

Treatment of lower limb spasticity in adults using a multimodal intervention: A mixed-methods approach evaluating the impact across all domains of the ICF

by

Jasmine Min Jung Kim  
B.Sc. Kinesiology, University of Victoria, 2012

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University of Victoria

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## **Supervisory Committee**

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Dr. Sandra R. Hundza, (School of Exercise Science, Physical and Health Education)  
**Supervisor**

Dr. Vivienne A. Temple, (School of Exercise Science, Physical and Health Education)  
**Departmental Member**

## Abstract

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Spasticity is highly prevalent in neurological conditions involving upper motor neuron lesions (UMNL). Lower limb spasticity is known to impair gait and limit participation in physical activity. Multimodal interventions including botulinum toxin A, orthoses, and physiotherapy have shown longer lasting improvements compared to unimodal interventions. Studies to date, however, have not examined the long term efficacy of this multimodal intervention nor have they examined the impact across a breadth of domains necessary to comprehensively and fully understand its impact. The aim of this study was to investigate the efficacy of a multimodal intervention to treat lower limb spasticity in adults using a longitudinal mixed-methods approach, including a comprehensive set of outcome measures spanning the domains of the International Classification of Functioning, Disability and Health (ICF) model. Seven-teen participants with chronic UMNL were included in the analysis as per inclusion criteria and showed improvements at 6 and 12 months, compared to baseline, within all domains of the ICF model.

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## Chapter 1: Review of the Literature

### 1.1 Introduction

This manuscript format thesis is comprised of two chapters: the first chapter is a review of the extant literature and the second chapter consists of a manuscript style presentation of the thesis project. The thesis project is an evaluation of a local spasticity clinic's practice, for treatment of lower limb spasticity using a multimodal intervention. Spasticity is a disabling neuromuscular condition resulting from an upper motor neuron lesion (UMNL) within the central nervous system (CNS) (Lance, 1980) and is prevalent in individuals with conditions such as stroke, multiple sclerosis (MS), spinal cord injury (both complete [SCI] and incomplete [iSCI]), traumatic brain injury (TBI), and cerebral palsy (CP) (Stevenson, 2010).

The prevalence of these diagnostic conditions currently ranges from approximately 86,000-315,000 among Canadians (Multiple Sclerosis International Federation, 2013; Public Health Agency of Canada, 2011), where SCI is found to be the least common (Spinal Cord Injury Canada, 2014) and stroke the most (Public Health Agency of Canada, 2011). CP on the other hand is a typical developmental disability with an estimated prevalence of 2.57 per 1000 live births (Robertson, Svenson, & Joffres, 1998) or 16 per 1000 among those born prematurely (Robertson, Watt, & Yasui, 2007). Generally, the incidence of spasticity among each of these diagnostic groups have been inconsistently and scarcely evaluated (BurrIDGE et al., 2005). Estimates for the development of spasticity post-stroke ranges from 10-38% (Egen-Lappe, Köster, & Schubert, 2013; Watkins et al., 2002; Wissel, Manack, & Brainin, 2013) and around 60-84% among individuals with MS (Rizzo, Hadjimichael, Preiningerova, & Vollmer,



2004). Moreover within MS, predicting the incidence of spasticity as well as managing it is known to be even more challenging due to the fluctuating and often progressive nature of the condition itself (Amatya, Khan, La Mantia, Demetrios, & Wade, 2013). Among those having sustained a SCI or iSCI, as many as 93% and 78%, respectively, experience spasticity (Sköld, Levi, & Seiger, 1999). There are currently limited data on the incidence and management of focal spasticity in adults with chronic TBI or CP (Bergfeldt, Borg, Kullander, & Julin, 2006).

If spasticity is not well managed it can cause pain, negatively affect mobility, physical activity, self-esteem and quality of life (QOL), increase dependent behaviour as well as contribute to secondary health conditions and mortality (Adams & Hicks, 2005; Decq, Filipetti, & Lefaucheur, 2004; Graham, 2013; Kinnear, 2012; Olver, Esquenazi, Fung, Singer, & Ward, 2010; Ward, 2002). Specifically, lower limb spasticity can impair ambulation, increase the risk of falling, and lead to reduced participation in physical activity (Graham, 2013). In fact, impaired ambulation is the most characteristic deficit that results to referral for neurologic rehabilitation with improved gait function as the most highly self-stated goal (Kosak & Reding, 2000). Individuals with these types of neurological conditions are typically less physically active as a result of impaired body functions whether directly or indirectly associated with spasticity (Busse, Pearson, Van Deursen, & Wiles, 2004; Tefertiller, Pharo, Evans, & Winchester, 2011; Wissel, Olver, & Sunnerhagen, 2013).

The efficacy of botulinum toxin type A (BTXA), orthoses, and physiotherapy delivered in conjunction for the treatment of chronic lower limb spasticity in adults has been previously examined with promising outcomes such as reduced spasticity and pain,

some improvements in gait, and furthermore, is well known for providing longer lasting improvements compare to the unimodal treatment approach (Bergfeldt et al., 2006; Esquenazi et al., 2012; Giovannelli, Borriello, Castri, Prosperini, & Pozzilli, 2007; Johnson, Burridge, Strike, Wood, & Swain, 2004; Olver et al., 2010). However, the breadth of the outcome measures reported pertaining to increase participation, independence, and subjective report of barriers that these individuals experience to participation in life roles have been limited (Burridge et al., 2005; Olver et al., 2010). Life roles include areas of work and employment, recreation and leisure, domestic life, and self-care. Furthermore, only short-term treatment effects (i.e. typically one or two BTXA injections) have been evaluated and follow-up has not exceeded 6 months in the adult population. Also, the effect of repeated treatments delivered at prescribed intervals (i.e. successive injections, long term exercise monitoring, and ongoing orthoses modifications) has not been investigate in the chronic, adult population targeting lower limb spasticity (Esquenazi et al., 2012).

To more fully appreciate the complex interrelationships between spasticity and engagement in activities and life roles, it is essential to investigate a comprehensive set of outcomes that represent physical changes to the affected body structures, as well as improvements in functioning, participation, and contextual constituents of life. An organizing framework such as the International Classification of Functioning, Disability and Health (ICF) is ideal to guide such an investigation of the efficacy of the spasticity interventions and has been employed in the present study. Its guides the evaluation of not only on the physiological impairments of body functions and structures and activity, but also the level of participation in physical activity and the effect of the personal and

environmental factors on the level of engagement. Concurrent evaluation of these multiple outcomes will facilitate understanding of the interaction between the individual impairment, functioning and disability, as well as contextual factors. Therefore a holistic approach that includes a mixed method design driven by a model such as the ICF is ideal to provide a richer understanding of the efficacy of the treatment as well as elucidate the relationship between these factors. The following literature review will summarize the extant literature related to this research area comprising: the current accepted definition of spasticity, the prevalence of specific neurological conditions, the incidence and the impact of spasticity within specific diagnostic groups, the ICF as an organizing framework to evaluate the efficacy of the intervention on bio-psycho-social levels, the efficacy of previous interventions for the treatment of spasticity, and the standard outcome measures employed to quantify the dependent variables used to study efficacy of spasticity interventions.

## **1.2 Defining Spasticity**

Spasticity is a common component of upper motor neuron syndrome (UMNS) resulting from a CNS pathology (Brainin, 2013; Esquenazi et al., 2012) and is seen in UMNL's such as stroke, MS, iSCI, TBI, and CP (Stevenson, 2010). UMNS results from damage to the neurons anywhere along the descending motor pathways from the cerebral cortex to the lower end of the spinal cord (i.e. upper motor neuron lesion) (Burke, Wissel, & Donnan, 2013; Ward, 2012). Upper motor neurons include supraspinal inhibitory and excitatory fibres which descend the spinal cord and control the balance of spinal reflex activity (Sheean, 2001) and target lower motor neurons responsible for postural and muscular control of the upper and lower limbs (Ward, 2012). UMNS encompasses a

plethora of symptoms, commonly characterized as positive or negative features that result in the disruption of volitional capacity to execute motor functions (Decq et al., 2004; Esquenazi et al., 2012). Generally, positive signs are characterized by involuntary muscle over-activity due to hyperactive reflexes and negative signs are associated with weakness and fatigability (Decq et al., 2004; Esquenazi et al., 2012). As simplified by Decq and colleagues (2004) the UMNS consists of three general components and manifest as a result of the positive and negative signs; these components include spasticity, motor deficits, and loss of fine movement. Of these, spasticity has gained special recognition because it is the only one amenable to treatment (Decq et al., 2004). Spasticity results from an increased excitation and decreased inhibition of the motor neurons leading to increased muscle tone (Adams & Hicks, 2005).

Lance (1980) originally defined spasticity as “a motor disorder characterized by a velocity-dependent increase in tonic stretch reflex (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex as one component of the upper motor neuron syndrome” (p. 485). Although scientifically valid, this definition has been deemed problematic for clinical application. As described by Wissel, Manack, and Brainin (2013) “in clinical practice, spasticity is used to describe a combination of symptoms and clinical signs after lesion formation in sensorimotor brain areas and tracts in the CNS” (p. 13). Consequently, one or more symptoms of UMNS, which are clinically difficult to differentiate, may develop after sustaining an insult to the CNS and may affect functional motor recovery (Ada, Vattanasilp, O’Dwyer, & Crosbie, 1998; Welmer, von Arbin, Widén Holmqvist, & Sommerfeld, 2006; Wissel, Olver, et al., 2013). Similarly the Support Programme for Assembly of Database for Spasticity Management

(SPASM) has established a clinically applicable definition that encompasses the multitude of clinical features resulting from UMNL, such as enhanced stretch reflex, spasms, clonus, hypertonia, pathological co-contractions, dystonia, and other associated reactions (BurrIDGE et al., 2005; Fleuren, Snoek, Voerman, & Hermens, 2009). According to SPASM, spasticity is a ‘disordered sensori-motor control, resulting from an UMNL, presenting as intermittent or sustained involuntary activation of muscles’ (BurrIDGE et al., 2005, p. 72). For the purpose of this thesis spasticity will be operationally defined as per the SPASM definition.

When spasticity is left untreated it can often lead to secondary problems such as resistance to passive movement, development of contractures deformity, chronic pain and impaired mobility (Richardson, 2002). This in turn can limit activities of daily living (ADL), reduce QOL as well as negatively impact self-care, self-esteem and body image (Adams & Hicks, 2005; Esquenazi et al., 2012; Kinnear, 2012; Ward, 2012).

### **1.3 Diagnostic Groups – Prevalence & Incidence**

Stroke, MS, iSCI, TBI, and CP, are conditions resulting from UMNL. Spasticity is quite common within each of these conditions (Stevenson, 2010). The prevalence of stroke is over 50,000 per year in Canada and approximately 300,000 Canadians are currently living with the effects of stroke (Heart and Stroke Foundation, 2013). It is estimated that 100,000 Canadians have MS and the prevalence rate is estimated to be 140 per 100,000 people (Multiple Sclerosis International Federation, 2013). Currently 86,000 Canadians are living with SCI with an estimated 4,300 new cases each year (Spinal Cord Injury Canada, 2014). TBI occurs at a rate of 500 per 100,000 Canadians per year; this equates to over 165,000 people in Canada living with the effects of brain injury

(Braintrust Canada, 2012). Lastly, the prevalence of CP worldwide is estimated to be approximately 2-2.5 per 1,000 live born infants (Camargo et al., 2009; Odding, Roebroek, & Stam, 2006).

#### **1.4 Common Presentations – Spasticity and Physical Activity**

Among individuals with stroke, MS, iSCI, TBI, and CP, the prevalence of spasticity is common (Stevenson, 2010) and it, both indirectly and directly, interferes with body functions and structures which in turn contributes to reduced levels of physical activity (Busse et al., 2004; Tefertiller et al., 2011; Wissel, Olver, et al., 2013). From the extant literature, it is known that approximately 38% (range = 17 – 42.6%) of those living with chronic stroke (> 3 months post-stroke) experience spasticity (Ward, 2012; Watkins et al., 2002; Wissel, Manack, et al., 2013). Of those individuals living with MS and chronic iSCI about 67% and 78% experience spasticity, respectively, and in individuals with iSCI, spasticity is cited as the most problematic sequel of the condition (Adams & Hicks, 2005; Hsieh et al., 2008; Rizzo, Hadjimichael, Preiningerova, & Vollmer, 2004; Sköld, Levi, & Seiger, 1999). There is currently no epidemiological evidence describing the prevalence of spasticity in chronic TBI or CP; on the whole, studies on spasticity management in adults with CP and TBI are rare (Bergfeldt et al., 2006).

These clinical populations share common presentations such as physical inactivity as a result of the deleterious physical limitations and mobility related disability (Adams & Hicks, 2005; Busse et al., 2004; Richardson, 2002; Wissel, Olver, et al., 2013).

According to Janssen (2012), stroke survivors are among the most physically inactive of the seven most common chronic diseases. For 2009, stroke was ranked in the top three most costly chronic diseases in Canada with an estimated \$1.1 billion spent annually;

these costs were attributable to physical inactivity (Janssen, 2012). Fatigue and impairments that interfere with body functions such as spasticity limit the ability walk and overall physical activity (Olver et al., 2010; Tefertiller et al., 2011). Furthermore, research has demonstrated that the disability caused by chronic conditions can over time lead to a more severe course of long-term disability (Deeg, 2005; Graham, 2013; Stuifbergen, Blozis, Harrison, & Becker, 2006). Providentially, studies have demonstrated that increased exercise behaviors limit the degree of progression in functional limitations (Graham, 2013; Stuifbergen et al., 2006). Although there is evidence to support the promotion of physical activity among individuals with chronic neurological conditions, to contest the disability related decline in function over time, little is known about how targeting the treatment of spasticity in order to improve body functions and structures can increase the ability to exercise or if it results in increased physical activity over time.

### **1.5 Previous Interventions**

The two general categories under which the management of spasticity fall under include pharmacological and non-pharmacological treatment modalities (Thibaut et al., 2013). An approach that combines both is recognized as the best in clinical practice, however treatment has often been reported as fragmented (Demetrios, Khan, Brand, & Mcsweeney, 2013). The most trialed and well recognized modality is pharmacotherapy, specifically using botulinum toxin (BTX) to treat focal or multi-focal spasticity (Demetrios et al., 2013). Other pharmacological agents, that will not be discussed in this thesis, include oral antispastic meds, chemical denervation with phenol or alcohol injections, and intrathecal baclofen (Mullarkey, 2009; Thibaut et al., 2013).

### *Botulinum Toxin Interventions*

BTX is a naturally occurring and highly potent protein molecule made from the bacterium *Clostridium Botulinum* (Richardson & Thompson, 1999). Seven distinct serotypes of the toxin (A to G) exist but the most widely used in medicine is BTX type A (BTXA). BTXA is available on the market in three commercial forms including Botox® (Allergan, Inc., USA), Dysport® (Ipsen Limited, UK), and Xeomin® (Merz Pharma Canada, Inc.), of which only Botox® and Xeomin® are registered for use in Canada (Dystonia medical research foundation [DMRF] Canada, 2013). BTXA is a potent neurotoxin that gets injected intramuscularly and results in temporary and localized muscle weakening effect. It targets the neuromuscular junction and blocks the release of neurotransmitters (i.e. acetylcholine) at the presynaptic terminal (Teasell et al., 2012; Yaşar et al., 2010). With less acetylcholine released, the targeted muscle is transiently not activated and therefore “paralyzed”.

There is a plethora of evidence in the literature to support the use of BTXA in the management of both upper and lower limb spasticity (Richardson & Thompson, 1999). These include several randomized controlled trials (RCT's) (Burbaud et al., 1996; Kaji et al., 2010; Richardson et al., 2000; Snow, Tsui, Bhatt, & Varelas, 1990), open label trials (Béseler, Grao, Gil, & Martínez Lozano, 2012; Chan et al., 2013; Cioni, Esquenazi, & Hirai, 2006; Das & Park, 1989; Dengler, Neyer, Wohlfarth, Bettig, & Janzik, 1992; Fock, Galea, Stillman, Rawicki, & Clark, 2004; Pierson, Katz, & Tarsy, 1996; Rousseaux, Compère, Launay, & Kozlowski, 2005), and reviews (Anwar & Barnes, 2005; Beard, Hunn, & Wight, 2003; Reichel, 2001; Wong, 2003). In the majority of studies investigating the effectiveness of BTX, non-pharmacological therapies were mentioned



as being delivered concurrently, however, these therapies were not well documented and were not the focus of the studies discussed in this section.

BTXA injections in overactive muscles have been shown to reduce tone and pain, as well as improve resting joint posture and range of motion (Das & Park, 1989; Dengler et al., 1992; Pierson et al., 1996; Rousseaux et al., 2005). Treatment with BTXA is useful for providing indirect benefits to the mechanical (non-neural) components of the spastic muscle and the affected joints (Richardson & Thompson, 1999). For example, there is some evidence to suggest that it can reduce the progression of contractures (Rousseaux et al., 2005). BTXA injections can be effected for up to 3 months after which repeated injections are recommended for prolonged benefits (Snow et al., 1990). Overall, treatment of spasticity with BTXA has been established as a treatment of choice for having low associated risks, its ease of application, and most importantly, for effectively providing short-term reduction of focal spasticity (Richardson & Thompson, 1999; Ward, 2002).

