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THE EFFECT OF FUNCTIONAL ELECTRICAL STIMULATION OF THE
ABDOMINAL MUSCLES ON FUNCTIONAL ACTIVITY IN PATIENTS WITH
STROKE: A FEASIBILITY STUDY

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DECLARATION

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ABSTRACT:

Background: Stroke is a leading cause of death and disability in both developed and developing countries. Stroke results in a loss of movement on one side of the body and patients have trouble moving the trunk in relation to the pull of gravity, regardless of which muscle action is required. Re-educating the function of the trunk muscles is essential in successful rehabilitation of patients with stroke. Functional Electrical Stimulation (FES) of the abdominal muscles is an intervention which may result in increasing the activation of these muscles and improving proximal stability and function. However the effects of FES, although proved useful in other muscles groups, have not been tested when applied to the abdominal muscle in patients who have had a stroke.

Aims: The aim of this study was to evaluate the effect of FES of the abdominals on the functional recovery in patients with stroke, when used as part of physiotherapy treatment. Secondary aims are to document the content of physiotherapy received during rehabilitation and compare it to that of published literature.

Study Design and Participants: A single blinded randomised experimental study design was used. Participants were between the ages of 18 to 85 years of age who presented with a first time ever stroke which occurred within the past three months and was confirmed by an MRI or CT scan and a neurologist.

Instrumentation: The Barthel Index (BI) and the Rivermead Motor Assessment were used to monitor changes in function and motor recovery, respectively. The EQ-5D was used to monitor the health related quality of life and the QALY (quality adjusted life year) tariff was calculated. The Physiological Cost Index (PCI) was measured at discharge and at and at the four week follow-up for those participants able to walk either with the use of an aid or independently. Both channels of the FES Microstimulator was applied to the external oblique abdominal muscle on the affected side and was applied from the first day of inclusion to the study. The therapy planners were used to identify how many participants were treated by each physiotherapist. To document the content of physiotherapy, a list of the different types of treatment activities were drawn up and used to identify the different treatment activities performed during the treatment sessions over the study period.

Procedure: The BI was completed on all stroke patients who were admitted to the unit. Informed consent was obtained from potential candidates before admission to

the study. The candidate was then randomised into a group by the collaborators and treatment then commenced. Measurements were taken at admission to the study, discharge (after two weeks of receiving FES to the abdominals) and at four weeks post-discharge follow-up, by the assessor, who was blinded to the group allocation of the participants. The experimental group received FES from the first day of inclusion to the study. The therapy planner, indicated the total treatment time for each session as well as whether FES was applied, was completed daily for every participant at admission to the study by each physiotherapist. Therapist's daily treatment notes for all participants were assessed. The treatment activity list was completed for each participant and the physiotherapist identified on the list.

Data Analysis: Statistical analysis using Stastica version 10 was used to analyse data. Non-parametric statistics were used in most cases, as the sample size was small and the data were generally ordinal. The Chi-square and Mann-Whitney U tests were used to ensure the demographic and hemiplegic related variables were equally distributed between groups. The Mann-Whitney U was used to compare the two groups after the intervention on the ordinal outcome measures. The effect sizes were calculated for the primary outcome variables of BI, RMA Gross Function, the EQ-5DY tariff and the PCI. Analysis was by intention to treat. Spearman correlation coefficients were calculated. Scatterplots were created to depict the relationship between admission and discharge BI score and the change in score. The median change in score from admission to discharge was plotted for each therapist and a Median Test was undertaken to establish if any therapist performed significantly better in terms of one participant's improvement compared to others

Results: There were 19 participants enrolled in the study, nine in the control group and ten in the experimental group. Only the BI scores from admission to follow-up ($p=0.034$), the EQ-5D usual activities at discharge ($p=0.015$) and the PCI at discharge ($p=0.037$) were found to be significantly better in the experimental group. Although not significant on testing, the size of the effect of treatment on the difference in BI scores from admission to discharge was 0.75, a medium effect size. The treatment effect size on the EQ-5D tariff was 0.83 which indicates a large effect. As the PCI scores were not normally distributed, no effect size was calculated. However, the Mann Whitney U indicated a significantly lower ranking of PCI scores in the experimental group, indicating less effort on walking in this group. The therapy intervention received at the Rehabilitation Unit is comparable in quantity and content compared to therapy received internationally.

Discussion and conclusion: There is a clear indication that the use of the FES is feasible and might be beneficial in improving function in patients with stroke. Although the sample sizes were smaller than anticipated and resulted in non-significant probability values on testing, the effect size for most outcome parameters were medium to large. The researcher cannot therefore conclude that the results found were not by chance, but can conclude that the intervention was associated with an improvement in all parameters, apart from the RMA.

