EFFECT OF FUNCTIONAL ELECTRICAL STIMULATION (FES) WHEN COMBINED WITH GAIT TRAINING ON TREADMILL IN CHILDREN WITH SPASTIC DIPLEGIA

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EFFECT OF FUNCTIONAL ELECTRICAL STIMULATION (FES) WHEN COMBINED WITH GAIT TRAINING ON TREADMILL IN CHILDREN WITH SPASTIC DIPLEGIA

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ABSTRACT

OBJECTIVE: This study used the repeated measure design to investigate the effect of functional electrical stimulation (FES) when combined with gait training on treadmill in Thai children with mildly to moderately spastic diplegia. ***METHOD:*** Seven children with mildly to moderately spastic diplegia were four boys and three girls and aged between 6.12 and 11.46 years old (mean aged of 8.75±2.08 years). They could independently walk as GMFCS level I-II. The children received 2 conditions of training (gait training on treadmill only and gait training on treadmill with FES). They were trained 2 sessions per week for 6 weeks in each condition and had a rest for a week before the 2^{nd} condition. The Vicon motion analysis was used to collect and evaluate the gait parameters before and after each gait training condition. ***RESULTS:*** The average changes of maximal ankle dorsiflexion angle at the swing phase ($p = 0.008$), level of heel rising at the stance phase ($p = 0.001$), and stride length of gait cycle ($p = 0.031$) after gait training on treadmill combined with FES were statistically significantly more than the average for these parameters after gait training on treadmill only. ***CONCLUSION:*** The effect of a combination of the FES and gait training on treadmill can promote the stability of the standing leg and the mobility of the swinging leg during gait.

KEY WORDS: FUNCTIONAL ELECTRICAL STIMULATION / FES / SPASTIC DIPLEGIA / TREADMILL TRAINING / GAIT TRAINING

114 pages

ผลของการกระตุ้นไฟฟ้าร่วมกับการฝึกเดินบนสายพานในเด็กที่มีอาการเกร็งของขาเป็นหลัก
EFFECT OF FUNCTIONAL ELECTRICAL STIMULATION (FES) WHEN COMBINED WITH GAIT TRAINING ON TREADMILL IN CHILDREN WITH SPASTIC DIPLEGIA

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คณะกรรมการที่ปรึกษาวิทยานิพนธ์: สายพิณ ประเสริฐสุขดี, Ph.D., ชมพูนุท สุวรรณศรี, M.Sc., เซง เลิศมโนรัตน์, Ph.D.

บทคัดย่อ

วัตถุประสงค์: การศึกษานี้ใช้งานวิจัยแบบวัดซ้ำเพื่อตรวจสอบผลของการกระตุ้นไฟฟ้าร่วมกับการฝึกเดินบนสายพานในเด็กไทยที่มีอาการเกร็งของขาเป็นหลัก ระดับน้อยถึงปานกลาง ***วิธีวิจัย:*** เด็ก 7 คน เป็นเด็กชาย 4 คน หญิง 3 คน อายุระหว่าง 6.12-11.46 ปี (อายุเฉลี่ยเท่ากับ 8.75±2.08 ปี) ที่สามารถเดินได้ด้วยตนเองตามแบบประเมิน GMFCS ระดับ 1-2 เด็กได้รับการฝึกเดิน 2 รูปแบบ (การฝึกเดินบนสายพานอย่างเดียวและการฝึกเดินบนสายพานร่วมกับการกระตุ้นไฟฟ้า เด็กได้รับการฝึก 2 ครั้ง/สัปดาห์ เป็นเวลา 6 สัปดาห์ในแต่ละรูปแบบของการฝึกและพักเป็นเวลาหนึ่งสัปดาห์ก่อนการฝึกแบบที่ 2 การวิเคราะห์การเคลื่อนไหวด้วย Vicon ถูกใช้เพื่อเก็บข้อมูลและประเมินผลของตัวแปรของการเดินทั้งก่อนและหลังการฝึกเดินแต่ละรูปแบบ ***ผลการศึกษา:*** พบค่าเฉลี่ยของการเปลี่ยนแปลงของงองศาการกระดกข้อเท้าสูงสุด (p = 0.008) ระดับความสูงของส้นเท้าที่ลอยจากพื้น (p = 0.001) และความยาวของการก้าวเดิน (p = 0.031) ภายหลังการฝึกเดินบนสายพานร่วมกับการกระตุ้นไฟฟ้ามีค่ามากกว่าการฝึกเดินบนสายพานอย่างเดียวอย่างมีนัยสำคัญทางสถิติ ***สรุปผล:*** ผลของการกระตุ้นไฟฟ้าร่วมกับการฝึกเดินบนสายพานสามารถส่งเสริมความมั่นคงของขาที่รับน้ำหนักและการเคลื่อนไหวของขาที่ก้าวขณะเดิน

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LIST OF ABBREVIATIONS

Abbreviation	Page
Cerebral palsy (CP)	1
Central nervous system (CNS)	1
Activities of daily living (ADL)	2
Neurodevelopmental techniques (NDT)	2
Functional electrical stimulation (FES)	2
Spinal cord injury (SCI)	2
Weight acceptance (WA)	9
Single limb support (SLS)	9
Limb advancement (LA)	9
Electromyography (EMG)	13
Eccentric contraction (E)	15
Positive (+)	17
Negative (–)	17
Centimeters per second (cm/s)	18
Meters per second (m/s)	18
Physical therapy (PT)	20
Range of motion (ROM)	20
Occupational therapy (OT)	20
Proprioceptive neuromuscular facilitation (PNF)	21
Peripheral nervous system (PNS)	21
Second (s)	22
Potential of hydrogen (pH)	22
Microsecond (μs)	23
Millisecond (ms)	23
Hertz (Hz)	23
Gross motor function classification system (GMFCS)	27

LIST OF ABBREVIATIONS (cont.)

Abbreviation	**Page**
Modified asworth scale (MAS)	27
Gross motor function measurement (GMFM)	27
Pediatric evaluation of disability inventory (PEDI)	28
Functional independence measure for children (WeeFIM)	28
Three-dimensional motion (3-D)	29
Botulinum toxin type A (BTX-A)	31
Milliamp (mA)	31
Volt (v)	31
Kilometer per hour (km/hr)	34
Mahidol University Institutional Review Board (MU-IRB)	38
Millimeter (mm)	38
Kilogram (kg)	38
Centimeter (cm)	38
Anterior superior iliac spine (ASIS)	38
Posterior superior iliac spine (PSIS)	38
Resting heart rate (RHR)	39
Heart rate (HR)	39
First (1^{st})	46
Gait training on treadmill only (T)	46
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Influenza A (H1N1)	46
Year (yr)	46
Right (Rt)	47
Left (Lt)	47
p-value (*p*)	48
Standard deviation (SD)	49
Miles per hour (mph)	74

LIST OF ABBREVIATIONS (cont.)

Root mean square (RMS) 76

CHAPTER I
INTRODUCTION

Cerebral palsy (CP) is a relatively common disorder that affects approximately 1.2-3 per 1,000 of infants and children each year (1). It is generally caused by brain damage or injury that occurs during perinatal, prenatal, and postnatal period. The term of CP describes any of several similar conditions resulting from non-progressive or degenerative central nervous system (CNS) insult. It produces motor dysfunction (abnormal control of movement and postures), cognitive, and possible sensory deficits. This disorder may stem either from an insult to a normally developing brain or from a central nervous system that developed in an abnormal fashion from a first few years of life (e.g., 1-7 years old) (2-6).

Children with cerebral palsy suffer from a wide range of motor disturbances. Approximately 50-80% of children with cerebral palsy show predominantly spasticity (2, 7). Spastic diplegia accounts for approximately 30-50% of the children that are affected by this disorder (4, 8). Those exhibit a motor dysfunction of the lower extremities. Most of children with spastic diplegia who achieve ambulatory status usually have abnormal and unsafe gait. These children are often unable to stand and maintain their balance well. They usually use a momentum and velocity to maintain their upright posture during walking (2, 4, 8).

Gait pattern of children with spastic diplegia is determined by a combination of the dominant activity of hip flexors, hip adductor, hip internal rotators, knee flexors or knee extensors, and ankle plantar flexors (5, 8-10). This dominance may reflect the insufficient activity of the antagonist. In some subjects, the dominance develops into a contracture of the joint, which modifies the gait pattern. A number of gait patterns in children with spastic diplegia are classified on a purely observational basis, relate to spasticity or contracture of muscles. These gait patterns were observed and revealed associations between the contractures of psoas muscle and lumbar lordosis, the contractures of hip adductor muscles and scissoring gait, the contractures of hamstring muscles and knee flexion at the stance phase, the contractures of rectus femoris muscle and stiff knee gait, and the contractures of gastrosoleus muscle and tip-toe gait (2, 4, 5, 10). By linking these observed patterns to specific shortening of the muscles, the association with management was implied.

Treadmill training and functional electrical stimulation have been increasingly used for training gait in clients with disabilities (e.g., spinal cord injury, cerebral palsy, head injury, etc.) (11-32). Effing and co-worker (16) studied treadmill training with partial body weight support in clients with chronic incomplete spinal cord injury. The results showed performance of activities of daily living (ADL), perception, and walking ability were significantly improved. Schindl and co-worker (17) studied neurodevelopmental techniques (NDT) combined treadmill training with partial body weight support in non-ambulatory and ambulatory children with cerebral palsy. The results showed clinically significant improvements of gross motor abilities in both groups.

Functional electrical stimulation (FES) is a technique that uses low-level electrical currents to activate muscles or innervated nerves affected by paralysis resulting from spinal cord injury (SCI), cerebral palsy, head injury, and stroke or other neurological disorders for restoring function in clients with disabilities (33). Many studies applied FES in clients with disabilities (e.g., children with cerebral palsy, adults with hemiplegia) and determined that could increase ankle dorsiflexion during swing and initial contact phase, decrease an excessive knee flexion in stance phase, increase velocities and stride lengths, decrease cadences, improve gait performance, functional activities, balance, and motor control in the long term (11, 19, 23-25, 30, 32, 34-36).

Previous studies revealed both of techniques that could improve the gait performance of clients with disabilities. However, gait training with FES is more specific than treadmill training because the FES is applied specifically on muscles or nerves that generate actions in children with cerebral palsy. Previous studies applied treadmill training combined with traditional therapy. The results revealed an increase in symmetry between stride lengths and walking speed, an improvement of functional skill, and a decrease in step length and trend of falling (13-17, 26). Although treadmill training could improve many gait parameters, a problem of tip-toe walking pattern was not identified. This gait pattern increases a risk of falling during walking. Applying the FES over a common peroneal nerve and/or a tibialis anterior muscle which is expected to decrease the tip-toe manner would improve the corrected gait patterns on treadmill training. Therefore, this study will examine the effect of FES when combined with gait training on treadmill in children with spastic diplegia**.**

Purpose of the study

General objective

The purpose of this study examined the effect of the FES on gait parameters when combined with the gait training on the treadmill in children with spastic diplegia.

Specific objectives

To compare the changes of selected kinematic gait variables when children with spastic diplegia were trained between by gait training on treadmill only and gait training on treadmill combined with FES. These variables were as follows:

1. Maximal ankle dorsiflexion angle at the swing phase of gait cycle
2. Level of heel rising at the stance phase of gait cycle
3. Hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle
4. Knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle
5. Stride length of gait cycle
6. Gait speed of gait cycle
7. Cadence of gait cycle

Parameters of the study

Independent variables

1. Treatment techniques

    1.1 Gait training on treadmill only

    1.2 Gait training on treadmill combined with FES

Dependent variables

1. Maximal ankle dorsiflexion angle at the swing phase of gait cycle
2. Level of heel rising at the stance phase of gait cycle
3. Hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle
4. Knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle
5. Stride length of gait cycle
6. Gait speed of gait cycle
7. Cadence of gait cycle

Scope of the study

The repeated measure design was used to investigate the effect of a combination of the FES and gait training on treadmill in Thai children with mildly to moderately spastic diplegia aging between 6 and 12 years old.

Hypotheses of the study

1. The gait training on treadmill combined with the FES would significantly increase maximal ankle dorsiflexion angle at the swing phase of gait cycle.
2. The gait training on treadmill combined with the FES would significantly decrease level of heel rising at the stance of gait cycle.
3. The gait training on treadmill combined with the FES would significantly increase hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle.

4. The gait training on treadmill combined with the FES would significantly increase knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle.
5. The gait training on treadmill combined with the FES would significantly increase stride length of gait cycle.
6. The gait training on treadmill combined with the FES would significantly increase gait speed of gait cycle.
7. The gait training on treadmill combined with the FES would significantly decrease cadence of gait cycle.

Advantages of the study

The results from this study would provide the evidence of the effect of the FES on tip-toe gait and managing strategies of toe-walking in children with spastic diplegia or other patients who exhibit tip-toe gait.

CHAPTER II
LITERATURE REVIEW

2.1 Cerebral palsy

Cerebral palsy (CP) is a common disorder affecting approximately 1.2-3 per 1,000 of infants and children each year (1, 2, 7, 37-39). It is generally caused by brain damage or injury that occurs during perinatal, prenatal, and postnatal period. The term of CP used to describe any of several similar conditions resulting from nonprogressive or degenerative central nervous system (CNS) insult. It produces motor dysfunction (abnormal control of movement and posture), cognitive, and possible sensory deficits. This disorder may stem either from an insult to a normally developing brain or from a CNS fashion from a first few years of life (1-7 years old) (2-5, 37, 40-42), then it may affect children at differing levels of severity and in different ways at different stages in their life.

Classification of CP variously categorized but it is traditionally defined according to the type and topography of the positive signs, and pays no attentions to the important negative signs (42). CP can be classified according to the placement of the disorder (topography) or the particular movement disorder (physiology) (42-44).

2.1.1 Topographical classifications

Topographical classifications are an attempt to describe where the body parts involved (3, 42) such as hemiplegia, diplegia, quadriplegia, triplegia, paraplegia, and monoplegia (3-5, 37, 41, 42). Hemiplegia is affected both the upper and lower extremities on one side (most patients will eventually walk.). Diplegia is affected the total body with greater involvement in trunk and lower extremities than upper extremities and face. Quadriplegia is affected head, neck, trunk, and extremities equally or more involved than lower extremities. Triplegia is affected arm and both legs. Paraplegia is affected both legs. Monoplegia is affected only arm or leg.

2.1.2 Physiologic classifications

Physiologic classifications are an attempt to describe what the movement problems such as hypotonia or flaccid, spasticity, rigidity, hyperkinesia, athetosis, ataxia, and mixed type (2-5, 37, 41, 42, 45). Hypotonia/flaccid is usually a transient stage in the evolution of athetosis or spasticity. Spasticity, impaired cerebral cortex and/or corticospinal tracts, refers to the inability of a muscle to relax. Symptoms present increased muscle tone and hyperreflexia resulting in slow restricted movements. Athetosis/dyskinesia, impaired basal ganglia and management of hyperbilirubinemia, and prevention of kernicterus (a contributor to the extrapyramidal system), refers to an inability to control the movement of a muscle. Infants who at first are hypotonic wherein they are very floppy may later develop spasticity. Symptoms present involuntary, unpredictable movements, lacks the ability to sustain postural alignment, changes in speech, and inability to control the range of motion in a functional activity. Ataxia, impaired cerebellum, refers to balance and coordination problems. It usually associated with either spasticity or hypotonia. Symptoms present unable to coordinate muscles for voluntary movement, resulting in an unbalanced gait. Mixed type is term used most commonly to indicate children with spastic diplegia mixed with athetosis, but it may be used to describe a child who does not fit the characterizations describe above. Symptoms present a combination of spasticity and athetosis with whole body involvement.

Children with CP suffer from the wide range of motor disturbances. Data from surveys of children with CP populations suggest that approximately 50-80 percents of children with CP show a predominantly spasticity (2, 7) and spastic diplegia accounts for approximately 30-50 percents of children with spasticity (4, 8, 39). That means children with spastic diplegia are the most common type. Then this study will interested in children with spastic diplegia which main disability is a motor dysfunction of the lower extremities.

2.2 Gait

Locomotion means moving from one location to another (46, 47) such as creeping, crawling, cruising, walking, running, swimming, etc. Functional versatility allows the lower extremities to readily accommodate stairs, doorways, changing surface, and obstacles in the pass of progression. Efficiency in these attempts depends on free joints mobility and optimal muscle activity that selective in timing and intensity. It show as stride length, step length, waking speed, etc. during gait cycle (46).

2.2.1 Gait cycle

Gait cycle is defined as a time interval between successive events of single sequence of walking by one leg (46, 47). There is no specific starting or ending of point of event. This action generally has been used to initiate foot contact as start and it will end as next initiate foot contact of the same side (47). In normal persons initiate foot contact with their heel but not all patients have this ability, Perry (46) generated new term of the division of the gait cycle that is used to identify onset of the gait cycle. Each gait cycle is divided into two periods (figure 2.1) as follow.

2.2.1.1 Stance period is the term that used to call the whole onsets during foot contact on floor (46, 47), lasts from initial contact to toe-off (47).

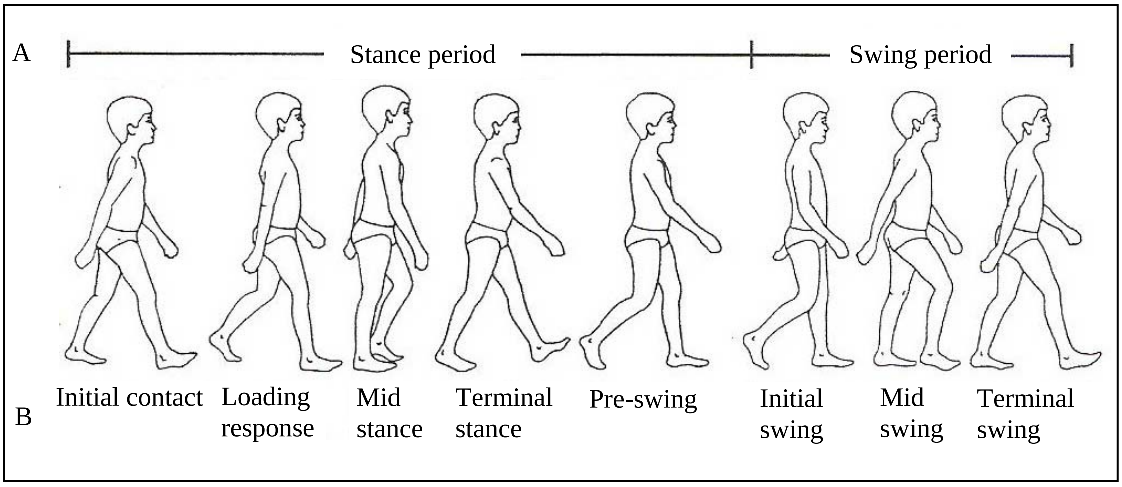

Figure 2.1 Divisions of the gait cycle:

A = Gait cycle divided into two periods

B = Gait cycle divided into eight phases

2.2.1.2 Swing period is the term used to call the whole onsets during lift foot from floor (46, 47), lasts from toe-off to next initial contact (47).

Analysis of the walking pattern more directly identifies the functional significance of the difference motions occurring at the individual joints. The phases of gait also provide a means of correlating of the walking pattern. This is a particularly important approach for interpreting the functional effect of disability. Each of eight phases of gait has a functional objective and critical pattern of selective synergistic motion to accomplish this goal. The sequential combinations of phases also enable the extremity to accomplish three basic tasks. These are weight acceptance (WA), single limb support (SLS), and limb advancement (LA). WA begins at the stance period and uses the first two gait phases (initial contact and loading response). SLS continues stance period with the next two phases of gait (mid stance and terminal stance). LA begins at the final of stance period (pre-swing) and then continues through the three phases of swing period (initial swing, mid swing, and terminal swing) (46). Each gait cycle divided into eight phases (figure 2.1) as follow:

2.2.1.1 Stance period

2.2.1.1.1 Initial contact phase

At the moment of the foot strikes the ground, the limb is optimally positioned to initiate both progression and knee stability. The ankle is in neutral dorsiflexion, the knee extended and hip flexed approximately 30° (46, 48). Floor contact is made by the heel. The pattern of muscle activity present at the time of initial contact anticipates the control needed as the limb is loaded. At the both hip extensor groups, the hamstrings and single joint muscles (gluteus maximus and adductor magnus), provide a counterforce to prevent knee hyperextension, decelerates the thigh, and foot placement (49). The foot is supported at neutral by the action of the pre-tibial muscles. Both of the ankle and subtalar joints are stabilized by the combined activity of tibialis anterior muscle (ankle inverter) and the long toe extensors (e.g., extensor digitorum longus and extensor hallucis longus as everters) (46). The activities of the major muscles of lower extremities at this phase were showed in figure 2.2

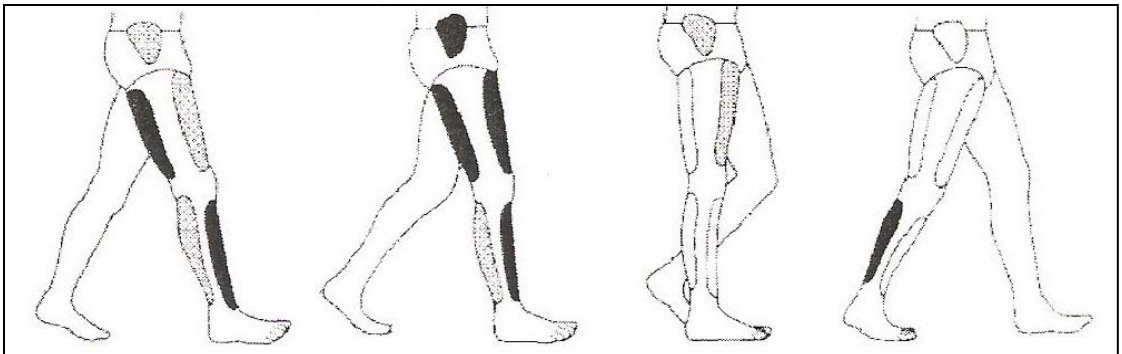

Figure 2.2 The activities of the major muscles of lower extremities at the stance period

2.2.1.1.2 Loading response phase

Loading response is the phase of greatest muscular activity. Limb loading provides shock absorption to lessen the effect of rapid weight transfer, and thigh retraction adds to knee stability. These actions are knee flexion to 18°, 10° of ankle plantarflexion. At the same time, motion at the hip is minimizes to stabilize the trunk over the weight accepting limb (approximately 30°) (46, 48).

Now the limb begins its loading response, in which it accepts the weight of body by contracting the knee extensors (vasti). The knee bends slightly and then begins extending under the shortening contraction of the knee extensors, acting much like a spring. This knee extension is aided by the ankle plantarflexion (concentric muscle contraction), which tends to move the contact point the limb forward and shift the reaction force of the body anteriorly at the knee, inducing the straighten. The gluteus minimus contracts isometrically and stabilizes the pelvis in the frontal plane (46, 49). The activities of the major muscles of lower extremities at this phase were showed in figure 2.2

2.2.1.1.3 Mid stance phase

This phase is the time when the body weight line changes its anterior/posterior alignments at each joint. As the limb rolls forward over the supporting foot, the critical site for dynamic stability shifts from the knee to the ankle. The intense muscle action at the hip and knee that was present during loading response rapidly terminates by early mid stance. Limb stability becomes dependant on the actions of the soleus augmented by the gastrocnemius. During mid stance, the vector becomes anterior to the ankle and knee, and posterior to the hip. Contralateral toe-off transfers total body weight to the mid stance limb. Progressional momentum from the contralateral swinging limb and residuals from the heel rocker draw the ankle into dorsiflexion. Advancement of the tibia from its position of 7° ankle plantarflexion at the moment of contralateral toe-off is more rapid during the first half of mid stance. Natural alignment is reached by the 20% point in the gait cycle. During the last half of mid stance, only 4° ankle dorsiflexion occurs. This difference in the rate of ankle dorsiflexion represents at relative anterior alignment of the vector and early response of the soleus muscle. Once both the vector and tibial alignments are anterior to vertical midline, there is strong stimulus soleus to stabilize the tibia for weight-bearing stability of the limb. The gastrocnemius tends to begin about 5% later in the gait cycle, and its intensity rises more slowly. These modifications are consistent with the knee flexion action (46, 48, 49).

At the knee, the added load of single limb support introduces a small increase in knee flexion to 18° at the onset of mid stance, since the vector is still posterior to the joint. Beyond this point, there is progressive extension of the knee as the femur advances over the tibia that has been restrained by the soleus muscle. Action of the quadriceps continues until the vector is anterior to the knee. During this time, the vasti are pulling the femur forward. This could be considered the contribution to progression (46, 48, 49).

The hip continually reduces its flexed posture, moving from the initial 30° flexion to 10° (46, 48). However, direct muscle control of the ongoing hip extension is minimal. During early mid stance, there is a low activity of semimembranosus and a continuing contribution by the posterior gluteus medius. Further hip extension is gained indirectly from the quadriceps pull on the femur and displacement of the vector posterior to the hip joint. The timing of this later event depends on the relative vertically of the trunk over the pelvis (46, 49). The recorded hip flexion (10°) represents the inclusion of the anterior pelvic tilt, as the thigh has attained a neutral posture by the end of mid stance (46, 48). The activities of the major muscles of lower extremities at this phase were showed in figure 2.2

2.2.1.1.4 Terminal stance phase

Provision of the forefoot rocker for the final phase of progression is the contribution of terminal stance to both progression and stability. As the body rolls forward over the forefoot, the ankle dorsiflexion to 10° and the heel rise at the knee completes its extension and the thigh reaches a trailing alignment (46, 48, 49).

Advancement of the trunk moves the vector to its most anterior alignment at the ankle and trailing posture of the limb allows body weight to drop at an accelerated rate that increases the vertical ground reaction force. The result is a large ankle dorsiflexion torque that requires strong gastrosoleus muscle action to stabilize the tibia at the ankle. Stability at the knee and hip is gained passively from the actions of the soleus on the tibia (46, 49).

At the end of terminal stance, rotation of foot/ankle complex on the forefoot rocker advances the knee center to and then slightly ahead of the vector. This unlocks the extended knee and flexion begins. Gastrocnemius muscle tension at this time may be a factor in initiating knee flexion (46, 49). The activities of the major muscles of lower extremities at this phase were showed in figure 2.2

2.2.1.2 Swing period

2.2.1.2.1 Pre-swing phase

The large arc of knee flexion that will be needed in swing is initiated during this phase of double limb support. As the ankle plantarflexes 20°, there is 40° knee flexion and hip flexion to neutral (46, 48). Muscle action during this pre-swing period is limited. Soleus and gastrocnemius muscle activity decreases in intensity to match the reduction in weight-bearing demand of double limb support as the limb is loaded. There is a similar, rapid decrease by the flexor hallucis longus. If the knee flexion threatens to become excessive, the rectus femoris is response. This restrains the knee while assisting hip flexion. Advancement of the thigh (hip flexion) from its trailing position reflects a flexor action of the adductor longus muscle as it contracts to restrain the passive abductor torque that is developing. With the rapid transfer of body weight onto the other limb, displacement of the pelvis preceded that of the trunk. This aligns the control vector lateral to the hip joint axis, creating an abductor torque that must be restrained to preserve weight-bearing balance. The anteromedial alignment of the adductor longus results in a flexor as well as adduction torque, and both are desirable (46, 49).

