"AN EXPERIMENTAL STUDY ON EFFECTIVENESS OF FUNCTIONAL ELECTRICAL STIMULATION TO IMPROVE FUNCTIONAL MOBILITY AND BALANCE AMONG SUBJECTS WITH SUB ACUTE ISCHEMIC MIDDLE CEREBRAL ARTERY STROKE - A DOUBLE BLINDED RANDOMIZED STUDY"

A Dissertation submitted to

THE TAMILNADU DR. M. G. R. MEDICAL UNIVERSITY

CHENNAI

In partial fulfillment of the requirements for the award of the

MASTER OF PHYSIOTHERAPY

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Submitted by

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The Dissertation is entitled

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Under the guidance of

Prof. Dr. M. SANKAR SAHAYARAJ,

MPT (Neurology), MIAP, PGDSPT, TTCY.

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Dissertation Evaluated on: ……………………...

INTERNAL EXAMINER **EXTERNAL EXAMINER**

CERTIFICATE - I

This is to certify that the dissertation entitled **"AN EXPERIMENTAL STUDY ON EFFECTIVENESS OF FUNCTIONAL ELECTRICAL STIMULATION TO IMPROVE FUNCTIONAL MOBILITY AND BALANCE AMONG SUBJECTS WITH SUB ACUTE ISCHEMIC MIDDLE CEREBRAL ARTERY STROKE - A DOUBLE BLINDED RANDOMIZED STUDY"** is a bonafide compiled work, carried by **Reg. No: 271520203,** PPG College of Physiotherapy, Coimbatore-641035 in partial fulfillment for the award of degree in Master of Physiotherapy as per the doctrines of requirements for the degree from **THE TAMILNADU DR. M. G. R. MEDICAL UNIVERSITY, CHENNAI-32.**

This work was guided and supervised by **Prof. Dr. M. SANKAR SAHAYARAJ, MPT (Neurology), MIAP, PGDSPT, TTCY**.

PRINCIPAL

DATE:

PLACE:

CERTIFICATE - II

This is to certify that the dissertation entitled **"AN EXPERIMENTAL STUDY ON EFFECTIVENESS OF FUNCTIONAL ELECTRICAL STIMULATION TO IMPROVE FUNCTIONAL MOBILITY AND BALANCE AMONG SUBJECTS WITH SUB ACUTE ISCHEMIC MIDDLE CEREBRAL ARTERY STROKE - A DOUBLE BLINDED RANDOMIZED STUDY"** is a bonafide compiled work, carried by **Reg. No: 271520203,** PPG College of Physiotherapy, Coimbatore-641035 in partial fulfillment for the award of degree in Master of Physiotherapy as per the doctrines of requirements for the degree from **THE TAMILNADU DR. M. G. R. MEDICAL UNIVERSITY, CHENNAI-32,** under my guidance and supervision.

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PLACE:

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ABSTRACT

INTRODUCTION:

The cerebrovascular accident is one of the leading causes of mortality and morbidity in worldwide. According to the WHO 2012, about 56 million global deaths were estimated, on that 38 million or 68% were due to non-communicable diseases (NCDs). The leading causes of NCD deaths were cardiovascular disease (46% of all NCD deaths), which included an estimated 7.4 million deaths due to coronary heart disease and 6.7 million deaths due to cerebrovascular accident or stroke. [1, 2]

METHODOLOGY:

Based on the selection criteria 24 patients with sub-acute ischemic middle cerebral artery stroke were selected for this study and they were divided into two group by using concealed envelop method.

Subjects in control group (Group A) received body weight supported treadmill training. Subjects in experimental group (Group B) received body weight supported treadmill training along with functional electrical stimulation therapy. Both the groups were received intervention for 30 minutes per session, 6 days in a week for 6 weeks.

The pre and post score values of berg balance scale and timed up and go test were measured and the values were analysed.

RESULT:

The post-test mean values and standard error mean of balance for both groups were 39.66 $\pm$ 0.541 and 47.666 $\pm$ 0.864. The F value was 2.888 and the P value was 0.000 showed there were significant differences between the groups.

The statistical report of timed up and go test showed significant improvement in the gait speed after the application of the BWSTT along with FES but only turning and turn sitting variables of the TUGT showed insignificant result.

CONCLUSION:

The study concluded that the 6 weeks of gait training program with body weight supported treadmill training along with the functional electrical stimulation showed statistically significant improvement in functional mobility and balance when compared to the body weight supported treadmill training alone.

In addition the use of functional electrical stimulation during the body weight supported treadmill training was preferred by the subjects and facilitated the work of the physiotherapist.

KEYWORDS:

Cerebrovascular accident, Ischemic Stroke, BWSTT, Functional electrical stimulation, Functional mobility, Balance.

CHAPTER – I

1.1 BACKGROUND OF THE STUDY:

The term Stroke is “rapidly developing clinical sign of focal or global distribution of cerebral function, persisting for more than 24 hours or leading to death, with no apparent cause other than that of vascular origin. (1)

The cerebrovascular accident is classically characterized as a neurological deficit attributed to an acute focal injury of the central nervous system (CNS) by a vascular cause, including intra-cerebral hemorrhage (ICH), cerebral infarction and subarachnoid hemorrhage (SAH) and is a major cause of death and disability in worldwide.

Stroke is classified by the etiological categories (atherosclerosis, thrombosis, embolus or hemorrhage), specific vascular territory (anterior cerebral artery syndrome, middle cerebral artery syndrome and so forth), and management categories (transient ischemic attack, minor stroke, major stroke, deteriorating stroke, young stroke).

The cerebrovascular accident is one of the leading causes of mortality and morbidity in worldwide. According to the WHO 2012, about 56 million global deaths were estimated, on that 38 million or 68% were due to non-communicable diseases (NCDs). The leading causes of NCD deaths were cardiovascular disease (46% of all NCD deaths), which included an estimated 7.4 million deaths due to coronary heart disease and 6.7 million deaths due to cerebrovascular accident or stroke. (2)

The Indian Collaborative Acute Stroke Study (ICASS); a multicenter study conducted among 2162 admitted stroke patients across the India. On that ischemic stroke in 77%, hemorrhagic stroke in 22% and unspecified stroke in 1% were observed based on cerebral computer tomography. (3)

Hence, in India, the survey studies reveal that ischemic stroke occurs in 68-80% and hemorrhagic stroke occurs in 20-32%. The Ischemic stroke comprises large vessels (41%), lacunar (18%), cardio-embolic (10%), other determined (10%) and undetermined (20%) subtypes. The intracranial carotid disease is the etiological factor in

30% of ischemic stroke and extra-cranial carotid disease in 25-26% of ischemic stroke cases. (4)

According to the India stroke factsheet updated in 2012, the estimated age-adjusted prevalence rate for stroke ranges between 84/100,000 and 262/100,000 in rural and between 334/100,000 and 424/100,000 in urban areas. (5)

Nearly one-fifth of patients with stroke admitted to hospital have been estimated to be aged 40 years or less. The stroke occurred at rate of 7.1 per 1000 per year in people aged ≥55 years, and the rate escalated to 13.3 in people aged ≥75 years. (6)

The men had a higher stroke incidence rate than women. The incidence rate is 149/100,000 of men versus 141/100,000 of women were documented. The women were older (68.9 years) when compared to the men (63.4 years). (7)

The studies from India on cardiovascular risk factor have shown a 2 to 3 time's high prevalence of hypertension, hyperlipidemia, obesity, diabetes mellitus, and smoking (in men) in urban communities when compared to stroke population in rural area. (8,9)

The important risk factors were hypertension (57%), hypocholestreomia (34%), alcohol (15%), and anticoagulants (3.5%). Underlying etiologies were hypertension (79%), vascular malformation (4%), coagulopathy (4%), thrombocytopenia (0.7%), vacuities (0.5%), and cryptogenic stroke (9%). (10)

Ischemic stroke may manifest in the form of embolic stroke, thrombotic stroke (large vessel and small vessel types), systemic hypo perfusion (watershed or Border Zone stroke) or venous thrombosis.

Ischemia causes brain damage by activating the ischemic cascade, which progresses to local depletion of oxygen or glucose, causing failure of production of high energy phosphate compounds like adenine triphosphate (ATP). (11)

This adversely affects energy dependent processes necessary for cell survival, and sets off a series of interrelated events culminating in cellular injury and death. The extent of damage usually depends on duration, severity and location of ischemia.

The various mechanisms involved in the tissue damage/Neuro-protein are as follows:

- Depletion of cellular store due to failure of mitochondria. This causes further energy depletion and may trigger cell death due to apoptosis. Ischemia may cause to produce loss of potassium and ATP, which are essential for energy exchange. Ischemic changes do not cause complete occlusion of blood supply, however even a partial occlusion for prolonged period may produce harmful effect due to deterioration of ion gradient and by products of anaerobic metabolism like lactic acid, hydrogen ions. [12]
- Ischemia may leads to loss of membrane ion pump function and its deleterious effects. Inadequate energy supply at the cellular level may lead to malfunction of ion gradient which results in exchange of sodium, chloride and calcium ions. This accompanied by an inflow of water, resulting in rapid swelling of nerve cell and glial cells in the brain (cytotoxic edema).
- Ischemic changes may stimulate the release of excitatory neurotransmitter in the brain through glutamate and aspartate. The glutamate plays a vital role in neuronal plasticity. The uncontrolled release of excitatory neurotransmitter in the ischemic area mediate excitotoxic synaptic transmission via activation of N-methyl-D-aspartate (NMDA), $\alpha -$amino-3-hydroxy-5-methyl-4-propionate (AMPA) which allows Na_+ and $Ca2_+$ influx. These metabolic products, such as oxygen free radicals, damage cell membrane and structural proteins in the neurons ultimately lead to cell death. [13]

The cerebrovascular tissue may undergoing ischemia has two layers: a) inner core of severe ischemia with blood flow below 10-25%, displaying necrosis of both neuronal as well as supporting glial cells; and b) outer layer of less severe ischemia (penumbra), supplied by collaterals, and contain cells which can be retrieved by timely therapeutic intervention. [14]

The Middle cerebral artery is the one of the most frequently affected due to stroke. The MCA territory infarction can be subtle or a devastating clinical syndrome depends upon the site of the occlusion, the extent of ischemic changes, and the collateral network.

Clinically, a stroke patient with an acute complete middle cerebral artery infarction presents contralateral hemiparesis, hemi-hypesthesia, hemianopia, and ipsilateral conjugated eye and head deviation. In case of a left side lesion: aphasia, apraxia and the cognition signs always present. In case of right side lesion: contralateral multimodal heminedlect, anosognosia (denial of illness), anosodiaphoria (indifference to illness), asomatognosia (lack of awareness of part of one's own body) and confusion are seen.

Clinical studies suggest that an early start and high intensity of therapies are decisive for a favorable long term outcomes. On the basis of pathophysiological evidence the first 3 weeks after stroke are considered as a particularly promising period to better functional recovery and sprouting, whereas inactivity results in additional loss of ability. [15-17]

Walking is an important objectives in early stroke rehabilitation, conventional gait training programs such as PNF techniques on the floor being routine practice. In recent Neuro-rehabilitation practice various methods such as treadmill training without body supported, body weight supported treadmill training, functional electrical stimulation, aquatic therapy, robotic rehabilitation are widely used to improve quality of life among subjects with neurological impairment.[18]

Gait training on the body weight supported treadmill (BWSTT) has received special attention in neurorehabilitation. It consists of a suspension system to which a subject is connected so that the weight shifting, balance and stepping can be controlled. The walking is facilitated by treadmill. Many research outcomes have shown the feasibility of supported treadmill ambulation training in patient with cerebrovascular accident. [19-22]

Partial unloading of the lower extremities (40%) results in a straighter trunk and knee joint alignment during the stance phase of gait, a decrease in double limb support time and an increase in single limb support time, stride length and speed. On the basis of research evidence suggest that this rehabilitation strategy apparently drives spinal motor programs through proprioceptive inputs and modulates spinal rhythms generators. [23,24]

It may leads to an improvement in sensory system and improved functional motor reorganization. [25,26]

The concept of Functional Electrical Stimulation (FES) is first described by Liberson et al, [27] uses electrical impulses to stimulate the peripheral nerves and to produce controlled functional movements. Functional electrical stimulation uses the electrical impulses to produce the muscular contraction in order to induce functional outcomes of non-innervated muscles in patient with neurological disorder. The FES is applied on the tibialis anterior muscle to enhance coordination during the gait cycle and to increase the angle range of ankle joint and walking speed, which improving the quality of gait pattern in patient with foot drop.

