TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION IN THE MANAGEMENT OF SPASTICITY IN CEREBRAL PALSY

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TITLE PAGE

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BY

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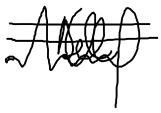
DECLARATION

I, Delali Ed-Bansah do hereby declare that apart from cited and acknowledged literatures, this thesis is my own work produced from research under the supervision of Dr. Patrick Adjei, Head of Department of the Department of Medicine and Therapeutics and Dr. Thomas Tagoe of the Department of Physiology, College of Health Sciences, University of Ghana

Signature  Date: 29th July 2020

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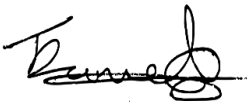
Signature  Date: 29th July, 2020

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DEDICATION

I dedicate my thesis to God Almighty and to all those who made this work a success.

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ABSTRACT

BACKGROUND

Spastic Cerebral palsy accounts for 70-80% of all types of Cerebral palsy. Spasticity as a major feature limits and restricts patients' ability to walk, stand, sit, or roll effectively due to excessive muscle contraction interfering with lengthening of the affected muscles. It poses a challenge even though there are well known interventions. Rehabilitation which includes physiotherapy is one of the widely accepted interventions. Physiotherapists in other countries and in Ghana use stretches, splinting and motor control/ training treatment strategies to reduce spasticity. There is growing interest in the use of Transcutaneous Electrical Nerve Stimulation (TENS) in the management of spasticity in Cerebral palsy. TENS is widely used as a pain management tool in Ghana. However, its use in spasticity management has not been explored and this study seeks to investigate the potential of TENS in the management of spasticity in Cerebral palsy, in Ghana.

GENERAL AIM: The aim of this study was to evaluate the effectiveness of TENS in the management of calf muscle spasticity among children with Cerebral palsy.

METHODOLOGY: This study was a Quasi-Experimental, One group Pre-test – Post-test design. Fifteen (15) children with spastic cerebral palsy who had spasticity in their calf muscles (gastrocnemius and soleus) were recruited for this study. All participants had two different modes of spasticity assessment electrophysiologically using the H reflex responses of calf muscles and clinically using the Modified Ashworth Scale (MAS). A biomechanical assessment was conducted using the Goniometer to assess Range of Motion (ROM) at the ankle joint in ankle dorsiflexion. All participants then received TENS application to the calf muscles

for a duration of thirty (30) minutes after which the H-reflex response, MAS and ROM were assessed again respectively, after the intervention. MAS and ROM carried out before and after the intervention were assessed twice for intrarater reliability. Statistical analysis was done using Mann Whitney U test, Spearman's rank correlation coefficient and Wilcoxon sign rank test. Predictor analysis was also done to evaluate whether application of TENS could lead to low MAS scores.

RESULTS: Results from this study showed that there was no significant difference ($p>0.05$) between left and right H reflex responses, MAS, and ROM scores at the baseline. There was no correlation (left: $p = 0.133$, right: $p = 0.479$) between pre-test left and right H reflex Amplitude (HA) scores and the MAS scores. After application of TENS, there was a reduction in spasticity of the calf muscles as measured by the H reflex, MAS, and ROM. However, only the left sided measures were statistically significant ($p = 0.011$) for the H reflex Amplitude whilst this asymmetry was not seen in MAS (left: $p = 0.009$, right: $p = 0.004$) and ROM (left: $p = 0.02$, right: $p = 0.003$).

CONCLUSION: TENS may be an effective tool for managing spasticity in spastic Cerebral palsy by reducing neuronal excitability. The asymmetry in response to TENS may have been from asymmetrical pathophysiology in the participants of the study.

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LIST OF ABBREVIATIONS

TENS	Transcutaneous Electrical Nerve Stimulation
MAS	Modified Ashworth Scale
ROM	Range of Motion
H-reflex	Hoffman reflex
EMG	Electromyography
F wave	Recognition to the foot
NMES	Neuromuscular Electrical Nerve Stimulation
FES	Functional Electrical Stimulation
GABA	Gamma-Aminobutyric Acid
HA Max/MA Max	H- reflex maximum Amplitude/ Muscle response maximum Amplitude
APGAR	Appearance, Pulse, Grimace, Activity & Respiration
IVH	Intraventricular Haemorrhage
PVL	Periventricular Leukomalacia
MRI	Magnetic Resonance Imaging
CT	Computed Tomography
EEG	Electroencephalogram
M wave	Muscle response wave
T reflex	Tendon reflex

LIST OF ABBREVIATION CONTD.

HA	H reflex Amplitude
MA	Muscle response Amplitude
RCTs	Randomized Control Clinical Trials
SES	Sensory Electrical Stimulation
FA Max/MA Max	F wave maximum Amplitude/ Muscle response maximum Amplitude
NCS	Nerve Conduction Studies
HL	H reflex Latency

CHAPTER 1

1.0 BACKGROUND

1.1 INTRODUCTION

Cerebral palsy describes "a group of permanent disorders that affect the development of movement and posture, causing limitation in activity. It is attributed to non-progressive disturbances in the developing foetal or infant brain" (Rosenbaum *et al.*, 2007). There are four major classifications of Cerebral palsy based on neuromuscular presentation (Sankar & Mundkur, 2005) namely; spastic Cerebral palsy, dyskinetic Cerebral palsy (athetoid and dystonic), ataxic Cerebral palsy and mixed Cerebral palsy. Globally the most common classification is spastic Cerebral palsy, accounting for 70-80% of all Cerebral palsy cases (Wolting, 2018; Sankar & Mundkur, 2005). In Africa as whole and in Ghana, spastic Cerebral palsy may account for more than 60% (Abas, Abdelaziem & Kilany, 2017; Adei-Atiemo, Rodrigues, & Badoe 2015).

Spasticity, a challenge for children with spastic Cerebral palsy (Alabdulwahab & AL-Gabbani, 2010) is an impairment that distorts motor function after brain damage (Boyd & Ada, 2008). It is a key component of the Upper Motor Neuron Syndrome (Rethlefsen, Ryan & Kay, 2010) and presents as hypertonia and stiffness. There is a velocity dependent increase in resistance to passive movement (Rethlefsen, Ryan & Kay, 2010). Spasticity contributes to activity limitation by causing excessive muscle contraction which resists lengthening of the affected muscle (Boyd & Ada, 2008). In clinical practice, children with spastic Cerebral palsy experience spasticity in hip adductors, the hamstrings, and the calf muscles- ankle plantar flexors. Spasticity in the calf muscle affects the child's ability to stand, to ambulate and to perform activities of daily living (Lin *et al.*, 2016). It also limits the Range of Motion (ROM) available at a joint and in some cases, may lead to contractures (Sheean, 2008).

Assessment of spasticity can be done subjectively by using a spasticity grading scale and objectively using Electromyography (EMG), an electrophysiological test. A spasticity grading scale that is widely recognised and used clinically is the Modified Ashworth Scale (MAS) derived from an original scale by Bohannon and Smith in 1987. The MAS is a 6-point scale which grades the level of spasticity. Electromyography plays a pivotal role in the diagnosis of neuromuscular disorders" (Katirji & Kaminski, 2002). It assesses the integrity of the Peripheral Nervous System using Nerve Conduction Studies, Needle EMG and some specialized electro diagnostic studies like F waves, H reflexes, and blink reflexes, repetitive nerve stimulation and single-fiber EMG (Katirji, 2016). The H reflex described and named after Paul Hoffman (Hoffman, 1910) and F wave, derived from "foot" (Katirji, 2016) have been identified as a more reliable measure for assessing spasticity (Tekgul *et al.*, 2013). There is a strong correlation between MAS and the H reflex in assessing spasticity as described by Tekgul *et al*. (2013) and the H reflex can be reliably used to electrophysiologically test for spasticity in children with Cerebral palsy. With respect to ROM limitation in spasticity, it is commonly assessed using the goniometer (Soucie *et al.*, 2011).

Various techniques used in the management of spasticity includes stretches, strengthening, casting, nerve or muscle blocks, medications, tendon lengthening, dorsal rhizotomy and therapeutic electrical stimulation (Transcutaneous Electrical Nerves Stimulation (TENS), Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES)) (Ved & Shah, 2017). There is paucity of information on the available treatment options for spasticity in Ghana but in practice, it is managed pharmacologically, mainly with Baclofen- a $GABA_B$ receptor activator and non-pharmacologically with stretches and positioning. The cost of medications coupled with its use over a long period of time, poses a challenge (The Finder, 2016). In addition, even though physiotherapy management for Cerebral palsy in Ghana include stretches and positioning, spasticity still poses a challenge during rehabilitation for

therapists as well as caregivers for children with spastic Cerebral palsy. Recent studies have shown TENS to be effective in reducing spasticity in various conditions including spastic Cerebral palsy (Mills & Dossa, 2016; Sultan, Helal & Awaad, 2005; Ayden *et al.*, 2005). Although this technique is available in Ghana and it is used to manage other conditions like pain in various physiotherapy centres, it has not been used in spasticity management in Ghana. Exploring the use of TENS within the Ghanaian context may provide information on its effectiveness in spasticity management considering that it is easily accessible and available in various physiotherapy centres where Cerebral palsy is also managed.

1.2 PROBLEM STATEMENT

Spasticity in Cerebral palsy affects various muscles including the calf muscles. It impairs a child's ability to stand or walk and also limits activities of daily living (Lin *et al.*, 2016; Shamsoddini *et al.*, 2014). Spasticity presents as shortening and stiffness of the muscles which makes the joint resistant to stretching thereby preventing normal movement (Shamsoddini, 2010; Meythaler, 2001); in the case of calf muscle spasticity, normal walking movement is prevented. A study conducted in Accra by Adei-Atiemo, Rodrigues and Badoe (2015) at Korlebu Neuro-clinic revealed that 60.6% of the children with Cerebral palsy had bilateral spasticity.

Across the globe various pharmacological and non-pharmacological approaches are employed in managing spasticity but it still poses a challenge to rehabilitation. In Ghana both approaches are also used in spasticity management. Physiotherapists use the non-pharmacological techniques such as, muscle stretches and motor training strategies to reduce spasticity. These techniques have however not been sufficient in managing spasticity efficiently. This is as a result of the limited amount of time that physiotherapists have with the children and inability

of caregivers to effectively continue these techniques at home. In addition, the high cost of medications leaves gaps in the effective management of spasticity. Another effective and less expensive method is Transcutaneous Electrical Nerve Stimulation (TENS). This has been used to manage spasticity in other countries with convincing results (Mills & Dossa, 2016; Alabdulwahab & AL-Gabbani, 2010; Ayden *et al.*, 2005) but its use in Ghana is particularly restricted to chronic pain management and muscle strengthening. There is no available literature that describes the use of TENS and its effect in spasticity management in Ghana. It is possible that this study may provide the basics for further studies investigating the use of TENS in spasticity management in Ghana.

1.3 JUSTIFICATION OF THE STUDY

Spasticity management during the rehabilitation process (Alabdulwahab & AL-Gabbani, 2010; Ved & Shah, 2017) requires a multimodal approach for effective management. Globally Botulinum Toxin injections, intrathecal and oral baclofen, surgery, splinting and physiotherapy interventions like stretches are used concurrently in the management of spasticity. In Ghana, the cost and lack of availability of medications, leads to gaps in the management of patients with spastic Cerebral palsy. Physiotherapy interventions therefore play a key role in managing spasticity in Cerebral palsy.

Recent evidence suggests the use of TENS as an effective tool in the management of spasticity (Park *et al.*, 2014) through its ability to decrease spasticity (Rha *et al.*, 2008). The underlying mechanism of this intervention is through reversing the presynaptic excitation mechanism of spasticity (Oo, 2015; Burke, 1988). TENS is readily available and employed by many physiotherapists in Ghana to manage pain and muscle weakness. However, its use for spasticity management has not been explored. The overall purpose of this study is therefore to evaluate the effectiveness of TENS in the management of spasticity in Ghanaian children with Spastic Cerebral palsy. Data from this study may provide the evidence to consider the use of TENS as

an alternative or adjunct therapeutic approach in spasticity management in Ghanaian children with spastic Cerebral Palsy.

1.4 HYPOTHESIS

1. Application of TENS will lead to a significant improvement in calf muscle spasticity measured by the H reflex and MAS scores.

2. Application of TENS will lead to a significant improvement in ankle Range of Motion (ROM) as measured by the Goniometer.

1.5 AIM AND OBJECTIVES

The aim of this study was to evaluate the effect of TENS on calf muscle spasticity among children with spastic Cerebral palsy at Korle Bu Teaching Hospital.

1.6 OBJECTIVES

- To assess and describe baseline spasticity characteristics of calf muscles-ankle plantar flexors as measured by electromyography (EMG)-H reflex responses and Modified Ashworth Scale (MAS) among children with spastic Cerebral palsy.
- To determine the correlation between the ratio of maximum H reflex Amplitude to maximum Motor response Amplitude (HA Max/MA Max) and MAS scores
- To identify and describe baseline ankle ROM measurements using the goniometer in children with Cerebral palsy.
- To evaluate the post treatment effect of TENS on calf muscle spasticity and ankle ROM in children with spastic Cerebral palsy.

CHAPTER 2

2.0 LITERATURE REVIEW

2.1 DEFINITION OF CEREBRAL PALSY

Cerebral palsy is defined medically as a non-progressive disorder caused by an injury to, or anomaly of the developing brain (Alabdulwahab & Al-Gabbani, 2010). Another definition by Rosenbaum et. al. and Bax, Tydeman and Flodmark (2007) provides a more comprehensive explanation and a better pictorial presentation of Cerebral palsy. They define Cerebral palsy as;

"A disorder of the development of movement and posture that causes activity limitation; which is attributed to non-progressive disturbances that occurred in the development of the infant brain"

2.2 EPIDEMIOLOGY

Cerebral palsy has been named, the most common disability of childhood (Nass, Sidhu & Ross, 2016). Globally the incidence rate of Cerebral palsy is 1.5-4/1000 live births (Arneson et. al., 2009; Surveillance of Cerebral palsy in Europe, 2002) with other studies reporting an estimated prevalence as 2-2.5/1000 live births (Shevel, Dagenais & Oskui, 2013). The high prevalence figures have been attributed to the high survival rate of children with Cerebral palsy (Ali *et. al.*, 2006). In Africa, the prevalence rises to about 10 per 1000 live births as reported by Burton (2015). Epidemiology of Cerebral palsy in Ghana has not been well documented in literature, however a project conducted in Ghana by Kalb, Huette and Bass (2012) from University of North Dakota estimated prevalence in Ghana to be 1 in 300 births. Cleves, Lee and Kabongo (2011) outlined that, Cerebral palsy affects more males than females in a ratio of 1.5:1 and

added that people with low socio-economic status may have a higher incidence rate than people with a high socio-economic status due to poor prenatal care.

2.3 RISK FACTORS

Various risk factors are associated with Cerebral palsy. Maclennan, Thompson and Gecz (2015) outlined some clinical risk factors as Preterm delivery, co-existing congenital anomalies, intrauterine infection, abnormal foetal inflammatory response and thrombophilia, intrauterine growth restriction, multiple pregnancy, tight nuchal cord at delivery, prolonged shoulder dystocia, placental pathology, viral infection in pregnancy, the male gender and some genetic risks. Others are; low APGAR (Appearance, Pulse, Grimace, Activity and Respiration) score, medical ventilation for over 4 weeks, brain haemorrhage, congenital malformations in the heart, kidney or spine, a baby weighing less than 1500 g, seizures (Miller & Bachrach, 2006) and Assisted Reproductive Technology (Centre for Disease Control and Prevention, 2018). A study conducted in Accra established some additional risks factors associated with Cerebral palsy to be; neonatal hyperbilirubinemia, neonatal seizures, birth asphyxia, irregular menstrual cycle, prematurity and neonatal sepsis (Adei-Atiemo, Rodrigues & Badoe, 2015). These risk factors are however not a definite basis for the development of Cerebral palsy.

2.4 AETIOLOGY

Cerebral palsy mostly occurs without a known cause. Only a small percentage can be attributed to what is known in literature (Platt *et al.*, 2007). These causes have been grouped into three. Namely; Prenatal (commonest), during birth (natal) or post-natal (Jan, 2006). Prenatal causes account for approximately 70-80% of all cases of Cerebral palsy (Cleves, Lee & Kabongo, 2011). Some outlined in literature are; perinatal ischaemic stroke, placental pathologies, neonatal encephalopathy, maternal infections and gene mutations (Light & Nelson, 2018; Nelson, 2008; Graham *et al.*, 2016). Birth asphyxia which is the number one cause of Cerebral

palsy accounts for 10-28% of all Cerebral palsy cases (Centre for disease Control, 2018; Light & Nelson, 2018; Graham *et al.*, 2016; Cleves, Lee & Kabongo, 2011; Nelson, 2008). Post-natal causes outlined are; infectious meningitis, encephalitis and traumatic conditions (Sankar & Mundkur, 2005).

2.5 PATHOPHYSIOLOGY OF CEREBRAL PALSY

Due to the varied causes of Cerebral palsy, it presents with multiple pathophysiological mechanisms such as brain lesions and phenotypical variability. Brain lesions occurs as a result of hypoxia or/and Ischaemia. The type of injury, site of injury and specific response to injury is dependent on the stage of brain maturation during which the injury occurs (Graham *et al.*, 2016). Phenotypical Variability is explained by the disruption of cortico-striatal-thalamic-cortical networks, cortico-cerebellar cortical networks and descending motor pathways that terminate in the brain stem and the spine. An anomaly that results in the persistence of primitive reflexes, hyperactive reflexes, abnormal muscle tone and abnormal organization of movement & posture in Cerebral palsy is the retention of circuits that are supposed to disappear or form new pathways with maturation (Graham *et al.*,2016)

There are two main pathologies associated with premature neonatal brain injuries which mostly result in Cerebral palsy. These are; Intraventricular Haemorrhage (IVH) and Periventricular Leukomalacia (PVL) (Rogers & Wong, 2007). Cerebral palsy occurs with these pathologies because the corticospinal tracts, made up of descending motor axons go through the periventricular region (Rogers & Wong, 2007). PVL is closely related to the development of Cerebral palsy in preterm and term neonates as compared to IVH and it is the leading cause of neuropathological abnormality in the cerebral white matter in preterm neonates (Volpe, 2017).

A cross sectional, population-based study which was conducted in 8 European study centres on 351 children with Cerebral palsy (Bax, Tydeman & Flodmark, 2007) showed that 11.7% of the children had normal MRI findings, 42.5% had White matter injury, 12.8% had Basal Ganglia lesions, 9.4% had cortico-subcortical lesions, 7.4% had focal infarcts, 7.1% had miscellaneous lesions and 9.1% had malformations. **Table 1** below shows some common sites of pathological injury in the brain as related to the motor presentation in children with Cerebral palsy (Marret, Vanhulle & Laquerriere, 2013).