The actions occurring during pre-swing commonly are called push-off and it assumed the body is driven forward. More accurately, this is push-off of the limb, with the action providing the force that advances the limb in swing (46). The activities of the major muscles of lower extremities at this phase were showed in figure 2.3

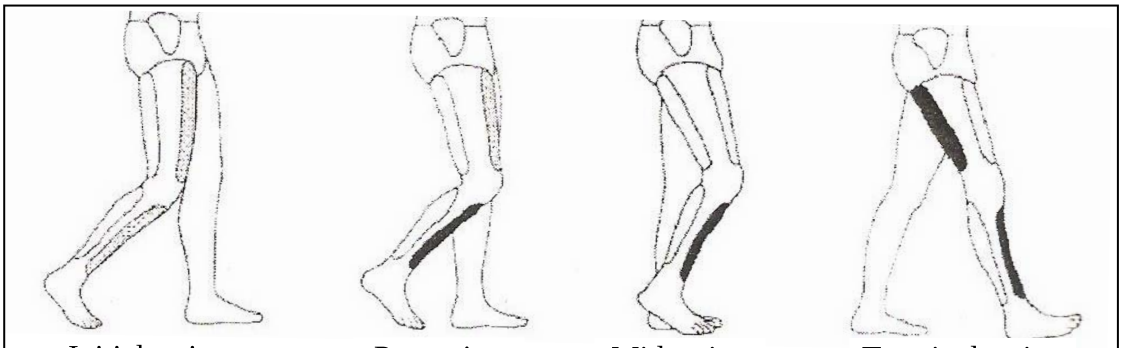

Figure 2.3 The activities of the major muscles of lower extremities at the swing period

2.2.1.2.2 Initial swing phase

Toe rise signals the advancement of the unloaded limb. Knee flexion increases to 60° to lift the foot above the ground. The ankle only partially reduces its plantarflexion (10°). Hip flexion advances the thigh 20° (46, 48). At the hip and knee, muscle action during initial swing is variable. The most consistent knee flexor is the short head of the biceps femoris. Because the two heads of biceps share the same tension, this action often is erroneously attributed to the lateral hamstrings (long head of biceps femoris). Such action, however, would inhibit hip flexion as the long head of the biceps femoris also is a hip extensor. EMG recordings clearly differentiate the action of the two biceps muscles. Combined hip and knee flexion may be gained by low levels of sartorius or gracillis activity. Independent hip flexion is provided by the iliacus in the majority of subjects during free walking and regularly when pace is fast or slow (46, 49). Pre-tibial muscle action (tibialis anterior and the long toe extensors) is brisk during initial swing as the muscles begin lifting the foot. The limited motion that is accomplished reflects the inertia that must be overcome (46). The activities of the major muscles of lower extremities at this phase were showed in figure 2.3

2.2.1.2.3 Mid swing phase

Foot clearance is dependent on ankle and hip position. The ankle dorsiflexes to neutral and the hip flexion attains 30°. Knee flexes decreases to 30° (46, 48). Muscle control at the ankle is low-intensity continuation of brisk action of the tibialis anterior, extensor hallucis longus, and extensor digitorum longus begun in the initial swing. Hip flexor muscle action is minimal. Knee extension is purely passive. At the end of mid swing, the hamstrings begin their action that will become intense in terminal swing (46, 49). The activities of the major muscles of lower extremities at this phase were showed in figure 2.3

2.2.1.2.4 Terminal swing phase

This is the transition phase between swing and stance. Advancement of the thigh is stopped while the knee continues to extend to neutral (0-5° flexion). The ankle remains at neutral (or may drop into 5° ankle plantarflexion) (46, 48). Muscle activity is intense. During the first half of terminal swing, all three hamstrings (semimembranosus, semitendinosus, and long head of biceps femoris) contract vigorously to restrain hip flexion. Their simultaneous knee flexion action avoids excessive hyperextension from tibial momentum acting on a stationary femur. Then, the hamstrings rapidly reduce their action. At this time the quadriceps (vasti) become active to complete knee extension. Activity of the pre-tibial muscles is also brisk to assure continued ankle dorsiflexion. As a result of this combination of muscle action the limb is optimally poised for the onset of weight-bearing as the next initial contact occurs (46, 49). The activities of the major muscles of lower extremities at this phase were showed in figure 2.3

The muscle activations and motion of hip, knee, and ankle joint during the normal human walking were summarized in the table 2.1-2.4

Table 2.1 Muscle activation and motion of hip, knee, and ankle joint during initial contact and loading response

Joint /Phase		Initial contact	Load response
Hip	**M. activator**	lower-Gluteus Maximus (E)	Gluteus Maximus
		Gluteus Medius	Gluteus Medius
		Ilio tibial band (E)	Tensor fascia lata
		Tensor fascia lata (posterior)	Adductor magnus
		Adductor magnus	
	Motion	Flex 30°	passive - Flex
Knee	**M. activator**	Popliteus (E)	Popliteus
		Hamstring (E)	Hamstring
		Quadriceps	Quadriceps (E)
	Motion	Extend -2° - 5°	Flex 15°
Ankle	**M. activator**	Tibialis anterior	Tibialis anterior (E)
		Extensor digitorum longus	Extensor digitorum longus (E)
		Extensor hallucis longus	Extensor hallucis longus (E)
		Tibialis posterior	Soleus
			Gastrocnemius
			Tibialis posterior
	Motion	Neutral	Plantarflex 25° - 35°

E = Eccentric contraction

Table 2.2 Muscle activation and motion of hip, knee, and ankle joint during mid stance and terminal stance

Joint /Phase		Mid stance	Terminal stance
Hip	**M. activator**	upper-Gluteus Maximus	Tensor fascia lata
		Gluteus Medius	Adductor longus
		Tensor fascia lata	
	Motion	passive - Flex	Hyperextend
Knee	**M. activator**	Quadriceps	Popliteus
		Semimembrinosus (E)	short-Biceps femoris
		Semitendinosus (E)	
	Motion	Flex 5°- Extend	passive - Extend
Ankle	**M. activator**	Soleus (E)	Soleus
		Gastrocnemius (E)	Gastrocnemius
		Tibialis posterior	Tibialis posterior
		Flexor digitorum longus	Flexor digitorum longus
		Peroneus longus	Peroneus longus
		Peroneus brevis	Peroneus brevis
		Flexor hallucis longus	Flexor hallucis longus
	Motion	Plantarflex 8° - Dorsiflex 10°	Dorsiflex 10° - Neutral

E = Eccentric contraction

Table 2.3 Muscle activation and motion of hip, knee, and ankle joint during pre-swing and initial swing

Joint /Phase		Pre-swing	Initial swing
Hip	**M. activator**	Sartorius	Sartorius
		Gracilis (E)	Gracilis
			Iliacus
			Rectus femoris
			Adductor longus
	Motion	Neutral	passive -Flex
Knee	**M. activator**	Popliteus	Rectus femoris
		Rectus femoris	short-Biceps femoris
	Motion	passive - Flex 40°	Flex 60°
Ankle	**M. activator**	Tibialis anterior	Tibialis anterior
		Extensor digitorum longus	Extensor digitorum longus
		Extensor hallucis longus	Extensor hallucis longus
		Soleus (E)	
		Gastrocnemius (E)	
		Tibialis posterior	
		Flexor digitorum longus	
		Peroneus brevis	
		Flexor hallucis longus	
	Motion	Plantarflex 20° rapidly	Plantarflex 5° - Neutral

E = Eccentric contraction

Table 2.4 Muscle activation and motion of hip, knee, and ankle joint during mid swing and terminal swing

Joint /Phase		Mid swing	Terminal swing
Hip	**M. activator**	Gluteus Maximus	Gluteus Maximus
		Hamstring	Gluteus Medius
			Adductor longus
			Adductor magnus
			Hamstring
	Motion	passive-Flex	Flex 30°
Knee	**M. activator**	Hamstring	Quadriceps
		short-Biceps femoris	Popliteus (E)
			Hamstring (E)
	Motion	passive - Flex	Extend
Ankle	**M. activator**	Tibialis anterior	Tibialis anterior
		Extensor digitorum longus	Extensor digitorum longus
		Extensor hallucis longus	Extensor hallucis longus
	Motion	Neutral - Dorsiflex	Plantarflex -3° - 5° - Neutral

E = Eccentric contraction

2.2.2 Foot placement

Foot placement parameters were used to describe distance or angle of feet on the ground (46-48, 50) (figure 2.4). In the line of walking progression, step length and stride length, these are the linear distance between foot contacts on the ground. Steps length is the interval between two consecutive contralateral initial foot contacts on the walking surface (46, 47, 50, 51). For one gait cycle, there are two step lengths, designated by right and left step length. Stride length is the interval between two consecutive ipsilateral initial foot contacts on the walking surface. So this definition of stride length is consisting of one step of each side (46, 47, 50, 51). Step and stride length are typically reported in centimeters or meters (50, 51).

The relative of the line of walking progression, step width is the perpendicular distance between mid heel placement locations that measured during two consecutive steps (48, 50). If mid heel locations are apart, the measure is positive (+), and if the consecutive heel locations cross over, the measure should be designated as negative (-). Step width is typically reported in centimeters or meters (50).

Foot angle is angle bounded by the line of forward progression and a line representing the long axis of the foot while in the foot flat position of the gait cycle (48, 50). Outward- and inward-turned foot locations might be designated as positive (+) and negative (-), respectively. It is typically reported in degrees (50).

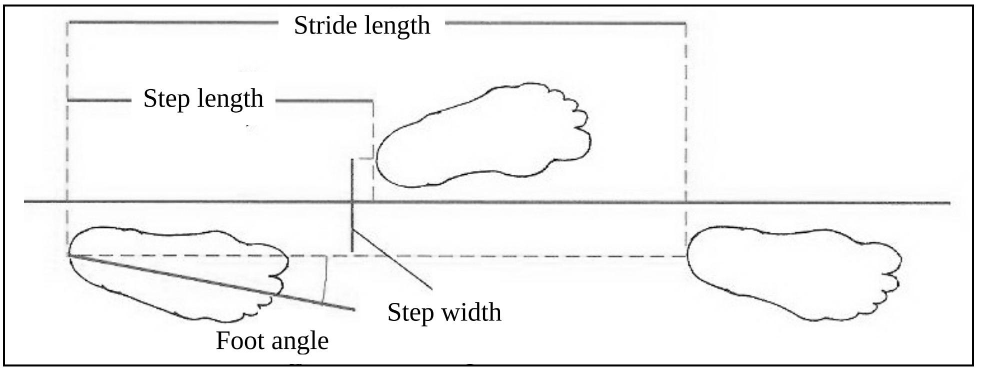

Figure 2.4 The foot placement of gait cycle

2.2.3 Gait velocity, gait speed, and cadence

The rate of linear forward motion of the body, velocity and speed, these are the product of distance and time walked (50). Gait velocity is the distance covered by whole body per unit of the time, particular the direction and magnitude classifies as vector quantity (46, 50). Gait speed is the distance covered by whole body per unit of the time, particular the magnitude classifies only as scalar quantity (46, 47, 50). Gait velocity and speed can be calculated by measuring the distance between the location of an initial right foot placement (e.g., heel or toe) and a subsequent right foot placement and then divide the distance by the associated elapsed time. Another method of calculation is to multiply the average step length by cadence in steps per second or to multiply the stride length by strides per second (50). Gait velocity and speed are typically reported in centimeters per second (cm/s) or meters per second (m/s) (46, 47, 50). Centimeters may be preferred because a decimal is avoided (50).

Cadence is a number of steps or strides per unit of the time (46, 50). By counting the number of steps and dividing this number by the elapsed time, cadence can be reported in the steps per second. The alternately counting, stride can be counted and cadence reported in the strides per second. The cadence is also frequently reported steps per minute (50).

There are a relative of stride length, gait speed, and cadence of gait cycle. As the constant gait speed, if the man increases a stride length, the cadence will decrease. The purpose of this study investigated the effect of a combination of the FES on nerve and muscle that activate the ankle dorsiflexion. The generated movement is obviously seen in the sagittal plane. The foot placement parameters that represent the distance in the sagittal plane are step length and stride length. However, the stride length also defines placement of each side. Therefore, this study will correct stride length, gait speed, and cadence of gait cycle for observing the indirect effect of the FES on kinematic gait parameter after the children received two conditions of gait training.

Walking of neuromuscular patients is a presence of severe impairment as the various types of pathology after mobility and motor control, the patients substitute wherever possible. Observation of compensatory reaction of gait requires an ability to identify abnormal patterns and the knowledge of normal mechanism of gait. As the body move forward, one leg serves as a mobile source of support while the other leg advances its self to a new support site. Then the legs reserve their roles. For the transfer of body weight from one leg to another, both feet are contact with the ground. This series of events are repeated by each leg (46, 47).

Almost 90 percents of children with spastic diplegia achieve ambulatory status but most have an easily recognized pathologic gait. The gait pattern of these children often is unsafely and may be observed as a "controlled fall" from one limb to the next (8). These children often are unable to stand and balance well statically, using momentum and velocity to maintain their upright posture and forward advancement (2, 4, 8). Many children with spastic diplegia have limited mobility in their lumbar spine, pelvis, and hip joints and show limited asymmetric pelvis tilt or pelvic rotation during walking (2). In an effort to compensate for lack of mobility of lower body, this children shift their weight and maintain balance by excessive mobility through head, neck, upper trunk, and upper extremities. Their hips stay flexed during the stance phase, and fully extension of hip is never achieved. Excessive adduction and internal rotation of hip are frequently found. Depending on the function of the pelvic, lumbar, and musculature, the knees may be either flexed or hyperextended during the stance phase. The feet may support in plantar flexion with the heels rising from the floor (2, 4, 5, 8, 37, 40, 47, 52)

Gait patterns of children with spastic diplegia are determined by a combination of the dominant activity of hip flexors, hip adductors, hip internal rotators, knee flexors or knee extensors, and ankle plantar flexors (3, 9). These dominances may reflect the insufficient activity of the antagonist. In some of subjects, the dominance develops into a contracture of the joint, which modifies the gait pattern. A number of gait patterns in children with spastic diplegia and classified them on a purely observational basis, related to spasticity or contracture of muscles which work in the sagittal plane (10). They observed associations between contractures of the psoas muscle and lumbar lordosis, the hip adductor muscles and scissoring, the hamstring muscles and knee flexion, rectus femoris muscle and stiff knee gait, and gastrosoleus muscle and tip-toe gait. Dynamically, the limbs are oriented internally with various disruptions to base levers. The children with hypotonicity predispose them to more crouched gait with foot and ankle pronation, excessive dorsiflexion, and sustained knee flexion. Hypertonicity, the foot-ankle complex may present as sustained equinus with a toe-walking pattern punctuated by knee hyperextension moments (2, 8, 10). By linking these observed patterns to specific shortening of the muscles, the association with management was answered.

When evaluating the gait of children with spastic diplegia, nearly all children have deficits at the foot and ankle as severity increases, the ability to exert control at the knee and hip joint is compromised. These children typically demonstrate a toe-strike with ankle equinus, a stiff, crouched position at the knees with limited extension at stance phase and reduced flexion at swing phase. There is also exaggerated flexion, adduction, and internal rotation at the hips. Abel and Damiano (53) compared the velocity, stride length, and cadence between children with spastic diplegia and normal children. The normalized results showed that the velocity, stride length, and cadence of children with spastic diplegia were less than the normal children.

Therapeutic team of CP children should consist of the family, various allied health professionals, and school staff (2, 6, 42, 54). The application of different therapeutic modalities the most frequently in use being physical therapy (PT); aimed to encourage development of normal motor system patterns that should positively influence functions of activities daily living (ADL), standing and walking by improve muscle strength, maintain range of motion (ROM) of joints, coordination, balance, prevent secondary consequences of disabilities, and increase the child's independence and self-reliance to increase self-esteem (2, 4-6, 40, 54-58). Occupational therapy (OT); aimed to advise on ADL like feeding, bathing, dressing, toilet training etc., co-ordination, sensory-perceptual integration, and the equipment needed to facilitate these

(54, 55). The role of PT and OT are so closely linked that they could in fact be considered together. Physician by local intraspinal or systematic administration of anti-spastic drugs; aimed to decrease spasticity, reduce involuntary movements (4, 6, 37, 42, 44, 55, 58-60), orthoses, splinting, and casting; aimed to adequate positioning of joints, maintain ROM, improve stability during casting, muscle tone reduction, and prevent deformities (4, 6, 40, 44, 54, 60), and orthopedic surgery; aimed to releasing and lengthening of tendons usually performed in the 4-5 year age group (4, 6, 37, 40, 42, 44, 54, 55, 58, 59). Young children with spastic diplegia respond best to treatment of physician, PT, OT, etc. from as early as 2 years of age. This is because they rarely have contractures and are more receptive to changes in motor patterning (9).

PT program for children with CP may include neurodevelopmental technique (NDT) by Bobaths, therapeutic exercise, hydrotherapy, weight shift, functional electrical stimulation (FES), proprioceptive neuromuscular facilitation (PNF), positioning, taping, splinting, casting, orthoses, etc. (2, 4, 37, 40-42, 44, 54-56, 58, 61). These program attempt to correct the equines by encourage tip-toe gait, maintain muscle, balance and coordination. New strategy may also necessitate new assistive devices or modifications in the old ones.

2.3 Functional Electrical Stimulation (FES)

Functional electrical stimulation (FES) is a technique that uses electrical stimulation of muscle deprived of normal control to produce a functional movement, or series of movements for restoring function in people with disabilities. It used low-level electrical currents to activate muscles or innervated nerves which affected by damage to central nervous system (CNS) as long as the peripheral nervous system (PNS) is intact, the muscle can be stimulated as previously. In the most cases when the CNS is damaged, such as hemiplegia, paraplegia, quadriplegia, children with cerebral palsy, and patients suffering from impairment or disease of the CNS; multiple sclerosis, head injuries, etc., the PNS remains intact (33, 62-66).

The aim of functional electrical stimulation is enhance or produce functional movement such as maintain or gain joint ROM, management of spasticity (reduce spasticity), increasing muscle strength and endurance of the weak muscles, improvement in voluntary movement and walking, prevent or reverse the progression of a disabling condition considerations in establishment of functional goals, and neural prosthetic applications (66) . Some studies applied FES in patients as an orthoses and determined that could increase ankle dorsiflexion ankle during swing, terminal swing, and initial contact phase, improve ROM of ankle, decrease an excessive knee flexion during stance phase, increase velocities and stride lengths, decrease cadences, improve gait performance, functional activities, balance, and motor control in the long term (18-25, 27, 30, 32, 34-36, 67-70).

Excitability of nerve and muscle tissue provides a basis for therapeutic application of electrical stimulation, which was used throughout the twenties century. Early studies used interrupted galvanic (unidirectional pulses lasting for more than 1 s) currents to produce contraction in denervated muscle. More recently, electrical stimulation has been used to supplement exercise programs in innervated muscle (33). Clinical FES application for improve voluntary movement and walking in children with spastic diplegia has many factors. FES parameters are the importance factor. It consist of current waveform, pulse duration, pulse frequency, duty cycle, ramp modulation, and duration of stimulation (33, 64).

2.3.1 Functional Electrical Stimulation parameters are as follows;

2.3.1.1 Current waveform

A waveform is the shape obtained by plotting the instantaneous amplitude of varying quantity against time in rectangular coordinates, which for alternative signals includes the deviation across the resting (zero) value. The difference between pulses and waveforms show two unidirectional pulses, one is symmetrical biphasic waveform and asymmetrical biphasic waveform (33). When applied asymmetrical biphasic pulses over the skin, the electrolytic effects will occur. These are because of the build-up of ions under each electrode. That result is a change in the potential of hydrogen (pH) of the couplant between electrodes and skin surface.

The area under cathode (negative electrode) will become more alkaline and that under the anode (positive electrode) will become more acid. A sufficient ionic build-up will cause itchiness or discomfort, especially under the cathode. Too great build-up will produce chemical burn. If applied symmetrical biphasic pulses over the skin, there are no charges in pH of skin under the electrodes as amount of charge following in each direction is the same (63).

2.3.1.2 Pulse duration

Pulse duration, pulse width, is defined as time taken for instantaneous value of a pulse to rise and fall to a specified fraction of the peak value. It is measured in microsecond (µs) or millisecond (ms) for most clinical applications. An electrical pulse needs to produce a curtain minimal amount of charge movement to cause an action potential. Thus, if short duration pulses are used, the current will need to be high. Longer duration pulses can be effective at lower peak currents but can be uncomfortable and increase risk of skin damage (33, 63). Used current applications are based on the knowledge that pulse duration and current produced action potential. Most studies used pulse duration of FES for strengthening muscle in children with cerebral palsy between 100-300 µs (18, 23, 65, 67, 70-72).

2.3.1.3 Pulse frequency

Pulse frequency, inter-pulse interval, is the number of occurrences per second and is specified in hertz (Hz). Thus, if stimulus pulses are applied 10 times per second, the pulse frequency is 10 Hz. Pulse frequency is particularly important when the objective is muscle stimulation. One reason is that it affects the type of muscle contraction and the level of force produced when motor nerves are stimulated. A single pulse per second (1Hz) produces a twitching response as there is sufficient time between stimuli for muscle to relax. If the frequency is more than a few Hz, the muscle fibers do not have time to relax completely between pulses. Each successive contraction occurs on the tail of the previous one and the peak force is greater. With a further increase in the frequency it becomes more difficult to distinguish the effects of individual stimuli. The twitch responses fuse and the contraction becomes stronger still. With most human muscles, at a stimulus frequency of about 20 Hz, show partial tetany. Between 20-50 Hz, the contractile force reaches a plateau and show tetanic contraction (33, 63). The frequency varies between muscles and depends on the muscle fiber types present. In term of twitch, two groups of fibers are distinguish; fast and slow twitch. The slow twitch type shows long twitch contraction time and low frequency. At the opposite extreme, the fast twitch type shows short twitch contraction time and high frequency (63). Frequency around 30-40 Hz cause smooth contractions of muscle and are commonly used clinically (11, 18, 19, 25, 32, 63, 65, 67, 69-72).

2.3.1.4 Duty cycle

Duty cycle of the treatment is compromised of an on-time reflecting the duration of pulse delivery and an off-time reflecting the duration of recovery and quiescence. The total duty cycle time is the sum of the on- and off-time. It usually presents in percentage of duty cycle, on-time per sum of the on- and off-time (33, 63). The main relevance of duty cycle is one of factors determining the extent of electrolytic effects and the rate of fatigue (63). Many studies used FES has a foot switch, the duty cycle will control by foot switch during walking (11, 18, 23, 24, 67-70, 73).

2.3.1.5 Ramp modulation

In order to automatically increase or decrease the phase or pulse charge in pattern of electrical stimulation, ramp modulation controls are included in several types of commercially available stimulators. These controls allow the therapist to set the number of seconds over which the pulse duration will gradually increase to the maximal value and decrease to the quiescence value which set by the amplitude control. Ramp modulations on the leading and trailing ends of train pulses provide a more comfortable onset and cessation of stimulation in variety of applications (33, 63, 64). In neuromuscular stimulation applications, the inclusion of a ramp up time on the leading edge of train of pulse allows for the gradual recruitment of motor nerve fibers and a ramp down time on the leading edge of train of pulse hence the gradual decrease in muscle fiber contraction, which results in the smooth increase and decrease in motor force input. The gradual onset of muscle stimulation produces contractions that more closely mimic those produced in functional activities during voluntary muscle activation, and the gradual onset is more comfortable for individual receiving the FES (64). In the previous studies of FES training was used the ramp modulation, the ratio of the ramp up and ramp down were set at 0.2- 0.5 seconds (18, 71, 74).

2.3.1.6 Duration of stimulation

Duration of stimulation may be defined as the time for which stimulation was applied, usually stimulation for hours or minutes (33).

2.3.2 Electrode location

In order to FES parameters are importance, electrode locations are the one factor that effects clinical applications. The electrode locations to achieve an electrically elicited contraction, two surface electrodes are placed on the skin over the muscle. There are two techniques as follow;

2.3.2.1 Unipolar technique

One electrode (the cathode has proved to be the more comfortable) is placed over the motor point of muscle and the other electrode, the anode, is placed elsewhere on the body, generally more distally on the muscle belly. This electrode should be larger, so that current density across is lower and unlikely elicited either motor or sensory responses. The placement over the motor point of a muscle means identifying the motor point on the skin where maximal muscle contraction can be achieved and used the least energy (intensity). It is often associated with the point at which the nerve supplying a muscle enters its muscle belly. Frequently located at the junction of the proximal one-third with the distal two-thirds of the muscle belly, this is the position where possible to influence the greatest number of motor and nerve fibers. If the peripheral nervous system is intact, stimulation is achieved by the intramuscular branches of the nerve supplying that muscle. This method is suitable for innervated muscle and sometimes called a unipolar technique (33, 62-65, 75).

2.3.2.2 Bipolar technique

Secondary technique, electrodes of a similar size may be placed at either end of a muscle belly. This method is suitable for both innervated and denervated muscle and may be called a bipolar technique (33, 62-65, 75).

Many studies of clinical FES during gait training used bipolar technique and place electrodes over varies body landmarks such as over the tibialis anterior muscle (23-25, 67, 68, 70), over the gastrocnemius muscle (11, 18, 23-25, 70), and over the common peroneal nerve (21, 24, 32, 69, 71), etc. Some of studies combined electrode placements. Postans and Granat (24) applied FES over the motor point of tibialis anterior in children with spastic diplegia, over the gastrocnemius muscle in children with spastic hemiplegia and spastic diplegia, and over the common peroneal nerve and the motor point of tibialis anterior in children with spastic hemiplegia and children with spastic diplegia during walking. The timing of the stimulation during the gait cycle controlled by four switches were placed on sole of each foot, located on the heel, first metatarsal, fifth metatarsal, and great toe. They determined that FES showed the positive effects on the gait of some children with CP. Clinically significant improvements, including increased swing phase dorsiflexion and improved prepositioning of the ankle at initial contact. In this study will apply FES over the common peroneal nerve and motor point of tibialis anterior muscle with controlling of the pulse delivery by the foot switches under heel to assist the ankle dorsiflexion at the swing phase and heel pressing on the floor at the stance phase of gait cycle.

2.4 Treadmill

The gait training on treadmill is a technique which used in neurological rehabilitation of clients with disabilities (e.g., post-stroke, spinal cord injury, and children with cerebral palsy, etc.). That technique provides task-specific gait cycle with multiple repetitions and active participation (12-17, 26, 28, 31, 76, 77). The walking reflex or autonomic walking reflex is obvious when a young baby is held upright with feet barely touching the surface below; the infant alternately puts weight on each foot. It is primitive reflexes that are present in the first few months of life (newborn to two months) (5, 17, 29). The theoretical basis of the treatment concept was an activation of spinal and supraspinal pattern generators. Primitive reflex can even be performed by anencephalic children. It possible to transfer the concept of activated innate locomotor capabilities by treadmill training in children with CP (15, 17). Effing and co-worker (16) studied treadmill training with partial body weight support in clients with chronic incomplete spinal cord injury. The results showed performance of activities of daily living (ADL), perception, and walking ability were significantly improved. Schindl and co-worker (17) studied neurodevelopmental techniques (NDT) combined treadmill training with partial body weight support in non-ambulatory and ambulatory children with CP. The results showed clinically significant improvements of gross motor abilities in both groups.

2.5 Gross Motor Function Classification System (GMFCS)

Cerebral palsy (CP) is caused by brain damage or injury that occurs during perinatal, prenatal, and postnatal period. It is a nonprogressive or degenerative central nervous system insult. It produces motor dysfunction, cognitive, and possible sensory deficits. Although the pathology may not progress, but its physical impairments and functional limitations are change with children growth. Rehabilitation may target impairments, activity limitations of patients as well as environmental factors, the outcome of these interventions are usually best seen by the client in terms of patients' ability to perform an activity or participate with their family or community. Impairment outcome do not correlate highly with activity (disability) and participation (handicap) outcome. For this reason, outcome measures that determine the level of the patients' ability to be active and participate in life as their wishes are usually more useful to therapist in determining if intervention has been effective (78). The uses of outcome tools include the measurement of functional performance as baseline descriptive clinical assessment, mean to select treatment goals, and mean to evaluate treatment results (79). Therapists have focused on effect of treatments and measuring associated changes due to treatments as indicators of outcome. These changes should be evaluated by objective, subjective with technical outcome measures. Function may be objectively measured using videos, formal gait analysis, and EMG. Range of movement of joint may be assessed clinically and with goniometry. Evaluate spasticity; the Ashworth scale and modified ashworth scale (MAS) are more recently resonance frequency has been used. The gross motor function measures (GMFM) and physician rated scales are also widely used to evaluate the motor functional abilities of the children with disabilities. Standardized questionnaires such as Pediatric evaluation of disability inventory (PEDI), GMFM, Gross motor function classification System (GMFCS), the functional independence measure for children (WeeFIM), etc. These may be used to measure the wider functional effects of treatment. The subjective impressions of the patient and guardians about posture, function, pain, and cosmetic should also be evaluated (6, 78, 80, 81). Palisano (82) said that when evaluation of gross motor function children with CP by comparison with children of the same age and GMFCS level has implications for decision making and interpretation of intervention outcomes.

