout the child’s day i.e.
at home or at school (Durham et al., 2004; Damiano et al., 2013; Prosser et al.,
2012; van der Linden et al., 2008), at home during set periods at pre-designated
times (Carmick, 1995; Galen et al., 2012; Seifart et al., 2010) or within clinical or
gait laboratory conditions (Comeaux et al., 1997; Ho et al., 2006; Pierce et al., 2004;
Postans & Granat, 2005). From this research, the greatest potential appears to be
when FES is applied in gait throughout the child’s day with improvements in both
gait kinematics and temporal-spatial parameters (Durham et al., 2004; Damiano et
al., 2013; Prosser et al., 2012; van der Linden et al., 2008). This raises important
questions regarding specificity of intervention, dosage, frequency and context of
treatment application and its relationship to overall outcome.

FES has been applied in conjunction with BoNTA and whilst this would seem
feasible, the lack of controlled studies means that it is currently unclear whether
FES enhances or complements the effect of BoNTA (Wright et al., 2012). Based on
the few studies available, it seems that the combination of FES and BoNTA may
result in improved outcomes. However, it is difficult to isolate the effect of each
intervention particularly given that BoNTA has been shown to be an effective
treatment modality whilst FES continues to be somewhat inconclusive (Galen et al.,
2012; Seifart et al., 2010).

Studies using FES have similar limitations to that noted in NMES literature. The six
systematic reviews that have been published on the use of electrical stimulation in
children with CP conclude that as an intervention, it can neither be discarded nor
fully supported due to the wide variety of different treatment parameters, different
target muscles for stimulation, lack of robust outcome measures particularly
relating to activity and participation and non-homogenous groups underpowered
to detect significant differences (Cauraugh et al., 2010; Chiu & Ada, 2014; Kerr et
al., 2004; Seifart et al., 2009; Merrill, 2009; Wright et al., 2012). These reviews are
summarised in Table 2. There have been new studies published since these reviews (Prosser et al., 2012; Damiano et al., 2013; Meilhan, 2013) that reflect new technology with pioneering insights to the effects of FES. However these studies did not have a control group, making it more challenging to differentiate between the effects of treatment and natural development and growth. This is particularly relevant when considering a paediatric population. As such, muscle electrical stimulation remains a “yellow light” intervention, requiring further investigation due to inconclusive evidence supporting its effectiveness (Novak et al., 2013).

There are only a few studies that have investigated the effects of FES beyond treatment periods. This is known as the therapeutic effect. Reports have been mainly limited to therapist observation and anecdotal parental report rather then on quantitative measurements (Carmick, 1995; Cauraugh et al., 2010; Comeaux et al., 1997). Establishing whether or not FES can produce a therapeutic effect has many clinical implications. A therapeutic effect would suggest secondary repertoire expansion with neuroplastic changes as already demonstrated in the adult stroke population following FES in gait (Everaert et al., 2010; Rushton, 2003; Stein et al., 2010). This would also impact service provision because therapy services typically diminish as children reach adulthood (Donkervoort et al., 2007; Moll & Cott, 2013) yet secondary musculoskeletal problems and functional decline continue to exist despite years of rehabilitation throughout childhood and adolescence (Hilberink et al., 2007; Moll & Cott, 2013; Opheim et al., 2009). Therefore considering whether interventions expand secondary repertoires is relevant from a life span and service provision perspective (Frisch & Msall, 2013).
Table 2. Summary of systematic reviews on electrical stimulation in children with CP.

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<th>Author</th>
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<th>Included trials</th>
<th>No. trials</th>
<th>Conclusion</th>
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<tr>
<td>Kerr et al (2004)</td>
<td>Electrical stimulation in cerebral palsy: a review of effects on strength and motor function</td>
<td>FES, NMES, TES, Controlled trials (RCT and non-randomized), case studies.</td>
<td>18</td>
<td><strong>Scarcity of well-controlled trials, difficult to support or discard ES in CP.</strong></td>
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<td></td>
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<td>More evidence to support NMES than TES.</td>
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- Non-randomized studies (RCT and non-randomized) and case studies were included.
- Poor inter-study differences in terms of characteristics of a group of children.
- No protocol for pain control and parameters of protocols.
- Lack of standard measures in the literature.

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<tr>
<td>Seifart et al</td>
<td>The effect of lower limb functional electrical stimulation on gait of children with cerebral palsy</td>
<td>FES (surface or per-cutaneous) investigating therapeutic effects without FES.</td>
<td>5</td>
<td>Positive effect of FES on gait and function when stimulation is applied either to pre-tibials or triceps surae muscle group.</td>
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<td></td>
<td></td>
<td>Case studies, single subject design, cross over design.</td>
<td></td>
<td>Inconsistent reports on therapeutic effects.</td>
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<tr>
<td>Merrill,</td>
<td>Review of electrical stimulation in cerebral palsy and recommendations for future directions</td>
<td>FES, NMES, TES (surface and per-cutaneous).</td>
<td>17</td>
<td>Support the results from Kerr et al's systematic review. Dominated by case studies and uncontrolled studies suffering from a lack of standards.</td>
<td>(2009)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Controlled trials (RCT and non-randomized) and case studies.</td>
<td></td>
<td>Results in ES holds promise for therapeutic value.</td>
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- Analogue (difficult to standardize across studies).  
- Wide ranging treatments and outcome measures. 
- Intensity and duration of treatment poorly reported. 
- Lack of control of activator with outcome measures. 
- Living.
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<tr>
<td>Cauraugh et al (2010)</td>
<td>Children with cerebral palsy: a systematic review and meta-analysis on gait and electrical stimulation</td>
<td>FES, NMES, TES (surface and percutaneous) measuring impairments and activity outcome measures.</td>
<td>17</td>
<td>Cautiously advocate that electrical stimulation can reduce impairments and activity limitations in gait. Supports previous reviews. TES is not effective for improving activity limitations</td>
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| Chiu et al 2014 | Effect of Functional Electrical Stimulation on activity in children with cerebral palsy: a systematic review | FES only with activity outcome measures; RCT only | 5          | **FES is no more effective than no FES.**  
FES has similar effect as activity training alone.  
**No evidence of effects maintained beyond intervention period.** |
Recommendations for future research in the area of FES in CP are:

1. To include outcome measures beyond body structure and function such as the effect of FES on activity and participation (Damiano et al., 2013; Kerr et al., 2004; Seifart et al., 2009).

2. To implement well-designed, powered and controlled studies investigating the therapeutic effect of daily FES on range of motion, spasticity, gait and functional mobility (Cauraugh et al., 2010; van der Linden et al., 2008; Wright et al., 2012).

3. To apply FES outside of gait laboratory and clinical conditions (Cauraugh et al., 2010). This may ultimately increase the dosage and frequency of intervention in more relevant contexts.

4. To use a device that can be easily placed on the leg by children and families and free from wires and sensors in shoes (Durham et al., 2004).

5. To report on clinically significant or meaningful changes rather than just statistical significance (Kerr et al., 2004).

6. Homogenise the groups by limiting groups to one topographic presentation so that the effects can be comparable and more easily transferable to a specific presentation (Kerr et al., 2004).

Before applying electrical stimulation to a clinical population, it is imperative that the physiology behind electrical stimulation be first considered. This will maximise the potential of electrical stimulation as a treatment modality.

**3.16 Electrical stimulation and muscle recruitment**

Electrical stimulation can be used to induce an action potential in the motor nerve in the absence of a central command i.e. without voluntarily action. To achieve this, two electrodes are placed over the skin above the target muscle. The electrodes provide a conductive surface serving as an interface between the electrical stimulation device and the muscle and skin. The externally applied electrical current enters from one electrode and returns through the other electrode to
complete the electrical circuit. The flow of electrons from the electrical device is converted into a flow of ions in the motor nerve (in the same way as described previously) so that an action potential can be generated at a rate that is specified and pre-set on the device itself (Reed, 1997). An externally applied electrical current synchronously recruits motor units according to electrode distance from axons and axon diameter. This sequence of stimulation involves what is referred to as the peripheral pathway. The peripheral pathway will generate a peripheral torque but it will not enable alterations in motor unit recruitment patterns or modulation of firing frequency as with normal physiological recruitment patterns (Bergquist et al., 2011; Bickel et al., 2011; Dean et al., 2007). Hence motor unit recruitment contrasts with physiological patterns because electrically induced motor units are recruited in a “non-selective, spatially fixed and temporally synchronous pattern” (Gregory & Bickel 2005, pg 362). So despite the advantage of an electrical circuit that can produce a muscle contraction when it may not otherwise be possible, early muscle fatigue is a likely consequence because the central nervous system isn’t involved in co-ordinating the sequence of action potential summation. It is possible to manipulate the electrical stimulation parameters to involve the central nervous system, otherwise referred to as the central pathway. The greater the central pathway involvement in electrical stimulation, the greater the potential for electrical stimulation to be a useful treatment modality because muscle fatigue can be better managed.

### 3.17 Central pathway involvement in electrical stimulation

Sensory axons with signals from golgi tendon organs and cutaneous receptors are also depolarized during electrical stimulation. When sensory axons are depolarized, they send a sensory volley back up into the central nervous system through the spinal cord (Bergquist et al., 2011). This sensory volley contributes to the recruitment of motor units through the spinal cord by recruiting spinal motor neurons - this is known as the central pathway (Dean et al., 2007). Central pathway recruitment is advantageous because motor units are recruited by the synaptic activation of motor neurons, in a way that is similar to the order of recruitment seen in normal physiological voluntary contractions (Bergquist et al., 2011). This is preferable when using electrical stimulation for neurological conditions mainly
because it enables muscles to contract whilst minimising fatigability. Manipulating electrical stimulation parameters (frequency, pulse width and amplitude) and location of electrode placement (either over the muscle belly or nerve) can enhance the potential for the sensory volley to contribute in muscle activation. Central pathway recruitment may also contribute to central nervous system changes by strengthening motor cortical areas and corticospinal connections (Everaert et al., 2010; Khaslavskia & Sinkjaer, 2005).

3.18 Stimulation parameters

As shown in Figure 8, electrical stimulation parameters include frequency (measured as pulses per second hertz/Hz), pulse width (measured in microseconds μs) and amplitude (measured in milliamps/mA).

![Diagram of stimulation parameters](image)

**Figure 8.** Diagrammatic representation of biphasic electrical stimulation parameters that can be adjusted to form the appropriate protocols of treatment.
3.18.1 Frequency

The frequency of stimulation that is available in most hand-held, portable, Therapeutic Goods Act approved devices can range from 10 Hz to 150 Hz. This describes how quickly the pulses deliver the action potentials that travel along the motor and sensory axons (in pulses per second) (Bickel et al., 2011). The higher the frequency; the greater the muscle force output and central pathway stimuli but also the greater the muscle fatigue due to the greater summation of the stimuli (Bergquist et al., 2011; Gregory & Bickel, 2005; Reed, 1997). Human skeletal muscle fires at low frequencies, typically between 10 and 30Hz to reduce fatigability (Bellemare et al., 1983). However with the application of electrical stimulation, such low frequencies may not sustain tetanic contractions and so higher frequencies are often required. Frequencies ranging from 20 to 40 Hz are recommended and are well tolerated by children with CP (Damiano et al., 2013).

3.18.2 Nerve Trunk vs Muscle Belly Stimulation

Stimulation applied over the nerve trunk or muscle belly will involve both peripheral and central pathways. However, stimulation that is applied over the nerve trunk typically requires lower frequencies for central pathway involvement whilst muscle belly stimulation requires higher frequencies i.e. 100 Hz for central pathway involvement (Bergquist et al., 2011). Electrical stimulation applied over the nerve trunk may not only increase central pathways but may also improve the spatial recruitment of motor units within the muscle to more closely mimic physiological recruitment patterns (Bergquist et al., 2011; Maffuletti, 2010). Therefore, current thought suggests that nerve trunk stimulation is ideal so as to limit fatigue and increase motor unit recruitment.

3.18.3 Pulse Width

Longer pulse widths are associated with greater central pathway involvement, torque generation and sensory axon recruitment (Bergquist et al., 2011; Collins, 2007; Maffuletti, 2010). Although longer pulse widths can more effectively activate sensory axons for a larger sensory volley, it may be more uncomfortable and intolerable to patients because the cutaneous nociceptor receptors are also
stimulated. Some electrophysiology studies have based their pulse widths to be as wide as 1 millisecond (ms) (Collins, 2007; Dean et al., 2007; Paillard, 2008). However most clinical devices do not have the capacity to deliver a 1ms pulse width. For a muscle like tibialis anterior, wide pulse widths may be preferential to evoke central nervous system changes but it needs to be balanced with potential overflow of the electrical current into surrounding muscles. A low pulse width i.e. 25 microseconds is best tolerated in the paediatric population (Damiano et al., 2013) and serves as a good starting point. However, as the child becomes more accustomed to the sensation, pulse widths should be gradually increased to take advantage of the potential central pathway involvement.

### 3.18.4 Pulse Amplitude

Although higher amplitudes result in larger contractions as more motor axons are depolarized, they are also more uncomfortable (Paillard, 2008). High amplitudes limit the extent of which the sensory volley can evoke the central pathway to contribute to the muscle contraction. This occurs when the sensory volley driven orthodromic signal i.e. signals that travel in the usual direction from the spinal motor neurons, is blocked because the amplitude is too high and overflows or backfires (known as the antidromic transmission) to prevent this signal from getting to the muscle (Bergquist et al., 2011; Rushton, 2003). Figure 9 demonstrates the block of orthodromic transmission signals that can occur with high amplitudes. Lower amplitudes are recommended to encourage central pathway involvement. Therefore pulse width should be increased first to generate more torque and central pathway recruitment before amplitude is increased. This enables amplitudes to be individually set and adjusted by balancing patient tolerance and the desired motor response (Reed 1998).
Figure 9. The peripheral and central pathways are demonstrated. High amplitudes produce antidromic transmission which blocks the orthodromic transmission generated from the sensory volley recruited motor pathway (Bergquist et al., 2011). Figure used with permission.

3.18.5 Electrode Placement

With one electrode placed over the nerve trunk, the other electrode will need to be carefully positioned over the motor end point of the muscle belly. This is defined as the point where the motor nerve enters the muscle (Petrofsky, 2004). Impedance is at its lowest over the motor end point, due to the density of sodium channels present. This is advantageous because this means less electrical current is required to stimulate the muscle, making it more tolerable (Alon et al., 1994; Petrofsky, 2004). The motor end point can be located clinically by the site where the motor response is at its greatest with the least current amplitude and reported by the patient to be the most comfortable position (Alon et al., 1994; Carmick, 1997; Petrofsky, 2004). Electrode size is also important because larger electrodes improve comfort by lowering current density (Alon et al., 1994). However, large electrodes may not be specific enough and will cause an overflow of stimulation to surrounding muscles resulting in unwanted movements (Reed, 1997). Therefore smaller electrodes are required for greater specificity (Petrofsky, 2004). The tibialis anterior muscle in children with USCP is small in size (Bland et al., 2011) meaning overflow of current is likely, particularly to peroneus longus which is also
innervated by the common peroneal nerve. Overflow of current to peroneus longus is of particular concern when foot deformities such as equino-plano-valgus are already present and so stimulation would only exacerbate the existing foot deformity (Davids, 2010). Hence the use of small electrodes is necessary when stimulating tibialis anterior for equinus in children with USCP.

3.19 Electrical Stimulation Combined with Voluntary Contractions

When electrical stimulation is combined with voluntary contractions, there is potential for this to augment motor unit recruitment because a larger ratio of fast and slow twitch fibers are recruited when compared to voluntary contractions alone (Paillard, 2008). This may be significant for addressing muscle atrophy (Gregory & Bickel, 2005). The application of electrical stimulation is unique in that it works peripherally at the site of the muscle but it can also work centrally through reflex pathways that involve the central nervous system. The combination of these pathways and voluntary effort through activity based therapies could be a reason why a therapeutic effect has been observed in adults with central neurological disorders (Everaert et al., 2010; Rushton, 2003; Stein et al., 2010). The use of drop foot stimulators in the adult population has provided evidence demonstrating central pathway involvement with motor cortical area activation strengthening the corticospinal connections (Everaert et al., 2010). Such evidence suggests that activity-based therapies combined with the unique properties of electrical stimulation to elicit central pathways suggests this might also be possible for children with USCP.

To summarise, the application of FES has the potential to be an effective treatment for children with USCP. It has the potential to be embedded into the ICF-CY domains of functioning. Further, stimulation parameters need to also be carefully considered in order to:

1. Ensure adequate motor output sufficient for function i.e. adequate dorsiflexion;

2. Ensure tolerability of stimulation;

3. Limit early onset fatigue; and
4. Increase the likelihood of central pathway involvement.

To address these requirements intervention will need to:

1. Achieve tetany but at a frequency that does not induce early fatigue i.e. < 60 Hz;

2. Ensure accurate placement of electrodes over the site of least resistance i.e. motor end point to ensure the sensation is most tolerable for the paediatric patient;

3. Be applied to the nerve trunk to increase the likelihood of central pathway involvement to elicit physiological recruitment patterns to reduce muscle fatigue;

4. Increase pulse width preferentially to amplitude in order to generate adequate torque. This will increase the likelihood of sensory axon depolarization to activate central pathways whilst controlling for antidromic transmission; and

5. Be activity-based in contextually relevant environments enabling adequate frequency to maximise potential neuroplastic changes.

3.20 Description of Selected FES Device

The Walk Aide® (Innovative Neurotronics, Austin, TX, USA) is a pager like device worn on the leg that can apply FES in patient specific environments. It delivers surface electrical stimulation in a synchronized manner to stimulate active dorsiflexion of the ankle during the swing phase of gait. During a gait cycle, the WalkAide® stimulates the common peroneal nerve, which innervates tibialis anterior and other muscles that produce dorsiflexion of the ankle. The device can be easily placed on the leg via a cuff by a parent/carer or the child/adolescent and is shown in Figure 10. The Walk Aide® utilizes sensors that detect changes in the position of the tibia and so triggers electrical stimulation to activate dorsiflexion of the ankle during the swing phase of gait. An appropriate timing pattern of the device is initially determined manually by synchronizing it with the wearer's comfortable walking pattern. Once the appropriate timing has been determined,
the program is saved to the device so that the stimulation is always delivered and terminated at a particular tibial angle in swing. There are a variety of settings that can be applied including a pulse width (up to 300μs), frequency (up to 33 Hz), ramp up and down times and intensity. Users can adjust intensity using a dial on the device. The device records hours of use and total number of stimulations.

Unlike devices previously described in the literature, this device was chosen because it was the most compact device with fewer wires as this was described as a limitation in previous research (Durham et al., 2004). Furthermore, the Walk Aide® was chosen as it is the only commercially available device where the trigger for electrical stimulation is not dependent on a heel sensor as this would limit patient selection due to equinus gait patterns. The main limitations of the Walk Aide® are that it is relatively large especially for children and that it is limited to a maximum frequency setting of 33 Hz. Another limitation is that instead of providing a reading of true milliamp output, there is only a dial for the amplitude settings that ranges from zero to eight.
Figure 10.

Walk Aide® on a 5 year old child (Removed due to privacy issues)

The Walk Aide® in combination with the expertise of physiotherapy within a community clinical context forms a feasible ABR approach to facilitate motor learning in an ICF-CY contextual framework. It is compelling to investigate this through a series of studies.

The proposed series of studies are formed under the NGST, ICF-CY and ABR frameworks (outlined in Figure 11):

1. Under the NGST, this framework recognises that children with USCP have limited repertoires of movement and that this is influenced by impairments in body structure and function domain of in the ICF-CY. As a
consequence, the necessary variability of movement required to perform essential activities for safe community ambulation is also limited.

2. An ABR approach enables the intervention to be delivered during functional activity with the intention to optimise motor learning with high frequency and dosage of intervention.

3. Given the “yellow light” state of evidence indicating inconclusive evidence supporting the use of FES in children with CP, the effects of the intervention will be assessed comprehensively on all levels of the ICF-CY.

The design of both studies will enable the effects to be assessed both:

• with FES for the orthotic effects and;

• after FES is removed in order to determine the potential carry-over or therapeutic effects.

Results from this series of studies will translate to provide a comprehensive clinical picture and framework for therapists in the use of FES in children with USCP. The studies will add to the current knowledge base on the use of FES to provide evidence for informed practice.
Figure 11. The proposed investigation (red arrows) within the theoretical framework to determine the immediate and therapeutic effect of FES.
4 PAPER 1: EFFECTS OF SHORT-TERM DAILY COMMUNITY WALK AIDE USE ON CHILDREN WITH UNILATERAL SPASTIC CEREBRAL PALSY

Authors: Dayna Pool¹,², A Marie Blackmore², Natasha Bear¹, Jane Valentine³.

The Walk Aide® is a relatively new device for children. At the time this study was conducted, there was limited information and literature published around the use of these devices for children with CP. Prior to the planned randomised controlled trial, it was therefore essential that the procedure for introducing the device was consolidated along with a firm understanding of the degree of input required to support its use at home and school. Further, there was a need to pilot outcome measures to refine the necessary assessments given the breadth of outcomes that would be required to represent the domains of the ICF-CY. A single subject design not only enabled detailed collection of data to adequately evaluate length of treatment and follow up required but also enabled detailed analysis of each individual given the heterogeneity of CP. Tables that were published as part of the online publication are also presented following the article in section 4.1.

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Effects of Short-Term Daily Community Walk Aide Use on Children With Unilateral Spastic Cerebral Palsy

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The Centre For Cerebral Palsy (Ms Pool and Dr Blackmore) and School of Sport Science, Exercise and Health (Ms Pool), The University of Western Australia, Perth, Western Australia, Australia; Natasha Bear Statistics (Ms Bear), Perth, Western Australia, Australia; Department of Pediatric Rehabilitation (Dr Valentine), Princess Margaret Hospital for Children, Perth, Western Australia, Australia.

Purpose: To determine the effects of functional electrical stimulation (FES) on the main impairments affecting gait in children with unilateral spastic cerebral palsy. Methods: A 20-week, multiple single-subject A-B-A design included a 6-week pre-FES phase, an 8-week FES phase, and a 6-week post-FES phase. Twelve children, aged 5 to 16 years, wore an FES device (the Walk Aide) daily for 8 weeks. Weekly measures included ankle range of motion, selective motor control, dorsiflexion and plantar flexion strength, gastrocnemius spasticity, single-limb balance, Observational Gait Scale (OGS) score, and self-reported toe drag and falls in the community. Results: Compared with the pre-FES phase, the FES phase showed significant improvements in ankle range of motion, selective motor control and strength, and reductions in spasticity, toe drag, and falls, but no change in OGS score. These improvements were maintained during the post-FES phase. Conclusions: Intermittent, short-term use of FES is potentially effective for reducing impairments affecting gait in children with unilateral spastic cerebral palsy. (Pediatr Phys Ther 2014;26:308–317) Key words: accidental, adolescent, cerebral palsy, child, electrical stimulation therapy, falls, gait, motor activity/physiology, muscle strength, postural balance, spasticity, spastic unilateral

INTRODUCTION

Cerebral palsy (CP) refers to a group of permanent motor dysfunctions caused by nonprogressive damage to the developing brain. Unilateral spastic CP is the most common topographical pattern of involvement, with most children functioning at a Gross Motor Function Classification System (GMFCS) level I or II. These children commonly show sagittal plane gait deviations with true equinus due to a combination of gastrocnemius spasticity, plantar flexion contracture, poor ankle selective motor control (SMC), and reduced ankle power generation. These impairments contribute to poor foot clearance in the swing phase of gait, which can result in tripping or falling.

The challenge in clinical practice is to provide the optimal intensity and dosage of physiotherapy treatment to facilitate motor learning and acquisition of functional activities such as gross motor skills and refinement of gait to reduce falls. Physiotherapy interventions are often
implemented alongside intramuscular injections of botulinum toxin type A (BoNT-A), which reduces focal spasticity and improves range of motion (ROM), gross motor progression, and quality of gait. As the effects of BoNT-A are not sustained long term, BoNT-A must be implemented in conjunction with physiotherapy and orthotic intervention to ensure ongoing clinical and functional improvements. Ankle-foot orthoses (AFOs) are often used to improve ankle kinematics in gait and maintain ROM. However, AFOs may impede power generation for effective push off and further weaken ankle musculature. Cosmesis and comfort also affect AFO acceptance by some children. Therefore, alternative interventions need to be explored.

Synchronized surface functional electrical stimulation (FES) of the ankle dorsiflexors is a treatment that has the potential to provide adequately dosed intervention for children with unilateral spastic CP, especially if there are issues with AFO acceptance. Functional electrical stimulation has been recommended to improve gait quality, particularly for foot drop in adults with stroke. Functional electrical stimulation uses an electrical current to activate intact motor units through the depolarization of motor nerves, and is usually applied to muscles that cannot be contracted voluntarily because of weakness, lack of SMC, antagonist spasticity, or muscle length deficiency, making FES potentially effective for upper motor neuron conditions.

Recent studies have reported that FES in children with CP is well tolerated, with improved active and passive ROM, ankle kinematics, and clinically significant improvements in gait quality. Few studies have systematically investigated the effect of FES on a range of impairments, activity limitations, and participation restrictions when applied daily in the community.

This study tested the hypothesis that 8 weeks of FES would improve ankle dorsiflexion strength, SMC, ROM, gastrocnemius spasticity, balance, and gait with a reduction in toe drag and falls in children with unilateral spastic CP. The second hypothesis in this study was that these effects would continue following treatment in a 6-week follow-up period. A single-subject design was used because it enabled us to undertake individualized intervention with intensive assessment protocols over a period of many weeks. This research design also allowed for the heterogeneity that exists among children with CP and enabled us to monitor each child’s responses individually over time. Common, readily available assessment tools were used because of their relevance to community clinical practice.

METHODS

The Human Research Ethics Committee at Princess Margaret Hospital for Children granted ethics approval for this research.

### Study Design

A 20-week, multiple single-subject A-B-A design with 12 participants included a 6-week pre-FES phase (A), an 8-week FES intervention phase (B), and a 6-week post-FES phase (A).

### Participants

Inclusion and exclusion criteria, shown in Table 1, defined a group whose ability to benefit from the FES device would not be restricted by biomechanical limitations such as inadequate ankle ROM or knee flexion contracture inhibiting heel strike. Uncontrolled seizure disorder was considered a safety risk. A 3-month washout period was allowed following BoNT-A injections so that the effects of FES could be better isolated. Twelve participants were recruited through The Centre for Cerebral Palsy, Western Australia. Their characteristics are shown in Table 2.

### Intervention

The Walk Aide (Innovative Neurotronics, Austin, Texas) is a small (8.2 cm x 6.1 cm x 2.1 cm, 87.9 g) device that delivers asymmetrical biphasic surface electrical stimulation (ES) in a synchronized manner to stimulate active ankle dorsiflexion during the swing phase of gait. During a gait cycle, the Walk Aide stimulates the common fibular/peroneal nerve, which innervates the tibialis anterior and other ankle dorsiflexors.

The device was attached just below the knee with a cuff, and could be removed and replaced, as required, by parents and children. The device’s sensors detected changes in the position of the shank and triggered ES to activate ankle dorsiflexion during the swing phase of gait.

### TABLE 1

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis of unilateral spastic cerebral palsy</td>
<td>History of uncontrolled seizure disorder</td>
</tr>
<tr>
<td>Age 5 to 18 years</td>
<td>Orthopedic lower limb surgery on the affected side in the past 12 months</td>
</tr>
<tr>
<td>Passive dorsiflexion range of affected ankle of at least 5°</td>
<td>Pins or plates at the site of electrical stimulation</td>
</tr>
<tr>
<td>Gross Motor Function Classification System level I or II</td>
<td>Routine use of AFO lower limb in the past 3 months</td>
</tr>
<tr>
<td>Achieves full passive knee extension bilaterally</td>
<td></td>
</tr>
<tr>
<td>Dynamic plantarflexion angle of 45° on the affected side</td>
<td></td>
</tr>
<tr>
<td>Able to cooperate with assessment procedures</td>
<td></td>
</tr>
<tr>
<td>Willing to use the Walk Aide at least 1 hour a day, 6 days a week for 8 weeks</td>
<td></td>
</tr>
</tbody>
</table>

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The device was initially manually synchronized with each child's individual walking pattern.

The first author was responsible for the initial setup of the FES device, with technical support from Orthopaedic Appliances Pty Ltd available if required. Once the appropriate timing had been determined, the program was saved to the device so that the stimulation was always delivered and terminated at a particular shank angle. Pulse width was set to a maximum of 300 μs and frequency to a maximum of 33 Hz. Users could adjust intensity (mA) using a dial on the device. The device recorded hours of use and the total number of stimulations. Dorsiflexion was achieved by common fibular/peroneal nerve stimulation with 1 electrode at the head of fibula and the other on the main muscle belly of the tibialis anterior. Stimulation parameters are shown in Table 3. Electrodes were replaced every 2 to 3 weeks. The position of the cuff and electrodes on the leg was marked on the skin with a permanent marker, and parents were asked to refresh the markings throughout the week. The principal investigator trained parents and children to test the quality of the contraction manually to ensure dorsiflexion without excessive eversion. They were asked to do this each time they used the device.

Children were provided with the FES device 1 week before the commencement of the FES intervention phase. To accommodate them to the sensation of the stimulation (at home only for a maximum of 15 minutes a day) and to enable them to practice putting the cuff on in the correct position. During the FES intervention phase, children were asked to use the device for at least 1 hour a day, 6 days a week for 8 weeks. Children wore their AFOs during the pre-FES phase but not during FES and post-FES phases.

### Clinical Assessment and Outcome Measures

The outcome measures were routinely used in the community setting. As part of best practice and ongoing clinical care, bilateral measures were taken to monitor adverse changes (increases in spasticity or clinically significant loss of range). However, only the ankle ROM and spasticity measures on the affected side were used for reported comparisons. All testing in all phases of the study occurred without AFOs.

**Range of Motion.** The first author took passive ankle dorsiflexion measures (with the knee extended) in subtalar neutral with the child in the supine position. Passive measures of popliteal angle, dorsiflexion with knee flexion, ankle eversion in plantigrade, and knee extension were taken bilaterally to ensure no loss of range. A goniometer was used for all measures because of excellent reliability in children with CP.16

Spasticity, Dynamic ROM (Modified Tardieu Scale) was measured in the supine position described earlier concurrently with passive ROM measurement to determine the first point of catch.17 The Australian Spasticity Assessment Scale18 was also used to measure spasticity in the gastrocnemius muscle (Table 4). This 3-point ordinal scale considers the angle of the point of catch, as well as the presence of any resistance throughout the remaining available passive range. This scale was chosen because it is easy to administer in the clinical setting, it is a more

<table>
<thead>
<tr>
<th>Participant</th>
<th>Age at Start of Baseline</th>
<th>Sex</th>
<th>Affected Limb</th>
<th>WGHI</th>
<th>GMFCS</th>
<th>Use of Orthosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4y, 10 mo</td>
<td>Male</td>
<td>Left</td>
<td>Ila</td>
<td>I</td>
<td>AAFO</td>
</tr>
<tr>
<td>2</td>
<td>4y, 11 mo</td>
<td>Female</td>
<td>Left</td>
<td>Ila</td>
<td>I</td>
<td>Nil</td>
</tr>
<tr>
<td>3</td>
<td>5y, 4 mo</td>
<td>Male</td>
<td>Right</td>
<td>IIb</td>
<td>I</td>
<td>AAFO</td>
</tr>
<tr>
<td>4</td>
<td>5y, 4 mo</td>
<td>Female</td>
<td>Right</td>
<td>Ila</td>
<td>I</td>
<td>AAFO</td>
</tr>
<tr>
<td>5</td>
<td>6y, 7 mo</td>
<td>Female</td>
<td>Left</td>
<td>Ila</td>
<td>I</td>
<td>AAFO</td>
</tr>
<tr>
<td>6</td>
<td>9y, 2 mo</td>
<td>Male</td>
<td>Right</td>
<td>Ila</td>
<td>I</td>
<td>FAFO</td>
</tr>
<tr>
<td>7</td>
<td>12y, 3 mo</td>
<td>Female</td>
<td>Right</td>
<td>Ila</td>
<td>I</td>
<td>FAFO</td>
</tr>
<tr>
<td>8</td>
<td>15y, 5 mo</td>
<td>Male</td>
<td>Left</td>
<td>IIb</td>
<td>I</td>
<td>AAFO</td>
</tr>
<tr>
<td>9</td>
<td>9y, 4 mo</td>
<td>Female</td>
<td>Right</td>
<td>Ila</td>
<td>II</td>
<td>FAFO</td>
</tr>
<tr>
<td>10</td>
<td>11y, 2 mo</td>
<td>Male</td>
<td>Right</td>
<td>IIb</td>
<td>II</td>
<td>FAFO</td>
</tr>
<tr>
<td>11</td>
<td>11y, 6 mo</td>
<td>Male</td>
<td>Right</td>
<td>Ila</td>
<td>II</td>
<td>AAFO</td>
</tr>
<tr>
<td>12</td>
<td>14y, 9 mo</td>
<td>Male</td>
<td>Right</td>
<td>Ila</td>
<td>II</td>
<td>FAFO</td>
</tr>
</tbody>
</table>

Abbreviations: AAFO, articulated ankle-foot orthosis; FAFO, fixed ankle-foot orthosis; GMFCS, Gross Motor Function Classification System; WGHI, Western Gage and Hilde classification.

### Table 3

<table>
<thead>
<tr>
<th>Participant</th>
<th>Frequency, Pulse Width, Stimulations/d</th>
<th>Average Daily Use, h</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25 Hz, 100 μs, 1824</td>
<td>3.4</td>
</tr>
<tr>
<td>2</td>
<td>33 Hz, 100 μs, 1857</td>
<td>5.7</td>
</tr>
<tr>
<td>3</td>
<td>33 Hz, 25 μs, 2188</td>
<td>4.2</td>
</tr>
<tr>
<td>4</td>
<td>33 Hz, 25 μs, 1431</td>
<td>3.6</td>
</tr>
<tr>
<td>5</td>
<td>33 Hz, 50 μs, 1603</td>
<td>2.4</td>
</tr>
<tr>
<td>6</td>
<td>25 Hz, 100 μs, 3304</td>
<td>7.0</td>
</tr>
<tr>
<td>7</td>
<td>33 Hz, 25 μs, 757</td>
<td>1.2</td>
</tr>
<tr>
<td>8</td>
<td>33 Hz, 25 μs, 1007</td>
<td>4.8</td>
</tr>
<tr>
<td>9</td>
<td>25 Hz, 200 μs, 1002</td>
<td>2.8</td>
</tr>
<tr>
<td>10</td>
<td>25 Hz, 200 μs, 1746</td>
<td>4.4</td>
</tr>
<tr>
<td>11</td>
<td>25 Hz, 100 μs, 1123</td>
<td>2.6</td>
</tr>
<tr>
<td>12</td>
<td>33 Hz, 50 μs, No data*</td>
<td>3.9</td>
</tr>
</tbody>
</table>

*Download from device unsuccessful. Hours of daily use taken from weekly diary.

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Table 4

Australian Spasticity Assessment Scale

<table>
<thead>
<tr>
<th>Description</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>No catch on RPM (ie, no spasticity)</td>
<td>0</td>
</tr>
<tr>
<td>Catch occurs on RPM followed by release. There is no resistance to RPM</td>
<td>1</td>
</tr>
<tr>
<td>throughout rest of range</td>
<td></td>
</tr>
<tr>
<td>Catch occurs in second half of available range (after halfway point) during</td>
<td>2</td>
</tr>
<tr>
<td>RPM and is followed by resistance throughout remaining range</td>
<td></td>
</tr>
<tr>
<td>Catch occurs in first half of available range (up to and including halfway</td>
<td>3</td>
</tr>
<tr>
<td>point) during RPM and is followed by resistance throughout the remaining</td>
<td></td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>When attempting RPM, the body part appears fixed but moves on slow passive</td>
<td>4</td>
</tr>
<tr>
<td>movement</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: RPM, rapid passive movement. Table is used with permission from the authors.

valid and reliable measure of spasticity than the Modified Ashworth Scale, and can be performed concurrently with passive and dynamic ROM testing.16

Strength. Ankle dorsiflexion strength was measured using handheld dynamometry (Lafayette Nicolas Manual Muscle Tester Model 01160 with output in kilogram, Lafayette Instruments, Lafayette, Indiana). The stabilisation test position for ankle dorsiflexion followed the protocol described by Crompton et al.19 to improve reliability and reduce measurement error. Three measurements were taken for each side, and median scores were calculated for affected and unaffected sides. Single-limb heel raises were used to measure functional ankle plantar flexion strength because handheld dynamometry for ankle plantar flexion is an unreliable measure.19,20 The procedure followed the description provided by Yocum et al.20 but with 2 adaptations. As this was a community-based study, it was not possible to use a laser pointer to measure heel raise height, and so a heel raise was accepted if the child could rise onto the metatarsal heads with knee extended. Because of contracture and spasticity, children were also permitted to touch the wall with their forearm on the affected side, not merely their fingertips as in the original method.20 The maximum number of heel raises was recorded.

Selective Motor Control. Selective motor control assessment of ankle dorsiflexion described by Boyd and Graham17 was used. This 5-point ordinal scale is commonly used in clinical practice and quickly and simply performed with children as young as 4 years of age.

Balance. The single-limb balance assessment was used because of excellent test-retest reliability21 and because single-limb stance is associated with ankle stability.22 Single-limb balance with eyes open was measured using a stopwatch, with the child standing barefoot on a firm and level surface. Instructions were: "Stand on your left/right foot for as long as you can or until I tell you to stop." The maximum of 3 trials was recorded.

Gait. The Observational Gait Scale (OGS), a modification of the Physician’s Rating Scale that places a greater emphasis on the foot and knee,17 was the most appropriate tool available in the community setting for measuring changes at the level of the foot and ankle. The scale items include knee and foot position in midstance, initial foot contact, timing of heel rise, and base of support.17 Silicon Coach Pro7 (Siliconcoach Ltd, Dunedin, New Zealand), a software program that enables frame-by-frame analysis of limb position, was used for video analysis. Markers were placed on the medial epicondyles, lateral epicondyles, patella, medial malleolus, lateral malleolus, head of the fifth metatarsal, and calcaneus. Two video cameras capturing sagittal and coronal views (1080p 50i) were positioned 5 m away from a marked central 1 m x 1 m square. Each child was video-recorded while walking barefoot at a self-selected speed without the Walk Aide in all 3 phases. Videos of walking without the Walk Aide were presented in randomized order to a blinded assessor, who gave each child a OGS score out of 20. The OGS is normally scored out of 22, but the final question regarding a change in the overall gait pattern was omitted to preserve blinding.

Self-reported Toe Drag and Falls. No published qualitative or quantitative scale is reported that rates the incidence of toe drag and falling for this population, and so a 5-point ordinal scale questionnaire was developed (Table 5), including an option for written comments. Test-retest reliability was moderate for toe drag (κ = 0.41) and good for falls (κ = 0.71).

Assessment Procedure

Potential participants and their parents attended an initial appointment at The Centre for Cerebral Palsy to become familiar with the device and to determine whether FES would be an appropriate intervention. All children who attended this appointment entered the study and completed all phases.