This technique makes use of afferent impulses during the contraction, a process that, with a subjects help may maximize motor relearning during the active repetitive movement training. [28,29] Functional electrical stimulation therapy apparently increases the neural stem or progenitor cell pool in the sub-ventricular zone (SVZ), promoted the generation of neuronal precursors which could be recruited to the injury site within 14 days after the application of FES, and may contribute to improved functional outcomes. [30]

The purpose of the study is to find out the efficacy of Body weight supported treadmill training versus Body weight supported treadmill training added Functional Electrical Stimulation to improve functional mobility and balance among subjects with sub-acute ischemic middle cerebral artery stroke.

1.2 NEED OF THE STUDY:

The stroke is growing financial burden in many urban areas of India. It is because of its institutionalization and long term disability of the cerebrovascular accident population and their impact on a variety of health resources.

The gait impairment will be present even after 3 months of stroke and more than half of the people with stroke at the sub-acute phase are not able to walk.

The effectiveness of gait rehabilitation has become primary goal in stroke survivors. An early start and high intensity of therapies are decisive for a favorable long term outcomes. On the basis of pathophysiological evidence the first 3 weeks after stroke are considered as a particularly promising period to better functional recovery and sprouting.

And also only few research has been studied the effectiveness of functional electrical stimulation added body weight supported treadmill training among subjects with cerebrovascular accident.

So the need of the study is to examine the effectiveness of Body weight supported treadmill training versus Body weight supported treadmill training added Functional Electrical Stimulation to improve functional mobility and balance among subjects with sub-acute ischemic middle cerebral artery stroke.

1.3 AIM OF THE STUDY:

The aim of the study was to examine the efficacy of Body weight supported treadmill training versus Body weight supported treadmill training added Functional Electrical Stimulation to improve functional mobility and balance among subjects with sub-acute ischemic middle cerebral artery stroke.

1.3 OBJECTIVES OF THE STUDY:

- ❖ To find out the effectiveness of body weight supported treadmill training to improve functional mobility among subject with stroke.
- ❖ To find out the effectiveness of body weight supported treadmill training to improve balance among subject with stroke.
- ➢ To find out the effectiveness of body weight supported treadmill training added functional electrical stimulation to improve functional mobility among subject with stroke.
- ➢ To find out the effectiveness of body weight supported treadmill training added functional electrical stimulation to improve balance among subject with stroke.

To compare the effectiveness of body weight supported treadmill training and bodyweight supported treadmill training added functional electrical stimulation to improve functional mobility among subject with stroke.

To compare the effectiveness of body weight supported treadmill training and bodyweight supported treadmill training added functional electrical stimulation to improve functional balance among subject with stroke.

1.4 HYPOTHESIS:

1.4.1: NULL HYPOTHESIS:

There would not have been any statistically significant difference in functional mobility after the application of intervention in both the groups among subjects with stroke.

There would not have been any statistically significant difference in balance after the application of intervention in both the groups among subjects with stroke.

1.4.2: ALTERNATE HYPOTHESIS:

There would have been any statistically significant difference in functional mobility after the application of intervention in both the groups among subjects with stroke.

There would have been any statistically significant difference in balance after the application of intervention in both the groups among subjects with stroke.

1.5 OPERATIONAL DEFINITION:

CEREBROVASCULAR ACCIDENT:

The term Stroke or cerebrovascular accident is "rapidly developing clinical sign of focal (or global) distribution of cerebral function, lasting for more than 24 hours or leading to death, with no apparent cause other than that of vascular origin.

- **WORLD HEALTH ORGANIZATION**

ISCHEMIC STROKE:

Ischemic (clots) stroke occurs as a result of an obstruction within the blood vessels supplying to the central nervous system which is caused by atherosclerotic formation in the blood vessels, cerebral thrombus and cerebral emboli.

- **AMERICAN STROKE ASSOCIATION**

PROPRIOCEPIVE NEUROMUSCULAR FACILITATION:

It is a method of stretching muscle to maximize their flexibility that is often performed with a trainer and that involves a series of contraction and relaxation with enforced stretching during the relaxation phase.

- **KABAT and MARGARET KNOTT**

BODY WEIGHT SUPPORTED TREADMILL:

It consists of a suspension system to which a subject is connected so that the weight shifting, balance and stepping can be controlled. The walking is facilitated by treadmill.

- **SUSAN B O'SULLIVAN**

FUNCTIONAL ELECTRICAL STIMULATION:

Functional electrical stimulation uses the electrical impulses to produce the muscular contraction in order to induce functional outcomes of non-innervated muscles in patient with neurological disorder.

- **SUSAN B O'SULLIVAN**

FUNCTIONAL MOBILITY:

The term functional mobility is defined as the manner in which people are able to move around in the environment in order to participate in the activities of daily living and move from place to place. The activities include standing, walking, bending and stair climbing.

- **SUSAN B O'SULLIVAN**

BALANCE:

The term balance is a condition in which all the forces acting on the body are balanced such that the center of mass (COM) is within the limits of stability and the boundaries of the base of support (BOS).

- **SUSAN B O'SULLIVAN**

CHAPTER – II

REVIEWS OF LITERATURE

2.1 REVIEWS RELATED TO STROKE:

- **NIJASRI C. SUWANWELA[31], et al., (2016):**

She did the study on stroke burden and stroke care system in Asia. Her survey study is categorized into five main parts including the general country information, stroke epidemiology, stroke risk factors, stroke care systems, and national stroke professional societies.

Her result states that a higher proportion of ischemic stroke in comparison to hemorrhagic stroke was found in all the countries. The overall incidence of stroke in Asia is between 116 and 483/100,000 per year. When compared to 1999, a 2-3 fold increase number of neurologists were observed in all the countries.

- **TAPAS KUMAR BANERJEE[32] et al., (2016):**

He conducted a fifty years of stroke research in India. He states that the stroke incidence in India is much higher than western industrialized countries. On that large vessel intracranial atherosclerosis is the commonest cause of ischemic stroke in India. The common risk factors, that is, hypertension, diabetes, smoking, and dyslipidemia are quite prevalent and inadequately controlled; mainly because of poor public awareness and inadequate infrastructure.

Only small numbers of ischemic stroke cases are able to have the benefit of thrombolytic therapy. Benefits from stem cell therapy in established stroke cases are under evaluation. Presently prevention of stroke is the best option considering in India scenario through control and/or avoiding the risk factors of stroke.

- **VALERY L. FEIGIN[33], et al., (2015):**

He conducted a research on update on the global burden of ischemic and hemorrhagic stroke in 1990-2013: the GBD 2013 study. His study objectives is to estimate the incidence, prevalence, mortality, disability adjusted life years (DALYs) and years lived with disability (YLDs) and their trends for ischemic stroke (IS) and hemorrhagic stroke (HS) for 188 countries from 1990-2013.

He found that there were globally almost 25.7 million stroke survivors (71% with IS), 6.5 million deaths from stroke (51% died from IS), 113 million DALYs due to stroke (58% due to IS) and 10.3 million new strokes (67% IS).

Finally he concluded that the there was a significant increase in the absolute number of DALYs due to ischemic stroke, and of deaths from ischemic stroke and hemorrhagic stroke, survivors and incidents for both IS and HS. The preponderance of the burden of stroke continued to reside in developing countries; comprising 75.2% of deaths from stroke and 81.0% of stroke related DALYs.

- **ALEX POLLOCK [(34),] et al., (2015):**

He conducted study on the Physical Rehabilitation Approaches for the Recovery of Function and Mobility after Stroke Major Update. A total of 96 studies (10,401 participants) in this review. More than half of the studies (50/96) were carried out in China. Generally the studies were heterogeneous, and many were poorly reported. Physical rehabilitation was found to have a beneficial effect, as compared with no treatment, on functional recovery after stroke (27 studies, 3423 participants; standardized mean difference (SMD) 0.78, 95% confidence interval (CI) 0.58 to 0.97, for Independence in ADL scales), and this effect was noted to persist beyond the length of the intervention period (nine studies, 540 participants; SMD 0.58, 95% CI 0.11 to 1.04). Subgroup analysis revealed a significant difference based on dose of intervention (P value < 0.0001, for independence in ADL), indicating that a dose of 30 to 60 minutes per day delivered five to seven days per week is effective.

This evidence principally arises from studies carried out in China. Subgroup analyses also suggest significant benefit associated with a shorter time since stroke (P value 0.003, for independence in ADL). We found physical rehabilitation to be more effective than usual care or attention control in improving motor function (12 studies, 887 participants; SMD 0.37, 95% CI 0.20 to 0.55), balance (five studies, 246 participants; SMD 0.31, 95% CI 0.05 to 0.56) and gait velocity (14 studies, 1126 participants; SMD 0.46, 95% CI 0.32 to 0.60). Subgroup analysis demonstrated a significant difference based on dose of intervention (P value 0.02 for motor function), indicating that a dose of

30 to 60 minutes delivered five to seven days a week provides significant benefit. Subgroup analyses also suggest significant benefit associated with a shorter time since stroke (P value 0.05, for independence in ADL). No one physical rehabilitation approach was more (or less) effective than any other approach in improving independence in ADL (eight studies, 491 participants; test for subgroup differences: P value 0.71) or motor function (nine studies, 546 participants; test for subgroup differences: P value 0.41). These findings are supported by subgroup analyses carried out for comparisons of intervention versus no treatment or usual care, which identified no significant effects of different treatment components or categories of interventions.

- **BEYAERT C[(35),] et al" (2015):**

He conducted a study on Gait post-stroke: Pathophysiology and rehabilitation strategies. We reviewed neural control and biomechanical description of gait in both non-disabled and post-stroke subjects. In addition, they reviewed most of the gait rehabilitation strategies currently in use or in development and observed their principles in relation to recent Pathophysiology of post-stroke gait. In both non-disabled and post-stroke subjects, motor control is organized on a task-oriented basis using a common set of a few muscle modules to simultaneously achieve body support, balance control, and forward progression during gait. Hemiparesis following stroke is due to disruption of descending neural pathways, usually with no direct lesion of the brainstem and cerebellar structures involved in motor automatic processes.

Post-stroke, improvements of motor activities including standing and locomotion are variable but are typically characterized by a common postural behavior which involves the unaffected side more for body support and balance control, likely in response to initial muscle weakness of the affected side. Various rehabilitation strategies are regularly used or in development, targeting muscle activity, postural and gait tasks, using more or less high-technology equipment. Reduced walking speed often improves with time and with various rehabilitation strategies, but asymmetric postural behavior during standing and walking is often reinforced, maintained, or only transitorily decreased. This asymmetric compensatory postural behavior appears to be robust, driven by support and balance tasks maintaining the predominant use of the unaffected side over the initially impaired affected side. Based on these elements, stroke rehabilitation including affected muscle strengthening and often stretching would first need to correct the postural asymmetric pattern by exploiting postural automatic processes in various particular motor tasks secondarily beneficial to gait.

- **JAYARAJ DURAI PANDIAN[36] et al., (2013):**

He did the study on stroke epidemiology and stroke care services in India. He reviewed the changing burden of stroke and also the available stroke care services in India. The papers were searched in the search engine PUBMED. The search terms used were 'stroke in India', 'Stroke epidemiology', 'Stroke Burden', 'Stroke and India', 'Stroke care in India', etc. Totally 1620 papers were listed; out of this around fifty papers were short listed and reviewed. The stroke range, 84-262/100,000 in rural and 334-424/100,000 in urban areas. The incidence rate is 119-145/100,000 based on the recent population based studies. There is also a wide variation in case fatality rates with the highest being 42% in Kolkata.

He states that stroke units, thrombolysis, and rehabilitation are predominantly available in urban areas, particularly, in private sector hospitals. As a first step, the government of India has started the National program for prevention and control of cancer, diabetes, cardiovascular disease & stroke (NPCDCS). The government is focusing on early diagnosis, management, infrastructure, public awareness, and capacity building at different levels of health care for all the non-communicable diseases including stroke. An organized effort from both the government and the private sector is needed to tackle the rising stroke burden in India.

2.2 REVIEWS RELATED TO BODY WEIGHT SUPPORTED TREADMILL TRAINING:

- **YU-RONGMAO[37], et al., (2015):**

He did the study on effect of body weight supported treadmill training on gait recovery, proximal lower limb motor pattern and balance in patient with sub-acute stroke. 24 subjects with unilateral hemiplegia in the sub-acute stage were randomized to the BWSTT (n=12) and CT (n=12) groups. The patient in both groups receives intervention for 30minutes per day, 5 days per week for 3 weeks. The balance was measured by the

Brunel balance assessment. Lower extremity function was evaluated by the Fugl-Meyer assessment scale. Kinematic data were collected and analyzed using a gait capture system before and after the intervention.

Both the groups improved on balance and lower extremity motor function measures ($P \leq 0.05$), with no significant difference between two groups after the intervention. However, the kinematic data were significantly improved ($P \leq 0.05$) after BWSTT but not after CT. Maximum hip extension and flexion angles were significantly improved ($P \leq 0.05$) for the BWSTT group during the stance and swing phase compared to baseline.