This was a pragmatic trial in that it took place within the natural context of in-patient physiotherapy management. The FES was tested as an adjunct to treatment and it was clear from the description of the physiotherapy interventions that the participants received a standard of care which was comparable to that in the published literature. In a clinical trial it would be preferable to remove these confounding interventions from both groups and to compare the outcome simply of FES or no FES. This was clearly not ethically or practically possible and hence the trial was pragmatic. The effect of FES can therefore be regarded as adding marginal value to an already comprehensive programme. The medium to large, effect sizes would therefore indicate that FES does add value to the conventional therapy.

In conclusion, application of FES of the abdominal muscles is a feasible. It can be integrated, albeit cautiously, into physiotherapy management and the impact monitored on an on-going basis. As the results are promising but not conclusive, there is room for a large scale, multi-centre trial to further investigate the efficacy of this intervention. It would also be useful to test the effects of FES in a situation where regular, high quality therapy is not available on a daily basis as it might be an affordable method of providing therapy to those unable to receive regular therapy.

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ABBREVIATIONS:

FES:	Functional Electrical Stimulation
RMA:	Rivermead Motor Assessment
PCI:	Physiological Cost Index
BI:	Barthel Index
WHR:	Walking Heart Rate
RHR:	Heart Rate
HRQoL:	Health Related Quality of Life
NDT:	Neurodevelopmental therapy
WHO:	World Health Organisation
ADL:	Activities of daily living
VAS:	Visual Analogue Scale
EO:	External Oblique
IO:	Internal Oblique
TrA:	Transverse Abdominus
RA:	Rectus Abdominus
ODFS:	Odstock Dropped Foot Stimulator
ICF:	International Classification of functioning and disability
hz:	Hertz
mA:	Milliamps
µs:	Microseconds
SD:	Standard Deviation
CI:	Confidence Interval
QALY:	Quality adjusted life year

1. INTRODUCTION:

1.1 BACKGROUND TO THE STUDY

Stroke is a leading cause of death and of disability in both developed and developing countries (Duncan et al., 1992, Connor and Bryer, 2006, (SASPI), 2004b, Sommerfeld and Von Arbin, 2001). Stroke survivors may require assistance with activities of daily living and this has an impact on their quality of life (Dewar, 1990, Connor and Bryer, 2006). Disability caused by stroke can be permanent and places a burden on a country's health system and economy (Connor and Bryer, 2006).

Rehabilitation plays an important role in aiding the recovery of function and decreasing permanent disability and should start early (Group, 2000). The therapist requires a good evidence-based knowledge of recovery in order to plan a clinically effective, goal-orientated treatment program (Ashburn, 1997). The main objective of rehabilitation is to assist the patient in achieving the highest level of independence, which would allow them to integrate into the home and community as fully as possible (Kwakkel et al., 2004). There is evidence emerging that greater intensity of exercises are the basis of effective rehabilitation after stroke (Stein, 2004). Many studies have helped to identify the pattern of muscle activation after a stroke and this helps the therapist to gain a better understanding of general impairments and trunk impairments as well as therapeutic methods required to improve trunk function after stroke (Dickstein et al., 2004a).

The trunk provides a stable anchor to allow movement of the upper and lower limbs (Davies, 1990). Co-ordination between the trunk and the limbs is needed to perform everyday movements (Michaelsen et al., 2004). Stroke causes a loss of motor control on one side of the body (Ashburn, 1997, Davies, 1990). Stroke patients have trouble moving the trunk in relation to the pull of gravity, regardless of which muscle action is required. There is a notable loss of trunk activity and tone (Davies, 1990). Co-ordination of trunk and limbs is disrupted in stroke and results in the use of compensatory patterns to perform the tasks (Michaelsen et al., 2004) There is also greater trunk activity which results in trunk compensatory strategies in reaching after a stroke (Cirstea and Levin, 2000, Roby-Brami et al., 2003). Trunk recruitment and

trunk rotation is significantly higher in stroke individuals than in healthy individuals when reaching (Cirstea and Levin, 2000).

Research, however, is still lacking as to the nature of the impact of stroke on the trunk muscles (Winzeler-Mercay and Mudie, 2002). Tsuji et al suggests that re-educating the function of the trunk muscles is essential in successful rehabilitation of patients with stroke. This is especially important for basic activities of daily living (Tsuji et al., 2003).