When the effect of BTXA on functional improvements, namely gait capacities, was investigated there were some inconsistencies. Some studies have shown small improvements in functional capacity (Chan et al., 2013; Foley et al., 2010; Reichel, 2001) while other studies found minimal or no impact on functional capacity (Bailey, Doherty, & Rouse, 2012; Bergfeldt et al., 2006; Elovic, Simone, & Zafonte, 2004; Teasell et al., 2012). Two studies have demonstrated significant improvement in base of support and foot positioning, resulting in better balance during ambulation (Cioni et al., 2006; Rousseaux et al., 2005). However, despite greater stability, Cioni and colleagues (2006) found no improvements in gait velocity or step length while Rosseaux and colleagues

(2005) reported increased gait velocity and step length in only one-third of the study participants. No improvements in functional mobility were found in both a large-scale RCT (Kaji et al., 2010) and a small scale open label study (Béseler et al., 2012) that examined the effects of BTXA injections on the clinical, functional, and biomechanical gait patterns in patients with lower limb spasticity. While both studies demonstrated reduction in spasticity, the lack of translation into functional changes were attributed to the short term nature of the studies such that there was insufficient time for changes to occur on the physical, biomechanical, or neural levels (Kaji et al., 2010), especially since these patterns had been well-established as a result of the chronicity of the condition (Béseler et al., 2012; Burbaud et al., 1996). Lastly, in a meta-analysis by Foley and colleagues (2010), a small yet significant improvement in gait velocity was generated from a pooled analysis; however, the clinical significance of the improvement was tenuous (Foley et al., 2010).

Explanations for the inconsistency in findings across studies could include poor tool sensitivity/responsiveness of measurement tools (Chan et al., 2013; Dean, Richards, & Malouin, 2000; Gracies, Singer, & Dunne, 2007), high baseline functioning levels of participants resulting in the ceiling effect (Ackman et al., 2005; Anwar & Barnes, 2005; Dean et al., 2000), large variability/heterogeneity of selected samples (Rousseaux et al., 2005), and lastly, the short-term nature of majority of the studies which are unable to capture changes in the chronic population (Kaji et al., 2010). Poor methodological quality and small sample sizes are also commonly mentioned limitations (Foley et al., 2010). In the majority of these studies BTX was the primary intervention of focus and though non-pharmacological therapies were mentioned as being delivered concurrently these

therapies were not well documented or adequately reported as controlled. Therefore, there is a need for studies with repeated injections over a long period of time (greater than 6 months) and clearly outlined non-pharmacological therapies prescribed at predetermined intervals which also incorporate responsive measurement tools that evaluate outcomes beyond the impairment level (i.e. impact on participation, activities, and life roles).

#### *Non-Pharmacological Physical Interventions*

Various forms of non-pharmacological treatment options currently exist and are being compared in order to determine levels of efficacy. As described by Thibaut and colleagues (2013), these modalities can be grouped into three general categories (1) physical therapy, which includes stretching (Katalinic et al., 2010), casting (i.e. a form of prolonged stretching), aerobic training (Gjellesvik, Brurok, Hoff, Tørhaug, & Helgerud, 2012), and strength training (Morris, Dodd, & Morris, 2004; Sunnerhagen, Olver, & Francisco, 2013), (2) orthoses, also referred to as splinting or bracing (Danielsson & Sunnerhagen, 2004; Doğan, Mengüllüoğlu, & Özgirgin, 2011; Kerem, Livanelioglu, & Topcu, 2001; Kobayashi, Leung, Akazawa, & Hutchins, 2012; Neuhaus et al., 1981), and (3) forms of functional electric stimulation (Burrige, Taylor, Hagan, Wood, & Swain, 1997). Despite extensive research being conducted, there are currently no evidence-based guidelines for the application of various non-pharmacological treatments, in conjunction with or without BTXA injections, for the treatment of adults with neurological impairments (Kinnear, 2012; Thibaut et al., 2013).

There is evidence to support the potential for functional recovery and reduced disability among elderly patients with chronic stroke using a generalized physiotherapy

intervention (Dean et al., 2000; Salbach et al., 2004; Wade, Collen, Robb, & Warlow, 1992). However the results for interventions specifically targeting stretching are more inconsistent. A recent systematic Cochrane review of the effectiveness of stretching (i.e. manual, positioning, splints or serial casts) in those with neurological conditions found that stretching done in isolation does not significantly modulate joint mobility, pain, spasticity, or activity limitation (Katalinic et al., 2010). However in a double-blind placebo controlled trial, not included in this review showed that casting with or without BTXA was most effective in preventing loss of ankle range of motion following severe brain injury (Verplancke, Snape, Salisbury, Jones, & Ward, 2005). Similarly positive results were demonstrated in a study of children with spastic CP (Ackman et al., 2005). Despite the beneficial effects of casting it has been argued that it may not be the most practical intervention to implement (Carda, Invernizzi, Baricich, & Cisari, 2011). There is some evidence to support the efficacy of short duration stretching with the use assisted devices to improve ambulatory ability, ankle mobility, and spasticity using dynamic-repeated-passive ankle movement with weight loading (Tsai, Yeh, Chang, & Chen, 2001; Wu et al., 2006).

The use of orthoses, for example the ankle foot orthosis (AFO), is yet another valuable physical management tool because it allows patients to build physical stamina and start walking sooner than would be possible without assisted devices (Kosak & Reding, 2000). The aim of orthoses is to reduce spasticity and pain, promote function, prevent contractures and deformities, and lastly, provide a sense of protection. Kobayashi and colleagues (2012) revealed increased gait velocity and step length, decreased step width, and improved heel strike in post-stroke patients. The authors concluded that the

use of AFO's may enable more efficient exchange of energy during stance phase of the affected limb (Kobayashi et al., 2012). This was in concurrence to other studies that demonstrated positive effects on balance activities and ambulation (Doğan et al., 2011) as well as decreased cost of energy required for walking in chronic stroke patients (Danielsson & Sunnerhagen, 2004).

### *Multimodal Interventions*

There is a strong recommendation for the use of a multimodal treatment approach consisting of physical interventions in conjunction with pharmacotherapy (Esquenazi et al., 2012; Gracies et al., 2007; Olver et al., 2010). The multimodal intervention strategy is thought of as the ideal clinical approach because extensive stretching or casting has been shown to improve the uptake of the toxin once injected in the homonymous muscle and therefore has potential to provide enhanced and longer-lasting treatment effects (Carda et al., 2011; Giovannelli et al., 2007; Karadag-Saygi, Cubukcu-Aydoseli, Kablan, & Ofluoglu, 2010). This comprehensive approach is also most effective when the therapies are focused on functional patient-centered goals including gait, balance, and assisted ADL's (Amatya et al., 2013; Esquenazi et al., 2012; Graham, 2013).

A 2013 Cochrane review, which reviewed all controlled trials comparing various multidisciplinary interventions of either upper or lower limb spasticity post-stroke, only found 3 studies of which all were RCT's involving the treatment of upper limb spasticity (Demetrios et al., 2013). The conclusion was that there was "low level" evidence for the effectiveness of multidisciplinary interventions in improving active function and impairments. This review also concluded that there needs to be higher quality studies

exploring the impact of multidisciplinary interventions for lower limb spasticity related to chronic stroke.

A retrospective chart review done in an outpatient spasticity program, found that in adult patients from diverse clinical backgrounds treated with a multimodal approach (i.e. BTXA, orthoses, and physiotherapy) showed an overall improvement (“better”) in 90% of the patients (Bergfeldt et al., 2006). The comprehensive management and evaluation was individualized for each patient; therefore, despite the use of broad spectrum of outcome measures that captured changes in the level of impairments, function, and participation, the outcomes were not consistent across participants, which prevented meaningful analysis. Furthermore, the study was short-term, 6 week follow-up after first BTXA injection and 12 week follow-up only in those getting a second set of injections, and upper and lower extremities were equally frequent targets for treatment.

Comparative analyses of the efficacy of non-multimodal vs multimodal interventions including BTXA, casting, physiotherapy, and/or EMS showed greater and longer lasting improvements in the multimodal interventions in spasticity, gait, ROM, and ankle joint integrity among adult patients with chronic lower limb spasticity resulting from stroke, MS, and/or TBI (Giovannelli et al., 2007; Johnson et al., 2004; Verplancke et al., 2005; Yaşar et al., 2010). However, these studies rarely included diverse (i.e. more than 2) clinical populations, had relatively short-term follow-up, generally 12 weeks, and the impact on increase participation and independence was not evaluated (Olver et al., 2010). More recently Esquenazi and colleagues (2012) conducted a prospective multi-centered study documenting real-world clinical practice in the multimodal management of upper and lower limb spasticity in adult patients with stroke and TBI and had a 6

month follow-up. Main outcomes measures included goal attainment, pain, and spasticity; significant improvements in pain and spasticity were reported. However, the outcome measures did not consistently measure, across participants, the level of activity and engagement in life roles (i.e. goals were highly variable). To date, no study has clearly demonstrated long term trends on the impact over time and with repeated treatments delivered at prescribed intervals among the adult population (Esquenazi et al., 2012).

In contrast, there has been a more full and well-rounded approach to the management and study of spastic CP in children (Molenaersa, Desloovere, Eyssens, Decaen, & Cock, 1999). The multimodal approach typically includes BTXA, gait analysis, physiotherapy, casting, and/or orthotic management (Molenaersa et al., 1999). The effectiveness of a multimodal long term treatment was shown to improve major gait abnormalities and gross motor function (Camargo et al., 2009; Desloovere et al., 2002; Desloovere et al., 2012; Faes et al., 2010; Molenaersa et al., 1999; Unlu, Cevikol, Bal, Cehk, & Kose, 2010). Furthermore, to provide a more holistic evaluation of the effects of a multimodal approach for the treatment of spasticity, the International Classification of Functioning, Disability, and Health for Children and Youth (ICF-CY) has been used (Preston, Clarke, & Bhakta, 2011; Thomas, Johnston, Boyd, Sakzewski, & Kentish, 2014). In a long-term study of treatment efficacy of spasticity in children, the combined effect of physiotherapy and splintage with 3 successive injections of BTXA resulted in better improvements that were maintained up to 18 months post-intervention compared to physiotherapy and splintage alone (Hawamdeh, Ibrahim, & Al-Qudah, 2007). Results from this study suggested that BTXA may influence physical management by prolonging

and enhancing its effects as well as increasing functional capacity (Hawamdeh et al., 2007). Effects observed in children, who are in their growth and development phase, are known to be different than what can be expected in adults with chronic conditions (Camargo et al., 2009). This level of detail and comprehensiveness has yet to be implemented in a study including adult with chronic lower limb spasticity as a result of various UMNL diagnoses. In sum, the multidisciplinary approach to treating spasticity in adults is highly recognized and is considered common practice yet there is a paucity of information of how this approach implemented over a long period of time (i.e. greater than 6 months) can impact health on the level of structural impairment and further translate to more distal health outcomes such as symptoms, participation, goal achievement, activity limitation, as well as QOL (Anwar & Barnes, 2005; Bergfeldt et al., 2006; Demetrios et al., 2013). Lastly, to date there have been no reported mixed-method studies taking a bio-psycho-social perspective of how the treatment of lower limb spasticity can impact an individual's life both objectively and subjectively.

The findings of a review by Mulligan and colleagues (2012) identifies that across diagnostic groups with UMNL and chronic spasticity there may be common functional or physiological impairments of body functions and structures and activity limitations that inhibited participation in physical activity. This review highlights an interesting conceptual relationship between common impairment and common barriers and perhaps a need for a methodological shift in how researchers examine these relationships. There is a lack of research that examine the relationship between common physical impairments across multiple clinical diagnoses and the barriers they experience to participation in physical activity as it relates to the treatment of spasticity. This complex question is best



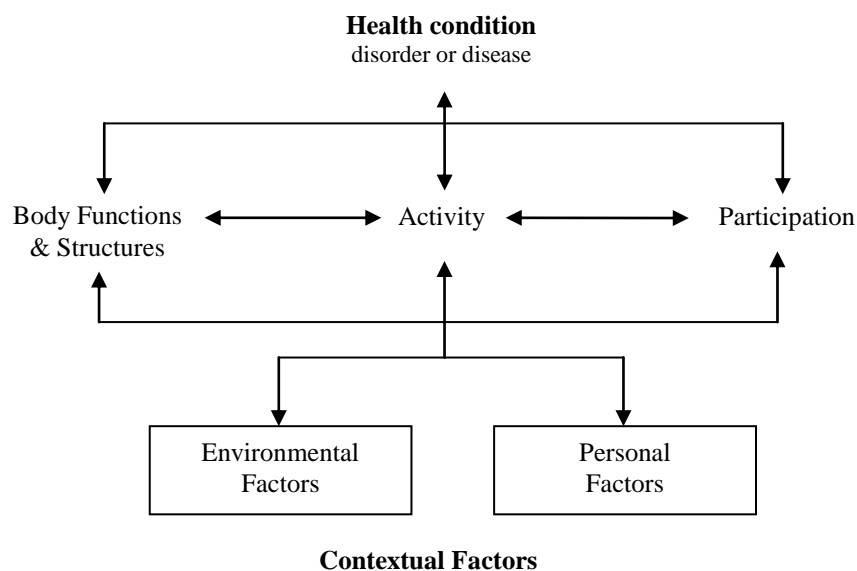
addressed with a multifaceted approach to elucidate the interaction between the individual impairments and limitations and their physical and social environment. Therefore a holistic approach that includes a mixed method design with concurrent measurement of body functions and structure, activities and participation, and contextual barriers to engagement in life roles, among different clinical populations that presents with a common impairment, is best suited to investigate these relationships.

### **1.6 ICF model**

The ICF is a model developed by the World Health Organization (2001) that identifies how performance in a standard and usual environment is affected by changes in body function and structure as a result of a health condition (WHO, 2002). The ICF model is an etiological framework that concentrates on the individual's level of health, thereby, acknowledging disability as a universal human experience. It provides a common language to facilitate communication, clinical practice and patient care to accommodate individual needs (Steiner, Ryser, & Huber, 2002). Lastly, the ICF model develops a complete view on disability which in turn can facilitate healthy behaviors.

The ICF model displayed in Figure 1 consists of two parts. Part one outlines the components of functioning and disability; and part two describes their interactions with the contextual factors (WHO, 2001). Part one is divided into three domains of human functioning: 1) body structures and functions, 2) activity and, 3) participation. These domains can be used to classify the outcome of health. Part two outlines the contextual factors of personal and environmental conditions. This model will indicate how body functions and structures, activity and participation interact with each other and how they are influenced by environment and personal conditions (Salter, Jutai, Teasell, Foley, &

Bitensky, 2005; Schepers, Ketelaar, van de Port, Visser-Meily, & Lindeman, 2007; Steiner et al., 2002). The model uses the term functioning to describe all body functions and structures and the performance of activities and participation in communal life (Simeonsson et al., 2003). The World Health Organization (2002) defines disability as “an umbrella term for impairments, activity limitations and participation restrictions” (p. 3). The ICF model uses the interaction of disability and functioning to view outcomes of interactions between health conditions and the contextual factors outlined in this model (WHO, 2002). The ICF model uses all domains to capture a complete view of the human experience when living with a disability. To further understand how significant this model is for implementing healthy practice each domain of the model is investigated further.



**Figure 1 Components of the ICF model (WHO, 2001)**

As displayed in Figure 1, the first component of the ICF model is body functions and structures. This domain facilitates description of how health conditions such as disease, disorders or illness impact an individual’s body structure and function (Steiner et

al., 2002). Body structures are anatomical parts of the body and represent the limbs and organs (WHO, 2002). Body functions are defined as the physiological function of body systems (WHO, 2002). Body structures and functions such as: the nervous system, ear, eyes, voice, speech, respiratory, digestive, metabolic, and structures related to movement and skin, can all be susceptible to impairment. Problems in body structures and functions lead to restrictions that are due to significant loss or deviation in human function (Jette, 2009). Health conditions can result in deficits in the anatomical structures and human physiology. These deficits can cause problems such as: pain, weakness and loss of hearing and contribute to loss of human function in which can further lead to sedentary lifestyles. This component of the ICF model can be used to characterize the limitations in body structures and functions of individuals to further understand the barriers they encounter.

The ICF uses both the domain of activity and participation to describe how human functioning is effected at an individual (activity) and societal (participation) level. Activity, the second component, is defined by WHO (2001), as the execution of a task or action by an individual. This domain describes the individual's perspective on functioning and how disability affects the execution of a task. Health conditions can lead to difficulties executing tasks and therefore lead to sedentary lifestyles (Jette, 2006). According to the WHO/ESCAP training manual (2008) on disability, limitations in activity can range from minor to major deviations in events associated with quality or quantity of a task.