Finally he concluded that, in sub-acute patient with stroke, BWSTT can leads to improved gait quality when compared with conventional gait training. Both methods can improve balance and motor function.

- **HAMADA EI SAYED ABD ALLAH AYOUB[38], et al., (2015):**

He did the study on impact of body weight supported backward treadmill training on walking speed in children with spastic diplegia.

Twenty children with spastic diplegia enrolled in the study, they were classified into two groups of equal number. The control group (A) received selected physical therapy program based on the neurodevelopmental approach for such cases, while the study group (B) received partial body weight supported backward treadmill training in addition to regular exercise program. Gait pattern was assessed using the Biodex Gait trainer II for each group pre and post three months of the treatment program.

There was statistically significant improvement in the walking speed in the study group ($P \leq 0.05$) with significant difference when comparing post treatment results between groups ($P \leq 0.05$). These findings suggested that the partial body weight supported backward treadmill training can be included as a supplementary therapeutic modality to improve walking speed and functional abilities of children with diplegic cerebral palsy.

- **ADDIE MIDDLETON[39], et al., (2014):**

He did the study on body weight supported treadmill training is not better than over ground training for individual with chronic stroke - A randomized control trial.

The purpose of this study was to determine whether an intensive intervention (intensive mobility training) including BWSTT provides superior gait, balance, and mobility outcomes compared with a similar intervention with over ground gait training in place of BWSTT. Forty-three individuals with chronic stroke (mean [*SD*] age, 61.5 [13.5] years; mean [*SD*] time since stroke, 3.3 [3.8] years), were randomized to a treatment (BWSTT, n = 23) or control (over ground gait training, n = 20) group. Treatment consisted of 1 hour of gait training; 1 hour of balance activities; and 1 hour of strength, range of motion, and coordination for 10 consecutive weekdays (30 hours). Assessments (step length differential, self-selected and fast walking speed, 6-minute walk test, Berg Balance Scale [BBS], Dynamic Gait Index [DGI], Activities-specific Balance Confidence [ABC] scale, single limb stance, Timed Up and Go [TUG], Fugl-Meyer [FM], and perceived recovery [PR]) were conducted before, immediately after, and 3 months after intervention.

There was no significant differences ($\alpha = 0.05$) were found between groups after training or at follow-up; therefore, groups were combined for remaining analyses. Significant differences ($\alpha = 0.05$) were found pretest to posttest for fast walking speed, BBS, DGI, ABC, TUG, FM, and PR. DGI, ABC, TUG, and PR results remained significant at follow-up. Effect sizes were small to moderate in the direction of improvement.

- **CATARINA O SOUSA[40], et al (2011)**

She did the study on effect of gait training with partial body weight support during over ground walking for individuals with chronic stroke. Twelve individual with chronic stroke participated of a gait training program with BWS during over ground walking and evaluated before and after the gait training period.

In both evaluations individuals were videotaped walking at a self-selected comfortable speed with no BWS. Measurement were obtained for mean walking speed, step length, stride length and speed, toe-clearance duration of total double stance and single limb support and minimum and maximum foot, shank, thigh and trunk segmental angles.

After gait training, individuals walked fasted, with symmetrical steps, longer and faster strides, increased toe clearance. Also they displayed increased rotation of foot, shank, thigh and trunk segmental angles on both sides of the body. However the duration of single limb support remained asymmetrical between each side of the body after gait training. Finally she concluded that the gait training individuals with BWS during over ground walking improved the walking in the terms of temporal-spatial parameters and segmental angles. This training might be adopted as a safe, specific and promising strategy for gait rehabilitation after stroke.

- **PAMELA W DUNCAN[41], et al., (2011):**

She did the study on body weight supported treadmill rehabilitation after stroke. They stratified 408 participants who had had a stroke 2 months earlier according to the extent of walking impairment — moderate (able to walk 0.4 to <0.8 m per second) or severe (able to walk <0.4 m per second) — and randomly assigned them to one of three training groups. One group received training on a treadmill with the use of body-weight support 2 months after the stroke had occurred (early locomotor training), the second group received this training 6 months after the stroke had occurred (late locomotor training), and the third group participated in an exercise program at home managed by a physical therapist 2 months after the stroke (home exercise program). Each intervention included 36 sessions of 90 minutes each for 12 to 16 weeks.

The primary outcome was the proportion of participants in each group who had an improvement in functional walking ability 1 year after the stroke. At 1 year, 52.0% of all participants had increased functional walking ability. No significant differences in improvement were found between early locomotor training and home exercise (adjusted odds ratio for the primary outcome, 0.83; 95% confidence interval [CI], 0.50 to 1.39) or between late locomotor training and home exercise (adjusted odds ratio, 1.19; 95% CI, 0.72 to 1.99). All groups had similar improvements in walking speed, motor recovery, balance, functional status, and quality of life.

Locomotor training, including the use of body-weight support in stepping on a treadmill, was not shown to be superior to progressive exercise at home managed by a physical therapist.

❖ **MELANIE M. ADAMS[42], et al., (2011):**

He did the study on comparison of the body weight supported treadmill training and tilt table standing on spasticity in individual with chronic spinal cord injury.

Seven individuals with chronic SCI and spasticity performed thrice-weekly BWSTT for 4 weeks and thrice-weekly TTS for 4 weeks, separated by a 4-week wash-out. Clinical (Modified Ashworth Scale, Spinal Cord Assessment Tool for Spinal reflexes) and self-report (Spinal Cord Injury Spasticity Evaluation Tool, Penn Spasm Frequency Scale) assessments of spasticity, quality of life (Quality of Life Index Spinal Cord Injury Version – III), functional mobility (FIM Motor Subscale), plus soleus H-reflex were measured at baseline, after the first training session and within 2 days of completing each training condition.

In comparison with TTS, a single session of BWSTT had greater beneficial effects for muscle tone (effect size (ES) = 0.69), flexor spasms (ES = 0.57), and the H/M ratio (ES = 0.50). Similarly, flexor spasms (ES = 0.79), clonus (ES = 0.66), and self-reported mobility (ES = 1.27) tended to benefit more from 4 weeks of BWSTT than of TTS. Participation in BWSTT also appeared to be favorable for quality of life (ES = 0.50). In contrast, extensor spasms were reduced to a greater degree with TTS (ES = 0.68 for single session; ES = 1.32 after 4 weeks).

The study finally concluded that both BWSTT and TTS may provide specific benefits with respect to spasticity characteristics, data from this pilot study suggest that BWSTT may result in a broader range of positive outcomes.

❖ **SARA J[43], et al., (2010):**

The purpose of this study was to identify gait parameters associated with improved walking speed after a locomotor training program that included body-weight–supported treadmill training (BWSTT).

Fifteen people, ranging from approximately 9 months to 5 years after stroke, completed 1 of 3 different 6-week training regimens. These regimens consisted of 12 sessions of BWSTT alternated with 12 sessions of: lower-extremity resistive cycling; lower-extremity progressive, resistive strengthening; or a sham condition of arm ergometer. Gait analysis was conducted before and after the 6-week intervention program. Kinematics, kinetics, and electromyography (EMG) activity were recorded from the hemi paretic lower extremity while participants walked at a self-selected pace. Changes in gait parameters were compared in participants who showed an increase in self-selected walking speed of greater than 0.08 m/s (high response group) and in those with less improvement (low-response group).

Compared with participants in the low-response group, those in the high-response group displayed greater increases in terminal stance hip extension angle and hip flexion power (product of net joint moment and angular velocity) after the intervention. The intensity of soleus muscle EMG activity during walking also was significantly higher in participants in the high-response group after the intervention.

Task-specific locomotor training alternated with strength training resulted in kinematic, kinetic, and muscle activation adaptations that were strongly associated with improved walking speed. Changes in both hip and ankle biomechanics during late stance were associated with greater increases in gait speed.

2.3 REVIEWS RELATED TO FUNCTIONAL ELECTRICAL STIMULATION:

- **MAIJKE VAN BLOEMENDAAL[44], et al., (2016):**

The aim of his study is to investigate the therapeutic effects of up to 10 weeks of multi-channel functional electrical stimulation (MFES)-assisted gait training on the restoration of spatiotemporal gait symmetry and walking capacity in sub-acute stroke patients.

In a proof-of-principle study with a randomised controlled design, 40 adult patients with walking deficits who are admitted for inpatient rehabilitation within 31 days since the onset of stroke are randomised to either MFES assisted gait training or conventional gait training. Gait training is delivered in 30-minute sessions each workday for up to 10 weeks. The step length symmetry ratio is the primary outcome. Blinded assessors conduct outcome assessments at baseline, every 2 weeks during the intervention period, immediately post intervention and at 3-month follow-up.

The study finally concluded that the multi-channel functional electrical stimulation is more effective intervention to improve gait function among patient with stroke.

- **EUN JUNG CHUNG[45], et al., (2015):**

He did the study on effect of brain computer interface-based functional electrical stimulation on brain activation in the stroke patients: a pilot randomized controlled trial.

The subjects were randomized to in a BCI-FES group (n=5) and a functional electrical stimulation (FES) group (n=5). Patients in the BCI-FES group received ankle dorsiflexion training with FES for 30 minutes per day, 5 times under the brain-computer interface-based program. The FES group received ankle dorsiflexion training with FES for the same amount of time. The BCI-FES group demonstrated significant differences in the frontopolar regions 1 and 2 attention indexes, and frontopolar 1 activation index. The FES group demonstrated no significant differences. There were significant differences in the frontopolar 1 region activation index between the two groups after the interventions. The results of this study suggest that BCI-FES training may be more effective in stimulating brain activation than only FES training in patients recovering from stroke.

- **ZHIMEI TAN[46], et al., (2014):**

He did the research on the effectiveness of functional electrical stimulation based on a normal gait pattern on subjects with early stroke.

Forty-five subjects were randomly assigned into a four-channel FES group (n = 16), a placebo group (n = 15), or a dual-channel group (n = 14). Stimulation lasted for 30 min in each session with 1 session/day, 5 days a week for 3 weeks. All subjects were assessed at baseline, at 3 weeks of treatment, and at 3 months after the treatment had finished. The assessments included Fugl-Meyer Assessment (FMA), the Postural Assessment Scale for Stroke Patients (PASS), Berg Balance Scale (BBS), Functional Ambulation Category (FAC), and the Modified Barthel Index (MBI). All 3 groups demonstrated significant improvements in all outcome measurements from pre- to post treatment and further gains at follow up. The score of FMA and MBI improved significantly in the four-channel group at the end of the 3 weeks of training. And the scores of PASS, BBS, MBI, and FAC in the four-channel group were significantly higher than those of the placebo group.

This study indicated that four-channel FES can improve motor function, balance, walking ability, and performance of activities of daily living in subjects with early ischemic stroke.

❖ NAAZ KAPADIA[(47),] et al., (2014):

He did the study on a randomized trial of functional electrical stimulation for walking in incomplete spinal cord injury: effect on walking competency.

Individuals with traumatic and chronic (≥18 months) motor incomplete SCI (level C2 to T12, American Spinal Cord Injury Association Impairment Scale C or D) were recruited from an outpatient SCI rehabilitation hospital, and randomized to FES-assisted walking therapy (intervention group) or aerobic and resistance training program (control group). Outcomes were assessed at baseline, and after 4, 6, and 12 months. Gait, balance, spasticity, and functional measures were collected.

Spinal cord independence measure (SCIM) mobility sub-score improved over time in the intervention group compared with the control group (baseline/12 months: 17.27/21.33 vs. 19.09/17.36, respectively). On all other outcome measures the intervention and control groups had similar improvements. Irrespective of group allocation walking speed, endurance, and balance during ambulation all improved upon completion of therapy, and majority of participants retained these gains at long-term follow-ups. The study concluded that the functional electrical stimulation improves walking ability in individuals with incomplete SCI, even in the chronic stage. Further randomized controlled trials, involving a large number of participants are needed, to verify if FES-assisted treadmill training is superior to aerobic and strength training.

❖ SHMUEL SPRINGER[(48),] et al., (2013):

He did the study on dual channel functional electrical stimulation improvements in speed based gait classifications.

Thirty-six subjects with chronic hemiparesis demonstrating foot-drop and deficits in knee and/or hip control were fitted with a dual-channel FES system activating the dorsi flexors and hamstring muscles. Gait was assessed during a 2-minute walk test with and without stimulation. A second assessment was conducted after 6 weeks of daily use. Analysis was performed with the subjects stratified into three functional ambulation classes according to their initial gait categories.

The dual-channel FES improved the gait velocity of all three subgroups. No minimal gait velocity was required in order to gain benefits from FES. For example, subjects with limited household ambulation capabilities improved their gait speed by

63.3% (from 0.30 ± 0.09 m/sec to 0.49 ± 0.20 m/sec; *P* , 0.01), while subjects with functional community ambulation capabilities improved their gait speed by 25.5% (from 0.90 ± 0.11 m/sec to 1.13 ± 0.22 m/sec; *P* , 0.01).