Surface electrical stimulation is the most commonly used electrical modality used to regain function in the clinical setting. Functional Electrical Stimulation (FES) is one of these techniques used in therapy (Durfee, 1999). FES involves the use of electrical stimulation to evoke muscle contraction, thereby assisting functional movements in an individual with neurological deficits. FES is a form of neuromuscular stimulation which causes contraction of weak or paralysed muscles (Taylor et al., 1999). It also causes an increase in the recruitment of muscle motor units which result in a stronger muscle contraction (Bajd and Muni, 2010). A systematic review done by Glinsky et al, suggests that electrical stimulation included in therapy, results in a substantial increase in muscle strength of a weak muscle after stroke (Glinsky et al., 2007). In the US, the use of FES during physiotherapy session is routine (Durfee, 1999). The application of FES can include increasing joint range of motion and muscle strength. Muscles commonly strengthened with FES application, are the wrist extensors, ankle dorsiflexors, quadriceps and hamstrings as well as gluteus muscles. A lesser known application of FES is to reduce shoulder subluxation (Durfee, 1999). A literary search, however yielded no papers in which FES was applied to the abdominal muscles during a physiotherapy session in the treatment of stroke.

1.2 AIMS OF THE STUDY:

The aim of this study was to evaluate the effect of FES of the abdominals on the functional recovery in patients with stroke, when used as part of physiotherapy treatment and patient's perception of Health Related Quality of life after stroke. Secondary aims are to document the content of physiotherapy received during rehabilitation and compare it to that of published literature.

1.3 SPECIFIC OBJECTIVES:

The primary objective was to determine if there is a significant difference in mean score or ranking between participants who receive FES of the abdominals and conventional physiotherapy and a control group who will only receive conventional physiotherapy with regard to:

- The activities related to functional independence as measured by the Barthel Index (BI) and the Rivermead Motor Assessment (RMA).
- The Health Related Quality of Life (HRQoL) as measured by the EQ-5D.
- In those participants who are able to ambulate independently, in the Physiological Cost Index (PCI) of walking.

A secondary objective was to document the content of physiotherapy intervention that the participants received and to compare it to that of physiotherapy interventions found in published literature by:

- Identifying the most common treatment modalities used by the therapists involved in the study.
- Comparing the spread of modalities with those offered by other facilities and described in the literature.

1.4 RESEARCH SETTING

The Hospital (not named in order to respect confidentiality) is a private in-patient rehabilitation facility, which specialises in the treatment of neurological and spinal conditions. As patients are responsible for their own fees, either directly or through medical aid societies, the patients tend to be of a higher socio-economic bracket than the general population. The rehabilitation unit utilises a multidisciplinary approach. The multidisciplinary team consists of one neurologist, five physiotherapists, three occupational therapists, a speech therapist, social worker and dietician. The physiotherapists who participated in the study were all trained in Neuro-Developmental Therapy (NDT) and FES. The physiotherapists had experience ranging from 2 years to 15 years in the acute rehabilitation treatment setting.

The Rehabilitation Unit admitted three to seven stroke patients a month. Length of stay was dependent on funding (private or medical aid) and was negotiated with the relevant parties before admission. The recommended length of stay was two to four

weeks for moderate stroke (patient requires assistance with activities of daily living but is able to assist in these tasks) and four to six weeks for severe stroke (patient requires assistance with activities of daily living and unable to assist in these tasks). The average length of stay was approximately four weeks.

Patients received daily therapy (physiotherapy, occupational therapy and if indicated speech therapy) during their stay at the rehabilitation unit and the physiotherapy was provided by four physiotherapists. Families and friends received caregiver training as well as general advice. The therapy team assisted in the ordering of equipment required for discharge.

Weekly multidisciplinary meetings were held to discuss patient progress and to set goals for each patient for that week.

There was a daily activity program set up for patients. The daily program included activities of daily living (ADL) such as showering, dressing and transfers in the ward. Experienced rehabilitation nursing staff assisted the patients with these activities and reported back to the therapy staff if any problems were encountered with ADL activities. The program encouraged patients to carry over what they had learned in therapy in the general ward. Patients were allocated definite time slots for each therapeutic discipline thereby ensuring that each patient received the same amount of therapy hours in a day. Patients received one hour of therapy per therapy discipline. If a patient could not cope with a full hour of therapy, then the hour was divided into half hour slots till the patient was able to cope with a full hour. The program was set up in such a way that therapy sessions were spread out and ADL activities were included without causing the patient to fatigue.

The Rehabilitation Unit closed on the 31 October 2011 and patients were referred to another private hospital. This situation was not anticipated at the commencement of the study and resulted in a premature cessation of data collection.

1.5 SIGNIFICANCE OF STUDY:

Therapists are particularly concerned with the return of motor control of post-stroke patients (Ashburn, 1997). Trunk recovery is a neglected area of research in stroke rehabilitation when compared to research performed on limb rehabilitation (Verheyden et al., 2007). There is also a lack of research which evaluates treatment aimed at improving trunk function (Verheyden et al., 2009). It is important for

therapists to develop evidence-based treatment strategies, which aim at improving trunk function. Therapy interventions should focus on trunk activation patterns to improve trunk strength and stability in patients with stroke (Pereira et al., 2010).