All outcomes were measured weekly throughout the 20-week study period, except for the 2-dimensional gait analysis and toe drag and falling self-report, which were assessed every 3 weeks (totaling 7 probes throughout the study). Measures were taken by the first author at home or school to encourage children to incorporate the use of the device in their home and community settings. These appointments provided the opportunity to address any problems with the device, monitor electrode integrity and replace electrodes if necessary, check for skin condition at the point of stimulation, probe for adverse effects, assess for quality and timing of contractions, and make any necessary parameter and timing adjustments.

Families completed a weekly diary, which included recording the hours of usage of the device each day (see...
TABLE 5

<table>
<thead>
<tr>
<th>How Often Do You Drag Your Toes When You Are Walking?</th>
<th>How Often Do You Fall Over?</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 never drag my toes</td>
<td>1 never fall over</td>
<td>0</td>
</tr>
<tr>
<td>2 drag my toes occasionally</td>
<td>1 fall over less than once a week</td>
<td>1</td>
</tr>
<tr>
<td>3 drag my toes a few times a week</td>
<td>1 fall over once a week</td>
<td>2</td>
</tr>
<tr>
<td>4 drag my toes a few times a day</td>
<td>1 fall over several days a week</td>
<td>3</td>
</tr>
<tr>
<td>5 drag my toes whenever I walk</td>
<td>1 fall over everyday</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 3. Intensity level, skin integrity, and any other observations. Each week, the first author collected the diaries and downloaded hours of usage and the number of stimulations from the device. The first author completed all measurements, except for the rating of gait analysis videos. It was not possible to blind either the child or the principal investigator to phases of the study. Because of budget constraints, the same person administered the intervention and took the measurements.

Statistical Analysis

Means and standard deviations for interval data or medians and ranges for ordinal data were calculated for each outcome measure for each child on the affected side. Comparisons between pre-FES and FES intervention phases and between pre-FES and post-FES phases were made for each child individually, using (a) visual analysis for changes in level, (b) the 2 standard deviation band (2SD) method (for interval data) or the percentage of nonoverlapping data method (for ordinal data) to assess change in level, and (c) the C-statistic to assess change in slope/trend. Statistical significance was reached in the 2SD band method if 2 consecutive data points lay outside the 2SD band in the FES or post-FES phases. In the percentage of nonoverlapping data method, a median line was drawn from the baseline data, and the strength of change depended on the percentage of points in the FES and post-FES phases that lay above and below this line (as indicated in the Supplemental Digital Content Table 6 through 12 available at http://links.lww.com/PPT/A65). The C-statistic assessed trend in the pre-FES phase, and if no significant trend was found, the C-statistic was computed for the combined pre-FES and FES phases. If this result was significant, a treatment effect was found. This process was repeated for the pre-FES and post-FES phases. Autocorrelation was calculated for each outcome measure to ensure that serial dependency would not influence our interpretation of the visual analysis and the 2SD band method. Autocorrelation can decrease the variability in the data and increase the likelihood of concluding incorrectly that a difference exists between phases when using visual analysis and the 2SD band method. When autocorrelation is found, these methods need to be applied with more caution. As the sample was relatively homogeneous and larger than usual for a single-subject design, we undertook a secondary analysis of the grouped data. The medians for each phase were calculated, and Wilcoxon signed rank tests were used to compare performance between the pre-FES phase and the 2 other phases. For the C-statistic and Wilcoxon signed rank test, a was .05.

RESULTS

Weekly diaries indicated that all children wore the device at least 1 hour a day, 6 days a week, with no reported side effects. Walk Aide usage data were successfully downloaded from all devices, except for participant 12. However, the weekly diary indicated 185 hours of device wear over 8 weeks (mean of 3.3 hours a day) for this child. Weekly measures were taken on all children with 3 exceptions: (a) no measure was taken for participant 7 in week 3 of the post-FES phase because of a sprained ankle, (b) no handheld dynamometry measurement was taken for participant 2 in week 1 of the FES phase because of the unavailability of the dynamometer, and (c) heel raises for participant 8 were not taken until the final week of the pre-FES phase because participant 8 was the first child to be tested and the decision to include heel raises as an outcome measure was not made until that point. Gait analysis and toe drag and falls data were complete for all participants. Clinical measures of hamstrings, knee extension, and ankle eversion indicated no loss of range or increases in spasticity. Measures taken on the unaffected side indicated no clinically adverse changes. Gait in all participants was classified in level II according to Winters Goige and Hicks classification.

Range of Motion

Six children improved their passive range of ankle dorsiflexion in the FES phase when compared with the pre-FES phase and 8 children improved in the post-FES phase compared with the pre-FES phase on at least 2 of the tests (Supplemental Digital Content Table 6, available at http://links.lww.com/PPT/A65). Although the baseline ROM values for 7 children fluctuated by more than 5°, the group as a whole improved significantly between both the pre-FES and FES phases (P < .01) and the pre- and post-FES phases (P = .01). Throughout the study, loss of range was noted in 2 children (1.7° and 2.1°) between the pre- and post-FES phases.

Spasticity

Compared to the pre-FES phase, 7 children improved their dynamic ankle range on at least 2 of the 3 tests in the FES phase and 8 children demonstrated improvement in the post-FES phase (see Supplemental Digital Content Table 7, available at http://links.lww.com/PPT/A65). The baseline values varied by more than 5° for all but 1 child. However, the group as a whole improved significantly
between the pre-FES and FES phases ($P < .01$) and the pre- and post-FES phases ($P < .01$).

Three children demonstrated a decrease in spasticity assessed on the Australian Spasticity Assessment Scale in the FES and post-FES phases when compared with the pre-FES phase (see Supplemental Digital Content Table 8, available at http://links.lww.com/PPT/A65). As a group, a significant reduction in Australian Spasticity Assessment Scale scores was found between the pre-FES and FES phases ($P = .03$), as well as between the pre- and post-FES phases ($P < .01$). Median scores and ranges are shown in Supplemental Digital Content Table 8, available at http://links.lww.com/PPT/A65. Of the 12 participants, 9 received 6-monthly BoNT-A to the gastrocnemius muscle. At the end of this study, 3 of the 9 children did not require their scheduled 6-monthly BoNT-A as it was not clinically indicated.

**Strength**

Ten children improved their ankle dorsiflexion strength during the FES and post-FES phases when compared with the pre-FES phase on at least 2 of the 3 tests (see Supplemental Digital Content Table 9, available at http://links.lww.com/PPT/A65). The group as a whole improved significantly between the pre-FES and FES phases ($P < .01$) and between the pre- and post-FES phases ($P < .01$). The Figure demonstrates a typical graph for this outcome measure in this study. Six children performed a greater number of heel raises in the FES and post-FES phases when compared with the pre-FES phase on at least 2 of the 3 tests (see Supplemental Digital Content Table 10, available at http://links.lww.com/PPT/A65). The group as a whole improved significantly between the pre-FES and FES phases ($P < .01$) and between the pre- and post-FES phases ($P < .01$).

**Selective Motor Control**

Six children improved their ankle SMC in the FES and post-FES phases when compared with the pre-FES phase, on at least 2 of the 3 tests (see Supplemental Digital Content Table 11, available at http://links.lww.com/PPT/A65). The group as a whole improved significantly between the pre-FES and FES phases ($P = .02$) and between the pre- and post-FES phases ($P < .01$). Median and ranges are shown in Supplemental Digital Content Table 11, available at http://links.lww.com/PPT/A65.

**Balance**

Improved balance was seen between the pre-FES and FES phases in 1 child and in 6 children between the pre- and post-FES phases. Median scores were shown on at least 2 of the 3 tests (see Supplemental Digital Content Table 12, available at http://links.lww.com/PPT/A65). As a group, no significant change was found between the pre-FES and FES phases ($P = .16$). A significant improvement was found between the pre- and post-FES phases ($P < .01$).

**Observational Gait Score and Self-reported Toe Drag and Falls**

As a group, no statistically significant change in OGS scores was found between the pre-FES and FES phases ($P = .73$) and the pre- and post-FES phases ($P = .45$). A significant reduction was found in self-reported frequency of falling ($P = .03$) and toe dragging when walking ($P = .02$) between the pre-FES and FES phases. Between the pre- and post-FES phases, a significant reduction was found in falling ($P < .01$) and toe dragging/tripping when walking ($P = .02$).

Low levels of autocorrelation were found, and these are indicated in Supplemental Digital Content Tables 6 to 12, available at http://links.lww.com/PPT/A65. These tables show autocorrelation in only 5% of participants across the outcomes measures at baseline. Visual analysis of baseline data identified a trend in 17% to 33% of participants across variables. Where this occurred, the 2SD band method was not used. Baseline stability was not achieved in 17% to 25% of participants for the last 5 variables, as shown in Supplemental Digital Content Tables 6 to 12, available at http://links.lww.com/PPT/A65. Moreover, considerable baseline instability was observed for passive dorsiflexion ROM (58%) and dynamic ankle range (92%), where any variation exceeding 5° was rated as unstable, as shown in Supplemental Digital Content Tables 6 and 7, available.

**Fig.** Handheld dynamometry for dorsiflexion strength. FES indicates functional electrical stimulation.
at http://links.lww.com/PPT/A65. Baseline stability results are shown in Supplemental Digital Content Tables 6 to 12, available at http://links.lww.com/PPT/A65. On the basis of the combined results of visual analysis, 2SD band method, percentage of nonoverlapping data, and C-statistic, 60% of all possible comparisons for children classified in GMFCS level 1 showed a change and only 14% of comparisons for children classified in GMFCS level II showed a change.

**DISCUSSION**

The results support the hypothesis that FES would improve ankle dorsiflexion SMC, ROM, and dorsiflexion strength, and reduce gastrocnemius muscle spasticity and the frequency of toe drag and falls during an 8-week FES intervention period. The OGS scores and balance did not improve as the result of the FES intervention.

The improvements in ROM and associated reductions in spasticity during ES have been reported previously. The mechanism for spasticity reduction and ROM improvements following ES is not well understood, but a possible hypothesis involves reciprocal inhibition, proposing an increase in muscle cocontraction at the ankle joint by addressing impaired reciprocal inhibition. In the case of the Walk Aide, stimulation of the tibialis anterior muscle would cause inhibition of the gastrocnemius muscle, thereby enabling better prepositioning of the foot for the stance phase of gait. It is possible that this reciprocal inhibition coupled with increased awareness caused by the stimulation might also account for the observed improvements in SMC of the ankle joint. Although previous literature has reported that ES improves both passive and active ROM, our knowledge is limited. No studies have reported the effects of ES on SMC, which is defined as an "impaired ability to isolate the activation of muscles in a selected patient response to demands of a voluntary posture or movement." The development of interventions to address ankle SMC impairments is an important clinical goal, as in our experience, the ankle joint is typically more impaired than more proximal joints and can significantly affect motor function and response to therapy interventions. This study provides preliminary data supporting the use of FES to improve ankle ROM and reduce spasticity, which in turn may facilitate improvements in SMC.

Electrical stimulation is commonly used in rehabilitation to improve strength of the stimulated muscle, by improving muscle synaptic efficiency through selective recruitment of type II muscle fibers. The tibialis anterior muscle is typically weak in children with unilateral spastic CP and may be confounded by a restriction in ROM and SMC at the ankle joint due to spasticity and contracture. The results from this study support the use of FES to improve the strength of the stimulated muscle, which may have also been facilitated by the positive clinical effect of FES on ROM, spasticity, and SMC. Daichman et al similarly found that the use of ES increased agonist muscle strength that was coupled with decreased antagonist spasticity. They speculated that ES might have enabled stronger contractions that increased joint excursion, resulting in increased motor unit activation and motor learning. Given that this treatment was well tolerated by the children in the present study, FES applied during gait presents an efficient and viable option for addressing strength, spasticity, SMC, and ROM impairments concurrently. The interplay and possible relationships between these variables may account for the greater apparent response in children at GMFCS level I in our sample. This study was not designed to compare the differences between children at GMFCS levels I and II. Given the greater apparent response in children classified in GMFCS level I and the small number of children classified in GMFCS level II in this study, further investigation comparing the outcomes of these 2 groups is required.

The significant improvement in ankle plantar flexion strength during the FES phase was an unexpected finding because the plantar flexors were not electrically stimulated. The increase in strength may be partially attributed to the removal of the AFOs, which typically block ankle plantar flexion during gait. Ankle plantar flexors are weak in children with unilateral spastic CP, producing only one-third of the force generated in gait by individuals who are healthy, hence the possibility of a greater potential improvement and response to intervention. Prosser et al used the same FES device provided kinematic data that supported the preservation of ankle plantar flexion at toe off in children with unilateral spastic CP. This finding highlighted the potential for synchronized FES to also influence stance phase kinematics.

McNee et al demonstrated that ankle plantar flexion strengthening exercises in children with CP could significantly increase the number of heel raises that could be performed following a 10-week training period. Participants in the present study were not given formal plantar flexion strengthening exercises. Therefore, the significant increase in the number of heel raises during the FES phase can be attributed to only the combination of FES to preposition the foot during swing (thereby facilitating the ankle rocker mechanisms) and the removal of AFOs for an 8-week period of daily FES use. Further investigation is warranted as improvements in plantar flexion strength may have implications for gait efficiency and muscle volume/growth.

Reports in the literature of the effects of FES on participation are scarce; limited to only a handful of anecdotal reports on improvements in sport participation and reduction in falls. In the current study, we did not measure participation, but we did collect some preliminary data on direct ankle dorsiflexion activation by the ES in the swing phase of gait that may have resulted in reductions in self-reported toe drag and falls. This was previously described as an orthotic effect. The reductions in toe drag and falls were not reflected in the OGS measures, possibly because of poor OGS sensitivity and the lack...
of quantitative measurements during gait. Given that a change of the ankle joint of as little as 2° can significantly alter foot clearance, the OGS would not have been able to account for such a small difference and may have underestimated the direct effect of FES on foot clearance for the reduction in toe drag and falls. However, it is also possible that the discrepancy between self-reported toe drag and falls and the blinded OGS score might reflect an expectation on the part of the children and their families rather than a real change. This is consistent with previous studies that investigated the effects of ES where positive parent report was not supported by clinical data, highlighting the importance for blinded and extensive assessments.42

The continued reduction in toe drag and falls, improvements in ankle dorsiflexion SMC, ROM, ankle dorsiflexion and plantar flexion strength, and gastrocnemius muscle spasticity in the 6-week follow-up phase supports the second hypothesis. The carryover is commonly referred to as the therapeutic effect and suggests the possible role of motor learning.43 Functional electrical stimulation applied during gait has the potential to address the requirements for motor learning. Best practice guidelines dictate that treatment needs to be applied frequently with adequate dosages of task-specific opportunities to practice in environmentally relevant contexts, at the limit of performance.43 Continued reduction in toe drag and falls and improvements in single-limb balance in the post-FES phase support this recommendation. In the post-FES phase, participants no longer had their Walk Aide or AFO. It is possible that this may have challenged the ambulation and balance requirements for activity and participation, accounting for the significant improvements in single-limb balance noted only in the post-FES phase and for the ongoing reduction of toe drag and falls. Results from this study are consistent with previous reports that support the role of high-intensity, task-specific training for high-functioning children with CP.44 Therefore, FES may be a plausible treatment for improving activity and participation, based on motor learning principles.

Children are encouraged to wear their AFOs throughout the day to prevent the loss of ROM at the ankle. In this study, we noted an improvement of ankle ROM with reductions in gastrocnemius muscle spasticity in the FES and post-FES phases. This suggests that time spent walking without an AFO while the Walk Aide was being used did not result in a loss of ankle ROM. This supported the conclusion derived by Hazlewood et al.45 that ES can be an appropriate home-based intervention for improving ankle dorsiflexion ROM. The delay in BoNT-A injections by 3 to 6 months in 5 children in the current study warrants further investigation concerning the effect of FES on ROM and spasticity, as this may have implications for BoNT-A scheduling.

Several limitations of this study are notable. All but 3 criteria on the quality rating scale for single-subject research designs were met, scoring 11 of 14 (strong).46 The 3 unmet criteria were (a) assessment of interrater or intrarater reliability of dependent measures before and during each phase, (b) blinding of the assessor, and (c) stability of baseline data. The assessor's reliability was not evaluated during the study because previously established protocols were followed, and all but SMC have been shown to have at least moderate intrarater reliability. The rating of the OGS was the only blinded component, which raises the possibility that the other measures were influenced by the assessor's expectations. To prevent this bias, the assessor followed strict protocols and avoided looking at previous results. The alteration of OGS scoring to preserve blinding has not been previously reported, and this may have implications for its validity. Baseline stability was established for most participants on most variables. However, stability for passive or dynamic ankle dorsiflexion ROM was not achieved because of the true variability in children's day-to-day ROM. Other limitations arose from the fact that this was a community-based study. Two-dimensional gait analysis was used because of its accessibility and cost-effectiveness, but the OGS may not have been sensitive enough to evaluate change. There are also obvious limitations to 2-dimensional gait analyses, and 3-dimensional data for ankle kinematics and kinetic information for ankle power profiles would have strengthened this study. To our knowledge, no valid measures of toe drag and falls have been reported for this population, so we developed our own questionnaire for this study, which has not been validated; thus, results must be interpreted with caution. An adequately powered, randomized controlled trial addressing all levels of the International Classification of Functioning, Disability and Health for Children and Youth Version47 is recommended.

CONCLUSION

This study supports the use of FES to address the main impairments affecting gait in children with unilateral spastic CP, during and beyond treatment periods. This is true particularly for children functioning at GMFCS level I. These results must be interpreted with some caution because of the limitations mentioned earlier. Functional electrical stimulation was well accepted in this study, with all children adhering to the recommended dosage. Functional electrical stimulation offers the potential for high-frequency, individualized treatments in contextually relevant environments, which is believed to facilitate motor learning through specificity of intervention. This study documents a carryover effect for a minimum of 6 weeks. This suggests that intermittent and short-term use of FES can be a potentially efficient, economical (as devices can be shared) and effective treatment strategy for community clinical practice.

ACKNOWLEDGMENTS

We thank the children and families who participated in this study for their cooperation. We also thank Georgina Jones, Michael Chan, Noulia Gibson, Sarah Laue, Tomie

Pediatric Physical Therapy
Pfeiffer, and Catherine Elliott for their support and assistance with this research. We thank the journal’s 2 anonymous reviewers for their very helpful advice. For this study, the Walk Aides were donated by Orthopaedic Appliances Pty Ltd.

REFERENCES


4.1 Paper 1 Supplementary Results

The following tables were published as part of the online publication.

Table 3. Passive ankle dorsiflexion ROM statistics and comparisons between phases

<table>
<thead>
<tr>
<th>Participants</th>
<th>Mean (SD) of each phase (degrees)</th>
<th>Pre-FES to FES</th>
<th>Pre-FES to Post-FES</th>
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<td></td>
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</tr>
<tr>
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<td>18.3 (2.3)</td>
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<td>13.0 (3.7)</td>
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<td>12.4 (0.9)</td>
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<td>10.0 (2.8)</td>
<td>9.3 (1.0)</td>
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<td></td>
</tr>
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<td>13.3 (2.4)</td>
</tr>
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<td>7.5 (1.9)</td>
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<td>5.4 (1.7)</td>
</tr>
</tbody>
</table>

SD indicates standard deviation; FES, functional electrical stimulation; Vis, visual analysis; 2SD, 2 standard deviation band method; C, Child Function Classification System; ↑, Significant improvement; NS, not significant (p>0.05); u, Unstable baseline (>5° difference between baseline and FES; trend identified at baseline by visual analysis; *, 2SD not reported because trend at baseline identified by visual analysis; NC, not compared.
Table 4. Spasticity – Dynamic ankle dorsiflexion range of motion statistics and comparison between phases.

<table>
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<tr>
<th>Participants</th>
<th>Mean (SD) of each phase (degrees)</th>
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<th>Pre-FES</th>
<th>GMFCS I</th>
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<tbody>
<tr>
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<td>Post-FES</td>
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<td>1</td>
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<td>2</td>
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<td>↑</td>
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<tr>
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<td>↑</td>
</tr>
<tr>
<td>4</td>
<td>12.3 (2.3)</td>
<td>19.8 (6.3)</td>
<td>25.0 (4.9)</td>
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</tr>
<tr>
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<td>↑</td>
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<td>2.3 (3.2)&lt;sup&gt;u&lt;/sup&gt;</td>
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<tr>
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<td>10.5 (6.4)</td>
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<td></td>
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SD indicates standard deviation; FES, functional electrical stimulation; Vis, visual analysis; 2SD, 2 standard deviation band method; C, Classification System; <sup>u</sup>, Unstable baseline (>5° difference between minimum and maximum value); ↑, Significant improvement; NS, does not exist; <sup>ut</sup>, trend identified at baseline by visual analysis; -, 2SD not reported because trend at baseline identified by visual analysis; NC, No Change; ROM indicate plantarflexion.
Table 5. Spasticity - ASAS descriptive statistics and comparisons between phases

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<th>Participants</th>
<th>Median (min to max) of each phase</th>
<th>Pre-FES to FES</th>
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<th>Post-FES Vis</th>
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FES indicates functional electrical stimulation; Vis, visual analysis; PND, percentage of non-overlapping data method; C, C-statistic; Classification System; ↑, Unstable baseline (>1 point difference between minimum and maximum value); ↑, trend identified at baseline with mild or questionable effect (50% to 70% of data points below baseline median); ↑, moderate effect (70% to 90% of data points below baseline median); ↑, Significant improvement; NS, not significant (p>0.05).
Table 6. Strength – Ankle dorsiflexion hand held dynamometry descriptive statistics and comparisons between GMFCS I and II.

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<tr>
<th>Participants</th>
<th>Mean (SD) of each phase (kg)</th>
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<td>4.3 (0.7)</td>
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<td>4.4 (0.4)</td>
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<td>4.4 (1.1)</td>
<td>5.4 (1.6)</td>
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<td>3.5 (1.8)</td>
<td>5.5 (1.1)</td>
</tr>
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<td>8</td>
<td>4.2 (1.9)</td>
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<td>11.4 (2.8)</td>
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<td>4.8 (0.3)</td>
</tr>
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<td>4.1 (1.8)</td>
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<tr>
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<td>3.1 (2.0)</td>
</tr>
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<td>0.6 (0.6)</td>
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SD indicates standard deviation; kg, kilograms; FES, functional electrical stimulation; Vis, visual analysis; 2SD, 2 standard deviations; GMFCS, Gross Motor Function Classification System; ↑, Significant improvement; NS, not significant (p>0.05); NC, no change; †, trend identified by visual analysis; ‡, Unstable baseline (>5° difference between minimum and maximum).
### Table 7: Strength - Heel raise descriptive statistics and comparisons between phases

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<tr>
<th>Participants</th>
<th>Mean (SD) of each phase (number of raises)</th>
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<th>Pre-FES to FES</th>
</tr>
</thead>
<tbody>
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<td>Mean (SD) of each phase (number of raises)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pre-FES</td>
<td>FES</td>
<td>Post-FES</td>
</tr>
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<td>23.7 (5.4)</td>
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<tr>
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<td>19.0 (2.0)</td>
</tr>
<tr>
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<td>29.8 (1.6)</td>
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<tr>
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<td>2.7 (1.6)*</td>
<td>6.3 (1.4)</td>
<td>7.7 (2.6)</td>
</tr>
<tr>
<td>5</td>
<td>3.2 (1.3)*</td>
<td>7.6 (2.9)</td>
<td>6.0 (2.5)</td>
</tr>
<tr>
<td>6</td>
<td>0.0 (0)</td>
<td>1.1 (1.4)</td>
<td>1.0 (2.5)</td>
</tr>
<tr>
<td>7</td>
<td>0.0 (0.0)</td>
<td>0.0 (0)</td>
<td>0.0 (0)</td>
</tr>
<tr>
<td>8</td>
<td>0.0 (0)</td>
<td>4.3 (3.1)</td>
<td>7.2 (3.1)</td>
</tr>
<tr>
<td>GMFCS II</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>0.0 (0)</td>
<td>1.3 (2.1)</td>
<td>3.8 (0.8)</td>
</tr>
<tr>
<td>10</td>
<td>0.0 (0)</td>
<td>0.0 (0)</td>
<td>0.0 (0)</td>
</tr>
<tr>
<td>11</td>
<td>0.0 (0)</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>12</td>
<td>0.0 (0.0)</td>
<td>0.0 (0)</td>
<td>0.0 (0)</td>
</tr>
</tbody>
</table>

SD indicates standard deviation; FES, functional electrical stimulation; Vis, visual analysis; 2SD, 2 standard deviation band method; Function Classification System; * Unstable baseline (>5° difference between minimum and maximum value); ↑ Significant improvement identified at baseline by visual analysis; -, 2SD not reported because trend at baseline identified by visual analysis; NS, not significant.

*Group: 1.3 (1.6) | 5.1 (5.8) | 8.2 (10.3)*
Table 8. Selective motor control descriptive statistics and comparisons between phases

<table>
<thead>
<tr>
<th>Participants</th>
<th>Median (minimum to maximum) of each phase</th>
<th>Pre-FES to FES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-FES</td>
<td>FES</td>
</tr>
<tr>
<td>GMFCS I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>4 (3-4)↑</td>
<td>4 (4-4)</td>
</tr>
<tr>
<td>2</td>
<td>4 (4-4)</td>
<td>4 (4-4)</td>
</tr>
<tr>
<td>3</td>
<td>4 (4-4)</td>
<td>4 (4-4)</td>
</tr>
<tr>
<td>4</td>
<td>2 (2-2)</td>
<td>2.5 (2-3)</td>
</tr>
<tr>
<td>5</td>
<td>2 (2-3)</td>
<td>4 (2-4)</td>
</tr>
<tr>
<td>6</td>
<td>2 (2-2)</td>
<td>4 (3-4)</td>
</tr>
<tr>
<td>7</td>
<td>2 (2-2)</td>
<td>3 (2-4)</td>
</tr>
<tr>
<td>8</td>
<td>2 (2-2)</td>
<td>4 (2-4)</td>
</tr>
<tr>
<td>GMFCS II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>3 (1-3)w</td>
<td>3 (2-3)</td>
</tr>
<tr>
<td>10</td>
<td>2 (1-3)w</td>
<td>2 (1-3)</td>
</tr>
<tr>
<td>11</td>
<td>3 (2-3)</td>
<td>3 (1-3)</td>
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<tr>
<td>12</td>
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<td>1 (0-1)</td>
</tr>
<tr>
<td>Group</td>
<td>2 (0-4)</td>
<td>3.5 (1-4)</td>
</tr>
</tbody>
</table>

FES indicates functional electrical stimulation; Vis, visual analysis; PND, percentage of non-overlapping data method; C, C-statistic. Classification System; ↑, trend identified at baseline by visual analysis; NC, no change; NS, not significant (p>0.05); ✤, Significant effect (50% to 70% of data points below baseline median); ✤✤, moderate effect (70% to 90% of data points below baseline median); ✤✤✤, large effect (>90% of data points below baseline median); w, Unstable baseline (>1 point difference between minimum and maximum value).
Table 9. Single limb balance descriptive statistics and comparisons between phases

<table>
<thead>
<tr>
<th>Participants</th>
<th>Mean (SD) of each phase (seconds)</th>
<th>Pre-FES to FES</th>
<th>Post-FES</th>
<th>Vis</th>
<th>2SD</th>
<th>C</th>
<th>V</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMFCS I</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1.3 (0.5)</td>
<td></td>
<td>2.0 (0)</td>
<td>↑</td>
<td></td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2.2 (0.8)</td>
<td></td>
<td>3.5 (0.8)</td>
<td>↑</td>
<td></td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>4.3 (1.0)</td>
<td></td>
<td>8.8 (5.4)</td>
<td>NC</td>
<td>↑</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>8.0 (6.5)</td>
<td></td>
<td>22.2 (7.3)</td>
<td>NC</td>
<td></td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>3.2 (1.2)</td>
<td></td>
<td>6.0 (2.3)</td>
<td>↑</td>
<td></td>
<td>↑</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>4.8 (2.6)</td>
<td></td>
<td>4.5 (0.5)</td>
<td>NC</td>
<td></td>
<td>-</td>
<td>NS</td>
</tr>
<tr>
<td>7</td>
<td>2.5 (0.5)</td>
<td></td>
<td>2.4 (0.5)</td>
<td>NC</td>
<td></td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>8</td>
<td>10.5 (4.1)</td>
<td></td>
<td>17.3 (7.5)</td>
<td>NC</td>
<td></td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>GMFCS II</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>1.7 (0.5)</td>
<td></td>
<td>2.8 (0.8)</td>
<td>NC</td>
<td></td>
<td>↑</td>
<td>NS</td>
</tr>
<tr>
<td>10</td>
<td>3.0 (0.6)</td>
<td></td>
<td>4.3 (0.5)</td>
<td>NC</td>
<td></td>
<td>-</td>
<td>NS</td>
</tr>
<tr>
<td>11</td>
<td>1.3 (0.5)</td>
<td></td>
<td>1.8 (0.4)</td>
<td>NC</td>
<td></td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>12</td>
<td>1.5 (0.6)</td>
<td></td>
<td>2.0 (0.7)</td>
<td>NC</td>
<td></td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Group</td>
<td>3.7 (2.9)</td>
<td>4.2 (2.7)</td>
<td>6.5 (6.6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SD indicates standard deviation; FES, functional electrical stimulation; Vis, visual analysis; 2SD, 2 standard deviation band method; Function Classification System; ↑, trend identified at baseline by visual analysis; ↑, Significant improvement; -, 2SD not reported; Visual analysis; NS, not significant (p>0.05); NC, no change; U, Unstable baseline (>5° difference between minimum and maximum).
5 RANDOMISED CONTROLLED TRIAL

The pilot study provided a foundation to develop a comprehensive investigation into the effect of FES in a randomised controlled trial. The randomised controlled trial is reported here as Papers 2, 3 and 4. The presentation of the trial begins with the results from self-perceived scores for performance and satisfaction of child- and parent-identified priorities using the Canadian Occupational Performance Measure. This sets the scene for understanding the effect of FES on activity and participation from the child and parent’s perspective. Paper 3 will then explore the effect of FES on body structure and function with particular focus on muscle size, strength and selective motor control. The final paper will focus primarily on the effect of FES on gait and activity by investigating both the orthotic and therapeutic effects.

This trial is adequately powered as it was based on pilot study data to determine clinically meaningful changes in strength, range of motion and spasticity. The strength of investigating outcomes in a randomised controlled trial is that the effects of growth and usual physiotherapy care could be accounted for by comparing two groups of children with USCP. However, the heterogeneity of CP particularly in a relatively small sample is a well-known challenge. For this reason, children were randomly assigned using matched pairs or method of minimisation (Blair 2004). To preserve allocation concealment, random assignment only occurred once two children had enrolled in the study that were (a) within two years of each other if they were under ten years of age or within six years of each other if they were aged between 11 and 18 years and (b) of the same GMFCS level (GMFCS level I or II). This method aimed to improve the homogeneity of the groups based on age and GMFCS level. These factors appeared to be influential in the pilot study hence this method improves the confidence of comparing two like groups of children within a relatively large age range with differing mobility skills but within the clinical classification of USCP.

Table 10 summarises the main limitations and clinical observations from the pilot study and method to address them in the randomised controlled trial.
<table>
<thead>
<tr>
<th>Limitation identified in Pilot Study</th>
<th>How they will be addressed in RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of blinded assessments</td>
<td>Inclusion of blinded assessments where possible to represent each level of the ICF-CY.</td>
</tr>
<tr>
<td></td>
<td>• Body Structure and Function: Muscle volume and sensation</td>
</tr>
<tr>
<td></td>
<td>• Activity and Participation: COPM</td>
</tr>
<tr>
<td>Removal of AFO with no substitute foot support, unable to account for leg length discrepancy</td>
<td>Obtain funding to ensure provision of semi-rigid custom made orthotics for each participant if required. This will occur following an assessment from an Orthotist upon removal of AFO.</td>
</tr>
<tr>
<td>Unable to account for differences in activity levels.</td>
<td>Activity monitor to establish level of activity at baseline and during treatment.</td>
</tr>
<tr>
<td>Discrepancy between parent report and objective measures</td>
<td>Inclusion of comprehensive measures to represent all domains of the ICF-CY.</td>
</tr>
<tr>
<td></td>
<td>Incorporate assessment on activity level that include high level balance skills such as the Community Balance Mobility Scale (CBMS).</td>
</tr>
<tr>
<td></td>
<td>Include COPM for measures of performance and satisfaction of self identified performance problems to better reflect mobility in the community.</td>
</tr>
<tr>
<td>Variability in range of motion at baseline</td>
<td>Endeavor to homogenise groups by method of minimization. Less emphasis on determining the effect of FES on range of motion. Rather, continue to include range of motion to monitor and detect loss of range of motion after AFO removal.</td>
</tr>
<tr>
<td>Use of 2D gait video and Observational Gait Scale</td>
<td>Enhance the use of 2D gait video with the use of ground reaction force platforms for a more objective identification of gait events and measurement of sagittal plane joints.</td>
</tr>
</tbody>
</table>
All assessments are referenced and included in Appendix D and E. Parent and child information forms and consent forms are included in Appendix F and G. Examples of feedback forms to parents, treating therapists and rehabilitation physicians regarding individual results after the study are found in Appendix H.

The CONSORT study design flow diagram for the randomised controlled trial is demonstrated in Figure 12. All 32 participants who entered the trial, completed the trial in their original group allocation.

The presence of an orthotic effect is determined in the between group comparison at post treatment, when the treatment group is wearing the FES device. This is investigated by the:

• gait analysis assessment; and

• Canadian Occupational Performance Measure (COPM) as parents and participants rate their performance and satisfaction in their self identified mobility performance problems over the eight week treatment period.

The therapeutic effect will be determined both at post treatment and at follow-up through the examination of between group differences for the:

• lower limb clinical measures;

• community mobility balance scores;

• gait analysis (but only when the treatment group is not wearing the FES device); and

• COPM as parents and participants rate their performance and satisfaction in their self identified mobility performance problems over the six week follow-up period.
Figure 12. CONSORT flow diagram for the randomised controlled trial.
6 PAPER 2: DAILY FUNCTIONAL ELECTRICAL STIMULATION DURING EVERYDAY WALKING ACTIVITIES IMPROVES PERFORMANCE AND SATISFACTION IN CHILDREN WITH UNILATERAL SPASTIC CEREBRAL PALSY: A RANDOMIZED CONTROLLED TRIAL

Authors: Dayna Pool\textsuperscript{1}, Jane Valentine\textsuperscript{2}, Blackmore AM\textsuperscript{3}, Jennifer Colegate\textsuperscript{4}, Natasha Bear\textsuperscript{1}, Katherine Stannage\textsuperscript{5}, Catherine Elliott\textsuperscript{6}

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\textsuperscript{3}The Centre for Cerebral Palsy, Perth, Australia.

\textsuperscript{4}Department of Occupational Therapy and Paediatric Rehabilitation, Princess Margaret Hospital for Children, Perth, Australia

\textsuperscript{5}Department of Orthopaedics, Princess Margaret Hospital for Children, Perth, Australia.

\textsuperscript{6}Faculty of Health Science, Curtin University of Technology, Perth, Australia.

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Daily functional electrical stimulation during everyday walking activities improves performance and satisfaction in children with unilateral spastic cerebral palsy: a randomized controlled trial

Dayna Pool1*, Jane Valentine2, A. Marie Blackmore3, Jennifer Colegate4, Natasha Bear1, Katherine Stannage5 and Catherine Elliott6

Abstract

Background: The aim of this paper is to determine whether daily functional electrical stimulation (FES) is effective in improving self-perceptions of individually identified mobility performance problems in children with unilateral spastic cerebral palsy (USCP). We hypothesized that children receiving 8 weeks of FES treatment would have higher scores for self-perceived performance and satisfaction on the Canadian Occupational Performance Measure (COPM) for individually identified priorities than children not receiving FES.

Methods: Thirty-two children (mean age 10 y 8 mo SD 3 y 3 mo) with USCP and a Gross Motor Function Classification System I or II were randomly assigned to the FES treatment group (8 weeks of daily FES) and control group (usual treatments). Participants were assessed at baseline (week 0), post treatment (week 8) and 6 weeks follow-up (week 14). The primary outcome measures were self-perceived scores for performance and satisfaction of child- and parent-identified priorities assessed using the COPM post treatment and at follow-up. The secondary outcome measures were the categorization of the performance problems from the COPM and self-report responses according to the International Classification of Functioning Child and Youth version (ICF-CY). This was clinically important because an understanding of mobility performance problems for children with USCP is needed for family-centred service planning.

Results: Performance scores (mean difference 1.6, 95% CI 0.1 to 3.2, p = 0.034) and satisfaction scores post treatment (mean difference 2.4, 95% CI 0.5 to 4.2, p = 0.004) were significantly higher in the treatment group than in the control group. There were no significant differences between the groups for performance scores at follow up, however there was a significant difference between the groups for satisfaction (mean difference 1.9, 95% CI 0.1 to 3.8, p = 0.039) in favour of the treatment group. Priorities were identified across all levels of the ICF-CY but were most commonly identified in the activity and participation domains of the ICF-CY (79.5%).

Conclusions: Daily FES applied during everyday walking is effective in addressing self-perceptions of individually identified priorities by improving the performance and satisfaction of functional skills after treatment.

Trial registration: Australian New Zealand Clinical Trials Register ACTRN12614000945684. Registered 4 September 2014.

Keywords: Cerebral palsy, Unilateral spastic cerebral palsy, Spastic hemiplegia, Randomized controlled trial, Canadian occupational performance measure, Functional electrical stimulation, Activity, Participation, Satisfaction, Gait

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Background
Cerebral palsy describes a group of permanent motor dysfunctions caused by non-progressive brain injuries that can exacerbate activity limitations [18]. Unilateral spastic cerebral palsy (USCP) is the most common topographic presentation of cerebral palsy [1]. Most children with USCP are classified as having a Gross Motor Function Classification System (GMFCS) level of I or II [13]. This means that though children are independently ambulant, they still have limitations when walking in the community. This is largely attributed to the common lower limb secondary musculoskeletal impairments that are exacerbated with growth in children with USCP. These include a combination of gastrocnemius muscle spasticity, contracture, ankle dorsiflexion weakness and poor ankle selective motor control. The combination of these impairments limits effective foot clearance during the swing phase of gait and can cause tripping or falling when walking [24].

Functional electrical stimulation (FES) applied to the ankle dorsiflexors during the swing phase of gait can be used to address problems with foot clearance. FES refers to the application of neuromuscular electrical stimulation to muscles that may not be able to contract voluntarily within a task-specific functional activity such as walking [12]. An electrical current is used to produce an involuntary muscle contractions by inducing an action potential through the placement of two electrodes over the surface of the skin above the target skeletal muscle [17].

Evidence to support the effectiveness of FES in children with cerebral palsy has been increasing over recent years, particularly because devices suitable for children can now be purchased commercially. They are also more user-friendly, enabling FES to be managed by children and families in the community [11, 14, 15]. Common outcome measurement used to evaluate the effectiveness of FES have been focused mainly on the body structure and function level, which include range of motion, spasticity, strength, muscle volume and gait mechanics [7, 15, 19]. Although these measures have provided useful clinical information, they are not able to indicate how FES impacts the performance of individually specific daily activities in the community and the satisfaction of the user. Given that the application of FES during walking enables the intervention to be applied in the community, there is also a need to determine its effectiveness within these environments.