Table 1: Common pathological sites in an injured neonatal brain

PERIOD	SITE OF PATHOLOGICAL INJURY	MOTOR PRESENTATION
PRETERM	WHITE MATTER (DIFFUSED) WITH INTRAPARENCHYMAL HAEMORRHAGE CAVITY OF THE PERIVENTRICLE	SPASTIC DIPLEGIA
	CORTICOSPINAL TRACTS (DISRUPTION)	*** DEVELOPMENTAL MOTOR DISORDERS
FULL TERM	ANTENATAL PORENCEPHALY UNILATERAL SCHIZENCEPHALY PERINATAL ARTERIAL ISCHAEMIC OR HAEMORRHAGIC STROKE	HEMIPLEGIA
	DIFFUSE BASAL GANGLIA AND THALAMIC DAMAGE CORTICO – SUBCORTICAL WATERSHED PATTERN DAMAGE	QUADRIPLEGIA OR DYSKINESIA

***Developmental motor disorder occurs in this case because the corticospinal tracts are the final pathways that mediate the influence of brainstem and spinal cord of nearly all cerebellar efferent and basal ganglia on the motor neurons (Marret, Vanhulle & Laquerriere, 2013).

2.6 DIAGNOSIS

For effective management, Cerebral palsy should be accurately diagnosed. Cerebral palsy assessment should be done thoroughly to prevent misdiagnosis. It should involve a complete documentation of events that took place during gestation, perinatally and after delivery (Ali *et al.*, 2006). It should consider events relating to both mother and child. Making a diagnosis below 6 months is sometimes difficult, and studies have suggested that accurate diagnosis can only be made after 6 months (Alabdulwahab & Al-Gabbani, 2010; Krigger, 2006). Even though this is mostly the case, detecting early signs can help in identifying children with Cerebral palsy. These signs are; "presence of hand preference in the first year, prominent fisting of hands beyond two (2) months, tone abnormalities, persistence of abnormal neonatal reflexes, abnormal asymmetric tonic neck reflex, delay in emergence of protective and postural reflexes, feeding problems and paucity of movement or excessive or disorganize movement" (Ali *et al.*, 2006). According to Alabdulwahab and Al-Gabbani (2010), diagnosis is centred around neurological examination for reflexes, muscle tone and brain/motor function. If the child has started ambulating, gait analysis is carried out to evaluate the child's walking pattern. One key assessment that should not be overlooked is the need to establish that the child is not losing function progressively since that may be associated with other autoimmune or neurodevelopmental conditions such as Delayed motor development, Autism or Cerebral Malaria (Cleves, Lee & Kabongo, 2011). There are specialized tests that can be used to assess the extent of brain damage such as MRI, CT Scans, EEG and Cranial Ultrasonography (Ali *et al.*, 2006; Alabdulwahab & Al-Gabbani, 2010).

2.7 CLASSIFICATION OF CEREBRAL PALSY

Cerebral palsy can typically be classified using two methods. The first method is classification based on topography (Sankar & Mundkur, 2005) and movement disorder (Gorter *et al.*,2004) while the second method is classification based on pathophysiology (Jones *et al.*, 2007).

Under the topographic classification, a child with Cerebral palsy is monoplegic, diplegic, triplegic, quadriplegic or hemiplegic. A child is monoplegic when only one limb is affected. This type is not common in most Cerebral palsy presentations. A child is considered diplegic when the two lower limbs are affected. It accounts for about 30-40% of all cases of Cerebral palsy. A child is triplegic when the two lower limbs and one upper limb or two upper limbs and one lower limb is affected. Children classified quadriplegic are those with both upper limbs and lower limbs affected. It accounts for about 10-15% of all cases of Cerebral palsy. Lastly, a child is classified as hemiplegic when either the left upper limb and lower limb or the right upper limb and lower limb are affected. It accounts for about 20-30% of all cases (Sankar & Mundkur, 2005).

Under classification by movement disorder, a child with Cerebral palsy is either spastic, dyskinetic, ataxic or mixed (Ali *et al.*, 2006). Spastic Cerebral palsy is the commonest form of Cerebral palsy and accounts for about 70% of all cases (Günel, 2011). Dyskinetic Cerebral palsy is mainly considered as choreoathetoid due to its nature which appears as a dance movement. It accounts for about 10-20% of all cases (Wolting, 2018). Ataxic Cerebral palsy accounts for approximately 5-10% of all cases (Wolting, 2018). Lastly, mixed Cerebral palsy presents with a combination of two (2) of the above-mentioned classifications.

This method of classification is mostly presented as a combination of the two (Topography and the type of movement disorder). Spastic diplegic Cerebral palsy is considered as the most

common form of spastic Cerebral palsy (Jan, 2006) and therefore requires the need for effective management.

The second method classifies Cerebral palsy cases into Pyramidal; Spastic type, describing damage to the corticospinal tracts) and Extra-pyramidal; the non-spastic type, describing damage to brain in areas outside the corticospinal tracts (Jones *et al.*, 2007).

2.8 MANAGEMENT OF CEREBRAL PALSY

Two children with Cerebral palsy, with similar symptoms will present with different brain abnormalities (Ali *et al.*, 2006). Even though Cerebral palsy cannot be cured, there are several approaches to its management. Careful selection of management approaches can improve the functional capabilities of a child living with Cerebral palsy (Alabdulwahab & Al-Gabbani, 2010). Management focuses on a multidisciplinary approach (Aisen *et al.*, 2011) and requires a multidisciplinary team. Some management approaches are; medications (oral muscle relaxants, phenol, intrathecal baclofen and botulinum toxin-A injection), surgery (Selective Dorsal Rhizotomy, Achilles Tendon Release and Orthopedic Selective Spasticity Control Surgery) & braces, hippotherapy, counselling and therapies such as physical, occupational, speech and behavioural (Matsuo, 2002; Sharan, 2005; Alabdulwahab and Al-Gabbani, 2010). The team involved in the management of Cerebral palsy include; Paediatricians, Physical, Occupational and speech therapists, Neurologist, Neurosurgeon, Orthopaedic Specialist, Psychiatrist, Educational experts and Counsellors (Ali *et al.*, 2006). Spasticity, a major challenge to the management team (Ved and Shal, 2017) presents in most Cerebral palsy cases and various methods have been adapted in its management during Cerebral palsy rehabilitation. The goal of spasticity management aims at regulating sensory feedback and coordination between receptors, neuronal pathways, and the higher centres.

2.9 SENSORY RECEPTORS

Sensory receptors are structures that respond to physical stimulus in the environment, either internally or externally (Sincero, 2013). Impulses are transmitted from sensory receptors as nerve signals. The point of termination of these signals determine how the stimulus is perceived by an individual (Marzvanyan, 2019). **Table 2** below presents a list of sensory receptors, classified according to the stimuli they respond to.

Table 2: Sensory receptor and their stimulus. Adapted from Sincero (2013) and Boundless (2019).

Sensory Receptor	Adequate Stimulus (sensory receptor responds to…)
Ampullae of Lorenzini (electroreceptors)	Electric fields, salinity, temperature
Baroreceptors	Pressure in blood vessels
Chemoreceptors	Chemical stimuli
Hydroreceptors	Humidity changes
Mechanoreceptors	Mechanical stress or mechanical strain
Nociceptors	Damage to body tissues (which leads to pain perception)
Osmoreceptors	Osmolarity of fluids
Photoreceptors	Light
Proprioceptors	Sense of position
Thermoreceptors	Temperature, heat, cold or both
Electromagnetic receptors	Electromagnetic waves
Pacinian Corpuscles	Pressure on skin; weight of an object
Meissner's Corpuscles	Fine touch
Magnetoreceptors	Magnetic fields
Ultraviolet receptors	Ultraviolet radiation
Infrared receptors	Infrared radiation

There are four receptors responsible for positioning (proprioception) and movement (kinaesthesia) of the limbs (Villis, 2013). These receptors are, joint afferents, muscle spindles, golgi tendons and tactile afferents. Of these, two receptors; Golgi Tendon organs and Muscle spindles are located in the muscle and are associated with sensitivity to stretch in a muscle (Cameron-Tucker, 1983). Signals from these sensory receptors are mainly for intrinsic muscle control and their operation is mostly at the subconscious level (Guyton & Hall, 2011). The Joint afferents are found in the joints, and tactile afferents, in the overlying skin (Villis, 2013). For the purpose of this study, the focus will be on the Muscle spindle receptor.

2.10 MUSCLE SPINDLE

As stated earlier, muscle spindles are proprioceptors. They are made up of several muscle fibres and are enclosed in a sheath of connective tissue (Brukner, 2012). Each muscle spindle is 3-10 mm long and is built around 3-12 small intrafusal fibres (Guyton & Hall, 2011). The two ends of intrafusal fibres are made up of mainly, contractile proteins. The central portion however has little or no contractile protein (Guyton & Hall, 2011; Enoka, 2015). Within a typical muscle spindle, 3 main types of intrafusal fibres can be identified. These are Bag 1, Bag 2 and the chain fibres (Mileusnic, Brown & Loeb, 2002). Bag 1 has a primary role of detecting or sensing velocity in a muscle spindle. Bag 2 and the chain fibres are responsible for length sensitivity. Bag 1 deals with dynamic fusimotor control for dynamic response and Bag 2, static fusimotor control for static response (Guyton & Hall, 2011; Mileusnic, Brown & Loeb, 2002).

Muscle spindles are innervated by two sensory afferents (Primary and Secondary endings), located in the middle of the spindle (Cuoco & Tyler, 2012; Physiopedia, 2019). The secondary endings are eccentrically on bag 2 and the chain fibres (Mileusnic, Brown & Loeb, 2002). Primary afferents (Group 1a) respond to speed and size of change in muscle length, this makes them contribute to the sense of limb position and movement. Secondary afferents (Group II)

respond to change in length and therefore contribute to sense of limb position (Roatta & Passatore, 2006; Guyton & Hall, 2011; Physiopedia, 2019).

One of the major roles of a muscle spindle is to act as a stretch detector by sensing how much and how fast a muscle was lengthened (Kröger, 2018).

2.10.1 MUSCLE SPINDLE'S RESPONSE TO STRETCH

A Stretch reflex or Myotatic reflex occurs when muscle spindles are able to induce a muscle contraction using reflex activities to prevent over stretching and damage (Grunewald *et al.*, 1997). It is considered, the simplest manifestation of a muscle spindle (Guyton & Hall, 2011).Stretch reflexes are mostly mediated by excitation of the Ia afferent fibres from the spindle fibres of muscles, which make connection with alpha motoneurons in the same muscle (Trompetto *et al.*, 2014).There are three types of spinal reflexes; Monosynaptic reflex (mediated by Ia spindle afferents), Reflex mediated by Golgi Tendon organ (Ib) and Withdraw reflex mediated by pain receptors (Villis, 2013). When muscles are stretched, their spindles are also stretched. This action sends impulses immediately to the spinal cord and the spinal reflex is activated as a protective response to prevent the muscles from being pulled forcefully (Mukherjee & Chakravarty, 2010). There are two (2) components associated with the stretch reflex; Dynamic Stretch reflex and Static stretch reflex. Dynamic Stretch reflex is elicited from the primary sensory endings of muscle spindles when the muscle is either rapidly stretched or "unstretched". This component of the reflex last for a moment, as a response to the increase in muscle length. Static stretch reflex which is transmitted by both primary and secondary endings on the other hand, lasts for the entire stretch period and helps the maintain a constant level of muscle contraction (Guyton & Hall, 2011; Physiopedia, 2019). Muscle spindles do not "switch off" when there is no stretch activity. The fibres continually send impulses when the muscle is returning from a stretched position to a contracted or shortened position (Cuoco & Tyler, 2012).

During the different stages of walking, the calf muscle is stretched to allow a forward or backward progression.

2.11 CALF MUSCLE

The calf muscle is made up of two muscles: the gastrocnemius and the soleus muscle. It is innervated by the tibial nerve and serves the function of ankle joint plantarflexion. It also plays a key role in jumping and running (Binstead & Varacallo, 2019).

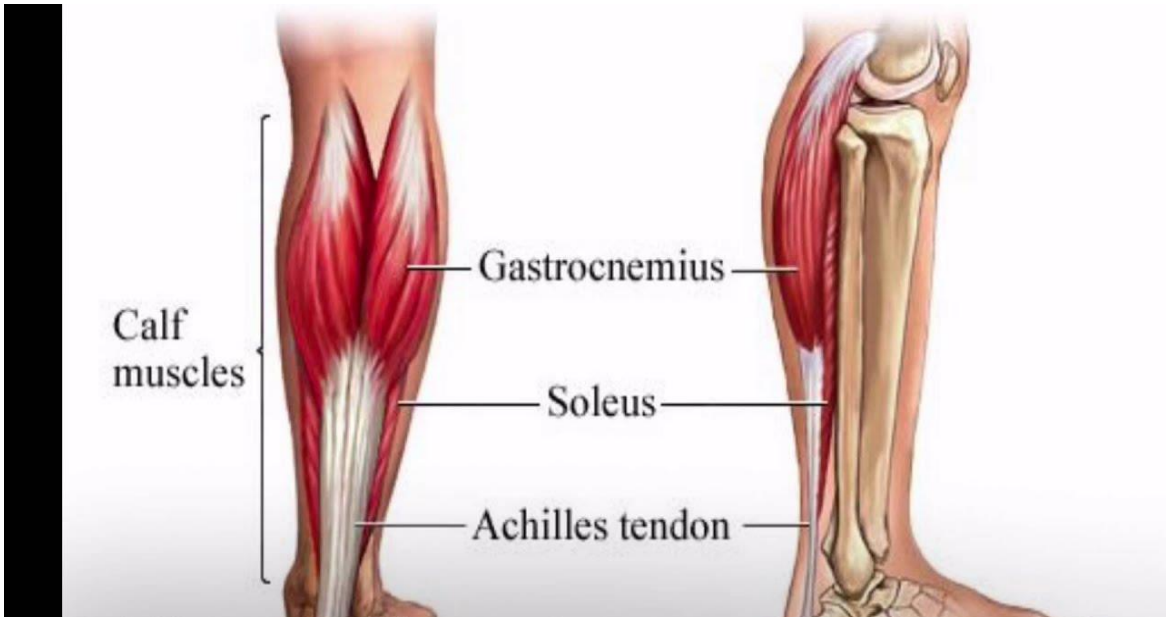


Figure 1: A human calf muscle. A pictorial presentation of the posterior and lateral view of a calf muscle from Nursing Study Guide (2012-13 Solazzo), by STUDYBLUE, 2018, https://www.studyblue.com/notes/note/n/nursing-study-guide-2012-13-solazzo/deck/9711975

2.12 SPASTICITY

Spasticity as described by Lance (1980) is a "motor disorder, characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the Upper motor neuron syndrome". This definition is largely excepted but there have been recent modifications. Pakula, Braun and Yeargin-Allsopp (2009) defined spasticity as a clinical sign manifested by

an increased resistance of a limb to an externally imposed joint movement. It is also defined as a "stretch reflex disorder, manifested clinically as an increase in muscle tone that becomes more apparent with more rapid stretching movement" (Trompetto *et al.*, 2014). Spasticity is considered a part of the Upper Motor Neuron Syndrome (Boyd & Ada, 2008) and presents as muscular hyperactivity (Mall *et al.*, 2016).

2.12.1 PATHOPHYSIOLOGY OF SPASTICITY

Two (2) mechanisms are associated with spasticity; spinal mechanisms in relation to changes in function of spinal neurons and the motor subsystem and Supraspinal and suprasegmental mechanisms (Mukherjee & Chakravarty, 2010). Spasticity leads to a distortion or disruption of the spinal stretch flex, mediated partly by muscle spindles (Trompetto *et al.*, 2014).

According to Kheder and Nair (2012), muscle stretch causes muscle spindle Ia afferents to excite spinal motor neurons. This leads to contraction of agonist and relaxation of antagonist muscles. In spasticity, motor neurons respond to stretch at a lower threshold than normal with long discharges (Nielsen, Crone & Hultborn, 2007). An increased tone, as seen in spasticity, results from excessive neural drive of spinal motor neurons (Kheber & Nair, 2012).

Spasticity is caused by a disruption of select descending pathways **(Figure 2)** involved in motor control. These pathways control spinal reflexes responsible for proprioception, cutaneous sensation and nociception (Sheean, 2008). Spinal reflex hyperexcitability or stretch reflex excitability, associated with patients with spasticity is produced by mainly 2 factors; Increased excitability of muscle spindles and abnormal processing of sensory inputs from muscle spindles at the level of the spinal cord which causes excessive activation of alpha motor neurons (Trompetto *et al.*, 2014; Fernández-Tenorio *et al.*, 2018).

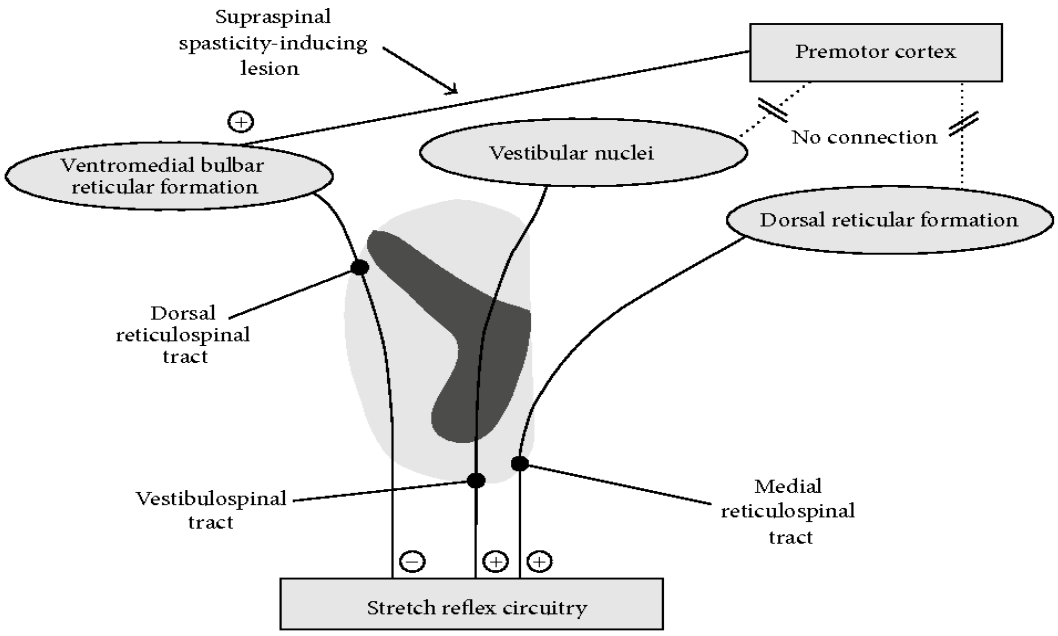


Figure 2: Descending pathways mediating spinal reflexes. Animal studies show that there are two (2) major balancing descending systems which control reflex activity: The dorsal reticulospinal tract (inhibitory) and the medial reticulospinal and vestibulospinal tract (facilitatory). The ventromedial bulbar reticular formation which gives rise to the dorsal reticulospinal tract is under corticospinal control. Spinal reflex is exaggerated when the "facilitating system" prevails over the "inhibitory system". Picture from Pathophysiology of Spasticity: Implications for Neurorehabilitation by Marinelli (2014), Biomed Research International, http://dx.doi.org/10.1155/2014/354906.