FES is the application of an electrical impulse to a muscle, at the point closest to the peripheral nerve or nerve root, which results in a muscle contraction that aids in both functional and beneficial movement in persons who have sustained an Upper Motor Neuron Lesion (Donovan-Hall et al., 2011, Thrasher and Popovic, 2008, Dimitrijevic, 2008). FES is one method of increasing the activation of motor units required to perform a muscle action (Bajd and Munih, 2010). FES is a feasible, affordable and easily applied modality, which could be integrated routinely into the physiotherapy treatment of stroke patients in the acute stages.

1.6 OUTLINE OF CHAPTERS:

Chapter one described the basis of the study. This includes aims and objectives of the study, the research setting and the significance of the study.

Chapter two is the literature review which highlights the current literature on stroke aetiology and stroke rehabilitation. It also highlights the effect of stroke on the trunk and impairments after stroke.

Chapter three presents the methodology of the study. It highlights the sample, instrumentation, data collection and data analysis used in the study.

Chapter four presents the results of the study. The demographic characteristics of the sample are presented as well as the results of the outcome measure used.

Chapter five is the discussion which attempts to interpret the results of the current study and comparisons of the current study to similar studies.

Chapter six is the conclusion and recommendations which summarises the main finding of the current study and proposals for future studies are suggested.

2. LITERATURE REVIEW

2.1 INTRODUCTION:

This chapter reviews the current literature on the incidence, economic burden, aetiology and rehabilitation of stroke. The body of this chapter covers literature on stroke impairments, the trunk, the effect stroke has on trunk function and FES. This chapter also contains a review of current literature on rehabilitation interventions and therapeutic programmes, predictors of outcome and outcome measures commonly used in rehabilitation and clinical investigations of stroke.

Searches on PUBMED, EBSCO, Ovid, CINAHL and PEDRO databases were used. Keywords such as stroke, FES, abdominal strengthening, trunk control, motor impairments and rehabilitation were used to identify relevant literature.

2.2 INCIDENCE, MORTALITY AND PREVELANCE OF STROKE:

Stroke is the second most common cause of death worldwide (Strong et al., 2007, WHO, 2004). In 2004, an estimated 5.7 million people died of stroke, nine million people suffered their first-ever stroke and there were 30, 7 million stroke survivors globally (WHO, 2004). People with disability after a stroke account for an estimated 12,6 million worldwide (WHO, 2004). It was estimated that there were 16 million first-ever stroke in 2005 (Strong et al., 2007).

Stroke was ranked as the third leading cause of death in South Africa in 2000 (Norman et al., 2007) In 2002, stroke resulted in 22 474 reported deaths in South Africa, of which 2,657 stroke related reported deaths were in the Western Cape (Lehohla, 2004). In 2007, stroke accounted for 5% of reported deaths in South Africa (Bradshaw et al., 2010). Connor and Bryer reported that stroke was the most common cause of death in the 55-74 year old age group and the second most common in the 35-54 year old and ≥ 75 year old age group (Connor and Bryer, 2006). Stroke mortality in South Africa is already high and the prevalence of people requiring help with activities of daily living is already higher than that of high-income countries (Connor and Bryer, 2006, Foundation, 2009, (SASPI), 2004b).

Approximately 66% of stroke survivors in South Africa require assistance with activities of daily living, while only 22% of stroke survivors in New Zealand require assistance with activities of daily living ((SASPI), 2004a)

Should health trends continue as they are, the World Health Organization (WHO) predicts that stroke will continue to be one of the top leading causes of death by 2030. Stroke mortality could increase to eight million, an estimated 23million people to suffer first-ever stroke and prevalence of stroke could increase to 77 million, globally, by 2030 (Strong et al., 2007, WHO, 2004).

The prevention of stroke mortality and reduction in morbidity will pose increasing challenges to the already overburdened health care system of South Africa.

2.3 ECONOMIC BURDEN:

Stroke related death and disability places a strain on the national income and health system of a country (Connor and Bryer, 2006, Abegunde et al., 2007). The burden of stroke is higher in developing countries than that of developed countries but will continue to grow in developing countries (Strong et al., 2007, Pongvarin, 1998) Developing countries have fewer resources to allocate to the prevention and treatment of stroke both in absolute and relative terms as most of the resources are used in the treatment of infectious diseases (Johnston et al., 2009, Abegunde et al., 2007).

In 1997, Australia spent an estimated U\$420 million on costs related to stroke (Paul et al., 2007). The cost of stroke in the United States in 2005 exceeded U\$50 billion (Tattisumak and Rantanen, 2007). In the United Kingdom, it is estimated that £57 235 is spent on one person who has had a stroke, over a 5 year period. This cost includes acute care, social services and informal care (Youman et al., 2003).