The GMFCS for the children with CP develops in response to the need to have a standardized system to measure the severity of movement disability in children with CP and designs for these children who are 12 years of age or younger. Each level of the GMFCS provides functional descriptions for four ranges of age; before 2 years old, between 2 and 4 years old, between 4 and 6 years old, and between 6 and 12 years old. It is based on self-initiated movement with particular emphasis on sitting and walking (38, 82, 83) and divided into 5 level classification system, GMFCS provides a method of describing the functional ability of children with CP in one of five levels. Distinctions between levels of motor function are based on functional limitations, the need for assistive technology, including mobility devices (such as walkers, crutches, and canes) and wheeled mobility, and to much lesser extent quality of movement (82-84). According to the efficacy of GMFCS, this study will use the GMFCS to classify children who could walk independently.

2.6 Vicon™ motion analysis system

Gait analysis is a method of measurement, description, and evaluation of the functional quantities thought to characterize the way which a person walks (46, 47, 85). Through gait analysis, kinematic, kinetic, electromyography (EMG), and spatiotemporal data are acquired and analyzed to provide information (85). This study is interested kinematical variables of gait analysis in the sagittal plane include: (i) maximal ankle dorsiflexion angle at the swing phase of gait cycle, (ii) level of heel rising at the stance of phase of gait cycle, (iii) hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle, (iv) knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle, (v) stride length of gait cycle, (vi) gait speed of gait cycle and (vii) cadence of gait cycle. As the basic clinical technique is observational analysis, the gait patterns are described first by this technique. The gait analysis techniques which are used in clinical gait assessment vary enormously, with the nature of the clinical condition, the skills and facilitations available in the individual clinic or laboratory, and the purpose for which the analysis is being conducted. In general, however, gait assessments are made for two possible reasons as decision making or documentation (47). Then, as available, laboratory data are used to clarify and collect the gait deviations seen. Varying with the complexity of the abnormal movement, muscle action was documented by dynamic EMG, using wire electrodes. The motion has been recorded either with electrogoniometers or an automated, Vicon™, multiple video camera system (46).

Now, quantitative gait analysis using three-dimensional motion (3-D) analysis systems commonly used in many laboratories. Collins and Scholar (85) found Vicon 370 system that showed better intra- and inter-rater repeatability for kinematic measurement. Therefore, this study will use the Vicon™ motion analysis, Vicon 612 system, to collect the kinematic parameters of the gait cycle.

CHAPTER III
MATERIALS AND METHODS

3.1 Design of this study

This study used the repeated measure design to investigate the effect of a combination of the functional electrical stimulation (FES) and gait training on treadmill in Thai children with mildly to moderately spastic diplegia.

3.2 Subjects

Subjects were the Thai children with spastic diplegia aged between 6 and 12 years. They were recruited from special child centers or schools, physical therapy departments in hospitals and clinics.

3.2.1 Inclusion criteria

The children's functional abilities were classified at the level I-II based on the gross motor function classification system (GMFCS) (APPENDIX A).

3.2.1.1 Children could walk independently without devices and/or orthotic shoes.

3.2.1.2 Children exhibited typical tip toe pattern when walking.

3.2.1.3 Children's ankle dorsiflexor could be at least palpated.

3.2.1.4 Children's ankles could passively move to neutral position with knee extension.

3.2.1.5 Children's hip and knee flexion could actively and passively move toward middle range.

3.2.1.6 Children were able to follow simple instructions (e.g., ยืนนิ่งๆนะจ๊ะ, เริ่มเดินจ้า, หยุดเดินได้จ้า, etc.).

3.2.2 Exclusion criteria

3.2.2.1 Children have been undergone any previous soft tissue surgery, any serial casting, and Botulinum toxin type A (BTX-A) injection for at least 6 months.

3.2.2.2 Children were allergic to adhesive electrodes and/or tapes.

3.2.2.3 Children were unable to tolerate to any intensity of FES.

3.3 Instrumentations

3.3.1 Functional electrical stimulator

The functional electrical stimulator is an instrument that provides low-level electrical currents to activate muscles or innervated nerves. It is the single channel FES stimulator that could produce a functional movement, or series of movements for restoring function in clients with disabilities. The FES called electronic ankle-foot orthosis. They were produced by the Jockey Club Rehabilitation Engineering Center, Hong Kong Polytechnic University, Hong Kong, China (model R01–0093). In the present study used two FES stimulators (figure 3.1). The characteristics of the stimulators are as follows:

3.3.1.1 Symmetrical biphasic waveform

3.3.1.2 Frequency 40 Hertz (Hz)

3.3.1.3 Pulse width 306 microseconds (μs)

3.3.1.4 Stimulation period 5 seconds (s)

3.3.1.5 Rising edge ramp 0.3 seconds (s)

3.3.1.6 Falling edge ramp 0.3 seconds (s)

3.3.1.7 Duty cycle triggered by the foot switch

3.3.1.8 Maximal intensity 60 milliamps (mA)

3.3.1.9 Power supply 9 volts (v)

With the fixed frequency of the FES stimulators at 40 Hz, it can reduce the spastic muscle and strength the atrophied muscle (65, 72), the fixed pulse width was set at 306 µs due to set both approximate pulse width in the pulse duration of FES for strengthening muscle in children with cerebral palsy between 100-300 µs and the easy calculation of the intensity of the FES stimulators. Although it is a short pulse width, the current will need the high intensity but the narrow pulse width is more comfortable and low risk of skin damage than the wide pulse width (33, 63), and the fixed ramp modulations was set at 0.3 seconds. The fixed setting was adjusted as the gradual onset of muscle stimulation produces contractions that more closely mimic those produced in functional activities during voluntary muscle activation, and the comfortable for individual receiving the FES.

Figure 3.1 Functional electrical stimulator

3.3.2 Foot switch

The foot switch is a sensor of FES that controls the timing of stimulation during gait cycle (figure 3.2). In this study, two foot switches were active when the heels rise from the floor and these sensors were used to control the ankle dorsiflexor muscle activations during the gait training.

Figure 3.2 Foot switch

By the foot switches controlled the duty cycle of the FES stimulators characteristics during the gait cycle, it assisted to activate the ankle dorsiflexor at the swing phase and press the heel on the floor at the stance phase. Furthermore the foot switches can prevent the rate of fatigue (24, 30, 32, 34, 67, 68, 71) when the children received the gait training on treadmill combined with FES for 30 minutes.

3.3.3 Adhesive electrode

Four adhesive electrodes were used in this study (figure 3.3).

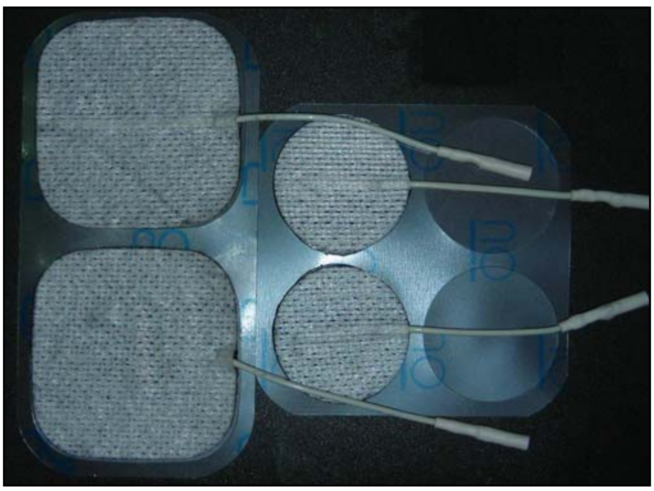

Figure 3.3 Adhesive electrodes

3.3.4 Treadmill

The treadmill is an exercise machine for running or walking while staying in place. The speed of treadmill could be adjusted from 0.0 km/hr to 16.0 km/hr (with the increments of 0.1 km/h). In this study, a treadmill was used to train the children walking (figure 3.4).

Figure 3.3 Treadmill

3.3.5 Lite gait II and harness

The Lite gait II and harness are gait training instruments that simultaneously control weight bearing, posture, and balance over a treadmill or over ground. In this study, these instruments were used to control a fall when children received gait training on treadmill (figure 3.5).

Figure 3.5 Lite gait II and harness

3.3.6 Heart rate monitor (Polar)

The Polar is an instrument that monitors and records heart rate. In this study, the polar was used for monitoring the children's heart rate when they walk and rest (figure 3.6).

Figure 3.6 Heart rate monitor (Polar)

3.3.7 Vicon™ motion analysis laboratory

The motion analysis laboratory (figure 3.7) consisted of

3.3.7.1 Six cameras (100 Hz)

3.3.7.2 Vicon 612 workstation

3.3.7.3 Personal computer workstation with Microsoft Windows XP

Figure 3.7 Vicon™ motion analysis laboratory

3.3.8 Reflective spherical markers and calibration kit

Sixteen reflective spherical markers were used in this study (figure 3.8).

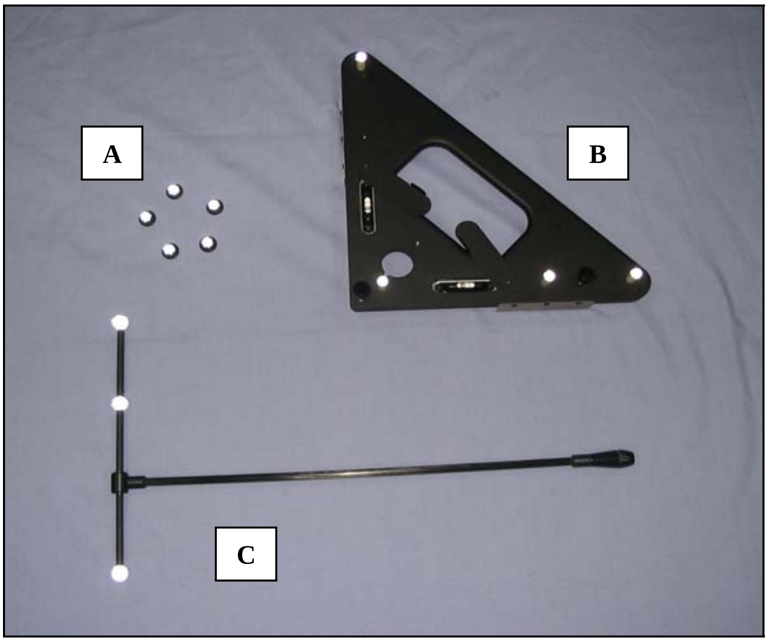

Figure 3.8 A = Reflective spherical markers (diameter 9.5 mm)
B = L-frame with 4 control markers (diameter 14 mm)
C = Wand with 3 control markers (diameter 14 mm)

3.3.9 Double-sided adhesive tape and hypoallergenic tape

3.3.10 Digital bathroom scale

3.3.11 Wedge board

The wedge board was used to stretch gastrocnemius and soleus muscle of both sides before each session of training (figure 3.9).

Figure 3.9 Wedge board

3.4 Experimental procedures

This study was approved the Ethic in Human Research by Mahidol University Institutional Review Board (MU-IRB) (APPENDIX B). The procedures were clearly explained to each child's parents or guardians. They read and signed informed consent (APPENDIX C) prior to participate in the study.

Baseline data were collected at the beginning of the study. The data include (1) maximal ankle dorsiflexion angle at the swing phase (degree), (2) level of heel rising at stance phase (mm), (3) hip flexion angle while maximal ankle dorsiflexion angle at swing phase (degree), (4) knee flexion angle while maximal ankle dorsiflexion angle at swing phase (degree), (5) stride length (mm), (6) gait speed (m/s), (7) cadence of gait cycle (steps/min), (8) body weight (kg), (9) body height (cm), (10) leg length (cm), (11) knee width (cm), and (12) ankle width (cm). The kinematic and gait data were collected by the Vicon™ motion analysis laboratory. A physical therapist (PT) attached sixteen reflective markers on legs bilaterally at anterior superior iliac spine (ASIS), posterior superior iliac spine (PSIS), knee joint center, lateral malleoli, head of the second metatarsal joint, lateral mid-shank (in line with the malleoli and the knee joint markers), lateral mid-thigh (in line with the greater trochanter and the knee joint center), and tip of calcaneous. Before the data collection, the children were passively stretched gastrocnemius and soleus muscles bilaterally by the wedge board for 15 seconds and repeated 10 trials. The children walked with bared feet around 5 meters and the data of 3-6 steps were collected during each trial depending on each child preferred gait speed. The first training session was then appointed.

Two conditions of gait training were gait training on treadmill only and gait training on treadmill when combined with FES. Children were trained in a totally of 24 sessions (12 sessions of gait training on treadmill only and 12 sessions of gait training on treadmill when combined with FES). The counterbalanced order was used to order the conditions of gait training. The first child randomly selected the first condition of gait training as on treadmill only. When the first condition of training was completed, the kinematic and gait data were collected after the twelfth session. The children were allowed to have a rest for a week before the proceeding of the second condition of gait training. Before the second condition was started, the kinematic and gait data were collected as the baseline data before thirteenth session. The second condition of gait training was set on the next appointment. When the second condition of training was completed, the kinematic and gait data were collected after the twenty-fourth session.

3.4.1 Details of the conditions of gait training as followings:

3.4.1.1 Gait training on treadmill only

Gait training on treadmill only was a control condition. The PT recorded resting heart rate (RHR) and passively stretched gastrocnemius and soleus muscle bilaterally by wedge board for 15 seconds and repeated 10 trials. The children walked on treadmill with self selected speed for 10 minutes and repeated 3 trials. A total training time was 30 minutes per session. The children rested after each training trial until the heart rate (HR) reached the RHR. They were trained 2 sessions per week for 6 weeks. During gait training on treadmill, a PT sat behind the children to facilitate the gait patterns: (1) foot clearance at the swing phase, PT held the ankles for assisting the legs to swing reciprocally and (2) heel contact and prolongation at the stance phase, PT held the ankles for assisting heel pressing and prolongation on the floor reciprocally.

3.4.1.2 Gait training on treadmill combined with FES

Gait training on treadmill combined with FES was an intervention condition. The PT used two small electrodes as dominant electrodes over common peroneal nerve bilaterally for activating ankle dorsiflexion in neutral position and two big electrodes over motor point of tibialis anterior muscle bilaterally. Each foot switch was placed at the heel bilaterally (figure 3.10). The PT recorded RHR and passively stretched gastrocnemius and soleus muscle bilaterally by the wedge board for 15 seconds and repeated 10 trials. The PT gradually increased the currents at the child’s tolerance level during standing. The children walked on the treadmill with self selected speed for 10 minutes and repeated 3 trials. A total training time was 30 minutes per session. The children rested after each training trial until the heart rate (HR) reached the RHR. They were trained 2 sessions per week for 6 weeks.

During gait training on treadmill, the PT sat behind the children to facilitate the gait patterns: (1) foot clearance at the swing phase, the PT held the distal leg closer to the knees for assisting the legs to swing reciprocally and (2) heel contact and prolongation at the stance phase, the PT pressed the leg down for assisting heel pressing and prolongation on the floor reciprocally.

Figure 3.10 The attachments of electrodes and foot switches

3.5 Data analysis

The kinematic and gait data in the sagittal plane were carried out before and after each condition by using the Vicon™ motion analysis laboratory. The collected data were collected by six video cameras with 100 Hz sampling frequency and digitized and smooth by a fourth order, zero-lag Butterworth filter at 10 Hz cutoff frequency to get the kinematic and gait parameters. These parameters are maximal ankle dorsiflexion angle at the swing phase, level of heel rising at the stance phase, hip flexion angle while maximal ankle dorsiflexion angle at the swing phase, knee flexion angle while maximal ankle dorsiflexion angle at the swing phase, stride length, gait speed, cadence of gait cycle. These parameters were used to compare the average data of kinematic and gait parameters between pre- and post-gait training on treadmill only, the average data of kinematic and gait parameters between pre- and post-gait training on treadmill combined with FES, and the average changes of kinematic and gait parameters between gait training on treadmill only and gait training on treadmill combined with FES.

3.6 Statistical analysis

3.7.1 The Kolmogorov-Smirnov goodnees of Fit test was used to determine the distribution of data. Statistical analysis was performed at *p*-value = 0.05.

The calculated data possibly showed normal distribution or non-normal distribution. The parametric statistic, paired t-test, was used to calculate the statistically significant of calculated data that showed normal distribution. In the addition, the non-parametric statistic, Wilcoxon signed rank test, was used to calculate the statistically significant of the calculated data that showed non-normal distribution.

3.7.2 Paired t-test was used to compare:

3.7.2.1 The difference of the average data of kinematic and gait parameters between pre- and post-training during gait training on treadmill only and training during gait training on treadmill combined with FES

3.7.2.2 The difference of the average changes of kinematic and gait parameters between gait training on treadmill only and gait training on treadmill combined with FES

Statistical analysis performed at the level of significant *p*-value = 0.05.

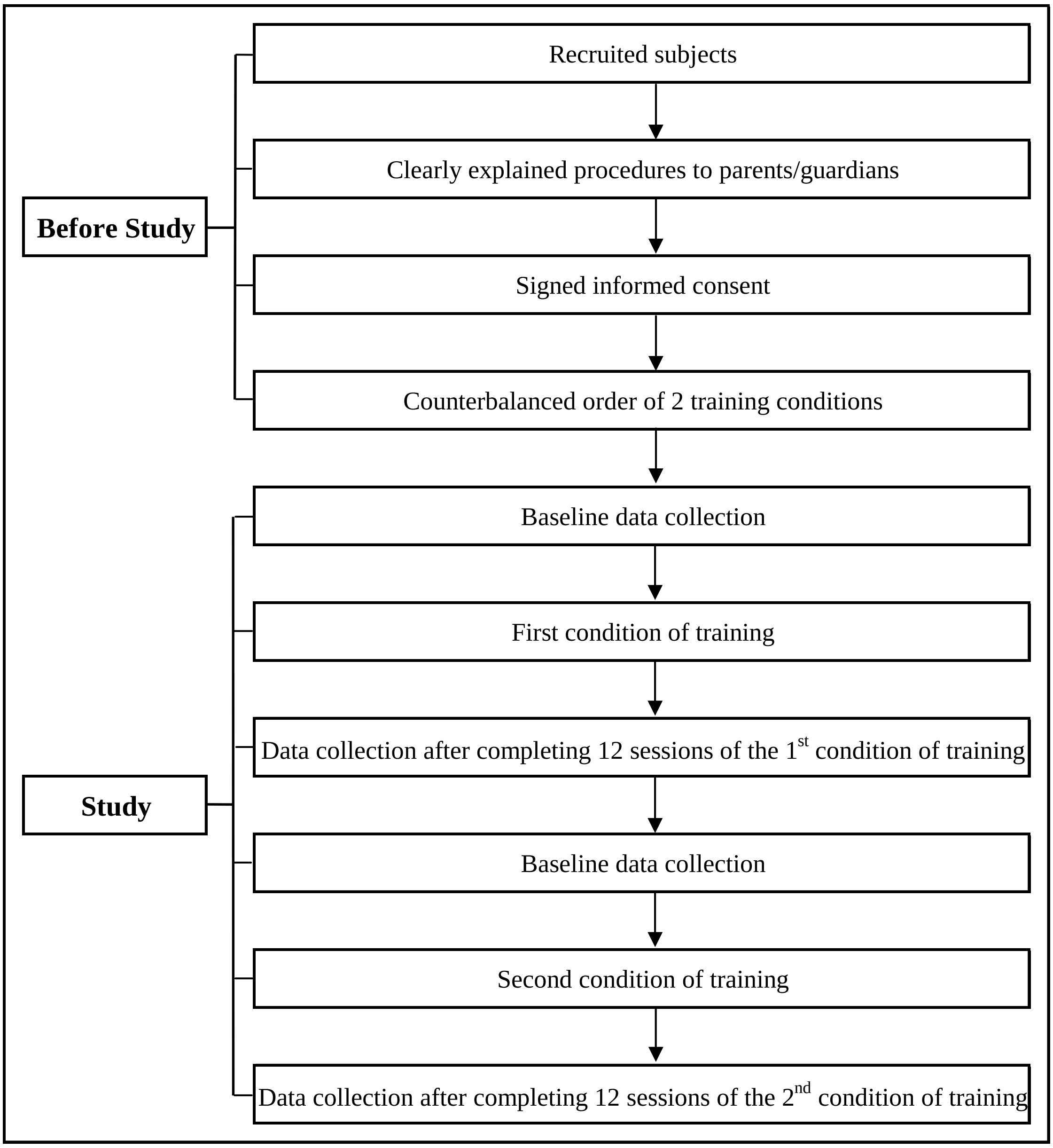

Figure 3.11 Flow chart of the whole experimental procedure

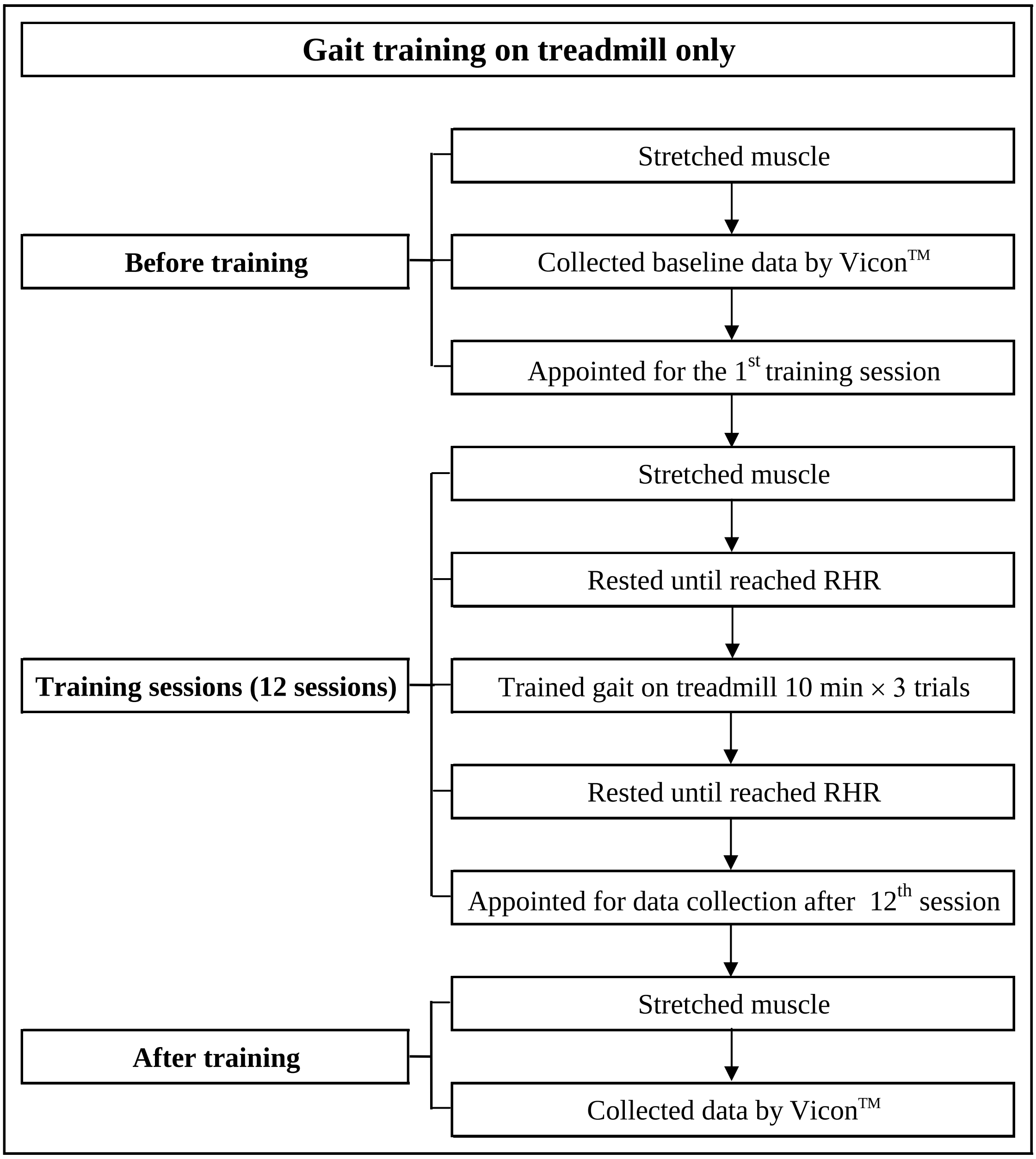

Figure 3.12 Flow chart of whole procedure of the training on treadmill only

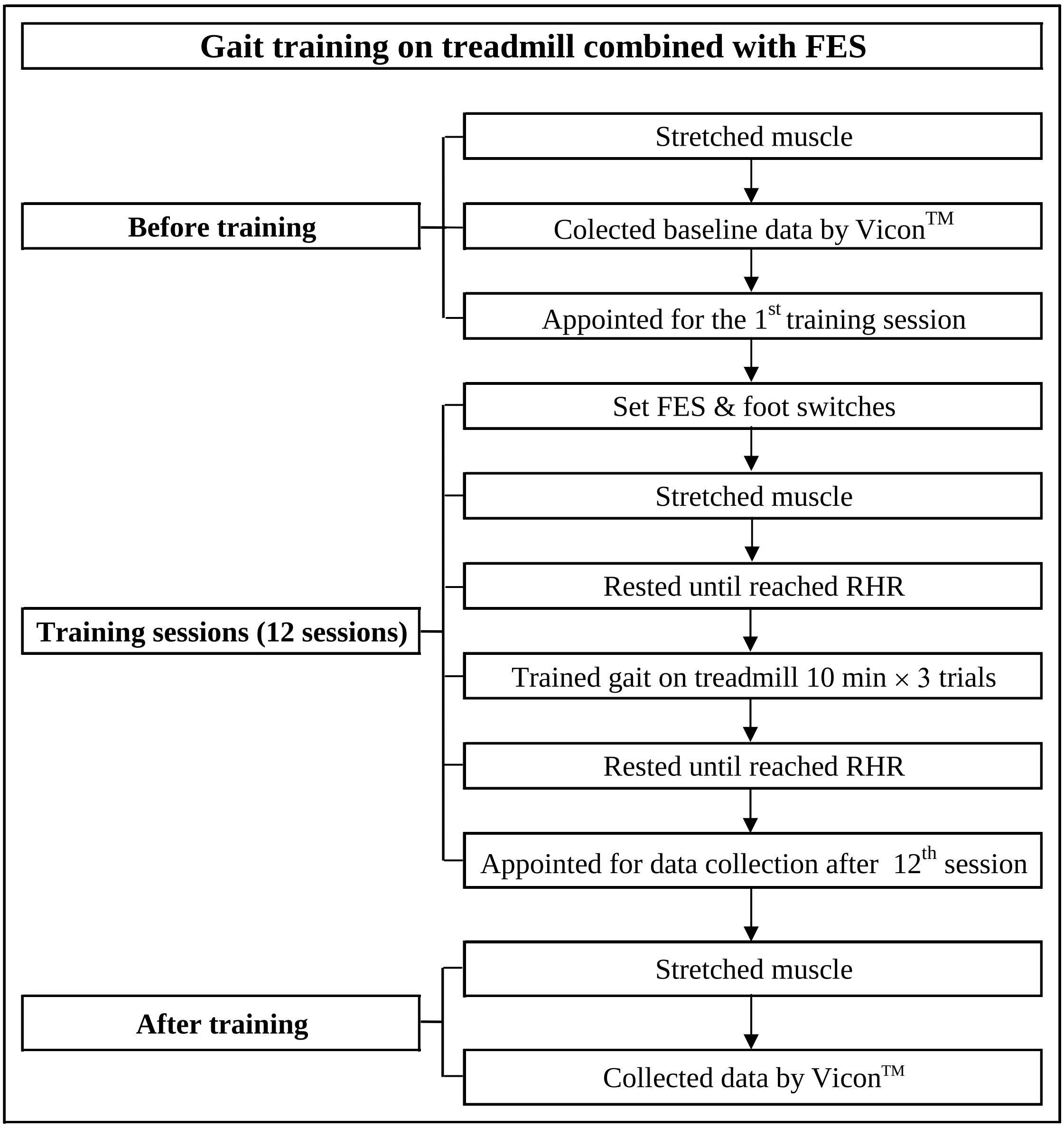

Figure 3.13 Flow chart of whole procedure of the training on treadmill when combined with FES

CHAPTER IV
RESULTS

4.1 Demographic data of the subjects

The present study used the repeated measure design to investigate the effect of functional electrical stimulation (FES) when combined with gait training on treadmill in Thai children with mildly to moderately spastic diplegia. The functional ability of these children were relatively high according to the gross motor function classification system (GMFCS) at the level I*-II**. Nine children were five boys and four girls whom recruited from special child centers or schools, physical therapy departments in hospitals and clinics in Bangkok. Their age range were 6.12 to 11.46 years old with a mean aged of 8.80±1.82 years.