Participation, the third component, is defined as "involvement in a life situation" (WHO, 2001, p. 3), and focuses on a person's QOL and well-being. However, health

conditions may restrict participation and individuals may experience difficulty engaging in roles and activities such as: working for pay, joining in community activities or grand-parenting. It is important to identify why and how the roles and activities for individuals with disabilities are difficult by identifying how the impairment restricts participation. According to the WHO/ESCAP Training Manual on Disability (2008), people with the same impairment experience different levels of incapacities and restrictions in performing ADL. It is easier to implement resources to improve health in individuals with disabilities if the conditions of the impairment are understood. According to Noonan and colleagues (2009), reducing disability is a significant rehabilitation outcome for improving health. A reduction in disability will improve life participation and ultimately, lead to a more active lifestyle. Participation and activities include the following: learning and applying knowledge, communication, mobility, self-care, domestic life responsibilities, interpersonal relationships and community, social and civil life (WHO, 2002).

Part two of the ICF model consists of contextual factors; both environmental and personal. Environment is defined as “physical, social and attitudinal environment in which people live and conduct their lives” (WHO, 2002, p.10). Environmental factors are external to the individual’s condition and can be represented by social attitudes, architectural characteristics, legal and social structures as well as climate and terrain (WHO, 2001; 2002). The ICF identifies how products and technology, natural environment and human-made changes to the environment, support and relationships, attitudes, services, systems and policies may inhibit or facilitate function and disability (WHO, 2001; 2002). The ICF model distinguishes between disability, function and environment. With this distinction health professionals are able to acquire information to

implement resources, and, thus improve health outcomes. When health is compromised by environmental factors it may restrict activity and participation and, ultimately lead to poor health behaviors.

The other category of contextual factors identified in the ICF model is personal factors. Personal factors are defined as individual features independent to health conditions or health status (Jette, 2009). Personal factors include, gender, race, age, fitness, lifestyle, habits, upbringing, education, coping styles, social background, past and current experience, character style and other traits that influence how disability is perceived by the individual (Jette, 2009; WHO, 2002). Separate from the individual's health condition, it is important to identify personal traits that may contribute to health outcomes. Along with the other ICF domains, personal factors can contribute information for implementing optimal rehabilitation strategies to enhance QOL by characterizing personal factors that result in barriers to participation.

QOL is a broad personal valuation over the nature of one's life; in other words, it's an individual's perception of satisfaction with life in domains of significance to that individual (Oleson, 1990). QOL can be seen as emerging from the interaction between an individual's health condition and their context i.e. the personal and environmental factors (McDougall, Wright, & Rosenbaum, 2010). McDougall and colleagues recommend that when assessing a person's health and functioning, QOL should be assessed to more fully represent the individual. It is also useful to employ mixed-methods designs to more fully capture the complexity of interactions between the person's condition, functioning and context, as modeled by the ICF (WHO, 2001b).

Given the complexity of the research question in the current study, the ICF model was adopted. In research using an ICF model, a mixed-methods design is often employed in order to fully support the multiplicity of the ICF model (WHO, 2001b). By incorporating quantitative and qualitative measures in a mixed-method approach the understanding of individual experiences can effectively be enriched by integration of knowledge and conclusions from various methods of data collection. This ultimately allows us to satisfy each level and domains of the ICF model and, as a result, generate a holistic perspective of each participant. Lastly, a mixed-methods design permits triangulation of data sources and types to take advantage of both the representativeness and generalizability of quantitative findings, and the rich contextual contributions of qualitative data (Punch, 1998).

## **1.7 Measurement Tools**

In this section I will describe dependent measures which were examined both quantitatively and qualitatively in the present thesis. Specifically, I will describe the dependent variables, the specific associated measurement tools and the rationale for the use of these tools. The quantitative measures include ROM of the ankle joint, spasticity in the ankle flexors, pain, cognitive status, functional mobility, spatial-temporal parameters of gait, occurrence of falls, physical activity levels, and quality of life. The participants' subject perspective on the influence of the intervention was evaluated in semi-structured interviews.

### *Ankle mobility*

Ankle range of motion (ROM) was measured directly using manual goniometry (Gajdosik & Bohannon, 1987; Soucie et al., 2011). ROM for ankle dorsiflexion, with the

knee flexed and extended, was assessed both actively and passively with the participant lying supine. The universal goniometer is generally accepted as a valid clinical tool (Gajdosik & Bohannon, 1987).

### *Spasticity*

The most commonly used spasticity measurement tools include the Modified Ashworth Scale (MAS) (Allison, Abraham, & Petersen, 1996; Bohannon & Smith, 1987) and the Modified Tardieu Scale (MTS) (Held et al., 1969; Tardieu et al., 1954), both of which have shortcomings. The MAS is quick and easy to administer but has limited inter-rater reliability; in comparison, the MTS has superior reliability but is time consuming and much more complicated (Mehrholtz et al., 2005). Other impediments associated with measuring spasticity include the variety of influences that may modulate the intensity of spasticity between evaluations (Pierson, 1997). The distribution and intensity of spasticity within a single patient may be affected by the time of day, patient's emotional state, concurrent illness, and any training effects (Pierson, 1997). Moreover, the clinical consequences of spasticity is highly variable between patients (Bergfeldt et al., 2006). As identified by Burke, Wissel, and Donnan (2013) the mechanisms contributing to the disability experienced by one individual may vary extensively from those affecting another therefore emphasizing the importance of individualized management.

To address the shortcomings of the MAS and MTS, the APFTS (Takeuchi, Kuwabara, & Usuda, 2009), which is a relatively new measurement tool that has not been tested in many clinical settings, was chosen. The APFTS was specifically designed to assess spasticity of the ankle flexors (gastrocnemius and soleus muscles) and was therefore useful in the current study aims to evaluate the ankle joint and the muscles

responsible for its movement. The APFTS has been reported to have high inter-rater reliability (.72 - .94) as well as high intra-rater reliability (.63 - .82). Both central and peripheral components of hypertonicity were assessed and graded on the APFTS ranging from 0 to 4 (5 grades). Spasticity, the central component, was measured as a stretch reflex with the knee flexed and extended which involves passively moving the ankle into dorsiflexion as fast as possible. Peripheral components were measured by passively moving the ankle into dorsiflexion as slow as possible, with the knee flexed and extended, and the resistances were graded at the middle and final ranges.

Clonus in the plantar flexors, which is an additional measure of spasticity, was quantified by counting clonic beats (Hoppenfeld, Gross, Andrews, & Lonner, 1997; Welmer et al., 2006). Clonus is defined as a series of rhythmic involuntary reciprocating muscle contractions induced by the sudden passive stretching of a muscle or tendon (Rossi, Mazzocchio, & Scarpini, 1990). While the participant was lying supine, the researcher applied a passive rapid stretch to the ankle plantar flexor muscles. This was done with both the knee extended and flexed. The number of clonic beats was counted as best as possible. Due to the difficulty in counting each beat when surpassing 10 beats of clonus, a value of 10 was assigned to anything greater than 10 beats and a value of 15 was assigned to inexhaustible beating lasting greater than 10 seconds (s) (>10s of continuous beating represents the max score on the stretch reflex scale). To my knowledge, no reliability and/or validity tests have been conducted, however the described procedure has been used in the past (Welmer et al., 2006).

### *Pain*



Rating of pain was self-assessed using a hybrid tool. The Numeric Rating Scale (NRS) (Downie et al., 1978) and the Visual Analogue Scale (VAS) (Paice & Cohen, 1997) were superimposed to facilitate the use of the tool by individuals with more severe cognitive deficits and/or language barriers. As described in the literature, the VAS and the NRS, individually, are problematic for patients requiring translation, as well as with visual, cognitive, and/or physical impairments (Paice & Cohen, 1997). Upon integration of the two scales, it made it a more comprehensive and valuable self-rating tool for the purposed use in the present study. Moreover, it has been shown that the correlation between the VAS and NRS is strong and statistically significant ( $r = 0.847$ ) (Paice & Cohen, 1997). The NRS/VAS was used to evaluate participants' usual level of pain (intensity) in a particular joint within the lower extremities in the week prior to testing. The pain described had to represent a specific location of persistent pain experienced during walking. This location of pain was identified during the baseline period and then consistently evaluated throughout the entire study. New locations were added and similarly tracked if mentioned at any point during the intervention program. Accordingly, if a location of initially described pain was alleviated (i.e. score of 0 out of 10) 'no pain' was recorded and participants were asked if there is still 'no pain' in subsequent data collection periods.

### *Cognition*

The Standardized Mini Mental State Exam (SMMSE) (Molloy, Alemayehu, & Roberts, 1991) and clock drawing were used to quantify cognitive status. The SMMSE is a modified version of the original MMSE (Folstein, Folstein, & Hugh, 1975). A study using a sample of elderly individuals living in care facilities, demonstrated enhanced ease

of administration (i.e. less time consuming) and improved intra- and inter-rater variance in the SMMSE compared to the MMSE (Molloy et al., 1991). The clock-drawing task (Shulman, Pushkar, Cohen, & Zuccherro, 1993), known for its greater degree of sensitivity, was also used to describe cognitive function. Scores on the SMSSE may range from 0 - 30 points; and a score below 24 is indicative of cognitive impairment (Goring, Baldwin, Marriott, Pratt, & Roberts, 2004). Clocks were scored according to the 'Classification of clock-drawing errors' established by Shulman and colleagues (1993).

#### *Functional Mobility*

The timed-Get-Up and Go test (TUG) (Podsiadlo & Richardson, 1991) was performed while walking at one's normal pace was used to assess participant's functional mobility, gait speed, and balance. The TUG has been tested in various populations including stroke, SCI, MS, and CP (Rehabilitation Measures Database [RMD], 2010). It is known as a valid tool with very high intra-rater reliability ( $r = 0.92 - 0.99$ ) (Podsiadlo & Richardson, 1991; Rockwood et al., 2005) as well as very strong content and criterion validity (ICC = 0.92 and 0.91) (Shumway-cook & Brauer, 2000). As tested in a chronic stroke population ( $n = 50$ ; 6-46 months post-stroke; mean age = 58 years) the 95% smallest real difference (SRD) was calculated to be 23% and showed excellent test-retest reliability (ICC = 0.96) (Flansbjerg, Holmbäck, Downham, Patten, & Lexell, 2005).

#### *Gait Parameters*

Gait parameters including gait velocity (cm/s), cadence (steps/min), step length right and left, and stride length right and left, were measured using the GAITRite system (CIR Systems Inc., 2010) which is an automated pressure sensing mat. Measuring spatio-temporal gait parameters is a successful method for analyzing gait mechanics for

individuals with disabilities. The GAITRite system is portable, relatively cost efficient, easy to operate, and can objectively quantify both spatial and temporal gait parameters at various walking speeds with strong concurrent validity and test re-test reliability (Bilney, Morris, & Webster, 2003). Test-retest reliability in various parameters of gait was found to be more highly variable at slower walking speeds as compared to normal or fast walking speeds (Bilney et al., 2003).

### *Falls*

Falls were prospectively recorded using a fall recording calendar (Mackenzie, Byles, & D'Este, 2006). It has been established in the literature that calendar-recorded falls data is more accurate compared to retrospective self-reported falls data (Mackenzie et al., 2006).

### *Physical Activity*

Participation in physical activity was quantified using the Physical Activity Scale for Individual with Physical Disabilities survey (PASIPD) (Washburn, Zhu, McAuley, Frogley, & Figoni, 2002). The PASIPD provides scores for five domains of physical activity (home repair, lawn and garden, housework, vigorous sport and recreational activities, light-moderate sport and recreational activities as well as occupation and transport) as well as a total score. The score for each question was calculated by multiplying the average hours per day for each item by a metabolic equivalent of a task (MET) associated with the intensity of the task. A MET is a physiological term for expressing the amount of energy used during physical activity. One MET is equal to 3.5ml of oxygen per kg of body-weight per minute and is considered the proxy of resting metabolic rate (Washburn et al., 2002). A lower score corresponds to lower levels of

physical activity. Washburn et al. (2002) demonstrated internal consistency and construct validity of the measurement tool when tested on individuals with locomotor disabilities.

### *Quality of Life*

Participants' quality of life was quantified using the Short-Form health survey with 36 questions version 2.0 (SF-36v2) (Ware, 2000). Version 2.0 of the SF-36 was introduced in 1996 with corrections relating to the deficiencies in the original version. The SF-36v2 measurement model consists of 2 main measures including 'physical health' and 'mental health' each of which is comprised of multiple subscales which are further stratified into items (i.e. 36 questions that make up the survey) (Ware, 2003). The SF-36v2 has well-established concurrent, predictive, convergent, and discriminate validity; as well as moderate to excellent test-retest reliability (Finch, Brooks, Stratford, & Mayo, 2002).

### *Participants' Perspective*

One-on-one semi-structured interviews (Dicicco-Bloom & Crabtree, 2006) were conducted with each participant to describe their current (at baseline) and change within and across both 'functioning and disability' and 'contextual factor' levels of the ICF. Interview questions were structured according to the ICF model (WHO, 2001); informants were prompted to discuss their participation in life roles, such as domestic, exercise, leisure, and community engagement as well as any relevant barriers and affordances.

## **1.8 Gaps & Summary**

Spasticity related disability is a significant health and socioeconomic problem in individuals with UMNL (Bergfeldt et al., 2006; Decq et al., 2004; Ward, 2012; Wissel et

al., 2013). Studies that clearly evaluated multimodal interventions in adults with chronic lower limb spasticity, demonstrated improvements in many impairment level measures (Giovannelli et al., 2007; Johnson et al., 2004; Verplancke et al., 2005; Yaşar et al., 2010) as well as some measures of function and participation (Bergfeldt et al., 2006; Esquenazi et al., 2012), however, on the whole these studies had several limitations. They rarely included a mixed clinical population (i.e. more than 2), only evaluated short-term treatment effects (i.e. typically one or two BTXA injections), and had a narrow breadth of outcome measures that did not comprehensively measure the impact of treatment on body impairments, functional activities, participation, and QOL (Anwar & Barnes, 2005; Bergfeldt et al., 2006; Demetrios et al., 2013). Further, to my knowledge, no study in the adult population with chronic lower limb spasticity, has clearly demonstrated long term impact of treatment over time as well as the impact of repeated treatments delivered at prescribed intervals (Esquenazi et al., 2012).

In a recent review Mulligan et al (2012) identified that there may be common functional or physical impairments of body functions and structures and activity limitation across diagnostic groups that inhibited participation in physical activity. These findings highlight an interesting conceptual relationship between common impairment and common barriers and perhaps a need for a methodological shift in how researchers examine these relationships. The treatment of spasticity is known to affect body impairments, mobility and function (Johnson et al., 2004; Snow et al., 1990; Yaşar et al., 2010) which may be a key factor limiting the engagement in physical activity (Adams & Hicks, 2005; Busse et al., 2004; Richardson, 2002; Wissel, Olver, et al., 2013) and independent performance of ADL's (Brainin, 2013). Previous studies have not framed

spasticity as a common physical impairment across multiple clinical diagnoses and, furthermore, have not evaluated how the treatment of spasticity can impact barriers to participation in physical activity and engagement in life roles. To fully understand the effect of a multimodal intervention aimed at reducing spasticity, on all levels of function including engagement in physical activity and other domains of life (i.e. bio-psycho-social), a multifaceted approach is required. Therefore a holistic approach that includes a mixed method design driven by a model such as the ICF, and includes a breadth of measures spanning functioning and disability as well as contextual factors, is ideal to provide a richer understanding of the efficacy of the treatment as well as elucidate the relationship between these factors. To our knowledge, a mixed-methods approach to assess the effects of a multimodal intervention to treat chronic lower limb spasticity in the adult population has yet to be reported.

This study aims to answer the following questions 1) what is the influence of the multimodal intervention on functioning and disability among these individuals experiencing chronic lower limb spasticity? 2) What were relationships between changes in body functions and structure, activities and participation, and contextual factors that resulted from the treatment program? 3) How did the treatment influence the barriers to and affordances for participating in physical activity and ADL's experienced by the participants? The present study will use a repeated measures design in order to evaluate the effects of a long-term, repeated multimodal modal treatment program (i.e. successive injections, long term exercise monitoring, and ongoing orthoses modifications) lasting 12 months in duration.

## Chapter 2: Manuscript

### 2.1 Introduction

Spasticity is highly prevalent in a variety of neurological conditions involving upper motor neuron lesions (UMNL) such as stroke (Burke et al., 2013; Ward, 2012; Wissel, Manack, et al., 2013), multiple sclerosis (MS) (Rizzo et al., 2004), incomplete spinal cord injury (iSCI) (Adams & Hicks, 2005), traumatic brain injury (TBI), and cerebral palsy (CP) (Stevenson, 2010). The definition of spasticity has evolved since it was originally defined by Lance (Lance, 1980). In the current study, spasticity was defined as a “disordered sensori-motor control, resulting from an UMNL, presenting as intermittent or sustained involuntary activation of muscles” (BurrIDGE et al., 2005, p. 72). The clinical symptoms of spasticity include pain, involuntary movements, abnormal postures, and resistance to passive movement (Demetriou et al., 2013; Graham, 2013). These impairments negatively impact quality of life (QOL) through limiting activities of daily living (ADL) and impairing mobility (Adams & Hicks, 2005; Esquenazi et al., 2012; Kinnear, 2012; Ward, 2012). Spasticity, particularly in the lower limbs, impairs gait and participation in physical activity (Graham, 2013).