The Canadian Occupational Performance Measure (COPM) is a valid and reliable client-centred instrument that provides the opportunity to evaluate self-perceived effectiveness of treatment whilst considering the individually specific environment in which it is performed in [2, 5, 22]. Hence the COPM will also be used to evaluate the changes in the self-perception of performance and satisfaction of individually identified priorities following daily FES during everyday walking activities.

The aim of this paper is to determine whether FES in children with USCP is effective in improving self-perceptions of individually identified mobility performance problems when compared to children receiving usual treatments. We hypothesized that children receiving 8 weeks of FES treatment would have higher scores for self-perceived performance and satisfaction on the COPM for individually identified priorities than children not receiving FES. We also hypothesized that children who received FES treatment would continue to have higher scores for self-perceived performance and satisfaction at follow-up than children not receiving FES. The secondary aim of this study was to explore the mobility performance of children with USCP by employing the International Classification of Functioning Child and Youth version (ICF-CY) framework. This is clinically important because an understanding of mobility performance problems for children with USCP is needed for family-centred service planning.

Methods
Study design
The study design was a randomized controlled clinical trial of daily FES during every day walking activities to the ankle dorsiflexors compared with usual treatments (control group).

Participants
Participant inclusion criteria (Table 1) included: USCP; Gross Motor Function Classification System [13] level and Winters Gage and Hicks Classification [24] of I or II, age 5 to 18 years, at least 5 degrees passive ankle dorsiflexion and full knee extension, ability to co-operate with the assessment procedures. and willingness to use FES daily over 8 weeks. The schedule for study commencement was dictated by current clinical care involving botulinum toxin type A injections that is routinely delivered every 6 months. With the exception of 4 children who do not have routine botulinum toxin type A injections (2 children in the treatment group and 2 children in the control group), all remaining children have 6 monthly botulinum toxin type A injections. For these children, baseline measures commenced 3 months after injections which is widely accepted to be after the peak technical response due to motor end plate regeneration [8]. Participants were excluded if they had orthopaedic malunions at the site of stimulation, or if they had an uncontrolled seizure disorder.
Table 1 Inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive dorsiflexion range of affected ankle of at least 5°</td>
<td>History of uncontrolled seizure disorder</td>
</tr>
<tr>
<td>Full passive knee extension bilaterally</td>
<td>Orthopaedic lower limb surgery on the affected side in the past 12 months</td>
</tr>
<tr>
<td>Dynamic popliteal angle of no more than 45°</td>
<td>Orthopaedic metal wear at the site of electrical stimulation</td>
</tr>
<tr>
<td>Able to cooperate with assessment procedures</td>
<td>Botulinum toxin in lower limb in the past 3 months</td>
</tr>
<tr>
<td>Willing to use the Walk Aide® at least 4 h a day, 6 days a week for 8 weeks</td>
<td></td>
</tr>
<tr>
<td>GMFCS I or II, unilateral spastic cerebral palsy (with or without dystonia)</td>
<td></td>
</tr>
<tr>
<td>Winters Gage and Hicks gait classification of Type I or II</td>
<td></td>
</tr>
<tr>
<td>Aged between 5 and 18 years</td>
<td></td>
</tr>
</tbody>
</table>

Participants were referred from Physiotherapists and Paediatric Rehabilitation consultants between June and July 2013 from clinics of the Cerebral Palsy Mobility Service at Princess Margaret Hospital for Children and The Centre for Cerebral Palsy in Perth, Australia. The trial commenced in August 2013 with the final assessments completed by April 2014. Ethics committees at Princess Margaret Hospital for Children and The University of Western Australia approved the trial. The committees’ recommendations were adhered to. Written and informed consent for participation and publication was obtained from all participants. This trial was retrospectively registered (ACTRN12614000949084). However no changes were made to the protocol that was approved by the ethics committees.

Procedure
An initial appointment was firstly arranged by the first author (DP); a Physiotherapist, to determine FES tolerance and discuss the study protocol. Randomization to either the FES or control group was achieved through a coin toss, by an individual uninvolved with the study once 2 matched participants were enrolled. Matched participants were of the same GMFCS level, and were within 2 years of age for children aged between 5 and 10, and within 6 years for children aged between 11 and 18. This method was applied to improve the homogeneity of each group in terms of age and gross motor function.

Outcome measures
The primary outcome measures were self-perceptions of performance and satisfaction of individually prioritised mobility performance problems derived from the COPM.

The secondary outcomes were the categorization of the priorities identified in the COPM and self-reported parent/participant observations post treatment (FES group only at post treatment) into the domains of the ICF-CY [25].

Canadian occupational performance measure
A single interviewer (JC); an Occupational Therapist performed the COPM at all time points and was blinded to group allocation. At baseline, the interviewer assisted the child and family to identify occupational performance problems in the areas of self-care, productivity or leisure. Once they had identified these problems, they were written positively as goals, which participants and their parents then prioritised by importance on a scale from 1 to 10 (10 indicating greater importance). Scores out of 10 for self-perceived performance and satisfaction were then obtained from each participant (if the child was 12 years or older) or parent (if the child was under 12 years). The scores were summed and averaged over the number of priorities identified to produce two overall scores out of 10 for each participant; one for performance and one for satisfaction. At post-treatment and follow-up, participants were blinded to their previous ratings in order to limit potential bias [23]. A 2 point change in score on the COPM is considered to be clinically meaningful [23].

Participant and parent self-report
At post-treatment, participants and their parents were asked for written comments in answer to the question: “Have you noticed any changes in yourself since using the Walk Aide®?” Again, parents answered on behalf of children under 12 years.

FES intervention
Participants in the FES group received the FES device after the baseline assessment. The Walk Aide® (Innovative Neurotronics, Austin, TX, USA) is a small (8.2 cm x 6.1 cm x 2.1 cm, 87.9 g) device that delivers asymmetrical biphasic surface electrical stimulation (ES) in a synchronized manner to stimulate active dorsiflexion of the ankle during the swing phase of gait. The Walk Aide® is attached to the participant’s leg by a cuff and sits just below the knee on the affected side. During a gait cycle, the Walk Aide® stimulates the common peroneal nerve, which innervates tibialis anterior and other ankle dorsiflexors (extensor digitorum longus, peroneus tertius and extensor hallucis longus). Ankle dorsiflexion was achieved by the placement of one electrode over the fibular head to stimulate the peroneal nerve and the other electrode on the motor end point of tibialis anterior. Pulse width was set to a maximum of 300 microseconds (μs) and frequency was set at 33 hertz (Hz). Users could adjust intensity (mA) using a dial on the device. The Walk Aide’s tilt sensor was individually synchronized and
saved on the device so that the stimulation to the ankle dorsiflexors could occur immediately after toe-off, remaining activated during the swing phase of gait until initial contact.

Weekly to fortnightly community physiotherapy home and school visits were provided for parents and teachers/education assistants to support FES use in different environments whilst ensuring correct use of the cuff and accurate electrode placement. Participants were asked to change electrodes every two weeks. Any adverse events were to be reported immediately (via text message or email) to the first author (DP) in order to ensure follow-up in a reasonable time frame. Participants were asked to use the FES device for at least 4 h a day, 6 days a week during the 8-week treatment period. This was monitored through the usage log on the device itself. To enable participants an opportunity to accommodate to the device, they were asked to build up gradually to the required dosage over the first week. The 8-week treatment period and 6-week follow-up period was chosen based on the results from our pilot study [14] as well as around current clinical care on the use of botulin toxin injections (essentially so that the study duration would not be interrupted by botulin toxin injections in an effort to minimize the confounding effect of the injections to overall outcome).

Participants in the treatment group did not wear their ankle foot orthosis (AFO) either during the FES treatment phase or in the follow-up phase but where appropriate, were provided with customized in-shoe orthosis at the commencement of the study to support foot posture and accommodate for leg length discrepancies. Participants in the control group were asked to continue with their usual orthotic protocol. To maintain consistent contact with the participants, fortnightly home or school visits were also provided for each participant in the control group.

Statistical analysis

Normality was established for the COPM scores through examining distributional plots, Q-plots and the Shapiro-Wilk Test. Means and standard deviations were reported for each group for each phase. Within group differences were assessed for a clinically meaningful change i.e. 2 point score change [23] from baseline. Between group differences were examined using a repeated measures ANOVA to account for the correlation between repeated measures over time. Post-hoc Tukey’s test was applied if a main effect for group and time or an interaction of these was found, enabling adjustments for multiple comparisons and calculation of mean differences and 95% confidence intervals. Assumptions for the repeated ANOVA were examined and met.

Statistical significant was accepted as p < 0.05. All statistical analyses were performed using STATA version 12.1 (StataCorp, Texas).

To further explore the performance components of the identified priorities, each priority was analysed using 2 methods. Firstly, each priority was categorized by using the occupational performance model i.e. relating to occupational performance roles, areas or components [9, 10] which secondly, facilitated the translation to the ICE-CY to identify which domain or domains it addressed [16]. Two of the authors (DP and AMB) completed this process with 92% agreement (differences resolved by discussion).

Self-reported responses concerning overall impressions of the FES device were compiled, thematically analysed and categorized using the ICE-CY by 2 of the authors (DP and AMB). Examples are presented verbatim.

Results

Thirty-two children, mean age 10 y 8 mo (range 5 y 5 mo – 18 y 1 mo) with USCP GMFCS level I or II were recruited for the study. All participants had a Winters Gage and Hicks gait classification of I or II indicating foot clearance problems during walking gait. All participants completed the study in their original group allocation. There were no missing data (Fig. 1).

There were no clinically meaningful differences between the groups at baseline on the COPM (Table 2). Tests for normality showed that COPM scores were approximately normally distributed for performance (Shapiro-Wilk Test p = 0.133, Skewness -0.79, Q-plot normal) and satisfaction (Shapiro-Wilk Test p = 0.49, Skewness -0.36, Q-plot normal). Participants used the FES daily for a mean of 6.2 (SD 3.2) h over the 8-week intervention period. All participants had a frequency set at 33Hz and pulse width ranging from 25-100 μs. There were no reported unintended effects or adverse events using the FES device.

Primary outcome: COPM

There was a significant main effect for group (performance p < 0.001; satisfaction p < 0.001), time (performance p < 0.001; satisfaction p < 0.001) and for interaction of group and time (performance p = 0.003; satisfaction p = 0.002). Post treatment, performance scores (mean difference 1.6, 95% CI 0.1 to 3.2, p = 0.034) and satisfaction scores (mean difference 2.4, 95% CI 0.5 to 4.2, p = 0.004) were significantly higher in the treatment group than in the control group. At follow-up, there were no significant differences between the groups for performance scores (mean difference 1.2, 95% CI -0.4 to 2.8, p = 0.224). However, there was a significant difference between the groups for satisfaction (mean difference 1.9, 95% CI 0.1 to 3.8, p = 0.030), again in favour of the treatment group.

From the baseline performance score in the treatment group (3.97, SD 1.42), there were clinically meaningful changes (i.e. >2 point change) post treatment (6.97, SD 1.04) and at follow-up (6.66, SD 1.57). From the baseline satisfaction score in the treatment group (4.36, SD 1.69),
there were also clinically meaningful changes post treatment (7.45, SD 1.34) and at follow-up (6.99, SD 2.11). There was a trend for the control group having higher scores at post treatment and follow-up than at baseline for performance and satisfaction but these changes were not clinically meaningful. These results are shown graphically in Figs. 2 and 3.

Secondary outcome: ICF-CY classification of priorities
Participants in the study identified 1 to 3 priorities each. There were a total of 80 individual priorities for the 32 participants. Some of the priorities involved more than 1 domain on the ICF-CY. For example, one of the priorities was "to walk consistently with a heel to toe pattern to improve my symmetry (so I don’t have to wear an AFO)." This included 2 parts involving (a) improving walking mechanics (activity); (b) not need an AFO (personal). Hence, when the original 80 priorities were divided into their component parts, there were 122 specific priorities. These 122 priorities were categorized into body structure and function, activity and participation domains as well as personal and environmental factors. As shown in Table 3, 17% of the priorities were directed towards the need to improve impairments in body structure and function, 49% were directed towards improving functional mobility in the activities domain and 31% were directed towards improving community mobility and active recreation in the participation domain.

Secondary outcome: ICF-CY classification of self-reported changes in treatment group
ICF-CY analysis identified 5 major themes: (a) improved running and walking (activity, n = 13); (b) improved comfort with more options to wear different shoes (personal factor, n = 6) with comments such as "the walk aide means less blisters on my feet, easier to put on shoes and her dad got her ‘girls’ shoes and they stay on her feet – really pleased;" (c) reduction in trips and falls (participation, n = 4), (d) improved confidence (personal factor, n = 4) and; (e) increased foot awareness (body structure and
Table 2 Baseline characteristics of participants

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>38.5 (15.2)</td>
<td>37.4 (15.9)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male: 9</td>
<td>Male: 8</td>
</tr>
<tr>
<td></td>
<td>Female: 7</td>
<td>Female: 8</td>
</tr>
<tr>
<td>Side of hemiplegia</td>
<td>Right: 11</td>
<td>Right: 12</td>
</tr>
<tr>
<td></td>
<td>Left: 5</td>
<td>Left: 4</td>
</tr>
<tr>
<td>GMFCS</td>
<td>11.10</td>
<td>11.10</td>
</tr>
<tr>
<td></td>
<td>11.6</td>
<td>11.6</td>
</tr>
<tr>
<td>WGH</td>
<td>115</td>
<td>115</td>
</tr>
<tr>
<td></td>
<td>115</td>
<td>115</td>
</tr>
<tr>
<td>Age</td>
<td>10y 11mo</td>
<td>10y 5mo</td>
</tr>
<tr>
<td></td>
<td>2y 10mo</td>
<td>2y 8mo</td>
</tr>
<tr>
<td>COPM</td>
<td>Performance</td>
<td>3.07 (1.42)</td>
</tr>
<tr>
<td></td>
<td>Satisfaction</td>
<td>4.36 (1.69)</td>
</tr>
</tbody>
</table>

* Independent samples t test; GMFCS, Gross Motor Function Classification System; WGH, Wesnes Gage and Hicke; COPM, Canadian Occupational Performance Measure.

function, n = 2) with comments such as “feel more aware of your foot placement when wearing the walk aide” and “I can feel when it raises my toes when walking.”

The comments also yielded some disadvantages of the Walk Aide (n = 2) which included problems with the size and difficulties in getting clothing over it, causing the cuff to “fall apart quite often”. Three of the participants did not wish to continue wearing Walk Aide beyond the study period because of difficulties with accurate placement, bulkiness, problems with wearing school uniforms (stockings or leggings), and difficulties in attaining a good fit owing to the cuff sliding down the leg during walking. The remaining 13 participants in the FES group continued to use the Walk Aide either as an AFO replacement or as an adjunct to their AFO protocol.

Participant 10 wrote a more detailed account of her experiences post treatment:

“Although compared to many other cases, my CP is quite mild, it has had quite an effect on me over the years; mentally, physically and emotionally... To be honest I wasn’t very keen on it in the beginning; I felt like it added to the things that made me different... but as the study progressed it quickly became the thing that drew me closer to my peers. Emotionally, I struggled with feeling different or out of place; having to wear splints or orthotics, but through the use of the Walk Aide, I began to feel more confident and enthusiastic to do the things I had to do to maintain the physical effects of the Walk Aide. The Walk Aide for me, reduced, in fact eliminated my pain (foot, leg and low back), boosted my confidence, gave me the ability to wear shoes like thongs in summer (one of my goals), increased my energy levels, and gave me the ability to walk long periods of time without growing weak or sore.”

Discussion

The FES group achieved significantly higher scores for self-perceived performance and satisfaction on the COPM.
at post treatment than the control group. This supports the first hypothesis, that FES is effective in improving self-perceived performance and satisfaction of individually identified mobility performance problems in children with USCP. There has been limited support for the efficacy of FES, particularly in regard to the activity and participation domains of the ICF-CY. This has in part, been attributed to the limited inclusion of valid and reliable activity and participation outcome measures [3, 4]. Therefore, these results not only provide unique evidence supporting the effectiveness of FES on activity and participation but also, that the results are consistent with current knowledge on the effectiveness of FES on the main lower limb impairments observed in children with USCP. Currently, the literature supports that FES can improve selective motor control, range of movement, spasticity, strength and ankle kinematics during gait [11, 14, 15]. Therefore, it appears that by implementing FES during daily walking activities, the main impairments affecting gait in children with USCP are addressed alongside quantifiable functional benefits reflected in the activity and participation domains.

Children who received FES treatment continued to have higher scores for self-perceived satisfaction, but not for performance when compared to children not receiving FES at follow-up. This partially supports the second hypothesis. This is consistent with current findings documenting that the effects of FES on muscular adaptations are use-dependent [7]. This provides a plausible explanation for why the self-perceived performance scores were no longer significantly improved in the treatment group when compared to the control group at the 6 week follow-up. However, this result also suggests that a period of no FES (to a maximum of 6 weeks) can be incorporated into the management plan for children with USCP without significant detriment to the satisfaction of users. This may be advantageous because of the potential to develop dependence on the external stimulus replacing the internal control of movement [6]. Given that self-perceived performance scores were no longer significantly higher in the treatment group than in the control group at follow-up, a non-use period greater than 6 weeks would not be recommended. Alternating between FES use and non-use, as adopted in this study, could be implemented to suit individual and family needs such as planning around holidays, school camps and seasons. Further study is warranted to determine whether extending this regimen would maintain the effects reported in the present study.

The secondary analysis of the priorities identified in the COPM demonstrated that the majority of occupational performance problems for children and parents were related to functional mobility activities, community mobility and active recreation participation. However in some instances, children and parents also identified specific impairments in body structure and function. Although the construct of the COPM facilitates the identification of priorities more relating to activities and participation, we included this data to reflect the priorities of children and their parents. The inclusion of priorities in this domain highlights that children
Table 3 Breakdown of the number (out of a total of 122) and percentage of ICF-CY domains (alongside the occupational performance components, areas and roles) in the identified priorities

<table>
<thead>
<tr>
<th>Body Structure and Function Performance Components</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomechanical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strength</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Balance</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>ROM</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Sensory</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Leg pain</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Sub Total</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Activities Occupational Performance area</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional Mobility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improve walking mechanics</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>Improve walking endurance</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Improve running</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Improve high level gross motor skills</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Sub Total</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>Participation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupational performance; role competence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community mobility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduce falls</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Reduce trips</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Active Recreation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keep up with friends</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Improve sport performance</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Sub Total</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>Environmental/Personal Factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wear certain kinds of shoes</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Not need AFO</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Sub Total</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

and their parents understand the body structure and function components that influence performance and for Physiotherapists, the value of addressing them in treatments. However, it also reinforces the importance of clear and sensitive communication from clinicians, realizing the influence of language on the priorities of children and their parents.

In some instances, multiple domains were included within each priority, reflecting the complexity and breadth of outcome measures that would be required in order to capture and quantify potential effects of treatment. Previous FES studies have reported discrepancies between the outcomes of objective clinical outcome measures and the more favourable parent reports [14, 20]. The complexity of priorities may explain the discrepancy between clinical objective measures and parent report, because the objective outcome measures emphasized body structure and function assessed within a clinical environment. Hence the outcome measures did not align closely with the priorities of children and parents, which often emphasized activities and participation in their own environment and community.

The self-report also provided some additional insights to (previously unreported) effects of FES after 8-weeks of use. These included reports of improved confidence, improved foot awareness, and improved range of movement. The results of this study support the effectiveness of community applied FES to improve self-perceived individually identified priorities, particularly when they involve the performance of functional mobility, community mobility and active recreation in children with USCP.

Considerations and recommendations for the use of daily FES

Participants and their parents described some disadvantages to wearing the FES device. Their comments indicated that acceptance of the FES device goes beyond mere biomechanical physical and compliance requirements. Because the FES device needed to be strapped directly over skin, there were issues with clothing, in particular leggings or stockings for school uniforms. For younger children, the combination of the cuff and device were bulky, and parents struggled to find clothing to fit over it. Also for younger children, the cuff fitting was an issue, as it would slide down the leg during walking and running. Older children usually managed these problems, but younger children needed to have adequate support at home and school. When prescribing the Walk Aide®, it is important to consider the individually specific environmental factors that may affect treatment. Therefore, providing information and education to people involved in the child’s care is essential. This highlights the importance of ensuring that community therapy services are available and in place prior to considering this intervention. However it should be noted that the Walk Aide® is still essentially a device that was specifically designed for adults. Though small cuffs have been recently available, the size of the Walk Aide® continues to be a potentially limiting factor for patient selection. Further investment into the technology and fit of this device is recommended.

Future studies should consider the cost effectiveness of this intervention. Although the cost-effectiveness of FES in the adult population has been supported [21], this has not been evaluated in children with USCP. For some children, it may be appropriate for FES to replace the use of AFOs. However, in other children, FES may be an adjunct to current therapy and AFO intervention. Evidently, this influences costs and should be evaluated further. Further work is also warranted to develop a
questionnaire that would be appropriate for younger children to provide further perspectives on the effectiveness of FES treatments. There are some limitations to note. Although qualitative self-report provided insights into the FES experience, it was unstandardized, and so the comments must be considered with some caution. Also, the outcomes of the intervention were dependent on family and school support. This could not be controlled and may have varied across the participants.

**Conclusions**

Daily FES during everyday walking activities improves self-perceptions of individually identified priorities, particularly involving the performance of activities, community mobility and active recreation in children with USCP. Alternating between a period of use and non-use may be appropriate without detriment to the satisfaction of the user, and this may be beneficial to suit family needs. The role of community therapy is also highlighted for the education and training of both families and teachers so that this intervention can be successfully implemented within each child’s own relevant environments.

**Abbreviations**

FES: Functional Electrical stimulation; USCP: unilateral spastic cerebral palsy; COPM: Canadian Occupational Performance Measure; ICF: International Classification of Functioning Child and Youth version; AIFS: ankle foot orthosis; SD: Standard Deviation; CI: Confidence Interval; IQ: Intra-individual range; fE: treatment; CP: cerebral palsy; GMFCS: Gross Motor Function Classification System.

**Competing Interests**

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

**Authors’ contributions**

DP was the principle investigator and is a PhD student enrolled with The University of Western Australia. DP conceptualized and designed the study. The initial manuscript was co-written. JC performed the Canadian Occupational Performance Measurement assessment. DP and AMB performed the International Classification of Functioning analysis on the principles from the Canadian Occupational Performance Measurement and self-report. JV, KS, and CE supervised the data collection and carried out the initial analysis. DP and NS performed the statistical analysis of the data. All authors read and approved the final manuscript.

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**References**


6.1 Paper 2 Additional Results

To further investigate the achievement of child and parent-identified performance problems, additional analysis was undertaken to determine whether child-set or parent-set problems were more likely to be achieved. Although these results were not included in the published article, the results are still of benefit for clinicians.

Individual Canadian Occupational Performance Measure (COPM) performance problems were classified as achieved, (at least 2 point increase in COPM score) partly achieved (1 point increase) or not achieved (0 points change or decrease) at post treatment and at follow-up, based on a modified version of that used by Dunford (Dunford, 2011). Fisher Exact Probability Test was used to determine whether child-set or parent-set problems were more likely to be achieved at post treatment and at follow-up.

In the treatment group, there were 24 child-set and 18 parent-set performance problems. In the control group, there were 18 child-set and 20 parent-set performance problems. The similarity of numbers enabled comparisons to be made within each group to determine whether participant-set or parent-set performance problems were more likely to be achieved. However, owing to the small numbers, performance problems that were not achieved and performance problems that were partly achieved were combined (although shown separately as a percentage in the Table 11). These were compared with performance problems that were fully achieved. There was no statistically significant difference in the proportions of parental-set performance problems and the proportions of child-set performance problems that were fully achieved at either post treatment or follow-up for the treatment group ($p = 0.147$ and $0.338$ respectively) or the control group ($p = 0.740$ and $p = 0.724$ respectively). Either the child or parent may therefore complete the COPM without affecting the likelihood of achievement.
Table 11. Percentages of child-set and parent-set performance problems achieved at post treatment and follow-up

<table>
<thead>
<tr>
<th></th>
<th>Treatment Group (%)</th>
<th>Control Group (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Child</td>
<td>Parent</td>
</tr>
<tr>
<td><strong>Post treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not achieved</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td>Partly achieved</td>
<td>17</td>
<td>11</td>
</tr>
<tr>
<td>Achieved</td>
<td>67</td>
<td>89</td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not achieved</td>
<td>33</td>
<td>11</td>
</tr>
<tr>
<td>Partly achieved</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Achieved</td>
<td>54</td>
<td>72</td>
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</table>
PAPER 3: NEUROMUSCULAR ELECTRICAL STIMULATION-ASSISTED GAIT INCREASES MUSCLE STRENGTH AND VOLUME IN CHILDREN WITH UNILATERAL SPASTIC CEREBRAL PALSY

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Neuromuscular electrical stimulation-assisted gait increases muscle strength and volume in children with unilateral spastic cerebral palsy

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AIM To determine if neuromuscular electrical stimulation (NMES) applied to the ankle dorsiflexors during gait improves muscle volume and strength in children with unilateral spastic cerebral palsy (CP).

METHOD Thirty-two children (15 females, 17 males; mean age 10y 8mo, age range 5y 6mo–18y 1mo) with unilateral spastic CP and a Gross Motor Function Classification System of level I or level II were randomly assigned to either the 8-week daily NMES treatment group or control group (usual or conventional treatments). Outcomes at week 8 (post-NMES) and week 14 (carryover) included magnetic resonance imaging for muscle volumes (tibialis anterior, anterior compartment, and gastrocnemius), strength (hand-held dynamometry for isometric dorsiflexion strength and heel raises for functional strength), and clinical measures for lower limb selective motor control.

RESULTS At week 8, the treatment group demonstrated significantly (p<0.05) increased muscle volumes for tibialis anterior, anterior compartment, medial and lateral gastrocnemius, and dorsiflexion strength not only when compared to their baseline values but also when compared to the control group at week 8. At week 14, both tibialis anterior and lateral gastrocnemius volumes in the treatment group remained significantly increased when compared to their baseline values. However, only lateral gastrocnemius volumes had significantly greater values when compared to the control group at week 14. There were no between group differences in the clinical measures for lower limb selective motor control at week 8 and 14.

INTERPRETATION Eight weeks of daily NMES-assisted gait increases muscle volume and strength of the stimulated ankle dorsiflexors in children with unilateral spastic CP. These changes are use-dependent and do not carry over after the 8-week treatment period. Gastrocnemius volume also increased post-treatment with carryover at week 14.

Problems with ankle selective motor control (SMC), atrophy, and weakness to the muscles around the ankle joint are well-documented impairments in children with unilateral spastic cerebral palsy (CP). While the majority of children with unilateral spastic CP are ambulant, these impairments contribute to equinus when walking and result in the recruitment of compensatory strategies or incidence of trips and falls. Interventions such as strength training are often employed to address these impairments but these efforts can be hampered by poor SMC and insufficient training volume to achieve clinically meaningful changes. Investigating effective methods that aim to ameliorate these impairments are necessary to provide immediate functional benefit as well as for the maintenance of long-term mobility.

Neuromuscular electrical stimulation (NMES) is the application of an external electrical impulse to initiate a limited voluntary skeletal muscle contraction. A muscle contraction is elicited when an electrical current is delivered through electrodes placed over the skin of the target muscle or nerve to activate intact motor units by inducing an action potential. A unique feature of NMES is that it can be employed even if there are problems with SMC. Reduced SMC refers to the impaired ability to isolate the activation of muscles in a selected pattern in response to demands of a voluntary posture or movement. For this reason, NMES-assisted gait (also commonly referred to as functional electrical stimulation) has been used as a rehabilitation modality in adult stroke rehabilitation to address...
the functional consequences of equinus. More recently, NMES-assisted gait has been applied during walking in children with spastic CP to similarly overcome problems with equinus. The predictable and repetitive nature of a gait pattern enables NMES of the ankle dorsiflexors during swing to be triggered by predictable phases of gait, such as the tibial or shank angle at toe-off. Such technology has enabled NMES-assisted gait to be applied in the child’s own environment, which advantageously enables high dose intervention to be embedded within activity.

So far, the literature describes NMES applied to the ankle dorsiflexors during gait to be well tolerated, with compelling improvements in ankle kinematics, thus producing an orthotic effect, i.e. stimulation of tibialis anterior to clear the foot during swing phase of gait. Further, it has also been recognized that the orthotic effect of NMES-assisted gait can have the additional benefit of improving the muscle volume, strength, and ankle SMC of the stimulated muscle tibialis anterior in children with unilateral spastic CP.

While the recent emergence of these studies provides compelling results to support the efficacy of the NMES-assisted gait in children with CP, one limitation to these pioneering studies is that control groups were not included. The inclusion of control groups is particularly relevant in paediatric populations to enable distinctions between training-induced hypertrophy and natural development or growth. Therefore, there is a need to evaluate the effect of NMES-assisted gait in a randomized controlled trial to not only investigate its effect over time but also when compared to a control group undergoing conventional therapy. The investigation of potential carryover effects (also referred to as therapeutic effects) following the discontinuation of NMES, is also essential to improve our understanding of this intervention in children with CP.

The aim of this study is to conduct a randomized controlled trial to evaluate the effectiveness of an 8-week community-applied NMES-assisted gait programme on muscle strength and volume in children with unilateral spastic CP. We hypothesized that children undergoing an 8-week NMES-assisted gait treatment period would demonstrate a greater increase in ankle dorsiflexion strength and muscle volume compared to children without NMES. We also hypothesized that children who received 8 weeks of NMES-assisted gait would maintain the muscle hypertrophy and strength improvements at the 6-week follow-up compared to children without NMES.

**METHOD**

**Design**

The study design was a randomized controlled trial to investigate the effect of an 8-week daily community-applied NMES-assisted gait programme to the ankle dorsiflexors compared with usual or conventional care (control group).

**Participants**

Thirty-two children (17 females, 15 males; mean age 10y 8mo, SD 3y 3mo) with unilateral spastic CP, in Gross Motor Function Classification System (GMFCS) level I or II, were recruited for the study. Table 1 demonstrates that there were no significant between group differences in participant characteristics at baseline. Participants were referred to the study from physiotherapists and paediatric rehabilitation consultants. Participant inclusion criteria included children with unilateral spastic CP, GMFCS level I or II between the ages of 5 and 18. Participants needed to have at least 5 degrees of passive ankle dorsiflexion (with the knee extended) and full knee extension. Participants had to be able to co-operate with assessment procedures and be willing to use the NMES-assisted gait device daily for 8 weeks.

The schedule for study commencement was dictated by current clinical care involving botulinum toxin-A (BoNT-A). BoNT-A is injected at 6-monthly intervals if clinically indicated. With the exception of four children who do not have routine BoNT-A injections (two children in the treatment group and two children in the control group), all remaining children have 6-monthly BoNT-A injections. For these children, baseline measures commenced 3 months after injections, which is widely accepted to be after the peak technical response caused by motor end plate regeneration.

**Table 1: Characteristics of participants**

<table>
<thead>
<tr>
<th></th>
<th>Treatment (n=16)</th>
<th>Control (n=16)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
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<td>37.4 (15.9)</td>
<td>0.850*</td>
</tr>
<tr>
<td>Sex</td>
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</tr>
<tr>
<td></td>
<td>Female: 7</td>
<td>Female: 8</td>
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<tr>
<td>Side of hemiplegia (n)</td>
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<td>Right: 12</td>
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</tr>
<tr>
<td></td>
<td>Left: 5</td>
<td>Left: 4</td>
<td></td>
</tr>
<tr>
<td>GMFCS (n)</td>
<td>I: 10</td>
<td>I: 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>II: 6</td>
<td>II: 6</td>
<td></td>
</tr>
<tr>
<td>Age, y (SD)</td>
<td>10.11 (3.10)</td>
<td>10.25 (2.8)</td>
<td>0.950*</td>
</tr>
<tr>
<td>Orthoses (n)</td>
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<td>6</td>
</tr>
<tr>
<td></td>
<td>Fixed AFO</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>History of BoNT-A (n)</td>
<td>14</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>-10 injections</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>11-20 injections</td>
<td>9</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>-21 injections</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Muscle volume</td>
<td>Tibialis anterior</td>
<td>0.59 (0.21)</td>
<td>0.57 (0.13)</td>
</tr>
<tr>
<td>(symmetry ratio)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strength</td>
<td>Dorsiflexion (normalized)</td>
<td>0.11 (0.09)</td>
<td>0.12 (0.07)</td>
</tr>
<tr>
<td></td>
<td>Ankle motor control</td>
<td>3 (2-3)</td>
<td>3 (2-3)</td>
</tr>
</tbody>
</table>

*Test. *Mann-Whitney U test. GMFCS, Gross Motor Function Classification System; AFO, ankle-foot orthoses; BoNT-A, botulinum toxin-A; SMC, selective motor control.
Participants were excluded if they had orthopaedic surgery on the affected side in the past 12 months, had orthopaedic metalware at the site of stimulation, or had uncontrolled seizure disorder.

Study recruitment took place between June and July 2013 in Perth, Australia from clinics of the Cerebral Palsy Mobility Service at Princess Margaret Hospital for Children and The Centre for Cerebral Palsy, with the final assessments completed by April 2014. Ethics committees at Princess Margaret Hospital for Children and The University of Western Australia approved the registered trial (ACTRN12614000949684) and the committee's recommendations were adhered to, with written and informed consent for participation and publication obtained.

Procedure

An initial appointment with the principal investigator was scheduled to determine NMES tolerance and introduce the study protocol. Randomization to either the treatment or control group was achieved through a coin toss, performed by an individual uninvolved with the study, once two matched participants were enrolled. Criteria for matched participants were: (1) within 2 years of age for children aged between 5 and 10 years and within 6 years of age for children aged between 11 years and 18 years, and (2) in the same GMFCS level. This method was applied to improve the homogeneity of each group in terms of age and gross motor function.

Outcome measures were assessed at baseline, week 8, and week 14. Participants in both groups were asked not to participate in any new sporting activities during the study and to maintain pre-existing conventional therapy (including stretching, neurodevelopmental therapy, and strengthening programmes) throughout the 14-week study period to better isolate the effects of NMES treatment.

Outcome measures

This randomized controlled trial of community-based NMES assessed outcomes across all domains of the International Classification of Functioning, i.e., body structure and function, activity, and participation. The results on activity and participation are reported elsewhere.27,28 This paper reports on the results pertaining to body structure and function, i.e., muscle volume, strength, and motor control.

Calculation of overall muscle volume was achieved using magnetic resonance imaging (MRI).24 Bilateral MRI of the lower limb were taken at the Department of Diagnostic Imaging at Princess Margaret Hospital for Children, Perth, Australia. T1-weighted spin echo sequence was used following standardized protocols,24 with a slice thickness of 5 mm and mean inter-slice gap between 5 mm and 7 mm. Images were analyzed using Mimics visualization software (Version 16.0; Materialise, Leuven, Belgium) following a standardized procedure described previously.24 All volumes were normalized to tibia length to account for differences in participant stature and/or growth between scans.

Muscle volumes are also expressed as a symmetry ratio (with a value of 1 indicating perfect symmetry) in relation to the unaffected side. This enables quick and meaningful interpretation of the data while considering the effect of growth or activity in the unaffected limb. In addition to tibialis anterior, the volume of the anterior compartment (tibialis anterior, extensor hallucis longus, extensor digitorum longus, and peroneus tertius) was also included in the analysis because of its contribution to ankle dorsiflexion. The volumes for soleus and gastrocnemius were also obtained. The intra- and inter-rater (to ensure consistency of techniques with investigators in previous studies) reliability of the muscle volume measurements was high, with intraclass correlation coefficient values of 0.99 calculated by testing a random selection of five scans of all muscles (25 muscles in total).24,25

Strength was assessed using hand-held dynamometry for ankle dorsiflexion. Maximum isometric ankle dorsiflexion strength was measured using three times using hand-held dynamometry (Lafayette Nicolas Manual Muscle Tester Model 01160) using the stabilization test position following Crompton et al.24 protocol, i.e., supine with the knee stabilized in extension, foot held in plantarflexion position with resistance applied to the dorsal surface of the metatarsal heads. To enable equitable comparisons for children of different foot length and body size, the median value was normalized to weight and foot length.27 The maximum of single limb heel raises was used to estimate functional ankle plantarflexion strength.26,27 The method and procedure for a successful heel raise followed Yocum et al.'s description and that of our pilot work.13,28

SMC was assessed using two common clinical tools. Boyd and Graham's ordinal scale for ankle SMC assessment was used because of its relevance to clinical practice and applicability in young children.29 This 5-point ordinal scale ranges from 0 describing no active movement to 4, which describes balanced ankle dorsiflexion through full available range of motion with the knee extended. A score change of 1 was considered to be clinically meaningful.29

The Selective Control Assessment of the Lower Limb (SCALE) was also employed because of its established validity and reliability. Although the SCALE measures SMC of all lower limb joints (providing a score out of 10), it has a greater weighting for the ankle and foot.2 Only the affected limb score was used for analysis and we considered a score change of 2 to be clinically meaningful.

The assessments were all performed on the same day. An experienced physiotherapist and research assistant followed the outlined protocols for the strength and SMC assessments. MRI was randomized, then processed and analyzed by one assessor. The assessor was blinded to the assessment time point and group allocation.

NMES-assisted gait intervention

Participants in the treatment group received the NMES-assisted gait device after the baseline assessment. The Walk Aide (Innovative Neuromotronics, Austin, TX, USA) is a...
small (8.2cm x 6.1cm x 2.1cm, 87.9g) device that delivers asymmetrical biphasic surface electrical stimulation triggered by tibial motion to enable toe clearance by stimulating active dorsiflexion during the swing phase of gait. It is attached to the participant’s leg by a cuff that sits just under the knee on the affected side. One electrode is placed on the muscle belly of the tibialis anterior and the other on the common peroneal nerve, which innervates tibialis anterior and other ankle dorsiflexors (extensor digitorum longus, peroneus tertius, and extensor hallucis longus). Before the application of the Walk Aide in the gait cycle, electrode position, amplitude, and pulse widths were determined with the participant in long sitting. This process enabled individual settings to be established by balancing tolerance to the stimulation and in the attainment of dorsiflexion without excessive ankle movements into inversion or eversion (this limitation meant that only 5 degrees could be achieved in some children).

During a gait cycle, the Walk Aide is triggered by an individualized programme detecting changes in tibial angle to stimulate ankle dorsiflexion. The set-up procedure followed that described in our pilot study. Participants and parents were supported so that they were confident and independent with the NMES-assisted gait device, ensuring balanced dorsiflexion with every use. Weekly or fortnightly visits at home or school were necessary for education to support daily use, adjust parameters to ensure adequate dorsiflexion, monitor electrode integrity, and inspect for any adverse events.

Participants were asked to use the Walk Aide for at least 4 hours per day, 6 days per week during the 8-week treatment period. This was monitored through the usage log on the device itself. To enable participants an opportunity to accommodate to the device, they were asked to gradually build up to the required dosage over the first week. Participants in the NMES treatment group did not wear their ankle-foot orthoses (AFO) throughout the study. They were provided with customized in-shoe orthoses at the commencement of the study to support foot posture and account for leg length discrepancies particularly in the absence of AFOs. Participants in the control group were asked to continue with their usual orthotic treatments.

Statistical analysis
Based on effect sizes observed in our pilot study of NMES-assisted gait use, a one-tailed alpha of 0.05 and power of 80% power analysis suggested that each group required at least 15 participants per group to detect a clinically meaningful change of six heel raises.