It is estimated that in 2006, South Africa lost U\$0.6 billion in national income due to stroke, cardiovascular disease and diabetes and this amount could increase to U\$1.8 by 2015 (Abegunde et al., 2007). The impact that stroke has had on the health service and society in South Africa is not known but is being researched (Connor and Bryer, 2005).

An intervention which could reduce the functional limitations of people who have had stroke would help to reduce the long term impact of the disease.

2.4 AETIOLOGY:

2.4.1 Age and Gender:

Stroke affects persons of all ages and gender. However, increases with age and the risk of the onset of first ever stroke increases significantly over the age of 65 years (Kelly-Hayes et al., 2003, Anderson et al., 2010). At this age, gender is not a risk factor as men and women are at equal risk. Women, however tend to live longer than men and are at a higher risk of stroke over the age of 85 years (Anderson et al., 2010, Ones et al., 2009, Kelly-Hayes et al., 2003). Women also present with higher medical risk factors at this age and are more likely to be dependent in ADL after stroke (Kelly-Hayes et al., 2003).

In developing countries like Africa, most incidences of stroke occur at a younger age compared to developed countries (Bonita and Truelsen, 2003). This is partly due to the incidence of HIV/AIDS which is linked to stroke and the lack of resources available for stroke prevention and treatment (Johnston et al., 2009).

2.4.2 Modifiable Risk Factors:

Some of the most common modifiable risk factors for stroke are hypertension, diabetes mellitus, raised cholesterol, smoking and alcohol consumption. Hypertension was the strongest risk factor for stroke followed by diabetes mellitus (O'Donnell et al., 2010). Persons diagnosed with diabetes mellitus also have a higher risk of presenting with cardiac conditions and increased cholesterol levels (Ones et al., 2009). The risk of stroke also increases with an increase in the number of cigarettes smoked per day but the risk decreases when an individual stops smoking. Alcohol consumption of more than 30 drinks per month and binge drinking increases the risk of stroke compared to persons who no longer drink or have never consumed alcohol. Conversely, persons who consume one to 30 drinks per month decrease the risk of stroke (O'Donnell et al., 2010).

In a study conducted by the South African Medical Research Council, alcohol consumption, smoking, diabetes and hypertension are listed in the top ten risk factors for the burden of disease and injury in South Africa (Norman et al., 2007). The South Africa Stroke Prevention Initiative (SASPI) conducted a study in the north east district of rural South Africa to investigate the prevalence of risk factors and

preventative interventions in patients with stroke. The results of the study reported that 11.7% of participants were diabetic, 10.7% had cardiac conditions, 8.7% were smokers, 20.4 % consumed alcohol and 70.9% were hypertensive ((SASPI), 2004b).

The WHO has undertaken to decrease the incidence and mortality of stroke worldwide. To achieve this, the incidence of modifiable risk factors has to be reduced and this can only be achieved by education and change in lifestyle (O'Donnell et al., 2010, Strong et al., 2007)

2.4.3 Types of Stroke:

2.4.3.1 Haemorrhagic Stroke:

Haemorrhagic stroke accounts for 20% of all strokes and carries a high risk of immediate stroke mortality (Paolucci et al., 2003, Collins, 2007, Hopkins, 2005). Those patients who do survive, show better neurological and functional prognosis compared to ischemic strokes (Collins, 2007). Haemorrhagic stroke occurs when a cerebral blood vessel ruptures or tears and results in bleeding into the brain tissue(Hopkins, 2005, Collins, 2007).

There are two types of haemorrhagic strokes, namely intracerebral and subarachnoid haemorrhage (Hopkins, 2005). Intracerebral haemorrhage is described as bleeding which occurs in the deep tissue of the brain (Hopkins, 2005). This type of stroke occurs mostly in older persons and shows a better prognosis of neurological recovery as the haematoma resolves (Paolucci et al., 2003, Hopkins, 2005). Subarachnoid haemorrhage is described as bleeding which occurs between the brain and the skull (Hopkins, 2005). Subarachnoid stroke is uncommon and occurs mostly in younger persons but has the most fatalities of the stroke subtypes (Hopkins, 2005, van Gijn et al., 2007). It accounts for almost four percent of stroke but has a 40% mortality rate within the first month after a stroke (Whiteley, 2006).

2.4.3.2 Ischemic Stroke:

Ischemic stroke accounts for almost 80% of all strokes (Hopkins, 2005, Donnan et al., 2008). When the blood vessels in the brain become blocked, the brain tissue is starved of oxygen and nutrients and the neurons are damaged (Hopkins, 2005). There are two types of ischemic strokes, namely thrombotic and embolitic stroke (Hopkins, 2005). Thrombotic stroke occurs when a blood clot forms in the artery and

blocks off the blood flow to the brain. It is the most common of the ischemic type (Hopkins, 2005). Embolitic stroke occurs when a blood clot from another part of the body lodges itself in the brain. It is commonly associated with atrial fibrillation (Hopkins, 2005).