Dual-channel FES positively affects gait velocity in patients with chronic hemi-paresis, regardless of their initial gait velocity. Furthermore, gait velocity gains may be large enough to change an individual's ambulation status to a higher functional category.

- **CHANG SIK PARK[(49),] et al., (2013):**

He did the study on the effect of additional action observation training for functional electrical stimulation treatment on weight bearing, stability and gait velocity of hemiplegic patients.

Twenty subjects were randomized into two groups. Subjects more than six months post-stroke participated. Balance and gait velocity were measured at the baseline, and after six weeks of treatment. Both groups received functional electrical stimulation treatment. The experimental group additionally received action observational training.

The paired t-test was used to analyze differences in the outcome measures between before and after the intervention. The difference between the groups was compared using the independent t-test. The experimental group showed significant increases in weight bearing (anterior, posterior, right and left) on the affected side, stability index and gait velocity. The control group showed only a significant increase in anterior, posterior weight bearing on the affected side. Moreover, according to the comparison of training effects between in the two groups, the variables of anterior, posterior weight bearing, stability index and gait velocity revealed a statistically significant difference.

Additional action observational training for functional electrical stimulation treatment should be considered as a therapeutic method in physical therapy for the improvement of weight bearing, stability index and gait velocity of hemiplegic patients.

- **LIU HUI-HUA[(50),] et al., (2013):**

He did the study on functional electrical stimulation increases neural stem/ progenitor cell proliferation and neurogenesis in the sub-ventricular zone of rats with stroke.

Adult male Sprague-Dawley rats with permanent middle cerebral artery occlusion (MCAO) were randomly assigned to the control group, the placebo stimulation group, and the FES group. The rats in each group were further assigned to one of four therapeutic periods (1, 3, 7, or 14 days). FES was delivered 48 hours after the MCAO procedure and divided into two 10-minute sessions on each day of treatment with a 10-minute rest between them. Two intra peritoneal injections of bromodeoxyuridine (BrdU) were given 4 hours apart every day beginning 48 hours after the MCAO. Neurogenesis was evaluated by immunofluorescence staining. Wnt-3 which is strongly implicated in the proliferation and differentiation of neural stem cells (NSCs) was investigated by Western blotting analysis.

FES significantly increased the number of BrdU-positive cells and BrdU/glial fibrillary acidic protein double-positive neural progenitor cells in the SVZ on days 7 and 14 of the treatment ($P < 0.05$). FES augments the proliferation, differentiation, and migration of NSCs and thus promotes neurogenesis, which may be related to the improvement of neurological outcomes.

- **NILS A. HAKANSSON[(51),] et al., (2011):**

He did the study on effects of functional electrical stimulation gait training on mechanical recovery in post stroke gait.

The objective of this study was to test the effects of 12-weeks of Fast-FES gait training on mechanical recovery indices of post-stroke gait. Kinematic data were collected from 11 stroke survivors before and after 12-weeks of Fast FES training. Mechanical recovery was calculated from the positive changes in vertical, anterior-posterior, and medial-lateral components of COM energy. The average mechanical recovery increased from 34.5% before training to 40.0% after training. The increase was statistically significant (p=.014). The average self-selected walking speed increased from 0.4m/s to 0.7m/s after the 12-week Fast FES training. The results indicate that the subjects were better able to generate and utilize the external mechanical energy of walking after Fast FES gait training. Fast FES gait training has the capacity to increase the gait speed, improve the mechanical recovery, and reduce the mechanical energy expenditure of stroke survivors when they walk.

2.4 REVIEWS RELATED TO BODY WEIGHT SUPPORTED TREADMILL TRAINING ADDED FUNCTIONAL ELECTRICAL STIMULATION:

- **CHRISTIANE L. PRADO-MEDERIOS[(52),] et al., (2011):**

She did the study on the effects of the addition of functional electrical stimulation to ground level gait training with body weight support after chronic stroke.

Twelve people with chronic hemiparesis participated in the study. An A1-B-A2 design was applied. A1 and A2 corresponded to ground level gait training using BWS, and B corresponded to the same training with the addition of FES. The assessments were performed using the Modified Ashworth Scale (MAS), Functional Ambulation Category (FAC), Rivermead Motor Assessment (RMA), and filming. The kinematics analyzed variables were mean walking speed of locomotion; step length; stride length, speed and duration; initial and final double support duration; single-limb support duration; swing period; range of motion (ROM), maximum and minimum angles of foot, leg, thigh, and trunk segments. There were not changes between phases for the functional assessment of RMA, for the spatial-temporal gait variables and segmental angles, no changes were observed after the addition of FES. The use of FES on ground level gait training with BWS did not provide additional benefits for all assessed parameters.

- **MAPLE F.W. NG[(53),] et al., (2008):**

He did a study on gait training in sub-acute stroke patient with partial body weight support electromechanical gait trainer and functional electrical stimulation.

Fifty-four subjects were recruited within 6 weeks after stroke onset and were randomly assigned to 1 of 3 gait intervention groups: conventional over ground gait training treatment (CT, n_21), electromechanical gait trainer (GT, n_17) and, electromechanical gait trainer with functional electrical stimulation (GT-FES, n_16). All subjects were to undergo an assigned intervention program comprising a 20-minute session every weekday for 4 weeks. The outcome measures were Functional Independence Measure, Barthel Index, Motricity Index leg subscale, Elderly Mobility Scale (EMS), Berg Balance Scale, Functional Ambulatory Category (FAC), and 5-meter walking speed test. Assessments were made at baseline, at the end of the 4-week intervention program, and 6 months after the program ended.

By intention-to-treat and multivariate analysis, statistically significant differences showed up in EMS, FAC and gait speed. Post hoc analysis (univariate 2-way ANCOVA) revealed that the GT and GT-FES groups showed significantly better improvement in comparison with the CT group at the end of the 4 weeks of training and in the 6-month follow-up. For the early stage after stroke, this study indicated a higher effectiveness in post stroke gait training that used an electromechanical gait trainer compared with conventional over ground gait training. The training effect was sustained through to the 6-month follow-up after the intervention.

- **ANA RR LINDQUIST[(54),] et al., (2007):**

He did the study on the gait training combining partial body weight support, a treadmill, and functional electrical stimulation: effects on post stroke gait.

Eight people who were ambulatory after chronic stroke were evaluated. An A1-B-A2 single-case study design was applied. Phases A1 and A2 included 3 weeks of gait training on a treadmill with BWS, and phase B included 3 weeks of treadmill training plus FES applied to the peroneal nerve. The Stroke Rehabilitation Assessment of Movement was used to assess motor recovery, and a videography analysis was used to assess gait parameters.

An improvement (from 54.9% to 71.0%) in motor function was found during phase B. The spatial and temporal variables cycle duration, stance duration, and cadence as well as cycle length symmetry showed improvements when phase B was compared with phases A1 and A2. The combined use of FES and treadmill training with BWS led to an improvement in motor recovery and seemed to improve the gait pattern of subjects with hemiparesis, indicating the utility of this combination method during gait rehabilitation. In addition, this single-case series showed that this alternative method of gait training treadmill training with BWS and FES may decrease the number of people required to carry out the training.

2.4 REVIEWS RELATED TO RELIABILITY AND VALIDITY OF EXTENDED TIMED UP AND GO TEST:

❖ **CHRISTINA D. FARIA, [55] et al., (2012):**

She conducted a study to investigate the intra- and inter rater reliabilities of the Expanded Timed Up and Go (ETUG) test with subjects with stroke and to compare the ETUG scores between subjects with stroke and healthy control subjects.

48 Stroke participants and 48 healthy controls, matched by age, sex, and levels of physical activity were included in the study. Subjects with stroke spent more time in all of the ETUG activities when compared with control subjects. All of the activities appeared to contribute similarly to the poorer performances observed in subjects with stroke, because the ratio values were similar between the groups.

Considering the positive intra- and inter rater reliability results, the ETUG could be applied to assess the functional mobility of both groups.

❖ **SANKAR SAHAYARAJ [56] et al., (2012):**

He did a comparative study on extended timed get up and go (ETGUG) test between right and left hemiplegics.

Age between 45-55 years old left hemisphere dominant sixty males with hemiplegic (30 right side & 30 left side), satisfying the inclusion criteria were chosen for the study. Extended Timed Get Up & Go (ETGUG) test was used to assess the duration of sit to stand, gait initiation, walking, turn around, sitting down, and speed of the walk. Independent t test was used to compare the components of both the groups.

The findings showed that there were significant durational changes in the various components of ETGUG test between right side and left side hemiplegic subjects.

The gait rehabilitation should be emphasized on standing up, turning and sitting down for left sided hemiplegics and gait initiation, walking & speed for right sided hemiplegics. Temporal and the spatial parameters should be considered during gait training and gait training program should be given for right and left side hemiplegic subjects differently.

2.5 REVIEWS RELATED TO RELIABILITY AND VALIDITY OF BERG BALANCE SCALE:

- **YI MIAU CHEN(57), et al., (2017):**

He did the study on test reliabilities and minimal detectable change of two simplified 3-level balance measure in patient with stroke. The test reliability of both BBS-3P and PASS-3P were examined by intra-class correlation coefficient (ICC) and its percentage over the total score (MDC %) of each measure was calculated for examining the random measurement error.

The ICC values of the BBS-3P and PASS-3P were 0.99 and 0.97 respectively. The MDC% of the BBS-3P and PASS-3P were 9.1% (5.1 points) and 8.4% (3.0 points) respectively, indicating that both measures had small acceptable random measurement error. Our results showed that both the scales had test retest reliability, with small and acceptable random measurement error. These two simplified 3-level balance measure can provide reliable results over time.

- **ELISABETH WIKEN TELENIUS[58], et al., (2015):**

He did the study on inter-rater reliability of berg balance scale, 30 s chair stand test and 6 minutes walking test and construct validity of the berg balance scale in nursing home residents with mild to moderate dementia.

They included 33 nursing home patients with a mild to moderate degree of dementia. Weighted κ, intra class correlation coefficient (ICC) model 2.1 with 95% CIs and minimal detectable change (MDC) were used to measure inter rater reliability. Cronbach's α was calculated to evaluate the internal consistency of the BBS sum score.

The mean values of the BBS scored by the two evaluators were 38±13.7 and 38.0±13.8, respectively. Weighted κ scores for the BBS items varied from 0.83 to 1.0. ICC for the BBS's sum score was 0.99, and the MDC was 2.7% and 7%, respectively. The Cronbach's α of the BBS's sum score was 0.9. The ICC of the CST and 6 m walking test was 1 and 0.97, respectively. The MDC on the 6 m walking test was 0.08% and 15.2%, respectively. The results reveal an excellent relative inter-rater reliability of the BBS, CST and 6 m walking test as well as high internal consistency for the BBS in a population of nursing home residents with mild to moderate dementia. The absolute reliability was 2.7 on the BBS and 0.08 on the 6 m walking test.

CHAPTER – III

MATERIALS AND METHODOLOGY

3.1 STUDY DESIGN:

A Double blinded randomized experimental study with pre and post- test evaluations was used.

3.2 STUDY POPULATION:

Patients with sub-acute ischemic middle cerebral artery stroke were selected for this study.

3.3 SAMPLE SIZE:

24 subjects with sub-acute ischemic middle cerebral artery stroke were included for this study.

3.4 SAMPLING TECHNIQUE:

24 subjects were randomly allocated in to two groups by using concealed envelop method.

3.5 STUDY DURATION:

Duration of the treatment for control group and experimental groups was for 30 minutes per session, 6 days in a week for 6 weeks.

3.6 SELECTION CRITERIA:

❖ **INCLUSION CRITERIA:**

- Stroke with middle cerebral artery involvement confirmed by computer tomography or MRI,
- Unilateral hemiparesis for no more than 1 months resulting from first stroke [34]
- adequate mental and physical capacity to attempt the tasks as instructed (Mini Mental State Examination score ≥ 27)
- Subject who can walk approximately 3 meter with or without assistance.

❖ **EXCLUSION CRITERIA:**

- Refusal to give informed consent form,
- Problem with weight bearing due to unstable lower extremity fracture or history of osteoporosis,
- Subject with severe cardio vascular and respiratory disorder,

- Other neurological disorder like parkinsonism, brain injury, peripheral neuropathy
- A body weight ≥ 90 kg [22]
- Cardiac pacemaker,
- Hip, Knee, Ankle arthrodesis,
- Metallic implant at the affected lower limb
- Present or suspected cancerous lesion at the affected lower extremity,

3.7 MATERIALS USED:

- Informed Consent Form
- Patient information sheet
- Body weight supported treadmill and its accessories
- Functional Electrical Stimulator and its accessories
- ETGUG Test
- Berg Balance Scale
- Chair with arm support and back rest
- Tripod Cane
- Stop watch
- Inch tape

3.8 STUDY PROCEDURE:

The objectives and need of the study was clearly explained to the ethical committee of PPG College of Physiotherapy and Ashwin Stroke care unit. After getting approval from the ethical committee the study was conducted at Department of Neurorehabilitation, Ashwin Stroke Care Unit, Coimbatore.