Normality was established through examining distributional plots, Q-plots, and the Shapiro–Wilk test. For normally distributed interval data (muscle volume symmetry ratios, normalized dorsiflexion strength, and SCALE), repeated measures analysis of variance was used to establish within and between group differences. To examine between group differences at week 8 and week 14, baseline measures were entered as a covariate, resulting in a repeated analysis of the covariance model. If a significant main effect for group and time or an interaction of these was found, post hoc Tukey’s analysis was applied. This enabled adjustments for multiple comparisons, calculation of mean differences, and 95% confidence intervals. Normalized muscle volume data was transformed using the natural log because of skewed distributions. Following the analysis, data was back-transformed by taking the exponential, with the interpretation in terms of percentage change.

Back-transformation outputs are expressed as ratios of the geometric mean, with any back-transformed coefficients with a 95% confidence interval crossing the value 1, indicating a non-significant result. Effect sizes were determined for statistically significant comparisons by using Cohen’s d calculation, with a value of 0.8 considered a large effect, 0.5 to be a medium, and 0.2 to be a small effect.

Between group differences for ordinal data (ankle SMC) and when assumptions for normality even after transformation were not met (heel raises), the Mann–Whitney U test was applied to change scores. Correspondingly, the Wilcoxon signed-rank test was used for examining within group changes over time. Relationships between the variables were examined using scatterplots and correlation coefficients. Intention to treat principle was applied. For all statistical tests, significance was p<0.05 with analyses performed using Stata version 12.1 (StataCorp, College Station, TX, USA). Given the heterogeneity of CP, individual intervention effectiveness was also explored by reviewing individual graphs. We reasoned that this might provide clinicians with an understanding of the variations in individual response.

RESULTS
All participants who provided informed consent entered and completed the study in their original group assignment. The baseline MRI for one participant in the control group was eliminated because of movement artifact. The clinical measures of strength and SMC were complete for all 32 participants.

All participants had a frequency set at 33Hz with pulse width ranging from 25 to 100µs. Participants used NMES-assisted gait daily for a mean of 6.2 (SD 3.2) hours over the 8-week intervention period. There were no reported unintended effects or adverse events using the NMES device.

Muscle volume
The treatment group demonstrated significantly increased volumes (for both normalized volumes and muscle volume symmetry ratios) in all muscles except for soleus at week 8 when compared to baseline measures (Table II and Fig. 1). Notably, as indicated in Table III, the treatment group’s normalized tibialis anterior volume had significantly increased by 23% (95% CI 14–31; p<0.001; d=0.62) at week 8 when compared to baseline. At week 14, there were significant increases in lateral gastrocnemius muscle vol-
Table II: Mean (SD) of groups for muscle volume, ankle dorsiflexion strength, and Selective Control Assessment of the Lower Extremity (SCALE) Groups

<table>
<thead>
<tr>
<th></th>
<th>Wk 0</th>
<th></th>
<th>Wk 8</th>
<th></th>
<th>Wk 14</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rx</td>
<td>Con</td>
<td>Rx</td>
<td>Con</td>
<td>Rx</td>
<td>Con</td>
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<tr>
<td>Normalized muscle volume (affected side muscle volume/tibia length)</td>
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</tr>
<tr>
<td>Tib anterior</td>
<td>0.82 (0.23)</td>
<td>0.72 (0.29)</td>
<td>1.00 (0.34)</td>
<td>0.74 (0.36)</td>
<td>0.87 (0.27)</td>
<td>0.74 (0.33)</td>
</tr>
<tr>
<td>Anterior comp</td>
<td>1.49 (0.54)</td>
<td>1.57 (0.63)</td>
<td>2.00 (0.59)</td>
<td>1.57 (0.69)</td>
<td>1.76 (0.50)</td>
<td>1.61 (0.67)</td>
</tr>
<tr>
<td>Medial gastroc</td>
<td>1.84 (0.72)</td>
<td>1.84 (0.88)</td>
<td>1.71 (0.83)</td>
<td>1.84 (0.88)</td>
<td>1.60 (0.77)</td>
<td>1.53 (0.89)</td>
</tr>
<tr>
<td>Lateral gastroc</td>
<td>0.93 (0.39)</td>
<td>1.02 (0.54)</td>
<td>1.08 (0.49)</td>
<td>1.00 (0.59)</td>
<td>1.07 (0.50)</td>
<td>0.97 (0.51)</td>
</tr>
<tr>
<td>Soleus</td>
<td>3.91 (1.37)</td>
<td>3.99 (1.59)</td>
<td>3.85 (1.31)</td>
<td>3.97 (2.08)</td>
<td>3.89 (1.34)</td>
<td>3.56 (2.01)</td>
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<tr>
<td>Muscle volume symmetry ratio (affected/unaffected muscle volume)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tib anterior</td>
<td>0.59 (0.21)</td>
<td>0.57 (0.13)</td>
<td>0.72 (0.22)</td>
<td>0.68 (0.13)</td>
<td>0.63 (0.19)</td>
<td>0.6 (0.14)</td>
</tr>
<tr>
<td>Anterior comp</td>
<td>0.82 (0.16)</td>
<td>0.82 (0.12)</td>
<td>0.74 (0.14)</td>
<td>0.63 (0.13)</td>
<td>0.66 (0.13)</td>
<td>0.66 (0.13)</td>
</tr>
<tr>
<td>Medial gastroc</td>
<td>0.86 (0.13)</td>
<td>0.90 (0.21)</td>
<td>0.79 (0.25)</td>
<td>0.89 (0.21)</td>
<td>0.73 (0.26)</td>
<td>0.66 (0.21)</td>
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<tr>
<td>Lateral gastroc</td>
<td>0.69 (0.19)</td>
<td>0.70 (0.16)</td>
<td>0.73 (0.23)</td>
<td>0.71 (0.19)</td>
<td>0.73 (0.26)</td>
<td>0.69 (0.16)</td>
</tr>
<tr>
<td>Soleus</td>
<td>0.76 (0.16)</td>
<td>0.76 (0.15)</td>
<td>0.74 (0.16)</td>
<td>0.76 (0.16)</td>
<td>0.76 (0.19)</td>
<td>0.76 (0.19)</td>
</tr>
<tr>
<td>Strength and select motor control</td>
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<td></td>
<td></td>
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<tr>
<td>Dorsiflexion (normalized)</td>
<td>0.11 (0.09)</td>
<td>0.13 (0.07)</td>
<td>0.21 (0.13)</td>
<td>0.14 (0.07)</td>
<td>0.2 (0.12)</td>
<td>0.17 (0.07)</td>
</tr>
<tr>
<td>Heel raises*</td>
<td>0.9 (0.35)</td>
<td>0.8 (0.2)</td>
<td>4.1 (10.8)</td>
<td>2.8 (3)</td>
<td>6.1 (5.1)</td>
<td>1.6 (2.7)</td>
</tr>
<tr>
<td>SCALE (score out of 16)</td>
<td>4.94 (1.12)</td>
<td>5.4 (1.04)</td>
<td>6.06 (1.53)</td>
<td>5.96 (1.39)</td>
<td>5.76 (1.29)</td>
<td>5.67 (1.40)</td>
</tr>
</tbody>
</table>

*Reported as median and interquartile range. Rx, treatment; Con, control; tib, tibialis; comp, compartment; gastro, gastrocnemius.

There was a significant increase in normalized volume for tibialis anterior in the treatment group at week 14 compared to baseline (p=0.039) and this approached significance when expressed as a muscle volume symmetry (p=0.082). There were no significant changes for the control group over time when compared to baseline. Between groups at week 8 (Table III), the treatment group demonstrated significantly increased volumes (for both normalized volumes and volume symmetry) for all muscles except for soleus when compared to controls. There was a large effect for tibialis anterior, with a mean difference of 18% (95% CI 6.31 to 0.001; d=0.87). There was a medium effect for the anterior compartment, with a mean difference of 18% (95% CI 7.6 to 0.001; d=0.87). Medial gastrocnemius had a small effect with a mean difference of 10% (95% CI 2.2 to 0.014; d=0.21). Lateral gastrocnemius also had a small effect with a mean difference of 14% (95% CI 2.27 to 0.017; d=0.15). At week 14, the treatment group had significant increases in lateral gastrocnemius muscle volume only when compared to controls with a mean difference of 15% (95% CI 3.2 to 0.009; p=0.03; d=0.19).

**Strength**

The treatment group demonstrated significantly greater ankle dorsiflexion strength at week 8 (mean difference=0.1, 95% CI 0.06.14; p=0.001; d=0.89) and at week 14 (mean difference=0.09, 95% CI 0.06.13; p=0.001; d=0.85) when compared to baseline measures. The control group demonstrated significant gains in strength at week 14 only when compared to baseline (mean difference=0.04, 95% CI 0.03.08; p=0.012; d=0.57). Between groups, the treatment group had significant increases in ankle dorsiflexion strength when compared to controls at week 8 (mean difference=0.09, 95% CI 0.03.15; p=0.002; d=0.47) but not at week 14 (mean difference=0.05, 95% CI 0.01 to 0.12; p=0.116 Fig. 1).

There were significant within-group improvements over time in the number of heel raises for both the treatment (week 8 median difference=3.5, interquartile range [IQR] 16; p=0.002) and control (week 14 median difference=3, IQR 0.75; p=0.008) groups. Although these median changes did not represent clinically meaningful changes (defined as a minimum change of six heel raises10), individual analysis identified that there was a trend for more participants in the treatment group (5/16) than the control group (1/16) to achieve clinically meaningful improvements at week 8. Of note, seven out of 16 participants in the treatment group were just short of achieving a clinically meaningful improvement. At week 14, there was a trend for more participants in the treatment group (6/16) than in the control group (5/16) to achieve clinically meaningful improvements in the number of heel raises performed. There were no significant between group differences at week 8 (p=0.08) and at week 14 (p=0.3) for heel raises.

**Selective motor control**

The treatment group demonstrated significant improvements in ankle SMC and SCALE scores at week 8 (ankle SMC median difference=1, IQR 0.1; p=0.02; SCALE median difference=1.1, 95% CI 0.62.163; p=0.001; d=0.83) and week 14 (ankle SMC median difference=0.5, IQR 0.1; p=0.048; SCALE median difference=0.81, 95% CI 0.31.32; p=0.001; d=0.67) when compared to baseline measures. The control group demonstrated no significant improvements in ankle SMC at week 8 (median difference=0, IQR 0.1; p=0.1) and at week 14 (median difference=0, IQR 0.1).
Figure 1: Mean symmetry ratios of muscle volumes and normalized isometric dorsiflexion strength for the treatment (Rx) and control group across all time points. *Between group difference \( p<0.05; \) **Within group difference compared to baseline \( p<0.05 \).

\( p=0.65 \) when compared to baseline scores. The control group demonstrated significant SCALE improvements at week 8 (mean difference=0.67, 95% CI 0.14-1.19; \( p=0.007 \); \( d=0.43 \)) but not at week 14 (mean difference=0.47, 95% CI -0.06 to 0.99; \( p=0.098 \)) when compared to baseline measures. Further, individual analysis revealed that at week 8, there was a trend for more participants in the treatment group (9/16 in ankle SMC; 6/16 on the SCALE) than in the control group (5/16 in ankle SMC; 2/16 on the SCALE) to make clinically meaningful score changes. To note, six out of 16 participants in the treatment group made no changes in ankle SMC at week 8. At week 14, there was a trend for ankle SMC improvements only, with more participants in the treatment group (9/16) than in the control group (3/16) to maintain clinically meaningful score changes. There were no statistically significant differences between the groups at week 8 (ankle SMC \( p=0.10 \) and SCALE \( p=0.67 \)) and week 14 (ankle SMC \( p=0.16 \) and SCALE \( p=0.86 \)).

Scatterplots demonstrated that at week 8 in the treatment group, there was no relationship between change in tibialis anterior muscle volume and ankle dorsiflexion strength (\( p=0.09 \), \( p=0.714 \)) or change in anterior compartment MRI muscle volume and ankle dorsiflexion strength (\( p=0.37 \), \( p=0.159 \)). There was a strong positive relationship between ankle dorsiflexion strength and SMC with a Spearman’s correlation coefficient at baseline \( p=0.794 \) (\( p<0.001 \)), week 8 \( p=0.741 \) (\( p<0.001 \)), and week 14 \( p=0.635 \) (\( p<0.001 \)).

DISCUSSION
Supporting our first hypothesis, NMES-assisted gait significantly increased muscle volume and ankle dorsiflexion strength following an 8-week intervention. The inclusion
### Table III: Mean difference (95% confidence interval) within and between groups for muscle volume, ankle dorsiflexion strength, and Selective Control Assessment of the Lower Extremity

<table>
<thead>
<tr>
<th></th>
<th>Wk 8–0</th>
<th></th>
<th>Wk 14–0</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rx</td>
<td>Con</td>
<td>Rx</td>
<td>Con</td>
</tr>
<tr>
<td><strong>Normalized muscle volume (back-transformed)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tibialis anterior</td>
<td>1.23* (1.14-1.31)</td>
<td>1.05 (0.98-1.13)</td>
<td>1.07* (1.00-1.15)</td>
<td>1.06 (0.99-1.14)</td>
</tr>
<tr>
<td>d=0.62</td>
<td></td>
<td></td>
<td>d=0.2</td>
<td></td>
</tr>
<tr>
<td>Anterior comp</td>
<td>1.19* (1.12-1.27)</td>
<td>1.01 (0.95-1.08)</td>
<td>1.05 (0.98-1.12)</td>
<td>1.05 (0.99-1.12)</td>
</tr>
<tr>
<td>d=0.55</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medial gastroc</td>
<td>1.11* (1.05-1.17)</td>
<td>1.01 (0.96-1.07)</td>
<td>1.04 (0.98-1.09)</td>
<td>1.01 (0.96-1.07)</td>
</tr>
<tr>
<td>d=0.22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral gastroc</td>
<td>1.15* (1.08-1.22)</td>
<td>1.01 (0.94-1.08)</td>
<td>1.14* (1.07-1.21)</td>
<td>0.99 (0.93-1.06)</td>
</tr>
<tr>
<td>d=0.34</td>
<td></td>
<td></td>
<td>d=0.31</td>
<td></td>
</tr>
<tr>
<td><strong>Muscle volume symmetry ratio</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tibialis anterior</td>
<td>0.12* (0.08-0.16)</td>
<td>0.03 (–0.01 to 0.07)</td>
<td>0.04 (–0.004 to 0.08)</td>
<td>0.04 (–0.004 to 0.08)</td>
</tr>
<tr>
<td>d=0.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior comp</td>
<td>0.11* (0.07-0.15)</td>
<td>0.01 (–0.03 to 0.05)</td>
<td>0.03 (–0.01 to 0.07)</td>
<td>0.03 (–0.01 to 0.08)</td>
</tr>
<tr>
<td>d=0.76</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medial gastroc</td>
<td>0.09* (0.05-0.12)</td>
<td>0.005 (–0.03 to 0.04)</td>
<td>0.04* (0.004-0.07)</td>
<td>0.008 (–0.03 to 0.04)</td>
</tr>
<tr>
<td>d=0.34</td>
<td></td>
<td></td>
<td>d=0.17</td>
<td></td>
</tr>
<tr>
<td>Lateral gastroc</td>
<td>0.1* (0.05-0.14)</td>
<td>0.01 (–0.04 to 0.06)</td>
<td>0.09* (0.05-0.14)</td>
<td>–0.006 (–0.06 to 0.04)</td>
</tr>
<tr>
<td>d=0.42</td>
<td></td>
<td></td>
<td>d=0.41</td>
<td></td>
</tr>
<tr>
<td><strong>Strength and selective motor control</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dorsiflexion (normalized)</td>
<td>0.10* (0.06-0.14)</td>
<td>0.01 (–0.03 to 0.05)</td>
<td>0.09* (0.06-0.13)</td>
<td>0.04* (0.003-0.08)</td>
</tr>
<tr>
<td>d=0.89</td>
<td></td>
<td></td>
<td>d=0.86</td>
<td></td>
</tr>
<tr>
<td>SCALE (score out of 10)</td>
<td>1.13* (0.62-1.63)</td>
<td>0.67* (0.14-1.19)</td>
<td>0.81* (0.3-1.32)</td>
<td>0.47 (–0.06 to 0.99)</td>
</tr>
<tr>
<td>d=0.83</td>
<td>d=0.43</td>
<td>d=0.67</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*p<0.05. d= Cohen's d for statistically significant differences; Rx, treatment group; Con, control group; comp, compartment; gastroc, gastrocnemius; **
of a control group in this randomized controlled trial provides clinicians with the necessary clarity in the use of NMES-assisted gait within a community setting. Not only do the results provide evidence of further substantiating previous uncontrolled trials\textsuperscript{13,17} with benefits in muscle strength and volume, but that the effects are also more superior than conventional therapy. Traditionally, functional applications of NMES such as NMES-assisted gait is not used for muscle strengthening because impulses are generally not delivered at a high enough intensity to provide muscular improvements.\textsuperscript{12} However, the advantage of NMES-assisted gait is the high dosage that is offered through repetitive, non-selective recruitment of muscle fibers within functionally relevant and activity-based contexts.\textsuperscript{12,14} The non-selective recruitment ensures that all fibers regardless of type can be activated during everyday walking despite problems with SMC.\textsuperscript{14} The advantage of functionally applied NMES has similarly been reported in the spinal cord injury rehabilitation literature where muscle volume improvements were accompanied by greater strength gains when compared to muscles stimulated using NMES in non-functional contexts, i.e. in standardized positions.\textsuperscript{13,15} Hence, NMES-assisted gait can be considered to be a viable option in the management of children with unilateral spastic CP to facilitate muscular changes while having the advantage of being integrated within individualized contexts.

The treatment group's significant increase in ankle dorsiflexion strength and muscle volume was not maintained at week 14 when compared to the control group, thus rejecting our second hypothesis. To note, the treatment group did demonstrate significant improvement in ankle dorsiflexion strength and volume at week 14 compared to baseline; however, the changes were not significantly greater than the control group who maintained conventional or usual therapies only. Hence, the inclusion of a control group was beneficial to account for muscular changes from growth or conventional therapy input. The results from this time point support current literature that muscular changes following NMES are use-dependent\textsuperscript{19} and do not facilitate long-term or prolonged lasting neuromuscular adaptations. While it may be preferable to continue to use NMES to maintain the muscle hypertrophy and strength changes, ongoing use could increase dependence on an external stimulus.\textsuperscript{19} To limit this, devices should only be used for as long needed in order to promote movement control.\textsuperscript{16}

One strategy could be to alternate between a period of 8 weeks of use and a period of non-use (as used in the current study). Examination of individual responses in ankle SMC post-treatment provides some indication for the appropriateness of alternating between a period of NMES use and non-use. Although there were no statistically significant changes in SMC between the groups, the participant-specific responses provide useful clinical information. In the current study, nearly 40% of the participants in the treatment group made no SMC changes at week 8. For this group of children, NMES is needed to address impairments in SMC, hence a period of non-use may not be warranted. In contrast, 50% made clinically meaningful improvements at week 8 and week 14. For this group, a period of non-use would be appropriate for the therapeutic effect in SMC and to limit NMES dependence. Therefore, goals of treatment would be to either: (a) achieve muscle volume and strength gains and maintain the orthotic effect of NMES-assisted gait, or (b) achieve muscle volume and strength gains and obtain a therapeutic effect in SMC. This individual responsiveness may account for the limited and inconsistent evidence of therapeutic effects reported in the literature.\textsuperscript{12,13}

There were significant differences in medial and lateral gastrocnemius muscle volume at week 8 and for lateral gastrocnemius volume at week 14. The trend towards improvement in strength supports the results from our previous work\textsuperscript{13} and addresses previous concerns that stimulating only one muscle group at a joint would exacerbate muscle imbalances.\textsuperscript{13} To our knowledge, the volumetric improvement in medial and lateral heads of gastrocnemius following NMES to the ankle dorsiflexors has not been reported. These changes suggest that NMES could be a viable supplement to targeted strength training, especially if there are challenges with exercise compliance. Further, increases in gastrocnemius volume may be advantageous for children who undergo serial BoNT-A because of the documented volumetric loss that occurs soon after injections.\textsuperscript{21,22} Given that the control group had no within-group changes over time, it is likely that the improvements in both volume and strength of gastrocnemius is attributable to the removal of AFOs and the advantage of the NMES' orthotic effect to enable greater gastrocnemius contribution in mid- to late stance for push-off.\textsuperscript{17,18} Also, these muscle changes occurred after just 8 weeks of intervention, thus NMES may offer controlled breaks from AFO use. These breaks may provide an opportunity to facilitate strengthening and prevent atrophy from serial BoNT-A. For ambulant children with CP, addressing problems with muscle strength and volume may have long-term implications, particularly with the management of pain and reports of walking deterioration with increasing age.\textsuperscript{6,18} Given the significant muscular improvements noted in the present study, integrating NMES-assisted gait into current therapeutic management is superior to conventional therapy alone and may potentially have a role in forward planning for people with unilateral spastic CP. Further longitudinal investigation is therefore warranted.

While this study has provided further support for the use of NMES in children with CP in a randomized controlled trial, there are some limitations to note. One limitation is that participants actively sought to be in the study and this may account for the high compliance with use of the intervention. Another limitation is that funding restrictions meant that the assessor also provided the intervention.
Therefore it was not possible for the assessor to be blinded to group or assessment time point for the clinical measures. However, the assessor was presented with muscle volume scans in randomized time points, blinded for group and time with vigorous methods implemented to ensure that the assessor could not reference previous clinical results.

A further limitation is that all but four participants had a history of BoNT-A. This group was too small to enable subgroup analysis to yield adequate power. However, the application of analysis of covariance with the baseline as the covariate enabled adjustments for any baseline variation. Finally, there were limitations in the range of frequency parameters available on the Walk Aide. Higher frequencies reportedly have a greater effect on the central nervous system and this may be associated with more prolonged neuromuscular adaptations. Future studies should consider the use of devices that enable a greater selection of parameters to elicit neuroplastic changes for a longer lasting effect. The strength of this study was the inclusion of a control group that was adequately powered with all participants completing the study.

Our results support the efficacy of NMES-assisted gait as a viable treatment option by providing the opportunity for targeted intervention to address the known problems in ankle dorsiflexion SMC to improve muscle volume and strength in children with unilateral spastic CP. Although improvements in muscle volume and strength are use-dependent, clinicians should evaluate individual responses in ankle SMC after 8 weeks of NMES-assisted gait to determine an appropriate wear regime, i.e. ongoing NMES use or alternating between periods of use and non-use to promote SMC.

ACKNOWLEDGEMENTS
This study was supported financially by the Princess Margaret Hospital Foundation, Perth, Australia, Orthopedic Appliances Pty Ltd donated 10 Walk Aides to The Centre For Cerebral Palsy which were subsequently used for this study. We thank Martin Spitz from the Department of Diagnostic Imaging at Princess Margaret Hospital for Children for his time and expertise in performing the MRI. The authors have stated that they had no interests that might be perceived as posing a conflict or bias.

REFERENCES
26. Croopman J, Gams MP, Phillips R. Hand-held dynamometry for muscle strength measurement in chil...
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7.1 Paper 3 Additional results

Individual responses to FES treatment for clinical strength and selective motor control assessments provide further insights to the reported means and standard deviations. These results are discussed in the paper but are now also presented here in Table 12. This enables therapists to appreciate the heterogeneity of children with USCP despite the efforts to homogenise the groups as much as possible. For example, though there were no longer any significant differences between the groups at follow-up for ankle dorsiflexion strength, therapists may expect that the majority of children will continue to demonstrate more strength when compared to their baseline value. Furthermore without FES treatment, therapists may expect clinically meaningful changes and this could be attributed to regular therapy input.

All individual MRI symmetry ratio graphs were inspected and placed into four categories. This included (a) a peak in muscle symmetry ratio at post treatment with a drop off at follow-up, (b) constant increase where each subsequent assessment yielded greater symmetry ratio values than the previous assessment, (c) no change at post treatment and follow-up and finally (d) a decrease in muscle symmetry ratio values at each subsequent assessment when compared to the previous. Table 13 presents the number and percentage of responses at week 8 and 14 for tibialis anterior, anterior compartment, medial and lateral gastrocnemius for the treatment and control group. Based on this data, clinicians should expect that users of daily FES will increase their tibialis anterior and anterior compartment symmetry ratio values after 8 weeks of treatment. Clinicians may also expect that in a very small proportion of users, there may be further increases in symmetry ratio values even after six weeks of non-use. In addition, it is also possible for users to demonstrate no change at all. This table also provides data on the control group suggesting that though no change is the expected outcome, it is possible to have some muscle volume changes that once again, may reflect natural growth or regular therapy input.
Table 12. Number (n) and percentages (%) of typical responses in the strength and selective motor control (SMC) clinical measures at week 8 (Rx) and at week 14 for the FES and control group.

<table>
<thead>
<tr>
<th>Change in score</th>
<th>FES n(%)</th>
<th>Control n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 8</td>
<td>Week 14</td>
</tr>
<tr>
<td>Dorsiflexion strength</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No baseline score&lt;sup&gt;a&lt;/sup&gt;</td>
<td>4 (25)</td>
<td>4 (25)</td>
</tr>
<tr>
<td>↓ by up to 100%</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>↑ 1-50%</td>
<td>4 (25)</td>
<td>5 (31.25)</td>
</tr>
<tr>
<td>↑ 51-100%</td>
<td>4 (25)</td>
<td>1 (6.25)</td>
</tr>
<tr>
<td>↑ 101-200%</td>
<td>2 (12.5)</td>
<td>5 (31.25)</td>
</tr>
<tr>
<td>↑ &gt;200%</td>
<td>2 (12.5)</td>
<td>1 (6.25)</td>
</tr>
<tr>
<td>Plantarflexion strength</td>
<td></td>
<td></td>
</tr>
<tr>
<td>↓ &gt;1</td>
<td>1 (6.25)</td>
<td>1 (6.25)</td>
</tr>
<tr>
<td>0</td>
<td>3 (18.75)</td>
<td>4 (25)</td>
</tr>
<tr>
<td>↑ 1-5</td>
<td>7 (43.75)</td>
<td>5 (31.25)</td>
</tr>
<tr>
<td>↑ &gt;6 &lt;sup&gt;+&lt;/sup&gt;</td>
<td>5 (31.25)</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>SCALE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>↓ 1</td>
<td>0</td>
<td>1 (6.25)</td>
</tr>
<tr>
<td>0</td>
<td>5 (31.25)</td>
<td>4 (25)</td>
</tr>
<tr>
<td>↑ 1</td>
<td>5 (31.25)</td>
<td>8 (50)</td>
</tr>
<tr>
<td>↑ 2&lt;sup&gt;+&lt;/sup&gt;</td>
<td>5 (31.25)</td>
<td>3 (18.75)</td>
</tr>
<tr>
<td>↑ 3&lt;sup&gt;+&lt;/sup&gt;</td>
<td>1 (6.25)</td>
<td>0</td>
</tr>
<tr>
<td>SMC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>↓ 2</td>
<td>1 (6.25)</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>2 (12.5)</td>
</tr>
<tr>
<td>0</td>
<td>6 (37.5)</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>↑ 1&lt;sup&gt;+&lt;/sup&gt;</td>
<td>8 (50)</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>↑ 2&lt;sup&gt;+&lt;/sup&gt;</td>
<td>1 (6.25)</td>
<td>1 (6.25)</td>
</tr>
<tr>
<td>↑ 3&lt;sup&gt;+&lt;/sup&gt;</td>
<td>0</td>
<td>1 (6.25)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Unable to calculate percentage of change score due to score of 0 at baseline i.e. unable to attain plantigrade position for test (Crompton et al. 2007); <sup>+</sup> Clinically significant change.
Table 13. The number and percentage of muscle volume responses according to four categories: peak, constant increase, and no change for Tibialis Anterior, Ant. Compartment, Medial gastrocnemius, and Lateral gastrocnemius for the treatment group (n=16) and control group.

<table>
<thead>
<tr>
<th>Area</th>
<th>FES</th>
<th>Control</th>
<th>FES</th>
<th>Control</th>
<th>FES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tibialis Anterior</td>
<td>14 (87.5)</td>
<td>2 (13.3)</td>
<td>1 (6.25)</td>
<td>3 (20)</td>
<td>1 (6.25)</td>
</tr>
<tr>
<td>Ant. Compartment</td>
<td>14 (87.5)</td>
<td>2 (13.3)</td>
<td>1 (6.25)</td>
<td>3 (20)</td>
<td>1 (6.25)</td>
</tr>
<tr>
<td>Medial gastrocnemius</td>
<td>8 (50)</td>
<td>0</td>
<td>3 (18.75)</td>
<td>0</td>
<td>5 (31.25)</td>
</tr>
<tr>
<td>Lateral gastrocnemius</td>
<td>5 (31.25)</td>
<td>4 (26.7)</td>
<td>7 (43.75)</td>
<td>0</td>
<td>3 (18.75)</td>
</tr>
</tbody>
</table>
7.2 Mimics software and identification of muscle borders

The identification of the muscle groups is demonstrated in the images below. These images represent the limbs from a teenage participant. Figure 13 is a cross section of the leg inferior to the knee joint where gastrocnemius can be observed. This demonstrates the marked reduced muscle volume of the left when compared to the right. The borders for the muscles are clearly identifiable.

![Cross-section image](image)

**Figure 13.** Cross-section of a boy (12 years 3 months) with left side USCP.

To calculate muscle volume, masks are applied to each segment from the MRI. A sample of five images are shown here to demonstrate the shape and size of muscles through the length of the leg from the most proximal (Figure 14) to most distal (Figure 16). Once all borders were identified and traced, the Mimics® software then creates a three-dimensional image so that a volume can be calculated (Figure 17 and 18). This volume is normalised to tibia length, which was obtained from the longitudinal MRI view (Figure 19).
Figure 14. Proximal mask with the main bulk of medial and lateral gastrocnemius visible.

Figure 15. Medial and lateral gastrocnemius approaching connection to Achilles tendon.
Figure 16. Distal images with no tibialis anterior on the affected limb despite still being observable on the non-affected limb.
Figure 17. Masks are combined to create a 3D shape for each muscle.

Figure 18. Cross-section of the 3D view with the anterior compartment, soleus, medial and lateral gastrocnemius in view bilaterally.
Figure 19. Measurement of tibial length
8  PAPER 4: THE ORTHOTIC AND THERAPEUTIC EFFECTS FOLLOWING DAILY COMMUNITY APPLIED FUNCTIONAL ELECTRICAL STIMULATION IN CHILDREN WITH UNILATERAL SPASTIC CEREBRAL PALSY: A RANDOMISED CONTROLLED TRIAL

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The orthotic and therapeutic effects following daily community applied functional electrical stimulation in children with unilateral spastic cerebral palsy: a randomised controlled trial

Dayna Pool1,2, Jane Valentine1, Natasha Bear1, Cyril J. Donnelly3, Catherine Elliott2,4, and Katherine Stannage5

Abstract

Background: The purpose of this study was to determine the orthotic and therapeutic effects of daily community applied FES to the ankle dorsiflexors in a randomized controlled trial. We hypothesized that children receiving the eight-week FES treatment would demonstrate orthotic and therapeutic effects in gait and spasticity as well as better community mobility and balance skills compared to controls not receiving FES.

Methods: This randomized controlled trial involved 32 children (mean age 10 yrs 3 mo, SD 3 yrs 3 mo; 15 females, 17 males) with unilateral spastic cerebral palsy and a Gross Motor Function Classification System of I or II randomly assigned to a FES treatment group (n = 16) or control group (n = 16). The treatment group received eight weeks of daily FES (four hours per day, six days per week) and the control group received usual orthotic and therapy treatment. Children were assessed at baseline, post FES treatment (eight weeks) and follow-up (six weeks after post FES treatment). Outcome measures included lower limb gait mechanics, clinical measures of gastrocnemius spasticity and community mobility balance skills.

Results: Participants used the FES for a mean daily use of 6.2 (SD 3.2) hours over the eight-week intervention period. With FES, the treatment group demonstrated a significant (p < 0.05) increase in initial contact ankle angle (mean difference 11.9° 95% CI 6.8° to 17.1°), maximum dorsiflexion ankle angle in swing (mean difference 8.1° 95% CI 1.8° to 14.4°) normalized time in stance (mean difference 0.27 95% CI 0.05 to 0.49) and normalized step length (mean difference 0.06 95% CI 0.03 to 0.126) post treatment compared to the control group. Without FES, the treatment group significantly increased community mobility balance scores at post treatment (mean difference 8.3 units 95% CI 3.2 to 13.4 units) and at follow-up (mean difference 8.9 units 95% CI 3.8 to 13.9 units) compared to the control group. The treatment group also had significantly reduced gastrocnemius spasticity at post treatment (p = 0.039) and at follow-up (dynamic range of motion mean difference 6.9°, 95% CI 0.4° to 13.6°, p = 0.035) compared to the control group.

Conclusion: This study documents an orthotic effect with improvement in lower limb mechanics during gait. Therapeutic effects i.e. without FES were observed in clinical measures of gastrocnemius spasticity, community mobility and balance skills in the treatment group at post treatment and follow-up. This study supports the use of FES applied during daily walking activities to improve gait mechanics as well as to address community mobility issues among children with unilateral spastic cerebral palsy.

(Continued on next page)
Background

Cerebral palsy (CP) refers to a group of permanent motor dysfunctions due to non-progressive damage to the developing brain [1]. Unilateral spastic cerebral palsy (USCP) is the most common presentation of CP and children are typically classified as having a Gross Motor Function Classification System (GMFCS) and Winters Gage and Hicks gait classification of I or II [2-4]. This means that despite impairments such as spasticity and muscle contracture particularly at the ankle joint, children remain functionally ambulant. Equinus during gait is a common problem alongside functional issues with balance and community mobility [3, 4].

The neuronal group selection theory provides an essential framework to understanding the balance and community mobility limitations in children with USCP [5]. Based on this framework, children with USCP display primary repertoires of movement that enable functional mobility. However, the combination of impairments usually present in children with USCP may limit the development of secondary repertoires of movement that are essential for movement adaptability [6]. This deficit in movement adaptability restricts activity such as community mobility and balance skills, and may even increase their risk of falls during gait. The expansion of primary and secondary repertoires requires the implementation of the principles of motor learning. Principles of motor learning require treatments to be activity based or task specific that is frequently repeated and challenged in contextually relevant environments [7-9].

Current treatments to improve the gait of children with USCP include pharmacological strategies such as botulinum toxin type A, implemented alongside a range of physiotherapy treatments and/or the prescription of ankle foot orthoses (AFOs) [10]. Although AFOs improve ankle kinematics and temporal-spatial parameters during gait [11, 12], for high functioning children, the external support of an AFO may hinder balance strategies for secondary repertoire expansion as well as impede power generation for effective push off during walking and running [11-13]. Evidence supporting the use of AFOs is mainly focused on the effect it has on body structure and function. It is currently unclear what effect AFOs have with long term use as well as the effect it has on activity and participation [7, 14, 15]. Thus investigation into alternate interventions is warranted.

Functional Electrical Stimulation (FES) has the potential to meet the motor learning needs to expand movement repertoires because it can be implemented frequently during functional tasks such as walking. Muscles are artificially stimulated using an electrical current that is transmitted through electrodes placed over the surface of the skin above the target muscle and nerve [16]. When FES is applied to the ankle dorsiflexors during gait it can act as an orthosis by initiating a muscle contraction to dorsiflex the ankle joint, thus allowing for improved toe clearance during the swing phase of gait (known as the orthotic effect) [17, 18].

In a recent systematic review, the use of lower limb muscle electrical stimulation for improving gait and functional activity was cautiously advocated for children with CP [19]. However included in this review were studies where electrical stimulation was not functionally applied, hence given the overwhelming evidence supporting the need for specificity of treatment, the limited effect on gait and activity is understandable [7, 20, 21]. Since this review, research has emerged with FES applied to the ankle dorsiflexors during the swing phase of gait, and though not randomized controlled trials, results have supported an orthotic effect with improvements in ankle kinematics enabling toe clearance [17, 22, 23]. Determining whether the effects last beyond the treatment period with the removal of FES (known as the therapeutic effect) and whether it improves community mobility and balance skills has not yet been determined and so has been a recommendation for future research in this area [19].

This study aimed to determine the orthotic and therapeutic effects of daily community applied FES to the ankle dorsiflexors in a randomized controlled trial. We hypothesized that children who received the eight-week FES treatment would demonstrate an orthotic effect with improved lower limb kinematics (i.e. elevated dorsiflexion during the swing phase of gait) during the gait cycle compared to controls not receiving FES. Secondly, after the removal of FES, children who were in the FES treatment group would demonstrate a therapeutic effect with improved lower limb kinematics during gait, better community mobility and balance scores and reduced gastrocnemius spasticity compared to controls that did not receive FES.
Methods

Study design
The study design was a randomized controlled trial of daily community applied FES to the ankle dorsiflexors in gait compared with usual care (control group).

Participants
Participants were referred to the study by Physiotherapists and Paediatric Rehabilitation Consultants. Participant inclusion criteria are detailed in Table 1. Participants who had undergone botulinum toxin type A were included, but scheduled to commence the study at three months post injections [24]. Study recruitment took place between June and July 2013 from clinics of the Cerebral Palsy Mobility Service at Princess Margaret Hospital for Children and The Centre for Cerebral Palsy, Perth Australia with the final assessments completed by April 2014. Human ethics approval was obtained from the Human Research Ethics Committees of Princess Margaret Hospital, Perth Australia and The University of Western Australia, Perth Australia. The committee’s recommendations were adhered to and written and informed consent for participation and publication was obtained.

Procedure
An initial appointment with the principal investigator (DP) was scheduled to determine FES tolerance and study protocol. Randomization to either the FES or control group was achieved through a coin toss, by an individual uninvolved with the study. Randomization only occurred once two matched participants were enrolled. Matched participants were of the same GMFCS level, and were within two years of age for children aged between five and 10, and within six years for children aged between 11 and 18. This method was applied to improve the homogeneity of each group in terms of age and gross motor function.

Participants were asked not to participate in any new sporting activities during the study and to maintain pre-existing therapy throughout the 14-week study period so that the effects of FES treatment could be determined. The Actigraph® (GT3X, ActiGraph, Pensacola, Florida, USA), a triaxial device was used to monitor time spent in moderate to vigorous physical activity (MVPA) [25] because of its potential to confound the overall outcome from FES intervention.

Outcome measures were assessed at baseline, post-treatment (following eight weeks of FES intervention) and follow-up (six weeks after the post-treatment). The presence of an orthotic effect was determined in the between group comparison at post treatment, whilst the treatment group was wearing the FES device during the gait analysis assessment. A therapeutic effect was determined both at post treatment and at follow-up through the examination of between group differences for the community mobility balance measures, spasticity measures, as well as in the gait analysis, but only when the treatment group was not wearing the FES device.

Outcome measures
This randomized controlled trial of daily community FES assessed outcomes across all domains of the International Classification of Functioning Child and Youth Version. This paper focuses on the results pertaining to the effects of FES on the domains of body structure and function and activity. The primary outcomes were lower limb biomechanics and included ankle kinematics and temporal spatial measures during walking gait cycle and community balance and mobility estimates. The secondary measures were clinical assessments of gastrocnemius spasticity. As this study was conducted within the framework of current clinical care, measures of passive dorsiflexion with the knee extended and popliteal angles were also taken at all assessment time points to ensure no detrimental loss of range of motion over the 14 weeks study period. This was considered to be important particularly in the absence of AFOs. Though this was not an outcome measure, the results may be of interest to clinicians and so are presented as Additional file 1 in this paper.