2.5 GENERAL IMPAIRMENTS AFTER STROKE:

Impairments after stroke are numerous and the severity of the impairment is dependent on the severity of the stroke (Shumway-Cook and Woollacott, 2007, Connell et al., 2008). Impairments range from motor, sensory, perceptual, cognitive and behavioural (Paolucci et al., 2009). These impairments can lead to permanent disability (Cirstea and Levin, 2000).

2.5.1 Motor Impairments:

After a stroke, muscle weakness occurs in the upper and/or lower limb and trunk on one side of the body (Andrews and Bohannon, 2000). Muscle weakness or paresis in stroke is a result of an inability to recruit motor units to generate sufficient force and tension in a muscle for movement and posture. This results in a loss of movement (Shumway-Cook and Woollacott, 2007). This in turn affects the ability to perform functional tasks such as reaching, walking and balancing in sitting (Andrews and Bohannon, 2000, Shumway-Cook and Woollacott, 2007).

Coordination of normal movement requires the activation of muscles in the correct sequence, time and grading when performing a movement. Changes in the central nervous system, after a stroke, result in the inappropriate activation and sequencing of muscles. This leads to impaired coordination over multiple joints when performing a movement. The timing of the muscle activation is also important. Inappropriate activation time can result in the delay in initiating movement or the timing of executing a movement or the time required to stop movement. Grading of forces is also affected and this results in the overshooting or undershooting of movement when reaching or pointing (Shumway-Cook and Woollacott, 2007).

Muscle weakness, poor coordination, incorrect timing and poor grading of movements result in the use of compensatory movement strategies. One of these strategies is the fixation of a body segment in order to limit the degrees of freedom required to perform a movement (Cirstea and Levin, 2000, Shumway-Cook and Woollacott, 2007). The fixation patterns that occur are the pelvis on the lumbar

spine and the scapula on the thoracic spine. This is in response to the maintenance of postural balance during movement. The trunk compensates by increasing the degrees of freedom of the trunk required during movement of the upper and lower limbs (Cirstea and Levin, 2000). The excessive trunk movement inhibits the recovery of normal patterns of movement and functional recovery (Roby-Brami et al., 2003).

2.5.2 Sensory Impairments:

Position sense in relation to body parts and the environment is essential for coordinated movement. Sensory impairments contribute to the loss of motor control (Shumway-Cook and Woollacott, 2007). Loss of proprioception and stereognosis are more common impairments than the loss of tactile sensation (Connell et al., 2008). Somatosensory deficits relate to poor upper limb function especially with regard to reaching and finger pointing (Gao et al., 2010).

Visual-field impairment can also occur after stroke as a result of damage to the cerebral cortex. This results in the loss of visual information in one half of the visual field. Visual impairments affect depth perception and visual acuity which are important for mobility (Shumway-Cook and Woollacott, 2007).

Persons who present with sensory impairments will also present with perceptual and cognitive impairments (Shumway-Cook and Woollacott, 2007).

2.5.3 Perceptual Impairments:

Perception is described as the integration of sensory stimuli into meaningful information and is dependent on an intact sensory system (Shumway-Cook and Woollacott, 2007). Perceptual impairments are divided into various components. These are body scheme, unilateral neglect, spatial relation, agnosia and apraxia (Shumway-Cook and Woollacott, 2007, Paolucci et al., 2009). Perceptual impairments affect the way a person interacts with the environment and affects the functional outcome in stroke (Shumway-Cook and Woollacott, 2007).

2.5.4 Gait Impairments:

Impairments of gait and mobility are common after stroke (Hakansson et al., 2011, Robertson et al., 2010). Weakness of muscles in the lower affects gait and mobility performance (Andrews and Bohannon, 2000). Weak dorsiflexors which result in dropped foot results in patients developing compensatory strategies such as hip circumduction and excessive knee extension to ensure sufficient clearance of the foot in gait. These compensatory strategies result in an increase in the effort in walking (Robertson et al., 2010, Sabut et al., 2010b, Sabut et al., 2010a).

Patients with stroke have an increased oxygen consumption level with exercise after stroke. The oxygen consumption level is abnormally high with walking. The increase in oxygen consumption indicated an increase in the effort of performing tasks such as exercises and walking (Sabut et al., 2010b). In a study conducted by Fredrickson et al the PCI of stroke and healthy individuals were compared after walking on a treadmill at a constant speed for seven to ten minutes. It was found that PCI was abnormally elevated in stroke patients compared to healthy individuals. Fredrickson et al also reported that gait speed in stroke patients were significantly slower than healthy individuals (Fredrickson et al., 2007a).