It is well documented that multimodal interventions including BTXA, orthoses, physiotherapy, and/or EMS showed greater and longer lasting improvements in spasticity, gait, range of motion (ROM), and ankle joint integrity than unimodal interventions among adult patients with chronic lower limb spasticity (Giovannelli et al., 2007; Johnson et al., 2004; Verplancke et al., 2005; Yaşar et al., 2010). However, no studies, to date have evaluated the impact of repeated multimodal treatment at prescribed intervals over an extended period of time (i.e. over the course of 12 months (m)

implementing two or more successive BTXA injections, along with exercise and orthoses management) in adults with chronic lower limb spasticity (Esquenazi et al., 2012).

Further, studies are often focused on a narrow cohort of clinical populations.

Given the complexity of measuring the efficacy of treatments of spasticity, a holistic framework such as the International Classification of Functioning, Disability, and Health (ICF) model has been suggested (BurrIDGE et al., 2005; Demetrios et al., 2013). However, no studies within the chronic adult population no studies have included this framework nor have they included the breadth of outcome measures necessary to evaluate functioning and disability, including participation in life roles, as well as perception of contextual barriers to participation (BurrIDGE et al., 2005; Olver et al., 2010). In contrast, research involving children with spastic CP has included a long-term repeated treatment methodology and has incorporated the International Classification of Functioning, Disability, and Health for Children and Youth (ICF-CY) in order to more comprehensively evaluate the effect of multimodal treatment approaches (Molenaers et al., 1999; Preston et al., 2011; Thomas et al., 2014). Furthermore, research in children with spastic CP, has employed a mixed-methods approach to evaluate the impact of a single BTXA injection on the functioning and disability level of the ICF (Wright, Rosenbaum, Goldsmith, Law, & Fehlings, 2008). The present study addressed these research gaps within the adult population by evaluating the efficacy of a 12m multimodal intervention including BTXA, orthoses, and physiotherapy for the treatment of chronic lower limb spasticity, a common impairment across the multiple diagnostic groups. Further, this study incorporated the ICF model as a framework and included a comprehensive set of outcome measures that span all domains of the ICF using a mixed-



methods design.

## **2.2 Methods**

### **2.2.1 Participants**

The study participants were adults who were referred to a hospital-based interdisciplinary spasticity clinic. Inclusion criteria included: a neurologic condition resulting from an upper motor neuron lesion for greater than six months, lower limb spasticity, adherence to all three interventions as prescribed by the multidisciplinary clinical team for 12m, and medical stability. Participants were excluded if emerging co-morbidities influenced their physical or cognitive function throughout the course of the study. This study had joint University of Victoria and Vancouver Island Health Authority ethics approval; written informed consent was obtained. A total of 60 participants were screened as appropriate for inclusion by the clinic's physiatrist (CQ). Seventeen participants met the inclusion criteria throughout the course of the study and were included in the analysis. Table 1 provides a summary of participant characteristics.

Treatment fidelity refers to the extent to which an intervention is implemented as planned (Hildebrand et al., 2012; Horner, Rew, & Torres, 2006). As seen in previous multimodal studies involving BTXA, participants have been excluded over the course of the study due to extraneous factors such as health complications, fixed contractures, and use of anti-spastic drugs, such as baclofen (Bergfeldt et al., 2006; Carda et al., 2011). Moreover, the risk of reduced compliance has been identified as a threat to internal validity (Basaran, Emre, Karadavut, Balbaloglu, & Bulmus, 2012). In a RCT conducted by Giovannelli et al. (2007), patients who were enrolled and randomized in the study, were excluded from analysis due to discontinuation of therapy. The long term duration of

the current study as well as the required compliance to a tri-partite intervention in a medically vulnerable population, resulted in many participants not meeting the inclusion criteria for the duration of the study. The flow diagram in Figure 1 outlines participant attrition and exclusion. The limitations of this approach has been acknowledged, as well as the impact on internal and external validity (Dijkers, 2011). However, the inclusion of those who did not adhere to the intervention as well as those affected by extraneous physiological and social factors not controlled for in this study hinders the analysis of the research question.

Table 1

*Participant characteristics at enrolment*

Participant Number	Gender	Diagnosis	Age	Years since Diagnosis
1	M	Stroke	53	4
2	F	Stroke	68	31
6	F	Stroke	77	5
16	F	CP	50	50
27	F	Stroke	51	1
28	F	MS	57	12
33	F	MS	64	2
35	F	MS	52	13
37	M	MS	55	17
39	M	CP	32	32
49	M	Stroke	64	3
51	M	TBI	42	9
52	M	iSCI	59	14
55	M	CP	33	33
56	F	MS	27	1
59	F	Stroke	67	18
60	M	MS	49	10
Mean (SD)			52.9 (13.6)	15.0 (13.9)

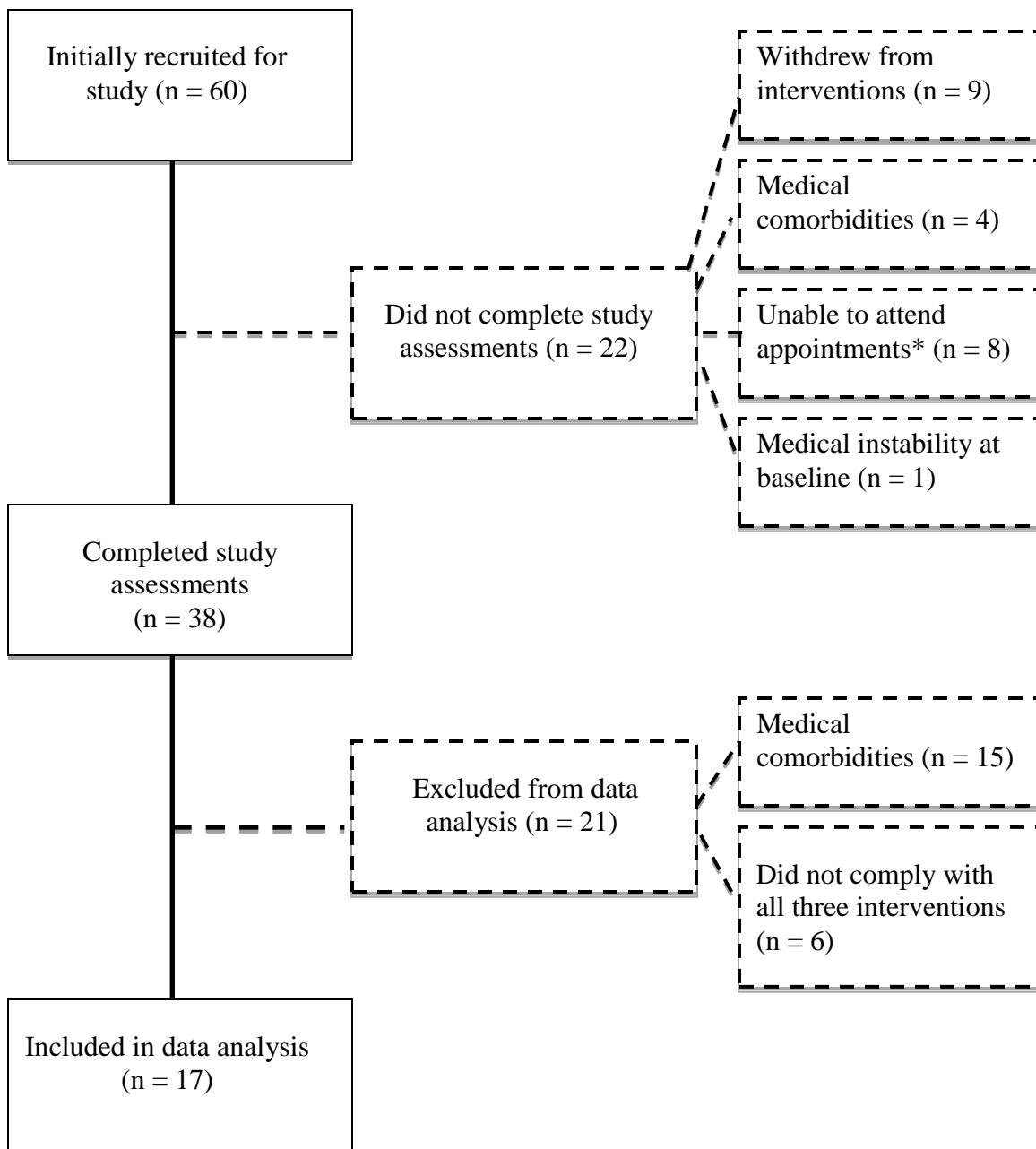


Figure 1. *Flow chart of participant attrition and exclusion.*

\* Includes reasons such as scheduling conflicts, travel, and incarceration.

### **2.2.2 Design**

The study design was a modified time-series with mixed-methods. Outcome assessments were performed five times throughout the course of the study (14m total), see Table 2 for data collection timeline. Baseline data were collected in three assessments (PRE 2m, PRE 1m, 0m), at one month intervals. An average score of the three baseline trials was calculated for each participant and used for further analysis.

The International Classification of Functioning, Disability and Health (ICF) model was used as the framework to structure the study outcome measures into components of (1) functioning and disability (consisting of three domains: body structures and functions, activities, and participation) and (2) contextual factors (two domains: environmental and personal). Quantitative measures assessed the components of functioning and disability and the qualitative data fulfilled two purposes: to capture changes across all domains of the ICF and to elucidate the interrelationships between domains.

Table 2.

*Data collection timeline*

Time	PRE 2m	PRE 1m	0m	6m	12m
<b>Measures</b>					
ROM	x	x	x	x	x
APFTS	x	x	x	x	x
Pain	x	x	x	x	x
TUG	x	x	x	x	x
GAITRite	x	x	x	x	x
Falls			x	x	x
PASIPD	x			x	x
SF-36v2	x			x	x
SMMSE	x				x
Clock	x				x
Interview	x			x	x

*Note:* **PRE 2m**= 2 months pre-treatment initiation; **PRE 1m**= 1 month pre-treatment initiation; **0m**= final pre-treatment assessment with intervention initiation on the same day; **6m**= 6 months post-treatment initiation; **12m**=12 months post-treatment initiation.

Table 3.

*Categorization of outcome measures according to the ICF model*

	Functioning & Disability		Contextual Factors	
BF&S	Activities	Participation	Environmental	Personal
SMMSE	GAITRite	PASIPD	Interview	
Clock	TUG	SF-36v2		
Pain	Falls	Interview		
APFTS	Interview			
ROM				
Clonus				
Interview				

### 2.2.3 Intervention

The multimodal intervention, which is the study's independent variable, consisted: BTXA injections, orthoses management, and physiotherapy. All participants were assessed by the multidisciplinary clinical team, comprising a physiatrist, orthotics specialists, and physiotherapist, who collaborated on the optimal treatment plan. Study assessments were delivered by the physiotherapist (JD) and researcher (JK).

BTXA (Botox®; Allergan, Inc., Irvine, CA, USA) injections were administered, by the clinic's physiatrist (CQ). After receiving the first BTXA injections, following injections were scheduled at least 3m apart. Selection of lower limb muscles to be injected was based on clinical assessment of range of motion (ROM) at the foot, ankle, knee, and hip, and the specific ambulation goals (as per detailed gait analysis and collaboration with orthotist and physiotherapist). All the BTXA injections (100U Botox in 1mL normal saline) were performed by the same experienced physician with extensive EMG background. EMG guidance was almost always used with the exception of psoas muscle is injections which were done by posterior approach under CAT scan guidance by an experienced radiologist. Injections were delivered into one or more of the following muscles: tibialis posterior and anterior, flexor hallucis longus, extensor hallucis longus, flexor digitorum longus, flexor digitorum brevis, rectus femoris, semi tendinosis, biceps femoris, medial and lateral gastrocnemius, and soleus (in doses ranging between 10U to as much as 50U per site). The total dose for a patient ranged from 300-600U. Where feasible, the aim was to gradually reduce and/or discontinue injections once the desired outcome was achieved and shift the focus on the non-pharmacological physical modalities.

The orthoses management was based on ongoing assessment and involved prescription of a new brace and/or modification of an old brace. A minimum of ten degrees of plantar flexion was the cut-off for the implementation of a hinged or solid ankle-foot-orthosis (AFO). A solid AFO was prescribed for those with weak quadriceps muscles. Patient preference and financial constraints influenced bracing prescription. The orthotists also provided customized shoes, shoe orthotics, heels lifts, and other supports. Lastly, gait aids (cane, sidesticks, etc.) were also prescribed.

Physiotherapy was provided either by the spasticity clinic's physiotherapist or an external physiotherapist. The frequency of the physiotherapy intervention was designed to be realistic and feasible for the real world with consideration given to typical client financial constraints. Participants were encouraged to attend physiotherapy sessions at a minimum of once a month and/or according to their individual requirements. The number of total formal sessions with a therapist ranged from 8 to 50 per participant. These sessions comprised of stretching, mobilization, strength training, gait re-education, balance, and function mobility training. Additional modalities included endurance training (e.g. biking or swimming), muscle stimulation, pool exercises, walking in the community, group circuit training (provided at the clinic by JD), and complementary therapy such as acupuncture, Tai Chi, and Yoga. Participants were also prescribed level-appropriate home exercise regimes which were updated on a regular basis. Furthermore, at each study assessment the physiotherapist and researcher discussed ongoing physical activity, provided advice and guidance where necessary to encourage maintenance of physical activity and adherence to prescribed exercises.



### 2.2.4 Measures

All research measures were collected by the researcher and physiotherapist.

Various measurement tools were used to assess multiple constructs of body functions and structures, activities, and participation. These dependent variables included ROM of the ankle joint, spasticity in the ankle flexors, pain, cognitive status, functional mobility, spatial-temporal parameters of gait, occurrence of falls, physical activity levels, and quality of life. The qualitative component captured participants' perspectives of how the impact of the intervention changed barriers and facilitators to participation in life roles and QOL. See Table 3 for the list of measurement tools used to assess these dependent variables that have been categorized according to the ICF model.

#### *Body functions and structures*

Measures of body functions and structures included ankle ROM, level of spasticity in the triceps surae muscles, rating of pain, and cognitive status. Ankle ROM was measured with a manual goniometry (Gajdosik & Bohannon, 1987; Soucie et al., 2011). Both active and passive ROMs, with the knee extended and flexed, were assessed with the participant lying supine. Passive ROM was measured with the researcher manipulating the ankle into dorsiflexion with maximum effort. The Ankle Plantar Flexors Tone Scale (APFTS) (Takeuchi, Kuwabara, & Usuda, 2009) was used to measure muscle spasticity of the triceps surae muscles with the participant lying supine with the knee extended and flexed. The central component of spasticity was measured by eliciting a stretch reflex (score from 0 to 4: 0 signifying no twitch, 4 indicating severe clonus, persisting >10s). The peripheral components were measured by rating the passive resistance to slow passive ankle into dorsiflexion (Allison et al., 1996). Clonus was also

used to measure spasticity and was quantified by counting clonic beats (Hoppenfeld et al., 1997; Takeuchi et al., 2009; Welmer et al., 2006).

Pain was self-assessed using a hybrid of the Numeric Rating Scale (NRS) (Downie et al., 1978) and the Visual Analogue Scale (VAS) (Paice & Cohen, 1997). The NRS/VAS was used to evaluate participants' usual level (intensity) of pain in a particular joint within the lower extremities experienced during walking. Cognitive function was assessed using the Standardized Mini Mental State Exam (SMMSE) (Molloy et al., 1991) and clock drawing task (Shulman et al., 1993). Clocks were scored according to the 'classification of clock-drawing errors' established by Shulman et al. (1993).

### *Activities*

Activity is the execution of a task or action by an individual (WHO, 2001) and this was quantified by testing functional ambulation, assessing parameters of gait, and observing fall frequency. The Time-Get-Up and Go test (TUG) (Podsiadlo & Richardson, 1991) is performed while walking at a comfortable pace and assesses functional mobility. The test was performed twice; time in seconds was recorded for the second trial only. Gait parameters including gait velocity, cadence, as well as bilateral step lengths and stride lengths were measured using the GAITRite system (CIR Systems Inc., 2010) which is an automated pressure sensing mat. Each participant completed two round trips on the mat (total of four passes) with shoes and walking aids, and then repeated without shoes or aids. The data is collected and analyzed via a PC interface and the GAITRite software. Each pass on the mat is processed individually and then combined into like trials; trials comprised of 2-4 passes after exclusion of passes that were not recorded properly. The processed trials from the software are then entered in Microsoft Excel for exporting.

Lastly, falls were recorded prospectively using a fall recording calendar (Mackenzie et al., 2006). Participants were given a calendar to take home at the first assessment and were asked to bring it back at each subsequent assessment in order to facilitate recording of fall occurrences by the researcher.