Gait analysis
Two dimensional gait assessment was conducted at The School of Sport Science, Exercise and Health Gait Laboratory at The University of Western Australia. Three Bonita® cameras (Vicon® Motion Systems Ltd UK) capturing at 100Hz for sagittal (left and right) and coronal (one camera) views were positioned and synchronized to capture video with two AMTI force platforms (1000Hz).
Children were asked to walk at a self-selected walking speed along a 10 m walkway to capture five successful trials i.e. uninterrupted foot strike on force platform. Bright coloured, round stickers were placed on bilateral greater trochanters, anterior superior iliac spine, posterior superior iliac spine, acromion clavicular joint, medial and lateral femoral epicondyles, patella, medial malleoli, lateral malleoli, head of the fifth metatarsal and calcaneus. This allowed identification of specific anatomical landmarks and joint centers during video motion capture. SiliconCoach Pro7 (Siliconcoach Ltd, Dunedin, New Zealand), was used for video analysis with initial contact and toe-off identified from the vertical ground reaction force measure from the platforms (>10 N and <10 N respectively). Ankle angle was calculated between the tibia and the foot from the sagittal plane high-speed video (using the markers on the lateral femoral epicondyle, lateral malleoli and head of the fifth metatarsal). Ankle dorsi/plantarflexion angles were calculated at four discrete time points: 1) initial foot contact, 2) maximum dorsiflexion in stance, 3) toe off and 4) maximum dorsiflexion in swing. Temporal-spatial measures included time in stance, step length normalized to height [26], velocity prior to initial foot contact and walking velocity over 5 m. Participants were assessed walking in shoes and in-shoe orthoses (if any) at all assessment time points. Participants in the FES treatment group were assessed both with (to determine the orthotic effect) and without (to determine the therapeutic effect) the FES device at post-treatment. It was not possible to blind the assessor regarding group and time point allocation due to the facial identity and Walk Aide® visibility on the video.

Clinical tests
The clinical tests were performed at Princess Margaret Hospital for Children by an experienced physiotherapist (DP) and research assistant, following the outlined protocols at all of the time points. It was not possible to blind the assessors to group or assessment time point allocation.

Community mobility and balance skills
The Community Balance and Mobility Scale (CBMS) is a valid and reliable clinical tool that rates performance quality (out of a possible 96 points) of high level community balance and mobility skills in ambulatory patients with neurological impairment [27-29]. It includes items relevant for everyday community mobility such as turning, step-ups, walking and looking, direction changes and picking things up off the ground when walking. The CBMS was chosen because it would not have a ceiling effect for children with a GMFCS level of I as used previously by Brien and Svistunop 2011 [28]. An overall change in score by five points is considered clinically meaningful, reflecting true change in confidence in community mobility and community integration [28].

The 4-Square Step Test (4SST), a valid, reliable and sensitive clinical tool was used to assess dynamic stepping balance and rapid changes in direction [30]. The 4SST measures the time it takes to step over four walking sticks placed in a four square configuration, requiring the participant to step over and clear a height of 2.5 cm in all directions following previously documented protocols [30]. Although this test is not routinely used for children with CP, it was included because of its use to predict falls in people with neurological impairments. A score of 15 seconds or more has been shown to be the cut-off point to identify falls risk in people with neurological impairments [30].

Self reported incidence of toe drag and falls was measured using a questionnaire from our pilot study [23]. The questions asked were “How often do you drag your toes when you are walking?” and “How often do you fall over?” Answers were given on a five point ordinal scale (0-4), with a higher score indicating an increased incidence.

Range of motion and spasticity
Goniometry measures of passive and dynamic (Modified Tardieu Scale) ankle dorsiflexion in subtalar neutral (with the knee extended) and popliteal angle in supine were taken by DP following previously documented protocols [23, 31]. A change in angle by 10 degrees was considered clinically meaningful [32]. The Australian Spasticity Assessment Scale (ASAS), a five point ordinal scale was done concurrently to measure spasticity for gastrocnemius and hamstrings because of its proven validity and reliability in documenting spasticity in clinical practice [33]. We considered that a score change of one was clinically meaningful.

FES intervention
Participants in the FES group received the FES device after the baseline assessment. The Walk Aide® (Innovative Neurotronics, Austin, TX, USA) is a small (8.2 cm x 6.1 cm x 2.1 cm, 87.9 g) device that delivers asymmetrical biphasic surface electrical stimulation (ES) in a synchronized manner to stimulate the motor neurons of the tibialis anterior muscle, which dorsiflexes the ankle during the swing phase of gait. It is attached to the participant’s leg by a cuff that sits just under the knee on the affected side. One electrode was placed on the muscle belly of tibialis anterior and the other on the common peroneal nerve, which innervates tibialis anterior and other ankle dorsiflexors (extensor digitorum longus, peroneus tertius and extensor hallucis longus). During a gait cycle, the Walk Aide® is triggered by an individualized program detecting changes in tibia angle to stimulate ankle
dorsiflexion. Specific attention and time was spent by DP to ensure appropriate electrode placement and pulse width settings for accurate ankle dorsiflexion without excessive and unwanted movements of the foot. The set up procedure followed that described in our pilot study [23]. Participants and parents were supported so that they were confident and independent with the FES device, ensuring balanced dorsiflexion (no excessive subtalar eversion) with every use. Weekly to fortnightly visits at home or school were necessary to support daily FES use. This included training parents, teachers and education assistants on the use of the device as well as conducting classroom talks so that the participant's peers were aware of what the device was and why it was being worn. These visits also enabled electrode placement and integrity checks and inspection for any adverse events.

Participants were asked to use the FES device for at least four hours per day, six days per week during the eight-week treatment period. This was monitored through the usage log on the device itself. To enable participants an opportunity to accommodate to the device, they were asked to build up gradually to the required dosage over the first week.

Participants in the FES intervention group did not wear their AFOs throughout the study period. They were all provided with customized in-shoe orthoses at the commencement of the study to support foot posture and account for leg length discrepancies particularly in the absence of AFOs. Participants in the control group were asked to continue with their usual orthotic protocol.

Statistical analysis

Based on effect sizes observed in our pilot study of FES use [23], a one-tailed alpha of 0.05 and power of 80% power analysis suggested that each group required at least 15 participants per group to detect a clinically meaningful change in functional muscle strength (by six heel raises).

Normality was established for all clinical and gait measures through examining distributional plots, Q-plots and the Shapiro-Wilk test. Means and standard deviations were reported for each group for each phase. Determining between group differences was the main focus and this was examined using repeated measures ANCOVA (using the baseline as the covariate) to account for the correlation between repeated measures over time. Tukey's post-hoc analysis was applied if a significant main effect for group and time or an interaction of these was found enabling appropriate adjustments for the multiple comparisons and calculation of mean differences and 95% confidence intervals. To better understand the significance of the statistically significant comparisons for the gait data, effect sizes were also determined by using Cohen's $d$ calculation with a value of 0.8 considered a large effect, 0.5 to be a medium and 0.2 to be a small effect [34]. Assumptions for the ANCOVA were examined and met. Actigraphy$^*$ was only measured at baseline and post treatment and so was examined using an independent $t$-test. The Mann–Whitney $U$ test was used to determine between group differences for ordinal scales of ASAS and self-reported toe-drag and falls with medians and interquartile ranges reported for each group in each phase. Statistical significance was accepted as $p<0.05$. All statistical analyses were performed using STATA version 12.1 (TestCorp, Texas).

Results

Thirty-two children, mean age 10 yr 8 mo (SD 3y 3mo) with USCP GMFCS I or II, were recruited for the study. Baseline participant characteristics are shown in Table 2. All participants had spasticity in the lower limb, three participants had mixed tone with spasticity and dystonia (as indicated by the Hypertonia Assessment Tool) [35]. All participants who attended the initial appointment completed the study. There was no missing clinical data in the study, with all 32 participants assessed at all three-time points in their original group allocation.

Table 2 Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>FES ($n = 16$)</th>
<th>Control ($n = 16$)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>38.5 (15.2)</td>
<td>37.4 (15.8)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>Male 9</td>
<td>Male 8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Female 7</td>
<td>Female 8</td>
<td></td>
</tr>
<tr>
<td>Side of hemiplegia</td>
<td>Right: 11</td>
<td>Right: 12</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Left: 5</td>
<td>Left: 4</td>
<td></td>
</tr>
<tr>
<td>GMFCS</td>
<td>1: 10</td>
<td>1: 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1: 6</td>
<td>1: 6</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>10 yr 11 mo</td>
<td>10 yr 5 mo</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(8 yr 10 mo)</td>
<td>(2 yr 8 mo)</td>
<td></td>
</tr>
<tr>
<td>AFO</td>
<td>10</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Winters Gage and Hicks</td>
<td>1: 0</td>
<td>1: 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1: 15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical measures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrocnemius ASAS</td>
<td>2 (1.5-3)</td>
<td>2 (1.5-3)</td>
<td>1.00$^*$</td>
</tr>
<tr>
<td>Passive Dorsiflexion ($^\circ$)</td>
<td>11.94 (5.87)</td>
<td>10.5 (5.54)</td>
<td>0.48$^p$</td>
</tr>
</tbody>
</table>

$^*$Mann Whitney U test; $^p$ test; GMFCS Gross Motor Function Classification System, AFO Ankle Foot orthosis, ASAS Australian Spasticity Assessment Scale.

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Table 3: Mean (SD) of groups and corresponding mean difference between groups (95% CI) reported for spasticity and activity clinical measures at baseline (A), post treatment (B) and follow-up (C).

<table>
<thead>
<tr>
<th></th>
<th>FES</th>
<th>Control</th>
<th>Mean difference (95% CI)</th>
<th>Between group p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASAS gastrocnemius (^a)</td>
<td>A: 2 (1.5–3)</td>
<td>2 (1.5–3)</td>
<td>-</td>
<td>p = 0.038(^b)</td>
</tr>
<tr>
<td></td>
<td>B: 1 (0.5–2)</td>
<td>2 (2–2)</td>
<td>-</td>
<td>p = 0.000</td>
</tr>
<tr>
<td></td>
<td>C: 2 (0.5–3)</td>
<td>2 (2–3)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Dynamic dorsiflexion ROM (^e)</td>
<td>A: 0 (10.7)</td>
<td>1.1 (8.8)</td>
<td>-</td>
<td>p = 0.245</td>
</tr>
<tr>
<td></td>
<td>B: 5.9 (9.9)</td>
<td>1.9 (7.1)</td>
<td>4.7 (–1.9 to 13.3)</td>
<td>p = 0.035(^b)</td>
</tr>
<tr>
<td></td>
<td>C: 4.5 (9.9)</td>
<td>–1.8 (10.9)</td>
<td>6.3 (0.4 to 13.6)</td>
<td></td>
</tr>
<tr>
<td>4SST (seconds)</td>
<td>A: 10.9 (2.8)</td>
<td>106 (3.3)</td>
<td>-</td>
<td>p = 0.182</td>
</tr>
<tr>
<td></td>
<td>B: 9.0 (2.6)</td>
<td>96 (2.1)</td>
<td>–0.1 (–0.2 to 0.03)</td>
<td>p = 0.160</td>
</tr>
<tr>
<td></td>
<td>C: 8.5 (2.8)</td>
<td>91 (2.6)</td>
<td>–0.1 (–0.3 to 0.03)</td>
<td></td>
</tr>
<tr>
<td>Self-report toe drag (^e)</td>
<td>A: 2 (1.5–4)</td>
<td>4 (2–5)</td>
<td>-</td>
<td>p = 0.002(^b)</td>
</tr>
<tr>
<td></td>
<td>B: 2 (1–3)</td>
<td>4 (2.5–5)</td>
<td>-</td>
<td>p = 0.069</td>
</tr>
<tr>
<td></td>
<td>C: 2 (1–3)</td>
<td>4 (2–4)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>CMRS (score out of 90)</td>
<td>A: 56.4 (14.9)</td>
<td>53.5 (16.5)</td>
<td>-</td>
<td>p = 0.001(^b)</td>
</tr>
<tr>
<td></td>
<td>B: 67.7 (12.8)</td>
<td>56.9 (16.9)</td>
<td>8.3 (3.2 to 13.4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C: 70.4 (11.3)</td>
<td>58.9 (16.2)</td>
<td>8.9 (3.8 to 13.9)</td>
<td></td>
</tr>
<tr>
<td>Self-report falls(^d)</td>
<td>A: 2 (1–3)</td>
<td>3 (2–4)</td>
<td>-</td>
<td>p = 0.089</td>
</tr>
<tr>
<td></td>
<td>B: 2 (1–2.5)</td>
<td>2 (2–3)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C: 1.5 (1–2)</td>
<td>2.5 (2–3.5)</td>
<td>-</td>
<td>p = 0.01(^b)</td>
</tr>
</tbody>
</table>

ASAS: Australian Spasticity Assessment Scale, ROM: Range of Motion, 4SST: Four Square Step Test, \(^a\)Mann Whitney U tests with reported medians and IQR; \(^b\)Significant difference between the groups p < 0.05; - Calculation and test not indicated; CMRS: Community Mobility Scale

All participants had the FES device set with a frequency of 33 Hz with pulse width ranging from 25 to 100 μs. Participants used the FES for a mean daily use of 6.2 (SD 3.2) hours over the eight-week intervention period. There were no reported unintended effects or adverse events.

**Gait measures**

At the post treatment assessment, the groups were significantly different (with small to medium effect sizes) when the treatment group was wearing the FES device (Table 4). With the FES device on at post treatment, the treatment group had an increased ankle angle at initial contact (mean difference 11.9°, 95% CI 6.8° to 17.1°; p < 0.001; d = 0.6), increased ankle angle in maximum dorsiflexion in swing (mean difference 8.1°, 95% CI 1.8 to 14.4°; p = 0.007; d = 0.4), increased normalized step length on the affected side (mean difference 0.06, 95% CI 0.003 to 0.126; p = 0.035; d = 0.4) when compared to the control group. Without the FES device on at post treatment, the treatment group continued to demonstrate increased normalized time in stance (mean difference 0.27, 95% CI 0.05 to 0.49; p = 0.011; d = 0.4) and increased normalized step length on the affected side (mean difference 0.06, 95% CI 0.003 to 0.126; p = 0.035; d = 0.4) when compared to the control group. Despite the FES device on at post treatment, the treatment group continued to demonstrate increased normalized time in stance (mean difference 0.23, 95% CI –0.001 to 0.47; p = 0.050; d = 0.4) when compared to the control group and this was considered a small/medium effect size. There were no other significant differences between the groups for the remaining ankle kinematic and temporal spatial gait measures at post treatment and at follow-up.

**Activity clinical measures**

The CMRS scores were significantly different between the groups with the treatment group demonstrating higher scores both at post treatment, (mean difference 8.3 units, 95% CI 3.2 to 13.4 units; p < 0.001) and at follow-up (mean difference 8.9 units, CI 3.8 to 13.9 units; p < 0.001). After the FES treatment, the treatment group had a significant reduction in the incidence of self-reported toe drag (p = 0.002) and a significant reduction in self-reported falls at follow-up (p = 0.022) when compared to the control group.

**Spasticity and range of movement**

There were significant differences between the groups for gastrocnemius spasticity with the median score in the treatment group decreasing from ASAS 2 at baseline to ASAS 1 post treatment (p = 0.038). The groups were also significantly different at follow-up, with the treatment group having increased dynamic ankle dorsiflexion range (mean difference 6.9°, 95% CI 0.4° to 13.6°; p = 0.035). There were no significant differences between the groups for passive dorsiflexion and popliteal angle range of movement post treatment and at follow-up (Additional file 1). Notably, there was no mean loss of ankle
or knee range of motion at both assessment time points in the treatment group.

**Discussion**

Supporting our first hypothesis, this study documents evidence of an FES orthotic effect in gait with improvements in ankle kinematics to enable toe clearance when walking. The improvement in ankle kinematics further strengthens the current literature supporting the use of FES to the ankle dorsiflexors in children with USCP, to increase the ankle angle in swing to functionally reduce toe drag when walking [18, 22, 36, 37]. The improvement in the time spent in stance on the affected leg provides further evidence that FES in swing can also affect some stance phase features. Once again this strengthens previous results where this effect has also been reported, but only in three children with CP [18]. Hence FES seems to offer some limited but similar features to AFOs, in terms of its effectiveness in improving ankle kinematics, time spent in stance and step length [11–13]. For children who do not require the stance phase knee and hip control that is offered by AFOs, clinicians may consider the implementation of FES for children with USCP that exhibit equinus gait patterns.

Supporting our second hypothesis, after eight-weeks of FES, and with the removal of the FES device, participants in the treatment group demonstrated a therapeutic effect with significantly better CBMS scores, reduced gastrocnemius spasticity and self-reported toe drag compared to the control group. There has been limited evidence supporting the therapeutic effect in CP and this has largely been attributed to variable intervention parameters with different length and setting of intervention, different target muscles for stimulation and underpowered sample sizes to detect significant differences [37–41]. However, the compelling evidence supporting the therapeutic effect in the adult post stroke population, where FES is also used for drop foot has been largely attributed to the application of FES in functional contexts [42]. Therefore the results from the current study support the implementation of daily community applied FES, as this appears to be a necessary component particularly if the goal is to achieve a therapeutic effect.

The mechanism for the therapeutic effect observed at post treatment is unclear. We reason that the reduced gastrocnemius spasticity, improvement in time in stance and community mobility and balance skills reflect more co-ordinated muscle activation at the ankle joint. Referred...
to as muscle co-contraction due to impaired reciprocal inhibition that is often observed at the ankle during gait, [43] can be used as a strategy to improve joint stability [44]. However it may also be functionally detrimental by impairing co-ordinated muscle activation consequently impacting balance control to result in asymmetrical gait patterns [45]. Stimulation to the ankle dorsiflexors may address problems with reciprocal inhibition due to the repetitive nature of the intervention by moving the ankle in and out of dorsiflexion with each step [18, 43]. In effect, this would enable more balanced muscle function at the ankle, improving stability thus accounting for the improvement in community mobility and balance scores.

The continued therapeutic effect in community mobility and balance skills noted at follow-up supports our pilot study results [23]. These changes provide some evidence to suggest the role of motor learning with the development of secondary repertoires of movement. This could be because the participants’ ambulation needs were challenged as they no longer had the orthotic benefits of FES or an AFO. Further work to substantiate the possibility of neuroplastic changes is therefore warranted in future studies. The evidence for supporting the therapeutic effect particularly regarding community mobility and balance skills is functionally important as it means that these changes are possible with minimal therapy face time, a significant consideration in community clinical practice.

There were no ankle kinematic gait therapeutic effects, suggesting that orthotic effects, as with AFOs, are use-dependent. We speculate that the absence of ankle kinematic therapeutic effects could be attributable to inadequate length or dosage of treatment. However, it could also be attributable to inadequate elicitation of the central nervous system from the FES settings as higher frequencies were not available, whilst higher pulse widths only resulted in discomfort and unwanted excessive movements into ankle eversion [46]. Contrary to previous reports, there were no significant improvements in passive ankle dorsiflexion range of motion [47]. It is worth noting that there was no significant loss in range of motion either. This is an important finding because it demonstrates that the removal of an AFO for a short period of FES will not detrimentally affect ankle range of motion for children in this age group. However, it should be noted that participants in this study did not have high levels of spasticity at baseline, hence these results are limited to children with a Winters Gage and Hicks classification of I and II with a gastrocneumius ASAS of no more than three.

Literature supporting the use of AFOs to maintain or even improve ankle range of motion has methodological limitations such as difficulties with standardization of materials and limitations in the outcome measures used. However, it continues to be acceptable in current clinical practice because it is coupled with clinical expertise and assessment [7, 12]. Certainly wearing AFOs or even using FES does not replace the need for vigorous range of movement monitoring, pharmacological or orthopaedic interventions. Individual assessments continue to be necessary when considering and applying FES for the orthotic and therapeutic effects. Specifically, clinicians will need to evaluate the effectiveness of dorsiflexion stimulation without exacerbating any pre-existing foot deformities as well as to ensure the lower limb biomechanical requirements are met before applying FES in gait i.e. able to meet the inclusion criteria specified for this study. The role of community therapy is highlighted here to ensure that FES is used appropriately at home, school and community.

Whilst the results do support both the orthotic and therapeutic effects of FES in a randomised controlled trial, there are some study limitations to note. Gait analysis was performed using two-dimensional video for easy replication in the community. The reliability of using software for sagittal plane measurements has been established [48] and our results match previous ankle kinematic measures obtained from three-dimensional analysis [22]. This procedure was also enhanced with force platforms to accurately determine significant gait events. However, three-dimensional analyses would have offered gait kinetic information. Also, it was not possible to blind the assessor either during the clinical assessments or during the gait video analysis due to observable facial identify and the presence of a Walk Aide® visibly attached to the leg. To our knowledge, there are no valid measures of toe drag and falls for this population. We therefore developed our own questionnaire for this study, which was used in our pilot study, but has not been validated. There was some missing Actigraph® data and this may have influenced the results. Due to limited number of Actigraph® devices available, follow-up assessments were not possible. Inclusion of this data for the follow-up assessment time point would have strengthened the study to confirm that the therapeutic effect was due to the residual effect of FES and not due to increased levels of MVPA. Another limitation is that although a statistically significant difference in dynamic ankle dorsiflexion range was determined between groups, the mean change did not exceed the variability in measurement at the joint [32]. Finally, many variables were explored here over several time points and this may be a limitation because of the potential for Type I error. The strength of this study however is the high compliance, with no missing data or drop-outs. This reflects the acceptability of the intervention as well as the efficacy and potential for this intervention to be implemented in community clinical practice.

Conclusion

Short-term daily community FES is an effective activity based treatment with both orthotic and therapeutic
effects. The improvements in community mobility and balance skills and spasticity are evident for up to six weeks post-treatment. This suggests that FES applied during everyday walking activities is a viable treatment option for children with USCP and equinus gait patterns.

Consent
Written informed consent was obtained from the patient for publication of this manuscript and any accompanying images. A copy of the written consent is available for review by the Editor of this journal.

Additional file

Additional file 1: Mean (SD) of groups and corresponding mean difference between groups (95% CI) reported for passive range of motion and spasticity dimension baseline (A), post treatment (B) and follow-up (K). (DOC 77 kb)

Abbreviations
FES= Functional Electrical stimulation; SD= Standard Deviation; CI= Confidence Interval; CP= Cerebral palsy; GMFCS= Gross Motor Function Classification System; USCP= Unilateral spastic cerebral palsy; AFO= Ankle foot orthosis; MVPA= Moderate to vigorous physical activity; CBMCS= Community balance mobility scale; 45ST= Four square step test; ASAS= Australian Spasticity Assessment Scale.

Competing interests
The authors declare that they have no competing interests.

Authors’ contributions
DP was the principle investigator and is a PhD student enrolled with The University of Western Australia. DP conceptualized and designed the study, drafted the initial manuscript, JG, GJ, CID and KJ carried out the initial analysis, CID designed the gait data collection instruments and supervised data collection. DP and NB analysed the data. All authors read, revised and approved the final version.

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References

123
43. Leonard CE, Sandstrom DA, Monahan JA, Queen S. Short- and long-term contributions to reciprocal inhibition during various levels of muscle contraction of individuals with cerebral palsy. J Child Neurol. 2006;21:4-6.
8.1 Paper 4 Additional results

Foot sensation

Assessment of dorsal and plantar surface foot tactile sensation was performed using Semmes-Weinstein monofilaments (Lower Extremity Form, NC12749, North Coast Medical). This assessment was included to determine the therapeutic effect of FES on tactile sensation. The results for the foot sensation assessment were not included in paper 4 following the editorial process undertaken with BMC Pediatrics. This was mainly due to the limited number of children in the study that demonstrated foot sensation impairment thereby preventing meaningful statistical analysis. However, there are some intriguing trends that were noted. As such, the results are presented here.

The Semmes-Weinstein monofilament foot tactile sensation assessment has high repeatability (Bell-Krotoski & Tomancik, 1987). It was performed by an experienced Occupational Therapist, blinded to group allocation. The test was performed at each assessment time point in a quiet room with participants positioned in a semi-reclined position with a curtain positioned at the knees (without touching the participant) so that they couldn’t see their feet during testing. Participants were required to indicate when they could feel the monofilaments, which varied in size and force. There were five grades of monofilaments and included normal (monofilament size 3.61), diminished light touch (4.31), diminished protective sensation (4.56), loss of protective sensation (5.07) and deep pressure sensation only (6.65).

The monofilament size is represented by a specific colour that is drawn onto the assessment form for both plantar and dorsal surfaces of the foot. All participants in the treatment group, apart from three, demonstrated normal sensation at all assessment time points. Three of the participants in the treatment group had a combination of “diminished protective sensation” and “loss of protective
sensation” on the plantar surfaces of their affected foot. Post treatment, all three participants improved a grade to “diminished light touch”. At follow-up, all three participants improved another grade to “normal” sensation.

There was only one participant in the control group at baseline that had a combination of “diminished protective sensation” and “loss of protective sensation” on the dorsal and plantar surfaces of both feet. There were no clinically meaningful changes in the grading for this participant in the remaining assessments. The assessment forms for three of the participants in the treatment group are shown in Figures 20-31.

Although the results are limited to only four participants, it does offer some useful insights. It is intriguing that all participants in the treatment group with tactile impairment improved their monofilament grading over time. Further study is warranted to determine whether FES treatment would be of benefit to children with sensory impairment.
Figure 20. Participant 4 in FES treatment group at baseline.

Figure 21. Participant 4 in FES treatment group at post treatment

Figure 22. Participant 4 in FES treatment group at follow-up
Figure 23. Participant 6 in FES treatment group at baseline.

Figure 24. Participant 6 in FES treatment group at post treatment

Figure 25. Participant 6 in FES treatment group at follow-up
**Figure 26.** Participant 8 in the FES treatment group at baseline

**Figure 27.** Participant 8 in the FES treatment group at post treatment

**Figure 28.** Participant 8 in the FES treatment group at follow-up
Figure 29. Participant 14 in the control group at baseline

Figure 30. Participant 14 in the control group at post treatment

Figure 31. Participant 14 in the control group at follow-up
8.2 Gait Analysis Measurements

To enable community therapists to replicate the assessment procedures, 2D gait videos were used. As described in the methods in Paper 4, sagittal plane measurements were taken and these were enhanced with the placement of markers over bony prominences. The videos were taken with high frequency cameras that were synchronised with the ground reaction force platforms. This ensured more accuracy in the identification of gait events. The sagittal plane measurements taken are demonstrated in Figures 32 to 35. Time in stance was calculated by subtracting the time (top left of the screen) at toe-off with the time at initial contact.

Figure 32. Lower limb measurements for left initial contact.
**Figure 33.** Lower limb measurements taken at left maximum dorsiflexion in stance.

**Figure 34.** Lower limb measurements at left toe-off
Figure 35. Left ankle measurement for maximum dorsiflexion in swing
SYNTHESIS OF RESULTS

This thesis investigated the effectiveness of commercially available, daily, community applied Functional Electrical Stimulation (FES) in children with USCP. The purpose was to investigate an activity-based approach to determine the orthotic and therapeutic effect of FES. This was investigated on the body structure and function, activity and participation domains of the International Classification of Functioning Child and Youth Version (ICF-CY) within each child’s own environment.

One of the essential roles of the paediatric physiotherapist is to evaluate and implement evidence-based practices to address impairments in body structure and function in order to mitigate the natural history of CP. This may serve to improve function in activity and participation in life situations. As indicated in Paper two, addressing mobility limitations in activity and restrictions in participation (including problems with walking, running, keeping up with friends, active recreation and community mobility) are important for parents and children with USCP. Addressing impairments in body structure and function are also prioritised, thus reinforcing the need for physiotherapists to consider treatment strategies that address a wide range of performance problems across the ICF-CY within contextually relevant environments.

The thesis provides Level II evidence to support the efficacy of FES as an activity based intervention for children with USCP in providing both an orthotic and therapeutic effect.

Orthotic Effect: Stimulation of tibialis anterior to clear the foot during swing

FES applied to tibialis anterior during the swing phase of gait promotes time in stance, increases step length and improves ankle kinematics by increasing ankle dorsiflexion at initial contact and during swing to promote toe clearance. Improved toe clearance during swing produces an orthotic effect, functionally reducing the incidence of toe drag when walking. The change in body structure and function provides evidence-based choice for children with USCP when choosing an orthotic
device particularly when the main impairments in gait are limited to ankle kinematics. This is relevant particularly for those who find it difficult to use AFO, strongly oppose the use of AFO or would perhaps just like to have more options for shoe wear.

The FES orthotic effect provides the necessary dosage of ankle dorsiflexion contractions over a daily treatment period of eight weeks to result in quantifiable improvements in body structure and function. This includes evidence of muscle plasticity with increases in agonist ankle dorsiflexion strength and volume (reflecting swing phase improvements) and antagonist gastrocnemius muscle volume (reflecting stance phase improvements). To obtain this change, dosage of treatment is important. This highlights the importance of the engagement of the child and family with the treatment as well as the role of community therapy to provide education and training at home and school to support regular and consistent FES use. This approach will ensure that the intervention can be implemented in all necessary environments where the child is most ambulant. Therefore, the use of FES during gait is not limited to its potential as an alternative to an AFO for some children but rather, a short term alternative strategy to facilitate strengthening and promote muscle growth even when there are problems with ankle selective motor control.

The direct effect of FES improves both the performance of mobility skills at the activity and participation level and also the satisfaction of the user. It is thus a viable treatment option that can be considered by therapists and parents of children with USCP.

**Therapeutic Effect: Ongoing effect after the removal of FES**

The studies support the therapeutic effect, which lasted up to six weeks after the removal of FES. The therapeutic effect on the body structure and function level is supported by reduced gastrocnemius spasticity and increased lateral gastrocnemius muscle volume at the six week follow up. Evidence of a therapeutic effect was also supported at the activity and participation level with improvements
in community mobility and balance skills. These skills were not only noted with improved clinical scores but of even greater importance, they were meaningful because children and their parents rated greater performance and satisfaction scores of their individually prioritised mobility performance problems within their own contextually relevant environments. The therapeutic effects on activity and participation after six weeks of non-FES use may reflect the expansion of secondary repertoires of movement, enabling more movement variability within daily activities. This could be attributed to the absence of any gait aides, effectively providing the necessary challenge component to promote motor learning. Hence a period of non-FES (by up to six weeks) can provide the opportunity to facilitate and maintain functional change without detriment to the performance and satisfaction of the user. A period of non-use should in particular, be considered for children that improve their ankle selective motor control after eight weeks of FES to optimise the therapeutic effect and limit device dependence.

Figure 36 summarises the process of FES prescription and clinical decision-making that is recommended as a result of the findings of the studies. It provides a guide to the assessment and intervention strategies that are required for each phase of prescription across all domains of the ICF-CY. The process of FES application based on this research can be directly translated into a prescription form for clinicians (Appendix I). Though the prescription form provides clinicians with a framework to base their FES approach on for children with USCP, it does not replace the importance of individual assessment and clinical expertise.

**Equipment Consideration**

One of the major drawbacks of the Walk Aide® is the size. Given the effectiveness of FES, further work should be directed toward device design, making it smaller and user-friendly for younger children. A smaller device would enable the application of activity-based rehabilitation to be implemented as early as possible. The possibility here is that it could drive neuroplastic changes particularly to address impairments in motor control and movement variability. The Walk Aide® is limited to a maximum of 33Hz. Higher frequencies could improve comfort and
enable more central contributions to a muscle contraction (balanced with the effect of FES on fatigue) and could result in longer lasting changes in muscle plasticity and gait mechanics. Unfortunately, there is no known commercially available device on the market that provides FES that is initiated by muscle activity i.e. EMG activated FES within an activity based, environmentally appropriate context. Such a device could reduce the potential for device dependence and possibly enhance the use of FES to drive neuroplastic changes. In view of this, FES may potentially be an appropriate precursor to biofeedback devices that are emerging onto the market to bridge the gap between an FES and no FES condition. Such an approach could result in centralised changes to address the impairments in ankle selective motor control.

**Direction for Future Research**

Further research should investigate the effect of long-term FES on acceptability or compliance and muscle plasticity. This would include the effect of long-term ongoing use (for the orthotic effect) as well as the long-term effect of alternating between periods of use and non-use (for the therapeutic motor learning effect). Combining FES with BoNTA should also be investigated particularly in terms of muscle plasticity. Lateral gastrocnemius muscle volume symmetry was the only muscle that was significantly different between the groups at follow-up and this might possibly be related to the effect and distribution of serial BoNTA injections. There were only three children who had a mixed presentation of CP with both spasticity and dystonia. This study was not designed to determine the effects of different tonal presentations but this may be an interesting line of investigation. Finally, the role of impaired sensation should be investigated in future research. Although the treatment group had only three children with significantly impaired tactile sensation at baseline, it was interesting to observe that all three improved their sensation to more normal grades post treatment and at follow-up (individual results shown as Additional results following Paper 4). This could have been due to either the effect of FES itself or from the removal of AFO. Given that community mobility and balance skills also improved after treatment, it is plausible that
sensation may also have a role to play in the development of secondary repertoires for movement adaptability.

In summary, the results from the studies provide NHMRC Level II evidence to support the efficacy of FES to mitigate the natural history of CP by addressing impairments in body structure and function. The unique feature of FES is that it is an activity-based intervention hence corresponding improvements are also observed in the activity domain. The improvements are relevant to children with USCP and their families because they address self identified mobility related performance problems that are represented across the ICF-CY. The studies also highlight the importance of observing individual responses (even within the randomised controlled trial) rather than just relying on the interpretation of group means (Damiano, 2014). This approach provided valuable insights, especially for selective motor control responses, recognising the heterogeneity of children with CP despite the efforts to homogenise the groups. The role and importance of community-based therapy input for a community-based intervention is also highlighted, reflecting the need for education and support for each child and their family.
**IDENTIFICATION OF APPROPRIATE CANDIDATES**

- Children with unilateral spastic CP aged 5-18 years, GMFCS and WGH1 or H
- Passive dorsiflexion ankle range of motion min 5°
- Full knee extension
- Australian Spasticity Assessment Scale ≤ 3
- Foot posture and ankle stability assessment

**BASELINE ASSESSMENT**

- Passive ankle dorsiflexion range of motion
- Dynamic ankle dorsiflexion range of motion (Modified Tardieu Scale)
- Australian Spasticity Assessment Scale
- Ankle selective motor control
- 2D gait analysis measuring ankle dorsiflexion at initial contact, max dorsiflexion in swing and stance, toe-off

- Ensure in-shoe foot orthoses are provided if necessary

**IMPLEMENTATION OF FES**

- Monitor passive and dynamic range of motion
- 2D gait video analysis to assess effectiveness of FES synchronisation during gait (particular focus on ankle angle during swing)

- Activate dorsiflexion without excessive ankle movement into eversion or inversion
- Increase pulse width preferentially to amplitude if more dorsiflexion is required to promote foot clearance during swing phase of gait

**DETERMINE SUITABILITY OF ONGOING FES**

- No change or deterioration in gait mechanics with FES
- Improvement in gait mechanics with FES particularly increase dorsiflexion in swing
- No change or reduction in spasticity (Modified Tardieu or ASAS)
- No loss of ankle range of motion

- Greater than 2 score change in performance and satisfaction score ratings on the Canadian Occupational Performance Measure

**Figure 36. Process of FES prescription and clinical decision flowchart**
APPENDICES

10.1 Appendix A: NHMRC Levels of Evidence

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<th>Level</th>
<th>Intervention 1</th>
<th>Diagnostic accuracy 2</th>
<th>Prognosis</th>
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<td>A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence</td>
<td>Analysis of prognostic factors among persons in a single arm of a randomised controlled trial</td>
<td>A retrospective cohort study</td>
<td>A comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case-control study</td>
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<td>Diagnostic case-control study 2</td>
<td>A retrospective cohort study</td>
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<td>A comparative study without concurrent controls: • Historical control study • Two or more single arm study 2</td>
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<td>Study of diagnostic yield (no reference standard) 2</td>
<td>Case series, or cohort study of persons at different stages of disease</td>
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*Explanatory notes are provided in the Merk et al. 2000 article, including glossary for the different study designs.

10.2 Appendix B: Registration of clinical trial and ethics approval

Trial from ANZCTR

Request Number: 136956
Current Page: Review

Trial ID: ACTRN12611005316110
Trial Status: Registered
Date Submitted: 20/05/2011
Date Registered: 23/05/2011
Prospectively registered

Page 1

Public title: The Walk Aide Study for children with spastic hemiplegia
Study title in ‘Participant- Intervention- Comparator- Outcome (PICO) format: Effect of Functional Electrical Stimulation (Walk Aide) on children with spastic hemiplegia - A Pilot Study
Secondary ID [1]: N/A
UTN: U1111-1121-5940
Trial acronym:

Page 2

Health condition(s) or problem(s) studied:
Cerebral Palsy - Spastic Hemiplegia
Condition category: Condition code:
Musculoskeletal - Physiotherapy

Page 3

Descriptions of intervention(s) / exposure: The application of functional electrical stimulation on children aged 5 to 18 years with cerebral palsy - spastic hemiplegia (Winters-Gage and Hicks classification Type 1 and 2). Children will be required to wear a small portable device on their leg which will stimulate the ankle dorsiflexors during the swing phase of gait for a period of 6 weeks. Children will be expected to wear the device for at least 1 hour per day, 6 days a week throughout this 6 week intervention phase.

Intervention Code: Rehabilitation
Intervention Code: Treatment: Devices
Comparator / control treatment: No control treatment as this is a single subject design
Control group: Uncontrolled

Page 4

Primary Outcome: Selective Motor Control - Measurement of selective and isolated dorsiflexion on a 5 point scale (Boyd and Graham 1999)
Timepoint: Weekly throughout the 3 phases of the study
Primary Outcome: Isometric Muscle Strength using a Hand Held Dynamometer for dorsiflexion and plantarflexion of the ankle joint
Timepoint: Weekly throughout the 3 phases of the study
Primary Outcome: 2D gait video analysis will be used to determine peak dorsiflexion during swing as well as degree of dorsiflexion at initial contact with and without the electrical stimulation. Physician Rating Scale for Gait Analysis (using Boyd et al 1999) will be used.
### Timepoint:
- **120 gait video will occur before the commencement of the first phase of the study (4 weeks pre-intervention phase to establish baseline) and every 3 weeks thereafter until the subject is 12 weeks post-intervention.**

### Secondary Outcome:
- **Range of Motion will be measured using manual goniometry for the popliteal angles (bilaterally) as well as dorsiflexion with knee flexion and extension and ankle eversion in plantigrade position.**

### Timepoint:
- **Weekly throughout the 3 phases of the study.**

### Secondary Outcome:
- **Spasticity using the Modified Tardieu and Australian Spasticity Assessment Scale for hamstrings, gastrocnemius, soleus and tibialis posterior.**

### Timepoint:
- **Weekly throughout the 3 phases of the study.**

### Secondary Outcome:
- **Single Limb Balance will be measured by the length of time (using a stop watch) the subject can balance on one leg for.**

### Timepoint:
- **Weekly throughout the 3 phases of the study.**

### Secondary Outcome:
- **Calf Circumference - circumferential measurements will be taken of the leg.**

### Timepoint:
- **Weekly throughout the 3 phases of the study.**

### Secondary Outcome:
- **Subjective Reports from the Subjects using a questionnaire which focuses on how the subjects perceive the intervention and the effects it has on their mobility.**

### Timepoint:
- **Pre 6 week intervention, Post intervention and then again at 6 weeks and 12 weeks post intervention.**

---

### Page 5

**Key inclusion criteria**
- Spastic Hemiplegia
- Children aged between 5 and 18 years
- Achieves full bilateral knee extension
- Has at least 5 degrees of ankle dorsiflexion on the affected side
- Dynamic posterior angle no more than 45 degrees
- Able to follow instructions
- Willing to use the Walk Aide device for at least 1 hour a day, 6 days a week for 5 weeks.