There were two conditions of training in this study (gait training on treadmill only and gait training on treadmill with FES). The counterbalanced order was used to order the conditions of gait training. The first child randomly selected the first condition of gait training. The first order condition was gait training on treadmill only. Therefore, five children received the gait training on treadmill only as a first condition of training and four children received gait training on treadmill combined with FES as a first condition of training, the first order condition of gait training of the subjects are show in table 4.1.

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* Children walk indoors and outdoors, and climb stairs without limitations. Children perform gross motor skills including running and jumping but speed, balance, and coordination are reduced.

** Children walk indoors and outdoors, and climb stairs holding onto a railing but experience limitations walking on uneven surfaces and inclines, and walking in crowds or confined spaces. Children have at best only minimal ability to perform gross motor skills such as running and jumping.

Table 4.1 The first order condition of gait training of the subjects

Subject	Order of the 1st training condition
A	T
B	F
C	T
D	F
E	T
F	F
G	T
H	F
I	T

T = gait training on treadmill only

F = gait training on treadmill combined with FES

When the study was completed, the final data analysis consisted of data from seven of nine children. Two children were withdrawn from the study because the boy got Influenza A (H1N1) and the girl was not willing to train because she could not tolerate the feeling of FES. The table 4.2 shows the characteristics of seven children and the table 4.3 shows the functional abilities and the 1st order condition of gait training of seven children.

Table 4.2 Characteristics of the subjects who completed the study

Name	A	B	C	E	F	G	I
Age (yr)	6.12	8.69	9.21	8.69	11.46	6.16	10.92
Gender	Boy	Boy	Girl	Girl	Girl	Boy	Boy
Body weight (kg)	20.50	20.13	16.00	24.83	24.38	15.75	36.00
Body height (cm)	115.25	118.00	112.00	133.33	120.25	110.50	133.75
Leg length (cm)	56.06	57.88	56.38	72.44	63.31	56.19	71.25
Knee width (cm)	7.74	7.31	6.23	7.23	7.64	6.43	7.38
Ankle width (cm)	5.81	5.11	4.86	5.31	5.21	4.75	7.24

The seven children aged between 6.12 and 11.46 years old with a mean aged of 8.75±2.08 years, with four boys and three girls. All of the children were collected the anthropometries as body weight and height, leg length, and knee and ankle width. The average values of the children's anthropometries were 22.51±6.94 kilograms, 120.44±9.54 centimeters, 61.93±7.23 centimeters, 7.14±0.58 centimeters, and 5.47±0.85 centimeters, respectively.

Table 4.3 Functional abilities and the 1st order condition of gait training of the subjects who completed the study

Subject	GMFCS	Severity	Gait pattern	Order of the 1st training condition
A	I	Rt > Lt	Knee hyperextension	T
B	II	Rt > Lt	Knee hyperextension	F
C	II	Rt > Lt	Knee Flexion	T
E	II	Lt > Rt	Knee Flexion	T
F	II	Lt > Rt	Knee hyperextension	F
G	I	Lt > Rt	Knee hyperextension	T
I	I	Lt > Rt	Knee hyperextension	T

T = gait training on treadmill only
F = gait training on treadmill combined with FES

According to the levels of GMFCS, three children were classified into level I, whereas four children were classified into level II. Four of all children exhibited severity of the left leg more than the right leg. The pattern of children walking, five children walked with knee hyperextension at the stance phase, while two children walked with knee flexion at the stance phase. Because of drop-out children, five children received gait training on treadmill only as the first condition of training, while two children received gait training on treadmill combined with FES as the first condition of training.

When the children received the gait training on treadmill only and the gait training on treadmill combined with FES, the children walked on treadmill with self selected speed and some of children chose to increase their own speed. The treadmill was adjusted the minimal speed at 0.7 km/hr to maximal speed at 1.5 km/hr with increased minimum at 0.1 km/hr to maximum at 0.5 km/hr.

4.2 Comparisons of gait parameters between pre- and post-training in two conditions of gait training

The children received two conditions of training (gait training on treadmill only and gait training on treadmill with FES) as counterbalanced order. Each condition of training, consisted of 12 training session, children were trained 2 sessions per week for 6 weeks.

The Kolmogorov-Smirnov goodness of Fit test was used to determine the distribution of data. The results shown that all data were normally distributed (p > 0.05).

4.2.1 Comparisons of gait parameters between pre- and post training when received gait training on treadmill only

The individual values and average values of gait parameters when the children received the gait training on treadmill only are reported.

4.2.1.1 Maximal ankle dorsiflexion angle at the swing phase of gait cycle

The individual values and average values of the maximal ankle dorsiflexion angle at the swing phase of gait cycle were shown in a figure 4.1 and a table 4.4, respectively.

Table 4.4 Average values of gait parameters between pre- and post-gait training on treadmill only

Parameters	Pre-treadmill Mean (SD)	Post-treadmill Mean (SD)	Difference (Pre-Post) Mean (SD)	Outcome (+/-)	*p* -value
Maximal ankle dorsiflexion angle (degree)	2.13 (7.23)	4.54 (7.66)	2.41 (1.46)	+	0.000
Level of heel rising (mm)	35.62 (9.76)	31.96 (8.14)	-3.65 (2.06)	+	0.000
Hip flexion angle (degree)	35.81 (11.72)	34.50 (8.83)	-1.31 (11.50)	-	0.677
Knee flexion angle (degree)	46.83 (11.19)	43.83 (7.88)	-3.00 (10.80)	-	0.318
Stride length (mm)	611.69 (216.87)	517.80 (181.06)	-93.88 (85.56)	-	0.027
Gait speed (m/s)	0.49 (0.24)	0.44 (0.23)	-0.05 (0.16)	-	0.476
Cadence (steps/min)	87.86 (30.32)	79.62 (25.49)	-8.24 (16.29)	+	0.229

+ = improved - = not improved

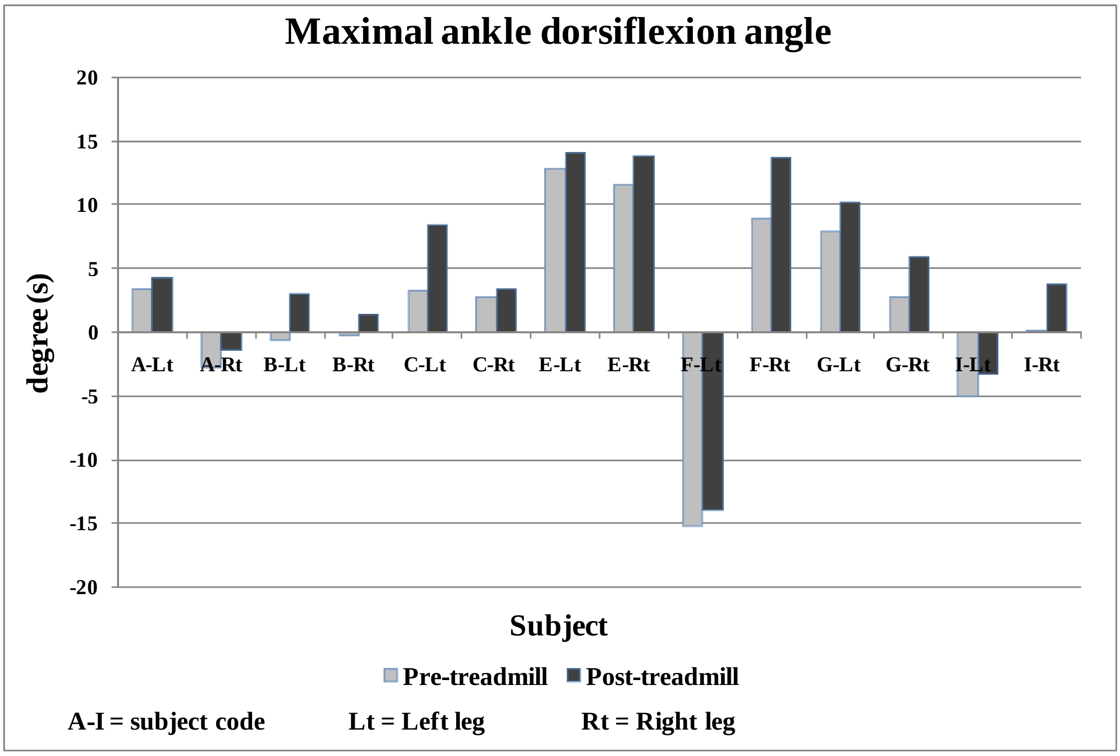

Figure 4.1 The maximal ankle dorsiflexion angle (degree) of the swing phase of gait cycle between pre- and post-gait training on treadmill in 7 subjects

All children showed more ankle dorsiflexion angle after received the gait training on treadmill. The average degrees of maximal ankle dorsiflexion angle at the swing phase were increased to 2.41±1.46 degrees. The results indicated as an improvement of ankle dorsiflexion angle at the swing phase. According to paired t-test, the maximal ankle dorsiflexion angle at the swing phase of gait cycle was statistically significantly increased (*p* = 0.00).

4.2.1.2 Level of heel rising at the stance phase of gait cycle

The individual values and average values of the level of heel rising at the stance phase of gait cycle are shown in a figure 4.2 and a table 4.4, respectively.

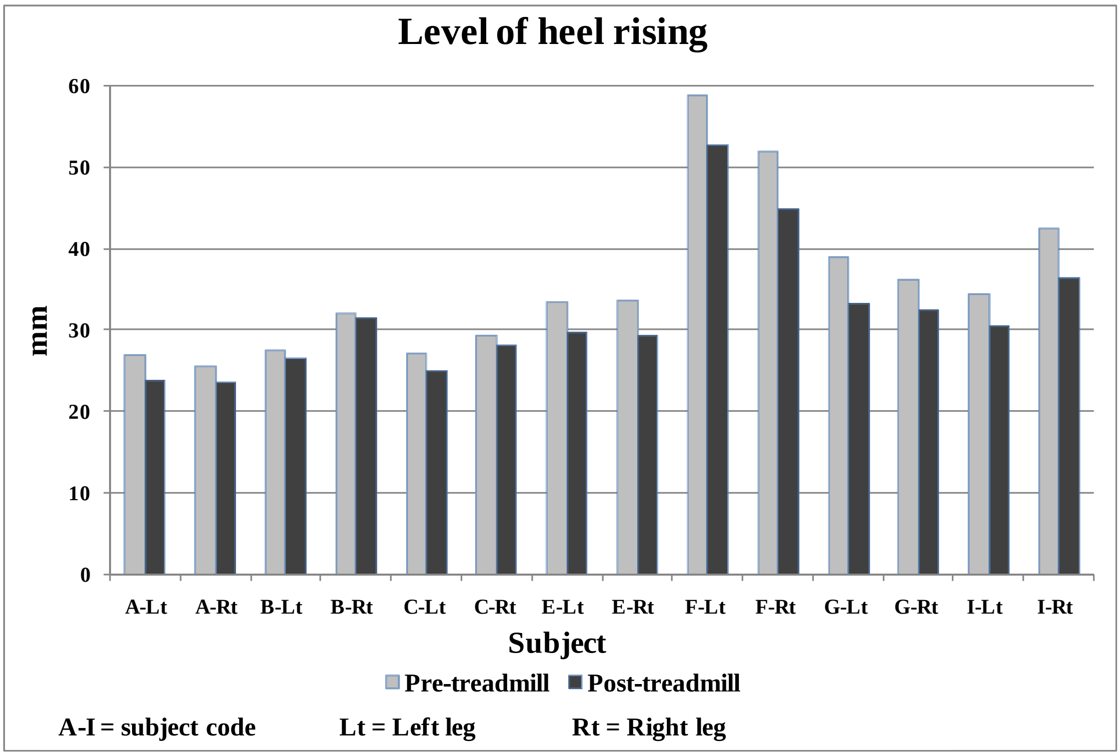

Figure 4.2 The level of heel rising (mm) of the stance phase of gait cycle between pre- and post-gait training on treadmill in 7 subjects

All children decreased the level of heel rising after received the gait training on treadmill. The average values of level of heel rising at the stance phase were decreased to 3.65±2.06 mm. The results indicated as an improvement of level of heel rising at the stance phase. According to paired t-test, the level of heel rising at the stance phase of gait cycle was statistically significantly decreased (*p* = 0.00).

4.2.1.3 Hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle

The individual values and average values of the hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle are shown in a figure 4.3 and a table 4.4, respectively.

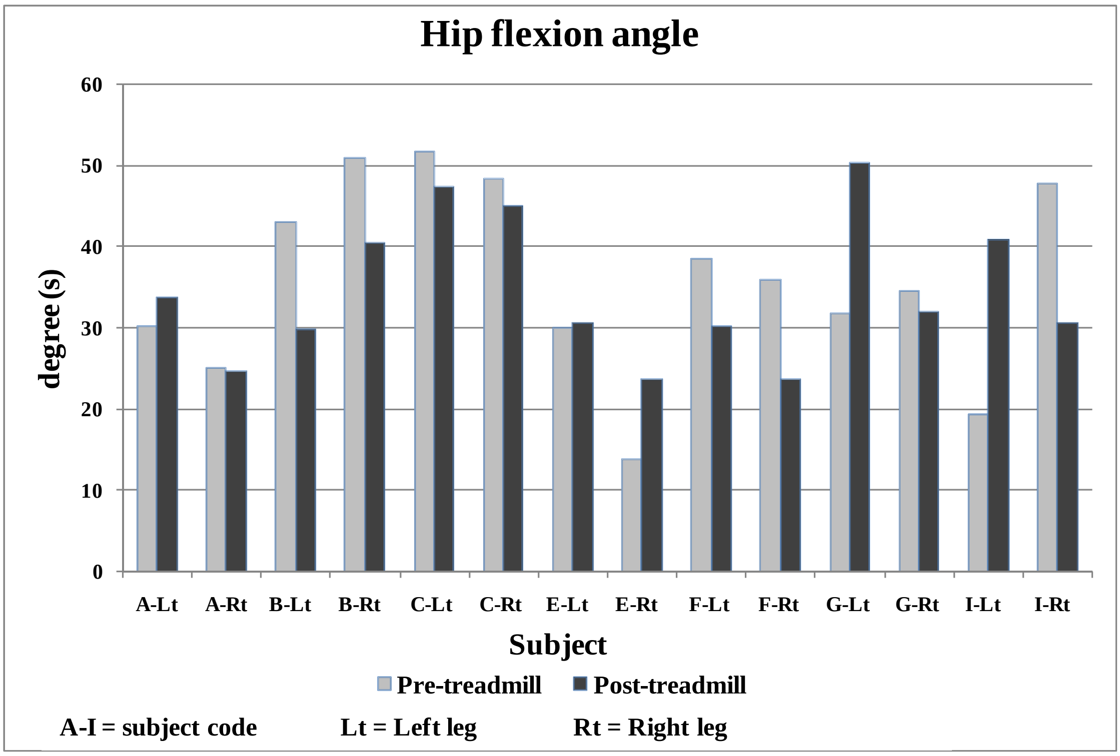

Figure 4.3 The hip flexion angle (degree) while maximal ankle dorsiflexion angle at the swing phase of gait cycle between pre- and post-gait training on treadmill in 7 subjects

According to the individual values, the hip flexion angle while maximal ankle dorsiflexion angle at the swing phase after received the gait training on treadmill were decreased in 9 of 14 individual values, whereas the remaining (5 of 14) showed an increasing of the hip flexion angle after received the gait training on treadmill. The average values of hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle were decreased to 1.31±11.503 degrees after treadmill training only. The results indicated as a non-improvement of hip flexion angle while maximal ankle dorsiflexion angle at the swing phase. According to paired t-test, the hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle was not statistically significantly changed (*p* = 0.677).

4.2.1.4 Knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle

The individual values and average values of the knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle are shown in a figure 4.4 and a table 4.4, respectively.

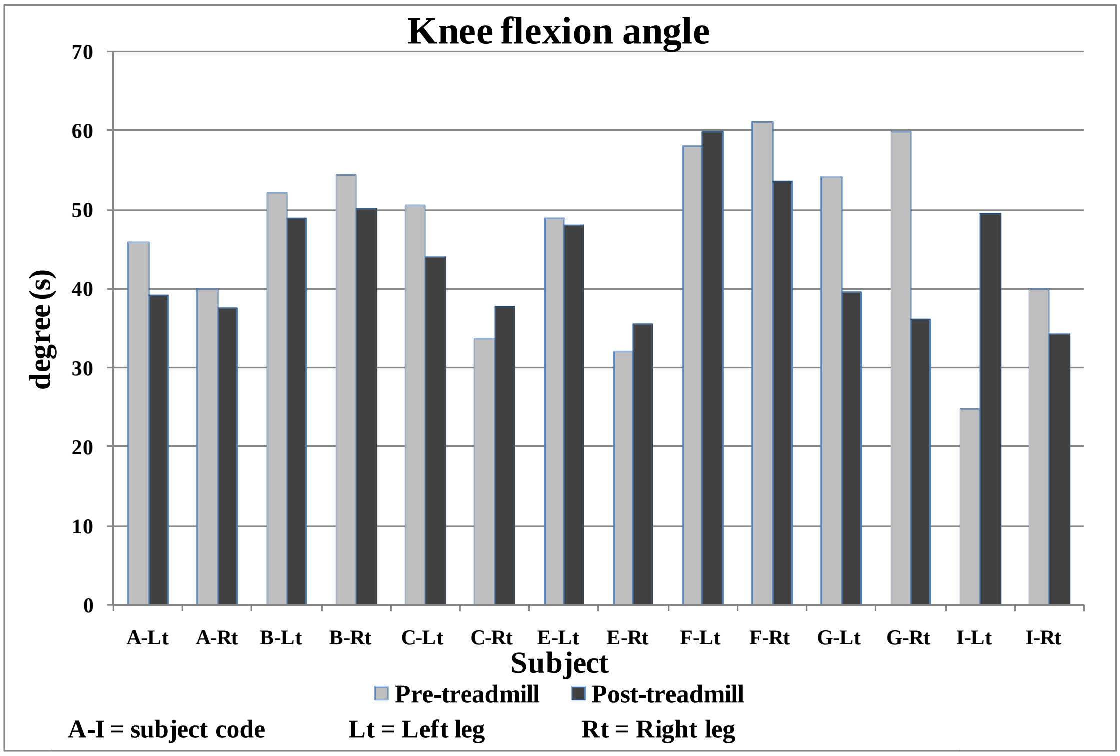

Figure 4.4 The knee flexion angle (degree) while maximal ankle dorsiflexion angle at the swing phase of gait cycle between pre- and post-gait training on treadmill in 7 subjects

According to the individual values, the knee flexion angle while maximal ankle dorsiflexion angle at the swing phase were decreased in 10 of 14 individual values, whereas the remaining (4 of 14) showed an increase of the knee flexion angle after received the gait training on treadmill. The average values of knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle were decreased to 3.00±10.80 degrees. The results indicated as a non-improvement of knee flexion angle at the swing phase. According to paired t-test, the hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle was not statistically significantly changed (p = 0.318).

4.2.1.5 Stride length of gait cycle

The individual values and average values of the stride length of gait cycle are shown in a figure 4.5 and a table 4.4, respectively.

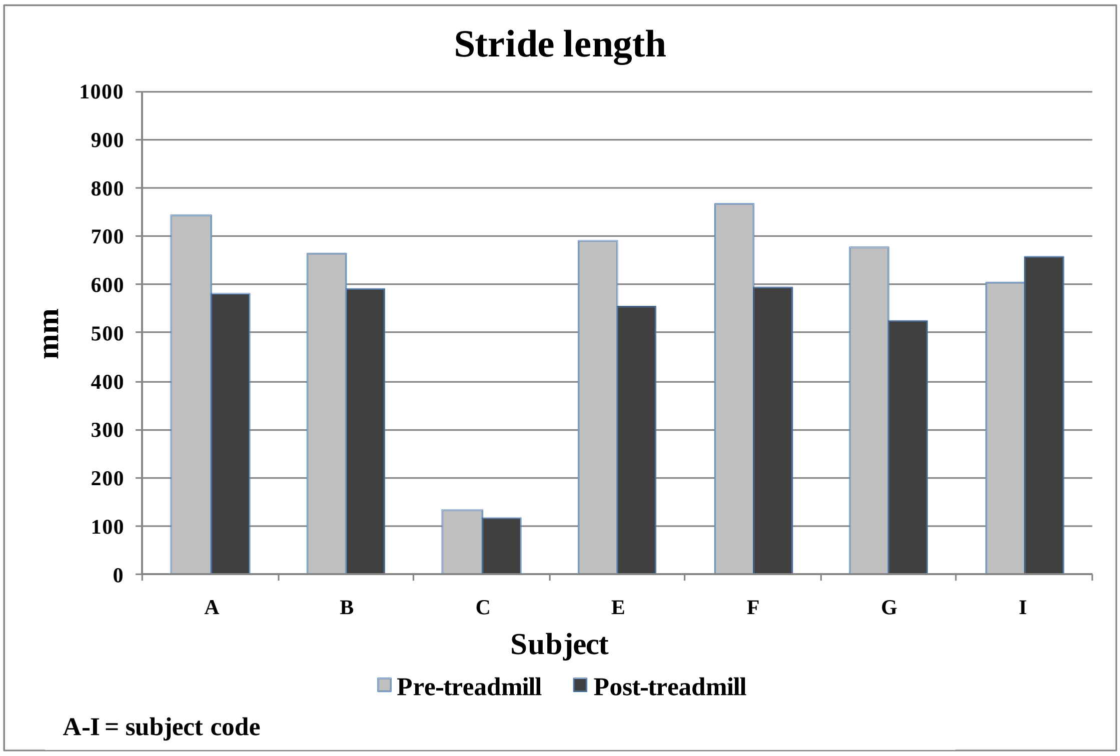

Figure 4.5 The stride length (mm) of gait cycle between pre- and post-gait training on treadmill in 7 subjects

According to the individual values, only 1 of 7 children increased the stride length after received the gait training on treadmill, whereas the remaining, 6 children, decreased the stride length after received the gait training on treadmill. The average values of stride length of gait cycle were decreased to 93.88±85.56 mm. The results indicated as a non-improvement of stride length. According to paired t-test, the stride length of gait cycle was statistically significantly decreased (p = 0.027).

4.2.1.6 Gait speed of gait cycle

The individual values and average values of the gait speed of the gait cycle were shown in a figure 4.6 and a table 4.4, respectively.

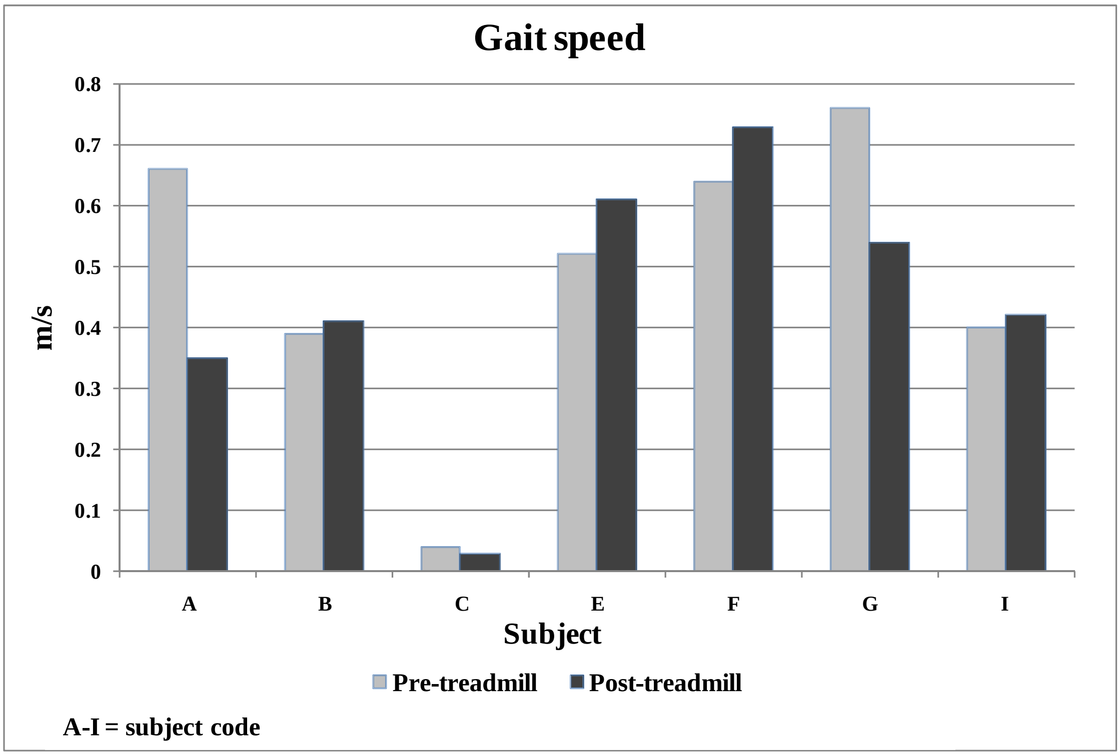

Figure 4.6 The gait speed (m/s) of gait cycle between pre- and post-gait training on treadmill in 7 subjects

According to the individual values, 4 of 7 children increased the gait speed after received the gait training on treadmill, whereas the remaining, three children, decreased the gait speed after received the gait training on treadmill. The average values of gait speed of gait cycle were decreased to 0.05±0.16 m/s. The results indicated as a non-improvement of gait speed. According to paired t-test, the gait speed of gait cycle was not statistically significantly changed (p = 0.476).

4.2.1.7 Cadence of gait cycle

The individual values and average values of the cadence of gait cycle are shown in a 4.7 and a table 4.4, respectively.