### *Participation*

Participation, the third domain of functioning and disability, is defined as “involvement in a life situation” (WHO, 2001, p. 3), and focuses on a person’s QOL and well-being. The Physical Activity Scale for Individual with Physical Disabilities survey (PASIPD) (Washburn et al., 2002) was used to quantify participation in physical activity. QOL was quantified using the Short-Form 36 questions version 2.0 (SF-36v2) health survey (Ware, 2000).

A semi-structured interview (Dicicco-Bloom & Crabtree, 2006) was conducted by the physiotherapist with each participant. Participants were asked to describe their current status within and across all domains of the ICF model at BL, and then, at 6 and 12m, were asked to describe any changes and reasons for changes across the previously described topics. Interview questions were structured according to the ICF model (WHO, 2001); informants were prompted to discuss their participation in life roles, such as domestic life, self-care, recreation and leisure, work and employment, as well as any relevant barriers and affordances.

### **2.2.5 Data Treatment and Statistical Analysis**

In order to establish stability across all baseline measures, a one-way analysis of variance (ANOVA) for repeated measures (PRE 2m, PRE 1m, and 0m) was conducted. Subsequently, the three baseline measurements were averaged to obtain a single baseline

value and labeled as 'baseline (BL)' for further statistical analyses. For participants with bilateral lower limb involvement, the worse limb was used (as determined by ROM and APFT scale scores). The use of one limb per participant allowed for equal weighting during analysis (Ackman et al., 2005); moreover, the more affected limb was chosen to effectively represent the degree of disability experienced. For descriptive purposes mean, standard deviation, and range for all quantitative outcome measures were computed. Furthermore, a one-way ANOVA for repeated measures was conducted for each dependent measure to assess change over time (BL, 6m, and 12m) relative to start of treatment. Post-hoc LSD was used to determine which post-treatment assessment times were significantly different relative to BL. Lastly, paired samples t-test was performed to compare pre and post outcome measures such as those for cognitive function (SMMSE and clock drawing). Significance was set at  $p \leq .05$ ; IBM SPSS version 20 was used for statistical analysis.

Each interview was digitally audio-recorded and transcribed verbatim. Using an inductive data-driven approach, transcripts were first read and coded openly by two independent reviewers (JK and VT) then triangulated to identify composite themes and relationships. Additionally, using an orientational approach, the transcripts were organized thematically using a deductive a priori template of codes (Patton, 1990; Crabtree & Miller, 1999); the template included all domains of the ICF model. The framework for interpreting both sets of codes (inductive and deductive) consisted of consideration of the actual words and their meaning, the context, the frequency and extensiveness of comments, the intensity, internal consistency, and specificity of responses, and larger trends (or big ideas) within these data.

## 2.3 Results

### 2.3.1 Quantitative

The participant characteristics of the 17 participants included in the final analyses are summarized in Table 1. ANOVA of baseline measures demonstrated stability in 18 out of 20 outcome measures ( $p \leq .05$ ;  $n=16$ ). The first difference was in one component of the APFTS (Takeuchi et al., 2009) and there was a significant increase in final range resistance with the knee extended between PRE 2 and 0m. The second difference was again between PRE 2 and 0m in the measurement of passive ROM with the knee extended. Despite a statistically significant increase in ROM, the mean change was only by two degrees (range: 0-7degrees), which is commonly recognized as not being clinically significant (Katalinic et al., 2010). No changes were seen in falls. Mean and standard deviations for outcome measures for BL, 6m, and 12m are presented in Table 4.

In relation to body functions and structures there was no change in cognitive function (SMMSE and clock drawing) or rating of pain. Stretch reflex with the knee flexed significantly improved from BL to 6 and 12m; however stretch reflex with the knee extended did not change. Clonus measured with knee both flexed and extended decreased significantly from BL at 6 and 12m. Measures of active ROM (knee extended and flexed) and passive ROM with the knee flexed did not change, but at 12m, passive ROM with the knee extended significantly increased relative to BL. Activities as measured by gait parameter and the TUG improved significantly from BL at both 6 and 12m, with the exception of cadence.

### *Participation*

Participation in physical activity according to the PASIPD showed no change. General health, social functioning, and the physical component summary of the SF-36v2 showed significant improvements at 6 and 12m.

Table 4.

*Outcome measures results, classified under domains of the ICF, across all assessment times(n = 17)*

Variable	BL mean (SD)	6m mean (SD)	12m mean (SD)	P-value main effect or t-test	Significant post-hoc
<b>Body Functions &amp; Structures</b>					
SMMSE	27.8 (3.4)	-	27.9 (3.5)	0.87	
Clock	2.0 (1.0)	-	2.1 (1.3)	0.82	
Pain	2.6 (2.7)	1.7 (2.3)	1.8 (1.8)	0.34	
<b>APFTS</b>					
KF_SR	1.7 (1.1)	1.1 (.83)	0.82 (.73)	0.01	a,b
KF_MRR	1.2 (.38)	1.5 (.62)	1.4(.51)	0.22	
KF_FRR	2.6 (.64)	2.9 (.86)	3.1 (.88)	0.02	b
KE_SR	1.2 (.86)	0.88 (.70)	0.82 (.64)	0.06	
KE_MRR	1.8 (.39)	1.9 (.60)	2.1 (.60)	0.13	
KE_FRR	3.2 (.66)	3.4 (.71)	3.5 (.80)	0.30	
<b>Clonus (beats)</b>					
KF	3.4 (5.2)	1.4 (2.8)	1.2 (2.7)	0.04	a,b
KE	2.0 (3.2)	0.71 (1.5)	0.47(1.4)	0.05	a,b
<b>ROM (°)</b>					
P_KFDF	12.8 (7.4)	14.1 (7.5)	14.1 (7.6)	0.48	
P_KEDF	4.2 (9.1)	7.7 (7.5)	6.8 (6.6)	0.02	b
A_KFDF	-4.8 (11.6)	-2.2 (12.5)	-1.9 (10.6)	0.20	
A_KEDF	-15.2 (14.7)	-14.5 (16.1)	-12.4 (15.6)	0.58	
<b>Activities</b>					
TUG (s)	17.4 (9.3)	15.1 (7.8)	15.1(9.4)	0.01	a,b
<b>Gait parameter</b>					
Velocity (cm/s)	75.8 (33.7)	86.2 (34.9)	87.8 (33.6)	0.03	a,b
Cadence (steps/min)	89.2 (17.7)	93.9 (16.5)	94.8 (16.7)	0.12	
Step Length L (cm)	49.2 (16.7)	53.2 (16.6)	54.3 (16.5)	0.01	a,b
Step Length R (cm)	50.0 (15.8)	54.0 (16.3)	54.0 (16.1)	0.01	a,b
Stride Length L (cm)	98.5 (32.0)	107.4 (31.8)	108.6 (31.6)	0.01	a,b
Stride Length R (cm)	98.5 (32.1)	107.6 (32.2)	108.5 (31.5)	0.01	a,b
Falls	1.76 (3.6)	0.82 (2.2)	1.18 (2.9)	0.22	
<b>Participation</b>					
<b>PASIPD</b>					
Total	16.1 (12.3)	21.0 (13.8)	18.7 (13.5)	0.13	
Home Repair, lawn and garden	1.1 (2.1)	1.4 (3.0)	1.8 (4.7)	0.79	
Housework	2.9 (3.2)	4.1 (4.5)	4.1 (4.0)	0.14	
Vigorous sport and RA	2.3 (4.5)	3.7 (8.2)	3.4 (6.0)	0.17	
Light-moderate sport and RA	3.3 (4.4)	3.5 (4.3)	3.2 (3.7)	0.96	
Occupation and transport	7.9 (7.3)	8.3 (7.0)	6.1 (6.1)	0.44	

SF-36v2

Physical Functioning	35.3 (7.3)	38.3 (8.2)	38.6 (7.1)	0.20	
Role-Physical	37.5 (9.6)	40.8 (8.4)	41.4 (8.1)	0.41	
Bodily pain	42.7 (13.5)	46.9 (10.1)	47.1 (9.9)	0.18	
General Health	49.5 (8.5)	54.1 (8.6)	54.4 (9.1)	0.01	a,b
Vitality	47.2 (10.2)	51.7 (9.7)	52.8 (9.3)	0.09	
Social Functioning	43.2 (10.2)	52.3 (5.0)	49.7 (9.1)	0.01	a,b
Role-Emotional	47.2 (10.8)	49.2 (7.8)	48.8 (8.2)	0.73	
Mental Health	49.8 (10.4)	53.2 (6.9)	52.6 (8.1)	0.21	
Physical Component Summary	37.5 (6.3)	41.3 (7.3)	41.1 (6.9)	0.01	a,b
Mental Component Summary	51.8 (12.5)	56.3 (6.7)	55.2 (8.6)	0.16	

*Note.* Significant post-hoc, **a**= significant difference detected between BL and 6m, **b**= significant difference detected between BL and 12m; **BL**= average of 3 baseline value; **6m**= 6 months post-treatment initiation; **12m**=12 months post-treatment; **SD**= standard deviation; for measurement tool acronyms refer to Appendix A Glossary of Acronyms.

### 2.3.2 Qualitative

In this section I have reported the findings related to change (or lack thereof) from participant responses in the semi-structured interviews conducted at BL, 6m, and 12m.

The findings have been divided into two sections: description of the changes and participants' perception of factors attributable to the changes. Each section was discussed in terms of the domains of the ICF model, specifically: body functions and structures, activities and participation, and contextual factors (both personal and environmental).

#### *Perceptions of change*

Changes in body functions and structures included increased stamina, strength, and balance. This overall perception of improved physical health was repeatedly reported by participants. As Participant #49 said, "I have made quite the progress [...] I feel a lot more balance and stable [...] I think physically I am better off". Participant #39 who walks as part of his job, stated "I have noticed considerable improvement in my stamina, in being able to... like I'm walking considerably further with [clients]". Lastly, although



perceived less often, better limb (i.e. foot) positioning was noted. At 0m Participant #16 indicated that in relation to her equinovarus deformity arising from spasticity “I catch my left foot on my right heel”; but at 6 and 12m she reported improvements in the structure and functioning of her foot pertaining to swimming: “I feel more coordinated in the water [...] I kick better [...] because my left foot is straighter”. A lack of change or negative changes in body functions and structures were reported less often. When describing that there had been no change, some participants mentioned their continuing struggle with restrictions in upper limb function and structure as well as ongoing pain in various body parts. Others felt a sense of regression; a few participants mentioned increased pain and one participant felt weaker. Three participants with MS reported mobility challenges and muscle weakness related to disease progression.

Improvement in walking was the most commonly reported change in activity across participants. Participants reported increases in walking distance and duration; and walking was a common mode of exercise. Participants were able to readily monitor and report their progress in walking. For example, Participant #27 started participating in a local 10 kilometer (6.2 miles) fun run/walk as part of her post-stroke recovery. At the beginning of this intervention she reported that she walked the last 10 feet of the course. One year later she walked one kilometer (.62 miles) of the course, and this upcoming year she is “hoping to do 5k [3.1 miles]”. At the time of the 12m interview she was training on the treadmill and was walking two kilometers (1.2 miles). Furthermore, other topics embodying positive change in activities and participation included increased exercise variety and mode as well as increased participation in life roles. Participant #33 increased her walking capacity, started routinely stretching, and joined a circuit training

class; she noted gains not only on the activity level but also commented “[circuit training] is a way of getting me out to do that kind of thing [...] I appreciate being able to be a part of it actually”. Participant #35 not only reported increased walking volume but started exploring different walking terrains (i.e. trails and sidewalks). Moreover, the same participant, since gaining mobility, described her ability to attend and participate at Sunday church had significantly improved:

Ever since I got my walker I haven’t dreaded going to church every Sunday. It’s really helped me socialize; after the service is over there tends to be a coffee social time and before I couldn’t wait to get out of there because I needed to get off of my feet and now that I have my walker I can sit down when I’m talking to people and I don’t have to worry about tripping anyone or falling over or being exhausted.

Participation in domestic duties, both inside and outside the home, varied substantially among participants. Some participants reported increased capacity to do chores around the home such as baking and standing for washing dishes becoming “a little easier” (Participant #28). On the other hand, participants who mentioned either ‘upper limb restrictions as predominant barrier to housework’ or ‘no intention of participating in domestic roles’ from the start, explained that there was no change. Several participants that had been active in the community before the study also reported no change in activities or participation. These individuals had continued to participate in activities such as volunteering and used the same modes of transportation i.e. riding the bus and/or walking. There were very few negative changes in this domain; two participants who were working full-time when they started the study took medical leave (as suggested by the physician) and Participant #56, who was working full-time at the start, enrolled as a full-time student (positive change) and continued working part-time but consequently had to reduce her engagement in other activities.

Personal factors, such as age and motivation, are factors that are independent of the health condition but they influence how a person functions (WHO, 2001).

Participants in this study consistently reported enhanced self-confidence, greater independence, and feelings of security. For example, participants described improved sense of confidence to push themselves during physical activity, independence to go to places on their own, and security to partake in social events. One participant described the process of building confidence as “stretching that envelope a bit” (Participant #37). Another form of personal change conveyed by participants was a growing sense of self-acceptance and the development of coping strategies. Participant #39 described the following on the topic of self-acceptance:

[Being in the study] made me realize, yes I’m disabled and because I could now look at my disability, I actually... it was a growth in perspective. It’s how I can minimize my disability [...] by ignoring it I was not progressing and by focusing on it, it allowed me to accept it [...] I could grow...

New strategies included taking mini breaks during activities and planning when to do certain activities in order to conserve and capitalize on their energy levels. Another strategy was prioritizing life goals, such as not spreading one-self too thin over multiple commitments at the risk of a burn-out. Finally, those who expressed no personal change generally had positive attitudes and strategies they had been using for a long time (e.g. doing activities in “short-spurts” and planning tasks ahead of time).

Environmental contextual factors are the facilitators and barriers to participation that are not within the direct control of the individual (WHO, 2001). Although environmental factors were mentioned less often than personal factors; participants did mention several positive changes in their environment across the duration of the study, including: joining social or educational programs within their community and moving

into more accessible living arrangements. The weather was a significant and reoccurring barrier to participating in life roles and physical activity in particular. For some this had not changed and had always been an issue; for others, they reported the weather as a barrier more often in the winter months. As Participant #51 said “now that it’s winter time, my limbs and joints are a lot tighter than in the summer time” and he also mentioned that he goes outdoors for exercise less in the winter due to the rain.

#### *Attributions for change*

In terms of attributions for change, two major themes emerged. The first theme directly related to the multimodal intervention. While some participants credited the changes to the intervention as a whole; a majority of the participants described certain helpful aspects of the intervention. The second theme that emerged was related to enhanced self-perception, which was, previously described as a positive personal change (i.e. confidence and acceptance).

#### *Theme 1: Multimodal intervention – BTXA, physiotherapy, and orthoses*

As previously mentioned, perceived improvements in walking was the most prominent overall change. Participants most directly attributed increased walking capacity to the acquisition and use of gait aids (orthoses, walker, side sticks, and cane). A majority of the participants were fitted for a new AFO as part of the intervention program but they were also provided with any other necessary mobility devices (cane, walker, side sticks, etc.) as part of their physical therapy. Participant #33 described the AFO and cane as helpful in that “it does lift my foot up and I don’t feel like I’m going to trip as much [...] the cane, I feel more confident walking with it.” As expressed by this participant, new assistive devices for gait were often described as affording a sense of confidence and

safety which, in turn, affected walking capacity. For example, Participant #60 described that the AFO prescribed through the program assisted his gait but also "... provided me a level of freedom to get out and move about that wouldn't have or would not otherwise exist given where I am at". Similarly, the physiotherapy component of the intervention was also described as having both a direct and indirect effect on gait capacities: for example, increased physical health (e.g. strength, balance, and coordination) was achieved through increased levels of physical activity. Lastly, a few participants mentioned that the BTXA component of the intervention helped achieve better foot positioning. As Participant #33 explained "another Botox treatment can help straighten my foot out"; similarly, Participant #16 credited her improved swimming "kick", as described in the section on 'change' to the "physio and Botox". Participant #55 attributed both the reduction in pain in his calf muscles and his enhanced ambulation to the BTXA treatment "with the Botox I noticed huge improvements" (Participant #55). In general however, the BTXA injections were less often associated with specific changes; as Participant #51 said "um... the Botox... it's hard to figure it out, but I'm sure... because I don't have a way to gauge my improvements... but I know it has done some benefits to my body".

Not everyone felt that BTXA resulted in positive outcomes. Participant #59 felt that the BTXA injections were associated with adverse outcomes such as having reduced "feeling in her legs", "weakness", and feeling "heavy" as well as resultant difficulties in movement. Lastly, a few participants credited their overall gains (physical and/or mental) to being in a multi-component intervention. For those who did perceive this affordance, being a part of a program providing individualized treatment, multiple perspectives and

types of expertise, a multitude of strategies, and ongoing support throughout the duration of the study contributed to their improved health status.