**Minimum age**
- 5 Years

**Maximum age**
- 18 Years

**Gender**
- Both males and females

**Healthy volunteers?**
- No

**Key exclusion criteria**
- Orthopaedic lengthening to gastrocnemius/achilles in the last 12 months
- History of Seizure Disorder

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### Page 6

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| Brief summary | Cerebral Palsy is a term that describes a group of primarily motor disorders. Spastic Hemiplegia is a common presentation of cerebral palsy where one side of the body is weaker and muscles are often tighter and more difficult to move. As such, walking can be affected as the foot "catches" on the floor when taking a step and can cause tripping or even falling over. The Walk Aide is a small device that is strapped to the leg just below the knee. It provides electrical impulses to stimulate the muscles that lift up the foot during walking thus preventing tripping and catching of the foot on the ground. The device is portable and can be worn where ever the child wishes to go. Our study aims to see what effects the Walk Aide might have on strength, ease of movement and balance whilst using the Walk Aide but also after using the Walk Aide to determine if the effects last even beyond the use of wearing the device. |

| Trial website |                |
| Trial related presentations / publications |                |
| Public Notes |                |

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<td><strong>Date Registered:</strong></td>
<td>4/09/2014</td>
</tr>
<tr>
<td><strong>Public Title:</strong></td>
<td>Functional electrical stimulation in children with spastic hemiplegia: A study of the effects based on the international classification of functioning framework.</td>
</tr>
<tr>
<td><strong>Study title in 'Participant- Intervention- Comparator- Outcome (PICO)’ format:</strong></td>
<td>Functional electrical stimulation in children with spastic hemiplegia: A study of the effects based on the international classification of functioning framework.</td>
</tr>
<tr>
<td><strong>Secondary ID [1]</strong></td>
<td>The Walk Aide Study</td>
</tr>
<tr>
<td><strong>UTN</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Trial acronym</strong></td>
<td>The W.A.L.K. Study (Walk Aide in Limbs of Kids)</td>
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</tbody>
</table>

**Health condition(s) or problem(s) studied:**

- Cerebral Palsy

**Condition category:** Neurological
**Condition code:** Other neurological disorders

**Descriptions of intervention(s) / exposure:**

- Community based functional electrical stimulation to the ankle dorsiflexors during the swing phase of gait

**Intervention Code:** Rehabilitation

**Comparator / control treatment:**

- Control group of no functional electrical stimulation. Participants in the control are asked to maintain their current levels of therapeutic input and use of ankle foot orthoses.

**Control group:** Active

**Primary Outcome:**

- Muscle volume of lower limb muscles measured by MRI and computed through Mimics Software for total volume

**Timepoint:**

- Baseline, post 8 weeks of FES treatment and 6 weeks follow up

**Primary Outcome:**

- Strength of ankle dorsiflexors and ankle plantarflexors measured by hand held dynamometry and total number of unilateral heel raises

**Timepoint:**

- Baseline, 8 weeks post FES treatment, 6 weeks follow up

**Primary Outcome:**

- Lower limb Selective motor control using the SCALE and Bayley and Graham’s ankle dorsiflexion measure

**Timepoint:**

- Baseline, 6 weeks post FES treatment and 6 weeks follow up

**Secondary Outcome:**

- Ankle range of motion and spasticity of gastrocnemius measured by goniometer and Australian Spastic Assessment Scale and Modified Tardieu

**Timepoint:**

- Baseline, 8 weeks post FES treatment and 6 weeks follow up

**Secondary Outcome:**

- Sensation of the foot measurement by the Semmes and Weinstein Monofilaments

**Timepoint:**

- Baseline, 8 weeks post FES and 6 weeks follow up

**Secondary Outcome:**

- Activity and participation measures including the Community Mobility Balance Scale and the Canadian Occupational Performance Measure
### Timepoint:
Baseline, 8 weeks post FES and 6 weeks follow up

### Secondary Outcome:
Ankle kinematics and temporal spatial measures using 2D gait analysis walking with and without the walk aide.

### Timepoint:
Baseline, 8 weeks post FES treatment and 6 weeks follow up

### Page 5

<table>
<thead>
<tr>
<th>Key inclusion criteria</th>
<th>Children with unilateral spastic hemiplegia, GMFCS I or II with at least 5 degrees of ankle dorsiflexion, 3 months post botulinum toxin, no knee flexion contracture and able to follow instructions required for assessment procedures.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum age</td>
<td>5 Years</td>
</tr>
<tr>
<td>Maximum age</td>
<td>18 Years</td>
</tr>
<tr>
<td>Gender</td>
<td>Both males and females</td>
</tr>
<tr>
<td>Healthy volunteers?</td>
<td>Yes</td>
</tr>
<tr>
<td>Key exclusion criteria</td>
<td>Uncontrolled seizure disorder, orthopaedic metalware around the knee and leg (site of electrical stimulation)</td>
</tr>
</tbody>
</table>

### Study type
Interventional

### Purpose of the study
Treatment

### Allocation to Intervention
Randomised controlled trial

### Describe the procedure for enroling a subject and allocating the treatment (allocation concealment procedures)
This is a matched pairs randomised controlled trial. Potential participants meeting the inclusion criteria are referred to the study from physiotherapists and paediatric rehabilitation consultants. An initial appointment is then scheduled to determine FES tolerance and study protocol. Once informed consent is obtained from two participants that meet the criteria for a match, they are then randomly allocated - one to the FES group and one to the control group.

### Describe the methods used to generate the sequence in which subjects will be randomised (sequence generation)
Simple randomisation using a coin toss

### Masking / blinding
Blinded (masking used)

### Who is / are masked / blinded (choose all that apply)
The people assessing the outcomes
The people analysing the results/data

### Assignment
Factorial

### Other design features
Participants are matched by age (within 2 years for children between 5 and 10 and within 6 years for children between 11 and 18) and GMFCS level (1 or 2)

### Type of endpoint (A)
Efficacy

### Statistical Methods/Analysis
The distributions of strength, ROM, muscle volume, ankle power and the COPM will be assessed for normality through the Shapiro-Wilk test and the Q plot. SMC, SCAPE, sensation, spasticity (ASAS) and CBPS are ordinal scales that cannot be assumed to be equal interval, therefore non-parametric tests will be used for these outcomes. Due to the heterogeneous nature of the subjects, difference between the groups at baseline will be assessed. Difference scores will be assessed using either an independent t test or the Mann Whitney U test (depending on the distribution of the variables). Between group analysis will be performed using an independent t test. When normality assumptions are not met the non-parametric equivalent will be used (Wilcoxon rank sum). Mixed model ANOVA will be used to determine significance between group and within the group for each time point.

### Page 7

<table>
<thead>
<tr>
<th>Phase</th>
<th>Phase 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipated date of first participant enrolment</td>
<td>3/06/2013</td>
</tr>
<tr>
<td>Date of first participant enrolment</td>
<td>7/06/2013</td>
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<tr>
<td>Anticipated date last participant recruited/enrolled</td>
<td>25/07/2013</td>
</tr>
<tr>
<td>Actual date last participant recruited/enrolled</td>
<td>26/07/2013</td>
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<tr>
<td>Target sample size</td>
<td>30</td>
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<td>Recruitment status</td>
<td>Closed: follow-up complete</td>
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Recruitment in Australia
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<tr>
<th>Recruitment state(s)</th>
<th>WA</th>
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</thead>
<tbody>
<tr>
<td>Hospital:</td>
<td>Princess Margaret Hospital - Subiaco</td>
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**Recruitment outside Australia**

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Charities/Societies/Foundations</th>
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<tbody>
<tr>
<td>Name:</td>
<td>Princess Margaret Hospital Foundation</td>
</tr>
<tr>
<td>Address:</td>
<td>Level 1, 68 Hay Street Subiaco WA 6008</td>
</tr>
<tr>
<td>Country:</td>
<td>Australia</td>
</tr>
</tbody>
</table>

**Primary Sponsor**

| Name:                  | University |
| Address:               | School of Sport Science Exercise and Health 35 Stirling Highway Crawley WA 6009 |
| Country:               | Australia |

**Secondary Sponsor**

| Name:                  | Hospital |
| Address:               | Roberts Road, Subiaco 6008 |
| Country:               | Australia |

**Has the study received approval from at least one Ethics Committee?** Yes

**Ethics Committee name:** Princess Margaret Hospital Ethics and Research Governance

| Address:               | Roberts Road Subiaco WA 6008 |
| Country:               | Australia |
| Approval Date:         | 24/05/2013 |
| Submitted Date:        | |
| HREC:                  | 2013041EP |

**Ethics Committee name:** University of Western Australia - Research Ethics and Biosafety Office Research Services

| Address:               | 35 Stirling Highway Crawley 6009 |
| Country:               | Australia |
| Approval Date:         | 05/07/2013 |
| Submitted Date:        | |
| HREC:                  | |

**Brief summary:** To determine the effects of community applied functional electrical stimulation in ambulant children with unilateral spastic cerebral palsy. A device known as the Walk Aide will be given to the intervention group to wear daily for a period of 6 weeks. This controlled trial will determine the effects of using such a device on a range of outcome measures covering the International Classification of Functioning (child and youth version). The outcome of this trial will deepen our understanding of the effects of functional electrical stimulation in a paediatric population and shape our clinical recommendations based on the available evidence.

**Trial website**

**Trial related presentations / publications**

**Public Notes**

---

**Principal Investigator**

| Title:          | Mrs. |
| Name:           | Dayna Pool |
| Address:        | Department of Physiotherapy and Paediatric Rehabilitation Level 5, Hay Street Subiaco WA 6008 |
| Country:        | Australia |
| Tel:            | +61893408503 |
| Fax:            | |
| Email:          | Dayna.Pool@health.wa.gov.au |
Contact person for public queries
Title:        Mr's
Name:        Dayna Pool
Address:     Department of Physiotherapy and Paediatric Rehabilitation Level 5, Hay Street, Subiaco WA 6008
Country:     Australia
Tel:         +618933438503
Fax:         
Email:       Dayna.Pool@health.wa.gov.au

Contact person for scientific queries
Title:        Mr's
Name:        Dayna Pool
Address:     Department of Physiotherapy and Paediatric Rehabilitation Level 5, Hay Street, Subiaco WA 6008
Country:     Australia
Tel:         +618933438503
Fax:         
Email:       Dayna.Pool@health.wa.gov.au

Contact person responsible for updating information
Title:        Mr's
Name:        Dayna Pool
Address:     Department of Physiotherapy and Paediatric Rehabilitation Level 5, Hay Street, Subiaco WA 6008
Country:     Australia
Tel:         +618933438503
Fax:         
Email:       Dayna.Pool@health.wa.gov.au
Ms Dayna Poole  
Department of Rehabilitation and Physiotherapy  
Princess Margaret Hospital for Children  
Roberts Road  
SUBIACO WA 6008  

Dear Ms Poole  

REGISTRATION NUMBER: 1928/EP  

TITLE: Effects of Functional Electrical Stimulation (Walk Aide®) on children with Spastic Hemiplegia – A Pilot Study  

MEETING DATE: 15 September 2011  

RGO and Ethics requirements satisfied 31 January 2012  

The Princess Margaret Hospital for Children Ethics Committee and the Research Governance Office consider that the study protocol conforms to the requirements of the NHMRC Statement on Ethical Conduct in Human Research (National Statement) and resolved at the meeting to recommend the protocol for approval to the Chief Executive. Please note that this study is to be compliant with the Letter of Exchange annexed hereto. This recommendation has been ratified by the Child and Adolescent Health Service.  

The Ethics Committee does however wish to be informed immediately of:  

I. any untoward effects experienced by any participant in the trial where these effects in degree or nature were not anticipated by the researchers, and steps taken to deal with these;  

II. substantial changes in the research protocol together with an indication of ethical implications, and  

III. other unforeseen events.  

The Ethics Committee has been charged with the responsibility of keeping the progress of all approved research under surveillance. A copy of the final result must be forwarded to the Committee upon completion of the research or if the research is not completed within twelve months you are asked to submit a progress report and annually thereafter. This information should include:
a) The status of the project (completed/in progress/abandoned/not commenced). In the event that a project does not commence within 12 months of being approved by the Ethics Committee the study must be resubmitted to the Committee for approval.

b) Compliance with conditions of ethical approval, including security of records and procedures for consent.

c) Compliance with any special conditions stated by the Ethics Committee as a condition of approval.

d) Results from the study to date, including outcome.

Please note that approval for studies is for **three years** and if the research is not completed within that period of time, a request for an extension of time should be submitted for consideration. In the event that a project does not commence within **12 months** of being approved by the Ethics Committee, the study must be resubmitted to the Committee for approval.

In accordance with the NHMRC National Statement on Ethical Conduct in Human Research Chapter 5.5.3, researchers have a significant responsibility in monitoring and must submit the following to the Ethics Committee:

- Annual Reports on the anniversary of the approval date of the study
- Adverse event reports as received
- Amendments and extensions to the study to be requested in adequate time

**Please quote the above registration number on all correspondence.**

Yours sincerely

[Signature]

Dr Mark Salmon
Executive Director
Medical Services

31 January 2012

- The Ethics Committee is constituted, and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans
Dear Ms Pool

REGISTRATION NUMBER: 2013041EP

TITLE: Functional Electrical Stimulation in children with spastic hemiplegia: A study of the effects based on the International Classification of Functioning. The WALK study (Walk Aide in Limbs of Kids)

MEETING DATE: 16 May 2013

RGO and Ethics requirements satisfied 24 May 2013

The Princess Margaret Hospital for Children Ethics Committee and the Research Governance Office consider that the study protocol conforms to the requirements of the NHMRC Statement on Ethical Conduct in Human Research (National Statement) and resolved at the meeting to recommend the protocol for approval to the Chief Executive. This recommendation has been ratified by the Child and Adolescent Health Service.

The Ethics Committee does however wish to be informed immediately of:

I. any untoward effects experienced by any participant in the trial where those effects in degree or nature were not anticipated by the researchers, and steps taken to deal with these,

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- Annual Reports on the anniversary of the approval date of the study
- Adverse event reports as received
- Amendments and extensions to the study to be requested in adequate time

Please quote the above registration number on all correspondence.

Yours sincerely

Dr Mark Salmon
Executive Director
Medical Services

24 May 2013

- The Ethics Committee is constituted, and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans
Our Ref: RA/4/1/6279

05 July 2013

Associate Professor Catherine Elliott
School of Sport Science, Exercise & Health
MBDP: M408

Dear Professor Elliott

HUMAN RESEARCH ETHICS OFFICE – RECOGNITION OF ETHICS APPROVAL FROM ANOTHER HUMAN RESEARCH ETHICS COMMITTEE


Thank you for your correspondence enclosing the necessary documents to facilitate recognition of the ethics approval for the above project granted by an external Human Research Ethics Committee (HREC) registered with the National Health and Medical Research Council (NHMRC).

It is noted that you have ethics approval from Princess Margaret Hospital, approval number 2013041EP.

The UWA students and researchers identified as working on this project are:

UWA Researchers:

<table>
<thead>
<tr>
<th>Name</th>
<th>Faculty / School</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Associate Professor Catherine Elliott</td>
<td>School of Sport Science, Exercise &amp; Health</td>
<td>Chief Investigator</td>
</tr>
<tr>
<td>Assistant Professor Siobhan Reid</td>
<td>School of Sport Science, Exercise &amp; Health</td>
<td>Co-Investigator</td>
</tr>
</tbody>
</table>

Student(s): Dayna Pool

Although The University of Western Australia reserves the right to subject any research involving its staff and students to its own ethics review process, in this case, the Human Research Ethics Office has recognised the existing approval of the external HREC. The project is exempt from ethics review at UWA and the involvement of the above-listed researchers has been authorised. Any conditions for the recognition of the external HREC’s existing approval are listed below:

Special Conditions

None specified

You are reminded that it will be the responsibility of the approving HREC to ensure compliance with all ethics requirements and to monitor and report on the project. However, should any relevant ethics issues arise during the course of the project, you should inform the Human Research Ethics Office of The University of Western Australia.

If you have any queries, please contact the HREO at hreo-research@uwa.edu.au.

Please ensure that you quote the file reference – RA/4/1/6279 – and the associated project title in all future correspondence.

Yours sincerely
Australian Register of Therapeutic Goods Certificate

Issued to

Orthopaedic Appliances Pty Ltd

for approval to supply

Orthopaedic Appliances Pty Ltd - Electrode, electric stimulator

ARTG Identifier: 152349 Class IIa
ARTG Start date: 14/05/2008
Product Category: Medical Device Included Class IIa
GMDN: 34374
GMDN Term: Electrode, electric stimulator
Intended Purpose: Uses 2 electrodes placed on the skin of the leg and powered by a battery to provide functional electrical stimulation to restore the nerve-muscle signals in the leg and foot allowing the foot to be effectively lifted at the correct time during the gait cycle.

<table>
<thead>
<tr>
<th>Manufacturer Details</th>
<th>Address</th>
<th>Certificate number(s)</th>
</tr>
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<tbody>
<tr>
<td>Innovative Neurotronics</td>
<td>Suite 150 3600-B N Capital of Texas Highway Austin, Texas, 78746 United States Of America</td>
<td>DV-20080312-MC-054058-11</td>
</tr>
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</table>

ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following conditions:

- The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.
- The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.
- For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that Information about the Sponsor is provided in such a way as to allow the sponsor to be identified.
- Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.
- The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.
- It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Devices, Blood and Tissues, Therapeutic Goods Administration following inclusion of the device in the ARTG; (as specified in 5.8 of the regulations) Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year.
- Wheres a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.
- A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.
10.3 Appendix C: Gross Motor Function Classification System

GMFCS – E & R
Gross Motor Function Classification System
Expanded and Revised

GMFCS – E & R © Robert Palisano, Peter Rosenbaum, Doreen Bartlett, Michael Livingston, 2007
CanChild Centre for Childhood Disability Research, McMaster University

CanChild Centre for Childhood Disability Research, McMaster University
(Reference: Dev Med Child Neurol 1997;39:214-223)

INTRODUCTION & USER INSTRUCTIONS

The Gross Motor Function Classification System (GMFCS) for cerebral palsy is based on self-initiated movement, with emphasis on sitting, transfers, and mobility. When defining a five-level classification system, our primary criterion has been that the distinctions between levels must be meaningful in daily life. Distinctions are based on functional limitations, the need for hand-held mobility devices (such as walkers, crutches, or canes) or wheeled mobility, and to a much lesser extent, quality of movement. The distinctions between Levels I and II are not as pronounced as the distinctions between the other levels, particularly for infants less than 2 years of age.

The expanded GMFCS (2007) includes an age band for youth 12 to 18 years of age and emphasizes the concepts inherent in the World Health Organization’s International Classification of Functioning, Disability and Health (ICF). We encourage users to be aware of the impact that environmental and personal factors may have on what children and youth are observed or reported to do. The focus of the GMFCS is on determining which level best represents the child’s or youth’s present abilities and limitations in gross motor function. Emphasis is on usual performance in home, school, and community settings (i.e., what they do), rather than what they are known to be able to do at their best (capacity). It is therefore important to classify current performance in gross motor function and not to include judgments about the quality of movement or prognosis for improvement.

The title for each level is the method of mobility that is most characteristic of performance after 6 years of age. The descriptions of functional abilities and limitations for each age band are broad and are not intended to describe all aspects of the function of individual children/youth. For example, an infant with hemiplegia who is unable to crawl on his or her hands and knees, but otherwise fits the description of Level I (i.e., can pull to stand and walk), would be classified in Level I. The scale is ordinal, with no intent that the distances between levels be considered equal or that children and youth with cerebral palsy are equally distributed across the five levels. A summary of the distinctions between each pair of levels is provided to assist in determining the level that most closely resembles a child/youth’s current gross motor function.

We recognize that the manifestations of gross motor function are dependent on age, especially during infancy and early childhood. For each level, separate descriptions are provided in several age bands. Children below age 2 should be considered at their corrected age if they were premature. The descriptions for the 6 to 12 year and 12 to 18 year age bands reflect the potential impact of environment factors (e.g., distances in school and community) and personal factors (e.g., energy demands and social preferences) on methods of mobility.

An effort has been made to emphasize abilities rather than limitations. Thus, as a general principle, the gross motor function of children and youth who are able to perform the functions described in any particular level will probably be classified at or above that level of function; in contrast, the gross motor function of children and youth who cannot perform the functions of a particular level should be classified below that level of function.
## OPERATIONAL DEFINITIONS

**Body support walker** – A mobility device that supports the pelvis and trunk. The child/youth is physically positioned in the walker by another person.

**Hand-held mobility device** – Canes, crutches, and anterior and posterior walkers that do not support the trunk during walking.

**Physical assistance** – Another person manually assists the child/youth to move.

**Powered mobility** – The child/youth actively controls the joystick or electrical switch that enables independent mobility. The mobility base may be a wheelchair, scooter or other type of powered mobility device.

**Self-propels manual wheelchair** – The child/youth actively uses arms and hands or feet to propel the wheels and move.

**Transported** – A person manually pushes a mobility device (e.g., wheelchair, stroller, or pram) to move the child/youth from one place to another.

**Walks** – Unless otherwise specified indicates no physical assistance from another person or any use of a hand-held mobility device. An orthosis (i.e., brace or splint) may be worn.

**Wheeled mobility** – Refers to any type of device with wheels that enables movement (e.g., stroller, manual wheelchair, or powered wheelchair).

## GENERAL HEADINGS FOR EACH LEVEL

<table>
<thead>
<tr>
<th>LEVEL I</th>
<th>- Walks without Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEVEL II</td>
<td>- Walks with Limitations</td>
</tr>
<tr>
<td>LEVEL III</td>
<td>- Walks Using a Hand-Held Mobility Device</td>
</tr>
<tr>
<td>LEVEL IV</td>
<td>- Self-Mobility with Limitations; May Use Powered Mobility</td>
</tr>
<tr>
<td>LEVEL V</td>
<td>- Transported in a Manual Wheelchair</td>
</tr>
</tbody>
</table>

## DISTINCTIONS BETWEEN LEVELS

**Distinctions Between Levels I and II** - Compared with children and youth in Level I, children and youth in Level II have limitations walking long distances and balancing; may need a hand-held mobility device when first learning to walk; may use wheeled mobility when traveling long distances outdoors and in the community; require the use of a railing to walk up and down stairs; and are not as capable of running and jumping.

**Distinctions Between Levels II and III** - Children and youth in Level II are capable of walking without a hand-held mobility device after age 4 (although they may choose to use one at times). Children and youth in Level III need a hand-held mobility device to walk indoors and use wheeled mobility outdoors and in the community.

**Distinctions Between Levels III and IV** - Children and youth in Level III sit on their own or require at most limited external support to sit, are more independent in standing transfers, and walk with a hand-held mobility device. Children and youth in Level IV function in sitting (usually supported) but self-mobility is limited. Children and youth in Level IV are more likely to be transported in a manual wheelchair or use powered mobility.

**Distinctions Between Levels IV and V** - Children and youth in Level V have severe limitations in head and trunk control and require extensive assisted technology and physical assistance. Self-mobility is achieved only if the child/youth can learn how to operate a powered wheelchair.
### BEFORE 2ND BIRTHDAY

**LEVEL I:** Infants move in and out of sitting and floor sit with both hands free to manipulate objects. Infants crawl on hands and knees, pull to stand and take steps holding on to furniture. Infants walk between 18 months and 2 years of age without the need for any assistive mobility device.

**LEVEL II:** Infants maintain floor sitting but may need to use their hands for support to maintain balance. Infants creep on their stomach or crawl on hands and knees. Infants may pull to stand and take steps holding on to furniture.

**LEVEL III:** Infants maintain floor sitting when the low back is supported. Infants roll and creep forward on their stomachs.

**LEVEL IV:** Infants have head control but trunk support is required for floor sitting. Infants can roll to supine and may roll to prone.

**LEVEL V:** Physical impairments limit voluntary control of movement. Infants are unable to maintain antigravity head and trunk postures in prone and sitting. Infants require adult assistance to roll.

### BETWEEN 2ND AND 4TH BIRTHDAY

**LEVEL I:** Children floor sit with both hands free to manipulate objects. Movements in and out of floor sitting and standing are performed without adult assistance. Children walk as the preferred method of mobility without the need for any assistive mobility device.

**LEVEL II:** Children floor sit but may have difficulty with balance when both hands are free to manipulate objects. Movements in and out of sitting are performed without adult assistance. Children pull to stand on a stable surface. Children crawl on hands and knees with a reciprocal pattern. Cruise holding onto furniture and walk using an assistive mobility device as preferred methods of mobility.

**LEVEL III:** Children maintain floor sitting often by “W-sitting” (sitting between flexed and internally rotated hips and knees) and may require adult assistance to assume sitting. Children creep on their stomach or crawl on hands and knees (often without reciprocal leg movements) as their primary methods of self-mobility. Children may pull to stand on a stable surface and cruise short distances. Children may walk short distances indoors using a hand-held mobility device (walker) and adult assistance for steering and turning.

**LEVEL IV:** Children floor sit when placed, but are unable to maintain alignment and balance without use of their hands for support. Children frequently require adaptive equipment for sitting and standing. Self-mobility for short distances (within a room) is achieved through rolling, creeping on stomach, or crawling on hands and knees without reciprocal leg movement.

**LEVEL V:** Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.

### BETWEEN 4TH AND 6TH BIRTHDAY

**LEVEL I:** Children get into and out of, and sit in, a chair without the need for hand support. Children move from the floor and from chair sitting to standing without the need for objects for support. Children walk indoors and outdoors, and climb stairs. Emerging ability to run and jump.

**LEVEL II:** Children sit in a chair with both hands free to manipulate objects. Children move from the floor to standing and from chair sitting to standing but often require a stable surface to push or pull up on with their arms. Children walk without the need for a hand-held mobility device indoors and for short distances on level surfaces outdoors. Children climb stairs holding onto a railing but are unable to run or jump.

**LEVEL III:** Children sit on a regular chair but may require pelvic or trunk support to maximize hand function. Children move in and out of chair sitting using a stable surface to push or pull up on with their arms. Children walk with a hand-held mobility device on level surfaces and climb stairs with assistance from an adult. Children frequently are transported when traveling for long distances or outdoors on uneven terrain.

**LEVEL IV:** Children sit on a chair but need adaptive seating for trunk control and to maximize hand function. Children move in and out of chair sitting with assistance from an adult or a stable surface to push or pull up on with their arms. Children may at best walk short distances with a walker and adult supervision but have difficulty turning and maintaining balance on uneven surfaces. Children are transported in the community. Children may achieve self-mobility using a powered wheelchair.

**LEVEL V:** Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.
**BETWEEN 6TH AND 12TH BIRTHDAY**

**Level I:** Children walk at home, school, outdoors, and in the community. Children are able to walk up and down curbs without physical assistance and are aware of the use of a railing when walking long distances. Children perform gross motor skills such as running and jumping but speed, balance, and coordination are limited. Children may participate in physical activities and sports depending on personal choices and environmental factors.

**Level II:** Children walk in most settings. Children may experience difficulty walking long distances and balancing on uneven terrain, inclines, in crowded areas, confined spaces or when carrying objects. Children walk up and down stairs holding onto a railing or with physical assistance if there is no railing. Outdoors and in the community, children may walk with physical assistance, a hand-held mobility device, or use wheeled mobility when traveling long distances. Children have at best only minimal ability to perform gross motor skills such as running and jumping. Limitations in performance of gross motor skills may necessitate adaptations to enable participation in physical activities and sports.

**Level III:** Children walk using a hand-held mobility device in most indoor settings. When seated, children may require a seat belt for pelvic alignment and balance. Sit-to-stand and floor-to-stand transfers require physical assistance of a person or support surface. When traveling long distances, children use some form of wheeled mobility. Children may walk up and down stairs holding onto a railing with supervision or physical assistance. Limitations in walking may necessitate adaptations to enable participation in physical activities and sports including self-propelling a manual wheelchair or powered mobility.

**Level IV:** Children use methods of mobility that require physical assistance or powered mobility in most settings. Children require adaptive seating for trunk and pelvic control and physical assistance for most transfers. At home, children use floor mobility (roll, creep, or crawl), walk short distances with physical assistance, or use powered mobility. When positioned, children may use a body support walker at home or school. Sit-to-stand and floor-to-stand transfers require physical assistance in mobility necessitate adaptations to enable participation in physical activities and sports, including physical assistance and/or powered mobility.

**Level V:** Children are transported in a manual wheelchair in all settings. Children are limited in their ability to maintain antigravity head and trunk postures and control arm and leg movements. Assistive technology is used to improve head alignment, seating, standing, and/or mobility but limitations are not fully compensated by equipment. Transfers require complete physical assistance of an adult. At home, children may move short distances on the floor or may be carried by an adult. Children may achieve self-mobility using powered mobility with extensive adaptations for seating and control access. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports including physical assistance and using powered mobility.

---

**BETWEEN 12TH AND 18TH BIRTHDAY**

**Level I:** Youth walk at home, school, outdoors, and in the community. Youth are able to walk up and down curbs without physical assistance and stairs without the use of a railing. Youth perform gross motor skills such as running and jumping but speed, balance, and coordination are limited. Youth may participate in physical activities and sports depending on personal choices and environmental factors.

**Level II:** Youth walk in most settings. Environmental factors (such as uneven terrain, inclines, long distances, time demands, weather, and peer acceptability) and personal preference influence mobility choices. At school or work, youth may walk using a hand-held mobility device for safety. Outdoors and in the community, youth may use wheeled mobility when traveling long distances. Youth walk up and down stairs holding onto a railing or with physical assistance if there is no railing. Limitations in performance of gross motor skills may necessitate adaptations to enable participation in physical activities and sports.

**Level III:** Youth are capable of walking using a hand-held mobility device. Compared to individuals in other levels, youth in Level III demonstrate more variability in methods of mobility depending on physical ability and environmental and personal factors. When seated, youth may require a seat belt for pelvic alignment and balance. Sit-to-stand and floor-to-stand transfers require physical assistance from a person or support surface. At school, youth may self-propel a manual wheelchair or use powered mobility. Outdoors and in the community, youth are transported in a wheelchair or use powered mobility. Youth may walk up and down stairs holding onto a railing with supervision or physical assistance. Limitations in walking may necessitate adaptations to enable participation in physical activities and sports including self-propelling a manual wheelchair or powered mobility.

**Level IV:** Youth use wheeled mobility in most settings. Youth require adaptive seating for pelvic and trunk control. Physical assistance from 1 or 2 persons is required for transfers. Youth may support weight with their legs to assist with standing transfers. Indoors, youth may walk short distances with physical assistance, use wheeled mobility, or, when positioned, use a body support walker. Youth are physically capable of operating a powered wheelchair. When a powered wheelchair is not feasible or available, youth are transported in a manual wheelchair. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports, including physical assistance and/or powered mobility.

**Level V:** Youth are transported in a manual wheelchair in all settings. Youth are limited in their ability to maintain antigravity head and trunk postures and control arm and leg movements. Assistive technology is used to improve head alignment, seating, standing, and mobility but limitations are not fully compensated by equipment. Physical assistance from 1 or 2 persons or a mechanical lift is required for transfers. Youth may achieve self-mobility using powered mobility with extensive adaptations for seating and control access. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports including physical assistance and using powered mobility.
10.4 Appendix D: Protocol for Assessments

1. **Selective Motor Control** (Boyd and Graham, 1999)

Long sitting, knees extended, ask subject to flex the ankle towards a target midway above the ankle joint. Observe the ability to dorsiflex without knee flexion and the balance between tibialis anterior (TA), extensor hallucis longus (EHL) and Extensor Digitorum Longus (EDL). Grade both sides as follows:

0  No active movement
1  Minimal AROM (<<PROM), EHL, ± EDL
2  Minimal AROM (<<PROM), EHL ± EDL, some TA
3  Fair/good AROM (<PROM), mainly TA with associated knee flexion
4  Full available ROM, balanced action of TA + peroneii, isolated DF with knee extended

2. **Hand Held Dynamometry** (Crompton et al 2007)

The make test will be employed using the Layfayette Nicolas Manual Muscle Tester Model 01160 with output in kilograms. 3 trials will be administered with the first trial to serve as a practice. The best time will be used from the remaining 2 trials. Constant force is applied perpendicular to the long axis of the limb segment. A zero score will be recorded if the participant is unable to isolate the movement or unable to produce enough force for a reading.

Starting Position: Supine

Ankle Dorsiflexion: Knee extended with foot in natural resting position. Force is applied over the dorsum of the foot. Subject asked to maximally resist examiner’s effort to move the ankle. Examiner will gradually apply force over 1 second so that the subject can adjust to the
force. Force is then applied for a further 4-5 seconds. Knee is not allowed to flex.

3. **Ankle Plantarflexion:** (Yocum et al 2010)

Stand, facing the wall with hands on wall at chest height with elbows flexed to 90 degrees. Flex the opposing limb at the knee joint enough to clear the foot from the floor to assume single limb stance on assessment limb. Participants must plantarflex at the tested ankle so the heel is clear from the floor with weight bearing occurring through the heads of metatarsals whilst maintaining knee extension. Test is discontinued when participant fails to adequately clear the heel or compensatory movements are noted eg flexing the knee. Maximum number of heel raises will be recorded.

4. **Tardieu Scale** (Boyd and Graham 1999)

Procedure

- An R1 (dynamic) and an R2 (passive range of movement) will be recorded for each test/range to be measured.
- R2 (V1 – slow) measurement is assessed before R1.
- Fast movement (V3) of the joint through available range will be used to determine R1 measures.
- After 3 fast movements, the R1 measure is then recorded.
<table>
<thead>
<tr>
<th>Test/ Range to be measured</th>
<th>Position of the Child</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Popliteal Angle</td>
<td>Supine</td>
<td>First flex the hip to 90 degrees– do not flex beyond 90°. Maintain neutral hip rotation. Secure the opposite leg onto the plinth. Extend the knee. Measure angle between the long axis of the tibia and the vertical. A gravity driven goniometer can also be aligned along tibia.</td>
</tr>
<tr>
<td>Ankle Dorsiflexion (knee extended)</td>
<td>Supine</td>
<td>Hold the heel in a neutral to varus position. Extend the knee (0 degrees). Dorsiflex the foot. Measure the angle between the long axis of the tibia and either the plantar aspect of the lateral side of the foot or the inferior border of the calcaneum.</td>
</tr>
<tr>
<td>Ankle Eversion (tibialis posterior)</td>
<td>Supine</td>
<td>Hold the heel in a neutral position. Evert the foot whilst maintaining the ankle joint in plantigrade position. Measure the angle between neutral and</td>
</tr>
</tbody>
</table>
long axis along the head of metatarsals.

5. **Australian Spasticity Assessment Scale** (Love et al 2008)

0  No catch on rapid passive movement (RPM) [i.e. no spasticity]

1  Catch occurs on RPM followed by release. There is no resistance to RPM throughout rest of range.

2  Catch occurs in second half of available range (after halfway point) during RPM and is followed by resistance throughout remaining range.

3  Catch occurs in first half of available range (up to and including halfway point) during RPM and is followed by resistance throughout the remaining range.

4  When attempting RPM. The body part appears fixed but moves on slow passive movement

Contracture is recorded separately

6. **Classification of Gait Patterns: Hemiplegic Gait** (Winters et al 1987)

**Type 1:** Foot Drop - foot drop in the swing phase of gait, normal dorsiflexion range in stance phase.

**Type 2A:** True equinus - excessive plantarflexion of the ankle in both stance and swing phase of gait.
**Type 2B:** True equinus/recurvatum knee - deviations plus limited flexion/extension range of motion at the knee during stance and swing phases of gait.

**Type 3:** True equinus/knee jump - deviations plus limited flexion/extension range of motion at the hip during stance and swing phases of gait.

**Type 4:** Equinus/knee jump - equinus with flexed, stiff knee, flexed, internally rotated & adducted hip with anterior pelvic tilt.
Four Step Square Test Instructions

**General Information:**

The patient is instructed to stand in square 1 facing square number 2 (see figure below)
The patient is required to step as fast as possible into each square in the following sequence: 2, 3, 4, 1, 4, 3, 2, and 1
- requires the patient to step forward, backward, and sideways to the right and left

Equipment required for the FSST includes a stopwatch and 4 canes.

**Set-up (derived from Dite and Temple 2002):** A square is formed with the 4 canes by resting them flat on the floor.

![Diagram of square test sequence]

**Patient Instructions (derived from Dite and Temple 2002):**

“Try to complete the sequence as fast as possible without touching the sticks. Both feet must make contact with the floor in each square. If possible, face forward during the entire sequence.”
Demonstrate the sequence to the patient.
Ask the patient to complete one practice trial to ensure the patient knows the sequence. Repeat the trial if the patient is unsuccessful.
at completing the sequence, loses balance, or contacts a cane during the trial. Two FSST are completed with the best time taken as the score. A score is still provided if the patient is unable to face forward during the entire sequence.

**Scoring:**
the best time of two FSST is the score stopwatch starts when the first foot contacts the floor in square 2 stopwatch finishes when the last foot comes back to touch the floor in square 1
SCALE: Directions for administration

The patient must be able to follow simple motor commands. To test this ability, ask the patient to move his or her least affected body part. Before asking the patient to perform each joint test, passively move the joint to assess ROM. To assure understanding, demonstrate the movement sequence while supporting the limb. The language in the instructions to the patient is suggested and may be modified as needed to elicit optimum performance for individual patients. To guide patients in the desired speed of movement, provide a verbal three-second count during the task. Multiple attempts are allowed and feedback to improve performance is acceptable.

**General instructions to patient** – “I am going to ask you to move in a certain way. Move the way I ask you to move. Try not to move any other part of your body. If you have any questions or you don’t understand what I am asking you to do, please tell me.”

**Hip**

Position – Side lying with the hip and knee fully extended. Support the limb medially at the knee and ankle. For stability, you may flex the lower untested limb. The tested motion is hip flexion while keeping the knee extended. Assess hip flexion ROM with the knee extended, as it may be limited by hamstring tightness. If the patient has difficulty with this task because of hamstring tightness, then ask him or her to extend, flex then extend the hip while keeping the knee flexed 90°. Evaluate hip extension ROM to assure an adequate arc of motion to assess performance of the task.

**Instructions to patient** – Ask the patient to flex, extend then flex the hip while keeping the knee extended. For example: “Move your leg forward, back then forward again while keeping your knee straight. I will take you through the motion first, and then I’d like you to do it yourself.”