2.12.2 SPASTICITY ASSESSMENT

There are several methods used in the assessment of spasticity. These methods are classified into three (Dimitrijević *et al.*, 2014), namely, Clinical, Biomechanical and Neurophysiological methods. The clinical methods involve the use of scales to grade the level of spasticity. The two major scales are the "Ashworth Scales" - Ashworth Scale, Modified Ashworth Scale Bohannon, and Modified Ashworth Scale Peacock, and "New York University Tone Scale". The other clinical method is the "Tardieu Method of assessment (Johnson & Pandyan, 2008; Alabdulwahab & Al-Gabbani, 2010). Some Biomechanical methods outlined in literature are; isokinetic measurement of certain features of limb movement like torque and work, Wartenberg test and powered systems (Johnson & Pandyan, 2008; Grippo *et al.*, 2011). Gait analysis is

considered a type of a Biomechanical method of spasticity assessment, however Johnson and Pandyan (2008) classified it as an Indirect Biomechanical Approach. The Neurophysiological method of spasticity assessment uses Tendon Jerks and some measures of Electromyography like H reflex studies and F wave studies (Fischer, 2002; Johnson & Pandyan, 2008).

Another useful measure that can be used to measure the effect of spasticity is Range of Motion (ROM) measurement which is done by Goniometry. Koshmahl (2018) defined goniometry as "measuring the available range of motion or the position of the joint"- a typical measure of passive motion. For the purpose of this study, Modified Ashworth Scale-Bohannon, ROM and Electromyography will be discussed as assessment tools of spasticity.

2.12.2.1 MODIFIED ASHWORTH SCALE AS AN ASSESSMENT TOOL

Modified Ashworth Scale is a 6-point grading scale which was derived from an original scale called the Ashworth Scale. This scale was first developed by Ashworth in 1964. It was designed to determine the degree of resistance encountered in a specific muscle group when the limb is moved passively (Alabdulwahab & Al-Gabbani, 2010). Bohannon and Smith (1987) modified the Ashworth Scale from a 5-point grading scale to a 6-point grading scale. Below are the Ashworth Scale and the Modified Ashworth Scale.

ASHWORTH SCALE

0: No increase in tone

1: Slight increase in tone, giving a catch when the limb was moved in flexion or extension

2: More marked increase in tone but limb is easily flexed

3: Considerable increase in tone; passive movement is difficult

4: Limb rigid in flexion or extension

MODIFIED ASHWORTH SCALE

0: No increase in muscle tone

1: Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension

1+: Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM

2: More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved

3: Considerable increase in muscle tone, passive movement difficult

4: Affected part(s) rigid in flexion or extension

Over the years, there have been various modifications to the Ashworth scale, however the Modified Ashworth Scale is commonly used in the clinical setting for spasticity assessment (Alhusaini *et al.*, 2010).

2.12.2.2 RANGE OF MOTION

Range of motion is defined as the range through which a joint can be moved (Segen, 2006). It provides information on the extent of movement available at a joint and it is mostly measured in degrees. Devices like goniometer **(Figure 3)** and inclinometer are used to measure movement available at the joint (Physiopedia, 2019).

Range of motion is measured to obtain baseline values and it helps to determine appropriate management and also helps to evaluate the effectiveness of a treatment by comparing baseline measure to subsequent measures (Gajdosik & Bohannon, 1987). In measuring joint ROM, intrarater testing is more reliable than when compared to inter rater testing and even though different types of goniometer sometimes produce different results, these differences are not statistically significant (Youdas, Carey & Garrett, 1991; Physiopedia 2019). Several studies have been conducted to provide standard ROM values across various age group. Some findings were;

- Birth – 2 years: 48°, 18 months – 19 years: 13°±5° (Physical Rehabilitation and Medicine, 2016)
- 2 – 8 years: Males- 22.8°, Females – 24.8° and 9 – 19 years: Males 16.3°, Females 17.3° (Soucie *et al.*, 2011)
- 4 – 7 years: 18.2° (Boucher, Onate & Bolte, 2014)
- 7-14 years: Males -25.5°, Females – 26.5° (Alanen *et al.*, 2001)

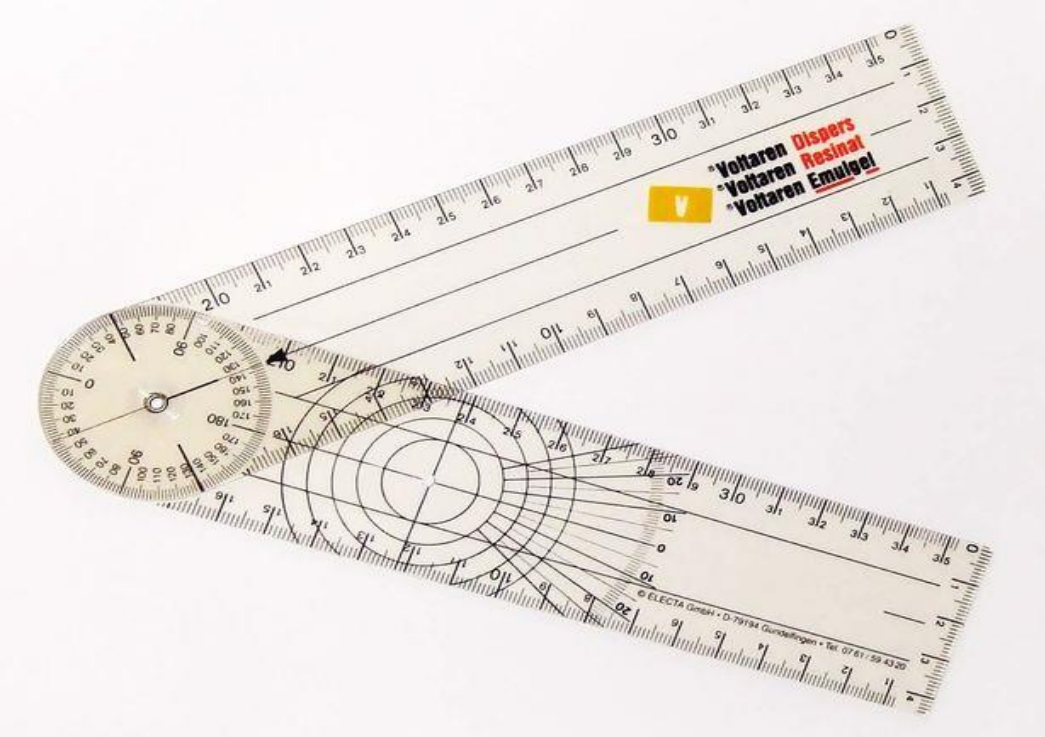


Figure 3: Universal Goniometer. Commonly used in Range of Motion assessment from Goniometer (Medizinischer Goniometer.jpg), by Physiopedia, 2019, https://www.physiopedia.com/index.php?title=File:Medizinischer_Goniometer.jpg&oldid=204351.

2.12.2.3 ELECTROMYOGRAPHY (EMG)

EMG is considered a discipline that plays a key role in neuromuscular disorder diagnosis (Katirji & Kaminski, 2002). Electromyography can be described as a technique used for evaluating and recording electrical activity produced by skeletal muscles (Bari, 2018). An electromyograph is a device that records muscle activity and can be used to measure the change in electric potential between 2 different points on a muscle. It uses electrodes to achieve this (Webster, 2009).

Electromyography signals were discovered and developed in 1666 by Francesco Redi. In 1890, a man called Marey recorded the first electrical signal of muscle activation and he named the generated electrical signal, electromyography. In 1966, a team of researchers and Hardyck, who were medical practitioners were the first to use electromyography. Later in 1980, Cram and Steger designed a clinical method that could scan variety of muscles with an EMG sensing

device (Abbink & Glas, 1998; Mabrouk & Kandil, 2012; Bari, 2018). EMG operates by receiving electric signals from muscle, using either non-invasive or invasive electrodes (Chowdhury *et al.*, 2013). It assesses the integrity of the Peripheral nervous system using Nerve Conduction studies, Invasive methods like Needle EMG and some specialized electrodiagnostic studies like F waves, M wave, T reflexes, H reflex, blink reflexes, repetitive nerve stimulation and single fibre EMG (Katirji, 2016). The F wave is measured to assess transmission between the stimulation sites and its motor neuron. M wave is measured to assess the motor response of the muscle being stimulated and T reflex is measured to assess the integrity of spinal cord and the peripheral nervous system. Lastly, the H reflex is measured to assess motor neuron excitability (Katirji, 2016).

Non-invasive electrodes, otherwise called surface electrode records electrical signals of several motor units. When a motor unit is stimulated by an electromyogram, action potential is carried down the motor neuron to the muscle. Action potential gets to a neuromuscular junction and it is transmitted across where it elicits another action potential in all the innervated muscle fibres of that motor unit. This action occurs across various motor units. Signals produced from this action is evaluated during an EMG procedure (Bari, 2018). EMG has been identified as a tool that can be used for the assessment of spasticity. Recording EMG signals with surface electrodes is commonly used in the laboratory for the evaluation of hypertonia or spasticity (Lebiedowska & Fisk, 2003).

EMG measures used for this assessment are; H-reflex, T-reflex, F-waves and M waves (Fischer, 2002). For the purpose of this study, the focus will be on H-reflex.

2.12.2.3.1 HOFFMAN REFLEX (H-REFLEX)

H reflex also known as the Hoffman reflex is an estimate of alpha motor neuron excitability when presynaptic inhibition and intrinsic excitability of the alpha motor neurons remain constant (Palmieri, Ingersoll & Hoffman, 2004). H reflex has a similar mechanism as the muscle stretch reflex. However, it bypasses the spindle by directly activating the motor neurons using electrical stimulation (Palmieri, Ingersoll & Hoffman, 2004). H reflex stimulation travels along the Ia sensory afferent through a motor neuron pool of the muscle being stimulated to the efferent motor fibres. The sensory afferents are activated from the point of electrical stimulation and leads to the propagation of action potentials which travel along these afferents until they synapse on the alpha motor neurons. After this synapse, generated action potentials move along the efferents till they reach the neuromuscular junction and produce a twitch response on the EMG recordings (Capady, 1997; Palmier, Ingersoll & Hoffman, 2004). Measures of H reflex include, H amplitude (HA), ratio of Maximum H Amplitude to Motor response Amplitude (HA Max/MA Max) and H latency (Palmieri, Hoffman and Ingersoll, 2002).

In spasticity, there is an alteration in the alpha motor neuron excitability and H reflex assessment helps to provide an estimate of this excitability (Arumugam, Bedi & Kaur, 2016). H reflex measures of calf muscle is one of the effective means to investigate the reflex circuitry and changes in transmission in the spinal pathway (Pierrot-Descilligny & Mazevet, 2000). In eliciting an H reflex, it is necessary to apply a percutaneous electrical stimulus to a mixed nerve to ensure that a the sensory Ia afferents can be activated (Schieppati, 1987). H reflex is elicited, starting at a low intensity which is increased gradually till there is a depolarization of the primary Ia afferent fibres. When H reflex reaches its maximum level, it begins disappearing from the EMG tracing and the Motor response wave takes over till it reaches a stable maximum

level (Pamieri, Ingersoll & Hoffman, 2004). There have been various concerns regarding the best position to elicit an accurate H reflex measure. Some studies have shown that positioning the subject in supine or prone and maintaining the same hand and head position during the test produces a reliable H reflex measure (Hopkins *et al.*, 2000; Palmieri, Hoffman & Ingersoll, 2002).

2.12.3 MANAGEMENT OF SPASTICITY

Spasticity is described as a complex phenomenon and necessitates proper diagnoses, evaluation and an understanding of multidimensional characteristics and presentations in order to effectively provide better rehabilitation protocols (Arumugam, Bedi & Kaur, 2016). Pharmacological and non-pharmacological approaches are used in the management of spasticity. Common pharmacological measures are Baclofen (both oral and intrathecal) and Botulinum toxins (Kheder & Nair, 2012). Others are Phenol (Gracies *et al.*, 1997) and Cannabinoids (Sastre-Garriga *et al.*, 2011). The non-pharmacological methods include selective dorsal rhizotomy (Kheder & Nair, 2012), passive stretches (Smania *et al.*, 2010), exercises to facilitate control (Pak & Patten, 2008), posture control and standing (Stevenson, 2010). There are also physical modalities like, ultrasound therapy, Magnetic stimulation, Functional Electrical Stimulation, and TENS (Kheder & Nair, 2012), which will be the focus of this study.

2.13 TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS)

TENS is an electrical modality that works by depolarization of a peripheral sensory nerve to offer an alternate and competing sensation to reduce nociception for pain modulation (Nelson, Hayes & Currier, 1999). This has warranted its popular use in pain treatment globally. Another aspect of its mechanism that has not been explored entirely is its role in activating sensory Ia

afferent fibres, switching on presynaptic inhibition which leads to a reduction in spasticity (Rha *et. al.*, 2008; Bosques *et al*., 2016; Manigandan & Bharathi, 2017). TENS has the ability to stimulate both sensory and motor cortices through its afferent inputs (Golaszeoski *et al.,* 1999; Joodaki, Olyaei & Baghen, 2001). It uses high frequency of about 50-150 Hz and low frequency electric current of below 50 Hz on the skin to produce therapeutic benefit (Watson, 2009).

Various studies have been conducted to determine, and in some cases evaluate the effect of TENS on spasticity. However, these studies presented, have great variability in the specific parameters that produce the "anti spastic effect" (Fernández-Tenorio *et al.,* 2018). Mechanism of action of TENS are based on the fact that, it stimulates an additional sensory input in the central nervous system and leads to the presynaptic inhibition of the suprasegmental pathway (Wang, Chan & Tsai, 2000). Parameter-specification for TENS is mostly around 99 and 100 Hz frequency and 0.1 – 0.25 ms pulse width with the minimum duration from literature that produces an 'anti-spastic' effect being 15 minutes (Fernández-Tenorio *et al.*, 2018). There are four (4) major mechanism associated with the use of TENS for spasticity management. These are; activation of large diameter afferent nerve fibres modulating abnormal interneuron activities in several spinal segments", "Continuous activation of sensory peripheral nerve fibres resulting in insensitivity to prolonged central excitation, accompanied by lower corticomotor neuron excitability", "stimulation of plasticity of the Central Nervous System" and "unmasking or recognition of somatosensory motor cortical connections" as outlined by Mills and Dossa (2016).

TENS application may activate two (2) or more mechanisms at a given time.

2.14 EFFECT OF TENS ON CALF MUSCLE SPASTICITY AS MEASURED BY H REFLEX, MAS, AND ROM

Effect of TENS on spasticity

Fernández-Tenorio *et al.* in June 2016, conducted a systematic review on the use of TENS for treating spasticity. The first aim of the review was to determine whether TENS is effective for treating spasticity or associated symptoms in patients with neurological involvement. The second aim was to determine which stimulation parameters exert the greatest effect on variables associated with spasticity. They reviewed a total of 10 Randomized controlled clinical trials with a total patient population of 207 Cerebrovascular accident cases, 84 Multiple sclerosis cases and 39 Spinal cord lesion cases with associated spasticity. They concluded that, the variability in TENS parameters made it difficult to assess and compare any results that can objectively determine the effectiveness of the technique and show how to optimize parameters.

A systematic review conducted by Mills and Dossa (2016) to summarize the effect of TENS for management of limb spasticity reviewed 14 Randomized controlled clinical trials (RCTs) involving 544 participants. Intervention was grouped into three (3) categories; 1. TENS vs No TENS or Placebo TENS (7 RCTs), 2. TENS vs another TENS protocol or another intervention for spasticity management (7 RCTs), 3. TENS as an adjunct to another intervention for spasticity management (4 RCTs). Four (4) studies overlapped between the three categories. They concluded a level 1 and 2 evidence for TENS improving spasticity related outcomes measures, including Modified Ashworth Scale (MAS).

Another systematic review to verify the efficacy of TENS or Sensory Electrical Stimulation (SES) in the control of spasticity and its consequences in spinal and corticospinal excitability reviewed 10 manuscripts. They concluded that even though the manuscripts evaluated the

efficacy of TENS/SES at both the spinal or cortical levels, results from various EMG measures were inconsistent (Garcia & Vargas, 2019).

An interventional study conducted to measure the clinical and electrophysiological effect of electrical stimulation on the spasticity of plantar flexor muscle in hemiplegic patients who have plantar flexor spasticity recruited 32 hemiplegic patients with a mean age of 57.42 for study group and 58.38 for the control group. TENS was applied for 20 mins per day for 15mins. Results obtained from this study showed a statistically significant increase in passive ankle dorsiflexion and a reduction in muscle tone. EMG measures (H reflex amplitude, H latency and HA Max/MA Max) showed no statistically significant difference between and within groups even though the results showed an increase in posttreatment latencies and a reduction in amplitudes of the intervention group. The study concluded that electrical stimulation (TENS) can be a good functional option for treating patients having plantar flexor spasticity (Gürcan *et al.*, 2015).

Another study conducted by Joodaki, Olyaei and Bagheri (2001) investigated the effects of electrical nerve stimulation on alpha motoneurons excitability. They recruited ten (10) non-athletic, healthy men and three (3) spastic hemiplegic patients. TENS was applied for 30minutes and EMG measures were recorded before and after the intervention. Results showed that mean H reflex amplitude, F- wave amplitude and HA Max/ MA Max, FA Max/MA Max ratios reduced after TENS application for both healthy and hemiplegic participants. Mean H reflex and F wave latencies increased after TENS application. They concluded that reduction in H reflex amplitude, F wave amplitude and HA Max/ MA Max, FA Max/MA Max ratios demonstrated reduction of spasticity in the three (3) spastic hemiplegic patients.

2.13.1 Effect of TENS on calf muscle spasticity as measured by the H reflex

A study conducted by Ved and Shah (2017) to compare the immediate effect of TENS and Cryotherapy on calf muscle spasticity in children with Cerebral palsy recruited 20 children within the ages of 5-18. The results showed that those in the TENS group had a reduction in HA Max/MA Max ratio (From 0.396 pretest to 0.237 posttest) and increase in H latency (From 24.58ms to 25.56ms). This was however not the case for the group that had cryotherapy. They concluded that TENS would lead to an immediate reduction in spasticity as compared to cryotherapy.