*Theme 2: Perceptions of the self and new strategies*

Participants' described change in their sense of self and self-awareness; such as having a different understanding of their capacities and/or limits, less conditional self-acceptance (e.g. not viewing their disability as a negative barrier), and enhanced self-confidence (e.g. pushing their limits and exploring their own potential). Participant #39, for example, became more positive about exercising and he attributed this more positive outlook to greater self-acceptance, as he said "... I am letting go of this need to compare myself with my peers who are more capable". Similarly, although Participant #33 felt that her condition would continue to decline over time, she explained that "I don't feel quite so negative about the whole process [decrease in mobility] now [...] it's easier to cope".

Many participants conveyed a positive mental outlook and a greater sense of determination to participate in life roles such as exercise, housework, getting out and about with family and friends at both 6 and 12m. Self-confidence was expressed in many ways; "I think I walk more [...] I just feel more confident" (Participant #6) and "just being a little more gutsy [...] I just talk myself into it really" (Participant #28). Along with a greater sense of confidence, participants mentioned they had developed new strategies during the intervention that also bolstered their confidence and assisted their participation in activities and life roles. Several participants had learned that using assistive devices and pacing themselves could help their balance and fatigue; which in turn boosted their confidence. As Participant #35 explained:

I think overall things have changed for me in terms of the confidence I have that I can actually go out and go into a grocery store or go and walk on the breakwater or go wherever I go safely and that I can actually do it ...

## **2.4 Discussion**

The purpose of this study was to evaluate the efficacy of treating adults with chronic lower limb spasticity over a 12m period using a multimodal intervention comprising repeated BTXA injections, ongoing physiotherapy, and orthoses management. BTXA injections are costly and only provide temporary benefits (Foley et al., 2010) with increased potential for the development of neutralizing antibodies when used too frequently (Hawamdeh et al., 2007; Jankovic & Schwartz, 1995); therefore, it is recommended that BTXA be used in moderation and always in conjunction with non-pharmacological treatments to maximize its efficacy. Physical therapeutic strategies are more feasible, cost effective, and should be seen as a long-term lifestyle change as opposed to a temporary solution (McAuley et al., 2007). Because one-on-one physiotherapy intervention can be costly over time, a more realistic and long term approach is to provide hands on, formal physiotherapy initially, but eventually, under the physiotherapist's guidance, transition to an ongoing independent, self-managed physical activity program (Hale, Mulligan, Treharne, & Smith, 2013). The physiotherapy intervention in the current study followed this approach to provide greater generalizability to the real world.

This is one of the first studies in adults to employ the necessary breadth of clinical outcome measures to purposefully and systematically evaluate the impact of this intervention across all the domains of the ICF model as a means of addressing the complexity of this question. Overall stability was seen across the three baseline measurement as indicated by no significant differences. This suggests that the

improvements observed in these outcome measures over the course of the study can be attributed to the intervention. Over the 12m improvements were seen across all the domains of the ICF and these improvements were triangulated by both quantitative and qualitative measures. Improvements in body functions and structures were quantitatively demonstrated through reduced spasticity and clonus, and an increase in one component of ROM and qualitatively demonstrated through participants' descriptions of enhanced stability of joint functioning, increased exercise tolerance, endurance, stamina, strength, and improved joint position or flexibility. Thus the qualitative data reflects clinically significant changes in physical health. Within the activity domain, significant quantitative improvements seen in all measures of gait function as measured by the TUG and GAITRite mat were similarly reflected in the qualitative interviews where the majority of participants described enhanced walking capacity. The average gait velocity improvements, of greater than 10cm/s, seen in the current study are also considered clinically significant (Perera, Mody, Woodman, & Studenski, 2006). Further, the sample as a whole changed from limited community ambulators (0.4 – 0.8m/s) to full community ambulators (> 0.8m/s) (Perry, Garrett, Gronley, & Mulroy, 1995).

Some participants subjectively reported a reduced number of falls, although quantitative occurrence of falls did not show a significant reduction. In the qualitative interviews, participants consistently described appreciable increases in participation in physical activities such as joining a fun run/walk or a circuit training class, walking on different terrains or walking in church. However only one component (i.e. total score) of the quantitative PASIPD scale showed a significant increase from BL to 6m, which was not maintained at 12m. It is possible that the PASIPD tool lacks the sensitivity to detect



the increases in physical activity reported in the qualitative interviews. Regardless the PASIPD did demonstrate that the levels of physical activity in this sample were very low at both the start and the end of the study both overall and in each subcategory with a final overall average score of 21.0 out of 199.5 (Washburn et al., 2002). In contrast the QOL survey did triangulate the qualitative findings and showed significant changes in the 'physical component summary' and 'general health', at 6 and 12m. The QOL survey also showed improvement in 'social functioning' which was reflected in the participants' accounts of increased participation at work, at home, in social events, and at leisure pursuits.

It is important to keep in perspective that this is a highly vulnerable group of chronically disabled individuals. Amongst individuals with disabilities, such as the participants in this study, deterioration in functional capacity can be more pronounced relative to non-disabled counterparts and it may begin at an earlier age as is seen in MS (Compston & Coles, 2008; Motl, McAuley, & Snook, 2005; Tutuncu et al., 2013), stroke (Pettersen, Dahl, & Wyller, 2002), CP (Houlihan, Opheim, Jahnsen, Olsson, & Stanghelle, 2009; Opheim, Jahnsen, Olsson, & Stanghelle, 2012), and SCI (Hitzig, Eng, Miller, & Sakakibara, 2011; Scivoletto et al., 2008). Medical complications (e.g. concomitant illness or disease progression) can contribute to deterioration in functional capacity (Deeg, 2005; Durstine et al., 2000; Pettersen et al., 2002; Stuifbergen et al., 2006). Therefore, in this population, attenuation of physical deterioration and/or maintenance of current levels of physical functioning is, in itself, a successful outcome (Durstine et al., 2000). Overall in the present study, outcomes measures improved or

were not significantly changed over the 12m, all of which could be considered clinically significant outcomes.

The 12m duration of the study was critical to allow time to observe how long it took for changes to occur and if these changes could be maintained longer term. For example, 12/37 measures were significantly improved at 6m and all were maintained until 12m. Moreover, only 1/37 measures did not improve until the final assessment. This was the first study to evaluate changes over long-term (12-17m range) within the adult population experiencing chronic lower limb spasticity resulting from mixed clinical diagnoses. Having a longer duration study also demonstrated the ability to maintain changes that occurred at 6m through until 12m. This is relevant to note because majority of the BTXA and orthotic interventions took place in the first 6m of the study. For example, 44 BTXA injections and all but one orthoses adjustments and/or the implementation of new assistive devices were delivered in the first 6m and within the second half, only 25 BTXA injections were delivered.

To ensure outcome measures spanned the domains of the ICF model it was essential to have a mixed-method approach. To my knowledge this study is the first to use a mixed-method approach to evaluate the efficacy of this type of multimodal intervention in adult populations with chronic spasticity. A mixed-methods approach is defined as “[T]he collection and analysis of both quantitative and qualitative data in a single study in which the data are collected concurrently or sequentially, are given a priority, and involves the integration of the data at one or more stages in the process of research” (Creswell, Plano Clark, Gutmann, & Hanson, 2003, p. 212). Mixed-method designs are used to enrich the understanding of individual experiences as it utilizes the

strengths from both qualitative and quantitative research, while providing different perspectives on the same topic (Bazley, 2002). Thus, a mixed-method approach allows for triangulation of data sources and types to take advantage of both the representativeness and generalizability of quantitative findings, and the rich contextual contributions of qualitative data (Punch, 1998). Using a mixed-method design in the current study provided a more sophisticated understanding of the research questions (Hanson, Creswell, Clark, Petska, & Creswell, 2005; Mertens, 2003) and allowed for the interactions within and between the two levels of the ICF model, ‘functioning and disability’ and ‘contextual factors’ to be better understood.

For example, within the level of functioning and disability, improvements in equinovarus foot deformity (body function and structure) lead to enhanced swimming abilities (activity). Further, the acquired AFO facilitated proper foot positioning (body functions and structures) during walking resulting in fewer falls and ultimately increased activity. Additionally, improvements in walking capacity (activity) facilitated grocery shopping ability as well as engagement in social gatherings (participation). Within the contextual factors, participants consistently reported increased self-confidence (personal) which influenced them to start walking in various environments, such as on busy streets and shopping malls (environment). Further, some participants reported increased self-awareness (personal) about their disability and improved self-acceptance; this for some, resulted in increased willingness to use assistive mobility devices (environmental). These contextual changes consisting of, increased self-confidence coupled with the acquisition of new assistive devices and advice from the multidisciplinary clinical team, was reported by participants to facilitate their participation in life roles such as exercising, work related

activities, home duties, socializing, and leisure pursuits. Thus there was clearly an interaction between and within the multiple domains of the ICF model.

Lastly there are several limitations associated with this study. It is a single-centre, study with a small sample size, and no randomized control group. The small sample and the lack of control group are related to challenges with participant recruitment and retention. The long term 12m design in a sample like this with so many comorbidities, or in some cases a progressive condition, led to many participants no longer meeting the inclusion criteria over the course of the study or choosing to withdraw. Moreover, the gold standard approach (double-blind randomized controlled trial) is debatably not the most appropriate due to its typical short-term duration and ethical issues around withholding treatment from medically vulnerable individuals. Accordingly, despite low generalizability of a single-subject study, there is support for the use of a single-subject design to comprehensively evaluate treatment outcomes (Pierson, 1997). Another limitation was that some participants with progressive MS, whose data is included, reported feelings of relapse at unexpected times throughout the study which likely influenced their performance on some of the outcomes. Specifically, one participant in particular reported experiencing a relapse the month prior to the 12m assessment which was reflected as decline in her 12m results. Another limitation involved the rolling recruitment process that occurred over the course of study which overall lasted approximately two and a half years. This meant that participants were starting and finishing the study at different times in the year where the weather may have influenced the outcomes measured. In addition, the potential poor tool sensitivity of the PASIPD tool perhaps influenced the lack of quantitative improvements in physical activity levels.

Lastly, because participants lived in diverse areas and had limited funds, it was difficult to standardize the physiotherapy intervention across participants. However, even if increased funds allowed for greater standardization of the physiotherapy intervention this would not be reflective of real life which was a goal of this study.

## **2.5 Conclusion**

To my knowledge this is the first study in adults, investigating chronic lower limb spasticity, to employ the necessary breadth of clinical outcome measures, including a mixed-methods design, to purposefully and systematically evaluate the impact of a multimodal intervention across all domains of the ICF over time. Evidently, there exists a complex interrelationship between this common impairment, body functions and structures, and the contextual factors experienced by individuals with UMNL. The multimodal intervention, when implemented wholly and accordingly, to suit individual needs both feasibly and sustainably, resulted in overall positive outcomes across both levels of the ICF model. Participants as a whole experienced significant reduction in spasticity and clonus, acquired and accepted a variety of new mobility aids, and increased their exercise tolerance and overall physical health which, more holistically, precipitated an enhanced perception of satisfaction with life over the course of a year.

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## Appendix A Glossary of Acronyms

Activities of Daily Living: ADL

Active Knee Extended Dorsiflexion: AKEDF

Active Knee Flexed Dorsiflexion: AKFDF

Ankle-Foot-Orthosis: AFO

Ankle Plantar Flexors Tone Scale: APFTS

Botulinum Toxin Type A: BTXA

Central Nervous System: CNS

Cerebral Palsy: CP

Computed Axial Tomography: CAT scan

Electromyography: EMG

Final Range Resistance: FRR

Gaitrite mat sytem: GAITRite

Incomplete Spinal Cord Injury: iSCI

International Classification of Functioning, Disability and Health model: ICF model

International Classification of Functioning, Disability and Health for Children and Youth model: ICF-CY model

Knee extended: KE

Knee flexed: KF

Left: L

Middle Range Resistance: MRR

Modified Ashworth Scale: MAS

Modified Tardieu Scale: MTS

Months: m

Multiple Sclerosis: MS

Numeric Rating Scale: NRS

Passive Knee Extended Dorsiflexion: PKEDF

Passive Knee Flexed Dorsiflexion: PKFDF

Physical Activity Survey for Individuals with Physical Disabilities: PASIPD

Pre-treatment: PRE

Quality of Life: QOL

Randomized Controlled Trial: RCT

Range of Motion: ROM

Recreational Activities: RA

Right: R

Short-Form 36 Version 2 Health Survey: SF-36v2 Health Survey

Spinal Cord Injury: SCI

Standardized Mini-Mental State Exam: SMMSE

Stretch Reflex: SR

Support Programme for Assembly of Database for Spasticity Management: SPASM

Timed-get-Up and Go test: TUG

Traumatic Brain Injury: TBI

Units: U

University of Victoria: UVic

Upper Motor Neuron Lesion: UMNL

Upper Motor Neuron Syndrome: UMNS

Vancouver Island Health Authorities: VIHA

Visual Analogue Scale: VAS

World Health Organization: WHO

## Appendix B Recruitment Script

The subsequent script will be followed by QACCH Spasticity Clinic Administrative Assistant when she/he has identified a potential participant for the study.

QACCH is currently involved in a study exploring the outcomes of receiving a combination of Botox, physiotherapy and bracing on mobility and aspects of quality of life. This study is being conducted in conjunction with researchers from the University of Victoria. I believe you may meet the eligibility criteria to participate in the study. Participating or not participating in the study does not influence your access to or the type of treatment you will receive. Would you be interested in hearing more about this study to determine whether or not you are interested in participating?

Please know that if you do decide to participate, you may withdraw at any time without any consequences or any explanation and agreeing to hear more about the study does not commit you to participating.

**If yes:** May a member of the research team from contact you directly by phone?

### Appendix C Recruitment Script for UVic Researcher

Hello, this is [Name] from the University of Victoria calling on behalf of the study being conducted by Dr. Quartly and the University of Victoria.

May I please speak with [contact]?

*a. Speaking                      or b. if new person comes to phone repeat beginning*

It is my understanding that [you or Name of client and contact if appropriate] is/are interested in hearing more about the study that was mentioned to you by Robin, Dr. Quartly's receptionist.

*a. No. ....That's fine, Dr. Quartly will see you at your scheduled appointment for your regular treatment.*

*or b. Yes.*

The aim of the study is to explore the outcomes of receiving the combination of therapies that you may be receiving, specifically Botox, physiotherapy and bracing on your mobility and quality of life. Our hope is that information gained from this study will help inform clinical practice in other regions.

There are a number of measures that will be taken over the course of your regular treatment over the next year that we would like your permission to track to determine whether there is a change. For example, the amount of movement you have at your ankle joint will be measured by Dr. Quartly and the physiotherapist. The treatment will be the same regardless of participation in the study.

In addition to the measures normally collected by the doctor, we would also like you to track your number of falls and complete two surveys about physical activity and quality of life. Each survey will be completed 4 times over the year.

At your first visit with Dr Quartly we would gather some of this information, so your appointment would be ½ an hour to 45 minutes longer. And you would have one extra visit of about 30 minutes after you initial assessment to confirm the initial measures. These 2 surveys would then be completed at 6 months and at one year.

Are you interested in participating in the study? If you are not interested, this in no way affects your treatment.

*a. No. Thank you for your time, we hope your treatment goes well.*

*b. YES. Great! The receptionist, Robyn, at the Spasticity clinic will either call to book the second appointment or she will do this at your scheduled assessment. Thank you and we will see you on [date].*

***If leaving message:***

Hello, this is [Name] from the University of Victoria calling on behalf of the study being conducted by Dr. Quartly and the University of Victoria.

I wanted to provide you with more information about the study. If possible could you please call 250-853-3144 and leave a message indicating when would be good time of day for me to contact you.

Thank you.



## Appendix D Consent Form (original)



### *Participant Consent Form*

#### **Using Botulinum Toxin A, bracing and physiotherapy to treat spasticity in individuals with neurological conditions.**

You are being invited to participate in a study entitled "*Using Botulinum Toxin A, bracing and physiotherapy to treat spasticity in individuals with neurological conditions*" that is being conducted by the Queen Alexandra Spasticity Clinic and the School of Exercise Science, Physical Health and Education at the University of Victoria. The research team members are:

Dr. Sandra Hundza	University of Victoria
Dr. Vivienne Temple	University of Victoria
Ms. Jill Dobrinsky	University of Victoria
Ms. Iris Loots	University of Victoria
Ms. Jasmine Kim	University of Victoria
Ms. Kim Choy	University of Victoria
Ms. Brayley Chow	University of Victoria
Dr. Caroline Quartly	VIHA and the Queen Alexandra Spasticity Clinic
Dr. Mike Rocheleau	VIHA and the Queen Alexandra Spasticity Clinic
Ms. Alexis Hampshire	VIHA and the Queen Alexandra Spasticity Clinic
Mr. Jamie Dunnett	VIHA and the Queen Alexandra Spasticity Clinic
Mr. Alan Plouffe	VIHA and the Queen Alexandra Spasticity Clinic
Mr. Gray Eakins	VIHA and the Queen Alexandra Spasticity Clinic
Ms. Lynn Purves	VIHA and the Queen Alexandra Centre

Please feel free to contact Dr. Hundza at (250) 721-8387 <[shundza@uvic.ca](mailto:shundza@uvic.ca)> or Dr. Temple at (250) 721-8373 <[vtemple@uvic.ca](mailto:vtemple@uvic.ca)> if you have any questions.