The period was given to enroll in the study is November 2016 to march 2017. During this period based on the selection criteria 28 patients with sub-acute ischemic middle cerebral artery stroke were enrolled for this study, in which 4 subjects was withdrawal from the study due to inconvenience. All the participants were received clear explanation about the study and they were asked to submit the written informed consent form.

After obtaining informed consent 24 patients were enrolled in this study. The patients were divided into two group by using concealed envelop method. Group A (control group) consisting of 12 subjects and group B (Experimental group) consisting of 12 subjects.

Subjects in control group (Group A) received body weight supported treadmill training. Subjects in experimental group (Group B) received body weight supported treadmill training along with functional electrical stimulation therapy.

Both the groups were received intervention for 30 minutes per session, 6 days in a week for 6 weeks. Both groups were received routine physiotherapy, occupational therapy and speech therapy treatment.

Before starting the study the pre score value of functional mobility were measured by using Extended timed get up and go test (ETGUG) and balance were measured by using Berg balance scale. After the 6 weeks, the post score were measured by using same measurement tool by the blinded evaluator and the data were recorded.

3.9 TECHNIQUES:

All the recruited subjects received one and half hours of rehabilitation every weekday. This includes 60 minutes of physical therapy and occupational therapy and speech therapy program. The routine rehabilitation session consisted approximately 30 minutes of therapeutic exercises such as range of motion exercise, strengthening exercise, task oriented approaches, Neuro Developmental technique (NDT), MAT exercise, and facilitation techniques to recruit muscle activity on the paretic extremity, etc.

For gait training, the subjects were randomly allocated to either BWSTT or BWSTT added FES therapy for 30 minutes.

- ❖ **BODY WEIGHT SUPPORTED TREADMILL TRAINING:**

The equipment for BWSTT consisted of a standard treadmill fitted with weight supported apparatus. The patient wore a modified mountain climber’s harness with an adjustable belt around the thigh and pelvis and an adjustable belt above to support their upper body weight.

The initial body weight support was set at 30% to 40% and the speed of the treadmill was set at 0.5mph (Miles per Hour), and the duration of the training program was 20 minutes. By the third week the body weight support was gradually decreased and the speed of the treadmill was increased to 2.5 mph (Miles per Hour) and the duration of the training program was 20 minutes.

These two parameters were not changed simultaneously. The subjects were monitored throughout the training for fatigue level and tolerance and progression.

A Physiotherapist assisted with the leg propulsion if the subjects could not able to lift paretic leg during the gait training session during the initiation. At the beginning phase of the treatment session some patient needed more assistance. So that two therapists assisted to guide the movement of pelvic forward and to flex and extend the hip, knee and ankle of the paretic leg during the stance phases and swing phases of the gait.

FREQUENCY AND DURATION:

The subjects in the Body Weight Supported Treadmill Training (BWSTT) group were received the gait training program for 30 minutes per session, 6 days in a week for 6 weeks.

- **BODY WEIGHT SUPPORTED TREADMILL TRAINING ADDED FUNCTIONAL ELECTRICAL STIMULATION:**

Subjects in experimental group (BWSTT-FES) underwent the same ambulatory training on the body weight supported treadmill as the control group but also received functional electrical stimulation simultaneously.

Each BWSTT-FES subjects were received standardized electrical stimulation modality, including the wave form and pulse width and the stimulation intensity was adjusted by the supervising physical therapist according to how successful the correct limb movement was elicited and to the subject's comfort threshold.

The Functional electrical stimulator has an adjustable frequency, contraction time, relaxing time and pulse width and consisting of a foot switch, a pair of surface electrode measuring 50 x 50 mm, and a stimulator. An inactive electrode was attached to the proximal tibialis anterior (located 5 cm below to the head of the fibula bone), which is an antagonist to the ankle plantar flexor group of muscle. An Active electrode was placed on the distal tibialis anterior (located on the lateral upper 5 cm of the fibula).

The parameters of functional electrical stimulation were symmetrical biphasic square waves with 150 microseconds, the frequency of 25 Hz and the intensity from 60 to 150 V. The pulse intensity was regulated according to the patient's tolerance and stimulation level needed to elicit effective muscle contraction. A sensory insole, connected to the stimulator, was placed on the affected foot heel while a strap kept the stimulator attached to the paretic limb.

The stimulation was activated only in the swing phase of the gait every time the patient started changing steps and it stopped during the patient's foot touched the ground.

FREQUENCY AND DURATION:

The subjects in the Body Weight Supported Treadmill Training (BWSTT) added Functional Electrical Stimulation (FES) group were received the gait training program for 30 minutes per session, 6 days in a week for 6 weeks.

DATA COLLECTION:

Functional Mobility and balance were measured by using Extended Timed Get Up and Go Test (ETGUG) and Berg Balance Scale (BBS). Measurements were recorded in the stroke subjects at the baseline and after the 6 weeks of training by an examiner who was blinded to group assignment.

CHAPTER – IV

DATA ANALYSIS AND RESULTS

This study comprised of two groups, group A subjects were treated with body weight supported treadmill training and subjects in group B were treated with body weight supported treadmill training added functional electrical stimulation.

The values of functional mobility and balance was analysed by SPSS-20 version. The Paired't' test was used for within group analysis. The unpaired't' test was used for inter group analysis.

4.1 DEMOGRAPHICAL DATA:

	CONTROL GROUP	EXPERIMENTAL GROUP
AGE (YEARS)	66.6 (11.3)	62.0 (10.0)
SIDE OF HEMIPLEGIA (RIGHT / LEFT)	8 / 4	7 / 5
DURATION OF STROKE (WEEKS)	2.5 ± 1.2	2.7 ± 1.2

Table No: 1: Demographical Data

4.2 WITHIN GROUP ANALYSIS OF GROUP A:

- **BERG BALANCE SCALE:**

TEST	MEAN ± STANDARD ERROR MEAN	STANDARD DEVIATION	T VALUE	P VALUE
PRE TEST	28.500 ± 0.857	2.969	-15.155	0.000
POST TEST	39.66 ± 0.541	1.874		

Table No: 2: Within group analysis of Berg balance scale in control group (Group A).

The Pre mean and standard error mean value of berg balance scale in group A were 28.50 ± 0.857 and the standard deviation value was 2.969 respectively.

The Post mean and standard error mean value of berg balance scale in group A were 39.66 ± 0.541 and the standard deviation value was 1.874 respectively.

The T value and P value were -15.155 and 0.000 respectively. The statistical report states that there was significant improvement in balance after the application of body weight supported treadmill training in control group.

❖ **EXTENDED TIMED GET UP AND GO TEST:**

TUGT VARIABLES	TEST	MEAN ± STANDARD ERROR MEAN	STANDARD DEVIATION	T VALUE	P VALUE
SIT TO STAND	**PRE TEST**	9.833 ± 0.270	0.937	6.189	0.000
	POST TEST	8.416 ± 0.228	0.792		
WALKING 1	**PRE TEST**	12.083 ±0.398	1.378	8.124	0.000
	POST TEST	10.083 ± 0.468	1.621		
TURNING	**PRE TEST**	7.833 ± 0.241	0.834	5.933	0.000
	POST TEST	6.500 ± 0.288	1.000		
WALKING 2	**PRE TEST**	12.333 ± 0.376	1.302	11.285	0.000
	POST TEST	9.750 ± 0.304	1.055		
TRUN SITTING	**PRE TEST**	10.833 ±0.321	0.114	9.931	0.000
	POST TEST	8.916 ± 0.287	0.996		

Table No: 3: Within group analysis of Extended timed get up and go test in control group (Group A).

➢ **SIT TO STAND:**

The Pre mean and standard error mean value of sitting to standing time in group A were 9.800 ± 0.270 and the standard deviation value was 0.937 respectively.

The Post mean and standard error mean value of sitting to standing time in group A were 8.416 ± 0.228 and the standard deviation value was 0.792 respectively.

The T value and P value were 6.189 and 0.000 respectively. The statistical report states that there was significant improvement in sitting to standing time after the application of body weight supported treadmill training in control group.

- **WALKING 1**

The Pre mean and standard error mean value of phase 1 walking time in group A were 12.083 ± 0.398 and the standard deviation value was 1.378 respectively.

The Post mean and standard error mean value of phase 1 walking time in group A were 10.083 ± 0.468 and the standard deviation value was 1.621 respectively.

The T value and P value were 8.124 and 0.000 respectively. The statistical report states that there was significant improvement in phase 1 walking time after the application of body weight supported treadmill training in control group.

- **TURNING:**

The Pre mean and standard error mean value of turning time in group A were 7.833 ± 0.241 and the standard deviation value was 0.834 respectively.

The Post mean and standard error mean value of turning time in group A were 6.500 ± 0.288 and the standard deviation value was 1.000 respectively.

The T value and P value were 5.933 and 0.000 respectively. The statistical report states that there was significant improvement in turning time after the application of body weight supported treadmill training in control group.

- **WALKING 2:**

The Pre mean and standard error mean value of phase 2 walking time in group A were 12.333 ± 0.376 and the standard deviation value was 1.302 respectively.

The Post mean and standard error mean value of phase 2 walking time in group A were 9.750 ± 0.304 and the standard deviation value was 1.055 respectively.

The T value and P value were 11.285 and 0.000 respectively. The statistical report states that there was significant improvement in phase 2 walking time after the application of body weight supported treadmill training in control group.

- **TURN SITTING:**

The Pre mean and standard error mean value of turning and sitting time in group A were 10.833 ± 0.321 and the standard deviation value was 0.114 respectively.

The Post mean and standard error mean value of turning and sitting time in group A were 8.916 ± 0.287 and the standard deviation value was 0.996 respectively.

The T value and P value were 9.931 and 0.000 respectively. The statistical report states that there was significant improvement in turn and sitting time after the application of body weight supported treadmill training in control group.

4.3 WITHIN GROUP ANALYSIS OF GROUP B:

- **BERG BALANCE SCALE:**

TEST	MEAN ± STANDARD ERROR MEAN	STANDARD DEVIATION	T VALUE	P VALUE
PRE TEST	28.833 ± 0.705	2.443	-22.122	0.000
POST TEST	47.666 ± 0.864	2.994		

Table No: 4: Within group analysis of Berg balance scale in experimental group (Group B)

The Pre mean and standard error mean value of berg balance scale in group B were 28.833 ± 0.705 and the standard deviation value was 2.443 respectively.

The Post mean and standard error mean value of berg balance scale in group B were 47.666 ± 0.864 and the standard deviation value was 2.994 respectively.

The T value and P value were -22.122 and 0.000 respectively. The statistical report states that there was significant improvement in balance after the application of body weight supported treadmill training added with functional electrical stimulation in experimental group.

❖ **EXTENDED TIMED GET UP AND GO TEST:**

TUGT VARIABLES	TEST	MEAN ± STANDARD ERROR MEAN	STANDARD DEVIATION	T VALUE	P VALUE
SIT TO STAND	**PRE TEST**	10.666 ± 0.355	1.230	15.358	0.000
	POST TEST	6.250 ± 0.250	0.866		
WALKING 1	**PRE TEST**	12.000 ± 0.369	1.279	14.963	0.000
	POST TEST	6.750 ± 0.217	0.753		
TURNING	**PRE TEST**	8.083 ± 0.287	0.996	10.383	0.000
	POST TEST	4.583 ± 0.193	0.668		
WALKING 2	**PRE TEST**	11.916 ± 0.398	1.378	10.952	0.000
	POST TEST	7.583 ± 0.228	0.792		
TRUN SITTING	**PRE TEST**	11.916 ± 0.398	1.378	8.749	0.000
	POST TEST	8.166 ±0.270	0.937		

Table No: 5: Within group analysis of Extended timed get up and go test in experimental group (Group B).

➢ **SIT TO STAND:**

The Pre mean and standard error mean value of sitting to standing time in group B were 10.666 ± 0.355 and the standard deviation value was 1.230 respectively.

The Post mean and standard error mean value of sitting to standing time in group B were 6.250 ± 0.250 and the standard deviation value was 0.866 respectively.

The T value and P value were 15.358 and 0.000 respectively. The statistical report states that there was significant improvement in sitting to standing time after the application of body weight supported treadmill training added functional electrical stimulation in experimental group.

- **WALKING 1:**

The Pre mean and standard error mean value of phase 1 walking time in group B were 12.000 ± 0.369 and the standard deviation value was 1.279 respectively.

The Post mean and standard error mean value of phase 1 walking time in group B were 6.750 ± 0.217 and the standard deviation value was 0.753 respectively.