2.13.2 Effect of TENS on calf muscle spasticity as measured by MAS

A study by Arati and Shraddha (2014) to evaluate the effect of high TENS with conventional therapy to sham TENS with conventional therapy on spasticity of plantar flexors (calf muscles) in children with Cerebral palsy revealed that children who had high frequency TENS showed a statistically significant improvement in MAS scores as compared to the sham (placebo) TENS group. TENS group MAS scores- Right (pre-test: 1.96 vs post-test: 1.17) and Left (pre-test: 1.81 vs post-test: 1.15)

2.13.3 Effect of TENS on calf muscle spasticity as measured by ROM

Arati and Shraddha (2014) also measured ROM as one of their outcome measures. Results show a higher statistical significance improvement in ROM after TENS application (Right: pre-test – 7.07° vs post-test – 12.43°; Left: pre-test – 9.50° vs post-test 14.19°) as compared to the "No TENS group". Even though there was a statistically significant increase in ROM after conventional therapy, those in the TENS group had higher ROM values as compared to the "No TENS" group.

These studies suggest that TENS has a role to play in the management of spasticity therefore, worthy of investigation as another or additional option in Ghana when managing spasticity in children with Cerebral palsy.

CHAPTER 3

3.0 METHODOLOGY

3.1 STUDY DESIGN

The study was a Quasi-Experimental design, using a One group pre-test – post-test design (Shadish, Cook & Campbell, 2002). This study design was chosen based on study objectives which did not meet the requirement for a true experimental study design. Even though this design may have effects on internal validity, the nature of the study reduced these effects through, Maturation - the time difference between the pre-test and post-test scores limits the effect of maturation on the post test scores; and Test-effect - the use of an objective measure, H reflex, limits the effect of Test-effect on internal validity. The other two outcome measures which were subjective in nature were measured twice on each assessment period for intrarater reliability. The One-group pre-test – post-test design has been previously employed in similar studies where the aim was also to test the effectiveness of an intervention (Alsubiheen *et al.*, 2017; Ellul & Gutt, 2016; Purepong *et al.*, 2012).

3.2 STUDY SITE

Korle-Bu Teaching Hospital

The study was conducted in the Neurophysiology/Electrophysiology Unit of the Department of Medicine, Korle-Bu Teaching Hospital and participants were recruited form the physiotherapy department of the Hospital. The hospital is the first of the three Teaching Hospitals to be established in Ghana. It is the largest hospital in Ghana offering tertiary care with an estimated bed capacity of about 2000 and the nation's leading national referral centre. It has 17 clinical and diagnostic departments/ units, has a daily hospital attendance of 1500 and about 250 in-patient admissions. The hospital also provides sophisticated and scientific investigative procedures and specialization in various fields of medicine.

Neurophysiology is a specialized field in the Department of Medicine and Therapeutics. Patients from all departments of the hospital and from other hospitals who need an electrophysiology assessment are referred to the neurophysiology unit of the Department of Medicine. The Neurophysiology Unit provides electrophysiology assessments like the EEG and EMG carried out by experts in the field. In all, a total of 10-15 EEGs and 2 EMG/ Nerve Conduction Studies (NCS) are performed per day in the unit

The physiotherapy unit of the Korle-Bu Teaching Hospital has a well-established paediatric unit where mothers bring children with various conditions for physiotherapy rehabilitation on outpatient basis. Children with Cerebral palsy form a part of the regular attendants to the unit. The physiotherapy unit has an average Cerebral palsy population of about thirty (30) children.

3.3 STUDY POPULATION

Children with spastic Cerebral palsy attending the Korle-Bu Physiotherapy Unit were recruited for the study. They were recruited as and when they attended physiotherapy sessions. Parents whose children were between the ages of 1-11 who met the inclusion criteria and consented to the study were given an Identification number that enabled easy tracking of the participants. This was repeated until the required number determined by the sample size calculation was reached.

3.4 SAMPLE SIZE

A total of 15 children with spastic Cerebral palsy participated in the study. Sample size was calculated based on One group pre-test post-test design. The sample size formula used was;

$$N = \frac{[S(\Delta)]^2(Z\alpha + Z\beta)^2}{E^2}$$

Where;

N = Sample size for a group

S(Δ) = Standard deviation of change in the outcome (0.970)

Zα = 1.96, (α) = 0.05, Confidence Interval = 95%

Zβ = 1.282, Type II error (β) = 0.2, Power = 0.9 (1-β)

E = Estimated effect size (0.8 – Large effect size)

Sample size was determined to be approximately 15.

3.5 SAMPLING TECHNIQUE

Purposive sampling technique was used to obtain sample size for this study. Due to the limited number of spastic cerebral palsy cases who have bilateral spasticity at the department, this technique was used to recruit children for the study.

3.6 INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria: Children included in the study were;

- children between the ages of 1 to 11 years,
- had been diagnosed with spastic Cerebral palsy and
- their parents or caregivers consented to the study.

Exclusion Criteria: Children excluded from the study were;

- children with history of seizures
- children who could not lie prone
- children who do not react to pain.

3.7 PROCEDURES

The study procedure and measurements were explained to parents who consented to the study. A consent form was made available for mothers to document their willingness to allow their

child to participate in the study. Children were recruited using a purposive sampling method. The children were then scheduled and sent to the Electrophysiology Unit at the Department of Medicine and Therapeutics, where the study was conducted.

A baseline assessment of the level of spasticity using the Modified Ashworth Scale (MAS) and H reflex responses (H reflex Amplitude, H-latency and HA Max/MA Max ratios) were measured on the bilateral calf muscles of the study participants by a licensed physiotherapist and a neurologist respectively. Range of Motion (ROM) measurement was also assessed twice on both ankle joints by the same physiotherapist. Children were positioned in prone, for EMG measurements, and in supine for MAS scoring and ROM assessment.

After the baseline assessments, TENS was applied to the bilateral calf muscles simultaneously for 30 minutes after which the calf muscles were reassessed for spasticity using the H-reflex and MAS, and the ankle joint assessed for ROM, using a Universal Goniometer. Due to the nature of the procedure, children were allowed at least a 10-minute rest when they arrived at the Electrophysiology unit to allow them some relaxation before the procedures begun. The procedure lasted for a total of 50 minutes per child.

3.7.1 OUTCOME MEASURES

3.7.1.1 PRIMARY OUTCOME MEASURES

ELECTROMYOGRAPHY RESPONSES (H REFLEX – H REFLEX AMPLITUDE, H LATENCY AND HA MAX/MA MAX)

H reflex responses were obtained using an EMG machine, Cadwell Serria II (CADWELL ®, USA). Participants were placed comfortably in the prone position over a pillow. Using a tape measure, a pen was used to create eight (8) equal divisions on the calf muscle between the popliteal fossa and the medial malleolus, after ensuring the skin was cleaned. Two disposable surface electrodes were used on each stimulation. The active electrode was placed on the 6th

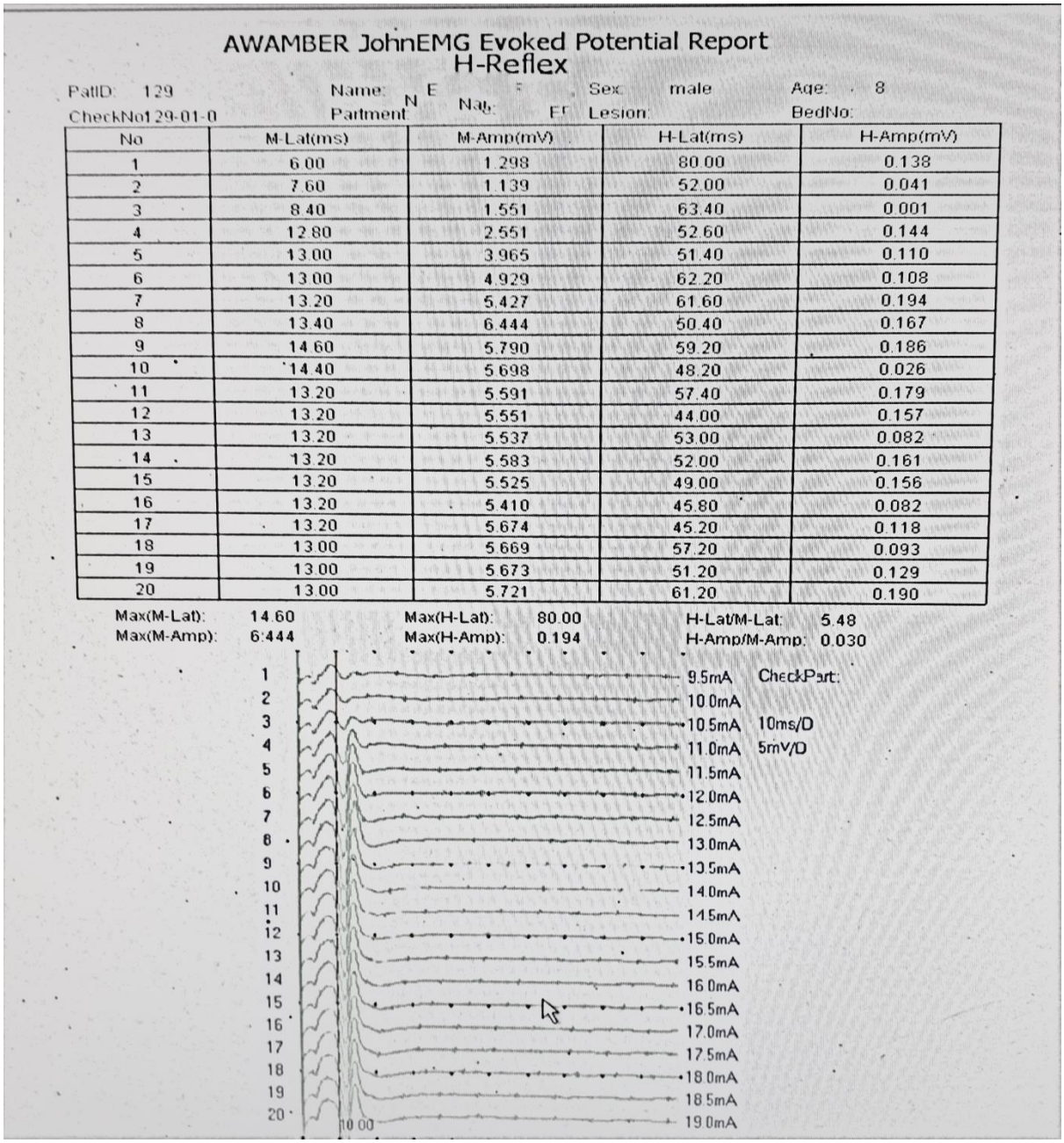
division and the reference electrode, on the last division, on the area of the Achilles tendon. A ground electrode (A silver plate) was placed between the popliteal fossa and the active electrode (that is; on the 3rd division). A bipolar electrode connected to an electrical stimulator was placed in the popliteal fossa to stimulate the tibial nerve.

Stimulation started at a low intensity of 9.5 mA and was gradually increased by a 0.5 mA till an intensity of 19.0 mA was attained. The sweep speed was set at 10ms/D and sensitivity, 5mV/D. In total 20 stimulations were given and its corresponding results for H-reflex and M-wave were produced.

H reflex and M-wave recordings were assessed at baseline and post intervention, both on the right and left lower limbs.

Figure 4: H reflex stimulation showing electrode, ground electrode and bipolar electrode placement. This picture was taken during the experiment.

Figure 5: Cadwell Serria II EMG machine



AWAMBER JohnEMG Evoked Potential Report
H-Reflex

PatID: 129 Name: N E Sex: male Age: 8
CheckNo129-01-0 Partment Nat: Er Lesion: BedNo:

No	M-Lat(ms)	M-Amp(mV)	H-Lat(ms)	H-Amp(mV)
1	6.00	1.298	80.00	0.138
2	7.60	1.139	52.00	0.041
3	8.40	1.551	63.40	0.001
4	12.80	2.551	52.60	0.144
5	13.00	3.965	51.40	0.110
6	13.00	4.929	62.20	0.108
7	13.20	5.427	61.60	0.194
8	13.40	6.444	50.40	0.167
9	14.60	5.790	59.20	0.186
10	14.40	5.698	48.20	0.026
11	13.20	5.591	57.40	0.179
12	13.20	5.551	44.00	0.157
13	13.20	5.537	53.00	0.082
14	13.20	5.583	52.00	0.161
15	13.20	5.525	49.00	0.156
16	13.20	5.410	45.80	0.082
17	13.20	5.674	45.20	0.118
18	13.00	5.669	57.20	0.093
19	13.00	5.673	51.20	0.129
20	13.00	5.721	61.20	0.190

Max(M-Lat): 14.60 Max(H-Lat): 80.00 H-Lat/M-Lat: 5.48
Max(M-Amp): 6.444 Max(H-Amp): 0.194 H-Amp/M-Amp: 0.030

Figure 6: A generated H-reflex report

MODIFIED ASHWORTH SCALE GRADING

The Modified Ashworth Scale (a scale adopted from Bohannon & Smith, 1987) was used to grade the level of spasticity of the calf muscle. Components of the Modified Ashworth Scale with their respective scores are;

0= no increase in muscle tone (0)

1= slight increase in muscle tone, manifested by a catch and release/ by minimal resistance at the end of the Range of Motion (1)

1+ = slight increase in muscle tone, manifested by a catch followed by minimal resistance throughout the remainder of the Range of Motion (2)

2= more marked increase in muscle tone throughout most of the Range of Motion, but the affected part is easily moved (3)

3= considerable increase in muscle tone, passive movement is difficult (4)

4= affected part is rigid in flexion or extension (5)

The child was positioned comfortably in supine on the assessment bed. Level of spasticity was assessed for passive ankle dorsiflexion from a neutral position with knee extended. This was graded and scored on the 6-point grading scale of MAS with scores of 0 to 5 as described earlier. The unexamined limb was kept stable by a non-examiner while ankle dorsiflexion was being carried out on the extended contralateral limb.

Assessment was carried out twice on each assessment period for the left and right lower limbs, by the investigator (licensed physiotherapist) for intrarater reliability at baseline and also at post intervention.

3.7.1.2 SECONDARY OUTCOME MEASURE

RANGE OF MOTION (ROM) MEASUREMENT

A 360 Degree Head – 12-inch Arm Universal Goniometer (BASELINE ® Plastic Goniometers, New York) was used to assess Range of Motion (ROM). It measured the angle allowed at the ankle joint during passive dorsiflexion.

The child was positioned comfortably in the supine position on the assessment bed with knee kept in extension by a non-examiner. The centre of the goniometer was placed over the lateral malleolus of the fibula with the stationary arm parallel to the fibula and movement arm, parallel to 5^{th} metatarsal. The ankle was moved passively to obtain maximum dorsiflexion. The movement arm was then aligned, parallel to the 5^{th} metatarsal bone. The angle obtained was recorded for each limb (Left and Right).

ROM measurements were assessed twice for intrarater reliability by the investigator (a licensed physiotherapist) for each measurement at baseline and post intervention.

3.8 INTERVENTION

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION UNIT AND ITS APPLICATION

TENS 3000 Analog Unit (ROSCOE MEDICAL, Strongsville-Ohio) was used to provide low intensity stimulations to the calf muscles. It is a portable two-channel electrode, powered by a 9 V battery. With children comfortably positioned in prone on the assessment bed, electrode pads were placed on the skin surface over the belly of the calf muscles after cleaning with an alcohol-based cleaning towel. The electrodes were placed three (3) fingers apart and connected by electrode cords to the TENS 3000 Analog Unit.

All participants received thirty (30) minutes of Transcutaneous Electrical Nerve Stimulation to the bilateral calf muscles, after the initial assessments have been conducted. Conventional TENS mode which has a frequency of 100 Hz and a pulse width of 200 µsec at a tolerable low intensity was used.

The TENS application was carried out by the investigator who is also a licensed physiotherapist.

Figure 7: Electrode placement for TENS application. This picture was taken during the experiment.

3.9 DATA HANDLING

All participants in this study were given number codes for confidentiality and to prevent duplication of data. Data was treated as confidential and was used solely for the purpose of this study.

3.10 STATISTICAL ANALYSIS

Statistical analyses were computed using Version 23 of the Statistical Package Social Sciences (SPSS). Both Descriptive statistics and inferential statistics were used to summarize and present the data.

Under the Descriptive statistics. Mean ± standard deviation was used to present age distribution of children and their heights. Most preferred position at home, gender and medication children were taking were recorded and were presented in frequencies.

Under the Inferential statistic, non-parametric tests were used to analyse data considering the sample size of the study, which is less than 30 and the distribution, which was not normally distributed. Mann Whitney U test was used to analyse median differences between Left and right calf muscle EMG, MAS, and ROM scores. A correlation analysis was used to establish an association between MAS and H reflex Amplitudes measures. Wilcoxon sign rank test was used to analyse median differences between pre-test and post-test results of EMG measures, MAS scores and ROM angles. A logistic regression was used to evaluate the effect of TENS as a predictor of MAS scores. Statistically significant results were defined with 95% confidence, and the alpha level was set at 0.05.

3.11 ETHICAL CONSIDERATION AND SAFETY MEASURES

The research procedure was explained to the parents/guardians of the children. Participation was entirely voluntary; a written informed consent was made available to willing parents and

they had the option to withdraw their consent at any point in the study without any consequences to their regular physiotherapy sessions.

Transcutaneous Electrical Nerve Stimulations (TENS) and Electromyography (EMG) are non-invasive standard of care and diagnostic stimulations which are applied at low intensities in children. TENS is used as the standard of care for babies with brachial plexus injuries in combination with exercises at Ghanaian Physiotherapy departments and it is well tolerated with no adverse effects.

To prevent the risk of electric shocks the EMG and TENS machines are well grounded. A portable TENS machine which uses a 9V battery instead of direct electricity was used for the intervention.

The study did not interfere with the normal therapeutic or medical procedures children were involved in.

This study was reviewed and approved by the Ethical Protocol and Review Committee of the School of Biomedical and Allied Health Sciences, College of Health Sciences of the University of Ghana, and Korle-Bu Teaching Hospital. Copies of the approval letters are attached in the appendix.

SAFETY MEASURES: Contraindications associated with TENS include, the presence of cardiac pacemakers, heart disease and application of the stimulation to areas such as the carotid sinus region. Mothers were asked if their children had an implant or had any of the conditions stated above. TENS was kept at a constant low-level intensity and applied for a duration of 30 minutes, a safe duration, to avoid any incidence of skin irritation or skin burn.

To reduce the possibility of skin irritation and skin burn as a potential adverse reaction during EMG, stimulation intensity was incremental to attain the point of maximal electrical response with minimal irritation.

There were no reported cases of unlikely events. All participants completed the study with no adverse reactions. Mothers were given a contact number to call and report any unusual incident when they got back home. None of them reported any unusual incident. Safety measures were applied appropriately.

3.12 DISSEMINATION OF RESULTS

Results from this study were presented to the Physiology department of the University in partial fulfilment for the award of an MPhil degree in Physiology. The results will be further processed and prepared for publishing in peer review journals to add to the knowledge in literature in the area of spasticity management.