**Knee**

Position – The remaining tests are done in sitting with legs over the edge of the exam table. During the remaining tests you may allow the patient to lean back on his or her hands so the trunk is approximately 20° from vertical to compensate for hamstring tightness.

**Instructions** – Ask the patient to extend, flex then extend the knee while keeping the hip flexed. For example: “Straighten your knee as much as you can, then bend it and straighten again. Try to do this without leaning further back or moving your other leg. I will take you through the motion first, and then I’d like you to do it yourself.”

**Limb Extension Synergy** – If quadriceps weakness is suspected, limb extension synergy may be assessed. Allow the patient to lean back on his or her hands or be supported so the trunk is approximately 45° from vertical. Position the limb in hip and knee flexion with ankle dorsiflexion. Ask the patient to push against your hand, extending the knee and plantar flexing the foot and toes. Resist at the metatarsal heads and compare extension excursion to the amount achieved during the knee selective voluntary motor control test.

**Ankle**

Position – Sitting, as in the knee extension test. The knee is extended and the examiner supports the calf. Assess passive ankle dorsiflexion ROM with the knee extended. The knee may be flexed to approximately 20° if needed to accommodate hamstring and/or gastrocnemius tightness.

**Instructions to patient** – Ask patient to dorsiflex, plantar flex then dorsiflex the ankle while maintaining knee extension. For example: “Keeping your knee straight while I support your leg, move your foot up, down then up again. I will take you through the motion first, then I’d like you to do it yourself.”

**Limb Flexion Synergy (Confusion Test)** – If dorsiflexor muscle weakness is suspected, limb flexion synergy may be assessed. Ask the patient to flex the hip while keeping the knee flexed. Resist hip flexion at the distal thigh. Compare dorsiflexion excursion to the amount achieved during the ankle selective voluntary motor control test.

**Foot/Subtalar Joint**

Position – Sitting, as in the knee and ankle tests. The calf is supported.

**Instructions to patient** – Ask patient to invert, evert then invert while maintaining knee extension. For example: “Move your ankle in, then out then in again while I support your leg. I will take you through the motion first, then I’d like you to do it yourself.”

**Toes**

Position – Sitting, as in the ankle test. The heel is supported.

**Instructions to patient** – Ask patient to flex, extend then flex toes without moving ankle or knee. For example: “Curl all your toes down, then up then down again while I support your leg. I will take you through the motion first, then I’d like you to do it yourself.”

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SCALE: Selective Control Assessment of the Lower Extremity
Instructions for Grading

Each joint is scored either 2, 1, or 0 points. These are summed for a Total Limb Score. The number of points for each grade is in parentheses. For each joint, check the joint score and all applicable descriptors on the SCALE Score Sheet.

**Hip**
- **Normal (2)**: Flexes, extends then flexes again. During flexion, movement occurs without knee flexion, within a three-second verbal count and without mirror movement (the same movement on the contralateral limb). If alternate hip extension test is used, extends, flexes then extends again. During extension, movement occurs without knee extension, within a three-second verbal count and without mirror movement.
- **Impaired (1)**: One or more of the following occur: extends or flexes ≤ 50% of available range of motion in the test position, performs task slower than three-second verbal count, exhibits mirror movements, movement occurs in only one direction or motion at untested joint occurs.
- **Unable (0)**: Does not flex or extend hip or does so only with simultaneous knee movement.

**Knee**
- **Normal (2)**: Extends, flexes and extends again. Movement occurs within three-second verbal count, without motion of the trunk or other joints and without mirror movement. A Normal grade may be given if the knee extends > 50% of available range of motion in the test position.
- **Impaired (1)**: One or more of the following occur: extends ≤ 50% of available range of motion, performs task slower than three-second verbal count, exhibits mirror movements, movement occurs in only one direction or motion at untested joint occurs.
- **Unable (0)**: Does not extend or only extends with simultaneous hip or ankle movement.

**Ankle**
- **Normal (2)**: Dorsiflexes, plantar flexes and dorsiflexes again. Movement occurs within a three-second verbal count, without motion at other joints and without mirror movement. At least 15° of ankle motion in the sagittal plane must be observed.
- **Impaired (1)**: One or more of the following occur: dorsiflexes ≤ 50% of available passive range of motion in the test position or active range during Limb Flexion Synergy, performs task slower than three-second verbal count, exhibits mirror movements, movement occurs in only one direction or motion at untested joint occurs. An "Impaired" grade is given if the motion is accompanied by toe extension or ankle inversion.
- **Unable (0)**: Does not dorsiflex or only dorsiflexes with hip and knee flexion.

**Foot/Subtalair Joint**
- **Normal (2)**: Inverts, everts and inverts again. Movement occurs within a three-second verbal count, without motion at other joints and without mirror movement. Active eversion must occur.
- **Impaired (1)**: One or more of the following occur: inverts or everts ≤ 50% of available range of motion, performs task slower than three-second verbal count, exhibits mirror movements, movement occurs in only one direction or motion at untested joint occurs.
- **Unable (0)**: Does not invert or evert or movement occurs only in synergy pattern. May dorsiflex, plantar flex or not move ankle at all.

**Toes**
- **Normal (2)**: Flexes, extends and flexes again. Movement occurs within a three-second verbal count, without motion at other joints and without mirror movement. Motion should occur at all five toes.
- **Impaired (1)**: One or more of the following occur: flexes or extends ≤ 50% of available range of motion, performs task slower than three-second verbal count, exhibits mirror movements, movement occurs in only one direction or motion at untested joint occurs.
- **Unable (0)**: Does not flex or extend toes.

**Difference between Unable and Impaired**
Unable (total synergy) has simultaneous movement at two or more joints. For every degree of motion at the desired joint, concomitant obligatory motion that is a part of the synergy pattern occurs at another joint in the limb. Patients with impaired motor control may be able to move the desired joint through a small arc of motion without any other joint motion, however a portion of the motion is accompanied by motion at an adjacent joint.

**Difference between Impaired and Normal**
Normal motor control is the ability to isolate joint motion through more than 50% of the available ROM within a three-second verbal count in an alternating fashion. The motion occurs without accompanying motion at any other joint of either limb. The inability to perform this task is impaired.
Gait Analysis Procedure – Walk Study

Ensure we collect height and weight.

1. Marker placement
   a. Silver, white or black stickers for shoes (for best contrast)
      i. 5th Metatarsal
      ii. Calcaneus (central on back)
   b. Orange dots for the rest of the body
      i. Lateral malleolus
      ii. Medial malleolus
      iii. Lateral epicondyle
      iv. Patella (top of the sticker is on the superior border of the patella)
      v. Greater Trochanter
      vi. ASIS
      vii. PSIS
      viii. C7
      ix. Medial border of spine of scapula
      x. Lateral border of spine of scapula
      xi. Inferior angle of scapula
      xii. Lateral epicondyle (Elbow)
      xiii. Most lateral point of the acromion
      xiv. Ulnar prominence i.e. wrist

Video Set up

- Ensure that the dots on the ground near the force platforms are clear for measurements

- Position vertical ruler on a board so that we can see them on the Bonita Cameras (for jump)

- Ensure Bonita cameras are at neutral zoom. Open aperture for adequate lighting. Both Bonitas need to film same “inpoints” and “outpoints”

- 3rd Bonita camera needs to be placed on pool side of the gait lab at the end of the walk way
• Walk WITH SHOES and orthotics (if they have them) unless otherwise specified.

Trials – Bonita cameras for all

1. Walking over force platforms – 5 successful trials over platforms on each leg

2. Walking with the Walk Aide (if appropriate – this is marked on the forms) over force platforms. 5 successful trials over platforms on each leg
Day to Day Walking Questionnaire

We want to know what your walking and running is like every day -- at home, at school, and wherever you go. Please answer all questions honestly. There are no right or wrong answers. Just tell us what you do and how you feel about your walking.

1. How often do you run?
   - I never run
   - Less than once a week
   - Once a week
   - Several days a week
   - Every day

2. How often do you drag your toes when you are walking?
   - I never drag my toes
   - I drag my toes occasionally
   - A few times a week
   - A few times a day
   - Whenever I walk

3. How often do you fall over?
   - I never fall over
   - Less than once a week
   - Once a week
   - Several days a week
   - Every day

4. How often are you worried that you will fall when you are running?
   - Never
   - Rarely
   - Sometimes
   - Often
   - Always

5. How often are you worried that you will fall when you are walking?
   - Never
   - Rarely
6. How often do you fully participate in Phys Ed?
- Never
- Rarely
- Sometimes
- Often
- Always

7. How often are you worried you might fall or get hurt when participating in Phys Ed?
- Never
- Rarely
- Sometimes
- Often
- Always

8. How often did you wear your walk aid?
- Never
- Less than once a week
- Once a week
- 2-3 days a week
- 4-6 days a week
- Every day

9. What changes have you noticed in yourself since you starting wearing the walk aid®?
## Walk Aide Diary

### Week 1
#### Day 1

**How long I used the Walk Aide for: (tick the correct box)**

<table>
<thead>
<tr>
<th></th>
<th>Did not use it today</th>
<th>30 minutes</th>
<th>1 hour</th>
<th>2 hours</th>
<th>3 hours</th>
<th>4 hours</th>
<th>5 hours</th>
<th>6 hours</th>
<th>7 hours</th>
<th>Other Please specify:</th>
</tr>
</thead>
</table>

**Intensity Level (circle each level you used today)**

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
</table>

**How it felt today**

<p>| | |</p>
<table>
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<tr>
<th></th>
<th></th>
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</table>

**What I was doing when using the Walk Aide**

<p>| | |</p>
<table>
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<tr>
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<th></th>
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</thead>
</table>

**Eg walking to school, at school, at the shops**

<p>| | |</p>
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<th></th>
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</table>

**How does your skin look today? Anything unusual?**

<p>| | |</p>
<table>
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<tr>
<th></th>
<th></th>
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</thead>
</table>

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## Observational Gait Scale

172
<table>
<thead>
<tr>
<th>1. Knee position in midstance</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crouch</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Moderate &gt;10 to 15°</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mild &lt; 10°</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Neutral</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Recurvatum</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Mild &lt; 5°</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Moderate 5-10°</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2 Initial foot contact</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Forefoot</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Foot Flat</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Heel</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3 Foot contact at midstance</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toe/toe (equinus)</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>Foot flat/early heel rise</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Foot flat/no early heel rise</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Occasional heel/foot flat</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Heel/toe (normal roll over)</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Timing of heel rise</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>No heel contact (fixed equinus)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Before 25% stance (very early)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Between 25-50% (slightly early)</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>At terminal stance</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Hindfoot at midstance</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varus</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Valgus</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Neutral</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Base of support</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frank scissoring</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Narrow base (poor knee clearance)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Wide base</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Normal base (width of shoulders)</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Gait assistive devices</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walker (forward/posterior) with assistance</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Walker (independent)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>---------------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Crutches, sticks</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>None, independent for 10m</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

8. Change

<table>
<thead>
<tr>
<th>Change</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worse</td>
<td>-1</td>
<td>-1</td>
</tr>
<tr>
<td>None</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Better</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

TOTAL (perfect = 22 per limb)
Weekly visit protocol treatment group

Participant Number: ___________ Date: ___________ Wk: ___________

CHECK WALK AIDE

Any signs of skin irritation under electrodes? ☐ ☐
Reports of any side effects:

__________________________________________________________________________

__________________________________________________________________________

Data from Walk Aide:

<table>
<thead>
<tr>
<th>Hours of Use</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. Stims per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Participant/Parent Comments:

__________________________________________________________________________

__________________________________________________________________________

________________________________________

Walk Aide Adjustments made: Y/N

Frequency: ___________

Pulse Width: ___________

Intensity: ___________
Collect Walk Aide diary

Weekly visit protocol control group

Participant Number: __________ Date: __________ Wk: __________

### Selective Motor Control

<table>
<thead>
<tr>
<th></th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMC Rating</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:


### Range Of Motion and Spasticity Assessment

<table>
<thead>
<tr>
<th></th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion knee flexion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dorsiflexion knee ext</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dynamic DF in knee ext</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tibialis Posterior (Ev in PG)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dynamic Tib Posterior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Popliteal Angle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dynamic Popliteal Angle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hamstrings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plantarflexors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tibialis Posterior</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments: ________________________________

176
## Canadian Occupational Performance Measure (COPM)

**Authors:** Mary Law, Sue Baptiste, Anne Carswell, Mary Ann McColl, Helene Polatakis, Nancy Pollock

### Client Information

- **Client Name:**
- **Respondent (if not client):**
- **DOB:**
- **ID#:**
- **Gender:**
- **Date of Assessment:**
- **Planned Date of Reassessment:**
- **Actual Date of Reassessment:**

### Therapist Information

- **Therapist:**
- **Facility/Agency:**
- **Program:**

### Step 1: Identification of Occupational Performance Issues

To identify occupational performance problems, ask clients to identify daily activities which they want to do, need to do or are expected to do but can’t do, don’t do, or aren’t satisfied with how they do.

#### Step 1A: Self-Care

<table>
<thead>
<tr>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

- **Personal Care**
  - e.g., dressing, bathing, feeding, grooming
- **Positional Mobility**
  - e.g., transfers, transfers to toilet
- **Community Management**
  - e.g., transportation, shopping, banking

#### Step 1B: Productivity

<table>
<thead>
<tr>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

- **Paid/Unpaid Work**
  - e.g., feeding, cleaning, cooking, outdoor activities
- **Household Management**
  - e.g., cleaning, laundry, cooking
- **Play/School**
  - e.g., work skills, homework

### Step 2: Rating Importance

Using scoring card provided, ask client to rate, on a scale of 1 to 10, the importance of each activity.
### STEP 1C: Leisure

#### Quiet Recreation
- e.g., hobbies, crafts, reading.

#### Active Recreation
- e.g., sports, outings, travel.

#### Socialize
- e.g., visiting, phone, mail, parties, companionship.

### STEP 3: SCORING

Confirm with the client the 5 most important problems and record them below. Using the scoring cards, ask the client to rate each problem on performance and satisfaction, then calculate the total scores. Total scores are calculated by adding together the performance or satisfaction scores for all problems and dividing by the number of problems.

### STEP 4: RE-ASSESSMENT

At an appropriate interval for reassessment, the client again scores each of the problems selected for performance and satisfaction.

<table>
<thead>
<tr>
<th>Initial Assessment:</th>
<th>Reassessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional Problems</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
</tr>
</tbody>
</table>

### SCORING:

- **Performance Score** = Number of problems scored × Total scores
- **Satisfaction Score** = Number of problems scored × Total scores

### STEP 5: COMPUTING CHANGE SCORES

- **Change in Performance** = Performance Score 2 - Performance Score 1
- **Change in Satisfaction** = Satisfaction Score 2 - Satisfaction Score 1

### ADDITIONAL NOTES AND OBSERVATION:

Initial Assessment:

Reassessment:

Published by CAOT Publications ACE © M. Lew, S. Baptiste, A. Carew, M. A. McCull, H. Poleszko, N. Pollack, 2008
Hypertonia Assessment Tool

HYPERTONIA ASSESSMENT TOOL (HAT) - SCORING CHART

<table>
<thead>
<tr>
<th>Name:</th>
<th>Chart/File #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Diagnosis:</td>
<td>Date of Birth:</td>
</tr>
<tr>
<td>Limb Assessed:</td>
<td>Gender: □ Male □ Female</td>
</tr>
<tr>
<td>□ Arm □ Left □ Right</td>
<td>HAT Assessor:</td>
</tr>
<tr>
<td>□ Leg □ Left □ Right</td>
<td>Date of Assessment:</td>
</tr>
</tbody>
</table>

HYPERTONIA ASSESSMENT TOOL (HAT)

<table>
<thead>
<tr>
<th>HAT ITEM</th>
<th>SCORING GUIDELINES (0=negative or 1=positive)</th>
<th>SCORE 0=negative 1=positive (circle score)</th>
<th>TYPE OF HYPERTONIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Increased involuntary movements/postures of the designated limb with tactile stimulus of a distal body part</td>
<td>0= No involuntary movements or postures observed 1= Involuntary movements or postures observed</td>
<td>0 1</td>
<td>DYSTONIA</td>
</tr>
<tr>
<td>2. Increased involuntary movements/postures with purposeful movements of a distal body part</td>
<td>0= No involuntary movements or postures observed 1= Involuntary movements or postures observed</td>
<td>0 1</td>
<td>DYSTONIA</td>
</tr>
<tr>
<td>3. Velocity dependent resistance to stretch</td>
<td>0= No increased resistance noticed during fast stretch compared to slow stretch 1= Increased resistance noticed during fast stretch compared to slow stretch</td>
<td>0 1</td>
<td>SPASTICITY</td>
</tr>
<tr>
<td>4. Presence of a spastic catch</td>
<td>0= No spastic catch noted 1= Spastic catch noted</td>
<td>0 1</td>
<td>SPASTICITY</td>
</tr>
<tr>
<td>5. Equal resistance to passive stretch during bi-directional movement of a joint</td>
<td>0= Equal resistance not noted with bi-directional movement 1= Equal resistance noted with bi-directional movement</td>
<td>0 1</td>
<td>RIGIDITY</td>
</tr>
<tr>
<td>6. Increased tone with movement of a distal body part</td>
<td>0= No increased tone noted with purposeful movement 1= Greater tone noted with purposeful movement</td>
<td>0 1</td>
<td>DYSTONIA</td>
</tr>
<tr>
<td>7. Maintenance of limb position after passive movement</td>
<td>0= Limb returns (partially or fully) to original position 1= Limb remains in final position of stretch</td>
<td>0 1</td>
<td>RIGIDITY</td>
</tr>
</tbody>
</table>

SUMMARY SCORE – HAT DIAGNOSIS

| DYSTONIA → Positive score (1) on at least one of the Items #1, 2, or 6 | Yes ☐ No ☐ |
| SPASTICITY → Positive score (1) on either one or both of the Items #3 or 4 | Yes ☐ No ☐ |
| RIGIDITY → Positive score (1) on either one or both of the Items #5 or 7 | Yes ☐ No ☐ |
| MIXED TONE → Presence of 1 or more subgroups (e.g. dystonia, spasticity, rigidity) | Yes ☐ No ☐ |

HAT DIAGNOSIS: (Fill in all that apply)
### SCALE: Selective Control Assessment of the Lower Extremity

**Score Sheet**

**Date:**

**Patient’s Name:**

**DOB:**

**GMFCS level:**

**Diagnosis:**
- spastic diplegia
- spastic quadriplegia
- spastic hemiplegia
- R
- L
- other:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal (2 points)</td>
<td>Hip</td>
<td>Knee</td>
</tr>
<tr>
<td>Impaired (1 point)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable (0 points)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Limb Score</strong></td>
<td><strong>L=</strong></td>
<td><strong>R=</strong></td>
</tr>
</tbody>
</table>

**Resisted Synergy**
- knee extension with resisted limb extension
- dorsiflexion with resisted limb flexion

**Descriptors**
- hip flexion contracture
- adductor contracture or spasticity
- knee flexion contracture
- hamstring tightness
- plantar flexion contracture
- plantar flexor spasticity
- inverts or everts, not pure dorsiflexion
- primarily moves toes
- mimics motion on opposite limb
- motion slower than 3 second verbal count
- moves one direction only (note motion achieved)
- movement of other joints
- motion < 50% of available ROM

**Other comments regarding test:**

________________________

________________________

________________________

___________

**Examiner**

---

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Four Square Step Test (4SST)

Name:______________________________________________

Assistive Device and/or Bracing Used:______________________________________________

Date:_______
Trial 1 _____ sec.  Trial 1 _____ sec.
FSST Score (best timed trial): _______ sec.

Date:_______
Trial 1 _____ sec.  Trial 1 _____ sec.
FSST Score (best timed trial): _______ sec.

Date:_______
Trial 1 _____ sec.  Trial 1 _____ sec.
FSST Score (best timed trial): _______ sec.

Date:_______
Trial 1 _____ sec.  Trial 1 _____ sec.
FSST Score (best timed trial): _______ sec.
Community Balance and Mobility Scale

**COMMUNITY BALANCE & MOBILITY SCALE (CB&M) SCORE SHEET**

Full CB&M guidelines must be reviewed to ensure accurate administration and scoring. To score 5, actions must appear coordinated and controlled without excessive equilibrium reactions.

<table>
<thead>
<tr>
<th>CB&amp;M Tasks</th>
<th>Notes</th>
<th>Initial</th>
<th>Mid</th>
<th>D/C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. UNILATERAL STANCE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>unable to sustain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2.00 to 4.49 sec.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>4.50 to 9.99 sec.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>10.00 to 19.99 sec.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>≥ 20.00 sec.</td>
<td>“Look straight ahead”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>45.00 sec., steady and coordinated</td>
<td>Test is over if stance foot moves from start position or raised foot touches ground.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2. TANDEM WALKING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>unable</td>
<td>“Look ahead down the track, not at your feet.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 step</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2 to 3 consecutive steps</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>&gt; 3 consecutive steps</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>&gt; 3 consecutive steps</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>7 consecutive steps</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. <strong>180° TANDEM PIVOT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>unable to sustain tandem stance</td>
<td>Test is over if touches heels down or steps out of position.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>sustains tandem stance but unable to unweight heels or initiate pivot</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>initiates pivot but unable to complete 180° turn</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>completes 180° turn but discontinuous pivot (e.g., pauses on toes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>completes 180° turn in a continuous motion but can’t sustain reversed position</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>completes 180° turn in a continuous motion and sustains reversed position</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4. LATERAL FOOT SCOOTING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>unable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 lateral pivot</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2 lateral pivots</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>≥ 3 pivots but &lt; 40 cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>40 cm in any fashion and/or unable to control final position</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>40 cm continuous, rhythmical motion with controlled stop.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>5. HOPPING FORWARD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>unable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 to 2 hops, uncontrolled</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2 hops, controlled but unable to complete 1 metre</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 metre in 2 hops but unable to sustain landing (touches down)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>1 metre in 2 hops but difficulty controlling landing (hops or pivots)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>1 metre in 2 hops, coordinated with stable landing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6. CROUCH AND WALK</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>unable to crouch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>able to descend only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>descends and rises but hesitates, unable to maintain forward momentum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>crouches and walks in continuous motion, time ≤ 8.00 sec. protective step</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>crouches and walks in continuous motion, time ≤ 8.00 sec. excess equilibrium reaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>crouches and walks in continuous motion, time ≤ 4.00 sec.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3 CB&M Scale

Toronto Rehab / U of T
### 7. LATERAL DODGING

- **0** unable to perform 1 cross-over in both directions without support
- **1** 1 cross-over in both directions in any fashion
- **2** 1 or more cycles, but does not contact line every step
- **3** 2 cycles, contacts line every step
- **4** 2 cycles, contacts line every step 12.00 to 15.00 sec.
- **5** 2 cycles, contacts line every step < 12.00 sec. coordinated direction change

“Do this as fast as you can yet at a speed that you feel safe.”

### 8. WALKING & LOOKING

- **0** unable to walk and look e.g. stops
- **1** performs but loses visual fixation at or before 4 metre mark
- **2** performs but loses visual fixation after 4 metre mark
- **3** performs and maintains visual fixation between 2-6 metre mark but protective step
- **4** performs and maintains visual fixation between 2-6 metre mark but veers
- **5** performs, straight path, steady and coordinated ≤ 7.00 sec.

“Walk at your usual pace.”

### 9. RUNNING WITH CONTROLLED STOP

- **0** unable to run
- **1** runs, time > 5.00 sec.
- **2** runs, time > 3.00 but ≤ 5.00 sec., unable to control stop
- **3** runs, time > 3.00 but ≤ 5.00 sec., with controlled stop, both feet on line
- **4** runs, time ≤ 3.00 sec., unable to control stop
- **5** runs, time ≤ 3.00 sec., with controlled stop, both feet on line, coordinated and rhythmical

“Run as fast as you can.” Hold position on finish line.

### 10. FORWARD TO BACKWARD WALKING

- **0** unable
- **1** performs but must stop to regain balance
- **2** performs with reduced speed, time > 11.00 sec. or requires 4 or more steps to turn
- **3** performs in ≤ 11.00 sec. and/or veers during backward walking
- **4** performs in ≤ 9.00 sec. and/or uses protective step during or just after turn
- **5** performs in ≤ 7.00 sec., maintains straight path

“Walk as quickly as you can yet at a speed that you feel safe.”

### 11. WALK, LOOK AND CARRY

(Score same as #8 Walking and Looking)

“Walk at your usual pace.”

### 12. DESCENDING STAIRS

- **0** unable to step down 1 step, or requires railing or assistance
- **1** able to step down 1 step with/without cane
- **2** able to step down 3 steps with/without cane, any pattern
- **3** 3 steps reciprocal or full flight in step-to-pattern
- **4** full flight reciprocal, awkward
- **5** full flight reciprocal, rhythmical and coordinated

+1 bonus for carrying basket

### 13. STEP-UPS X 1 STEP

- **0** unable to step up, requires assistance or railing
- **1** steps up, requires assistance or railing to descend
- **2** steps up and down (1 cycle)
- **3** completes 5 cycles
- **4** completes 5 cycles in > 6.00 but ≤ 10.00 sec.
- **5** completes 5 cycles in ≤ 6.00 sec., rhythmical

“Do this as quickly as you can. Try not to look at your feet.”

### TOTAL SCORE

<table>
<thead>
<tr>
<th></th>
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**Signature(s)**

**Date(s)**

4 CB&M Scale

Toronto Rehab / U of T
Foot Screening Mapping Examples
Touch-Test™ Sensory Evaluators

<table>
<thead>
<tr>
<th>Key</th>
<th>Monofilament Size</th>
<th>Representation</th>
<th>Dorsal Surface Threshold</th>
<th>Plantar Surface Threshold</th>
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</thead>
<tbody>
<tr>
<td>Calsus</td>
<td>2.83</td>
<td>Green</td>
<td>Normal</td>
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<tr>
<td>Pre-ulcer</td>
<td>3.61</td>
<td>Blue</td>
<td>Diminished light touch</td>
<td>Diminished light touch</td>
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<tr>
<td>Ulcer</td>
<td>4.31</td>
<td>Purple</td>
<td>Diminished protective sensation</td>
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<tr>
<td>Ulcer</td>
<td>4.56</td>
<td>Red</td>
<td>Loss of protective sensation</td>
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<tr>
<td>Ulcer</td>
<td>5.07</td>
<td>Red</td>
<td>Deep pressure sensation only</td>
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</tr>
<tr>
<td>Ulcer</td>
<td>6.65</td>
<td>Red</td>
<td>Deep pressure sensation only</td>
<td>Deep pressure sensation only</td>
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Initial Evaluation - Visit #1
RIGHT FOOT: Superficial ulcer on plantar surface over the second metatarsal head.
LEFT FOOT: Pre-ulcer proximal to the first dorsal web space.
Patient education, treatment intervention and wound care management initiated.

Re-evaluation - Visit #2
RIGHT FOOT: Ulcer healed. Improved to diminished protective sensation on plantar surface over the second metatarsal head.
LEFT FOOT: Pre-ulcer healed. Loss of protective sensation proximal to the first dorsal web space.

Re-evaluation - Visit #3
BOTH FEET: Diminished light touch sensation at toes and plantar surfaces.
LEFT FOOT: Improved to diminished protective sensation proximal to the first dorsal web space.

Re-evaluation - Visit #4
RIGHT FOOT: Normal throughout.
LEFT FOOT: Improved to diminished light touch sensation over dorsal web spaces.
**WALK Gait Assessment**

**PARTICIPANT DETAILS**

ID No: .................................................  Assessment Date: ..............................

Name: .................................................  Assessment

Age: .....................................................  Date of Birth: ..............................

Comments:

............................................................................................................................

**ANTHROPOMETRICS**

Height: ............................................. (cm)  Weight: ..................................... (kg)

**CAMERA SET UP**

Left: ...........................................................

Right: ...........................................................

<table>
<thead>
<tr>
<th>Walking without Walk Aide</th>
<th>Trial Number</th>
<th>Starting Position (Pool or River)</th>
<th>Comments (Force platforms: L, R or both)</th>
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<td>24.</td>
<td>Spacing with Walk Aide</td>
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Walk Aide ® Study

Why are we doing the study?
Foot drag is a common challenge for people with spastic hemiplegia. This occurs when the foot on the weaker side of the body drags or “catches” on the ground, which can cause tripping or even falling over. Sometimes this is because the muscles that pull the foot up during walking are weak. Sometimes it is because the calf muscles are tight.

We are investigating the effects of the Walk Aide ® in children with spastic hemiplegia. The Walk Aide ® is a small device worn on the leg. It is fitted with sensors, and sends electrical impulses to stimulate the muscles that lift the foot up during walking. It is synchronized with each child’s individual walking pattern. This ensures that the electrical stimulation is delivered at the right moment during walking to lift the foot up at the right time. It is comfortable to wear, and small enough to not get in the way of walking. It is designed to produce a more natural and smooth walking pattern without foot drag.

We will investigate what happens when children wear the Walk Aide ® for 6 weeks.

Who is carrying out the study?
Dayna Pool – senior physiotherapist, at The Centre For Cerebral Palsy will carry out the study. The Centre for Cerebral Palsy is an independent, not-for-profit organisation and is not part of the Government of Western Australia.

What will the study tell us?
We hope to find out what the Walk Aide ® does when a child uses it for 6 weeks. We will be recording children’s walking patterns as well as their strength and joint movements. This will tell us what changes happen when the Walk Aide ® is being used. At the end of the 6 weeks of using the device, we will keep on recording the children’s walking, strength and joint movements for another 6 to 12 weeks. This will tell us what changes happen straight after the Walk Aide ® is stopped. From here, we will have a better idea of how it works and how to apply it during treatment.

Does my child have to take part?
No, your child does not have to take part in this study. It is completely optional. Your child will continue to receive their usual therapy services regardless of whether or not they participate in the study.

What will you be asked to do if you decide to take part in this study?
The study will last for 18 to 24 weeks.

Every week, Dayna will do a weekly assessment with your child. These will be short appointments (about 10 minutes) at TCCP, home or even at school, whichever is most convenient for you.
In addition to this, every 3 weeks, you will need to come into TCCP so that we can make video of your child’s walking pattern. This will take up to 40 minutes.

For 6 weeks (Weeks 7 to 12), your child will be asked to use the Walk Aide ® for at least 1 hour per day, 6 days a week. (This is a minimum and your child can use it more throughout the day if they wish to). During these 6 weeks, there will be a structured diary, in which you will be asked to record how the Walk Aide ® was worn, and a few other details. This should take only a minute to complete each day.

**What does my child need to do to be in the study?**
Your child will need to wear the Walk Aide ® as often as they can when they are walking. They can use the device at school, when walking the dog, or when going to the shopping centre. It is designed to be comfortable and small enough to sit on the leg so that it can be used everywhere your child has to go. For this study, your child is asked to use the Walk Aide ® for at least 1 hour per day, 6 days a week for 6 weeks.

Your child will also need to attend regular weekly assessments (10 minutes long), and assessments at TCCP every three weeks at TCCP for gait analysis (up to 40 minutes long).

**Is there likely to be a benefit to my child?**
Yes. Through this study, your child will be able to use the Walk Aide ® for 6 weeks. During this time, muscles that lift the foot up will be stimulated so there should be no foot drag when using it. After the 6-week period of using the device, it is possible that there will be a carry-over effect even without using the Walk Aide ®.

**Is there likely to be a benefit to other people in the future?**
Yes. The results from this study will help physiotherapists understand how electrical stimulation works when it is applied during everyday walking. This way, we can determine the best way of using the Walk Aide ® to maximise benefits and improve walking in children with spastic hemiplegia.

**What are the possible risks and/or side effects?**
The Walk Aide ® sits on a cuff which is strapped on the leg just below the knee. The stimulation is transmitted through 2 gel electrodes, which are in contact with the skin. Some children may develop skin irritation at this site such as redness, pimple like lesions or blisters (burns) under the electrodes. This is rare, but if it does occur, stop using the Walk Aide ®, notify me immediately on the number provided so we can monitor it and discontinue the Walk Aide ® if necessary. Muscle soreness from overstimulation is also possible especially if the electrodes move slightly when used and stimulate other muscles in the leg. If your child complains of muscle soreness or notice that the foot is moving in a different direction to how it was originally set up, then you will need to report this to me so that I can assess the issues and make the appropriate adjustments.

**What are the possible discomforts and/or inconveniences?**
The only discomfort is the pins and needles feeling on the skin each time your child takes a step. The sensation stops the instant the foot is on the ground again. The level of stimulation is controlled by a dial on the Walk Aide ®. This means that your child has
full control over how high to turn up the dial. If discomfort or reports of pain continue even with the dial turned right down, please contact me so that I can review the settings of the Walk Aide® and the position of the electrodes.

Where is your information kept?
All information will be kept in a locked filing cabinet and all video data kept on a password protected laptop at TCCP.

What about my privacy?
When this research is published or shared at conferences, none of your child’s private details will not be divulged, and nobody will be able to identify which children participated in the study. Nor will your child’s results be shared with clinical or therapy services at Princess Margaret Hospital for Children, TCCP or any other therapy provider.

Who has approved the study?
This study has been approved by the Human Research Ethics Committees at Princess Margaret Hospital for Children.

Who to contact for more information about this study:
If you would like any more information about this study, please do not hesitate to contact one contact Dayna Pool on 9443 0388. She is very happy to answer your questions.

Who to contact if you have any concerns about the organisation or running of the study?
If you have any concerns or complaints regarding this study, you can contact the Director of Medical Services at PMH (Telephone No: (08) 9340 8222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

What to do next if you would like your child to take part in this research:
If you would like to take part in this research study, please read and sign the consent form provided.

The Centre for Cerebral Palsy is not part of the Government of Western Australia and that persons involved in the conduct of the research study at the Centre for Cerebral Palsy are not employees of the State.

THANK YOU FOR YOUR TIME
Walk Aide Study

Why are we doing the study?
Spastic Hemiplegia means that the muscles on one side of your body may be a bit weaker and tighter than the other side. You may find that when you walk, your foot sometimes catches on the ground and makes you trip or even fall over.

We are looking for ways that we can stop your foot from dragging or catching on the floor when you walk. The Walk Aide ® is a tiny little box that can be strapped to your leg. It can help your muscles work better when you are walking. It can help you lift your foot up when you take a step. This means less dragging of your foot and less tripping.

This is a research study. We want to find out what happens when children with CP wear the Walk Aide ® for 6 weeks.

Who is doing the study?
Dayna Pool is doing this study. Dayna is a physiotherapist at The Centre for Cerebral Palsy (TCCP). The Centre for Cerebral Palsy is an independent, not-for-profit organisation and is not part of the Government of Western Australia.

What will the study tell us?
The study will tell us how well the Walk Aide ® works. It will tell us whether it makes your muscles stronger. It will also tell us whether it helps you to walk better.

Do you have to take part?
No, you don’t have to take part if you don’t want to. This is not part of your regular therapy at TCCP. It is a research study, and you and parents can decide whether you want to take part or not.

Whether you take part or not, all the regular therapy you get at TCCP will go on just the same.

What will you be asked to do if you decide to take part in this study?
We will ask you to wear the Walk Aide ® for at least an hour a day for 6 weeks. You can wear if for more than an hour if you want to. You can wear the Walk Aide ® wherever you go. You can wear it at school, at the shops – whenever and wherever you have to walk.

Every week, your therapist will do some short tests to see how it is all going. And every 3 weeks we will need to take some video so that we can see exactly how you walk.

Is the study likely to help me?
Yes. When using the Walk Aide ® you won’t drag your foot as much. After the 6 weeks, your muscles might be stronger, and you might be able to lift your foot up by yourself better.
Is the study likely to help other people in the future?
Yes. This research study will help physiotherapists use the Walk Aide ® with other children who catch their foot or trip over when they walk.

What are the possible risks and/or side effects?
The Walk Aide ® is strapped onto your leg just under your knee. In some children, the skin can get red or form little blisters on it, which can get a bit itchy or even hurt. If this happens to you, tell your mum or dad. If you notice that your foot moves in a different direction to how we first set it up, it is important to let someone know because it could mean the Walk Aide ® is making the wrong muscles move. We can fix this very easily by changing where it is strapped to your leg.

What are the possible discomforts and/or inconveniences?
The Walk Aide ® might give you pins and needles in your leg when you use it. Most children don’t mind the feeling. If you don’t like it at first, try it for a little while and see if you get used to it. If you really don’t like the feeling and it hurts, then tell your mum and dad and stop using it for a while so that Dayna can have a look at it and make some changes to see if we can make it more comfortable. Your muscles might get tired because they have not been used so much before. If this happens, again just tell your mum or dad so we can change how you use it.

Every week, Dayna will need to see you either at TCCP, home or at school so she can see how it is all going. This will take about 10 minutes. Every 3 weeks we will need to take some video of how you walk at TCCP. This will take no more than 40 minutes.

Where is your information kept?
We will keep it locked up in a safe place at TCCP.

What about my privacy?
Dayna won’t tell anyone the names of the children who took part in this research study.

Who has approved the study?
The study has been approved by the Ethics committee at PMH.

Who to contact for more information about this study:
If you would like any more information about this study, please contact Dayna Pool on 9443 0388. She is very happy to answer your questions.

Who to contact if you have any concerns about the organisation or running of the study?
If you have any concerns or complaints regarding this study, you can contact the Director of Medical Services at PMH (Telephone No: (08) 9340 8222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

What to do next if you would like to take part in this research:
If you would like to take part in this research study, please read and sign the consent form provided.
The Centre for Cerebral Palsy is not part of the Government of Western Australia and that persons involved in the conduct of the research study at the Centre for Cerebral Palsy are not employees of the State.

THANK YOU FOR YOUR TIME
Consent Form

FORM OF CONSENT
(For Parent/Guardian)

PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND SUBJECTS CAN WITHDRAW AT ANY TIME WITH NO IMPACT ON CURRENT OR FUTURE CARE.

I ............................................................................................................................ have read
Given Names                                                             Surname

the information explaining the study entitled The Walk Aide Study

I have read and understood the information given to me. Any questions I have asked
have been answered to my satisfaction.

I agree to allow

...............................................................................................................................................
(full name of participant and relationship of participant to signatory)

to participate in the study.

I understand my child may withdraw from the study at any stage and withdrawal will not
interfere with routine care.

I understand that Centre for Cerebral Palsy is not part of the Government of Western
Australia and that persons involved in the conduct of the research study at the Centre
for Cerebral Palsy are not employees of the State.

I agree that research data gathered from the results of this study may be published,
provided that names are not used. I understand that the data collected will be part of a
PhD.

Dated ........................................... day of ......................................................... 20 ..........

Child's Signature ..........................................................
(Where appropriate)

Parent or Guardian’s Signature ........................................

I, .................................................................................. have explained the above to the
(Investigator’s full name)

signatories who stated that he/she understood the same.

Signature ..........................................................................................................................
FORM OF CONSENT

PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND SUBJECTS CAN WITHDRAW AT ANY TIME WITH NO IMPACT ON CURRENT OR FUTURE CARE.

I ............................................................................................................................ have read

Given Names                                                             Surname

the information explaining the study entitled **The Walk Aide Study**

I have read and understood the information given to me. Any questions I have asked have been answered to my satisfaction.

I understand I may withdraw from the study at any stage and withdrawal will not interfere with routine care.

I understand that Centre for Cerebral Palsy is not part of the Government of Western Australia and that persons involved in the conduct of the research study at the Centre for Cerebral Palsy are not employees of the State.