The T value and P value were 14.963 and 0.000 respectively. The statistical report states that there was significant improvement in phase 1 walking time after the application of body weight supported treadmill training added functional electrical stimulation in experimental group.

- **TURNING:**

The Pre mean and standard error mean value of turning time in group B were 8.083 ± 0.287 and the standard deviation value was 0.996 respectively.

The Post mean and standard error mean value of turning time in group B were 4.583 ± 0.193 and the standard deviation value was 0.668 respectively.

The T value and P value were 10.383 and 0.000 respectively. The statistical report states that there was significant improvement in turning time after the application of body weight supported treadmill training added functional electrical stimulation in experimental group.

- **WALKING 2:**

The Pre mean and standard error mean value of phase 2 walking time in group B were 11.916 ± 0.398 and the standard deviation value was 1.378 respectively.

The Post mean and standard error mean value of phase 2 walking time in group B were 7.583 ± 0.228 and the standard deviation value was 0.792 respectively.

The T value and P value were 10.952 and 0.000 respectively. The statistical report states that there was significant improvement in phase 2 walking time after the application of body weight supported treadmill training in control group.

- **TURN SITTING:**

The Pre mean and standard error mean value of turning and sitting time in group B were 11.916 ± 0.398 and the standard deviation value was 1.378 respectively.

The Post mean and standard error mean value of turning and sitting time in group B were 8.166 ± 0.270 and the standard deviation value was 0.937 respectively.

The T value and P value were 8.749 and 0.000 respectively. The statistical report states that there was significant improvement in turn and sitting time after the application of body weight supported treadmill training in control group.

4.4 BETWEEN GROUP ANALYSES:

- **BERG BALANCE SCALE:**

TEST	GROUP	MEAN ± STANDARD ERROR MEAN	STANDARD DEVIATION	F VALUE	P VALUE
PRE TEST	GROUP A	28.500 ± 0.857	2.969	1.169	0.767
	GROUP B	28.833 ± 0.705	2.443		
POST TEST	GROUP A	39.66 ± 0.541	1.874	2.888	0.000
	GROUP B	47.666 ± 0.864	2.994		

Table No: 6: Between group analyses of Berg balance scale (BBS).

The pre-test values of both group A and group B were calculated. The pre mean values and standard error mean of balance for both groups were 28.500 ± 0.857 and 28.833 ± 0.705. The F value was 1.169 and the P value was 0.767 showed there were no homogenicity among the groups.

The post-test mean values and standard error mean of balance for both groups were 39.66 ± 0.541 and 47.666 ± 0.864. The F value was 2.888 and the P value was 0.000 showed there were significant differences between the groups.

- **EXTENDED TIMED GET UP AND GO TEST:**

TEST	GROUP	MEAN ± STANDARD ERROR MEAN	STANDARD DEVIATION	F VALUE	P VALUE
SIT TO STAND					
PRE TEST	**GROUP A**	9.833 ± 0.270	0.937	1.261	0.075
	GROUP B	10.666 ± 0.355	1.230		
POST TEST	**GROUP A**	8.416 ± 0.228	0.792	0.005	0.000
	GROUP B	6.250 ± 0.250	0.866		
WALKING 1					
PRE TEST	**GROUP A**	12.083 ±0.398	1.378	0.100	0.879
	GROUP B	12.000 ± 0.369	1.279		
POST TEST	**GROUP A**	10.083 ± 0.468	1.621	5.167	0.000
	GROUP B	6.750 ± 0.217	0.753		
TURNING					
PRE TEST	**GROUP A**	7.833 ± 0.241	0.834	0.166	0.512
	GROUP B	8.083 ± 0.287	0.996		
POST TEST	**GROUP A**	6.500 ± 0.288	1.000	2.357	0.231
	GROUP B	4.583 ± 0.193	0.668		

WALKING 2					
PRE TEST	GROUP A	12.333 ± 0.376	1.302	0.019	0.455
	GROUP B	11.916 ± 0.398	1.378		
POST TEST	GROUP A	9.750 ± 0.304	1.055	0.752	0.000
	GROUP B	7.583 ± 0.228	0.792		
TURN SITTING					
PRE TEST	GROUP A	10.833 ±0.321	0.114	0.655	0.046
	GROUP B	11.916 ± 0.398	1.378		
POST TEST	GROUP A	8.916 ± 0.287	0.996	0.031	0.071
	GROUP B	8.166 ±0.270	0.937		

Table No: 7: Between group analyses of Extended timed get up and go test (ETGUG).

- **SIT TO STAND:**

The pre-test values of both group A and group B were calculated. The pre mean values and standard error mean of sitting to standing time for both groups were 9.833 ± 0.270 and 10.666 ± 0.355. The F value was 1.261 and the P value was 0.075 showed there were no homogenicity among the groups.

The post-test mean values and standard error mean of sitting to standing time for both groups were 8.416 ± 0.228 and 6.250 ± 0.250. The F value was 0.005 and the P value was 0.000 showed there were significant differences between the groups.

- **WALKING 1:**

The pre-test values of both group A and group B were calculated. The pre mean values and standard error mean of phase 1 walking time for both groups were 12.083 ± 0.398 and 12.000 ± 0.369. The F value was 0.100 and the P value was 0.879 showed there were no homogenicity among the groups.

The post-test mean values and standard error mean of phase 1 walking time for both groups were 10.083 ± 0.468 and 6.750 ± 0.217. The F value was 5.167 and the P value was 0.000 showed there were significant differences between the groups.

- **TURNING:**

The pre-test values of both group A and group B were calculated. The pre mean values and standard error mean of turning time for both groups were 7.833 ± 0.241 and 8.083 ± 0.287. The F value was 0.166 and the P value was 0.512 showed there were no homogenicity among the groups.

The post-test mean values and standard error mean of turning time for both groups were 6.500 ± 0.288 and 4.583 ± 0.193. The F value was 2.357 and the P value was 0.231 showed there were no significant differences between the groups.

- **WALKING 2:**

The pre-test values of both group A and group B were calculated. The pre mean values and standard error mean of phase 2 walking time for both groups were 12.333 ± 0.376 and 11.916 ± 0.398. The F value was 0.019 and the P value was 0.455 showed there were no homogenicity among the groups.

The post-test mean values and standard error mean of phase 2 walking time for both groups were 9.750 ± 0.304 and 7.583 ± 0.228. The F value was 0.752 and the P value was 0.000 showed there were significant differences between the groups.

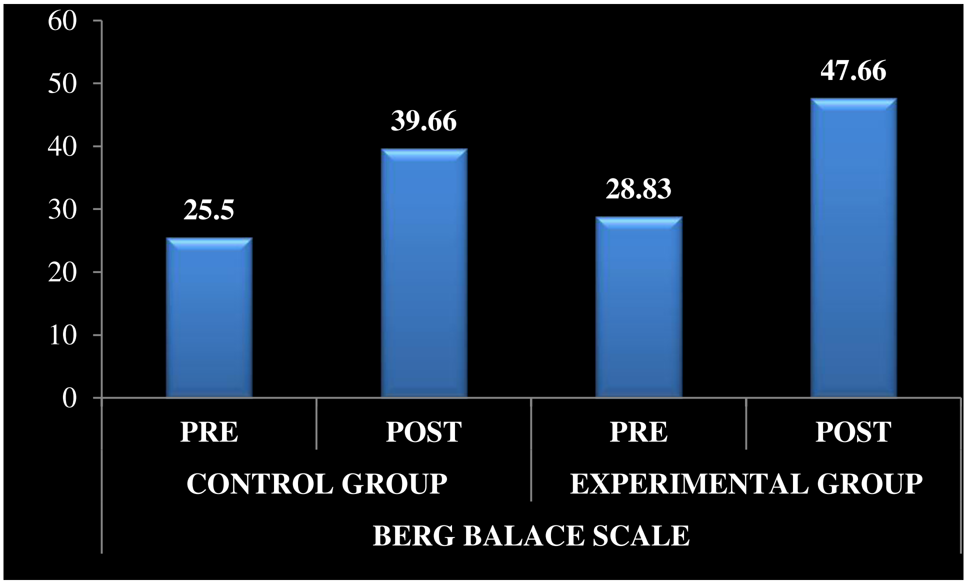
- **TURN SITTING:**

The pre-test values of both group A and group B were calculated. The pre mean values and standard error mean of turning and sitting time for both groups were 10.833 ±0.321 and 11.916 ± 0.398. The F value was 0.655 and the P value was 0.046 showed there were no homogenicity among the groups.

The post-test mean values and standard error mean of turning and sitting time for both groups were 8.916 ± 0.287 and 8.166 ±0.270. The F value was 0.031 and the P value was 0.071 showed there were no significant differences between the groups.

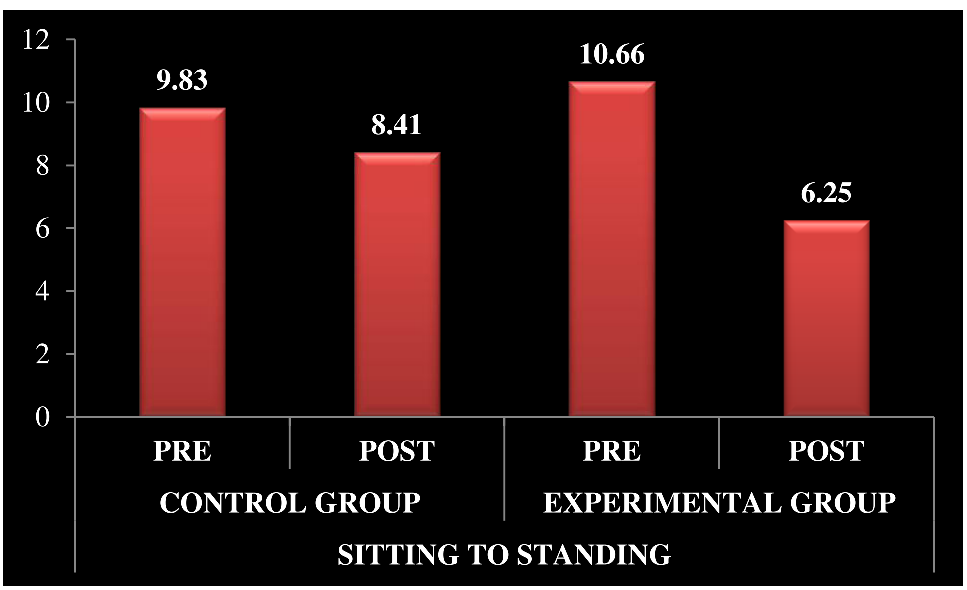
GRAPHICAL REPRESENTATION

❖ **BERG BALACE SCALE:**

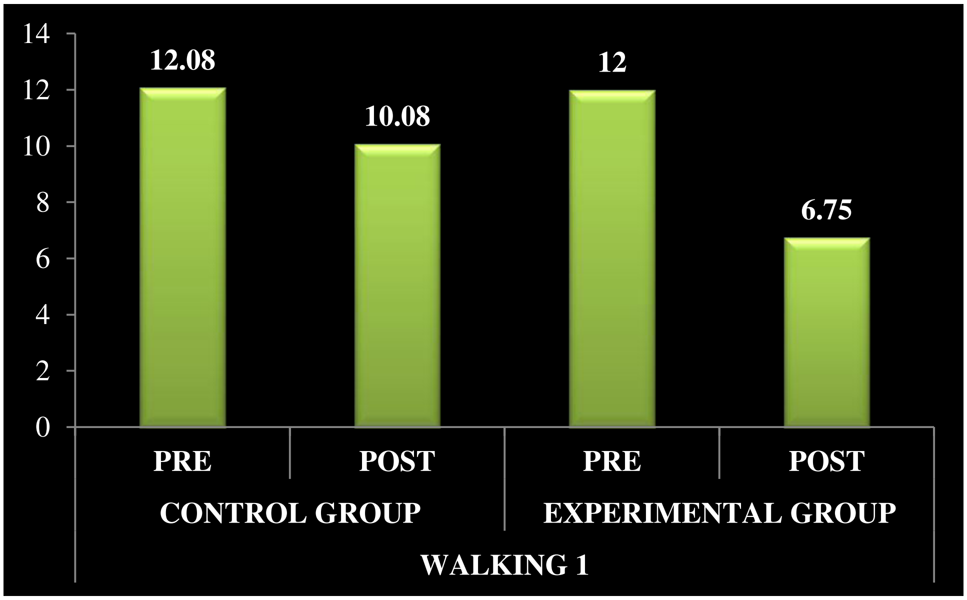


GRAPH: 1: Graphical representation of Berg Balance Scale.