Therapeutic interventions are not only aimed at improving the motor impairments but also at decreasing the effort required to perform tasks such as walking (Robbins et al., 2006, Fredrickson et al., 2007a). By measuring the effort of walking and the effect of therapeutic intervention has on the improvement of gait in stroke (IJzerman and Nene, 2002, Fredrickson et al., 2007a).

The PCI is one easy and cost-effective method of measuring the effort of walking in stroke(Fredrickson et al., 2007a). The PCI is discussed later in the chapter.

2.5.5 Cognitive impairments:

Cognition is defined as the process of acquiring, retrieving and sorting of information (Shumway-Cook and Woollacott, 2007).

Stroke can also affect a person's orientation to time, person and place. Stroke can affect a person's ability to concentrate on tasks without being distracted and also affects the ability of a person to shift attention from one subject to another.

Short term memory and/or long term memory can be affected after stroke (Shumway-Cook and Woollacott, 2007). Explicit motor learning strategies are also affected after stroke. Explicit learning occurs when a person is given instructions on how to perform a task (Shumway-Cook and Woollacott, 2007, Orrell et al., 2006). Recent studies have also suggested that use of explicit motor learning strategies in the rehabilitation of stroke are not effective in retraining a motor task and result in diminished ability to complete a motor task (Shumway-Cook and Woollacott, 2007, Orrell et al., 2006). Implicit motor learning strategies are less impaired after stroke (Boyd and Winstein, 2003, Boyd and Winstein, 2000, Shumway-Cook and Woollacott, 2007). Implicit motor learning is the ability to perform a motor task without verbal instruction and can be achieved by repetition of movement (Shumway-Cook and Woollacott, 2007, Orrell et al., 2006). Recent studies have suggested that patients show greater improvement in performing motor tasks in rehabilitation where implicit motor learning strategies are employed (Orrell et al., 2006, Boyd and Winstein, 2003, Boyd and Winstein, 2000).

2.6 THE TRUNK:

The core is considered to be the centre of a functional kinetic chain (Akuthota and Nadler, 2004, Borghuis et al., 2008). The musculature of the core is seen as a corset or girdle that works as a unit to provide a stable base for forces exerted during limb movement and in the absence of limb movement (Anderson and Behm, 2006, Borghuis et al., 2008, Akuthota and Nadler, 2004).

2.6.1 Anatomy of the Trunk:

The core is described as a box, with the diaphragm as the roof, the pelvic floor muscles and pelvis as the floor, the paraspinal muscles as the back and the abdominal muscles as the front of the box (Borghuis et al., 2008, Kibler et al., 2006).