The project will evaluate the effects of using a combination of therapy methods (Botulinum Toxin A, bracing, and physiotherapy) being provided by the Spasticity Clinic to improve mobility and increase quality of life for people experiencing spasticity, where muscles are overactive and tight. University of Victoria researchers will work with the Spasticity Clinic staff to evaluate the effects of the combination therapy on movement of the ankle joint, your ability to move around, pain, physical activity, and how you feel about your health (health-related quality of life).

Spasticity management is important to improve mobility, decrease pain, increase physical activity, and enhance quality of life and this has benefits to overall health. The benefits of this combination of therapies has not been established.



You are being asked to participate in this study because you will be receiving this combination of therapies for spasticity in your lower limb. The therapies are provided as part of your normal clinical care and are independent of the research study. Each participant's involvement in the study will occur over a 14 month period which coincides with your therapy at the Spasticity Clinic. If you agree to voluntarily participate in this research, your participation will involve completing the following: quality of life and physical activity questionnaires (collected four times) and a record of falls (if a fall occurs at each visit). We will also require access to assessment data routinely collected by the Spasticity Clinic clinicians at each appointment; specifically: movement of the ankle joint, measures of mobility (e.g. walking speed), pain, and spasticity. These measures and when each will be recorded are outlined in the 2 pages attached to this consent form. All therapy and assessment will be conducted at the Queen Alexandra Spasticity Clinic.

There is some inconvenience to you from this research. To establish a baseline level of functioning and mobility we will ask you to complete all of the measures prior to the your therapy commencing.

There is the possibility that you may uncomfortable answering questions about physical activity and quality of life. You do not have to answer any questions you do not wish to.

Participation in this research must be completely voluntary and we will confirm your ongoing consent every three months. Choosing not to participate in this study will in no way affect your clinical therapy or access to Spasticity Clinic services (i.e. treatment received will be the same whether you choose to participate or not). If you decide to participate, you may withdraw at any time without any consequences or any explanations. Choosing to withdraw from the study will in no way effect your therapy or access to the Queen Alexandra Spasticity Clinic. The Spasticity Clinic health care professionals (i.e. doctor, physiotherapist, and orthotist) will be providing your clinical care and are part of the research team; however these health care professionals will not be involved in the recruitment or consent process. If you do withdraw from the study your data will be used for statistical analysis if you give your permission to use your data, but the data will be destroyed if you do not give permission.



Your confidentiality and the confidentiality of the data will be protected by removing identifying information from the assessment as by using numerical codes for the data rather than names. Data will be stored in a locked cabinet or a password protected computer in the Institute of Physical Activity and Health Research at the University of Victoria. Electronic data will be erased and the paper files will be shredded after 5 years from the completion of the study.

A report of the findings of this study will be provided to the health care clinicians of the Vancouver Island Health Authority. We also anticipate that the findings will be presented at scientific conferences and published in scholarly journal articles and in graduate student theses. If you are interested in receiving a copy of the final report you may upon request.

You may verify the ethical approval of this study, or raise any concerns you might have, by contacting the Human Research Ethics Office at the University of Victoria at 250-472-4545 or [ethics@uvic.ca](mailto:ethics@uvic.ca) and the VIHA Research Ethics office at 250-370-8620.

Your signature below indicates that you understand the above conditions of participation in this study and that you have had the opportunity to have your questions answered by the researchers.

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*Name of Participant*

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*Signature*

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*Date*

### **Ongoing consent 1**

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*Name of Participant*

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*Signature*

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*Date*

**Ongoing consent 2**

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<i>Name of Participant</i>	<i>Signature</i>	<i>Date</i>
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**Ongoing consent 3**

\_\_\_\_\_

<i>Name of Representative</i>	<i>Signature</i>	<i>Date</i>
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*A copy of this consent will be left with you, and a copy will be taken by the researcher.*

## Appendix E Consent Form (modified)



### *Participant Consent Form*

#### **Using Botulinum Toxin A, bracing and physiotherapy to treat spasticity in individuals with neurological conditions**

You are being invited to participate in a study entitled “*Using Botulinum Toxin A, bracing and physiotherapy to treat spasticity in individuals with neurological conditions*” that is being conducted by the Queen Alexandra Spasticity Clinic and the School of Exercise Science, Physical Health and Education at the University of Victoria. The research team members are:

Dr Sandra Hundza	University of Victoria
Dr Vivienne Temple	University of Victoria
Ms. Jasmine Kim	University of Victoria
Ms. Iris Loots	University of Victoria
Dr Caroline Quartly	VIHA and the Queen Alexandra Spasticity Clinic
Mr. James Dunnett	VIHA and the Queen Alexandra Spasticity Clinic
Mr. Alain Plouffe	VIHA and the Queen Alexandra Spasticity Clinic
Ms. Emily Northcote	VIHA and the Queen Alexandra Spasticity Clinic
Mrs. Brianna Myring	VIHA and the Queen Alexandra Spasticity Clinic
Ms. Alexis Hampshire	VIHA and the Queen Alexandra Spasticity Clinic

Please feel free to contact Dr. Hundza at (250) 721-8387 <[shundza@uvic.ca](mailto:shundza@uvic.ca)> or Dr. Temple at (250) 721-8373 <[vtemple@uvic.ca](mailto:vtemple@uvic.ca)> if you have any questions.

The project will evaluate the effects of using a combination of therapy methods (Botulinum Toxin A, bracing, and physiotherapy) being provided by the Spasticity Clinic to improve mobility and increase quality of life for people experiencing spasticity; where muscles are overactive and tight. University of Victoria researchers will work with the Spasticity Clinic staff to evaluate the effects of the combination therapy on movement of the ankle joint, your ability to move around, pain, physical activity, and how you feel about your health (health-related quality of life).

Spasticity management is important to improve mobility, decrease pain, increase physical activity, and enhance quality of life and this has benefits to overall health. The benefit of this combination of therapies has not been established.



You are being asked to participate in this study because you will be receiving this combination of therapies for spasticity in your lower limb. The therapies are provided as part of your normal clinical care and are independent of the research study. Each participant's involvement in the study will occur over a 14 month period which coincides with your therapy at the Spasticity Clinic. If you agree to voluntarily participate in this research, your participation will involve completing the following: quality of life and physical activity questionnaires (collected four times), a few specific questions about supports and barriers to engaging in physical activity and a record of falls (if a fall occurs at each visit). We will also require access to assessment data routinely collected by the Spasticity Clinic clinicians at each appointment; specifically: movement of the ankle joint, measures of mobility (e.g. walking speed), pain, and spasticity. These measures and when each will be recorded are outlined in the 2 pages attached to this consent form. All therapy and assessment will be conducted at the Queen Alexandra Spasticity Clinic.

There is some inconvenience to you from this research. To establish a baseline level of functioning and mobility we will ask you to complete all of the measures prior to your therapy commencing.

There is the possibility that you may uncomfortable answering questions about physical activity and quality of life. You do not have to answer any questions you do not wish to.

Participation in this research must be completely voluntary and we will confirm your ongoing consent every three months. Choosing not to participate in this study will in no way affect your clinical therapy or access to Spasticity Clinic services (i.e. treatment received will be the same whether you choose to participate or not). If you have 3<sup>rd</sup> party medical insurance that could cover the costs of the bracing and physiotherapy associated with the study you will be asked to access these sources. However if you do not have such coverage then the costs of your bracing and physiotherapy associated with the study will be covered through the study.

If you decide to participate, you may withdraw at any time without any consequences or any explanations. Choosing to withdraw from the study will in no way affect your therapy or access to the Queen Alexandra



Spasticity Clinic. The Spasticity Clinic health care professionals (i.e. doctor, physiotherapist, and orthotist) will be providing your clinical care and are part of the research team; however these health care professionals will not be involved in the recruitment or consent process. If you do withdraw from the study your data will be used for statistical analysis if you give your permission to use your data, but the data will be destroyed if you do not give permission.

Your confidentiality and the confidentiality of the data will be protected by removing identifying information from the assessment as by using numerical codes for the data rather than names. Data will be stored in a locked cabinet or a password protected computer in the Institute of Physical Activity and Health Research at the University of Victoria. Electronic data will be erased and the paper files will be shredded after 5 years from the completion of the study.

A report of the findings of this study will be provided to the health care clinicians of the Vancouver Island Health Authority. We also anticipate that the findings will be presented at scientific conferences and published in scholarly journal articles and in graduate student theses. If you are interested in receiving a copy of the final report you may upon request.

You may verify the ethical approval of this study, or raise any concerns you might have, by contacting the Human Research Ethics Office at the University of Victoria at 250-472-4545 or [ethics@uvic.ca](mailto:ethics@uvic.ca) and the VIHA Research Ethics office at 250-370-8620.



Your signature below indicates that you understand the above conditions of participation in this study and that you have had the opportunity to have your questions answered by the researchers.

<i>Name of Participant</i>	<i>Signature</i>	<i>Date</i>
----------------------------	------------------	-------------

**Ongoing consent 1**

<i>Name of Participant</i>	<i>Signature</i>	<i>Date</i>
----------------------------	------------------	-------------

**Ongoing consent 2**

<i>Name of Participant</i>	<i>Signature</i>	<i>Date</i>
----------------------------	------------------	-------------

**Ongoing consent 3**

<i>Name of Representative</i>	<i>Signature</i>	<i>Date</i>
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***A copy of this consent will be left with you, and a copy will be taken by the researcher.***



## Appendix F Data Collection Form

Queen Alexandra Spasticity Clinic Project

PARTICIPANT ID#: \_\_\_\_\_

DATE: \_\_\_\_\_

### ROM

What side of the Body \_\_\_\_\_

	PASSIVE						ACTIVE			
	KNEE FLEXED		KNEE EXTENDED				KNEE FLEXED		KNEE EXTENDED	
Ankle	Indicate DF or PF		Indicate DF or PF		Resting Attitude		Indicate DF or PF END RANGE only		Indicate DF or PF END RANGE only	
Talo-crural	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left
Forefoot										
Knee ROM										

*Indicate dorsiflexed or plantar flexed for DF range*

### ANKLE PLANTAR FLEXORS TONE SCALE

<b>SUPINE</b>											
KNEE FLEXED						KNEE EXTENDED					
Stretch Reflex		Middle Range Resistance		Final Range Resistance		Stretch Reflex		Middle Range Resistance		Final Range Resistance	
Right	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left

### ANKLE CLONUS TEST

<b>SUPINE (# of beats)</b>			
Knee Flexed		Knee Extended	
Right	Left	Right	Left

### TUG

Score (seconds)	
Aid Used	

### FIM

SCORE (1-7)	
-------------	--

## Appendix G APFTS

Queen Alexandra Spasticity Clinic Project

### ANKLE PLANTAR FLEXORS TONE SCALE

#### Point of Note:

- All tests are measured by passive dorsiflexion from position of maximum plantarflexion to position of maximum dorsiflexion.
- All tests are performed 3 times, and the highest score is recorded.
- Results of measurement are compared with the nonparetic side in case of hemiplegia.
- Stretch reflex measures neurologic muscle reaction to passive movement.
- Middle range resistance measures resistance with passive movement, not including resistance of the final range.
- Final range resistance measures the resistance necessary to maintain the final position (i.e., excluding middle range resistance).

#### Velocity of Passive Dorsiflexion:

- Stretch reflex: As fast as possible
- Middle range resistance: As slow as possible
- Final range resistance: As slow as possible

#### Position:

- All measurements are given for the knee extended and knee flexed at 90° in a supine position.
- Beginning position of passive movement is the position of maximum ankle plantar flexion.
- When this method is difficult, the rater must record the difficulty.

#### Scoring:

Middle Range Resistance		Final Range Resistance		Stretch Reflex	
0	No resistance	0	No resistance	0	No twitch
1	Mild resistance, slight increase in resistance	1	Mild resistance, slight increase in resistance	1	Twitch and no clonus
2	Moderate resistance, greater increase in resistance	2	Moderate resistance, greater increase in resistance	2	Mild clonus, persisting <3s
3	Severe resistance, considerable increase in resistance, but able to achieve passive movement	3	Severe resistance, considerable resistance, but able to maintain final position	3	Moderate clonus, persisting 3-10s
4	Passive movement is difficult	4	Unable to maintain final position or passive movement is difficult	4	Severe clonus, persisting >10s

## Appendix H TUG

### MOBILITY: TIMED GET UP AND GO TEST (Podsiadlo & Richardson, 1991)

#### Equipment

- straight-backed armchair with a seat height of 46 cm
- one pylon
- stopwatch
- measuring tape
- masking tape



#### Positioning and preparation

- Place a piece of tape 3 metres from the front of the chair and place the pylon on the middle of the tape.
- Ensure the chair is stable and will not move when the participant moves from sit to stand or sits down
- Participant should be wearing regular footwear, may use usual walking aid if needed, and sitting with their back resting on the back of the chair.

#### Instructions to the participant

"Sit with your back against the chair and your arms on the arm rests. On the word 'go,' stand upright, then walk at your normal pace around the cone, walk back to the chair, and sit down."

#### Timing

The stopwatch is started on the word 'go' and stopped when the participant has returned to the starting position (i.e. buttocks touch seat).

Time the second effort

#### Interpretation

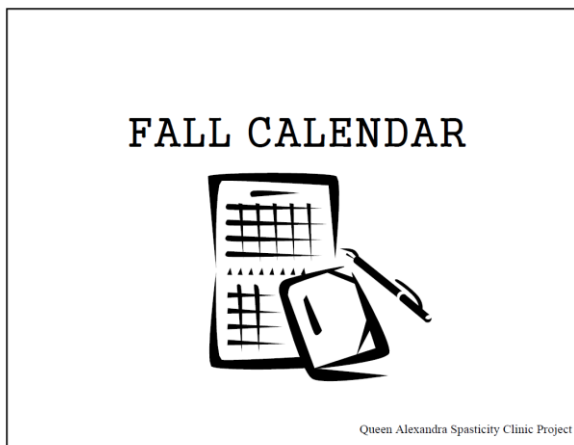
Values for healthy older adults: 8.1 (7.1–9.0) seconds for 60 to 69 year olds, 9.2 (8.2–10.2) seconds for 70 to 79 years, and 11.3 (10.0–12.7) seconds for 80 to 99 years (Bohannon, 2006). Participants whose performance exceeds the upper limit of reported confidence intervals can be considered to have worse than average performance. Cognitive functioning impacts time in 70+ individuals (Pondal & del Ser, 2008).

Bohannon, R. W. (2006). Reference values for the timed up and go test: A descriptive meta-analysis. *Journal of Geriatric Physical Therapy, 29*, 64-68.

Podsiadlo, D., & Richardson, S. (1991). The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *Journal of the American Geriatrics Society, 39*, 142-148.

Pondal, M., & del Ser, T. (2008). Normative data and determinants for the timed "up and go" test in a population-based sample of elderly individuals without gait disturbances. *Journal of Geriatric Physical Therapy, 31*, 57-63.

## Appendix I Excerpt of Fall Calendar



**July 2010**

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

♦ Please mark the calendar date with an 'X' if you have any fall, including a slip or trip, in which you lost your balance and landed on the floor or ground or lower level.  
 ♦ For each fall marked above (i.e. each 'X'), complete a section located at the back of the calendar.

**- Fall Calendar -**

Please use this calendar to record any falls, including slips or trips, in which you lost your balance and landed on the floor or ground or lower level. For each fall, mark the date on the calendar with an 'X' and complete a section describing your fall.

Example:

**Date of Fall:** October 3  
**Location:** (e.g. garden, sidewalk, kitchen, bedroom) front steps of home  
**Activity:** (e.g. walking, standing, up/down stairs, turning) walking down stairs  
**Cause:** (e.g. misjudgement, tripped, loss of balance, slipped) misjudged step and tripped  
**Weather and Time of day:** (e.g. morning, evening, raining, icy) raining / morning  
**Resulting Injury:** (e.g. fracture, bruise) small cut

Fall recording sheets are attached at the back of the calendar.

It is important that you bring your calendar with you to every appointment at the Spasticity Clinic.

Thank you!