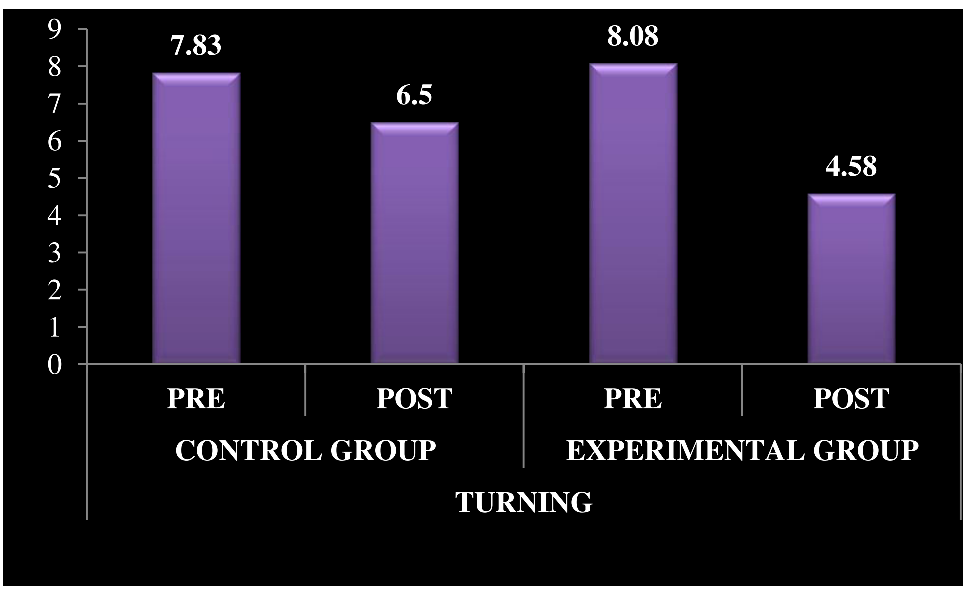
❖ **EXTENDED TIMED GET UP AND GO TEST:**



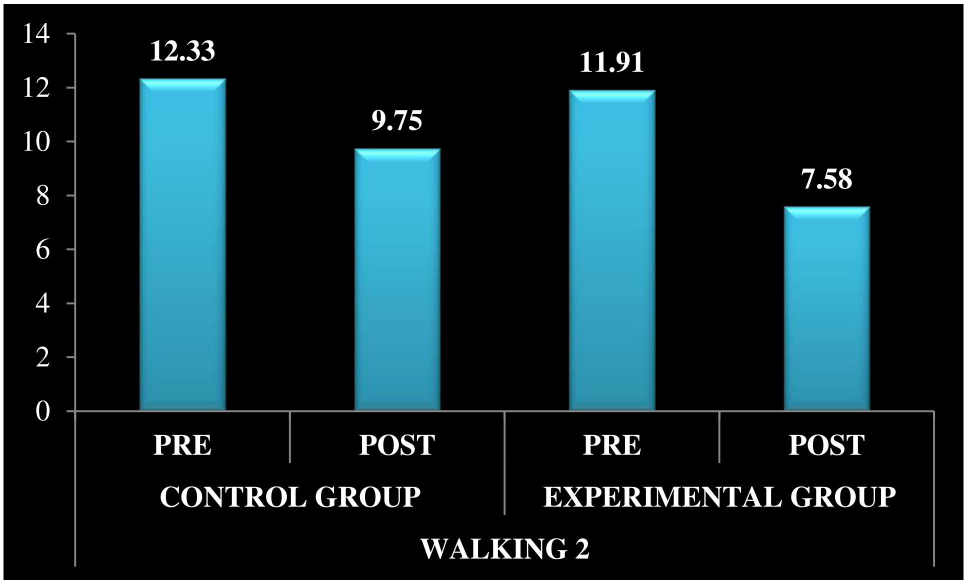
GRAPH: 2: Graphical representation of sitting to standing phase of Extended Timed Get Up and Go Test.



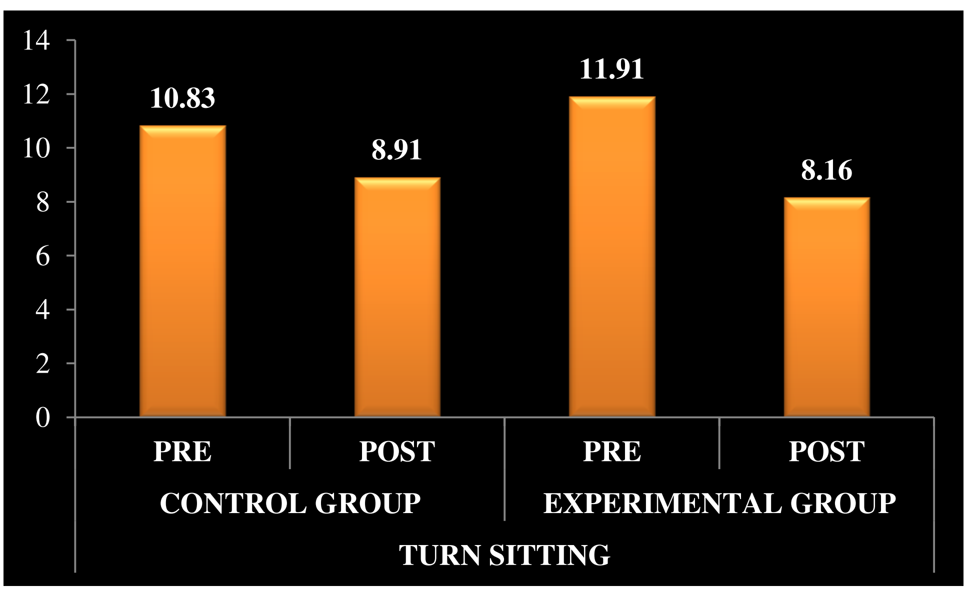
GRAPH: 3: Graphical representation of walking 1 phase of Extended Timed Get Up and Go Test.



GRAPH: 4: Graphical representation of turning phase of Extended Timed Get Up and Go Test.



GRAPH: 5: Graphical representation of walking 2 phases of Extended Timed Get Up and Go Test.



GRAPH: 6: Graphical representation of turn sitting phases of Extended Timed Get Up and Go Test.

PHOTOGRAPHICAL REPRESENTATION

	
FIG: 1: BODY WEIGHT SUPPORTED TREADMILL	**FIG: 2: BODY WEIGHT SUPPORTED TREADMILL TRAINING**

Figure: Body weight supported treadmill training for patient with right side hemiplegic.

CHAPTER – V

DISCUSSIONS

In this study, we showed that 6 weeks of body weight supported treadmill training with functional electrical stimulation resulted in improvements in functional mobility and balance in subjects with sub-acute ischemic middle cerebral artery stroke. However, 6 weeks of body weight supported treadmill training with functional electrical stimulation yield better results in gait speed than body weight supported treadmill training alone.

The result that functional mobility and balance improved after functional electrical stimulation added with body weight supported treadmill training indicates that the subjects were able to generate and utilize the external mechanical energy of walking. This finding implies that the training improved the subject's ability to use the plantar flexors to accelerate the COM vertically up and forward over the base of support. Improved utilization of the plantar flexors in late stance would lead to higher gait speeds, which are associated with increased energy efficiency and mechanical recovery in post-stroke gait.

After the gait training period, the subjects noted an improvement in their gait and balance and reported being more able to perform their activities of daily living in different environment.

We identified two main advantages of using functional electrical stimulation combined with body weight supported treadmill training.

i. All the subjects reported a preference for walking on the treadmill with body weight support combined with functional electrical stimulation and also it is easier to place their foot during early stance phase.
ii. Training with FES decreases the participation of the physiotherapist. Manual assistance was provided to help the subjects to optimize gait quality during training and the physiotherapist noted that a decrease in their work for the gait training session. BWSTT combined with FES was easier to assist the gait training and the paretic limb during the gait, but there was no change in the number of personnel involvement in the training program with functional electrical stimulation.

YU-RONGMAO, et al., did the study on effect of body weight supported treadmill training on gait recovery, proximal lower limb motor pattern and balance in patient with sub-acute stroke. 24 subjects with unilateral hemiplegia in the sub-acute stage were randomized to the BWSTT (n=12) and CT (n=12) groups. The patient in both groups receives intervention for 30minutes per day, 5 days per week for 3 weeks. The balance was measured by the Brunel balance assessment. Lower extremity function was evaluated by the Fugl-Meyer assessment scale. Kinematic data were collected and analyzed using a gait capture system before and after the intervention.

Both the groups improved on balance and lower extremity motor function measures ($P \leq 0.05$), with no significant difference between two groups after the intervention. However, the kinematic data were significantly improved ($P \leq 0.05$) after BWSTT but not after CT. Maximum hip extension and flexion angles were significantly improved ($P \leq 0.05$) for the BWSTT group during the stance and swing phase compared to baseline. Finally he concluded that, in sub-acute patient with stroke, BWSTT can leads to improved gait quality when compared with conventional gait training. Both methods can improve balance and motor function.

In this present study sub-acute stroke patients were treated with BWSTT and BWSTT added FES. Both the groups showed significant improvement in balance and functional mobility after 6 weeks of intervention. FES group showed better improvement in the outcomes when compare to the BWSTT group.

CHRISTIANE L. PRADO-MEDERIOS, et al., did the study on the effects of the addition of functional electrical stimulation to ground level gait training with body weight support after chronic stroke.

Twelve people with chronic hemiparesis participated in the study. An A1-B-A2 design was applied. A1 and A2 corresponded to ground level gait training using BWS, and B corresponded to the same training with the addition of FES. The assessments were performed using the Modified Ashworth Scale (MAS), Functional Ambulation Category (FAC), Rivermead Motor Assessment (RMA), and filming. The kinematics analyzed variables were mean walking speed of locomotion; step length; stride length, speed and duration; initial and final double support duration; single-limb support duration; swing period; range of motion (ROM), maximum and minimum angles of foot, leg, thigh, and trunk segments. There were not changes between phases for the functional assessment of RMA, for the spatial-temporal gait variables and segmental angles, no changes were observed after the addition of FES. The use of FES on ground level gait training with BWS did not provide additional benefits for all assessed parameters.

In this present study the subjects in group B (BWSTT added FES) received gait training program in body weight supported treadmill along with the functional electrical stimulation. After 6 weeks the functional mobility and the balance was improved when compared to the control group (BWSTT alone). The statistical reports suggest that the use of FES on body weight supported treadmill provide additional benefits to improve the motor recovery after stroke.

MAPLE F.W. NG et al., did a study on gait training in sub-acute stroke patient with partial body weight support electromechanical gait trainer and functional electrical stimulation.

Fifty-four subjects were recruited within 6 weeks after stroke onset and were randomly assigned to 1 of 3 gait intervention groups: conventional over ground gait training treatment (CT, n=21), electromechanical gait trainer (GT, n=17) and, electromechanical gait trainer with functional electrical stimulation (GT-FES, n=16). All subjects were to undergo an assigned intervention program comprising a 20-minute session every weekday for 4 weeks. The outcome measures were Functional Independence Measure, Barthel Index, Motricity Index leg subscale, Elderly Mobility Scale (EMS), Berg Balance Scale, Functional Ambulatory Category (FAC), and 5-meter walking speed test. Assessments were made at baseline, at the end of the 4-week intervention program, and 6 months after the program ended.

By intention-to-treat and multivariate analysis, statistically significant differences showed up in EMS, FAC and gait speed. Post hoc analysis (univariate 2-way ANCOVA) revealed that the GT and GT-FES groups showed significantly better improvement in comparison with the CT group at the end of the 4 weeks of training and in the 6-month follow-up. For the early stage after stroke, this study indicated a higher effectiveness in post stroke gait training that used an electromechanical gait trainer compared with conventional over ground gait training. The training effect was sustained through to the 6-month follow-up after the intervention.

In this current study body weight supported treadmill training was used. The subjects in group A received only body weight supported treadmill training and the subjects in group B received body weight supported treadmill training added functional electrical stimulation. This current study report reveals that for early stage stroke, body weight supported treadmill training added functional electrical stimulation indicated a higher effectiveness in post stroke motor recovery when compared to the body weight supported treadmill training alone.

ZHIMEI TAN, et al., did the research on the effectiveness of functional electrical stimulation based on a normal gait pattern on subjects with early stroke. Forty-five subjects were randomly assigned into a four-channel FES group (n = 16), a placebo group (n = 15), or a dual-channel group (n = 14). Stimulation lasted for 30 min in each session with 1 session/day, 5 days a week for 3 weeks. The assessments included Fugl-Meyer Assessment (FMA), the Postural Assessment Scale for Stroke Patients (PASS), Berg Balance Scale (BBS), Functional Ambulation Category (FAC), and the Modified Barthel Index (MBI). All 3 groups demonstrated significant improvements in all outcome measurements from pre- to post treatment and further gains at follow up. The score of FMA and MBI improved significantly in the four-channel group at the end of the 3 weeks of training. And the scores of PASS, BBS, MBI, and FAC in the four-channel group were significantly higher than those of the placebo group.