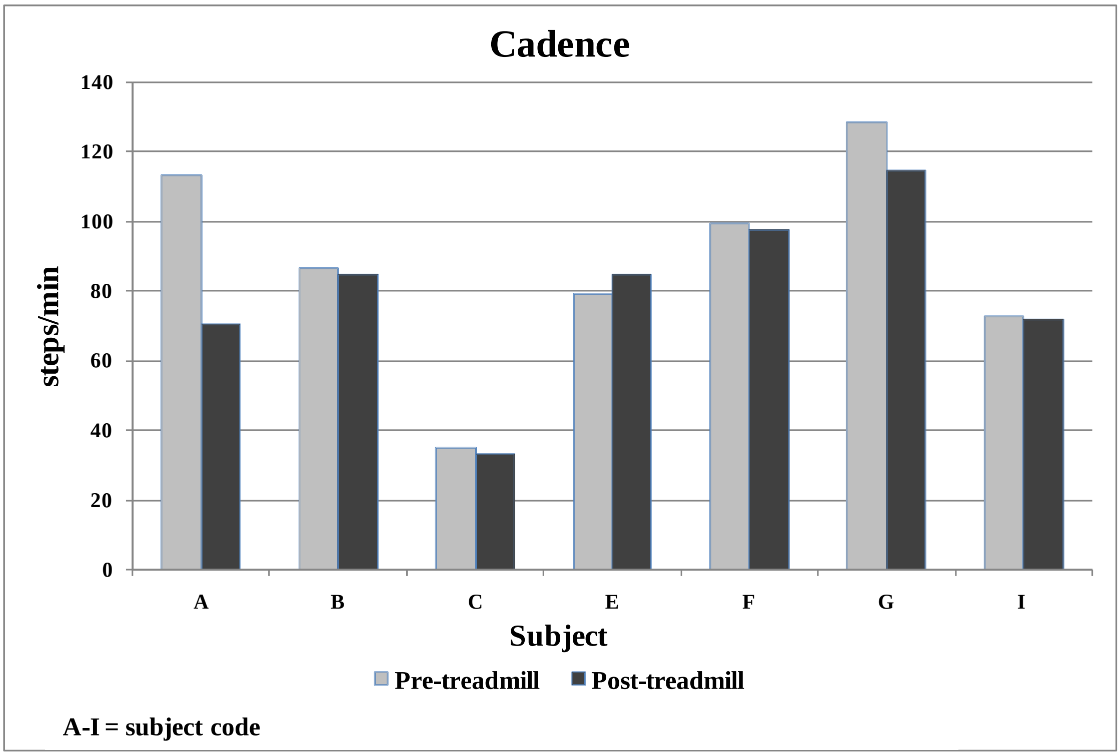

Figure 4.7 The cadence (steps/min) of gait cycle between pre- and post-gait training on treadmill in 7 subjects

According to the individual values, 6 of 7 children decreased the cadence after received the gait training on treadmill, whereas only one child increased the gait speed after received the gait training on treadmill. The average values of cadence of gait cycle were decreased to 8.24±16.29 steps/min. The results indicated as an improvement of cadence. According to paired t-test, the cadence of gait cycle was not statistically significantly changed (p = 0.229).

In summary, when the subjects received the gait training on treadmill**,** two gait parameters (i.e., maximal ankle dorsiflexion angle at the swing phase, the level of heel rising at the stance phase) were statistically significantly improved.

4.2.2 Comparisons of gait parameters between pre- and post-training when received gait training on treadmill with FES

When the children received the gait training on treadmill combined with FES, the currents of FES stimulators were gradually increased as the foot clearance at the swing phase and the heel pressing at the stance phase, and the children's tolerance level. The intensity approximately used at 18-36 mA.

The individual values and average values of gait parameters when the children received the gait training on treadmill with FES are reported.

4.2.2.1 Maximal ankle dorsiflexion angle at the swing phase of gait cycle

The individual values and average values of the maximal ankle dorsiflexion angle at the swing phase of gait cycle are shown in a figure 4.8 and a table 4.5, respectively.

Table 4.5 Average values of gait parameters between pre- and post-gait training on treadmill combined with FES

Parameters	Pre-FES + treadmill Mean (SD)	Post-FES + treadmill Mean (SD)	Difference (Pre-Post) Mean (SD)	Outcome (+/-)	*p* -value
Maximal ankle dorsiflexion angle (degree)	3.03 (7.46)	7.38 (7.89)	4.35 (2.12)	+	0.000
Level of heel rising (mm)	33.42 (8.46)	27.43 (6.23)	-5.99 (3.46)	+	0.000
Hip flexion angle (degree)	33.55 (9.19)	32.97 (10.29)	-0.58 (8.04)	-	0.791
Knee flexion angle (degree)	45.12 (9.22)	45.94 (10.55)	0.82 (9.09)	+	0.742
Stride length (mm)	564.24 (242.46)	584.38 (249.09)	20.14 (106.61)	+	0.635
Gait speed (m/s)	0.41 (0.21)	0.49 (0.26)	0.08 (0.10)	+	0.065
Cadence (steps/min)	76.04 (23.88)	76.77 (27.10)	0.73 (13.52)	-	0.892

+ = improved - = not improved

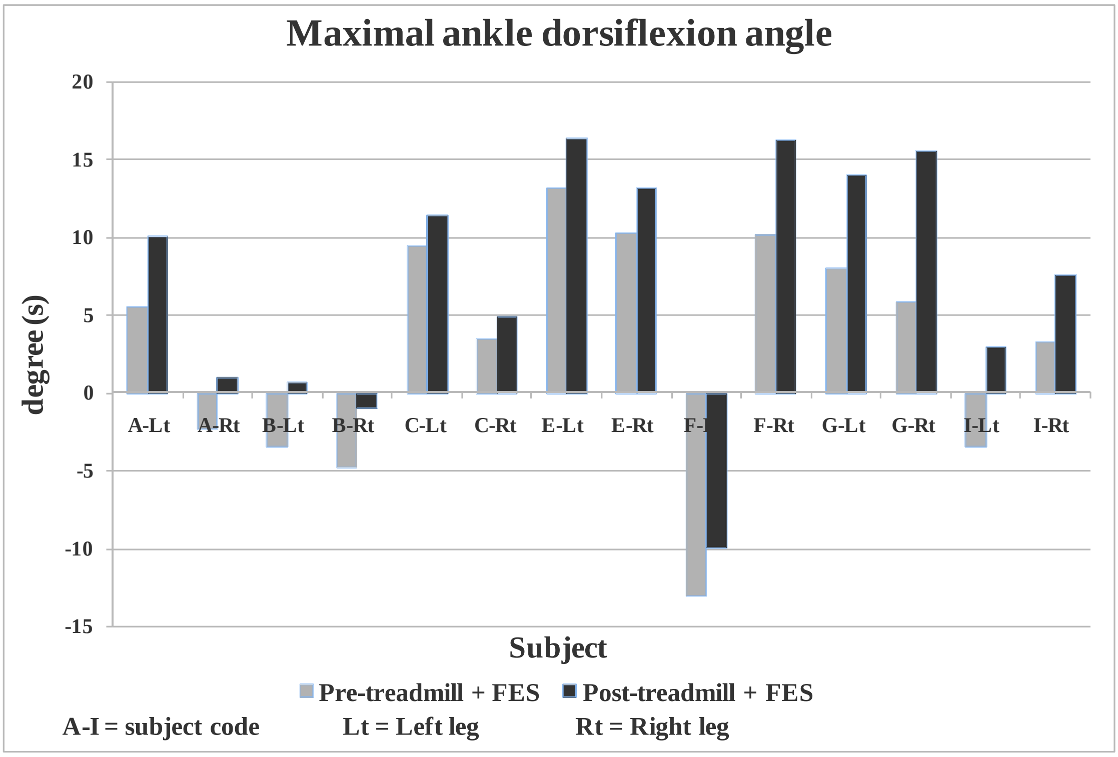

Figure 4.8 The maximal ankle dorsiflexion angle (degree) of the swing phase of gait cycle between pre- and post-gait training on treadmill combined with FES in 7 subjects

All children showed more ankle dorsiflexion angle after received the gait training on treadmill combined with FES. The average degrees of maximal ankle dorsiflexion angle at the swing phase were increased to 4.35±2.12 degrees. The results indicated as an improvement of ankle dorsiflexion at the swing phase. According to paired t-test, the maximal ankle dorsiflexion angle at swing phase was statistically significantly increased (p = 0.00).

4.2.2.2 Level of heel rising at the stance phase of gait cycle

The individual values and average values of the level of heel rising at the stance phase of gait cycle are shown in a figure 4.9 and a table 4.5, respectively.

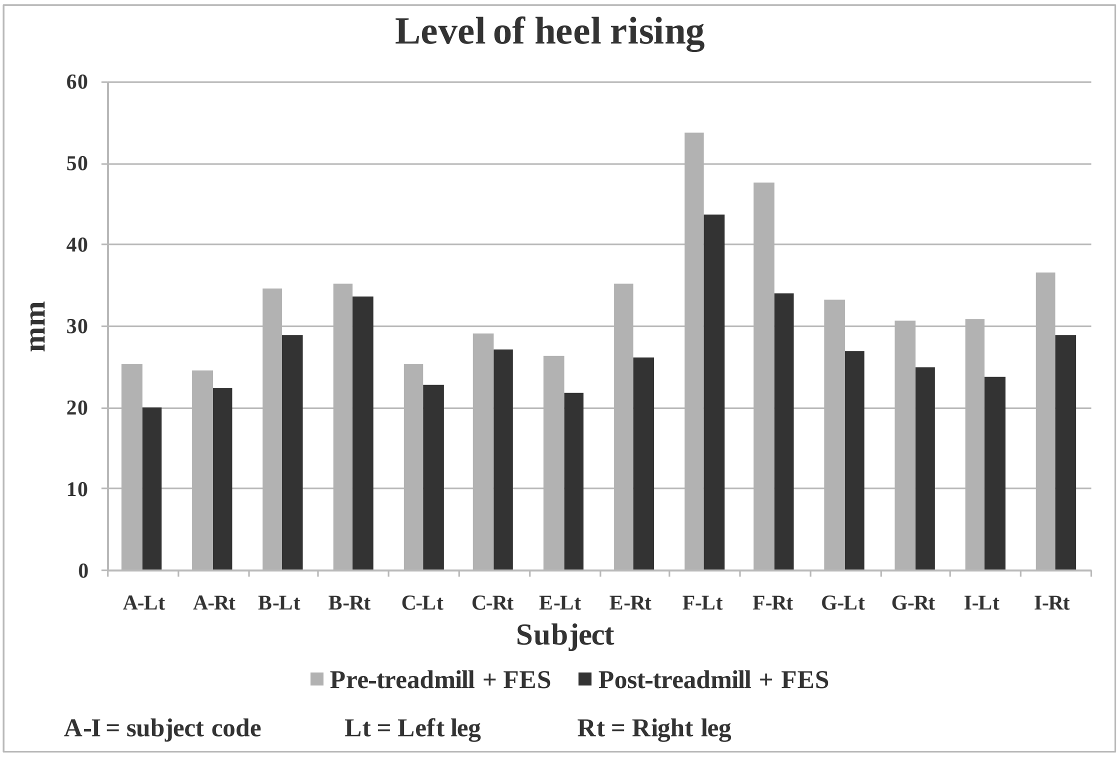

Figure 4.9 The level of heel rising (mm) of the stance phase of gait cycle between pre- and post-gait training on treadmill combined with FES in 7 subjects

All children decreased the level of heel rising after received the gait training on treadmill combined with FES. The average values of level of heel rising at the stance phase were decreased to 5.99±3.46 mm. The results indicated as an improvement of level of heel rising at the stance phase. According to paired t-test, the level of heel rising at the stance phase was statistically significantly decreased (p = 0.00).

4.2.2.3 Hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle

The individual values and average values of the hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle are shown in a figure 4.10 and a table 4.5, respectively.

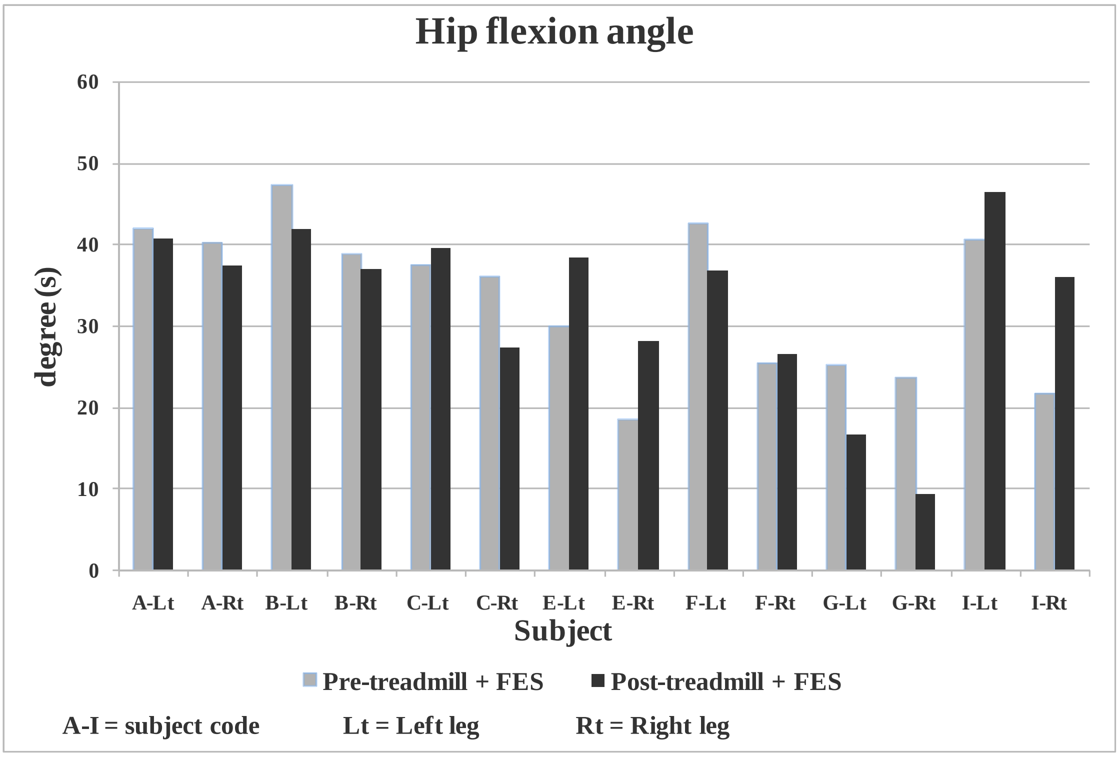

Figure 4.10 The hip flexion angle (degree) while maximal ankle dorsiflexion angle at the swing phase of gait cycle between pre- and post-gait training on treadmill combined with FES in 7 subjects

According of individual values, the hip flexion angle while maximal ankle dorsiflexion angle at the swing phase after received the gait training on treadmill combined with FES were decreased in 8 of 14 individual values, whereas 6 of 14 values showed increase of the hip flexion angle after received the gait training on treadmill combined with FES. The average values of hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle were decreased to 0.58 ± 8.04 degrees. The results indicated as a non-improvement of hip flexion at the swing phase. According to paired t-test, the hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle was not statistically significantly changed (p = 0.791).

4.2.2.4 Knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle

The individual values and average values of the knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle are shown in a figure 4.11 and a table 4.5, respectively.

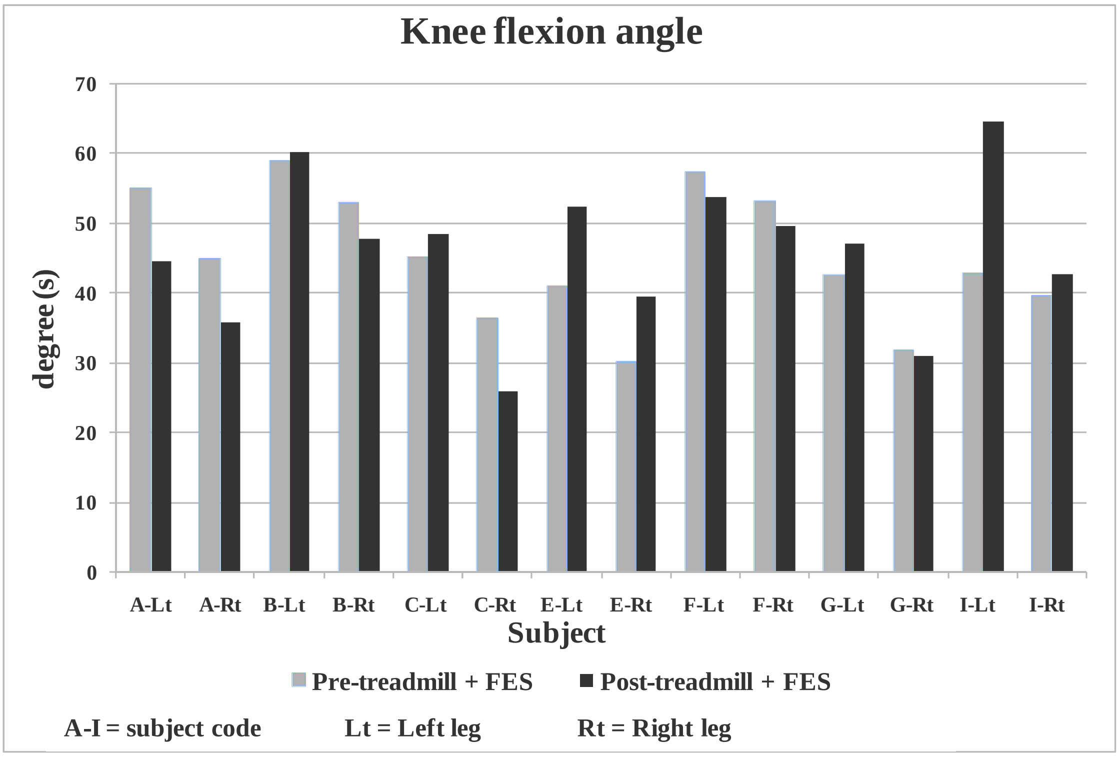

Figure 4.11 The knee flexion angle (degree) while maximal ankle dorsiflexion at the swing phase of gait cycle between pre- and post-gait training on treadmill combined with FES in 7 subjects

According of individual values, half of 14 raw data showed the decreases of the knee flexion angle while maximal ankle dorsiflexion angle at the swing phase after received the gait training on treadmill combined with FES, whereas the remaining showed the increases of the knee flexion angle after received the gait training on treadmill combined with FES. The average values of knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle were increased to 0.82±9.09 degrees. The results indicated as an improvement of knee flexion at the swing phase. According to paired t-test, the knee flexion angle while maximal ankle dorsiflexion at the swing phase of gait cycle was not statistically significantly changed (*p* = 0.742).

4.2.2.5 Stride length of gait cycle

The individual values and average values of the stride length of gait cycle are shown in a figure 4.12 and a table 4.5, respectively.

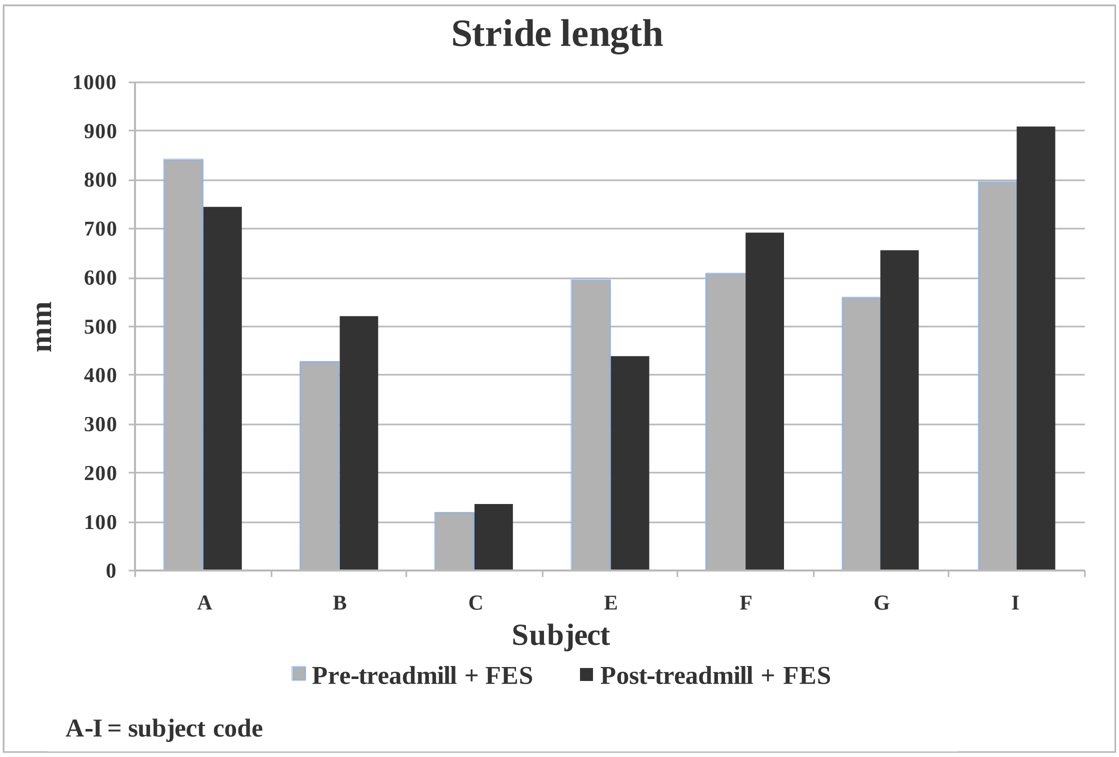

Figure 4.12 The stride length (mm) of gait cycle between pre- and post-gait training on treadmill combined with FES in 7 subjects

According of individual values, five children increased the stride length after received the gait training on treadmill combined with FES, whereas two children decreased the stride length after received the gait training on treadmill combined with FES. The average values of stride length of gait cycle were increased to 20.14±106.61 mm. The results indicated as an improvement of stride length. According to paired t-test, the stride length of gait cycle was not statistically significantly changed (*p* = 0.635).

4.2.2.6 Gait speed of gait cycle

The individual values and average values of the gait speed of gait cycle are shown in a figure 4.13 and a table 4.5, respectively.

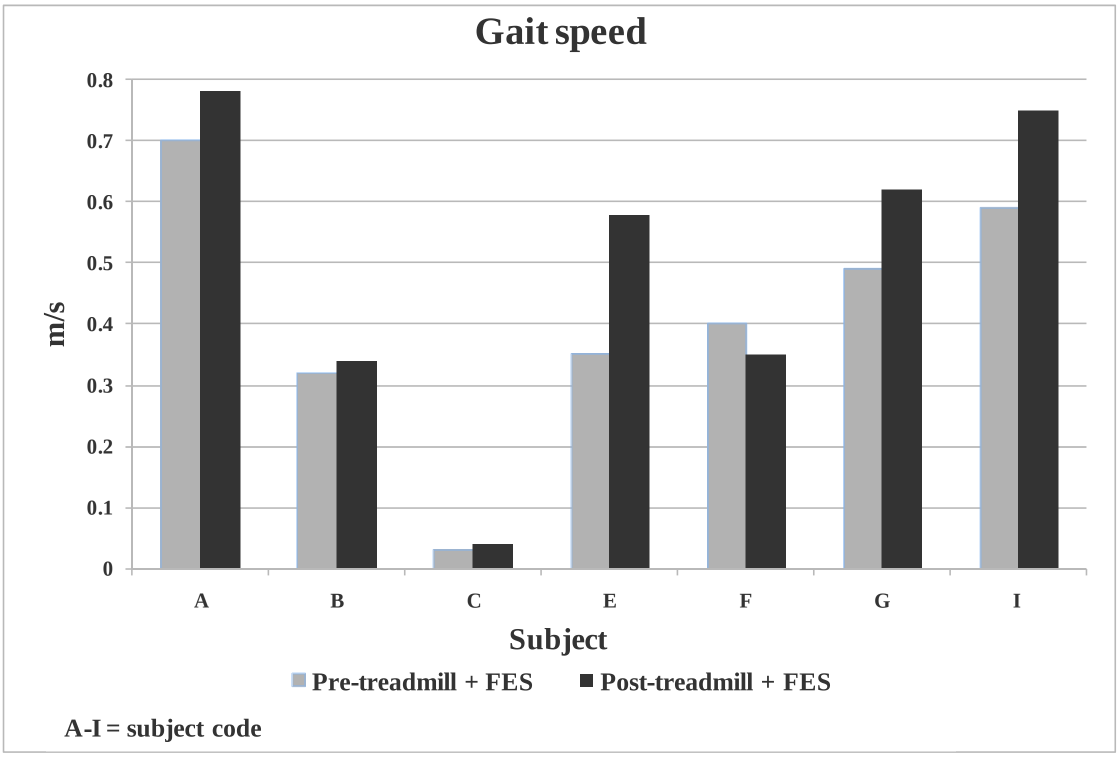

Figure 4.13 The gait speed (m/s) of gait cycle between pre- and post-gait training on treadmill combined with FES in 7 subjects

According of individual values, six children increased the gait speed after received the gait training on treadmill combined with FES, whereas a child decreased the gait speed after received the gait training on treadmill combined with FES. The average values of gait speed of gait cycle were increased to 0.08±0.10 m/s. The results indicated as an improvement of gait speed. According to paired t-test, the gait speed of gait cycle was not statistically significantly changed (p = 0.065).

4.2.2.7 Cadence of gait cycle

The individual values and average values of the cadence of gait cycle are shown in a figure 4.14 and a table 4.5, respectively.

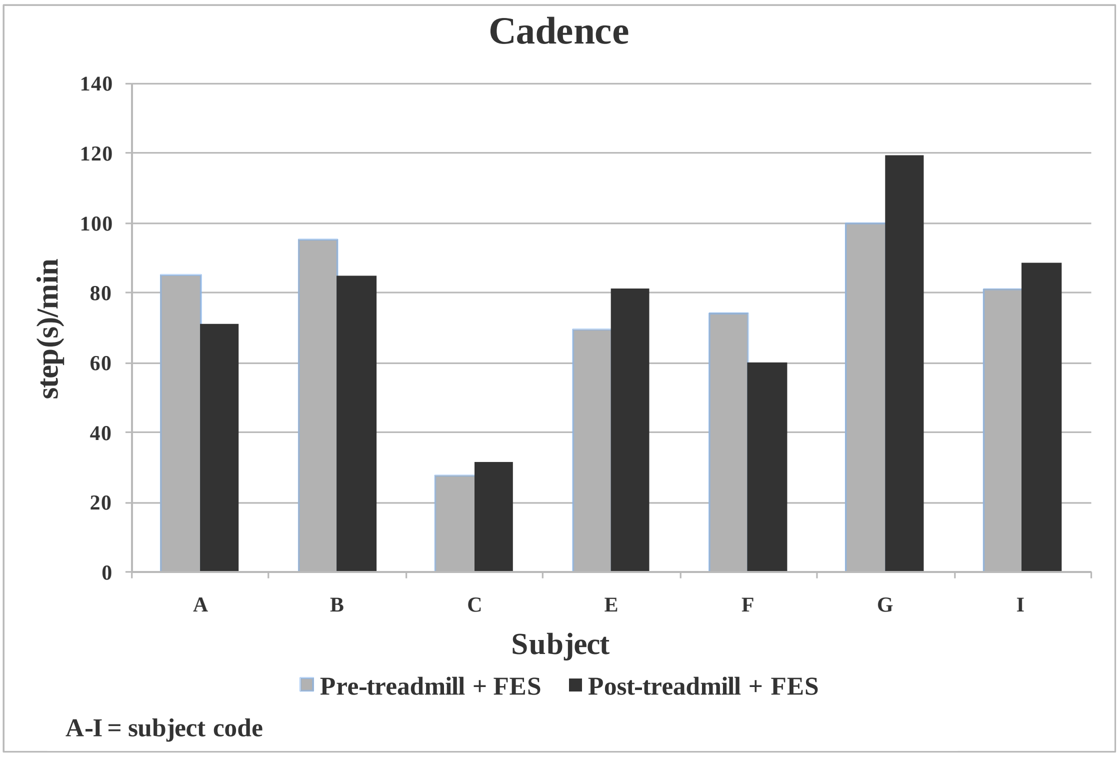

Figure 4.14 The cadence (steps/min) of gait cycle between pre- and post-gait training on treadmill combined with FES in 7 subjects

According of individual values, three children decreased the cadence after received the gait training on treadmill combined with FES, whereas four children increased the gait speed after received the gait training on treadmill combined with FES. The average values of cadence of gait cycle were increased to 0.73±13.52 steps/min. The results indicated as a non-improvement of cadence. According to paired t-test, the cadence of gait cycle was not statistically significantly changed (p = 0.892).