CHAPTER 4

4.0 RESULTS

4.1 DESCRIPTIVE STATISTICS OF PARTICIPANTS

Fifteen (15) children, recruited from the Physiotherapy unit of Korle-Bu teaching hospital participated in this study. All children who participated in the study had been diagnosed by a medical doctor with spastic Cerebral palsy and were receiving regular physiotherapy treatment. All parents gave a written informed consent to approve their children's participation. Table 3 presents information on the descriptive statistics of children who participated in this study.

TABLE 3: Demographic characteristics presenting the gender, age, height, most preferred position, and medication categories description of children with spastic Cerebral palsy who participated in the study.

		NUMBER OF PARTICIPANTS *(%)*
GENDER	MALE	10 *(66.7)*
	FEMALE	5 *(33.3)*
MOST PREFERRED POSITION OF CHILDREN AT HOME	SUPINE	5 *(33.3)*
	SUPINE BUT CAN ROLL	3 *(20.0)*
	SIDE LYING AND PRONE	1 *(6.7)*
	SIDE-LYING ALONE	1 *(6.7)*
	ACTIVE	5 *(33.3)*
MEDICATION CATEGORIES	NO MEDICATION	6 *(40.4)*
	SPASTICITY MEDICATION	5 *(33.3)*
	SPASTICITY MEDICATION PLUS ANY OTHER MEDICATION	3 *(20.0)*
	OTHER MEDICATIONS	1 *(6.7)*
AGE (YEARS)	MEAN AGE ± SD	5.10±2.93
	RANGE	1-10
	MEAN AGE (MALES)	5.90±2.88
	MEAN AGE (FEMALES)	3.5±2.55
HEIGHT (CM)	MEAN HEIGHT ± SD	91.47±14.60
	RANGE	67.0 -112.5
	MEAN HEIGHT (MALE)	94.55±13.67
	MEAN HEIGHT (FEMALES)	85.30±15.95

4.2 BASELINE SPASTICITY CHARACTERISTICS OF CALF MUSCLES AS MEASURED BY ELECTROMYOGRAPHY (EMG) AND MODIFIED ASHWORTH SCALE (MAS).

Spasticity of both calf muscles were assessed using the EMG and MAS. Result for these measures are presented under the headings 4.2.1 and 4.2.2.

4.2.1 BASELINE ELECTROPHYSIOLOGICAL CHARACTERISTICS OF CALF MUSCLES

H reflex response was determined. The H-reflex with the minimum latency (HL) and maximal amplitude (HA) were recorded. In addition, the ratio of the maximum amplitude H reflex response (HA Max) to the maximum muscle response amplitude (MA Max) was determined. The pretest H-reflex in the left and right calf muscle was measured, compared and analyzed using Mann Whitney U test. The left calf muscle had higher HA and HL median scores compared to the right. The right calf muscles had higher HA Max/MA Max ratio median scores compared to the left. However, the noted differences between the left and right calf muscles median scores did not reach statistical significance (Table 4).

Table 4: Differences in baseline EMG characteristics between Left and Right Calf muscles

EMG MEASURES	LEFT	RIGHT	U value	*p-value*
HA (mv)	0.228	0.181	106	0.775
HA Max/MA Max	0.390	0.430	110	0.935
HL (mms)	62.800	58.000	104	0.744

EMG scores are presented in Medians

4.2.2 BASELINE SPASTICITY LEVEL OF CALF MUSCLES USING THE MODIFIED ASHWORTH SCALE (MAS).

The median scores for both left and right MAS scores was 2. Participants' MAS scores ranged from 0 – 4. Out of the 15 participants, only one (1) had a "MAS" score of Zero (0) on both left and right calf muscles even though she had an observable lower limb spasticity. Pretest MAS scores were analysed with Mann Whitney U test for differences between left and right calf muscle spasticity (Figure 8). There was no statistically significant difference between the left and right calf muscle median MAS scores.

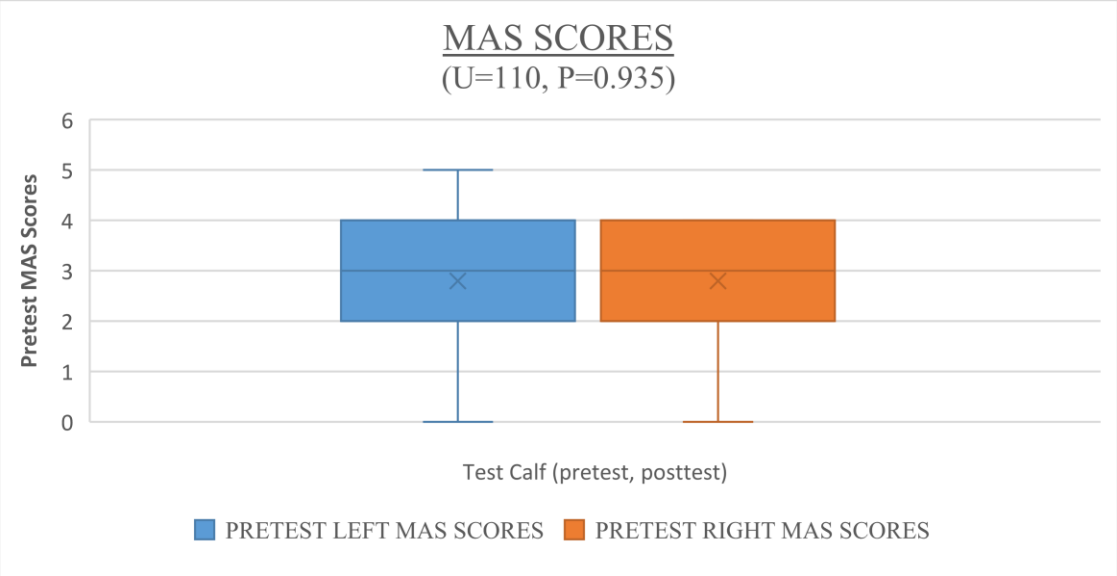


Figure 8: Left and Right MAS scores of participants with associated p-value.

4.3 CORRELATION BETWEEN PRETEST MAS SCORES AND PRETEST HA MAX/MA MAX RATIOS

Raw scores for pretest MAS with their corresponding HA Max/MA Max ratios are presented in Table 5.

Table 5: MAS scores and HA Max/MA Max ratio of participants

Participant's ID	Left pretest MAS scores	Left pretest HA Max/MA Max ratios	Right pretest MAS scores	Right pretest HA Max/MA Max ratios
1	4	0.081	4	0.043
2	3	0.023	4	0.027
3	3	0.035	2	0.041
4	3	0.039	4	0.047
5	1	0.035	1	0.220
6	5	0.043	4	0.071
7	0	0.032	0	0.030
8	2	0.059	3	0.023
9	4	0.042	4	0.035
10	2	0.023	2	0.044
11	4	0.068	3	0.037
12	1	0.075	1	0.052
13	3	0.021	3	0.013
14	3	0.069	3	0.051
15	4	0.039	4	0.056

Pretest scores for MAS were further analyzed for correlation with Pretest ratios of HA Max/MA Max using Spearman's rank order correlation. "There was no correlation between left pretest MAS scores and Left pretest HA Max/MA Max scores, r=0.307, n=15, p = 0.133". "There was also no correlation between right pretest MAS scores and right pretest HA Max/MA Max ratios, r = -0.015, n = 15, p = 0.479".

4.4 BASELINE GONIOMETER ROM MEASUREMENTS OF PARTICIPANTS

Dorsiflexion ROM angles were measured, and the medians computed. There were no notable trends in ROM as related to increase in age or participant's gender. Mann Whitney U test was used to determine the median difference between left and right ankle joints. Results obtained showed no statistically significant difference between median dorsiflexion ROM angles of the left (10 ^{o}) and right (12 ^{o}) ankle *(U=107.5, p=0.838)*.

Standardized ROM scores for dorsiflexion in healthy children have been computed in literature. They are used as reference points during rehabilitation for children with limited ankle dorsiflexion. Measured dorsiflexion ROM angles for both left and right ankles were therefore further compared with a computed median dorsiflexion ROM angle of 18.2 ^{o}, calculated from three (3) standard ankle dorsiflexion ROM of 13^{o}, 18.2^{o}, and 27^{o} across different age categories; 1$^{1/2}$-19 years, 4-7 years and 7-14 years (Alanen et al., 2001; Boucher, Onate & Bolte, 2014; Physical Rehabilitation and Medicine, 2016). A "one-sample" non-parametric test was used to compare the sample median of 11^{o} to the hypothesized median. The test showed a statistically significant difference *(t= -2.984, p=0.006)* between the sample median and hypothesized median ankle dorsiflexion ROM. Participants had low ankle dorsiflexion ROM angles as compared to the hypothesized ROM angle.

4.5 POST TREATMENT EFFECT OF TENS ON EMG MEASURES, MAS, AND ROM

4.5.1 EFFECT OF TENS ON EMG MEASURES

EMG measures were recorded post stimulation of both calf muscles. Pre and posttest scores were compared using Wilcoxon Signed Rank Test. The test showed statistically significant results between pretest (0.228) and posttest median (0.168) scores of Left calf muscle HA (p = 0.011) and overall HA scores of both calf muscles (p = 0.005). Statistical significance level is set at $p<0.05$. Graphical representation of median results of the various EMG measures are presented in Figures 9 – 11.

4.5.1.1 Effect of TENS on H reflex Amplitude

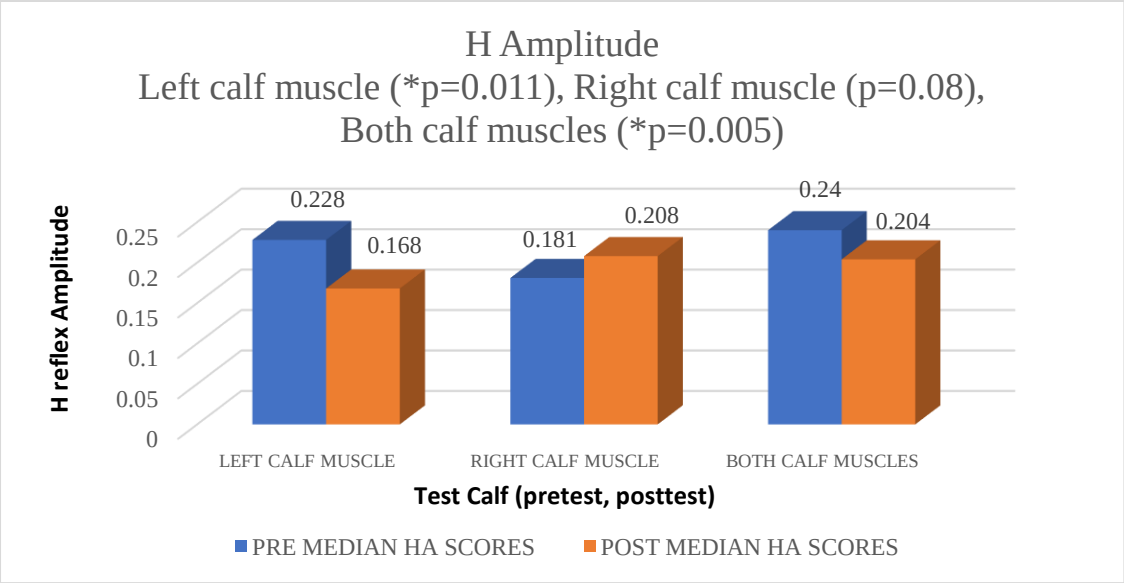


Figure 9: Median differences between pre and posttest H reflex Amplitude scores

4.5.1.2 Effect of TENS on Maximum H latency

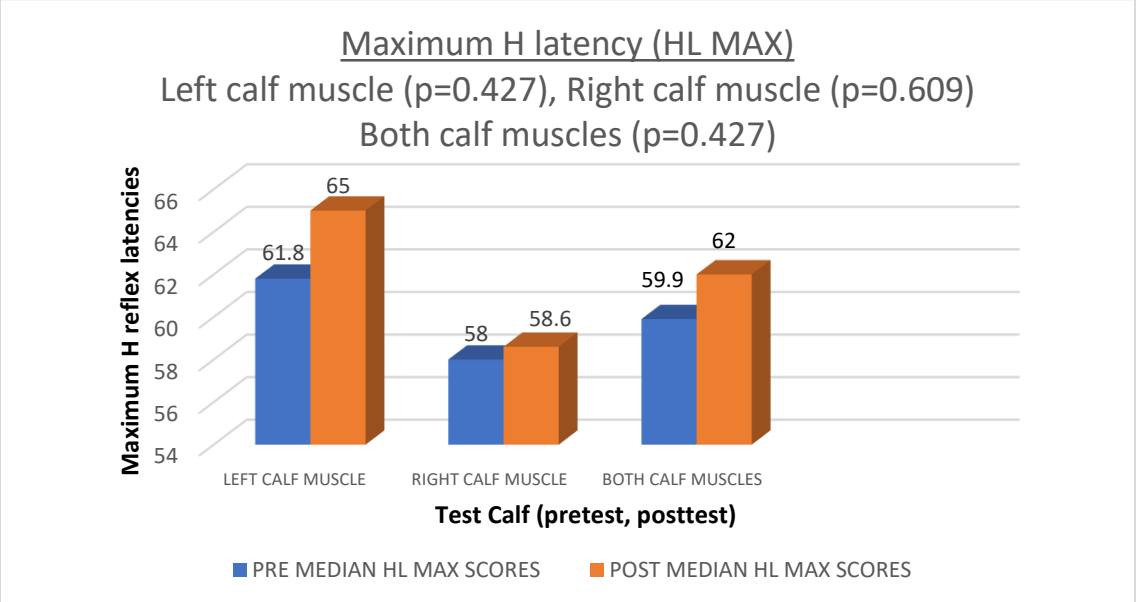


Figure 10: Median differences between pre and posttest maximum H latency scores

4.5.1.3 Effect of TENS on HA Max/MA Max ratio

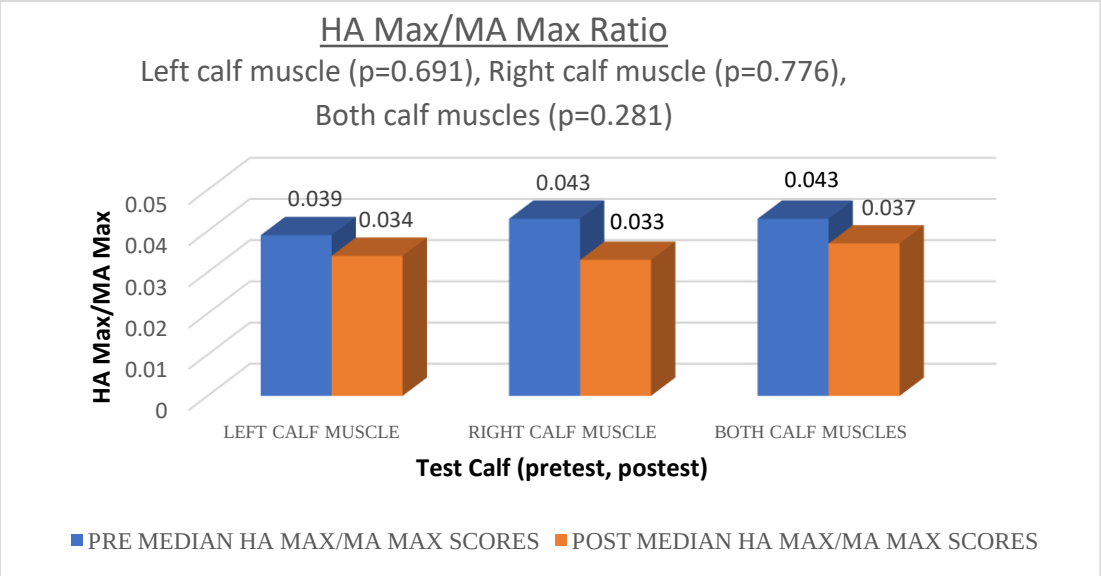


Figure 11: Median differences between pre and posttest HA Max/MA Max ratios

4.5.2 EFFECT OF TENS ON MAS SCORES

4.5.2.1 DIFFERENCE IN PRETEST AND POSTTEST MAS SCORES

Pretest and posttest MAS scores were compared using the Wilcoxon Signed Rank test. Results showed a statistically significant difference between pretest and posttest scores of the Left calf muscle (*p=0.009), Right (*p=0.004) calf muscle and average scores for both left and Right (*p=0.004). Posttest MAS scores were significantly lower than the pretest scores for both left and right calf muscles. Figure 12 shows graphical comparison of the median differences in pre and posttest MAS scores.

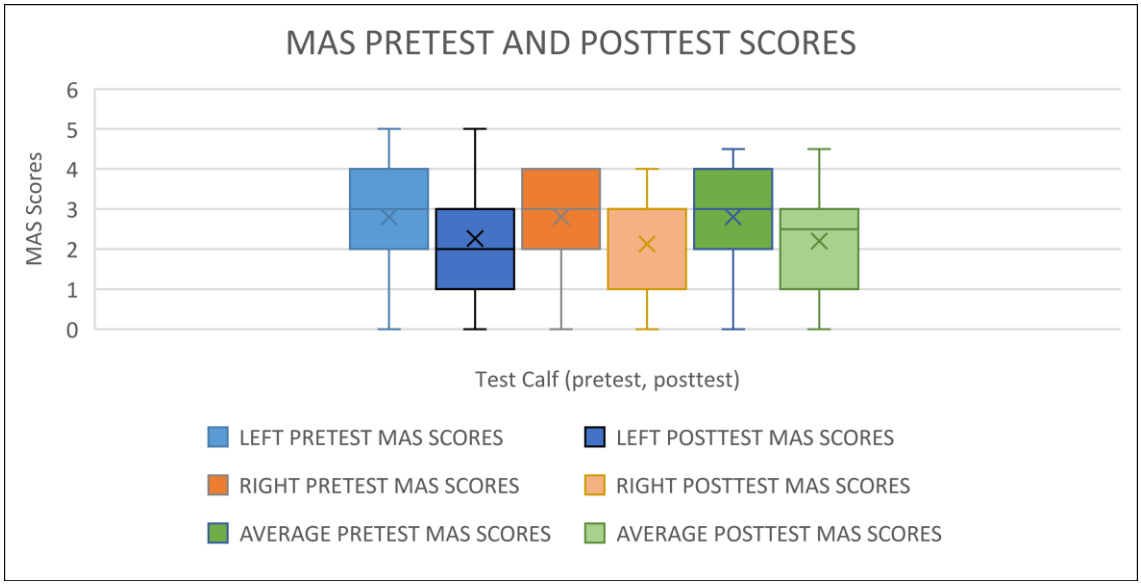


Figure 12: Pre and posttest MAS scores of Left (Blue), Right calf muscles (Orange) and average MAS scores (Green) of both calf muscles.

4.5.2.2 Regression Analysis

Modified Ashworth Scale scores were further categorized into a dichotomized variable. Participants who had MAS scores of 0, 1 and 1+ were grouped under "low spasticity" (reference group). Those with scores of 2, 3 and 4 were grouped under "high spasticity". An exploratory simple logistic regression analysis (low spasticity; high spasticity) showed that TENS application did not lead to low MAS scores *(p=0.458)*.