**Date of Fall:** July 7  
**Location:** (e.g. garden, sidewalk, kitchen, bedroom) Garden  
**Activity:** (e.g. walking, standing, up/down stairs, turning) standing up  
**Cause:** (e.g. misjudgement, tripped, loss of balance, slipped) loss of balance  
**Weather and Time of day:** (e.g. morning, evening, raining, icy) Sunny and dry / Afternoon  
**Resulting Injury:** (e.g. fracture, bruise) No injury

**Date of Fall:** \_\_\_\_\_  
**Location:** (e.g. garden, sidewalk, kitchen, bedroom) \_\_\_\_\_  
**Activity:** (e.g. walking, standing, up/down stairs, turning) \_\_\_\_\_  
**Cause:** (e.g. misjudgement, tripped, loss of balance, slipped) \_\_\_\_\_  
**Weather and Time of day:** (e.g. morning, evening, raining, icy) \_\_\_\_\_  
**Resulting Injury:** (e.g. fracture, bruise) \_\_\_\_\_

**Date of Fall:** \_\_\_\_\_  
**Location:** (e.g. garden, sidewalk, kitchen, bedroom) \_\_\_\_\_  
**Activity:** (e.g. walking, standing, up/down stairs, turning) \_\_\_\_\_  
**Cause:** (e.g. misjudgement, tripped, loss of balance, slipped) \_\_\_\_\_  
**Weather and Time of day:** (e.g. morning, evening, raining, icy) \_\_\_\_\_  
**Resulting Injury:** (e.g. fracture, bruise) \_\_\_\_\_

**Date of Fall:** \_\_\_\_\_  
**Location:** (e.g. garden, sidewalk, kitchen, bedroom) \_\_\_\_\_  
**Activity:** (e.g. walking, standing, up/down stairs, turning) \_\_\_\_\_  
**Cause:** (e.g. misjudgement, tripped, loss of balance, slipped) \_\_\_\_\_  
**Weather and Time of day:** (e.g. morning, evening, raining, icy) \_\_\_\_\_  
**Resulting Injury:** (e.g. fracture, bruise) \_\_\_\_\_

## Appendix J Pain Scale

Queen Alexandra Centre Spasticity Clinic Project

### Pain Numeric Rating Scale/Visual Analogue Scale

Date: \_\_\_\_\_

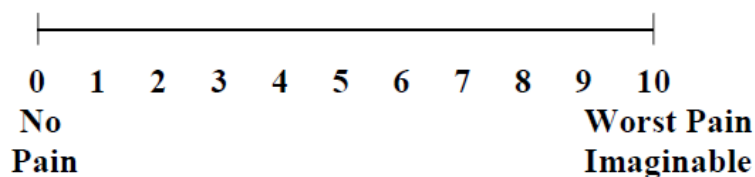
Participant: \_\_\_\_\_

Participant ID#: \_\_\_\_\_

*Ask the patient to rate his or her pain by indicating with a mark on the line. The numeric value of 0 indicates no pain and 10 represents the worst pain imaginable. Verbally ask the patient each question and record pain location.*

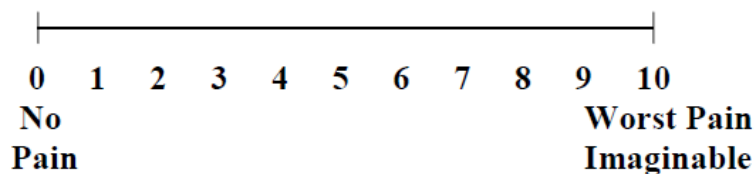
When you're walking, do you consistently have pain in any particular joint in your lower body? Please rate your pain by indicating a mark on the line. The numeric value of 0 indicates no pain and 10 represents the worst pain imaginable.

**1. On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your pain RIGHT NOW.**

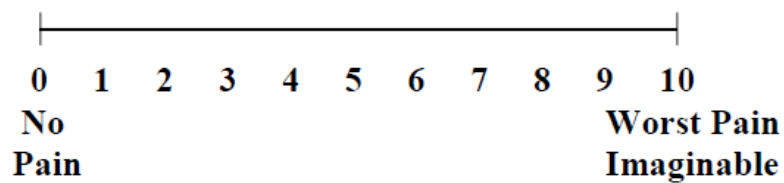


Pain Location: \_\_\_\_\_

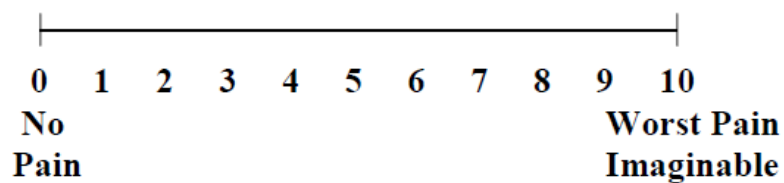
**2. On the same scale, how would you rate your USUAL level of pain during the last week.**



**3. On the same scale, how would you rate your BEST level of pain during the last week.**



**4. On the same scale, how would you rate your WORST level of pain during the last week.**



**Appendix K GAITRite****Gait Parameters  
Data Collection**

Date: \_\_\_\_\_

Participant: \_\_\_\_\_

Participant ID: \_\_\_\_\_

<b>Parameters</b>	
Velocity (cm/sec)	
Cadence (Steps/Min)	

<b>Bilateral Parameters</b>	<b>Left Foot</b>	<b>Right Foot</b>
Step Length (cm)		
Stride Length (cm)		

## Appendix L SMMSE & Clock

### STANDARDIZED MINI-MENTAL STATE EXAM

Participant: \_\_\_\_\_ ID #: \_\_\_\_\_ Date: \_\_\_\_\_

"I'm going to ask you some questions and give you some problems to solve. Please try to answer as best as you can."

	SCORE										
<b>ORIENTATION (10s for each reply)</b> What year is this? (accept exact answer only)	/1										
What season is this? (accept either last week of new season or first week of old season)	/1										
What month is this? (accept either 1 <sup>st</sup> day of new month or last day of previous month)	/1										
What is today's date? (accept previous or next day)	/1										
What day of the week is this? (accept exact answer only)	/1										
<b>(10s for each reply)</b> What country are we in? (exact answer only for all)	/1										
What province are we in?	/1										
What city are we in?	/1										
What is the name of this building? (accept QA, Spasticity clinic or fisher building)	/1										
What floor of the building are we on? (accept exact answer only)	/1										
<b>REGISTRATION (20s)</b> "I'm going to check your memory now. I'm going to say three words that I want you to remember. When I'm finished I want you to repeat them. Remember what they are because I'm going to ask you to rename them again in a few minutes" Name three words (bell jar fan). One second to say each. Then ask the patient to repeat all three after you have said them until they learn them, max 5 times. *do not use 'man' or 'car' (score 1 point for each correct reply on the first attempt.)	/3										
<b>ATTENTION AND CALCULATION (30s)</b> Spell the word "WORLD". You may help them spell it correctly. "Now spell it backwards please" (if the subject cannot spell world even with assistance, score 0.)	/5										
<table border="1" style="margin: auto;"> <tr> <td style="width: 20px; text-align: center;">D</td> <td style="width: 20px; text-align: center;">L</td> <td style="width: 20px; text-align: center;">R</td> <td style="width: 20px; text-align: center;">O</td> <td style="width: 20px; text-align: center;">W</td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </table>	D	L	R	O	W						
D	L	R	O	W							
<b>RECALL (10s)</b> "Now what were the 3 words I asked you to remember?" (Score one point for each correct answer.)	/3										
<b>LANGUAGE (10s each)</b> [show wristwatch] "What is this called?" (accept wristwatch or watch. Not clock or time) [show pencil – not mechanical] "What is this called?" (accept pencil, not pen)	/1 /1										
<b>REPEAT (10s)</b> "I would like you to repeat a phrase after me. 'No ifs, and, or buts.'" (score 1 point for exact phrase)	/1										



<b>READ and OBEY (10s)</b> "I want you to read the words on the page and do what it says" [hand the person the 'close your eyes' sheet.] if the subject does not obey you may repeat instructions (max 3 times) (score 1 point only if subject closes eyes. Do not have to read aloud)	/1
<b>WRITTEN SENTENCE (30s)</b> [hand the person a pencil and paper / note Hand Dominance___] "write any complete sentence on that piece of paper." (score 1 point. The sentence must make sense. Ignore spelling errors)	/1
<b>DESIGN (1 min)</b> [place design, eraser, and pencil in front of the person.] "copy this design please." Allow multiple tries. Wait until the person is finished and hands it back. (score 1 point for correct copied diagram. Person must have drawn a 4-sided figure between two 5-sided figures.)	/1
<b>HAND DOMINANCE (30s)</b> [hand the paper in the middle of their 2 hands] "take this paper in your left/right (non-dominant) hand. Fold the paper half and drop it on the floor." (score 1 point for each instruction executed correctly. Allowed to fold with 2 hands.)	
	Takes paper in correct hand /1
	Folds it in half /1
	Puts it on the floor /1
<b>TOTAL</b>	

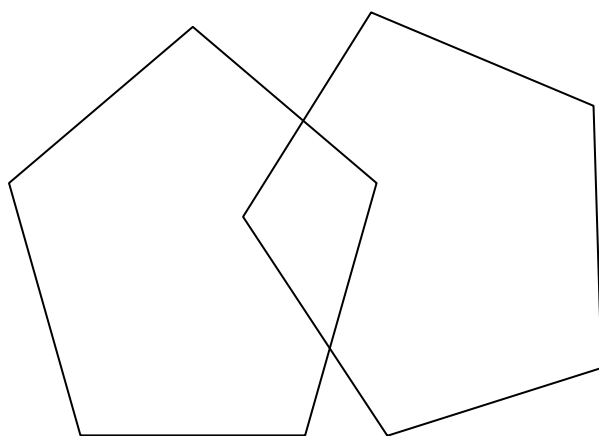
**CLOCK INSTRUCTIONS:** Draw the numbers on the clock face. Add the arms so the clock indicates 10 minutes after 11:00.

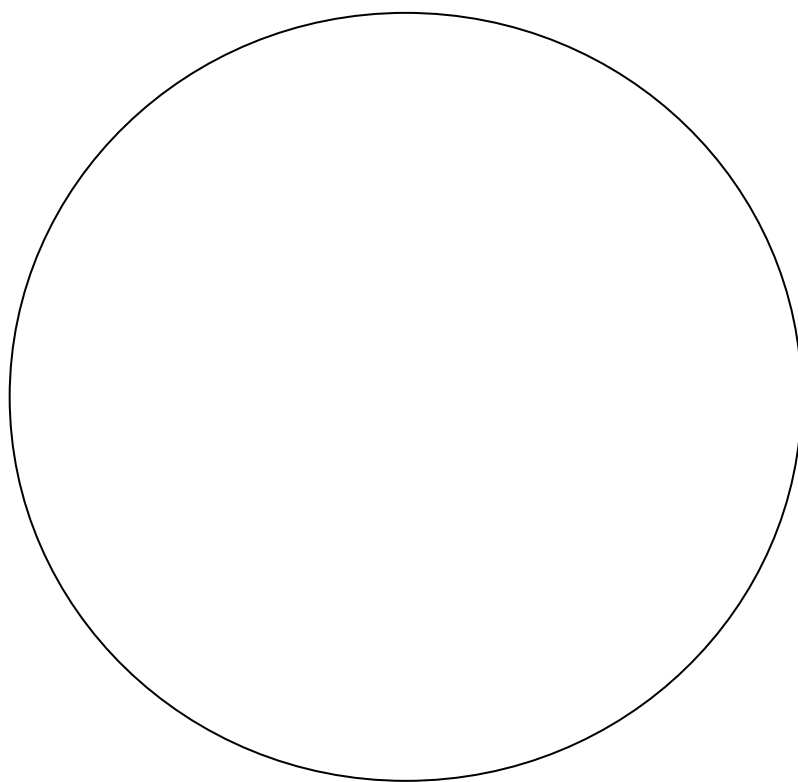
DATE: \_\_\_\_\_ SIGNATURE \_\_\_\_\_

D	L	R	O	W

\*score is the maximum amount of matching letters you can connect without lines crossing.

Write sentence here:





## Appendix M SF-36v2

### SF-36v2™ Health Survey

Participant ID: \_\_\_\_\_ Date: \_\_\_\_\_

This survey asks your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

**1. In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**2. Compared to one year ago, how would you rate your health in general now?**

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?**

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Lifting or carrying groceries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Climbing <u>several</u> flights of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Climbing <u>one</u> flight of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Bending, kneeling, or stooping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Walking <u>more than a mile</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Walking <u>several hundred yards</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. Walking <u>one hundred yards</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. Bathing or dressing yourself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <u>amount of time</u> you spent on work or other activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. <u>Accomplished less</u> that you would like	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Were limited in the <u>kind</u> of work or other activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Had difficulty performing the work or other activities (for example, it took extra effort)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <u>amount of time</u> you spent on work or other activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. <u>Accomplished less</u> that you would like	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Did work or activities <u>less carefully than usual</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

Not at all	Slightly	Moderately	Quite a bit	Extremely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**7. How much bodily pain have you had during the past 4 weeks?**

None	Very mild	Mild	Moderate	Severe	Very severe
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Have you been very nervous?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Have you felt so down in the dumps that nothing could cheer you up?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Have you felt calm and peaceful?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Did you have a lot of energy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Have you felt downhearted and depressed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Did you feel worn out?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Have you been happy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. Did you feel tired?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**11. How TRUE or FALSE is each of the following statements for you?**

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. I am as healthy as anybody I know	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. I expect my health to get worse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. My health is excellent	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Appendix N PASIPD

### The Physical Activity Scale for Individuals with Physical Disabilities: Development and Evaluation

*Instructions: This questionnaire is about your current level of physical activity and exercise. Please remember there are no right or wrong answers. We simply need to assess your current level of activity.*

Name: \_\_\_\_\_ ID: \_\_\_\_\_ Date: \_\_\_\_\_

#### Leisure Time Activity

1. During the past **7 days** how often did you engage in stationary activities such as reading, watching TV, computer games, or doing handcrafts?

- a) Never (Go to question #2)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

What were these activities?

On average, how many **hours per day** did you spend in these *stationary activities*?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

2. During the past **7 days**, how often did you *walk, wheel, push outside* your home *other than specifically for exercise*. For example, getting to work or the store, walking the dog shopping, or other errands?

- a) Never (Go to question #3)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

On average, how many **hours per day** did you spend walking, wheeling or pushing outside your home?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

3. During the past **7 days**, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, hunting or fishing, darts, billiards or pool, therapeutic exercise (physical or occupational therapy, stretching, use of a standing frame) or other similar activities?

- a) Never (Go to question #4)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)



What were these activities?

On average, how many **hours per day** did you spend in these *light sport or recreational* activities?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

4. During the past **7 days**, how often did you engage in *moderate sport and recreational* activities such as doubles tennis, softball, golf without a cart, ballroom dancing, wheeling or pushing for pleasure or other similar activities?

- a) Never (Go to question #5)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

What were these activities?

On average, how many **hours per day** did you spend in these *moderate sport and recreational* activities?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4h

5. During the past **7 days**, how often did you engage in *strenuous sport and recreational* activities such as jogging, wheelchair racing (training), off-road pushing, swimming, aerobic dance, arm cranking, cycling (hand or leg), singles tennis, rugby, basketball, walking with crutches and braces, or other similar activities

- a) Never (Go to question #6)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

What were these activities?

On average, how many **hours per day** did you spend in these *strenuous sport or recreational* activities?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

6. During the past **7 days**, how often did you do any exercise *specifically to increase muscle strength and endurance* such as lifting weights, push-ups, pull-ups, dips, or wheelchair push-ups, etc?

- a) Never (Go to question #7)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

What were these activities?

On average, how many **hours per day** did you spend in these *exercises to increase muscle strength and endurance*?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

### **Household Activity**

7. During the past **7 days**, how often have you done any *light housework*, such as dusting, sweeping floors or washing dishes?

- a) Never (Go to question #8)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

On average, how many **hours per day** did you spend doing *light housework*?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

8. During the past **7 days**, how often have you done any *heavy housework or chores* such as vacuuming, scrubbing floors, washing windows, or walls, etc?

- a) Never (Go to question #9)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

On average, how many **hours per day** did you spend doing *heavy housework or chores*?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

9. During the past **7 days**, how often have you done *home repairs* like carpentry, painting, furniture refinishing, electrical work, etc?

- a) Never (Go to question #10)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

On average, how many **hours per day** did you spend doing *home repairs*?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

\*NOTE: the following two questions pertaining to garden work are specific to heavy and light activities

10. During the past **7 days** how often have you done HEAVY *lawn work or yard care* including mowing, leaf or snow removal, tree or bush trimming, or wood chopping, etc?

- a) Never (Go to question #11)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

On average, how many **hours per day** did you spend doing *lawn work*?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

11. During the past **7 days**, how often have you done LIGHT *outdoor gardening*?

- a) Never (Go to question #12)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

On average, how many **hours per day** did you spend doing *outdoor gardening*?

- a) Less than 1hr
- b) 1 but less than 2 hr
- c) 2–4hr
- d) More than 4hr

12. During the past **7 days**, how often did you *care for another person*, such as children, a dependent spouse, or another adult?

- a) Never (Go to question #13)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

On average, how many **hours per day** did you spend *caring for another person*?

- a) Less than 1hr
- b) 1 but less than 2hr
- c) 2–4hr
- d) More than 4hr

### **Work-Related Activity**

13. During the past **7 days**, how often did you *work for pay or as a volunteer*? (Exclude work that mainly involved sitting with slight arm movement such as light office work, computer work, light assembly line work, driving bus or van, etc.)

- a) Never (Go to END)
- b) Seldom (1–2days)
- c) Sometimes (3–4days)
- d) Often (5–7days)

On average, how many **hours per day** did you spend *working for pay or as a volunteer*?

- a) Less than 1hr
- b) 1 but less than 4hr
- c) 5 but less than 8hr
- d) 8hr or more