In the summary, when the subjects received the gait training on treadmill combined with FES, two gait parameters (i.e., maximal ankle dorsiflexion angle at the swing phase and level of heel rising at the stance phase) were statistically significantly improved.

4.3 Comparisons of change of gait parameters between gait training on treadmill only and gait training on treadmill with FES

Paired t-test was used to compare the changes of gait parameters between gait training on treadmill only and gait training on treadmill with FES. The level of significant difference was set at 0.05. Table 4.6 shows the difference of gait parameters after gait training on treadmill only and gait training on treadmill when combined with FES.

Table 4.6 The difference of gait parameters between gait training on treadmill and gait training on treadmill when combined with FES

Parameters	Difference of treadmill treatment	Difference of FES+treadmill treatment	*p* -value
Maximal ankle dorsiflexion angle (degree)	2.41 ± 1.46	4.35 ± 2.12	0.008*
Level of heel rising (mm)	-3.65 ± 2.06	-5.99 ± 3.46	0.001*
Hip flexion angle (degree)	-1.31 ± 11.50	-0.58 ± 8.04	0.751
Knee flexion angle (degree)	-3.00 ± 10.80	0.82 ± 9.09	0.195
Stride length (mm)	-93.88 ± 85.56	20.14 ± 106.61	0.031*
Gait speed (m/s)	-0.05 ± 0.16	0.08 ± 0.10	0.127
Cadence (steps/min)	-8.24 ± 16.29	0.73 ± 13.52	0.216

* *p*-value = 0.05

4.3.1 Maximal ankle dorsiflexion angle at the swing phase of gait cycle

The average changes of the maximal ankle dorsiflexion angle at the swing phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES are shown in a table 4.6 and a figure 4.15.

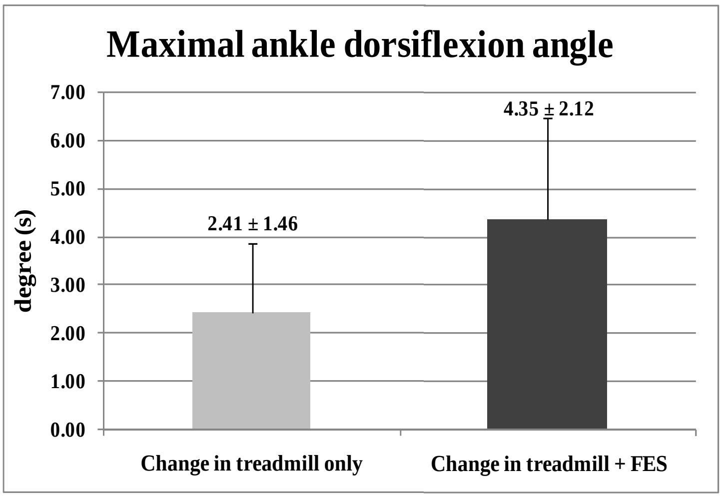

Figure 4.15 The difference of maximal ankle dorsiflexion angle (degree) at the swing phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES

The average changes of maximal ankle dorsiflexion angle at the swing phase after the gait training on treadmill only and gait training on treadmill combined with FES were 2.41±1.46 degrees and 4.35±2.12 degrees, respectively. According to paired t-test, the changes of maximal ankle dorsiflexion angle after gait training on treadmill combined with FES was statistically significantly more than the changes of maximal ankle dorsiflexion angle after gait training on treadmill only (p = 0.008).

4.3.2 Level of heel rising at the stance phase of gait cycle

The average changes of the level of heel rising at the stance phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES are shown in a table 4.6 and a figure 4.16.

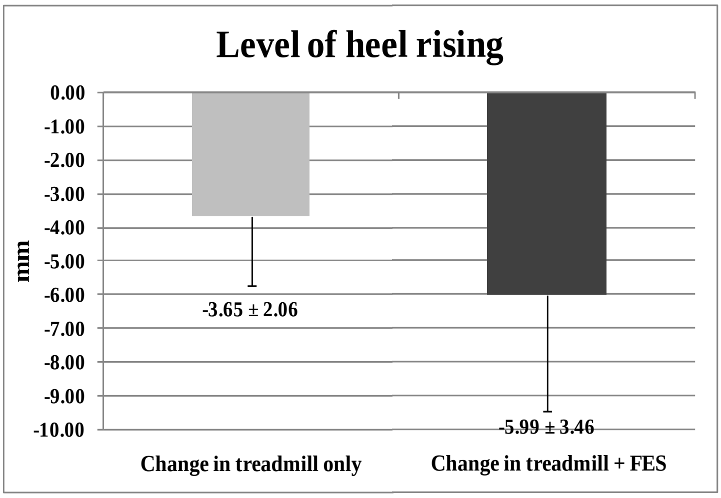

Figure 4.16 The difference of level of heel rising (mm) at the stance phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES

The average changes of level of heel rising at the stance phase after the gait training on treadmill only and gait training on treadmill combined with FES were -3.65±2.06 mm and -5.99±3.46 mm, respectively. According to paired t-test, the changes of level of heel rising after gait training on treadmill with FES was statistically significantly more than the changes of level of heel rising after gait training on treadmill only (p = 0.001).

4.3.3 Hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle

The average changes of the hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES were shown in a table 4.6 and a figure 4.17.

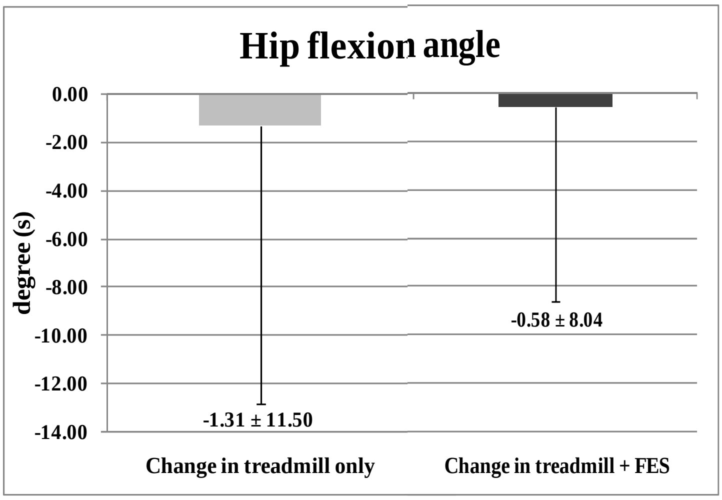

Figure 4.17 The difference of hip flexion angle (degree) while maximal ankle dorsiflexion angle at the swing phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES

The average changes of hip flexion angle while maximal ankle dorsiflexion angle at the swing phase after the gait training on treadmill only and gait training on treadmill combined with FES were -1.31±11.50 degrees and -0.58±8.04 degrees, respectively. In the average, when the children received the gait training on treadmill only decreased hip flexion angle more than when they received gait training on treadmill combined with FES. According to paired t-test, the changes of the hip flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES was not statistically significantly different (p = 0.751).

4.3.4 Knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle

The average changes of the knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES are shown in a table 4.6 and a figure 4.18.

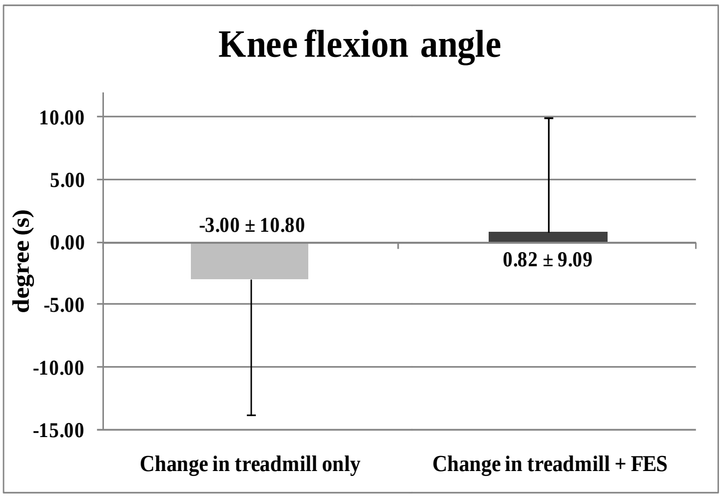

Figure 4.18 The difference of knee flexion angle (degree) while maximal ankle dorsiflexion angle at the swing phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES

The average changes of knee flexion angle while maximal ankle dorsiflexion angle at the swing phase after the gait training on treadmill only and gait training on treadmill combined with FES were decreased to -3.00±10.80 degrees and 0.82±9.09 degrees, respectively. In the average, after children received the gait training on treadmill only, they decreased knee flexion angle, whereas after they received the gait training on treadmill combined with FES, they increased knee flexion angle. According to paired t-test, the changes of knee flexion angle while maximal ankle dorsiflexion angle at the swing phase of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES was not statistically significantly different ($p = 0.195$).

4.3.5 Stride length of gait cycle

The average changes of the stride length of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES are shown in a table 4.6 and a figure 4.19.

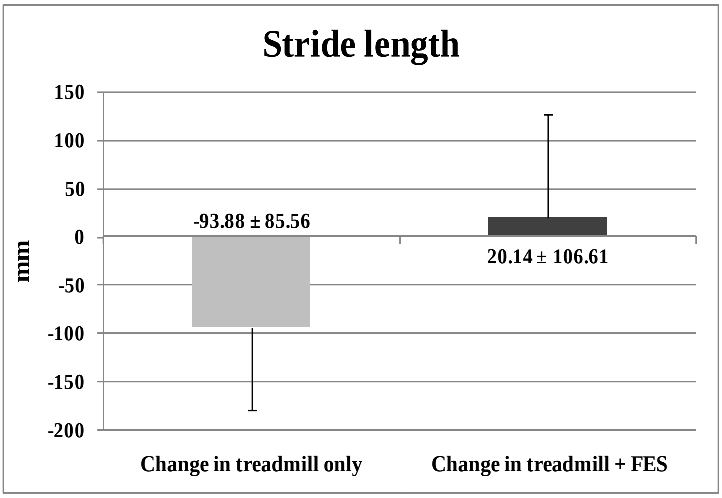

Figure 4.19 The difference of stride length (mm) of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES

The average changes of stride length of gait cycle after the gait training on treadmill only and gait training on treadmill combined with FES were -93.88±85.56 mm and 20.14±106.61 mm, respectively. In average, after children received the gait training on treadmill only, they decreased stride length, whereas after they received the gait training on treadmill combined with FES, they increased stride length. According to paired t-test, the changes of stride length of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES was statistically significantly different (p = 0.031).

4.3.6 Gait speed of gait cycle

The average changes of the gait speed of gait cycle between gait training on treadmill only and gait training on treadmill with FES are shown in a table 4.6 and a figure 4.20.

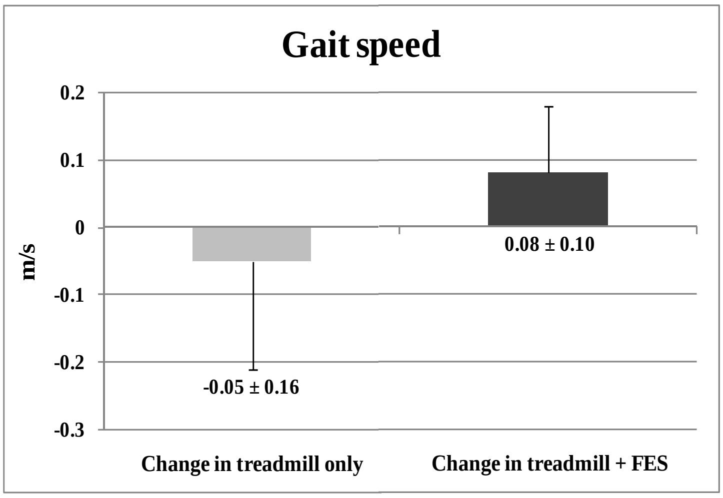

Figure 4.20 The difference of gait speed (m/s) of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES

The average changes of gait speed of gait cycle after the gait training on treadmill only and gait training on treadmill combined with FES were -0.05±0.16 m/s and 0.08±0.10 m/s, respectively. In average, after children received the gait training on treadmill only, they walked slower, whereas after they received the gait training on treadmill combined with FES, they walked faster. According to paired t-test, the changes of gait speed of gait cycle between gait training on treadmill only and gait training on treadmill combined with FES was not statistically significantly different ($p = 0.127$).

4.3.7 Cadence of gait cycle

The average changes of the cadence of gait cycle between gait training on treadmill only and gait training on treadmill with FES are shown in a table 4.6 and a figure 4.21.

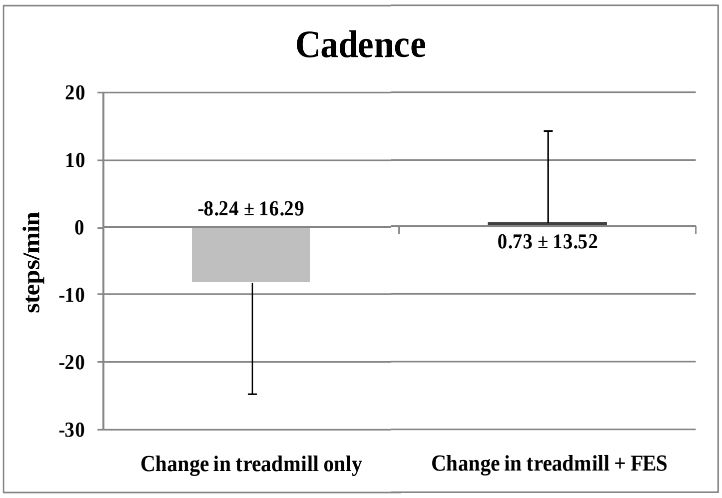

Figure 4.21 The difference of cadence (steps/min) of gait cycle between gait training on treadmill only and gait training on treadmill with FES

The average changes of cadence of gait cycle after the gait training on treadmill only and gait training on treadmill combined with FES were -8.24±16.29 steps/min and 0.73±13.52 steps/min, respectively. In average, after children received the gait training on treadmill only, they decreased cadence, whereas when they received the gait training on treadmill combined with FES, they increased cadence. According to paired t-test, the changes of cadence of gait cycle between gait training on treadmill only and gait training on treadmill with FES was not statistically significantly different (p = 0.216).

In the summary, when comparing the average changes of gait parameters between gait training on treadmill only and gait training on treadmill with FES. The average changes of three gait parameters after gait training on treadmill combined with FES were statistically significantly improve more than the average changes after gait training on treadmill only. These gait parameters are the maximal ankle dorsiflexion angle at the swing phase, the level of heel rising at the stance phase, and the stride length of gait cycle.

CHAPTER V
DISCUSSION

5.1 The subjects in this study

This study was the repeated measure design for investigating the effect of functional electrical stimulation (FES) when combined with the gait training on treadmill in seven Thai children with mildly to moderately spastic diplegia whose functional ability was relatively high (GMFCS level I-II). The children in this study had to walk independently without assistive device. Therefore, it is very difficult to recruit the numbers of subject as required.

However, numbers of the subjects in the study was reached the minimal requirement of calculation of sample size from the pilot study (i.e., 7 children). Although the subjects in this study is small, the results from this study can be used as a preliminary data of the effect of a combination of FES and gait training on treadmill in children with mildly to moderately spastic diplegia.

5.2 Effects of the training duration of the gait training on the changes of the kinematic and gait data

By the way, the training schedule of each condition was affected on the changes of the kinematic and gait data. According to the previous studies, Dodd and Foley (31) designed the gait training sessions that scheduled twice a week for 6 weeks in the children with CP. The outcomes showed the trend of the gait speed that increased (p = 0.083). Adam and co-worker (61) trained the children with CP twice a week for six weeks. The results suggested significant improvements in gait characteristics for children with CP using NDT and also suggested that children with spastic diplegia seem to the most benefit. Similar to the present study scheduled the training sessions as twice a week for 6 weeks per condition in the children with spastic diplegia. The outcomes reported that the average changes of three gait parameters after gait training on treadmill combined with FES were statistically significantly improve more than the average changes after gait training on treadmill only. These gait parameters are the maximal ankle dorsiflexion angle at the swing phase, the level of heel rising at the stance phase, and the stride length of gait cycle. This evidence creates a question of how long of training duration needed to make significant changes in the remaining of the kinematic and gait data.

5.3 Effects of the gait training on treadmill only on the gait parameters

The gait training on treadmill has been used in neurological rehabilitation of people with hemiparesis, spinal cord injury, children with cerebral palsy, etc. (12-17, 26, 28, 29). The technique provides task-specific gait cycle with multiple repetitions and active participation. In the present study, when the children received the gait training on treadmill only, the maximal ankle dorsiflexion angle at the swing phase and the level of heel rising at the stance of gait cycle were statistically significantly improved, whereas four gait parameters (i.e., hip and knee flexion ankle while maximal ankle dorsiflexion angle at the swing phase, stride length, and gait speed of gait cycle) were not improved. The cadence of gait cycle tended to be improve but not significant.

According to the previous studies of treadmill training in children with cerebral palsy (12, 13, 15, 17, 26, 77), the physical therapy (PT) facilitated the children's gait patterns of both lower limbs during the treadmill training. With similar to the present study, the PT facilitated the gait patterns: (1) foot clearance at the swing phase by holding the leg at the ankle level to assist swinging reciprocally and (2) heel contact and prolongation at the stance phase by assisting the heel to press on the floor reciprocally. The gait training on treadmill and the manual guidance that provided multiple repetitions of gait cycle with corrected gait pattern that can increase the maximal ankle dorsiflexion angle at the swing phase and decrease the level of heel rising at the stance phase of gait cycle.

The hip and knee flexion angle while maximal ankle dorsiflexion angle at the swing phase were not improved. A reason may be the manual guidance of the PT that emphasized the ankle dorsiflexion (foot clearance) more than hip and knee flexion. Kim and co-worker (76) studied the effectiveness of body weight-supported treadmill training on gait pattern in children with cerebral palsy. They found that gait speed, cadence, and stride length were increased following body weight-supported treadmill training, whereas the stride length of gait cycle in this study was significantly decreased. The position of the PT (i.e., sitting behind the children) probably limits the improvement of the stride length during gait training on treadmill.

Many previous studies (13, 16, 26, 28, 31) was adjusted the treadmill speed during gait training on treadmill. Effing and co-worker (16) studied the effects of treadmill training on functional health status and quality of life in subjects with a chronic incomplete spinal cord injury. Treadmill speed could be adjusted from 0.0 km/hr to 20 km/hr during the training sessions. Provost and co-worker (26) investigated changes in endurance, functional gait, and balance after intensive body weight-supported treadmill training in children with CP who were ambulatory. The treadmill speed was set at 1.5 to 1.9 miles per hour (mph). In all subjects and treadmill speed was gradually increased to 2.3 to 3.1 mph by the end of the two-week training. According to the previous studied, the results showed gait training on treadmill increased gait speed, whereas the gait speed in the present study was not increased after gait training on treadmill. The possible reason for the present study, the researcher allowed the children choose their own speed for walking. Therefore, some children chose to maintain the first selected speed through the whole training session.

Typically, on the basis of a constant gait speed, when a person increases his/her own stride length, the cadence decreases. However, the present study showed the average cadence was decreased. The possible reason is after the children received the gait training on treadmill, they walked slower and the stride was decreased, the cadence was then decreased.

5.4 Effects of the FES when combined with gait training on treadmill on the gait parameters

In the present study, after the children received the gait training on treadmill combined with FES, two gait parameters (i.e., maximal ankle dorsiflexion angle and level of heel rising) were statistically significantly improved. However, three gait parameters (i.e., knee flexion ankle, stride length, and gait speed) were improved but not significant. The remaining two gait parameters, (i.e., hip flexion angle, cadence) were not improved.

Previous studies (11, 19, 23-25, 32, 66) verified the advantages of the FES that were to maintain or gain joint range of motion, reduce spasticity, increase muscle strength and endurance of the weak muscles, and improve voluntary movement and walking. Many researches (11, 19, 23-25, 32) found that the patients increased ankle dorsiflexion during swing, terminal swing, and initial contact phases and decreased excessive knee flexion during stance phase. Moreover, the speed and stride length were increased and cadences were decreased.

The present study supports that FES directly effect on the improvement of the maximal ankle dorsiflexion angle at the swing phase and the level of heel rising at the stance phase of gait cycle. Although it showed statistical significant improvements of two parameters but there are slightly changes in these parameters. With the similar of the present study, Postans and Granat (24) applied FES over the common peroneal nerve and the motor point of tibialis anterior in children with spastic hemiplegia and children with spastic diplegia during walking. They found that the FES increase ankle dorsiflexion at swing phase and improve heel strike at initial contact by a minimum of 5°. Nearby this study, the average changes of the maximal ankle dorsiflexion angle at the swing phase increased 4.35° and the average changes of the level of heel rising at the stance phase decreased 5.99 mm after the children received the gait training on treadmill combined with FES. According to the Richards study of the error of the measurement of the Vicon 370 (86), the average changes of the maximal ankle dorsiflexion angle at the swing phase are more than the value of the root mean square (RMS) error (1.42°), whereas they are less than the value of the maximal absolute error (4.63°). The average changes of the level of heel rising at the stance phase are out of the error limit but they are more than the value of RMS error and nearly close the maximal absolute error (1.29 mm and 5.57 mm, respectively). Therefore, the clinical significant improvements are still questionable.

The knee flexion angle while maximal ankle dorsiflexion was improved after the children received gait training on treadmill combined with FES, but was not improved when receiving gait training on treadmill only. A possible reason is the subtle difference of the PT guidance between two conditions of gait training. During gait training on treadmill combined with FES, the currents of the FES directly activated the ankle dorsiflexor muscles. Therefore, the PT played more attention for assisting leg swinging by holding the distal leg closer to the knees than she did during gait training on treadmill only.

When comparing the average changes of gait parameters between gait training on treadmill only and gait training on treadmill with FES, the benefits of the FES were found. The present study showed the average changes of three gait parameters (i.e., maximal ankle dorsiflexion angle at the swing phase, level of heel rising at the stance phase, and stride length of gait cycle) after gait training on treadmill combined with FES were statistically significantly more than the average changes after gait training on treadmill only. The significant improvements of the maximal ankle dorsiflexion angle at the swing phase, level of heel rising at stance phase, and stride length of gait cycle would reflect on the efficiency of directly applied the FES over common peroneal nerve and tibialis anterior muscle when the children received the gait training on treadmill combined with FES.

A mechanism of the reciprocal inhibition of an agonist muscle explains the benefit of FES in the present study. The reciprocal inhibition describes muscles on one side of a joint relaxing to accommodate contraction on the other side of that joint. The reciprocal inhibition of the gastrocnemius muscles after the stimulation of the tibialis anterior muscles improves the ankle dorsiflexion angle at the swing phase and decreases the level of heel rising at the stance phase.

The FES directly affects on the maximal ankle dorsiflexion angle at the swing phase and the level of heel rising at the stance phase. It also indirectly affects on the stride length of gait cycle after the children received the gait training on treadmill combined with FES. A decrease of the level of heel rising probably improves the stability of the stance leg and promotes the mobility of the swing leg. As the result, the children showed an increase of the stride length.

The previous studies (14, 30) assessed the effects of gait training on treadmill with or without functional electrical stimulation in clients with neurological disease. Ng MF and co-worker (30) assessed the effectiveness of gait training using an electromechanical gait trainer with or without functional electrical stimulation for clients with subacute stroke. The target training velocity was relatively slow (0.20 m/s to 0.60 m/s), during gait training the speed was gradually increased by 0.1 m/s in next session if the subjects completed the last training session without discomfort. The results showed statistically significant differences of gait speed at the end of the 4 weeks of training and in the 6-month follow-up. During the gait training on treadmill in the present study, some of children chose to increase their own speed whereas the remaining children chose to maintain the first selected speed through the whole training session. Therefore, when comparing the average changes of gait speed between two gait training conditions, the results tended to be improve but not significant.

In the present study, the result was increased the cadences after the gait training on treadmill combined with FES. With similar to the previous study, Lindquist and co-worker (14) evaluated the effects of the combined use of FES and treadmill training with body-weight support on walking functions and voluntary limb control in people with chronic hemiparesis. After treadmill training with body-weight support combined with FES, the data analysis also showed a significant increase in stride length, gait speed, and cadence. The possible reason in the present and previous studies is the FES may help children easier to place their foot during the stance phase and decrease the manual assistance of PT. Therefore, the children can be walked based on their functional abilities.

In the addition, this study recruited the children with mildly to moderately spastic diplegia whose could independently walk without any assistive device. There were variations of the improvement of the both group of children. As the summary of the outcomes, after the children who were classified in the level I received the gait training on treadmill combined with FES, they increased the kinematic and gait parameters more than the children who were classified in the level II. Conversely, after the children who were classified in the level II, they increased the kinematic and gait parameters more than the children who were classified in the level I. The possible reasons of these outcomes are the functional limitations that should reflect on the improvement of the children because of the excitability of the children in level I were easier activated than the children in level II.

5.5 Limitation of this study and suggestion

The present study investigated the effects of FES when combined with gait training on treadmill children with mildly to moderately spastic diplegia whose functional ability was relatively high (GMFCS level I-II). The children had to walk independently without assistive device. Therefore, it was very difficult to recruit the numbers of subject. Even if the seven children are reached the minimal requirement but they may be too small to differentiate the significance of the other variables. Therefore, it is suggested to calculate the sample size based on all interesting parameters.

The counterbalanced technique was used to properly order the two conditions of training. Unfortunately, two conditions of training were imbalanced because a drop-out effect during the study. The first condition was selected by the first subject as gait training on treadmill only. When the procedures were continued, two children of all children dropped out from the study. According to the withdrawal, five children started the first order condition of training as gait training on treadmill only. However, when considering of the results of each individual subjects, the training order did not affect on the average changes of the kinematic and gait parameters.

The subtle difference of manual guidance of the PT and adjustment of treadmill speed based on the children's preference may affect the outcomes in the present study. During gait training on treadmill combined with FES, the PT held the legs closer to the knees than she did during the gait training on treadmill only. It is suggested to apply the same manual guidance across the conditions. For the adjustment of treadmill speed, the research allowed the children choose their own speed. Then some children chose to maintain the first selected speed through the whole training, whereas some children decided to change the walking speed during training. It is suggested to set standard protocol for the adjustment of treadmill speed in every subject.

The present study may be affected by tester bias because the person who trained the children was the same person who evaluated them. It is suggested to have different persons for training and evaluation. The blind of the trainer and the testers should be considered.

5.6 Clinical Implication and Further Study

The present study as results supported the effect of a combination FES and gait training on treadmill in the children with spastic diplegia. The results showed the gait training on treadmill combined with FES increased a maximal ankle dorsiflexion angle at the swing phase and decreased a level of heel rising at the stance phase.

Therefore, it is suggested for clinicians to apply the FES for assisting the children with spastic diplegia to activate the weak or inactive muscle when training gait.

Therefore, the study cannot represent the children with cerebral palsy who can walk with assistive device. They are a large population of the ambulatory children with spastic diplegia. The further study should be investigated the effect of the combination of FES with gait training treadmill in the children with spastic diplegia who can walk with assistive device.

The present study applied the FES over ankle dorsiflexor only. This FES application does not cover the required muscles of the legs for walking. The further study should apply the FES over the impaired muscles more than one muscle to better train walking with FES.

CHAPTER VI
CONCLUSION

This study investigated the effect of functional electrical stimulation (FES) when combined with gait training on treadmill in seven Thai children with mildly to moderately spastic diplegia aged between 6.12 and 11.46 years old who were able to independently walk without assistive device.