4.5.3 EFFECT OF TENS ON ROM

Angle differences in pretest and posttest ankle dorsiflexion ROM were compared using Wilcoxon Signed Rank Test. Computed results showed statistically significant difference in ankle pretest and posttest dorsiflexion ROM angles in left ankle (p=0.02), right ankle (p=0.003) and average ROM angles for both ankle joints (p=0.038) – Table 6.

Table 6: Median differences in ankle dorsiflexion ROM angles between pretest and posttest measurements.

TEST LIMB	PRETEST	POSTTEST	Z SCORE	P-VALUE
LEFT (°)	10°	20°	-2.314	0.02*
RIGHT (°)	12°	18°	-2.957	0.003*
AVERAGE (°)	11°	12°	-2.078	0.038*

Ankle dorsiflexion ROM angles are presented in medians, *$p < 0.05$

CHAPTER 5

5.0 DISCUSSION

Challenges related to the management of spasticity among children with Cerebral palsy requires the use of evidence-based interventions. Spasticity often employs the use of pharmacological methods, non-pharmacological methods, and some physical modalities like Transcutaneous Electrical Nerve Stimulation (TENS). This study aimed at evaluating the effect of TENS on calf muscle spasticity among children with spastic Cerebral palsy using selected electromyographic measures (H reflex Amplitude-HA, H reflex latency-HL, Ratio of maximum H reflex amplitude to maximum Motor response Amplitude-HA Max/MA Max and Motor response Amplitude), Modified Ashworth Scales (MAS) and Range of Motion (ROM).

5.1 DEMOGRAPHIC CHARACTERISTICS PRESENTING THE GENDER, AGE, HEIGHT, MOST PREFERRED POSITION, AND MEDICATION CATEGORIES DESCRIPTION OF CHILDREN WITH SPASTIC CEREBRAL PALSY WHO PARTICIPATED IN THE STUDY.

Data from this study recorded a higher percentage of male participants with higher mean height as compared to female participants. This finding is consistent with the male gender susceptibility to Cerebral palsy described in a previous study (Cleves, Lee, & Kabongo, 2011). Majority of the children recruited were either active or were kept in supine position at home. The children who depended on caregivers to move were kept in the same position for longer hours in the day. This finding is consistent with a previous study conducted by Sato *et al.* (2014) that revealed that caregivers do not regularly change positions of children with Cerebral palsy especially during the periods when caregivers sleep, and also when the caregivers are busy during the day. The most preferred position from this study was the supine position which

has been found to be associated with an increased extensor pattern and can easily introduce a windswept position- both lower limbs move towards one direction (Barnes, 1998).

A reason for the supine position preference is attributed to the introduction of discomfort in the prone position (flexor pattern). This leads to crying, which worsens spasticity and further compromises the children. Fifty-three percent (53.3%) of the children in this study were on medications for spasticity. The most common approach in spasticity management is the use of medications (Alabdulwahab & Al-Gabbani, 2010; Kheder & Nair, 2012; Ved & Shah, 2017). Children who were not on medications may be due to the fact that they had low spasticity levels and also caregivers may have had challenges with finances and could not afford the high cost of medications. Medications, used for spasticity requires regular dosing over a sustained period and this poses a challenge for caregivers with financial challenges (The Finder, 2016).

5.2 BASELINE SPASTICITY CHARACTERISTICS OF CALF MUSCLES AS MEASURED BY ELECTROMYOGRAPHY (EMG) AND MODIFIED ASHWORTH SCALE (MAS)

5.2.1 BASELINE ELECTROPHYSIOLOGICAL CHARACTERISTICS OF CALF MUSCLES

The H reflex assessment in this study showed no significant difference between left and right calf muscles at baseline. There is conflicting evidence in the literature. Whiles the results corroborates previous studies that concluded that there is no difference between EMG measures of the left and right calf muscles (Mezzarane & Kohn, 2002; Jankus, Robinson, & Little, 1994), another study showed a difference between the left and right sides (Tan, 1985). This difference may be explained by the young age group used in this study who has been described to have

lower H reflex responses (Palmieri, Ingersoll, & Hoffman, 2004). Also, the differences in methodology between the previous studies and the present study and the small sample size used in this present study as compared to the previous study may have accounted for differences in results. The lack of any statistically significant difference between left and right calf muscles may also be attributed to equal disruption of the descending pathways on both sides of the brain in the children with Cerebral palsy who participated in this study.

5.2.2 BASELINE MODIFIED ASHWORTH SCALE CHARACTERISTICS OF THE CALF MUSCLES

Almost all participants presented with similar MAS scores for both the left and right calf muscles ($p=0.935$). This score indicated that there was muscle spasticity in both calf muscles and a bilateral brain pathology (Kohan *et al.*, 2010). However, one (1) participant had a low MAS score. In this particular participant, other muscles aside the calf muscles also recorded a low MAS score even though these muscles were observed to be spastic. This could have arisen from positioning. When this participant was positioned supine, spasticity generally reduced and when positioned in prone, spasticity was observed to increase. This observation is contrary to the general effect that the supine position has on spasticity (Hallenborg 1990). When children with spastic Cerebral palsy have low MAS scores it is a reflection that spasticity has improved.

The low MAS scores may have been due to the fact that the child was regular on her spasticity medication, which was confirmed by her caregiver. Furthermore, the MAS scores recorded in this participant may have been because of a general flexion pattern as opposed to an extension pattern that was observed. Having a flexion pattern will imply that the supine position which encourages an extension pattern will introduce a counter positioning and therefore reducing spasticity in this position (Physiopedia, 2019). High MAS scores implies pronounced calf spasticity. Most of them had an extensor pattern and therefore had a general increase in

spasticity when positioned in supine, the position used during the acquisition of the MAS scores.

5.3 CORRELATION BETWEEN THE RATIO OF MAXIMUM H REFLEX AMPLITUDE TO MAXIMUM MOTOR RESPONSE AMPLITUDE AND MODIFIED ASHWORTH SCALE (MAS).

High pretest MAS scores did not present with associated high pretest HA Max/ MA Max ratios. Some children who were considered as having low spasticity scores had high HA Max/MA Max ratios. A high HA Max/MA Max ratio is consistent with high spasticity levels (Arumugam, Bedi, & Kaur, 2016). This would imply that a high MAS score which also suggests high spasticity should correlate with a high HA Max/MA Max ratio. In this study, there was no correlation between MAS and HA Max/MA Max ratios. This finding is consistent with previous studies that found no correlation between MAS and HA Max/MA Max ratios (Arumugam, Bedi, & Kaur, 2016; Kohan *et al.*, 2010). However, the findings are in contrast with a previous study that found a positive correlation between MAS scores and HA Max/MA Max ratios (Tekgul *et al.* 2013). The subjective nature of the MAS measured by the same physiotherapist may have introduced a bias even though it was measured twice**.** Assessment using this scale is entirely based on the examiner's clinical judgement on resistance produced by the muscle being assessed (Bakheit *et al.*, 2003) and may have therefore produced discrepancies in correlation when compared to an objective measure. Furthermore, the lack of correlation could be due to anatomical and biomechanical factors which influence scores reported by most ordinal scales used in spasticity assessment like MAS (Flamand, Massé-Alarie, & Schneider, 2013; Mutlu, Livaneliglu & Gunel, 2008).

5.4 BASELINE RANGE OF MOTION CHARACTERISTICS OF CALF MUSCLES

Ankle dorsiflexion ROM measures in children with spastic Cerebral palsy who participated in this study were significantly limited as compared to standardized ankle dorsiflexion measures in children who had no disease or joint pathology (Alanen, *et al.*, 2001; Boucher, Onate & Bolte, 2014; Physical Rehabilitation and Medicine, 2016; Soucie *et al.*, 2011). In comparing measured ROM with standardized ROM measures, it is recommended to use "side to side" and standardized ROM comparison methods (Soucie *et al.*, 2011; Macedo & Magee, 2008**;** Alanen *et al.*, 2001). There was no significant difference between left and right ankle ROM measures. This result is consistent with the study by Macedo & Magee (2008) who concluded that a healthy joint should be used as a reference when measuring ROM in a pathological joint. In addition, Cerebral palsy is usually diplegic or quadriplegic and can be hemiplegic sometimes. In this study majority of the participants presented with spastic quadriplegic Cerebral palsy and this may underpin this finding.

5.5 POST TREATMENT EFFECT OF TENS ON CALF MUSCLE SPASTICITY AND ANKLE ROM AS MEASURED BY EMG, MAS, AND ROM

5.5.1 EFFECT OF TENS ON CALF MUSCLE SPASTICITY AS MEASURED BY EMG - H REFLEX

In this study, there was a reduction in spasticity as measured by HA after TENS application in calf muscles however only the left-sided reached statistical significance. Therefore, TENS was effective in reducing alpha motor neuron excitability. This is consistent with previous studies that recorded a reduction in H reflex Amplitude after TENS application (Joodaki, Olyaei & Bagheri, 2001; Hui-Chan & Levin, 1993) and a further study by Gürcan et al. (2015), which reported no statistical significance between pre HA and post HA scores after TENS application.

The reason for asymmetry in statistical significance in pre and post HA scores of left and right calf muscles may have occurred because the present study recorded higher posttest median HA score as compared to the pretest median score on the right calf muscle as opposed to the left. Medians are a good measure of central tendency in non-parametric measures, yet still the right scores did not reach statistical significance. Furthermore, the small sample used in this study may have accounted for the asymmetry in results. Lastly, even though children had quadriplegic Cerebral palsy, there was asymmetry in baseline HA scores implying that the pathology may have been asymmetrical from the onset.

H reflex Latency increased after TENS application. This increase however did not reach statistical significance. Whiles this is consistent with previous studies (Garcia & Vargas, 2019; Gürcan *et al.*, 2015), other studies found statistically significant increase in H latency scores post TENS application (Ved & Shah, 2017; Joodaki, Olyaei & Bagheri, 2001). Inconsistency in the results could be due to the differences in methodology the present study.

HA Max/MA Max ratios reduced after TENS application however, the reduction did not reach statistical significance. This is consistent with previous studies that found no statistical significance between pretest and posttest HA Max/MA max ratios (Ved & Shah, 2017; Hui-Chan & Levin, 1993). The number of participants could have influenced and prevented these differences from reaching statistical significance.

5.5.2 EFFECT OF TENS ON SPASTICITY AS MEASURED BY MAS

In this study, MAS scores were observed to reduce after TENS application. This is consistent with various studies that have proven the effectiveness of TENS in reducing MAS scores which provides an indication of reduction in spasticity (Mills & Dossa, 2016; Arati & Shraddha, 2014; Seliem *et al.*, 2007). Regression analysis was done to confirm whether the application of TENS

will lead to low MAS scores. Results showed no statistical significance, which imply that TENS may not lead to low MAS scores. However, the results may have been influenced by the small sample size used for this study.

5.5.3 EFFECT OF TENS ON ROM AS MEASURED BY THE GONIOMETER

This study showed statistically significant improvement in ROM measures after TENS application. This result is consistent with a previous study by Arati and Shraddha (2016). Mechanisms associated with TENS, as outlined by Mills and Dossa (2016) leads to a corresponding reduction in spasticity by inhibiting its excitability. Application of TENS over a spastic calf muscle will therefore result in relaxation of the calf muscles which will ease tension on the ankle joint, considering the insertion point of the calf muscles (insertion points cross the ankle joint) and, allow movement at the ankle joint. This may account for the increased ROM observed in this study after TENS application.

CHAPTER 6

6.0 SUMMARY

6.1 CONCLUSION

Results from this study shows that;

- There is no difference in baseline spasticity characteristics of calf muscles as measured by H reflex responses (HA, HA Max/MA Max, HL) and MAS, between left and right calf muscles.
- There is no correlation between HA Max/MA Max and MAS scores
- There is no difference in baseline ankle ROM as measured by the goniometer between left and right calf muscles.
- Left calf muscles showed a statistically significant reduction in neuron excitability (HA) after TENS application. Even though post-test scores of the other EMG measures (Right HA, Left and Right HA Max/MA Max and HL) showed an improvement, this difference did not reach statistical significance.
- There is a statistically significant reduction in left and right calf muscle spasticity as measured by the MAS scores after TENS application.
- There is a statistically significant improvement in left and right ankle ROM after TENS application.

6.2 STUDY LIMITATIONS

- Large sample could not be recruited considering the cost of the electromyography test.
- The small sample size used in this study limits the generalizability of the data.
- There was a challenge in getting willing caregivers to allow their children participate in this study at a different department, on a day that was not designated for physiotherapy.

- The use of a single evaluator for MAS and ROM assessment could have introduced bias even though measurements were carried out twice.
- The duration and frequency of TENS used in this study could have influenced its post treatment effect.
- There was no long term follow up on the effect of TENS.

6.3 RECOMMENDATIONS

There recommendations from this study are that;

- further studies should consider recruiting larger samples.
- Further studies using Randomized control Clinical Trial design may help establish the actual effect of TENS on spasticity.
- Further studies may increase the duration and frequency of TENS application over consecutive days to identify if there is a cumulative and beneficial effect on spasticity.
- Further studies should consider a long term follow up on the effect of TENS.

REFERENCES

Abas, O., Abdelaziem. F. & Kilany, A. (2017). Clinical Spectrum of Cerebral palsy and associated disability in South Egypt: A local survey study. *Maced J Med, 5* (1), 37-41.

Abbink, V. D. B & Glas, V. D. (1998). Detection of onset and termination of muscle activity in surface electromyograms. *Journal of Oral Rehabilitation, 25* (5), 365-369.

Adei-Atiemo, E., Rodrigues, O. & Badoe, E. (2015). Classification and Risk Factors for Cerebral Palsy in the Korle Bu Teaching Hospital, Accra: A Case − Control Study. *135*, 5–7. doi: 10.1542/peds.2014

Aisen, M. L., Kerkovich, D., Mast, J., Mulroy, S., Wren, T. A., Kay, R. M. & Rethlefsen, S. A. (2011). Cerebral Palsy: Clinical care and neurological rehabilitation. *Lancet Neurol*, *10*, 844-52.

Alabdulwahab, S. S. & Al-Gabbani, M. (2010). Transcutaneous electrical nerve stimulation of hip adductors improves gait parameters of children with spastic diplegic Cerebral palsy. *Neurorehabilitation*, *26*(2), 115–122. doi: 10.3233/NRE-2010-0542.

Alanen, J. T., Levola J. V., Helenius H. Y. & Kvist, M. H. (2001). Ankle Joint Complex Mobility of Children 7 to 14 Years Old. *Journal of Pediatric Orthopaedics, 21*(6), 731–737. Available at: http://journals.lww.com/pedorthopaedics/Abstract/2001/11000/Ankle_Joint_Complex_Mobility_of_Children_7_to_14.6.aspx/

Alhusaini, A. A., Dean, C. M., Crosbie, J., Shepherd R. B., & Lewis J. (2010). Evaluation of spasticity in children with Cerebral Palsy using Ashworth and Tardieu scales compared with laboratory measures. *J Child Neurol, 25,* 1242-1247.

Alsubiheen, A., Petrosky, J., Dahar, N., Lohman E., Balbas, E. & Lee, H. (2017). Tai Chi mental imagery theory improves soleus H-reflex and nerve conduction velocity in patients with type 2 diabetes. *Complementary Therapies in Medicine, 31,* 59-64.

Ali, W., Iqbal, J., Ahmed, P. & Ahmed, S. (2006). Cerebral Palsy: An overview. *Curr Pediatr Res, 10* (1 & 2), pp 1-7 Available at: http://www.ncbi.nlm.nih.gov/pubmed/16417071 (Accessed: 6 April 2019).

Arati, P. & Shraddha, D. (2014). Effect of high frequency TENS versus Sham TENS on spastic plantar flexors in children with Cerebral Palsy. *Int J Physiother Res, 2* (3), 507-510.

Arneson, C. L., Durkin, M. S., Benedict, R. E., Kirby, R. S., Yeargin-Allsopp, M., Van Naarden Braun, K. & Doernberg, N. S. (2009). Prevalence of Cerebral palsy: Autism and Developmental Disabilities Monitoring Network, three sites, United States, 2004. *Disabil. Health J.* [Online] *2* (1), 45–48. Available from: doi: 10.1016/j.dhjo.2008.08.001 [Accessed 10th October 2018]

Arumugam, N., Bedi, P. K. & Kaur, G. (2016). Relationship between Modified Ashworth Scale and Alpha Motoneuron Excitability in Spinal Cord Lesions. *International Journal of Physiotherapy*, *3*(4), 439–444.

Ayden, G., Serap, T., Isk, K., Ozbudak, D. S., & Sevim, O. (2005). Transcutaneous electrical nerve stimulation versus baclofen in spasticity: clinical and electrophysiologic comparison. *Physical Medicine Rehabilitation. 84*(8), 584-592.

Bakheit, A. M.O., Maynard, V. A., Curnow, J., Hudson, N. & Kodapala, S. (2003). The relation between Ashworth scale scores and the excitability of alpha motor neurons in patients with post-stroke muscle spasticity. *J Neurol, 74*, 646-648.

Bari, A. (2018). Electromyogram (EMG). *International Journal of Scientific and Research Publications (IJSRP), 8*(9), 85–91.

Barnes, M. P. (1998). Management of spasticity. *Age and Ageing, 27*, 239-245.

Bax, M., Tydeman, C. & Flodmark, O. (2007). Clinical and MRI Correlates of Cerebral Palsy. *Survey of Anesthesiology*, *51*(3), 137–138. doi: 10.1097/01.sa.0000267037.42809.8c.

Binstead, J. T. & Varacallo, M. (2019). *Anatomy, Bony Pelvis and Lower Limb, Calf*, *StatPearls*. StatPearls Publishing. Available at: http://www.ncbi.nlm.nih.gov/pubmed/29083629 (Accessed: 13 June 2019).

Bohannon, R. W. & Smith, M. B. (1987). Interrater reliability of a Modified Ashworth Scale of Muscle spasticity. *Phys Ther*. [Online] *67* (2), 206-7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/3809245

Bosques, G., Martin, R., McGee, L. & Sadowsky, C. (2016). Does therapeutic electrical

stimulation improve function in children with disabilities? A comprehensive literature review. *Journal of Paediatric Rehabilitation Medicine* [Online] *9,* 83-99 Available from doi: 10.3233/PRM-160375 [Accessed 7th September 2018]

Boucher, L., Onate, J. & Bolte, J. (2014). Pediatric Ankle Range of Motion: What Is Considered "Normal"?', *Journal of athletic training*, *49*.

Boundless (2019). *Classification of receptors by stimulus*. Available at: https://med.libretexts.org/Bookshelves/Anatomy_and_Physiology/Book%3A_Anatomy_and_Physiology_(Boundless)/12%3A_Peripheral_Nervous_System/12.2%3A_Sensory_Receptors/12.2A%3A__Classification_of_Receptors_by_Stimulus (Accessed: 23 May 2019).