This study indicated that four-channel FES can improve motor function, balance, walking ability, and performance of activities of daily living in subjects with early ischemic stroke.

In this present study the dual channel functional electrical stimulator was used. The study group received functional electrical stimulation along with the body weight supported treadmill training. There was statistically significant improvement was found after 6 weeks of intervention. This current study indicated that dual channel functional electrical stimulation combined with body weight supported treadmill training can improve walking ability, balance, motor function and activities of daily living in subjects with sub-acute ischemic middle cerebral artery stroke population.

CHAPTER – VI

SUMMARY AND CONCLUSIONS

SUMMARY OF THE STUDY:

The study comprises of two groups. Group A (control group) consisting of 12 subjects and group B (Experimental group) consisting of 12 subjects. Subjects in control group (Group A) received body weight supported treadmill training. Subjects in experimental group (Group B) received body weight supported treadmill training along with functional electrical stimulation therapy.

Both the groups were received intervention for 30 minutes per session, 6 days in a week for 6 weeks along with their routine physiotherapy, occupational therapy and speech therapy treatment.

CONCLUSION OF THE STUDY:

The results of this study indicates that subjects with sub-acute ischemic middle cerebral artery stroke provided with training likely would benefit from a gait training program combined with body weight supported treadmill and functional electrical stimulation.

Finally the study concluded that the 6 weeks of gait training program with body weight supported treadmill training along with the functional electrical stimulation showed statistically significant improvement in functional mobility and balance when compared to the body weight supported treadmill training alone.

In addition the use of functional electrical stimulation during the body weight supported treadmill training was preferred by the subjects and facilitated the work of the physiotherapist.

CHAPTER - VII

LIMITATIONS AND SUGGESTIONS

1. Limited number of subjects.
2. Future studies should aim at including greater number of subjects i.e. large sample size so that variations can be more clearly understood.
3. Specific types of stroke were taken in the present study. Future studies should be conducted across various types of stroke and various arterial involvements and various duration of stroke. Thus, variations in finding under the influence of various types, various arterial involvements and various duration of stroke can be studied.
4. The same study can be conducted in patients with other neurological disorder such as spinal cord injury, cerebral palsy, traumatic brain injury.

CHAPTER - VIII

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CHAPTER IX

ANNEXURE I

INFORMED CONSENT FORM

TITLE: "AN EXPERIMENTAL STUDY ON EFFECTIVENESS OF FUNCTIONAL ELECTRICAL STIMULATION TO IMPROVE FUNCTIONAL MOBILITY AND BALANCE AMONG SUBJECTS WITH SUB ACUTE ISCHEMIC MIDDLE CEREBRAL ARTER STROKE - A DOUBLE BLINDED RANDOMIZED STUDY"

INVESTIGATOR: Mr. Dhivakar Murugan

CO-INVESTIGATOR: Prof. Dr. M. Sankar Sahayaraj

PURPOSE OF THE STUDY:

I __________________ have been informed that this study will help clinicians & therapists to find out the effectiveness of the abdominal binder on blood pressure in lying and standing position among young healthy self-reported college students.

PROCEDURE:

I ____________________ understand that I will undergo experiment with Mr. Dhivakar Murugan/Dr. M. Sankar Sahayaraj under the direct supervision of the physiotherapist. I am aware that I have to follow therapist's instruction as has been told to me.

RISKS AND DISCOMFORT:

I ____________________ understand that there are no potential risks associated with this procedure, and understand that Mr. Dhivakar Murugan/Dr. M. Sankar Sahayaraj will accompany me during this procedure. There are no known hazards associated with this procedure.

CONFIDENTIALITY:

I __________________ understand that the medical information produced by this study will be confidential. If the data are used for publication in the medical literature or for teaching purpose, no names will be used. And photographs, audio and videotapes will be used without identity for publication and presentation.

PHOTOGRAPHY CONSENT:

Mr. Dhivakar Murugan/Dr. M. Sankar Sahayaraj have been explained to me that photography are required in order to illustrate various aspects of the study for the thesis and at the presentation or conference by giving my consent I _______________ authorize Mr. Dhivakar Murugan/Dr. M. Sankar Sahayaraj to use any of the photography taken of me in printed format, in slides for presentation.

REQUEST FOR MORE INFORMATION:

I __________________ understand that I ask any questions about the study at any time Mr. Dhivakar Murugan/Dr. M. Sankar Sahayaraj are available to answer my question. Copy of this concern form will be given to me keep for my careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I _________________ understand that my participation is voluntary and I may withdraw consent and discontinue participation at any time after he has explained the reasons for doing so.

INJURY STATEMENT:

I understand that the treatment procedure, under the guidance of my therapist, is likely to cause any / no injury. In such case medical attention will be provide, but no compensation will be provided. I understand my agreement to participate in this study and I am not waiving any of my legal rights.

I ______________________ confirm that Mr. Dhivakar Murugan/Dr. M. Sankar Sahayaraj have explained me the purpose of the study, the study procedure and possible risk that I may experience. I have read and I have understood this concern to participate as a subject in this study.

_________________ _______________

SUBJECT **DATE**

_________________ _______________

WITNESS TO SIGNATURE **DATE**

I have explained (Mr. Dhivakar Murugan/Dr. M. Sankar Sahayaraj) the purpose of the research, the procedure required and the possible risks and benefits, to the best of my ability.

_________________ _______________

INVESTIGATOR **DATE**

1. Mr. Dhivakar Murugan
2. Prof. Dr. M. Sankar Sahayaraj

ANNEXURE II

ASSESSMENT CHART

SUBJECTIVE ASSESSMENT:

Name:

Age:

Gender:

Occupation:

Address:

Chief complaints:

HISTORY TAKING:

Present medical history:

Past medical history:

Personal history:

Family history:

Socio-economical history:

Treatment history:

- Medical treatment:
- Surgical
- Physiotherapy treatment

OBJECTIVE ASSESSMENT:

ON OBSERVATION:

Attitude of the limb:

Body built:

Posture:

Muscle wasting:

Pattern of movement:

Pressure sore:

Deformity / contracture:

Tropical changes:

Mode of ventilation:

External appliances:

ONPALPATION:

Warmth:

Tenderness:

Tone:

Swelling:

Edema:

VITALS:

Blood Pressure:

Heart rate:

Pulse rate:

Temperature:

ON EXAMINATION:

1. Higher mental function: (examine by using Glasgow coma scale)
2. Cranial nerve examination:

Motor examination:

Muscle tone: (examined by using Modified Aswarth scale)

Reflexes:

Superficial reflex:

Abdominal:

Plantar:

Deep:

Biceps:

Brachioradialis:

Triceps:

Knee:

Ankle:

Jaw:

Sensory Examination:

Superficial sensation:

Pain

Light Touch:

Temperature:

Pressure:

Deep:

Kinesthetic sensation:

Proprioceptive sensation:

Vibratory sensation:

Cortical sensation:

Tactile localization:

Two point discrimination:

Stereognaosis:

Barognosis:

Grasphesthesia:

Recognition of texture:

Double simultaneous stimulation:

Co-ordination:

Non equilibrium test:

Equilibrium test:

Balance:

Siting:

Standing:

Balance reaction:

Gait:

Posture:

Functional assessment:

Diagnosis:

Problem list:

Short term goal:

Long term goal:

ANNEXURE III

ETHICAL CLEARANCE CERTIFICATE

P.P.G COLLEGE OF PHYSIOTHERAPY

(A Unit of P. Perichi Gounder Memorial Charitable Trust)
(Affiliated to the The Tamilnadu Dr. MGR Medical University)
9/1, Keeranatham Road, Saravanampatti, Coimbatore - 641 035
Phone : +91 422 2669562 Cell : 97877 30200
E-mail : ppgphysiotherapy@ppg.edu.in ❖ Website : www.ppg.edu.in

PPG PHYSICAL THERAPY

MR. DHIVAKAR MURUGAN, DATE: 21st NOV 2016

PPG College of Physiotherapy,
Affiliated to the TN DRMGR Medical University,
9/1, Keeranatham Road, Saravanampatti,
Coimbatore – 641 035

Ref: Your dissertation synopsis entitled, **"AN EXPERIMENTAL STUDY ON EFFECTIVENESS OF FUNCTIONAL ELECTRICAL STIMULATION TO IMPROVE FUNCTIONAL MOBILITY AND BALANCE AMONG SUBJECTS WITH SUB ACUTE ISCHEMIC MIDDLE CEREBRAL ARTERY STROKE - A DOUBLE BLINDED RANDOMIZED STUDY "** submitted to the PPGIEC for approval.

Sub: Approval for conducting the referred study.

Dear Mr. Dhivakar Murugan,

The PPG college of Physiotherapy Institutional Ethical Committee (PPGIEC) has reviewed your above mentioned dissertation synopsis, we are pleased to inform you that after due delegations, the PPGIEC has approved your study to be conducted in the presented manner.

The PPG College of Physiotherapy Institutional Ethical Committee expects to be informed about the progression of the study every 3 months, any Serious Adverse Event (SAE) occurring in the due course of the study, and if any changes are made in the protocol or patient information or informed consent. These information should be informed to the PPG IEC in advance and additional permission should be taken from the committee members. The PPGIEC also requires you to submit a copy of the final study report before the given time.

21/11/16

Prof. K. Raja Senthil,
Member Secretory,
PPG College of Physiotherapy Institutional Ethics Committee.

www.ppg.edu.in

ANNEXURE - IV

MASTER CHART

- **BERG BALANCE SCALE:**

BERG BALANCE SCALE					
CONTROL GROUP			EXPERIMENTAL GROUP		
S. NO	PRE TEST	POST TEST	S. NO	PRE TEST	POST TEST
1	25	38	1	29	45
2	26	36	2	28	48
3	29	40	3	29	49
4	28	39	4	30	50
5	30	42	5	31	51
6	32	40	6	25	48
7	33	41	7	26	49
8	27	43	8	32	53
9	26	39	9	33	47
10	24	38	10	26	43
11	32	40	11	28	44
12	30	40	12	29	45

MASTER CHART: 1: Pre and post score value of Berg Balance Scale in both the groups.

- **TIMED UP AND GO TEST:**

SITTING TO STANDING					
CONTROL GROUP			EXPERIMENTAL GROUP		
S. NO	PRE TEST	POST TEST	S. NO	PRE TEST	POST TEST
1	10	9	1	11	7
2	11	9	2	12	8
3	10	9	3	11	7
4	9	8	4	12	7
5	8	8	5	13	6
6	9	8	6	10	6
7	9	7	7	10	6
8	11	8	8	9	5
9	10	9	9	10	5
10	10	8	10	11	6
11	10	8	11	10	6
12	11	10	12	9	6
WALKING 1					
CONTROL GROUP			EXPERIMENTAL GROUP		
S. NO	PRE TEST	POST TEST	S. NO	PRE TEST	POST TEST
1	10	8	1	11	7
2	12	9	2	12	7
3	13	10	3	13	8
4	14	12	4	14	8

5	11	9	5	10	7
6	10	8	6	11	6
7	11	9	7	11	6
8	12	10	8	11	7
9	14	11	9	12	6
10	13	12	10	13	6
11	12	10	11	14	7
12	13	13	12	12	6
TURNING					
CONTROL GROUP			**EXPERIMENTAL GROUP**		
S. NO	**PRE TEST**	**POST TEST**	**S. NO**	**PRE TEST**	**POST TEST**
1	7	6	1	9	5
2	8	8	2	7	4
3	9	8	3	8	6
4	7	6	4	8	5
5	7	6	5	9	4
6	8	6	6	7	5
7	9	8	7	7	5
8	7	6	8	8	4
9	8	6	9	9	4
10	7	5	10	7	4
11	9	6	11	10	5
12	8	7	12	8	4

WALKING 2					
CONTROL GROUP			EXPERIMENTAL GROUP		
S. NO	PRE TEST	POST TEST	S. NO	PRE TEST	POST TEST
1	13	10	1	11	8
2	12	10	2	13	9
3	14	11	3	14	8
4	11	10	4	12	7
5	10	8	5	14	8
6	14	10	6	13	7
7	13	11	7	12	6
8	12	9	8	11	8
9	12	9	9	10	7
10	12	10	10	10	7
11	14	11	11	11	8
12	11	8	12	12	8
TURN SITTING					
CONTROL GROUP			EXPERIMENTAL GROUP		
S. NO	PRE TEST	POST TEST	S. NO	PRE TEST	POST TEST
1	10	9	1	12	8
2	11	9	2	13	7
3	9	8	3	11	9
4	12	10	4	10	8
5	13	11	5	10	7

6	10	8	6	11	8
7	11	8	7	12	7
8	11	9	8	14	8
9	11	10	9	11	9
10	10	8	10	13	8
11	10	8	11	12	9
12	12	9	12	14	10

MASTER CHART: 2: Pre and post score value of Extended timed Up and Go Test in both the groups.