The objectives of this study were to compare the average changes of seven gait parameters between gait training on treadmill only and gait training on treadmill with FES in the children with mildly to moderately spastic diplegia. These parameters included maximal ankle dorsiflexion angle at the swing phase, level of heel rising at the stance phase, hip flexion angle while maximal ankle dorsiflexion angle at the swing phase, knee flexion angle while maximal ankle dorsiflexion angle at the swing phase, stride length, gait speed, and cadence of gait cycle. Seven children received two conditions of training (i.e., gait training on treadmill only and gait training on treadmill combined with FES). Each condition of training consisted of 12 training sessions. Children were trained 2 sessions per week for 6 weeks.

The results were found two gait parameters (i.e., the maximal ankle dorsiflexion angle at the swing phase, the level of heel rising at the stance phase) were statistically significantly improved when the children received the gait training on treadmill only and the gait training on treadmill combined with FES. As the results, the present study indicates the maximal ankle dorsiflexion angle at the swing phase and the level of heel rising at the stance phase can reflect on the efficiency of gait training on treadmill only and gait training on treadmill combined with FES.

In the addition, the average changes of three gait parameters (i.e., maximal ankle dorsiflexion angle at the swing phase, level of heel rising at the stance phase, and stride length of gait cycle) after gait training on treadmill combined with FES were statistically significantly more than the average changes of these parameters after gait training on treadmill only. The possible mechanisms of the gait improvements are (1) the current from FES directly activates the ankle dorsiflexor muscles affecting muscle strength and (2) the stimulation of common peroneal nerve and tibialis anterior muscle made the reciprocal inhibition of the gastrosoleus muscle. This leads to decrease the spasticity. Additionally, a decrease of the level of heel rising at the stance phase affects an improvement of stability of the stance leg and promotes the mobility of the swing leg. As the result, the children showed an improvement of the stride length of gait cycle. Therefore, these results of the efficiency of gait training on treadmill combined with FES beyond gait training on treadmill only.

However, the effect of the gait training combined with FES on the remaining gait parameters (i.e., hip flexion angle at the swing phase, knee flexion angle at the swing phase, gait speed, and cadence of gait cycle) were not significantly improved when these gait parameters compared with gait training on treadmill only. The small sample size may be issue.

As the results, the present study can be a preliminary study of the effect of a combination of FES and gait training on treadmill in children with mildly to moderately spastic diplegia. However, the results can not represent the children with cerebral palsy who walk with assistive device. They are large population of the ambulatory children with spastic diplegia. The further study should investigate in the children with spastic diplegia who walk with assistive device.

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APPENDICES

APPENDIX A
GROSS MOTOR FUNCTION CLASSIFICATION SYSTEM (GMFCS) FOR CEREBRAL PALSY

In the present study will be recruited children’s functional ability at the level I-II based on the gross motor function classification system (GMFCS) (83).

Before 2nd Birthday

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

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

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

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

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

Between 2nd and 4th Birthday

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

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

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

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

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

Between 4th and 6th Birthday

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

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

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

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

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

Between 6th and 12th Birthday

Level I Children walk indoors and outdoors, and climb stairs without limitations. Children perform gross motor skills including running and jumping but speed, balance, and coordination are reduced.

Level II Children walk indoors and outdoors, and climb stairs holding onto a railing but experience limitations walking on uneven surfaces and inclines, and walking in crowds or confined spaces. Children have at best only minimal ability to perform gross motor skills such as running and jumping.

Level III Children walk indoors or outdoors on a level surface with an assistive mobility device. Children may climb stairs holding onto a railing. Depending on upper limb function, children propel a wheelchair manually or are transported when traveling for long distances or outdoors on uneven terrain. Level IV Children may maintain levels of function achieved before age 6 or rely more on wheeled mobility at home, school, and in the community. Children may achieve self-mobility using a power wheelchair.

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

Distinctions between Levels I and II

Compared with children in Level I, children in Level II have limitations in the ease of performing movement transitions; walking outdoors and in the community; the need for assistive mobility devices when beginning to walk; quality of movement; and the ability to perform gross motor skills such as running and jumping.

Distinctions between Levels II and III

Differences are seen in the degree of achievement of functional mobility. Children in Level III need assistive mobility devices and frequently orthoses to walk, while children in Level II do not require assistive mobility devices after age 4.

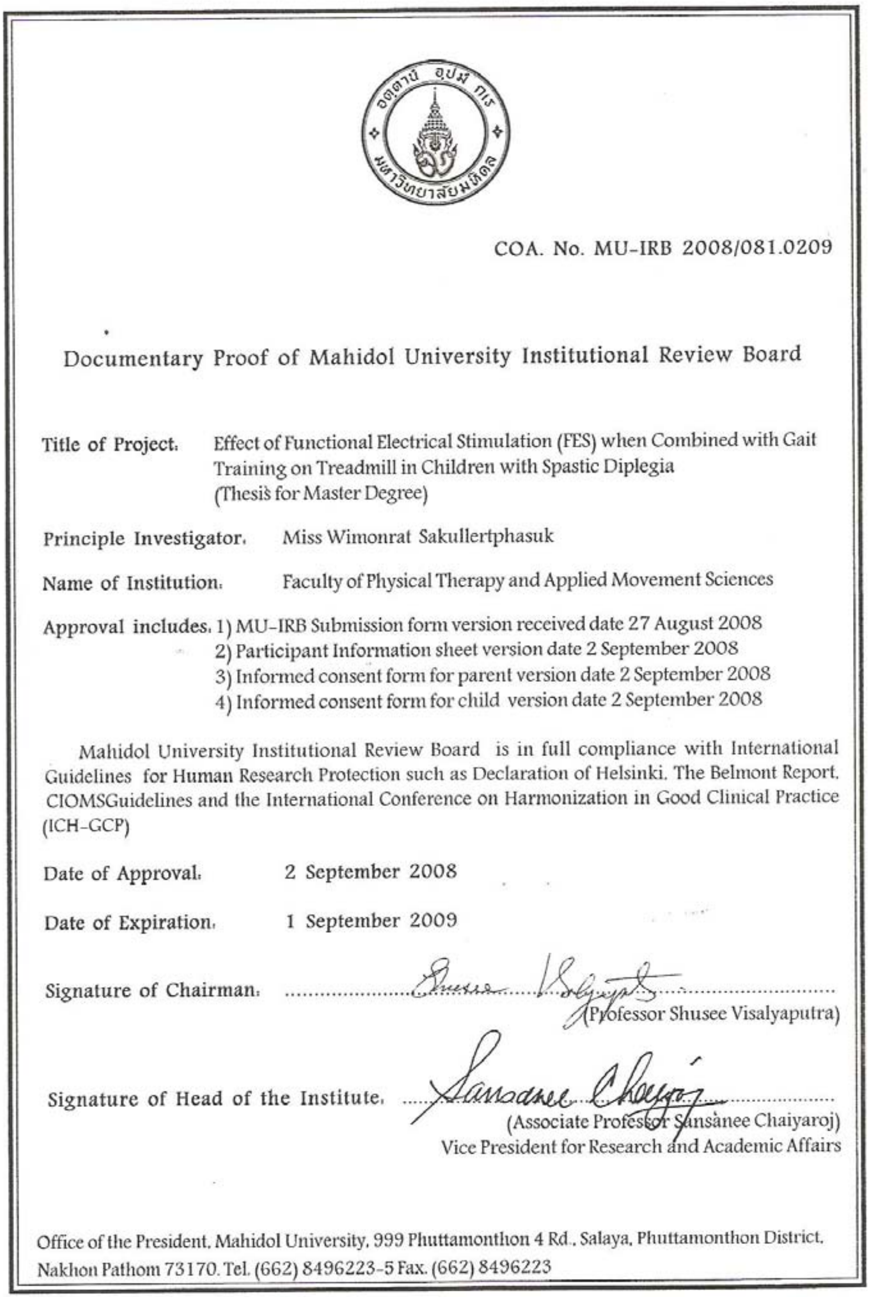
Distinctions between Level III and IV

Differences in sitting ability and mobility exist, even allowing for extensive use of assistive technology. Children in Level III sit independently, have independent floor mobility, and walk with assistive mobility devices. Children in Level IV function in sitting (usually supported) but independent mobility is very limited. Children in Level IV are more likely to be transported or use power mobility.

Distinctions between Levels IV and V

Children in Level V lack independence even in basic antigravity postural control. Self-mobility is achieved only if the child can learn how to operate an electrically powered wheelchair.

APPENDIX B
DOCUMENTARY PROOF OF MAHIDOL UNIVERSITY INSTITUTIONAL REVIEW BOARD



COA. No. MU-IRB 2008/081.0209

Documentary Proof of Mahidol University Institutional Review Board

Title of Project: Effect of Functional Electrical Stimulation (FES) when Combined with Gait Training on Treadmill in Children with Spastic Diplegia (Thesis for Master Degree)

Principle Investigator: Miss Wimonrat Sakullertphasuk

Name of Institution: Faculty of Physical Therapy and Applied Movement Sciences

Approval includes: 1) MU-IRB Submission form version received date 27 August 2008
2) Participant Information sheet version date 2 September 2008
3) Informed consent form for parent version date 2 September 2008
4) Informed consent form for child version date 2 September 2008

Mahidol University Institutional Review Board is in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMSGuidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval: 2 September 2008

Date of Expiration: 1 September 2009

Signature of Chairman: ....
(Professor Shusee Visalyaputra)

Signature of Head of the Institute: ....
(Associate Professor Sansanee Chaiyaroj)
Vice President for Research and Academic Affairs

Office of the President, Mahidol University, 999 Phuttamonthon 4 Rd., Salaya, Phuttamonthon District, Nakhon Pathom 73170. Tel. (662) 8496223-5 Fax. (662) 8496223

Figure B.1 Documentary Proof of MU-IRB (COA. No. MU-IRB 2008/081.0209)

COA. No. MU-IRB 2009/192.0309

Documentary Proof of Mahidol University Institutional Review Board

Title of Project: Effect of Functional Electrical Stimulation (FES) when Combined with Gait Training on Treadmill in Children with Spastic Diplegia

(Thesis for Master Degree)

Principle Investigator: Miss Wimonrat Sakullertphasuk

Name of Institution: Faculty of Physical Therapy

Approval includes: Annual Report version received date 2 September 2009

Mahidol University Institutional Review Board is in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Renwal (1st): 3 September 2009

Date of Expiration: 2 September 2010

Signature of Chairman: ....

(Professor Shusee Visalyaputra)

Signature of Head of the Institute: ....

(Associate Professor Sansanee Chaiyaroj)

Vice President for Research and Academic Affairs

Office of the President, Mahidol University, 999 Phuttamonthon 4 Rd., Salaya, Phuttamonthon District, Nakhon Pathom 73170. Tel. (662) 8496223-5 Fax. (662) 8496223

B.2 Documentary Proof of MU-IRB (COA. No. MU-IRB 2009/192.0309)

APPENDIX C
INFORMED CONSENT

เอกสารคำอธิบายโครงการสำหรับเด็ก อายุ 6-12 ปี

โครงงานวิจัยนี้ทำขึ้นเพื่อจะศึกษาว่า ถ้าเราใช้ไฟฟ้าจำนวนเล็กน้อยมากระตุ้นบริเวณกล้ามเนื้อขาที่มีอาการเกร็งนั้น จำทำให้การเดินเขย่งขาดีขึ้นหรือไม่

พี่ชวนน้องเข้าร่วมในโครงการนี้ เพราะน้องมีอาการเกร็งของขา ซึ่งพี่อยากจะศึกษาว่า ถ้าเราใช้ไฟฟ้าจำนวนเล็กน้อยกระตุ้นกล้ามเนื้อที่ขา พร้อมกับฝึกเดินบนสายพานจะช่วยให้น้องมีอาการดีขึ้นหรือไม่

ถ้าน้องยินดีเข้าร่วมโครงการนี้ น้องจะได้รับการปฏิบัติดังนี้

1. พี่จะลองใช้กระแสไฟจำนวนน้อยนี้ ทดลองกระตุ้นขณะน้องนั่งพักก่อน และทดลองกระตุ้นผู้ปกครองดูก่อนว่าไม่มีอันตรายหรือความเจ็บปวดอย่างใด จากนั้นจึงจะให้น้องและผู้ปกครองตัดสินใจว่า จะยินดีเข้าร่วมในงานวิจัยนี้หรือไม่
2. พี่จะขอให้น้องเดินบนสายพานรอบละ 10 นาที พัก 10 นาที ทำทั้งหมด 3 รอบ ใช้เวลาทั้งหมด ครึ่งชั่วโมง และในหนึ่งสัปดาห์จะฝึกเดินเช่นนี้ 2 ครั้ง รวมทั้งหมด 6 สัปดาห์ โดยจะใส่เครื่องช่วยพยุงน้ำหนักไว้ก่อน เพื่อป้องกันน้องหกล้มระหว่างการฝึกเดินบนสายพานด้วย
3. ระหว่างที่น้องฝึกเดินพี่จะกระตุ้นไฟฟ้าจำนวนเล็กน้อย


โดยที่จะเอาแผ่นเล็กๆ แปะที่ขาน้อง 2 อันที่ข้างขา
และอีก 2 อันที่หน้าแข้งของน้อง
และติดปุ่มเล็กๆ 2 อันที่ฝ่าเท้าของน้อง (ตามรูป)

4. พี่จะดูการเต้นของหัวใจน้อง โดยแปะขั้วกระดาษเล็กๆ 3 แผ่น โยงไปยังเครื่องดูการเต้นของหัวใจ
5. พี่จะยืดกล้ามเนื้อที่น่องของน้องด้วยเครื่องมือเป็นรูปลิ่มเล็กๆ จำนวน 10 ครั้ง
6. พี่จะติดเครื่องหมายสะท้อนแสงเล็กๆ ที่หลังและขา 2 ข้างของน้องด้วย

งานวิจัยนี้มีความเสี่ยงน้อย พี่จะคอยดูแลน้องอย่างดี ไม่ให้น้องเหนื่อยเกินไป แต่ถ้าน้องรู้สึกไม่สบายใจ อึดอัด ไม่อยากเข้าร่วมในการวิจัยนี้ น้องสามารถบอกพี่ได้ตลอดเวลา และถ้าน้องหรือผู้ปกครองมีเรื่องสงสัยประการใดสามารถถามได้ที่พี่ชื่อ วิมลรัตน์ สกุลเลิศผาสุข นักศึกษาหลักสูตรวิทยาศาสตรมหาบัณฑิต สาขาวิชากายภาพบำบัด คณะกายภาพบำบัดและวิทยาศาสตร์การเคลื่อนไหวประยุกต์ มหาวิทยาลัยมหิดล 25/25 ถนนพุทธมณฑลสาย 4 ตำบลศาลายา อำเภอพุทธมณฑล จังหวัดนครปฐม 73170 โทรศัพท์ 08-6570-0310…

พี่จะเก็บเรื่องส่วนตัวของน้องเป็นความลับ ไม่เปิดเผยให้ใครทราบ

ถ้าน้องเต็มใจเข้าร่วมในโครงการนี้ ☺ ลงชื่อ________________

ถ้าน้องไม่เต็มใจเข้าร่วมโครงการนี้ ☹ ลงชื่อ________________

รับรองโดยคณะกรรมการจริยธรรมการวิจัยในคน
มหาวิทยาลัยมหิดล
รหัสโครงการ MU-IRB ๒008/081.0209
วันที่ ๒ กันยายน ๒๕๕๑

เอกสารคำอธิบายโครงการวิจัยสำหรับผู้ปกครองของเด็ก
(Parent/guardian information sheet)

ในเอกสารฉบับนี้อาจมีข้อความที่ท่านผู้ปกครองอ่านแล้วไม่เข้าใจ ให้ถามหัวหน้าโครงการวิจัยหรือผู้แทนให้ช่วยอธิบายจนกว่าจะเข้าใจอย่างดี ท่านอาจจะขอเอกสารฉบับนี้กลับไปอ่านที่บ้านเพื่อปรึกษาหารือกับญาติพี่น้อง เพื่อนสนิท แพทย์ประจำตัวของเด็กในปกครองของท่านหรือแพทย์ท่านอื่น เพื่อช่วยในการตัดสินใจเข้าร่วมการวิจัย

ชื่อโครงการวิจัย ผลของการกระตุ้นไฟฟ้าร่วมกับการฝึกเดินบนสายพานในเด็กที่มีอาการเกร็งของขาเป็นหลัก

หัวหน้าโครงการวิจัย นางสาววิมลรัตน์ สกุลเลิศผาสุข

สถานที่ทำงานวิจัย ห้องวิเคราะห์การเคลื่อนไหว ชั้น 6 ตึกคณะกายภาพบำบัดและวิทยาศาสตร์การเคลื่อนไหวประยุกต์ มหาวิทยาลัยมหิดล 25/25 ถนน พุทธมณฑลสาย 4 ต.ศาลายา อ.พุทธมณฑล จ.นครปฐม 73170

หน่วยงานที่สังกัด คณะกายภาพบำบัดและวิทยาศาสตร์การเคลื่อนไหวประยุกต์ มหาวิทยาลัยมหิดล 25/25 ถนนพุทธมณฑลสาย 4 ตำบลศาลายา อำเภอพุทธมณฑล จังหวัดนครปฐม 73170 โทรศัพท์ 02-441-5450, 086-570-0310

อีเมล์ wicky_3@hotmail.com

ผู้ให้ทุน ไม่มี

1. เหตุผลที่มาของโครงการวิจัย

ภาวะสมองพิการเป็นความผิดปกติของสมองที่เกิดขึ้นในทารกและเด็ก ซึ่งมีสาเหตุจากการที่สมองพัฒนาไม่เต็มที่หรือถูกทำลาย ส่งผลให้เกิดความผิดปกติด้านการเคลื่อนไหว ซึ่งร้อยละ 50 ของเด็กสมองพิการมีอาการกล้ามเนื้อแข็งเกร็งและร้อยละ 30 – 40 ของเด็กกลุ่มนี้เป็นเด็กที่มีอาการเกร็งของขาเป็นหลัก จากการศึกษาพบว่าส่วนใหญ่เด็กเหล่านี้มีศักยภาพในการยืนและเดินแต่จะมีรูปแบบที่ผิดปกติ เช่น เดินเขย่งส้นเท้าตลอดเวลาเนื่องจากเด็กไม่สามารถควบคุมการทำงานที่สมดุลระหว่างกล้ามเนื้อกลุ่มเหยียดปลายเท้าและกล้ามเนื้อกลุ่มกระดกข้อเท้าได้ ในลักษณะที่กล้ามเนื้อ

กลุ่มเหยียดปลายเท้าหดสั้นและ/หรือกล้ามเนื้อกลุ่มกระดกข้อเท้าอ่อนแรง จึงสาเหตุหลักที่ทำให้เด็กหกล้มหรือเกิดอุบัติเหตุ

การรักษาทางกายภาพบำบัดในเด็กสมองพิการนั้นมีหลายวิธี ปัจจุบันมีการฝึกด้วยการเดินบนสายพานและการกระตุ้นการทำงานของกล้ามเนื้อด้วยไฟฟ้าในขณะเดินมากขึ้น จากการศึกษาที่ผ่านมาพบว่าการฝึกเดินบนสายพานและการกระตุ้นไฟเพียงอย่างใดอย่างหนึ่งสามารถเพิ่มความสามารถในการเดินได้เช่นเดียวกันแต่การกระตุ้นการทำงานของกล้ามเนื้อหรือเส้นประสาทในขณะฝึกเดินนั้นสามารถเจาะจงกลุ่มกล้ามเนื้อที่ต้องการฝึกเดินได้มากกว่าการฝึกเดินบนสายพานเพียงอย่างเดียว

การฝึกเดินในเด็กที่มีอาการเกร็งของขาเป็นหลัก นักกายภาพบำบัดทางเด็กพยายามลดรูปแบบการเดินแบบเขย่งปลายเท้าลงและกระตุ้นการเรียนรู้การลงน้ำหนักที่ส้นเท้า โดยการลดความตึงตัวและเพิ่มความยืดหยุ่นของกล้ามเนื้อกลุ่มเหยียดปลายเท้า เพิ่มความแข็งแรงของกล้ามเนื้อกลุ่มกระดกข้อเท้าและกระตุ้นให้เด็กเรียนรู้การทำงานที่สมดุลกันของกล้ามเนื้อขาทั้งสองกลุ่มในขณะลงน้ำหนัก เพื่อให้เด็กมีความสามารถในการเคลื่อนไหวในขณะเดินที่ดีขึ้น เพิ่มให้เด็กความมั่นใจในตนเองมากขึ้นและยังช่วยให้เด็กมีคุณภาพชีวิตที่ดีขึ้น ดังนั้นงานวิจัยนี้มีความจำเป็นต้องศึกษาการฝึกเดินบนสายพานเพียงอย่างเดียวกับการฝึกเดินบนสายพานร่วมกับการกระตุ้นไฟฟ้าบนเส้นประสาทที่อยู่บริเวณด้านข้างนอกของขาท่อนล่างและกล้ามเนื้อหน้าแข้งในเด็กที่มีอาการเกร็งของขาเป็นหลักเพื่อทำให้ทราบความแตกต่างระหว่างรูปแบบการฝึกทั้งสองอย่างและข้อมูลที่ได้จากการวิจัยสามารถนำไปประยุกต์ใช้ทางคลินิกกายภาพบำบัดในเด็กที่มีปัญหาความผิดปกติด้านการเคลื่อนไหวของขามากกว่าแขนและผู้ที่มีรูปแบบการเดินแบบเขย่งส้นเท้า เพื่อเพิ่มความมั่นคงในการทรงท่าขณะเดินและลดปัจจัยเสี่ยงหรืออุบัติเหตุที่เกิดจากการเดินสะดุดล้มขณะก้าวขา

2. วัตถุประสงค์

โครงการวิจัยนี้จัดทำขึ้นเพื่อศึกษาผลของการกระตุ้นไฟฟ้าเมื่อให้ร่วมกับการฝึกเดินบนสายพานในเด็กที่มีอาการเกร็งของขาเป็นหลักที่สามารถเดินได้

3. วิธีดำเนินงานวิจัย

เด็กที่เข้าร่วมการวิจัยทุกคนจะได้รับการฝึกทั้ง 2 รูปแบบคือ การฝึกเดินบนสายพานอย่างเดียวและการฝึกเดินบนสายพานร่วมกับการกระตุ้นไฟฟ้า โดยผู้วิจัยจะมีสลากให้เด็กเลือกว่าเด็กคนใดจะได้รับการฝึกด้วยวิธีการใดก่อน

รับรองโดยคณะกรรมการจริยธรรมการวิจัยในคน
มหาวิทยาลัยมหิดล
รหัสโครงการ MU-IRB 2008/081.0209
วันที่ ๒ กันยายน ๒๕๕๑

ผู้วิจัยมีรูปแบบวิธีการฝึก 2 รูปแบบคือ

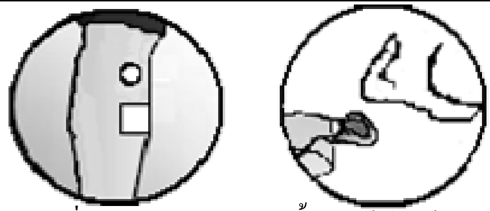
1. ฝึกเดินบนสายพาน (12 ครั้ง)

เด็กจะได้รับการฝึกเดินบนสายพานด้วยความเร็วที่เด็กเดินได้เองอย่างน้อย 10 นาทีต่อรอบ เดิน 3 รอบต่อครั้งเพื่อให้ได้เวลาในการฝึกเดินทั้งหมด 30 นาที ฝึก 2 ครั้งต่อสัปดาห์ นาน 6 สัปดาห์

2. ฝึกเดินบนสายพานร่วมกับการกระตุ้นไฟฟ้า (12 ครั้ง)

ผู้วิจัยจะติดขั้วกระตุ้นไฟฟ้า 4 อันและปุ่มควบคุมการจ่ายไฟฟ้า 2 อันที่ขาทั้ง 2 ข้างของเด็ก โดยมีตำแหน่งการวางดังนี้ (รูปที่ 1)

- ขั้วเล็ก 2 อัน บริเวณด้านข้างของเข่า
- ขั้วใหญ่ 2 อัน บริเวณกล้ามเนื้อหน้าแข้ง
- ปุ่มควบคุมการจ่ายไฟ 2 อัน บริเวณใต้ฝ่าเท้า



รูปที่ 1 แสดงตำแหน่งของขั้วกระตุ้นไฟฟ้า และปุ่มควบคุมการจ่ายไฟฟ้า

แล้วจึงค่อยๆเพิ่มความเข้มของไฟฟ้าที่ระดับการหดตัวสูงสุดของกล้ามเนื้อเท่าที่เด็กทนได้และฝึกเดินบนสายพานด้วยความเร็วที่เด็กเดินได้เองอย่างน้อย 10 นาทีต่อรอบ เดิน 3 รอบต่อครั้งเพื่อให้ได้เวลาในการฝึกเดินทั้งหมด 30 นาที ฝึก 2 ครั้งต่อสัปดาห์ นาน 6 สัปดาห์

ก่อนเริ่มการฝึกรูปแบบนี้ผู้วิจัยจะกระตุ้นไฟฟ้าให้กับเด็กขณะนั่งพักเพื่อให้เด็กปรับตัวและรู้ถึงความรู้สึกที่เด็กจะได้รับจากการกระตุ้นไฟฟ้า

ก่อนเริ่มงานวิจัย

ผู้วิจัยอธิบายขั้นตอนอย่างละเอียดให้ท่านและเด็กในปกครองของท่านทราบและเข้าใจ จากนั้นผู้วิจัยให้ท่านทดสอบพาเด็กเดินบนสายพานและทดลองกระตุ้นไฟฟ้าตามรูปแบบวิธีการฝึกที่ 2 กับท่านและเด็กก่อนเพื่อให้ทราบถึงความรู้สึกที่จะได้รับจากการกระตุ้นไฟฟ้าแล้วจึงให้ท่านและเด็กอ่านและเซ็นใบยินยอมก่อนเข้าร่วมงานวิจัย จากนั้นผู้วิจัยจะซักประวัติการรักษาประจำที่เด็กได้รับในขณะเข้าร่วมงานวิจัย แล้วจึงให้เด็กสุ่มลำดับฝึกและติดเครื่องวัดอัตราการเต้นของหัวใจ

เริ่มงานวิจัย

- รูปแบบที่ 1 (ตามลำดับการสุ่ม)

ผู้วิจัยบันทึกอัตราการเต้นของหัวใจขณะพักของเด็ก แล้วจึงยืดกล้ามเนื้อน่องทั้ง 2 ข้างของเด็กด้วยลิ่ม 3 เหลี่ยมเป็นเวลา 15 วินาที/มัด ทำ 10 ครั้ง จากนั้นผู้วิจัยจะให้เด็กพัก ในระหว่างพักผู้วิจัยจะติดเครื่องหมายสะท้อนแสง 18 อันที่หลังและขาทั้ง 2 ข้างให้กับเด็ก

ก่อนการฝึกครั้งแรก ผู้วิจัยจะเก็บข้อมูลก่อนการฝึกรูปแบบที่ 1ตามลำดับการสุ่มในห้องปฏิบัติการวิเคราะห์การเคลื่อนไหว โดยให้เด็กเดินตามปกติบนทางเดินที่ได้จัดไว้ให้เป็นระยะทาง 5 เมตรและเก็บข้อมูลในช่วง 3-6 ก้าวตรงกลาง

ในการฝึกทุกครั้งผู้วิจัยจะสวมเครื่องช่วยพยุงน้ำหนักให้กับเด็กเพื่อป้องกันการหกล้มขณะฝึกเดินบนสายพาน จากนั้นผู้วิจัยจะเริ่มฝึกเด็กเดินบนสายพานนาน 30 นาที โดยจะให้เด็กพักทุกๆ 10 นาที และเด็กจะได้นั่งพักอย่างน้อย 10 นาทีหรือจนกว่าเด็กจะหายเหนื่อยแล้วจึงฝึกเดินต่อ