Boyd, R. N. & Ada L. (2008). Physiotherapy management of spasticity. In: Johnson, G. and Pandyan, A. (eds). *Upper Motor Neurone Syndrome and Spasticity*, *2nd Edition*. New York: Cambridge University Press, pp 79-94.

Brukner, P. (2012). *Brukner & Khan's Clinical Sports Medicine*. North Ryde; McGraw-Hill.

Burke, D. (1988). Spasticity as an adaptation to pyramidal tract injury. *Adv Neurol* [Online] *47*, 401-23. Available from http://www.ncbi.nlm.nih.gov/m/pubmed/3278524 [Accessed 10th September 2018].

Burton, A. (2015). Fighting Cerebral Palsy in Africa. *Lancet, 14.*

Cameron-Tucker, H. (1983). The Neurophysiology of Tone: The Role of the Muscle Spindle and the Stretch Reflex. *Australian Journal of Physiotherapy*, *29*(5), 155–165. doi: 10.1016/S0004-9514(14)60687-5.

Capady, C. (1997). Neurophysiological methods for studies of the motor system in freely moving human subjects. *J. Neurosci Methods, 74*, 201-218.

Centre for Disease Control and Prevention (2018). Cerebral Palsy: Risk Factors. [Online] Available from http://www.cdc.gov/ncbddd/cp/causes.html [Accessed 6th October 2018].

Chowdhury, R. H., Raez, M. B. I., Bin Mohd Ali, M. A., Bakar, A. A. A., Chellappan, K. & Chang, T. G. (2013). Surface electromyography signal processing and classification techniques. *Sensors (Switzerland)*, 13(9), 12431–12466. doi: 10.3390/s130912431.

Cleves, C., Lee, J. W. & Kabongo, M. L. (2011). Cerebral Palsy. [Online] Available from http://pdfs.semanticscholar.org/ [Accessed 6th October 2018].

Cuoco, A. & Tyler, T. F. (2012). Plyometric Training and Drills. Fourth Edi, *Physical Rehabilitation of the Injured Athlete*. Fourth Edi. Elsevier Inc. doi: 10.1016/b978-1-4377-2411-0.00026-5.

Dimitrijevic, L., Colovic, H. Spalevic, M., Stankovic, A. Ziatanovic, D. & Cvetokovic, B. (2014). Assessment and Treatment of spasticity in Children with Cerebral palsy. *Scientific Journal of the Faculty in Nis, 31* (3), 163-169.

Ellul, C. & Gatt, A. (2016). Transcutaneous calf-muscle electrostimulation: A prospective t

reatment for diabetic claudicants? *Diabetes and Vascular Disease Research, 13* (6), 442-446.

Enoka, R. M. (2015). *Neuromechanics of Human Movement (5th ed.)*. Champaign, IL:

Sheridan Books

Fernández-Tenorio, E., Serrano-Munoz, D. Avendano-Coy, J. & Gomez-Soriano, J. (2018).

Transcutaneous electrical nerve stimulation for spasticity: A systematic review. *Neurología (English Edition)*. doi: 10.1016/j.nrleng.2018.08.001.

Fischer, M. A. (2002). H reflex and F waves: Fundamentals, normal and abnormal patterns.

Neurol Clin, 20, 339-60.

Flamand, V. H., Massé-Alarie, H. & Schneider, C. (2013). Psychometric evidence of spasticity

measurement tools in Cerebral palsy children and adolescents: A systematic review. *Journal of Rehabilitation Medicine, 45*(1), 14–23. doi: 10.2340/16501977-1082.

Gajdosik, R. L. & Bohannon, R. W. (1987). Clinical Measurement of Range of Motion

Review of Goniometry Emphasizing Reliability and Validity. *Phys Ther, 67*(12), 1867–72. Available at: https://pdfs.semanticscholar.org/9dc7/67d20fcb87936b350f1ec9f591a026aaf0f4.pdf

Gorter, J. W., Rosenbaun, P. L., Hanna, S. E, Palisano, R. J., Barlett, D. J., Rusell, D. J., Walter, S. D., Raina, P., Galuppi, B. E. & Wood, E. (2004). Limb distribution, motor impairment and functional classification of Cerebral palsy. *Dev. Med. Child Neurol* [Online] *46* (7), 461-67.

Garcia, M. A. C. & Vargas, C. D. (2019). Is somatosensory electrical stimulation effective in relieving spasticity? A systematic review. *Journal of Musculoskeletal and Neuronal Interactions*.

Golaszeoski, S., Kremser, C., Wagner, M., Feiberi, S., Aichner, F. & Dimitrijevic, M. M. (1999). Functional Magnetic Resonance Imaging of the human motor cortex before and after whole-hand afferent electrical stimulation. *Scand J Rehabil Med, 31,* 165-73.

Gracies, J. M., Nance, P., Elovic, E., McGuire, J. & Simpson, D. M. (1997). Traditional pharmacological treatments for spasticity part I: Local treatments. *Muscle Nerve* [Online] *6,* S61-91 Available from http://www.ncbi.nln.nih.gov/m/pubmed/9826984/ [Accessed 22nd September 2018]

Graham, H. K., Rosenbaum, P., Paneth, N., Dan, B., Damiano, D. L., Becher, J.G., Gaebler-Spira, D., Colver, A., Reddihough, D. S, Crampton K. E. & Lieber, R. L. (2016). Cerebral Palsy. Nature Reviews, *Disease Primer, 2* (1).

Grippo, A., Carrai, R., Hawamdeh, Z. Falsini, C., Aito, S., Pinto, F., Descisciolo, G. & Pizzi, A. (2011). Biomechanical and EMG assessment of spastic hypertonus in motor complete traumatic spinal cord injured individuals. *International Spinal Cord Society, 49*, 142-148.

Grünewald, R. A, Yoneda, Y., Shipman, J. M. & Sagar, H. J. (1997). Idiopathic focal dystonia: A disorder of muscle spindle afferent processing. *Brain, 120*, 2179-2185.

Günel, M. K. (2011). Physiotherapy for children with Cerebral Palsy In: Gadze, Z. P. (ed) *Epilepsy in Children: Clinical and Social aspects*. [Online] In Tech, pp 213-234 Available from: http://www.intechopen.com/books/epilepsy-in-children-clinical-and-social-aspects/physiotherapy-for-children-with-cerebral-palsy [Accessed 10th October 2018].

Gürcan, A., Selçuk, B., Önder, B., Akyuz, M. & Yavuz, A. A. (2015). Evaluation of Clinical and Electrophysiological Effects of Electrical Stimulation on Spasticity of Plantar Flexor Muscles in Patients with Stroke. *Turk J Phys Med Rehab, 61*(4), 307–313. doi: 10.5152/tftrd.2015.38981.

Guyton, A. C. & Hall, J. E. (2011). *Medical Physiology*. Twelve. Philadelphia: Saunders, Elsevier.

Hallenborg, S. C. (1990). Positioning: In. Glenn M. B., Whyte, J. (eds). *The practical*

management of spasticity in children and adults. Pp 97-117. Philadelphia, Lea and Febiger.

Hoffman, P. (1910). Beitrag zur kenntnis der menschlichen Reflexe mit besonderer Berucksichtigung der Erscheinungen. *Arch Anat Physiol, 1*, 223-246.

Hopkins, J.T. Ingersoll, C. D., Cordova, M.L. & Edwards, J. E. (2000). Intrasession and intersession reliability of the soleus H reflex in supine and standing positions. *Electromyogr Clin Neurophysiol, 40*, 89-94.

Hui-Chan, C. W. & Levin, M. F. (1993). Stretch reflex latencies in spastic hemiparetic subjects are prolonged after Transcutaneous Electrical Nerve Stimulation. *Can J Neurol Sci, 20,* 97-106.

Jan, M. M. S. (2006). Cerebral Palsy: Comprehensive Review and update. *Ann Saudi Med, 26* (2), 123-132.

Jankus, W. R., Robinson, L. R. & Little, J. W. (1994) Normal limits of side-to-side H reflex amplitude variability. *Arch Phys Med Rehabil, 75* (1), 3-7.

Johnson, G. R. & Pandyan, A. D. (2008). The measurement of spasticity In: *Upper Motor Neurone Syndrome and Spasticity (2008)*. New York: Cambridge University Press.

Jones, M. W., Morgan, E., Shelton, J. E. & Thorogood, C. (2007). Cerebral Palsy: Introduction and Diagnosis (Part I). *21*(3). doi: 10.1016/j.pedhc.2006.06.007.

Joodaki, M. R., Olyaei, G. R. & Bagheri, H. (2001). The effects of electrical nerve stimulation

of the lower extremity on H-reflex and F-wave parameters. *Electromyography and clinical neurophysiology, 41*(1), 23–8.

Kalb, A., Huette, D. & Bass, G. (2012). *An occupational Therapy-based education program for caregivers of individuals with Cerebral palsy in Ghana: A culturally conscious perspective*. Scholarly project and independent studies Grand forks, ND & Casper WY site, University Of North Dakota.

Katirji, B. (2016). Clinical Electromyography In: Daroff, R. B., Jankovic, J., Mazzotta, J. C. and Pomeroy, S. L. *Bradley's Neurology in Clinical Practice*. Volume 1, 7th Edition, New York, Elsevier, pp. 1301-1323.

Katirji, B. & Kaminski, H. J. (2002). Electrodiagnostic approach to the patient with suspected neuromuscular junction disorder. *Neurol Clin, 20*, 557-586.

Kheder, A. & Nair, K. P. S. (2012). Spasticity: Pathophysiology, evaluation and management. *Pract Neurol* [Online] *12* (5): 289-98 Available from doi: 10.1136/practneurol-2011-000155 [Accessed 6th October 2018]

Kohan, A. H., Abootalebi, S., Khosnervisan, A. & Rahgozar, M. (2010). Comparison of MAS and Hoffman reflex in study of spasticity. *Acta Med Iran, 48* (3), 154-7.

Koshmahl, E. M. (2018). *Goniometry*. University of Scranton [Online] Available from http://www.scranton.edu/faculty/koshmahl/courses/gonio/intro/def-procedure.shtml [Accessed 22nd October 2018]

Krigger, K. W. (2006). Cerebral palsy: An overview. *Am Fam Physician, 73* (1), 91-100.

Kröger, S. (2018). Proprioception 2.0: novel functions for muscle spindles. *Current opinion in neurology, 31*(5), 592–598. doi: 10.1097/WCO.0000000000000590.

Lebiedowska, M. K. & Fisk, J. R. (2003). Quantitative evaluation of reflex and voluntary activity in children with spasticity. *Arch Phys Med Rehabil, 84,* 828-837.

Lance, J. W. (1980). "Symposium," In Feldman R. G., Young R. R., Koella W. P. (Eds). *Spasticity: Disordered Motor Control*. Chicago: Yearbook Medical Publishers, Pp 485–495.

Light, V. & Nelson, J. (2018). Cerebral Palsy. Healthline [Online] Available from http://www.healthlline.com/health/cerebral-palsy#causes [Accessed 6th October 2018]

Lin, Y., Lin, I., Chou T. A. & Lee, H. (2016). Quantitative evaluation for spasticity of calf muscle after botulinum toxin injection in patients with Cerebral palsy: a pilot study. *Journal of NeuroEngineering and Rehabilitation,* (March). doi: 10.1186/s12984-016-0135-8.

Mabrouk, M. S. & Kandil, O. A. (2012). Surface Multi-Purposes Low Power Wireless Electromyography (EMG) system Design. *International Journal of Computer Applications*, *41*(12), 975–8887. doi: 10.5120/5592-7350.

Macedo, L. G. & Magee, D. J. (2008). Differences in range of motion between dominant and nondominant sides of upper and lower extremities. *Journal of Manipulative and Physiological Therapeutics, 31*(8), 577-582. doi: 10.1016/j.jmpt.2008.09.003

MacLennan, A. H., Thompson, S. C. & Gecz, J. (2015). Cerebral palsy: Causes, pathways and the role of genetics variants. *American Journal of Obstetrics and Gynecology,* 779-788. http://dx.doi.org/10.1016/j.ajog.2015.05.034

Mall, V., Heinen, F., Siebel, A., Bertram, C., Hafkemeyer, U., Wissel, J., Berweck, S., Haverkamp, F. Nass, G., Döderlein, L., Breitbach – Faller, N. & Korinthenberg, R. (2006). Treatment of Adductor spasticity with BTX-A in children with CP: A randomized, double- blind, placebo-controlled study. *Dev Med Child Neurol, 48,* 10-13.

Manigandan, G. & Bharathi, K. (2017). Effect of Transcutaneous Electrical Nerve Stimulation over Gastrocnemius Muscle Spasticity among Hemiparetic Patients. *iMedPub Journals,* 1–7.

Marret, S., Vanhulle, C. & Laquerriere, A. (2013). Pathophysiology of Cerebral palsy. *Handbook of Clinical Neurology*, *111*, 169–176. doi: 10.1016/B978-0-444-52891-9.00016-6.

Marinelli, L. [Image] (2014). Descending pathways mediating spinal reflexes. In. Pathophysiology of Spasticity: Implications for Neurorehabilitation. *Journal of*

Biomedicine and Biotechnology, [Online] *2014*, 1-8 Available from doi: 10.1155/2014/354906

Marzvanyan, A. (2019). *Physiology, Semsory Receptors*. Available at: https://www.statpearls.com/kb/viewarticle/36740 (Accessed: 21 May 2019).

Matsuo, T. (2002). Cerebral Palsy*: Orthopaedic Selective Spasticity-control Surgery*. Available at: http://soufusha.co.jp/igaku/cpe.html/ Accessed: 3 May 2019).

Meythaler, J. M. (2001). Concept of Spastic Hypertonia. *Physical Medicine and Rehabilitation Clinics of North America, 12*(4), 725–732. doi: 10.1016/S1047-9651(18)30029-9.

Mezzrane, R. A. & Kohn, A. F. (2002). Bilateral soleus H-reflexes in humans elicited by simultaneous trains of stimuli: Symmetry, variability, and covariance. *J Neuro Physiol, 87*, 2074-2083.

Mileusnic, M., Brown, I. E. & Loeb, G. E. (2002). Development of a muscle spindle model. pp. 2521–2522. doi: 10.1109/iembs.2002.1053406.

Miller, F. & Bachrach, S. J. (2006). *Cerebral Palsy: A Guide for Care*. The Alfred I. Dupont Institute, Wilmington, Delaware, Hopkins Press. [Online] p. 475 Available from http://www.gait.aidi.udel.edu/res695/homepage/pd_ortho/clinics/c_palsy/cpweb.htm [Accessed 10th October 2018]

Mills, P. B. & Dossa, F. (2016). Transcutaneous Electrical Nerve Stimulation for

Management of Limb Spasticity: A Systematic Review. *American Journal of Physical Medicine and Rehabilitation*, *95*(4), 309–318. doi: 10.1097/PHM.0000000000000437.

Mukherjee, A. & Chakravarty, A. (2010). Spasticity mechanisms - for the clinician. *Frontiers in Neurology*, 1–10. doi: 10.3389/fneur.2010.00149.

Mutlu, A., Livanelioglu, A. & Gunel, M. K. (2008). Reliability of Ashworth and Modified Ashworth Scales in children with spastic Cerebral palsy. *BMC, Musculoskelet Disord*, *9*, 44.

Nass, R., Sidhu, R. & Ross, G. (2016). Autism and other Developmental Disabilities In: Daroff, R. B., Jankovic, J., Mazzotta, J. C. & Pomeroy, S. L. *Bradley's Neurology in Clinical Practice*. Volume 1, 7th Edition, New York, Elsevier, pp. 1301-1323e7

Nelson, K. B. (2008). Causative Factors in Cerebral Palsy. *Clinical Obstetrics and Gynecology, 51*(40), 749-762.

Nelson, R., Hayes, H. & Currier, D. (1999). *Clinical Electrotherapy*. 3rd Edition. Standford, CT, Appleton, and Lange.

Nielsen, J. B., Crone, C. & Hultborn, H. (2007). The spinal pathophysiology of spasticity—from a basic science point of view. *Acta Physiol (Oxf), 189* (2), 171-8.

Oo, W. M. (2015). Spasticity In: Holloway, A. A. (ed.) *Paraplegia: Clinical Characteristics*,

prevalence and treatment outcomes. New York, Nova Science Publishers, pp 83-130.

Pak, S. & Patten, C. (2008). Strengthening to promote functional recovery post stroke: An evidence-based review. *Top Stroke Rehabil, 91,* 11-24.

Pakula, A. T., Braun, K. U. N. & Yeargin-Allsopp M (2009). Cerebral palsy: Classification & Epidemiology. *Phys Med Rehabil Clin, 20,* 425-452.

Palmieri, R. M., Hoffman, M. A. & Ingersoll, C. D. (2002). Intersession reliability for H-reflex measurements arising from the soleus, peroneal, and tibialis anterior musculature. *The International journal of neuroscience*, 112(7), 841–50. Available at: http://www.ncbi.nlm.nih.gov/pubmed/12424824 (Accessed: 12 June 2019).

Palmieri, R. M., Ingersoll, C. D. & Hoffman, M. A. (2004). The Hoffmann Reflex: Methodologic Considerations and Applications for Use in Sports Medicine and Athletic Training Research. *Journal of athletic training*, *39*(3), 268–277. doi: 10.1007/s00421-003-0967-3.

Park, J., Seo, D., Choi, W. & Lee, S. (2014). Effects of exercises with TENS on spasticity, Balance and Gait in patients with Chronic Stroke: A Randomized Control Trial. *Med Sci Monit. 20,* 1890-1896.

Physical Rehabilitation and Medicine. (2016). Paediatric Range of Motion. Available at: https://musculoskeletalkey.com/pediatric-range-of-motion/ (Accessed: 20th May, 2019).

Physiopedia. (2019). *Goniometer*. Available at: https://www.physio-pedia.com/Goniometer/

(Accessed:20th May, 2019)

Physiopedia [Image]. (2019). Medizinischer Goniometer. Retrieved from:

https://www.physio-pedia.com/index.php?title=File:Medizinischer_Goniometer.jpg&oldid=204351

Physiopedia. (2019). *Muscle spindles*. Available at:

https://www.physio-pedia.com/Muscle_spindles#cite_note-10 (Accessed: 20th May 2019).

Pierrot – Descilligny, E. & Mazevet, D. (2000). The monosynaptic reflex: A tool to

investigate motor control in humans' interest and limit. *Neurophysiol Clin, 30*, 67-80.

Platt, M. J., Cans, G., Johnson, A., Surman, G., Topp, M., Torriolo, M. G. & Krageloh-Mann,

I. (2007). Trends in Cerebral palsy among infants of very low birth weight (<1500g)

or born prematurely (<32 weeks) in 16 European centres: A database Study. *Lancet, 369* (9555), 43-50.

Purepong, N., Jitvimonrat, A., Boonyong, S., Thaveeratitham, P. & Pensri, P. (2012). Effect

of flexibility exercise on lumbar angle: A study among non-specific low back pain patients. *Journal of Body work and Movement Therapies, 16*, 236-243.