I agree that research data gathered from the results of this study may be published, provided that names are not used. I understand that the data collected will be part of a PhD.

Dated ........................................... day of ................................................................. 20 ..........

Signature .................................................................

I, ............................................................... have explained the above to the

(Investigator’s full name)

signatory who stated that he/she understood the same.

Signature .................................................................................................
WALK Study

Why are we doing the study?
Foot drag is a common challenge for people with spastic hemiplegia. This occurs when the foot on the weaker side of the body drags or “catches” on the ground, which can cause tripping or even falling over. Sometimes this is because the muscles that pull the foot up during walking are weak. Sometimes it is because the calf muscles are tight.

We are investigating the effects of the Walk Aide ® in children with spastic hemiplegia. The Walk Aide ® is a small device worn on the leg. It is fitted with sensors, and sends electrical impulses to stimulate the muscles that lift the foot up during walking. It is synchronized with each child’s individual walking pattern. This ensures that the electrical stimulation is delivered at the right moment during walking to lift the foot up at the right time. It is comfortable to wear, and small enough to not get in the way of walking. It is designed to produce a more natural and smooth walking pattern without foot drag.

We will investigate what happens when children wear the Walk Aide ® for 8 weeks.

Who is carrying out the study?
Dayna Pool – senior physiotherapist, at The Centre For Cerebral Palsy and Princess Margaret Hospital will carry out the study. The Centre for Cerebral Palsy is an independent, not-for-profit organisation and is not part of the Government of Western Australia. Dayna is also doing her PhD through the University of Western Australia.

What will the study tell us?
We hope to find out what the Walk Aide ® does when a child uses it for 8 weeks. We will be recording children’s walking patterns as well as their strength and joint movements. This will tell us what changes happen when the Walk Aide ® is being used. At the end of the 8 weeks of using the device, we want to determine if there is any carry over effect from using the device. We will do this by performing the same measures 6 weeks after the device was used. This will tell us what changes happen straight after the Walk Aide ® is stopped. From here, we will have a better idea of how it works and how to apply it during treatment.

Does my child have to take part?
No, your child does not have to take part in this study. It is completely optional and will not affect your usual therapy services.

What will you be asked to do if you decide to take part in this study?
The study will last for 14 weeks.
An initial appointment will be required to determine if the Walk Aide® is suitable for your child. This will involve an appointment at The Centre for Cerebral Palsy. This appointment should take no longer than 40 minutes. If the Walk Aide® is suitable then your child will be able to participate in the study. There are a few factors that need to be considered.

Firstly, if your child does have botulinum toxin type A (Botox ®), we can only commence the study once the effect has worn off (3 months following injections). Your child will then be randomly allocated to the treatment group (to use the Walk Aide®) or the control group (continue with your usual therapy routine). Regardless of which group your child is allocated, there are 3 assessment time points that will be required. This includes:

1. Baseline – this is 3 months post botulinum toxin type A injections (if your child does have botulinum toxin)
2. 8 weeks later.
3. Another 6 weeks later.

Each of these assessments may take around 3 hours in total.

We will be measuring how muscle responds when the Walk Aide® is used. One of the ways we will do this is through a scan of the legs from the knee downwards by Magnetic Resonance Imaging (MRI). This will be done at PMH with the whole procedure (including getting in and ready) taking around 45- 60 minutes on a Saturday morning. This is a very safe procedure and will not hurt. Your child will be able to pick a DVD to watch during the scan. You may even accompany your child in the MRI scan room.

We will also need to measure how your child walks. To do this, we will be using 3 dimensional gait analysis, which is a detailed way of looking at exactly how your child walks. This will occur at The University of Western Australia at the School of Sports Science Exercise and Health which may be on the same or separate day to the MRI. The gait analysis as well as some other measures (balance, strength, joint movements) will take around 2 hours. To summarise, this table outlines the procedure and requirements for the study. The main assessments are in the boxes shaded grey.
<table>
<thead>
<tr>
<th>Activity</th>
<th>When do I need to do this?</th>
<th>What do we need to do?</th>
<th>How long will this take?</th>
<th>Where will this be done?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial the Walk Aide®</td>
<td>2 weeks before the Walk Aide® trial begins</td>
<td>Attend an appointment to try out the Walk Aide®</td>
<td>About 40 - 60 minutes</td>
<td>The Centre For Cerebral Palsy</td>
</tr>
<tr>
<td>Start using the Walk Aide®</td>
<td>After the trial period</td>
<td>Attend baseline assessments appointment marking the beginning of the study</td>
<td>About 3 hours in total</td>
<td>Princess Margaret Hospital (for MRI) and The University of Western Australia (for gait analysis)</td>
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<tr>
<td>Use the Walk Aide®</td>
<td>Daily for 8 weeks</td>
<td>Just use the Walk Aide® everyday</td>
<td>Aim for 4 hours of Walk Aide® use a day</td>
<td>Home, school, community</td>
</tr>
<tr>
<td>Finish using the Walk Aide®</td>
<td>After 8 weeks of using the Walk Aide®</td>
<td>Repeat assessments that were done at baseline</td>
<td>About 3 hours in total</td>
<td>Princess Margaret Hospital (for MRI) and The University of Western Australia (for gait analysis)</td>
</tr>
<tr>
<td>Follow up from Walk Aide® use</td>
<td>After 6 weeks of not using the Walk Aide®</td>
<td>Repeat assessments that were done at baseline</td>
<td>About 3 hours in total</td>
<td>Princess Margaret Hospital (for MRI) and The University of Western Australia (for gait analysis)</td>
</tr>
</tbody>
</table>

If your child is randomly allocated to the control group, these assessments are still required. During the 14 weeks whilst the other group is using the Walk Aide®, your child can continue with their daily routine. Once the final assessment has occurred, your child will then be fitted with the Walk Aide® so that it can be used for the same 8 weeks. There will be no further measure appointments required.

If your child is randomly allocated to the treatment group, you will need to spend some time getting use to helping with putting the Walk Aide® on and off your child. It doesn’t take any longer than putting on an AFO but you may need some time just to get use to it.

**What does my child need to do to be in the study?**

Your child will need to wear the Walk Aide® as often as they can when they are walking. They can use the device at school, when walking the dog, or when going to the shopping centre. It is designed to be comfortable and small enough to sit on the leg so that it can be used everywhere your child has to go. For this study, your child is asked to use the Walk Aide® for at least 4 hours per day, 6 days a week for 8 weeks. An activity monitor (watch) will also need to be worn during the study. This will be used to get an idea on how active your child is during the study. The monitor can also be used as a watch during this time.

Your child will also need to attend the 3-assessment time points outline above. Dayna will keep weekly contact by either having appointments at The Centre for Cerebral Palsy as well as school and home visits when the study starts. This will ensure that
Dayna can help you and your child with the Walk Aide® and monitor its use as well as to check on how things are going. This should take no longer than 15 minutes. This will occur regardless of whether your child is in the control or treatment group.

**Is there likely to be a benefit to my child?**
Yes. Regardless of which group your child is allocated to, this study will give your child the opportunity to use the Walk Aide® for 8 weeks. During this time, muscles that lift the foot up will be stimulated so there should be no foot drag when using it. After the 8-week period of using the device, it is possible that there will be a carry-over effect even without using the Walk Aide®. The only difference between the groups is that if your child is in the control group, they will be a 14 week delay before they are given the Walk Aide® to use.

**Is there likely to be a benefit to other people in the future?**
Yes. The results from this study will help physiotherapists understand how electrical stimulation works when it is applied during everyday walking. This way, we can determine the best way of using the Walk Aide® to maximise benefits and improve walking in children with spastic hemiplegia.

**What are the possible risks and/or side effects?**
The Walk Aide® sits on a cuff which is strapped on the leg just below the knee. The stimulation is transmitted through 2 gel electrodes, which are in contact with the skin. Some children may develop skin irritation at this site such as redness, pimple like lesions or blisters (burns) under the electrodes. This is rare, but if it does occur, stop using the Walk Aide®, notify me immediately on the number provided so we can monitor it and discontinue the Walk Aide® if necessary. Muscle soreness from overstimulation is also possible especially if the electrodes move slightly when used and stimulate other muscles in the leg. If your child complains of muscle soreness or notice that the foot is moving in a different direction to how it was originally set up, then you will need to report this to me so that I can assess the issues and make the appropriate adjustments.

**What are the possible discomforts and/or inconveniences?**
The only discomfort is the pins and needles feeling on the skin each time your child takes a step. The sensation stops the instant the foot is on the ground again. The level of stimulation is controlled by a dial on the Walk Aide®. This means that your child has full control over how high to turn up the dial. If discomfort or reports of pain continue even with the dial turned right down, please contact me so that I can review the settings of the Walk Aide® and the position of the electrodes.

**Where is your information kept?**
All information will be kept in a locked filing cabinet and all video data kept on a password protected laptop at TCCP.

**What about my privacy?**
When this research is published or shared at conferences, none of your child’s private details will not be divulged, and nobody will be able to identify which children participated in the study. Nor will your child’s results be shared with clinical or therapy
services at Princess Margaret Hospital for Children, TCCP or any other therapy provider.

**Who has approved the study?**
This study has been approved by the Human Research Ethics Committees at Princess Margaret Hospital for Children.

**Who to contact for more information about this study:**
If you would like any more information about this study, please do not hesitate to contact one contact Dayna Pool on 9443 0388. She is very happy to answer your questions.

**Who to contact if you have any concerns about the organisation or running of the study?**
If you have any concerns or complaints regarding this study, you can contact the Director of Medical Services at PMH (Telephone No: (08) 9340 8222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

**What to do next if you would like your child to take part in this research:**
If you would like to take part in this research study, please read and sign the consent form provided

The Centre for Cerebral Palsy is not part of the Government of Western Australia and that persons involved in the conduct of the research study at the Centre for Cerebral Palsy are not employees of the State.

**THANK YOU FOR YOUR TIME**
Child Information Sheet

WALK Study

Why are we doing the study?
Spastic Hemiplegia means that the muscles on one side of your body may be a bit weaker and tighter than the other side. You may find that when you walk, your foot sometimes catches on the ground and makes you trip or even fall over.

We are looking for ways that we can stop your foot from dragging or catching on the floor when you walk. The Walk Aide ® is a tiny little box that can be strapped to your leg. It can help your muscles work better when you are walking. It can help you lift your foot up when you take a step. This means less dragging of your foot and less tripping.

This is a research study. We want to find out what happens when children with CP wear the Walk Aide ® for 8 weeks.

Who is doing the study?
Dayna Pool is doing this study. Dayna is a physiotherapist at The Centre for Cerebral Palsy (TCCP). The Centre for Cerebral Palsy is an independent, not-for-profit organisation and is not part of the Government of Western Australia. She is also a physiotherapist at Princess Margaret Hospital and a PhD student at the University of Western Australia.

What will the study tell us?
The study will tell us how well the Walk Aide ® works. It will tell us whether it makes your muscles stronger. It will also tell us whether it helps you to walk better.

Do you have to take part?
No, you don’t have to take part if you don’t want to. This is not part of your regular therapy. It is a research study, and you and parents can decide whether you want to take part or not.

What will you be asked to do if you decide to take part in this study?
We will ask you to wear the Walk Aide ® for at least 4 hours a day, 6 days a week for 8 weeks. You can wear it for more if you want to. You can wear the Walk Aide ® where ever you go. You can wear it at school, at the shops – whenever and wherever you have to walk. You will also need to wear a watch every day whilst you are in this study. This watch looks like any other watch but will tell us how much you walk and run each day during the study.

Every week, Dayna will do some short tests to see how it is all going. You will need to come into PMH and a gait laboratory for a total of 3 times during this study. These appointments will be around 3 hours long spread over 2 days, but are necessary so we can see how your muscles and walking changes.
Trial Use the Walk Aide ® for 8 weeks

Is the study likely to help me?
Yes. When using the Walk Aide ® you won’t drag your foot as much. After the 8 weeks, your muscles might be stronger, and you might be able to lift your foot up by yourself better.

Is the study likely to help other people in the future?
Yes. This research study will help physiotherapists use the Walk Aide ® with other children who catch their foot or trip over when they walk.

What are the possible risks and/or side effects?
The Walk Aide ® is strapped onto your leg just under your knee. In some children, the skin can get red or form little blisters on it, which can get a bit itchy or even hurt. If this happens to you, tell your mum or dad. If you notice that your foot moves in a different direction to how we first set it up, it is important to let someone know because it could mean the Walk Aide ® is making the wrong muscles move. We can fix this very easily by changing where it is strapped to your leg.

What are the possible discomforts and/or inconveniences?
The Walk Aide ® might give you pins and needles in your leg when you use it. Most children don’t mind the feeling. If you don’t like it at first, try it for a little while and see if you get used to it. If you really don’t like the feeling and it hurts, then tell your mum and dad and stop using it for a while so that Dayna can have a look at it and make some changes to see if we can make it more comfortable. Your muscles might get tired because they have not been used so much before. If this happens, again just tell your mum or dad so we can change how you use it.

Every week, Dayna will need to see you either at TCCP, home or at school so she can see how it is all going. This will take about 10 minutes.

Where is your information kept?
We will keep it locked up in a safe place at TCCP.

What about my privacy?
Dayna won’t tell anyone the names of the children who took part in this research study.

Who has approved the study?
The study has been approved by the Ethics committee at PMH.

Who to contact for more information about this study:
If you would like any more information about this study, please contact Dayna Pool on 9443 0388. She is very happy to answer your questions.
Who to contact if you have any concerns about the organisation or running of the study?
If you have any concerns or complaints regarding this study, you can contact the Director of Medical Services at PMH (Telephone No: (08) 9340 8222). Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

What to do next if you would like to take part in this research:
If you would like to take part in this research study, please read and sign the consent form provided.

The Centre for Cerebral Palsy is not part of the Government of Western Australia and that persons involved in the conduct of the research study at the Centre for Cerebral Palsy are not employees of the State.

THANK YOU FOR YOUR TIME
Consent Form

FORM OF CONSENT
(For Parent/Guardian)

PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND SUBJECTS CAN WITHDRAW AT ANY TIME WITH NO IMPACT ON CURRENT OR FUTURE CARE.

I ......................................................................................................................... have read
Given Names                                                             Surname
the information explaining the study entitled The WALK Study
I have read and understood the information given to me. Any questions I have asked
have been answered to my satisfaction.
I agree to allow
...............................................................................................................................................
(full name of participant and relationship of participant to signatory)
to participate in the study.

I understand my child may withdraw from the study at any stage and withdrawal will not
interfere with routine care.

I agree that research data gathered from the results of this study may be published,
provided that names are not used. I understand that the data collected will be part of a
PhD.

Dated ...................................... day of ......................................................... 20 ..........

Child's Signature ..............................................................
(Where appropriate)

Parent or Guardian's Signature ........................................

I, ........................................................................... have explained the above to the
(Investigator’s full name)
signatories who stated that he/she understood the same.

Signature ..............................................................................................................
FORM OF CONSENT

PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND SUBJECTS CAN WITHDRAW AT ANY TIME WITH NO IMPACT ON CURRENT OR FUTURE CARE.

I ................................................................................................................................. have read

Given Names                                                             Surname

the information explaining the study entitled  The WALK Study  

I have read and understood the information given to me. Any questions I have asked have been answered to my satisfaction.

I understand I may withdraw from the study at any stage and withdrawal will not interfere with routine care.

I agree that research data gathered from the results of this study may be published, provided that names are not used. I understand that the data collected will be part of a PhD.

Dated ................................. day of ............................................................ 20 ..........

Signature ....................................................

I, ........................................................................... have explained the above to the

(Investigator’s full name)

signatory who stated that he/she understood the same.

Signature .................................................................
10.8  Appendix H: Feedback forms for parents and clinicians

Example 1

**WALK** Study: Effects of Functional Electrical Stimulation (Walk Aide) in children with spastic hemiplegia.

Dear [Name],

Thank you for being apart of the WALK Study. Your contribution and commitment to the study has been invaluable.

I would like to provide you with some of the results from the study. As you may recall, there were three assessment time points:

<table>
<thead>
<tr>
<th>Botox</th>
<th>Assessment 1</th>
<th>Assessment 2</th>
<th>Assessment 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily Walk Aide use</td>
<td>No walk aide or AFO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I identified the following goals:

1. To improve his ankle range to help his soccer skills, in particular dribbling
2. To improve his walking endurance so his leg doesn't get sore

<table>
<thead>
<tr>
<th></th>
<th>Post Walk Aide</th>
<th>Follow Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ankle Range of Motion</td>
<td>Maintained. No loss of range (16° of dorsiflexion)</td>
<td>Maintained (12° of dorsiflexion)</td>
</tr>
<tr>
<td>Spasticity</td>
<td>✈ Spasticity (ASAS from 2 to 1)</td>
<td>✈ Spasticity (from 1 to 0)</td>
</tr>
<tr>
<td>Ankle dorsiflexion strength</td>
<td>✧ Strength</td>
<td>✧ Strength maintained</td>
</tr>
<tr>
<td>Ankle Plantarflexion strength</td>
<td>✧ number of heel raises (from 0 to 3)</td>
<td>✧ strength (back to 0 heel raises)</td>
</tr>
<tr>
<td>Selective Motor Control</td>
<td>✧ Ankle selectivity (SCALE score 4 to 6/10)</td>
<td>✧ score maintained</td>
</tr>
<tr>
<td>Goals set by child/family (COPM)</td>
<td>✧ Performance Score (from 6 to 9.5/10)</td>
<td>✧ Performance score maintained (8/10)</td>
</tr>
<tr>
<td></td>
<td>✧ Satisfaction Score (from 7 to 9/10)</td>
<td>✧ satisfaction score maintained (9.5/10).</td>
</tr>
<tr>
<td>Dynamic Balance (Community Mobility Balance Scale)</td>
<td>✧ Dynamic Balance Score (73/96 to 79/96)</td>
<td>✧ Score (81/96)</td>
</tr>
</tbody>
</table>
Summary of Findings

maintained his ankle dorsiflexion range of movement and demonstrated a reduction of spasticity at both the post walk aide and follow up assessment time points. He improved his ankle dorsiflexion strength and ankle selective motor control at both time points. There was a clinically meaningful improvement in his dynamic balance. These findings were also reflected by as evidenced by his ratings of his performance and satisfaction scores.

Recommendations:

demonstrated significant clinical improvements in these measures with excellent compliance throughout the study period. Based on these preliminary results, I would recommend the use of a Walk Aide for daily use in conjunction with a well fitting shoe and orthotic insert (which was provided as part of the study). The carry over effect noted suggests that would benefit from using the Walk Aide as he did in the study i.e. 8 weeks on and 6 weeks off. Ongoing focus on stretching the calf musculature is recommended.

If you have any queries regarding the study, please do not hesitate to contact me on 0422472622 or walkaidestudy@gmail.com

Kind Regards,

Dayna Pool
PhD Student
Senior Physiotherapist
University of Western Australia
The Centre for Cerebral Palsy
Princess Margaret Hospital

Cc Dr Anna Gubbay, PMH
Noula Gibson, PMH
Amanda Tandy, TCCP
Triston Hunter, Step Ahead Physio
Example 2

**WALK Study: Effects of Functional Electrical Stimulation (Walk Aide) in children with spastic hemiplegia.**

Dear Dr Langdon,

I participated in the Walk Aide trial over February and March 2014.

I would like to provide some feedback regarding his clinical and functional changes following the trial. I demonstrated fair compliance with the Walk Aide. There was considerable hesitation for particular in the initial stages of the trial. I did have a good few weeks however of full use of the Walk Aide. The use of the Walk Aide was hampered by some falls causing some loss of skin over the knee whilst camping. This made it difficult to place the Walk Aide on for several weeks.

The goals set by the were:

1. To walk with a symmetrical gait, keeping my foot straight in front of me.
2. To run faster with my friends at school.

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Improvement (From 3 to 4 out of 4)</th>
<th>Improvement from 8/10 to 9/10</th>
<th>Some improvement in dorsiflexion strength (from 9.6 kg to 10.8kg)</th>
<th>Unchanged (unable to complete a heel raise)</th>
<th>Unchanged (range of 26 degrees of dorsiflexion)</th>
<th>Improvement (From ASAS = 2 to ASAS = 0, dynamic dorsiflexion from 20 degrees of dorsiflexion to 0)</th>
<th>Unchanged: 4 square step test improvement from 10.56 to 9.5 seconds</th>
<th>This was not re-evaluated as Aaron did not want to re-score his goals.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective motor control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCALE score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dorsiflexion strength</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plantarflexion strength (heel raises)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dorsiflexion ROM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrocnemius spasticity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recommendations:

Despite hesitation with using the Walk Aide, there are some considerable clinical effects noted here. He demonstrated some clinical improvement in selective motor control, range of motion, spasticity and balance.

averaged a use of <2 hours/day in the Walk Aide. In the study, I generally recommend a minimum of 4 hours. Despite this though, still demonstrated
improvement. However, I am not sure how long these effects will continue with the removal of the Walk Aide. In saying this, [redacted] has not been using an AFO for quite some time and no longer has BoNTA. He is maintaining his range of motion at present regardless of orthotic or medical intervention.

Neither [redacted] have noted any improvement since using this Walk Aide. Given this feedback, I do not recommend that [redacted] have his own Walk Aide. I hope that participating in the study however has been beneficial in terms of exploring potential treatments for [redacted].

Please do not hesitate to contact me if you have any further queries regarding [redacted] results. Thank you for referring [redacted] to the WALK study.

Kind Regards

Dayna Pool  
Phd Student  
Senior Physiotherapist  
The Centre for Cerebral Palsy  
Princess Margaret Hospital  
University of Western Australia

Cc Parents Name (confidential)
## WALK AIDE PRESCRIPTION

### EQUIPMENT REQUIRED

<table>
<thead>
<tr>
<th>Item</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Electrical Stimulation Device</td>
<td>- Walk Aide®</td>
</tr>
<tr>
<td>Bi-Flex Cuff</td>
<td>- X small (7.5” to 10”)</td>
</tr>
<tr>
<td></td>
<td>- Small (10” to 15”)</td>
</tr>
<tr>
<td></td>
<td>- Medium (11” to 17”)</td>
</tr>
<tr>
<td></td>
<td>- Large (12” to 19”)</td>
</tr>
<tr>
<td>Electrodes (round clear or premium 1.25” or premium 1.875”)</td>
<td>- 1.25” - Round Clear or Premium</td>
</tr>
<tr>
<td></td>
<td>- 1.875” - Premium</td>
</tr>
<tr>
<td>Walk Link and Bluetooth Adapter</td>
<td>- Walk Link</td>
</tr>
<tr>
<td></td>
<td>- USB Bluetooth Adapter</td>
</tr>
<tr>
<td>Computer with Walk Analyst installed (free)</td>
<td>- Windows Laptop/Desktop</td>
</tr>
<tr>
<td>Video Hardware/Software</td>
<td>□ Video Camera OR Tablet</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>□ Video Analysis Software - Silicon Coach® OR Dartfish® OR Coaches Eye® (must be able to draw angles on screen)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assessment Tools</th>
<th>□ Goniometer</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Canadian Occupational Performance Measure <a href="http://www.thecopm.ca/">http://www.thecopm.ca/</a></td>
<td></td>
</tr>
</tbody>
</table>

| In-shoe orthotic | □ In-shoe orthotic (customized if required) |

<table>
<thead>
<tr>
<th>Contraindications:</th>
<th>□ Uncontrolled Seizures</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Orthopaedic Metalware at site of stimulation</td>
<td></td>
</tr>
</tbody>
</table>

Patient Name
Date of Birth
GMFCS
Winters Gage and Hicks
AFO prescription
Physiotherapist
Name of School/Teacher
Identification of Appropriate Candidates

☐ Unilateral Spastic Cerebral Palsy
☐ Minimum of 5 degrees of passive ankle dorsiflexion
☐ GMFCS I or II
☐ Australian Spasticity Assessment Scale ≤3
☐ Winters Gage and Hicks Classification of I or II
☐ Foot posture appropriate for removal of AFO.
☐ Age between 5 and 18 years
☐ Ankle stability appropriate for removal of AFO.

NB: Clinical assessment with orthotist and provide inshoe orthotic if appropriate

Canadian Occupational Performance Measure with child and family *Identify mobility performance problems, appropriateness of treatment to address priorities, performance and satisfaction rating using commerically available form

1.

2.

3.

Considerations before commencing FES *need for orthotics, school curriculum, availability of support at home/school, clothing:

Date to commence FES
<table>
<thead>
<tr>
<th>Biomechanical Assessment</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive ankle dorsiflexion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(R2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dynamic ankle dorsiflexion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(R1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective Motor Control</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| 2D Video Gait analysis                   | Right | Left |
| (Sagittal Plane Ankle kinematics)        |       |      |
| Initial Contact                         |       |      |
| Maximum dorsiflexion stance             |       |      |
| Maximum dorsiflexion swing              |       |      |
| Toe-off                                  |       |      |
Implementation of FES

Cuff Size

- [ ] X small
- [ ] Small
- [ ] Medium
- [ ] Large

Introduce FES

1) Approximate electrode placement with black lead over peroneal nerve, red lead electrode over main muscle belly of tibialis anterior. Ensure appropriate fitting of cuff

2) Start with a frequency set to 33Hz. Pulse Width 25 microseconds

3) Slowly introduce sensation, aim for tolerance not necessarily muscle contraction

4) Individually program ASAP with the aim to remove all leads so that child can accommodate to the sensation through play (may take up to 1 week)

Improved Motor Response and tolerance to sensation

1) Review electrode placement ensuring that it is comfortable whilst promoting dorsiflexion without excessive inversion or eversion

2) Re-program FES if necessary ensuring that dorsiflexion is activated through swing until initial contact. Confirm with 2D sagittal plane gait video

3) Gradually work up to 4 hours of daily FES application. Monitor through usage logs and weekly/fortnightly visits

4) Increase pulse width as required. Child can maintain control over amplitude.

Walk Aide Use and Fitting

- [ ] Child/parent/teacher able to demonstrate accurate cuff placement
- [ ] Child/parent/teacher able to demonstrate ability to change electrodes and battery
- [ ] Knowledge of how to store Walk Aide when not in use
- [ ] Knowledge of and able to demonstrate how to use exercise mode
<table>
<thead>
<tr>
<th><strong>Education and Information</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Discuss dosage (aim 4 hours/day) and how to implement at school/home</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provide parent handout on general use and procedure to stop handout</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consider appropriateness of classroom presentation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discuss electrode care and when to change (every 2-3 weeks)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Environmental Considerations</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sandpit play, sport curriculum, swimming lessons, weather</td>
</tr>
<tr>
<td></td>
<td>Schedule weekly or fortnightly home/school visits</td>
</tr>
</tbody>
</table>

**Dates of Home and School Visits**

- Visit 1
- Visit 2
- Visit 3
- Visit 4
### Determine Suitability of ongoing FES

<table>
<thead>
<tr>
<th>Biomechanical Assessment</th>
<th>Right</th>
<th>Left</th>
<th>Improvement</th>
<th>No Change</th>
<th>Deterioration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive ankle dorsiflexion (R2)</td>
<td>± 5°</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Dynamic ankle dorsiflexion (R1)</td>
<td>± 5°</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>ASAS</td>
<td>&gt; 1</td>
<td></td>
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<tr>
<td>Selective Motor Control</td>
<td>&gt; 1</td>
<td></td>
<td>Alternate between use and non-use</td>
<td>Ongoing use for orthotic effect (4/0 alternative)</td>
<td>Ongoing use for orthotic effect (4/0 alternative)</td>
</tr>
</tbody>
</table>

#### 2D Sagittal Ankle Kinematics

<table>
<thead>
<tr>
<th></th>
<th>Right</th>
<th>Left</th>
<th>Improvement</th>
<th>No Change</th>
<th>Deterioration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Contact</td>
<td>± 5°</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum dorsiflexion stance</td>
<td>± 5°</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Maximum dorsiflexion standing</td>
<td>± 5°</td>
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<tr>
<td>Toe-off</td>
<td>± 5°</td>
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</tbody>
</table>

#### Canadian Occupation Performance Measure

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<tr>
<th></th>
<th>Right</th>
<th>Left</th>
<th>Improvement</th>
<th>No Change</th>
<th>Deterioration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance Score (10)</td>
<td>± 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction Score (7/10)</td>
<td>± 2</td>
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</tr>
</tbody>
</table>

#### Usage Log (average hours/day)

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<tr>
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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
</table>

Evaluate suitability for ongoing FES based on clinically meaningful change. Identification of any areas marked as "Ongoing FES likely not suitable" will require therapist clinical judgement in conjunction with discussion with family and child regarding appropriateness of FES as an orthotic or treatment tool.
Recommendations:

☐ FES not indicated or not appropriate

☐ FES indicated for orthotic effect (ongoing use)

☐ FES indicated for therapeutic effect (alternate between use and non-use)

Signed:

Date:
Procedure for stopping use of the Walk Aide®

There is potential that participants develop a skin irritation under the electrode site. Please inspect the skin under the electrodes daily i.e. before putting on and taking off the device. If there is any irritation, all participants will be asked to cease use of the Walk Aide ® until it has cleared. If symptoms persist, they will be asked to seek further medical advice before continuing with the intervention.

Please stop using the Walk Aide ® and contact Physiotherapist on xxxxxxxxx if you note any of the following:

- Signs of skin irritation i.e. red areas, pimple like lesions or blisters under the electrodes
- The foot moving in a direction that is different to how it was originally set up
- Muscle soreness or discomfort as a result from using the Walk Aide ®
- Pain or discomfort caused by the stimulation even when then intensity is turned down

It is important that these reactions are addressed immediately. In most cases, some adjustments to the timing, placement and intensity of stimulation may eliminate the above described reactions. However, time out of the Walk Aide ® or attendance to the skin irritation may be required.

If you have any other concerns around the use of the Walk Aide ® please do not hesitate to contact your physiotherapist on the number provided above
The Pediatric Walk Aide is an advanced Functional Electrical System (FES) that is worn below the knee and stimulates the nerve to lift the foot at the right time during walking, promoting a more natural, efficient and safe walking pattern.

Important things to Remember

- My intensity setting is
- After fitting Walk Aide, press the test switch to test if Walk-Aide is in correct position.
- No one else (other than teachers, physiotherapist or Parents) should ever touch the walk-aide or adjust the intensity.
- Remove the Walk-Aide for activities in the sand or water.
- Cover the electrodes with little plastic covers when not in use.
- Place Walk Aide in carry bag when not in use.
- Watch for signs of irritation, pain or soreness.
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Dear Professor Graham,

I am writing to request permission for the use of your figure on Common Gait Patterns: Spastic Hemiplegia to appear in my PhD thesis.

I refer to Figure 1 on page 100 of the article you published in European Journal of Neurology (Titled: Classification of gait patterns in spastic hemiplegia and spastic diplegia: a basis for a management algorithm). I note that under this figure, it is marked with the copyright belonging to you (both Dr Rodda and yourself). This figure would appear in my literature review as I discuss the gait patterns for children with unilateral spastic cerebral palsy. This figure, if acceptable to you, would be printed 4 times so that it would appear in 4 bounded copies of my thesis for examination.

Thank you for considering my request. Please do not hesitate to contact me if you have any further queries regarding the use of this figure or if there is another more appropriate avenue for me to lodge this request.

Kind Regards,

Dayna Pool

iRehab Co-ordinator/Clinical Lead and Senior Physiotherapist
Departments of Paediatric Rehabilitation and Physiotherapy, Princess Margaret Hospital

Reply from Professor Kerr:

Dear Dayna,
Permission granted with pleasure.
Really like your recent publications on FES - Rowan shared them with me at the gait course in Melbourne
Good luck with the PhD
Not that you will need any luck - great work

Kerr

Reply from Dr Rodda

Hi Dayna
Delighted you wish to use the figure and thank you for asking for permission. I approached Kerr also as he is also co-author on this figure. Realise he has already emailed back to you. Yes you have my permission also.
Kind regards
Jill
10.11 Appendix K: Abstracts for presentations

AusACPDM abstract Hunter Valley 2014

Effects of functional electrical stimulation in children with spastic hemiplegia

Objective: To determine the effects of functional electrical stimulation (FES) on the main impairments affecting gait and participation (trips and falls) in children with spastic hemiplegia (SH).

Design: A single-subject research design included 6 weeks pre-FES, 8 weeks FES and 6 weeks post-FES for children aged between 5 and 16.

Method: 12 children with SH (mean 9.2 years, SD 3.8 years), GMFCS I and II, were recruited from TCCP. Pre-FES baseline data was collected at 3 months post BoNTA to minimise the confounding effect of spasticity reduction. All children were required to wear a portable FES device (the Walk Aide®) daily for at least 1 hour a day, daily for 8 weeks. Weekly measures were taken throughout all 3 phases of the study and included clinical measures commonly used in the community (total of 20 data points): ankle range of motion (ROM), selective motor control (SMC), dorsiflexion and plantarflexion strength, gastrocnemius spasticity, single limb balance, gait (2D video using the Observational Gait Scale), and frequency of self-reported trips and falls in the community. Comparisons between pre-FES and FES and post-FES and FES were made individually using visual analysis, two standard deviation (2SD) method and C statistic. Group comparisons were calculated using the Wilcoxon signed ranks test.

Results: FES was well tolerated amongst the 12 participants with all children adhering to the minimum recommended dosage. As a group, the FES phase showed significant improvements compared to pre-FES in ankle ROM \( p=.002 \), SMC \( p=.0157 \), dorsiflexion strength \( p=.0067 \), plantarflexion strength \( p=.0098 \), spasticity \( p=.0098 \), with reduction in trips \( p=.016 \) and falls \( p=.033 \). These improvements were maintained during the post-FES phase. There were no
improvements in gait scores in the FES or post-FES phase compared to pre-FES ($p=.732$ and $p=.454$ respectively). Single limb balance improvements were demonstrated in the post-FES phase only ($p=.0044$).

**Conclusion:** Intermittent, short-term use of FES is a potentially effective and well-tolerated therapeutic technique to improve a range of impairments and participation in children with SH during and beyond treatment periods. The carry-over effect noted in this study suggests that FES can be a potentially efficient and cost effective treatment strategy in community clinical practice.
World Congress ISPO Abstract Lyon 2015

The orthotic and therapeutic effect following daily community applied functional electrical stimulation in children with unilateral spastic cerebral palsy: a randomised controlled trial

Background: Children with unilateral spastic cerebral palsy (USCP) are functionally ambulant, but equinus and drop foot during gait are common, alongside functional issues with balance and community mobility. Whilst there have been some reports that Functional Electrical Stimulation (FES) may address these problems in gait (providing an orthotic effect) that may even be sustained without FES (therapeutic effect), the evidence supporting this in children with USCP has so far been inconclusive.

Aim: The aim of this study was to determine the orthotic and therapeutic effect of daily community applied FES to the ankle dorsiflexors in a randomized controlled trial. The primary outcome measures included ankle kinematics, temporal-spatial gait measures and community mobility.

Method: This randomized controlled trial involved 32 children (15 females, 17 males; age range 5y 5mo to 18y 1mo; median age 10y 3 mo) with USCP and a Gross Motor Function Classification System of I or II. Children were randomly allocated to a FES treatment group (n=16) or control group (n=16). The treatment group received eight weeks of daily FES that was worn at home and community (four hours/day, six days/week) whilst the control group received usual orthotic and physiotherapy treatment. Children were assessed at baseline, post FES treatment (eight weeks) and at follow-up (six weeks later). Ankle kinematic and temporal-spatial measures with and without FES were analysed using video software with force platform data to signal gait events. Community mobility was assessed using the Community Mobility Balance Scale and participant performance and satisfaction on the COPM.

Results: All 32 children who entered the study finished the study in their original group allocation. FES was well tolerated with usage logs indicating mean daily use
of 6.2 hours (SD 3.2 hours). Mixed ANCOVA for repeated measures revealed that with FES, the treatment group demonstrated a significant improvement in initial contact ankle angle ($p < 0.001$), maximum dorsiflexion ankle angle in swing ($p = 0.007$), time in stance ($p = 0.011$) and step length ($p = 0.035$) post treatment when compared to the control group. The treatment group had significantly better community mobility post treatment ($p < 0.001$) and at follow-up ($p < 0.001$). Participants in the treatment group reported significantly higher performance ($p = 0.034$) and satisfaction ($p = 0.004$) post treatment and in satisfaction only ($p = 0.030$) at follow-up.

**Discussion & Conclusion:** This study provides Level II level evidence supporting daily community FES in children with USCP. The direct orthotic effects in gait are use-dependent. However therapeutic effects in community mobility were not only noted in the treatment group post treatment but also at follow-up suggesting the role of motor learning. Therefore, FES can be considered to be an appropriate treatment option to address gait and community mobility problems in children with USCP.

**Reference:**

AACPDM abstract Adelaide 2016

The effect of daily, community-applied Functional Electrical Stimulation on muscle strength and volume in children with unilateral spastic cerebral palsy.

Objectives: To determine the effect of functional electrical stimulation (FES) on the ankle dorsiflexors during gait on muscle volume and strength in children with unilateral spastic cerebral palsy (USCP).

Design: Randomized controlled trial (matched-pairs).

Method: Children with a Gross Motor Function Classification System (GMFCS) of I or II with at least 5 degrees of passive ankle dorsiflexion and full knee extension, no botulinum toxin injections in the past 3 months or orthopaedic intervention on the affected side in the past 12 months were included. Thirty-two children with USCP (female n=15, male n=17; mean age 10y6mo SD 3y3mo) were matched by age and GMFCS were randomly assigned to the FES group (8 weeks daily FES) or control group (usual interventions). Children were assessed at baseline (week 0), post-FES treatment (week 8) and follow-up (week 14). Primary outcome measures included magnetic resonance imaging (MRI) for tibialis anterior muscle volume (expressed as a symmetry ratio between the affected and non-affected limb; 1 indicating perfect symmetry) and normalized isometric ankle dorsiflexion strength. Secondary outcome measures included anterior tibial compartment and gastrocnemius muscle volumes and the number of heel raises for functional plantarflexion strength. Repeated measures ANOVA was used to establish within (with post-hoc Sidak) and between group (post-hoc Tukey’s) differences. Effect sizes were determined for statistically significant (p <0.05) comparisons using Cohen’s d calculation.

Results: All children who entered the trial completed the trial in their original group allocation. Children in the treatment group used FES for a daily mean of 6.2 hours SD 3.2 hours. There were no significant differences at baseline between the groups. Post-treatment, the FES group had significantly increased symmetry ratios
for tibialis anterior (mean difference (MD) 0.10 95% CI 0.04 to 0.16), anterior compartment (MD 0.1 95% CI 0.04 to 0.16), medial (MD 0.08 95% CI 0.03 to 0.13) and lateral (MD 0.10 95% CI 0.02 to 0.17) gastrocnemius and normalized dorsiflexion strength (MD 0.09 95% CI 0.03 to 0.15) compared to controls. At follow-up, only the lateral gastrocnemius symmetry ratio was significantly greater in the FES group than in the control group (MD 0.11 95% CI 0.03 to 0.19).

*Conclusion:* This study provides evidence that 8-weeks of FES causes use-dependent improvements in muscle strength and volume in the stimulated ankle dorsiflexors with the secondary benefit of improvements in gastrocnemius muscle volume. FES may therefore be a beneficial therapeutic adjunct to current interventions.
REFERENCES