หลังการฝึกครั้งสุดท้ายของรูปแบบการฝึกที่ 1 ผู้วิจัยจะเก็บข้อมูลหลังการฝึกอีกครั้ง

- รูปแบบที่ 2 (ตามลำดับการสุ่ม)

ผู้วิจัยทำซ้ำคล้ายกับรูปแบบที่ 1 แต่จะแตกต่างกันตามรูปแบบวิธีการฝึกเหลืออยู่

เมื่อผู้วิจัยเก็บข้อมูลเสร็จเรียบร้อยแล้วจะนำค่าที่ได้จากผลต่างระหว่างข้อมูลหลังการฝึกในแต่ละรูปแบบหักด้วยข้อมูลที่ได้ก่อนการฝึกในแต่ละรูปแบบไปคำนวณทางสถิติ

4. เหตุผลในการเชิญให้ผู้ยินยอมตนเข้าร่วมโครงการวิจัย

เหตุผลที่เด็กในความดูแลของท่านได้รับเชิญให้เข้าร่วมโครงการวิจัยในครั้งนี้เพราะเด็กของท่านเป็นเด็กที่มีความสามารถในการเดิน อีกทั้งยังเป็นเด็กที่มีสุขภาพจิตที่ดีและมีคุณสมบัติตามเกณฑ์ที่ผู้วิจัยได้กำหนดไว้

5. ระยะเวลาที่ผู้ยินยอมตนต้องใช้ในโครงการวิจัย

โครงการวิจัยในครั้งนี้แบ่งออกเป็น 2 รูปแบบตามวิธีการรักษา โดยแต่ละรูปแบบจะใช้เวลาในการฝึกแต่ละครั้งประมาณ 1 ชั่วโมง รวม 24 ครั้ง โดยฝึก 2 ครั้งต่อสัปดาห์ นาน 12 สัปดาห์ เวลาที่ฝึกขึ้นกับเด็กและผู้ปกครองโดยไม่รบกวนตารางฝึกประจำที่มีอยู่

6. ประโยชน์ที่คาดว่าจะเกิดขึ้นจากโครงการวิจัยทั้งต่อผู้ยินยอมตนและต่อผู้อื่น

การที่เด็กที่มีอาการเกร็งของขาเป็นหลักไม่สามารถกระดกข้อเท้าพ้นพื้นในขณะก้าวขาจากการที่กล้ามเนื้อกลุ่มเหยียดปลายเท้าหดสั้นและ/กล้ามเนื้อกลุ่มกระดกข้อเท้าอ่อนแรง ทำให้เด็กเดินในลักษณะเขย่งปลายเท้า ซึ่งเป็นสาเหตุหลักของการหกล้มหรือการเกิดอุบัติเหตุในเด็กที่มีอาการเกร็งของขาเป็นหลัก

การฝึกเดินในเด็กที่มีอาการเกร็งของขาเป็นหลักนั้น นักกายภาพบำบัดทางด้านเด็กจะต้องพยายามลดรูปแบบการเดินแบบเขย่งปลายเท้าลงและกระตุ้นการเรียนรู้ให้เด็กลงน้ำหนักที่ส้นเท้า โดยการลดความตึงตัวของกล้ามเนื้อกลุ่มเหยียดปลายเท้า เพิ่มความแข็งแรงของกล้ามเนื้อกลุ่ม

กระดกข้อเท้าและกระตุ้นให้เด็กสามารถเรียนรู้การทำงานที่สมดุลกันของกล้ามเนื้อทั้งสองกลุ่มในขณะเดินเพื่อให้เด็กมีความสามารถในการเดินที่ดีขึ้นและเพิ่มความปลอกภัยให้กับเด็ก

ดังนั้นงานวิจัยนี้จึงมีความจำเป็นต้องศึกษาในเด็กที่มีอาการเกร็งของขาเป็นหลัก โดยการฝึกเดินบนสายพานร่วมกับการกระตุ้นไฟฟ้าบนเส้นประสาทของขาและกล้ามเนื้อหน้าแข้ง เพื่อทำให้ทราบข้อมูลที่เปลี่ยนแปลงระหว่างรูปแบบการฝึกทั้งสองอย่างแท้จริงและนำข้อมูลที่ได้จากงานวิจัยมาประยุกต์ใช้ทางคลินิกกายภาพบำบัดในเด็กที่มีอาการเกร็งของขาเป็นหลักและผู้ป่วยที่มีรูปแบบการเดินแบบเขย่งส้นเท้า

7. ความเสี่ยงหรือความไม่สบายที่คาดว่าจะเกิดขึ้นกับผู้ยินยอมตนในการเข้าร่วมโครงการวิจัย

โครงการวิจัยในครั้งนี้ไม่มีความเสี่ยงหรืออันตรายใดๆ ต่อเด็ก เนื่องจากผู้วิจัยมีการป้องกันการหกล้ม โดยการสวมเครื่องช่วยพยุงน้ำหนักให้กับเด็กในขณะฝึกเดินบนสายพาน สำหรับการกระตุ้นไฟฟ้า ผู้วิจัยจะทำการทดลองติดขั้วกระตุ้นและเปิดความเข้มของไฟให้ผู้ปกครองก่อนที่จะทำการติดขั้วกระตุ้นและเปิดความเข้มของไฟให้กับเด็ก

8. การเตรียมอุปกรณ์หรือกระบวนการรักษาที่พิสูจน์จากงานวิจัยแล้วว่าปลอดภัยและมีประสิทธิผลสำหรับผู้ยินยอมตนในการเข้าร่วมโครงการวิจัย

โครงการวิจัยในครั้งนี้จัดทำขึ้นเพื่อศึกษาผลของการกระตุ้นไฟฟ้าเมื่อให้ร่วมกับการฝึกเดินบนสายพานในเด็กที่มีอาการเกร็งของขาเป็นหลักที่สามารถเดินได้ อุปกรณ์ต่างๆที่ใช้ในงานวิจัยจัดเป็นอุปกรณ์ที่จำเป็นต้องติดบนผิวหนังของผู้ยินยอมตนในการเข้าร่วมโครงการวิจัย อุปกรณ์เหล่านี้จัดเป็นอุปกรณ์ผ่านมาตรฐานและมีการนำไปใช้ในงานวิจัยและการปฏิบัติงานทางกายภาพบำบัดที่ผ่านมา เช่น เครื่องเดินสายพานและเครื่องช่วยพยุงน้ำหนัก เป็นเครื่องที่ใช้ในการปฏิบัติงานทางรักษากายภาพในระบบเด็กและในระบบประสาท เครื่องกระตุ้นไฟฟ้าเป็นเครื่องที่ใช้ถ่านขนาด 12 โวลต์ซึ่งไม่สามารถทำให้เกิดอันตรายใดๆกับผู้ยินยอมตนได้ ปุ่มควบคุมการทำงานของเครื่องกระตุ้นไฟฟ้าที่ติดใต้ฝ่าเท้าเป็นวงจรที่ต่อออกจากเครื่องกระตุ้นไฟฟ้าเพื่อควบคุมการทำงานของเครื่องกระตุ้นไฟฟ้าตามรูปแบบการเดินของเด็ก เป็นต้น

ผู้วิจัยได้มีการจัดเตรียมอุปกรณ์เพื่อป้องกันความเสี่ยงหรืออันตรายต่างๆที่อาจจะเกิดขึ้นตามที่ได้กล่าวไว้ข้างต้นแล้ว ในกระบวนการของการเก็บข้อมูลอุปกรณ์ที่ใช้ในห้องปฏิบัติการวิเคราะห์การเคลื่อนไหวประกอบด้วย กล้องอินฟราเรดจำนวน 6 ตัวและกล้องดิจิตอลจำนวน 2 ตัว อีกทั้งผู้วิจัยจะเป็นผู้คอยระวังอยู่ข้างๆเพื่อป้องกันการเกิดอันตรายจากการหกล้ม

ดังนั้นโครงการวิจัยในครั้งนี้แทบจะไม่มีความเสี่ยงที่อาจก่อให้เกิดอันตรายต่อเด็กในความดูแลของท่าน แต่หากเด็กเกิดความผิดปกติใดๆ อันเนื่องมาจากการเข้าร่วมโครงการวิจัยในครั้งนี้ เช่น มีบาดแผลถลอก ฟกช้ำ ผื่นคัน เป็นต้น ผู้วิจัยจะทำการยุติงานวิจัยในทันทีและจะคอยติดตามอาการดังกล่าวและให้การรักษา รวมทั้งเป็นผู้รับผิดชอบค่าใช้จ่ายในการรักษาทั้งหมดจนกว่าอาการดังกล่าวจะหายเป็นปกติ หากผู้วิจัยมีสิ่งใดบกพร่องหรือท่านและเด็กในปกครองของท่านมีข้อสงสัยต้องการสอบถามเกี่ยวกับงานวิจัยหรืออาการบาดเจ็บ/เจ็บป่วยจากงานวิจัยสามารถติดต่อได้ทันทีที่ผู้วิจัยคือ นางสาว วิมลรัตน์ สกุลเลิศผาสุข นักศึกษาหลักสูตรวิทยาศาสตรมหาบัณฑิต สาขาวิชากายภาพบำบัด มหาวิทยาลัยมหิดล คณะกายภาพบำบัดและวิทยาศาสตร์การเคลื่อนไหวประยุกต์ มหาวิทยาลัยมหิดล 25/25 ถนนพุทธมณฑลสาย 4 ตำบลศาลายา อำเภอพุทธมณฑล จังหวัดนครปฐม 73170 โทรศัพท์ 08-6570-0310 ทุกวันและเวลา

งานวิจัยในครั้งนี้ไม่มีค่าตอบแทนและค่าใช้จ่ายที่หนูจะได้รับ

9. ทางเลือกการรักษาหรือวิธีการตรวจวินิจฉัยอื่นที่อาจจะเป็นประโยชน์แก่ผู้ยินยอมตนในการเข้าร่วมโครงการวิจัย

จากการศึกษาที่ผ่านมาพบว่าการฝึกเดินบนสายพานและการกระตุ้นไฟเพียงอย่างใดอย่างหนึ่งนั้นสามารถเพิ่มความสามารถในการเดินได้เช่นเดียวกัน แต่การกระตุ้นการทำงานของกล้ามเนื้อหรือเส้นประสาทในขณะฝึกเดินนั้นสามารถช่วยเจาะจงกลุ่มกล้ามเนื้อที่ใช้ในการเดินได้มากกว่าการฝึกเดินบนสายพานเพียงอย่างเดียวและเด็กที่มีอาการเกร็งของขาเป็นหลักมักมีรูปแบบการเดินแบบเขย่งส้นเท้าซึ่งเป็นปัจจัยเสี่ยงที่ทำให้เกิดการหกล้มหรืออุบัติเหตุได้ง่าย เนื่องจากขาดความสามารถในการกระดกข้อเท้าพ้นพื้นในขณะก้าวขา ดังนั้นงานวิจัยนี้จึงศึกษาผลของการกระตุ้นไฟฟ้าร่วมกับการฝึกเดินบนสายพานในเด็กที่มีอาการเกร็งของขาเป็นหลักเพื่อเป็นการศึกษากลยุทธ์ที่นำมาช่วยลดรูปแบบการเดินแบบเขย่งส้นเท้าในเด็กที่มีอาการเกร็งของขาเป็นหลักและผู้ป่วยที่มีรูปแบบการเดินแบบเขย่งส้นเท้าต่อไป

10. ขอบเขตการดูแลรักษาความลับของข้อมูลต่างๆ ของผู้ยินยอมตนในการเข้าร่วมโครงการวิจัย

ข้อมูลส่วนตัวทั้งหมดของเด็กที่เข้าร่วมงานวิจัยจะถูกเก็บรักษาไว้โดยไม่เปิดเผยต่อสาธารณะเป็นรายบุคคล เว้นแต่จะรายงานผลงานวิจัยเป็นข้อมูลส่วนรวม ข้อมูลส่วนตัวทั้งหมดของเด็กที่เข้าร่วมงานวิจัยเป็นรายบุคคลนั้นอาจมีคณะบุคคลบางกลุ่มที่สามารถขอตรวจสอบได้ อาทิเช่น สถาบันหรือองค์กรของมหาวิทยาลัยที่มีหน้าที่ตรวจสอบและคณะกรรมการจริยธรรมการวิจัยในคน มหาวิทยาลัยมหิดล เป็นต้น

รับรองโดยคณะกรรมการจริยธรรมการวิจัยในคน
มหาวิทยาลัยมหิดล
รหัสโครงการ MU-IRB 2008/031.0209
วันที่ 2 กันยายน 2551

11. การดูแลรักษาที่ผู้วิจัยจัดไว้สำหรับผู้ยินยอมตนในการเข้าร่วมโครงการวิจัย

เนื่องจากผู้วิจัยได้มีการจัดเตรียมอุปกรณ์เพื่อป้องกันความเสี่ยงหรืออันตรายที่อาจจะเกิดขึ้นตามที่ได้กล่าวไว้ข้างต้น โครงการวิจัยในครั้งนี้จึงแทบจะไม่มีความเสี่ยงที่อาจก่อให้เกิดอันตรายต่อเด็กในความดูแลของท่าน แต่หากเด็กเกิดความผิดปกติใดๆ อันเนื่องมาจากการเข้าร่วมโครงการวิจัยในครั้งนี้ เช่น มีบาดแผลถลอก ฟกช้ำ ผื่นคัน เป็นต้น ผู้วิจัยจำทำการยุติงานวิจัยในทันทีและจะคอยติดตามอาการดังกล่าวและให้การรักษา รวมทั้งเป็นผู้รับผิดชอบค่าใช้จ่ายในการรักษาทั้งหมดจนกว่าอาการดังกล่าวจะหายเป็นปกติ

12. กรณีการเกิดอันตรายหรือผลอันไม่พึงประสงค์กับผู้ยินยอมตนในขณะเข้าร่วมโครงการวิจัย ผู้ยินยอมตนจะได้รับการดูแลรักษาโดยไม่ต้องเสียค่าใช้จ่ายอย่างไรบ้าง

หากเด็กเกิดอันตรายหรือผลอันไม่พึงประสงค์ใดๆ อันเนื่องมาจากการเข้าร่วมโครงการวิจัยในครั้งนี้ ผู้วิจัยจะให้การรักษา คอยติดตามอาการและเป็นผู้รับผิดชอบค่าใช้จ่ายในการรักษาทั้งหมดจนกว่าอาการดังกล่าวจะหายเป็นปกติและจะขอให้ผู้ยินยอมตนทำการยุติงานวิจัยในครั้งนี้

13. สิทธิในการที่ผู้ยินยอมตนในการเข้าร่วมโครงการวิจัยจะยุติหรือถอนตัวออกจากโครงการวิจัยได้ทุกเมื่อโดยไม่มีผลกระทบใดๆ ต่อการดูแลรักษาที่พึงได้รับตามปกติ

หากท่านและเด็กในความดูแลของท่านมีความไม่สบายกายหรือไม่สบายใจในเข้าร่วมงานวิจัยในครั้งนี้ ท่านมีสิทธิ์ที่จะไม่เข้าร่วมหรือการถอนตัวออกจากโครงการวิจัยได้ทุกเวลา โดยไม่ต้องบอกให้ผู้วิจัยทราบล่วงหน้าและการไม่เข้าร่วมหรือการถอนตัวออกจากโครงการวิจัยในครั้งนี้จะไม่มีผลกระทบต่อท่านและเด็กในความดูแลของท่านทั้งสิ้น

14. ชื่อ ที่อยู่และเบอร์โทรศัพท์ของผู้วิจัยที่ผู้ยินยอมตนในการเข้าร่วมโครงการวิจัยสามารถติดต่อได้โดยสะดวกตลอดเวลา กรณีที่เกิดเหตุฉุกเฉินหรือมีเหตุจำเป็นในการติดต่อ

กรณีที่เกิดเหตุฉุกเฉินหรือมีเหตุจำเป็นในการติดต่อ ท่านสามารถติดต่อสอบถามเกี่ยวกับงานวิจัยได้ทันทีที่ผู้วิจัยคือ นางสาว วิมลรัตน์ สกุลเลิศผาสุข นักศึกษาหลักสูตรวิทยาศาสตรมหาบัณฑิต สาขาวิชากายภาพบำบัด คณะกายภาพบำบัดและวิทยาศาสตร์การเคลื่อนไหวประยุกต์ มหาวิทยาลัยมหิดล 25/25 ถนนพุทธมณฑลสาย 4 ตำบลศาลายา อำเภอพุทธมณฑล จังหวัดนครปฐม 73170 โทรศัพท์ 08-6570-0310 ทุกวันและเวลา

รับรองโดยคณะกรรมการจริยธรรมการวิจัยในคน
มหาวิทยาลัยมหิดล
รหัสโครงการ MU-IRB ๒๐๐๘/๐๒๑.๐๒๐๙
วันที่ ๑ กันยายน ๒๕๕๑

15. การติดต่อกับคณะกรรมการจริยธรรมการวิจัยในคนมหาวิทยาลัยมหิดล

โครงการวิจัยนี้ได้รับการพิจารณารับรองจากคณะกรรมการจริยธรรมการวิจัยในคนมหาวิทยาลัยมหิดล ซึ่งมีสำนักงานอยู่ที่ สำนักงานอธิการบดีมหาวิทยาลัยมหิดล ถนนพุทธมณฑลสาย 4 ตำบลศาลายา อำเภอพุทธมณฑล จังหวัดนครปฐม 73170 หมายเลขโทรศัพท์ 02-849-6241-6, 02-849-6066 โทรสาร 02-849-6247 หากเด็กในปกครองของท่านได้รับการปฏิบัติไม่ตรงตามที่ระบุไว้ ท่านสามารถติดต่อกับประธานคณะกรรมการจริยธรรมการวิจัยในคนมหาวิทยาลัยมหิดลหรือผู้แทนได้ตามสถานที่และหมายเลขโทรศัพท์ข้างบน

ข้าพเจ้าได้อ่านรายละเอียดในเอกสารนี้ครบถ้วนแล้ว

ลงชื่อ________________________________ผู้ปกครอง

ของผู้เข้าร่วมวิจัย

(____)

รับรองโดยคณะกรรมการจริยธรรมการวิจัยในคน
มหาวิทยาลัยมหิดล
รหัสโครงการ MU-IRB........๒008/0๔1.0๒0๙
วันที่........๒ กันยายน ๒๕๕๑

APPENDIX D
RAW DATA

Table D.1 Characteristics of the subjects

Name	Session	Weight (kg)	Height (cm)	Leg Length (cm)		Knee width (cm)		Ankle width (cm)	
				Lt	Rt	Lt	Rt	Lt	Rt
A	1	20	113	52	51.5	7.7	7.7	5.5	5.4
	2	20	114.5	57.5	57	8	8	6	5.9
	3	21	116	57	57	8	8	5.9	5.9
	4	21	117.5	58	58.5	7.2	7.3	5.9	6
	AVG	**20.5**	**115.25**	**56.125**	**56**	**7.725**	**7.75**	**5.825**	**5.8**
B	1	20	118	58	58	7.4	7.4	5.2	5.1
	2	20	118	57	57	7.1	7.4	5.2	5.1
	3	20	118	57	57	7.1	7.4	5.2	5.1
	4	20.5	118	60	59	7.4	7.3	5.2	4.8
	AVG	**20.125**	**118**	**58**	**57.75**	**7.25**	**7.375**	**5.2**	**5.025**
C	1	16	111.5	55	54	6.3	6.4	5.1	4.9
	2	16	111.5	57.5	56.5	6.2	6.2	5.1	5
	3	16	111.5	57.5	56.5	6.2	6.2	5.1	5
	4	16	113.5	57.5	56.5	6.2	6.1	4.1	4.6
	AVG	**16**	**112**	**56.875**	**55.875**	**6.225**	**6.225**	**4.85**	**4.875**
D	1	19	122	63	63	7.4	7.1	5.3	4.9
	2	-	-	-	-	-	-	-	-
	3	-	-	-	-	-	-	-	-
	4	-	-	-	-	-	-	-	-
	AVG	**19**	**122**	**63**	**63**	**7.4**	**7.1**	**5.3**	**4.9**
E	1	24.5	133	70.5	70.5	7.5	7.4	5.1	5.2
	2	25	133.5	72	73	7.1	7.3	5.4	5.3
	3	25	133.5	72	73	7.1	7.3	5.4	5.3
	4	25.5	134	75	73.5	7.1	7	5.4	5.4
	AVG	**25**	**133.5**	**72.375**	**72.5**	**7.2**	**7.25**	**5.325**	**5.3**
F	1	23.5	119.5	63	62.5	8	7.7	4.8	4.9
	2	24.5	120.5	63.5	63.5	7.8	7.3	5.3	5.3
	3	24.5	120.5	63.5	63.5	7.8	7.3	5.3	5.3
	4	25	120	63.5	63.5	7.7	7.5	5.4	5.4
	AVG	**24.375**	**120.125**	**63.375**	**63.25**	**7.825**	**7.45**	**5.2**	**5.225**
G	1	15	111.5	57	57	6.5	6.2	4.8	4.2
	2	16	110	56	56	6.6	6.4	4.8	4.8
	3	16	110	56	56	6.6	6.4	4.8	4.8
	4	16	110.5	55.5	56	6.4	6.3	5	4.8
	AVG	**15.75**	**110.5**	**56.125**	**56.25**	**6.525**	**6.325**	**4.85**	**4.65**

Table D.1 Characteristics of the subjects (cont.)

Name	Session	Weight (kg)	Height (cm)	Leg Length (cm)		Knee width (cm)		Ankle width (cm)	
				Lt	Rt	Lt	Rt	Lt	Rt
H	1	17.5	120	62	62	7.3	7.2	5.1	5.5
	2	-	-	-	-	-	-	-	-
	3	-	-	-	-	-	-	-	-
	4	-	-	-	-	-	-	-	-
	AVG	**17.5**	**120**	**62**	**62**	**7.3**	**7.2**	**5.1**	**5.5**
I	1	35.5	132	72	72	8.6	8.3	6	5.8
	2	35.5	134	71	70	6.1	6.1	8.6	8.7
	3	35.5	134	71	70	6.1	6.1	8.6	8.7
	4	37.5	135	72	72	8.9	8.8	5.6	5.9
	AVG	**36**	**133.75**	**71.5**	**71**	**7.425**	**7.325**	**7.2**	**7.275**

Table D.2 The raw data of maximal ankle dorsiflexion angle (degree) at the swing phase of gait cycle

Name	Maximal ankle dorsiflexion angle (degree)			
	Pre-treadmill	Post-treadmill	Pre-FES + treadmill	Post-FES + treadmill
A-Lt	3.34	4.29	5.56	10.14
A-Rt	-2.71	-1.33	-2.32	1.04
B-Lt	-0.66	3.06	-3.39	0.68
B-Rt	-0.19	1.33	-4.83	-0.94
C-Lt	3.28	8.44	9.51	11.44
C-Rt	2.82	3.45	3.46	4.89
D-Lt	13.19	16.39	12.88	14.04
D-Rt	11.55	13.89	10.33	13.19
E-Lt	-15.20	-13.92	-13.08	-9.97
E-Rt	8.87	13.76	10.23	16.32
F-Lt	7.89	10.17	8.05	14.01
F-Rt	2.83	5.92	5.88	15.51
G-Lt	-5.05	-3.30	-3.47	2.96
G-Rt	0.11	3.72	3.24	7.59

Table D.3 The raw data of level of heel rising (mm) at the stance phase of gait cycle

Name	Level of heel rising (mm)			
	Pre-treadmill	**Post-treadmill**	**Pre-FES + treadmill**	**Post-FES + treadmill**
A-Lt	26.91	23.84	25.32	19.95
A-Rt	25.55	23.63	24.49	22.31
B-Lt	27.60	26.52	34.61	28.80
B-Rt	32.15	31.45	35.15	33.56
C-Lt	27.08	24.94	25.32	22.74
C-Rt	29.37	28.11	29.05	27.08
D-Lt	33.53	29.63	26.25	21.77
D-Rt	33.70	29.36	35.14	26.03
E-Lt	58.90	52.69	53.77	43.63
E-Rt	51.87	44.88	47.65	33.89
F-Lt	38.96	33.19	33.07	26.77
F-Rt	36.11	32.37	30.61	24.80
G-Lt	34.46	30.45	30.85	23.78
G-Rt	42.43	36.44	36.58	28.90

Table D.4 The raw data of hip flexion angle (degree) while maximal ankle dorsiflexion angle at the swing phase of gait cycle

Name	Hip flexion angle (degree)			
	Pre-treadmill	**Post-treadmill**	**Pre-FES + treadmill**	**Post-FES + treadmill**
A-Lt	30.29	33.70	41.99	40.73
A-Rt	25.01	24.68	40.15	37.35
B-Lt	43.13	29.75	47.27	41.86
B-Rt	50.89	40.42	38.91	36.95
C-Lt	51.67	47.46	37.53	39.55
C-Rt	48.40	45.01	36.14	27.22
D-Lt	30.10	30.67	29.87	38.36
D-Rt	13.86	23.64	18.57	28.02
E-Lt	38.44	30.23	42.61	36.68
E-Rt	35.93	23.72	25.48	26.57
F-Lt	31.87	50.32	25.19	16.55
F-Rt	34.56	31.96	23.70	9.30
G-Lt	19.45	40.90	40.62	46.34
G-Rt	47.71	30.55	21.67	36.06

Table D.5 The raw data of knee flexion angle (degree) while maximal ankle dorsiflexion angle at the swing phase of gait cycle

Name	Knee flexion angle (degree)			
	Pre-treadmill	**Post-treadmill**	**Pre-FES + treadmill**	**Post-FES + treadmill**
A-Lt	45.88	39.10	54.96	44.58
A-Rt	39.94	37.59	44.89	35.90
B-Lt	52.07	48.82	59.02	60.21
B-Rt	54.29	50.20	53.06	47.76
C-Lt	50.58	44.08	45.05	48.49
C-Rt	33.69	37.67	36.48	25.92
D-Lt	48.93	48.04	40.98	52.25
D-Rt	32.07	35.47	30.20	39.55
E-Lt	57.94	59.76	57.31	53.66
E-Rt	61.15	53.65	53.24	49.52
F-Lt	54.27	39.47	42.54	47.10
F-Rt	59.94	36.04	31.68	31.07
G-Lt	24.83	49.52	42.78	64.46
G-Rt	40.01	34.21	39.53	42.66

Table D.6 The raw data of stride length (mm) of gait cycle

Name	Stride length (mm)			
	Pre-treadmill	**Post-treadmill**	**Pre-FES + treadmill**	**Post-FES + treadmill**
A	1490.86	1160.29	1686.27	1487.80
B	1326.15	1183.43	857.65	1041.96
C	270.09	235.13	235.13	271.34
D	1381.48	1111.05	1190.78	877.14
E	1532.85	1191.96	1213.99	1380.11
F	1353.53	1052.02	1121.10	1308.78
G	1208.64	1315.34	1594.43	1814.15

Table D.7 The raw data of gait speed (m/s) of gait cycle

Name	Gait speed (m/s)			
	Pre-treadmill	**Post-treadmill**	**Pre-FES + treadmill**	**Post-FES + treadmill**
A	0.66	0.35	0.70	0.78
B	0.39	0.41	0.32	0.34
C	0.04	0.03	0.03	0.04
D	0.52	0.61	0.35	0.58
E	0.64	0.73	0.40	0.35
F	0.76	0.54	0.49	0.62
G	0.40	0.42	0.59	0.75

Table D.8 The raw data of cadence (steps/min) of gait cycle

Name	Cadence (Steps/min)			
	Pre-treadmill	**Post-treadmill**	**Pre-FES + treadmill**	**Post-FES + treadmill**
A	113.47	70.63	85.28	71.27
B	86.35	84.85	95.15	85.03
C	35.11	33.19	27.69	31.55
D	79.29	84.81	69.35	81.38
E	99.70	97.70	74.07	60.11
F	128.29	114.50	99.73	119.52
G	72.80	71.64	81.00	88.50

BIOGRAPHY

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