Rethlefsen, S. A., Ryan, D. D. & Kay, R. M. (2010). Classification Systems in Cerebral

Palsy. *Orthop Clin N Am, 41*, 457-467.

Rha, D. W., Yang, E. J., Chung, H. I., Kim, H. B., Park, C. I. & Park, E. S. (2008). Is Electrical Stimulation beneficial for improving the paralytic effect of Botulinum toxin type A in children with spastic diplegic Cerebral palsy? *Yonsei Med J. 49* (4), 545-552.

Roatta, S. & Passatore, M. (2006). Muscle Sensory Receptors. *Wiley Encyclopedia of Biomedical Engineering*. doi: 10.1002/9780471740360.ebs0809.

Rogers, L. & Wong, E. (2007). *Cerebral palsy | McMaster Pathophysiology Review*. Available at: http://www.pathophys.org/cerebralpalsy/ (Accessed: 15 April 2019).

Rosenbaum, P. Paneth, N. Leviton, A., Goldstein, M., Bax, M., Damiano, D., Dan, B. & Jacobsson, B. (2007). A report: The definition and classification of Cerebral palsy. *Dev Med Child Neurol Suppl, 109*, 8.

Sankar, C. & Mundkur, N. (2005). Cerebral palsy – Definition, Classification, Etiology and Early Diagnosis. *Indian J Pediatr. 72* (10), 865–868.

Sastre-Garriga, J., Vila, C., Clissold, S. & Montalban X. (2011) THC & CBD oromucosal spray (Sativex) in the management of spasticity associated with multiple sclerosis. *Expert Rev Neurother, 11*, 527-37.

Sato, H., Iwasaki, T., Yokoyama, M. & Inoue, T. (2014). Monitoring of body position and

motion in children with severe Cerebral palsy for 24 hours. *Disability and Rehabilitation, 36* (14), 1156-1160, doi: 10.3109/09638288.2013.833308

Schieppati, M. (1987). The Hoffman reflex: A means of assessing spinal reflex excitability and its descending control in man. *Prog Neurobiol, 28,* 345-376.

Segen, J. C. (2006). Concise dictionary of modern medicine. McGraw-Hill.

Seliem, H. A., Nagieb, G. S., Eliewa, E. A. & Seliem, A. M. (2007). Efficacy of different modalities on spasticity management of spinal cord injury: Clinical and electrophysiological study. *Egypt Rheumatol Rehab, 34* (3), 405-416.

Shadish, W. R., Cook, T. D., & Campbell, D. T. (2002). *Experimental and quasi-experimental designs for generalized causal inference*. Belmont, CA: Wadsworth, Cengage Learning.

Shamsoddini, A., Susan, A., Hollisaz, M., Rahimnia, A. & Khatibi-Aghda, A. (2014). Management of spasticity in children with Cerebral palsy. *Iranian Journal of Pediatrics, 24* (4), 345–351. doi: 10.3944/AOTT.2009.081.

Shamsoddini, A. (2010). Comparison between the effect of neurodevelopmental treatment and sensory integration therapy on gross motor function in children with Cerebral palsy. *Iranian Journal of Child Neurology, 4* (1), 31–38.

Sharan, D. (2005). Recent advances in management of Cerebral palsy. *72* (8), 969–973.

Sheean, G. (2008). Neurophysiology of spasticity. In Johnson, G. R. and Pandyan, A. D.

(eds). Upper Motor Neurone Syndrome and Spasticity. doi: 10.1017/CBO9780511544866.004.

Shevell, M., Dagenais, L., & Oskui, M. (2013). The epidemiology of Cerebral palsy: New perspective from a Canadian Registry. *Semin Pediatr Neurol, 20,* 60-64.

Sincero, S. M. (2013). *Sensory Receptors*. Available at: https://explorable.com/sensory-receptors (Accessed: 21 May 2019).

Smania, N., Picelli, A., Munari, D. Geroin, C., Lanes, P., Waldner, A. & Gandolfi, M. (2010). Rehabilitation procedure in the management of spasticity. *Eur J Phys Rehabil Med, 46*, 423-38.

Soucie, J. M., Wang, C., Forsyth, A., Funk, S., Denny, M., Roach, H. E., Boone, D. & The Haemophilia Treatment Centre Network (2011). Range of motion measurements: Reference values and a database for comparison studies, *Haemophilia, 17*(3), 500–507. doi: 10.1111/j.1365-2516.2010.02399.x.

Stevenson, V. L. (2010). Spasticity Management. *Clin Rehabil*, 24, 293-304.

StudyBlue [Image]. (2018). Retrieved from https://www.studyblue.com/notes/note/n/nursingstudy-guide-2012-13-solazzo/deck/9711975

Sultan H. E., Helal A. M. & Awaad Y. (2005). Management of Spasticity in diplegic Cerebral

palsy: Evaluation of Botulinum Toxin A, Transcutaneous Electrical Stimulation and Kinesthetic gait training. *The Egyptian Journal of Paediatric Neuroscience, 2* (2), 5-11.

Surveillance of Cerebral Palsy in Europe (2002). Prevalence and Characteristics of children with Cerebral Palsy in Europe. *Dev. Med. Child Neurol, 44* (9), 633-640.

Tan, U. (1985). Left-Right differences in the Hoffman reflex recovery curve associated with handedness in normal subjects. *International Journal of pathophysiology, 3,* 75-78.

Tekgul, H., Polat, M., Tosun A., Serdaroğlu, G. & Gokben, S. (2013). Electrophysiologic assessment of spasticity in Children using H reflex. *Turk J Pediatr, 55,* 519-523.

The Finder. (2016) Mercy Killing: The story of parents with Cerebral Palsy Children. [Online] Available from: http://www.myjoyonline.com/news/2016/august-24th/mercy-killing-the-story-of-parents-with-cerebral-palsy-children.php [Accessed 9th January 2019].

Trompeto, C., Marinelli, L., Mori, E., Pelosin E., Curra, A., Molfettta, A. & Abbrizzese, G. (2014). Pathophysiology of Spasticity: Implications for Neurorehabilitation. *Journal of Biomedicine and Biotechnology*, [Online] *2014*, 1-8 Available from doi: 10.1155/2014/354906

Ved, V. & Shah, M. (2017). Immediate effect of Transcutaneous Electrical Nerve Stimulation

Versus cryotherapy on Calf muscle spasticity in Cerebral Palsy patients- An electrophysiological comparative study. *Indian Journal of Physical Therapy, 5* (1), 24-27.

Villis, T. (2013). *Muscle Receptor, Spinal Reflexes and Muscles*. Available at: http://www.tutis.ca/NeuroMD/index.htm (Accessed: 7 May 2019).

Volpe, J. J. (2017). Confusions in Nomenclature: "Periventricular Leukomalacia" and "White Matter Injury"—Identical, Distinct, or Overlapping? *Pediatric Neurology, 73,* 3–6. doi: 10.1016/j.pediatrneurol.2017.05.013.

Wang, R. Y., Chan, R. C. & Tsai, W. (2000). Effects of thoracolumbar electric sensory stimulation on knee extensor spasticity of persons who survive Cerebrovascular Accident. *J Rehabil Res Dev, 37,* 73-9.

Watkins, B., Darrah, J. & Pain, K. (1995). Reliability of passive ankle dorsiflexion measurements in children: Comparison of Universal and Biplane Goniometer. *Pediatr Phys Ther, 7,* 3-8.

Watson, T. (2009). *Electrotherapy: Practice based on evidence* (12th ed.). Elsevier, Espania.

Webster, J. G. (2009). *Medical Instrumentation: Application and design* (4th ed.). John Wiley and Sons, Hoboken, New Jersey.

Wolting, R. (2018). Classification of Cerebral palsy. Handicap International Group and Enablement Cerebral palsy Project [Online] Available from http://www.physio-pedia.com/Classification-of-cerebral_palsy [Accessed 22 September 2018].

Youdas, J. W., Carey, J. R. & Garrett, T. R. (1991). Reliability of measurements of cervical spine range of motion: Comparison of 3 methods. *Physical Therapy, 71* (2), 98-104.

APPENDIX

PARTICIPANT INFORMATION SHEET

INVESTIGATOR: DELALI ED-BANSAH

DEPARTMENT: DEPARTMENT OF PHYSIOLOGY

A copy of this information sheet will be given to you

PROJECT TITLE: TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION IN THE MANAGEMENT OF SPASTICITY IN CEREBRAL PALSY

You are invited to take part in a research study being carried out in electrophysiological unit of the medical block in Korle-Bu teaching Hospital. Before you make a decision to participate, you will be required to read this information. This is for you to understand why the research is being done and what it will involve. Take your time to decide and ask questions if you need clarification on anything.

What is the purpose of the study?

This is a study designed to investigate the effect of Transcutaneous Electrical Nerve Stimulation (TENS) on muscle spasticity due to Cerebral palsy and it is in partial fulfilment of a Master's degree programme at the University of Ghana, Department of physiology.

Why are you being invited?

You are invited to participate in this study because you have a child with spastic Cerebral palsy and your child has physiotherapy sessions at the Physiotherapy department of the Korle-Bu Teaching Hospital

Does my child have to participate?

Your child's participation in this study is entirely voluntary. You have the option to be part or not. This study will be described in detail to you and I will go through thus information sheet with you. You will then be required to sign a consent for indicating your agreement for your child to participate in the study. In case you do not feel like continuing with the study, you are free to withdraw your child no matter where we have gotten to in the study. I will also want you to know that your decision to participate or not will not interfere with child's regular therapy or medical procedures and if you withdraw your consent at any time, it will not be held against you or affect your child's regular treatment.

What happens if I do not want to continue after I have agreed to participate?

You are free to request for any information obtained on your child or from you at any point of the study. All your information will be taken out of the data collected.

What will happen to my child if I agree to participate?

Due to the nature of the study, all children who will participate will be given numbers to hide their identity. They will receive the TENS application to their inner thigh muscles.

When you arrive at the study site, you and your child will be allowed to rest for 10 minutes. You will be asked to lay your child on an assessment mat where the initial assessment will be carried out. Afterwards you would be allowed to take another 10 minutes. You will be asked to lay your child back on the assessment mat. TENS will be applied by placing the electrode pads, 2 on each limb, on the calf muscles of your child. If your child is moving too much, the pads will be secured with a bandage to hold it in place throughout the intervention which will last for 30 minutes.

After the TENS application, another assessment like the one conducted before the intervention will be carried out again. All assessment will be carried out twice both before the intervention and after the intervention. The assessments will be conducted again at 30-minute interval from the end of the intervention.

The study will require you and your child to be at the research site for a maximum of about 3 hours. This will entail the time for the assessment before the intervention, the 30-minute intervention, the time for the immediate post intervention and 30 minutes after intervention assessment

To prevent discomfort or skin irritation with the stimulation, a low intensity will be applied.

Are there adverse reactions associated with this study?

The possible adverse effect of this stimulation is skin irritation and skin burn which will be controlled by cleaning the skin with rubbing alcohol, using a low intensity, and applying the stimulation over an accepted safe duration (30 minutes).

What are the benefits of taking part?

If you allow your child to participate in this research, you will help in answering the reason for this study and this will go a long way to help the care of children with Cerebral palsy based on the outcome. Also note that your transportation and feeding for you and your child on that day will be catered for.

Is my participation confidential?

Information or any data taken from you or your child will be treated as confidential and data will not be tagged to your name or your child's name since the study will employ the use of a code to identify your child. Information taken will only be made available to the researcher and supervisors.

Who reviewed the study?

This proposal has been reviewed and approved by the Ethical and Protocol Review Committee of the University of Ghana and Korle-Bu Teaching Hospital, which is a committee responsible for ensuring that participants in this research are protected from harm.

What if I want further information regarding the study?

If you have any questions you can ask them now or later, even after the study has begun. If you wish to ask questions later please contact any of the following people;

1. Delali Ed-Bansah, 0246297532, delali2214@gmail.com
2. Dr. Thomas Tagoe, 0561327783
3. Dr. Patrick Adjei, 0549581079

CONSENT FORM

PART II: Certificate of Consent

My child has been invited to participate in the research to investigate another option of spasticity management. I understand that it will involve my child undergoing some stimulations which are not harmful and some assessment procedures which will require my child to be at the research centre for about 3 hours. I have been informed that the risks are minimal and there are no severe adverse reactions and that the only possible effect will be a slight irritation on my child's skin or if worse a skin burn of which I have been assured of proper medical care. I have also been assured of my transportation and feeding to and from the research centre. I have been given the number of someone I can contact in case I have a concern.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked, has been answered to my satisfaction. I consent voluntarily to allow my child to participate in this research and I understand that I have the right to withdraw from the research at any time without in anyway affecting my child's medical care.

NAME OF PARENT: ……..

SIGNATURE OF PARENT: ……

DATE: ……..

Day/month/year

I have accurately read or witnessed the accurate reading of the consent form to the potential participant's parent and he/she has had the opportunity to ask questions. I confirm that the individual has given consent freely.

NAME OF RESEARCHER: ……

SIGNATURE OF RESEARCHER: ……

DATE: ……

Day/month/year

A copy of this Informed Consent Form has been provided to participant's parent ……

DATA CAPTURING FORM

CODE NUMBER OF CHILD: ……

AGE OF CHILD: …….

HEIGHT: ……

DRUG HISTORY: ……

CHILD'S POSITIONS AT HOME ON A TYPICAL DAY: ……...

……

BASELINE ASSESSMENT

H LATENCY SCORE: …….

H_{MAX}/M_{MAX} RATIO: ……

MODIFIED ASHWORTH SCALE GRADING: ……..

RANGE OF MOTION MEASUREMENT: ……..

POST INTERVENTION ASSESSMENT

H LATENCY SCORE: ……..

H_{MAX}/M_{MAX} RATIO: …….

MODIFIED ASHWORTH SCALE GRADING: ……..

RANGE OF MOTION MEASUREMENT: ……..

ETHICAL CLEARANCE LETTER, COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA
COLLEGE OF HEALTH SCIENCES
ETHICAL AND PROTOCOL REVIEW COMMITTEE

Ref. No.: EPRC/FEB/2019 February 08, 2019

Ms. Delali Ed-Bansah
Department of Physiology
School of Biomedical and Allied Health Sciences
Korle-Bu

ETHICAL CLEARANCE

Protocol Identification Number: ***CHS-Et/M.6 – 5.9/2018-2019***

FWA: 000185779 **IORG: 0005170** **IRB: 00006220**

The College of Health Sciences Ethical and Protocol Review Committee (EPRC) at its February 08, 2019 full board meeting reviewed and approved your re-submitted research protocol.

Title of Protocol: **"Transcutaneous electrical Nerve stimulation in the Management of Spasticity in Children with Cerebral Palsy"**

Principal Investigator: **Ms. Delali Ed-Bansah**

This approval requires that you submit six-monthly review report(s) of the study to the Committee and a final full review report to the EPRC at the completion of the study. The Committee may observe, or cause to be observed, procedures and records of the study before, during and after implementation.

Please note that any significant modification(s) to this project/study must be submitted to the Committee for review and approval before its implementation.

You are required to report all serious adverse events related to this study to the EPRC within seven (7) days verbally and fourteen (14) days in writing.

As part of the review process, it is the Committee's duty to review the ethical aspects of any manuscript that may be produced from this study. You will therefore be required to furnish the Committee with any manuscript for publication.

This ethical clearance is valid till February 10, 2020.

Please always quote the protocol identification number in all future correspondence in relation to this protocol.

Signed: .....
Professor Andrew Anthony Adjei
Chair, Ethical and Protocol Review Committee

cc: Provost, CHS
Dean, SBAHS
Head, Department of Physiology

• P. O. Box KB 52, Korle Bu, Accra, Ghana. • **Telephone:** +233 (0) 306 665103/4 • **Fax:** +233 (0) 302 660762
• **Email:** admin.chs@ug.edu.gh / provost.chs@ug.edu.gh • **Website:** www.chs.ug.edu.gh

ETHICAL CLEARANCE LETTER, KORLE-BU TEACHING HOSPITAL

In case of reply the number
And the date of this
Letter should be quoted
My Ref. No. KBTH/MA/93/19
Your Ref. No.

KORLE BU TEACHING HOSPITAL
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-6
Fax: +233 302 667759
Email: Info@kbth.gov.gh
pr@kbth.gov.gh
Website: www.kbth.gov.gh

1st March, 2019

DELALI ED-BANSAH
C/O EDEM ED-BANSAH
PWC GHANA LTD
PMB CT 42
CANTONMENTS, ACCRA

INSTITUTIONAL APPROVAL: KORLE BU TEACHING HOSPITAL-SCIENTIFIC AND TECHNICAL COMMITTEE/INSTITUTIONAL REVIEW BOARD (KBTH-STC/IRB/000139/2018

Following approval of your study entitled "Transcutaneous electrical nerve stimulation in the management of spasticity in cerebral palsy: A study at Korle Bu Teaching Hospital" by the Korle Bu Teaching Hospital-Scientific and Technical Committee/Institutional Review Board.

I am pleased to inform you that institutional approval has been granted for the conduct of your study in Korle Bu Teaching Hospital.

Please contact the Head of Department to discuss the commencement date of the study.

Please note that, this institutional approval is rendered invalid if the terms of the Institutional Reviewed Board/Scientific and Technical Committee approval are violated.

Sincere regards,

Dr. Samuel Asiamah
Director of Medical Affairs
For: Chief Executive Officer

Cc: The Chief Executive
Korle Bu

In case of reply the number
And the date of this
Letter should be quoted

My Ref. No. KBTH/IRB/03/19

Your Ref. No.....

KORLE BU TEACHING HOSPITAL
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-6
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Email: Info@kbth.gov.gh
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Website: www.kbth.gov.gh

28th February, 2019

DELALI ED-BANSAH
C/O EDEM ED-BANSAH
PWC GHANA LTD
PMB CT 42
CANTONMENTS, ACCRA

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION IN THE MANAGEMENT OF SPASTICITY IN CEREBRAL PALSY: A STUDY AT KORLE BU TEACHING HOSPITAL

KBTH-IRB /000139/2018

Investigator: Delali Ed-Bansah

The Korle Bu Teaching Hospital Institutional Review Board (KBTH IRB) reviewed and granted approval to the study entitled "Transcutaneous electrical nerve stimulation in the management of spasticity in cerebral palsy: A study at Korle Bu Teaching Hospital"

Please note that the Board requires you to submit a final review report on completion of this study to the KBTH-IRB.

Kindly, note that, any modification/amendment to the approved study protocol without approval from KBTH-IRB renders this certificate invalid.

Please report all serious adverse events related to this study to KBTH-IRB within seven days verbally and fourteen days in writing.

This IRB approval is valid till 30th December, 2019. You are to submit annual report for continuing review.

Sincere regards,

MR OKYERE BOATENG
CHAIR (KBTH-IRB)

Cc: The Chief Executive Officer
Korle Bu Teaching Hospital