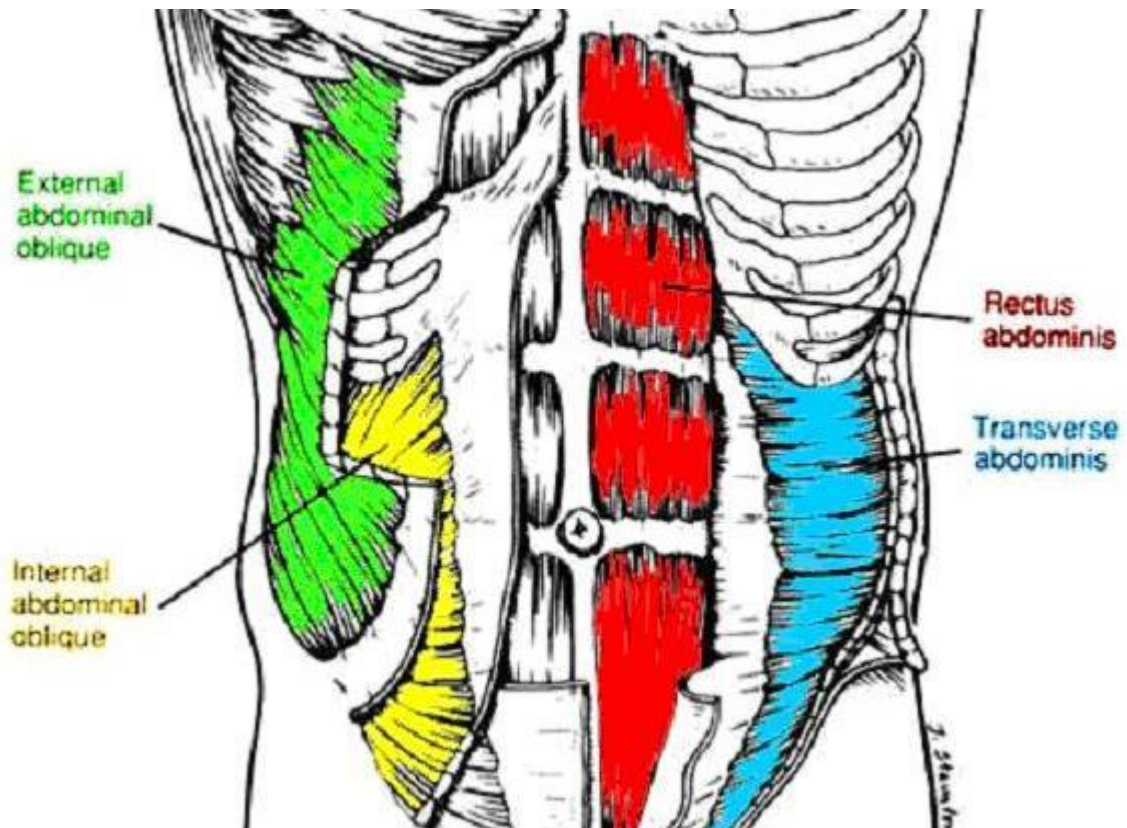


Figure 1: Abdominal muscles (Kmaru, 2011)

External Oblique (EO) (Figure 1) is the most superficial layer of the abdominal muscles and forms the anterior wall of the abdomen (Palastanga et al., 2006, Davies, 1990). Its fibres run medially from the ribs to the midline. The upper fibres of the muscle interdigitate with Serratus Anterior and Latissimus Dorsi and thus provide stability for the scapula and arm movements. The posterior fibres run vertically and insert on the anterior part of the iliac crest. The rest of the fibres run in a downward direction and insert into the aponeurosis which forms a part of the rectus sheath (Palastanga et al., 2006, Davies, 1990, Thibodeau and Patton, 2004, Tyldesley and Grieve, 2002). The EO contracts eccentrically with lumbar extension in the frontal plane and also pulls the pelvis into anterior pelvic tilt (Akuthota and Nadler, 2004).

The Internal Oblique (IO) (Figure 1) is the middle layer of the abdominal muscles and the muscle fibres run at right angles to the EO (Davies, 1990, Thibodeau and Patton, 2004). The muscle fibres run from the inguinal ligament, iliac crest and thoracolumbar fascia and fan out to the lower ribs and aponeurosis. The left and right aponeurosis form the linea alba which runs from the ribs to the pubis (Davies, 1990, Tyldesley and Grieve, 2002, Thibodeau and Patton, 2004, Palastanga et al.,

2006). The IO is a major stabiliser of the trunk. Along with EO, the IO plays an important role in trunk rotation and flexion. It also contributes to the production of intra-abdominal pressure (Hodges and Richardson, 1997a). The IO acts as part of a local stabilising system of the spine where low force production provides functional stability. The muscle activity increases in anticipation of movement (Anderson and Behm, 2006).

Transverse Abdominus (TrA) (Figure 1) is the innermost layer of the abdominal muscles and its fibres run transversely (Davies, 1990, Tyldesley and Grieve, 2002). The fibres run from the inguinal ligament, iliac crest, and thoracolumbar fascia posteriorly and lower six ribs superiorly. The muscle interdigitates with the diaphragm. Some of the muscle fibres run horizontally to fuse with the aponeurosis of the EO and continue till the linea alba. The rest of the muscle fibres run downward and join the IO and forms the conjoint tendon and attaches to the pubis (Tyldesley and Grieve, 2002, Davies, 1990, Thibodeau and Patton, 2004, Palastanga et al., 2006). The TrA is activated before limb movement (Akuthota and Nadler, 2004) The TrA is the first muscle to be activated before a movement and is considered to be the muscle involved in preparing the body for movement (Hodges and Richardson, 1997a, Hodges and Richardson, 1997b). The TrA is also involved in production of intra-abdominal pressure (Cholewicki and JJ, 2002, Hodges and Richardson, 1997a).

Rectus Abdominus (RA) (Figure 1) runs from the sternum to the pubis. The fibres run vertically and are interrupted by fibrous bands which are formed by the aponeurosis of the EO and IO. These bands divide the muscle into 3 sections vertically and the linea alba separates the two muscles on either side (Palastanga et al., 2006, Davies, 1990, Thibodeau and Patton, 2004, Tyldesley and Grieve, 2002). The contraction of RA results mainly in lumbar flexion in the frontal plane (Akuthota and Nadler, 2004).

2.6.2 Trunk Stability:

There is more than one definition used to describe core stability (Borghuis et al., 2008, Kibler et al., 2006).

Core stability involves complex interaction of different systems which control movement (Friedli et al., 1984). Panjabi described core stability as a system consisting of three subsystems which are interdependent. The passive subsystem

does not contribute significantly to stability but develops reactive forces. The passive subsystem is involved in monitoring the transducer signals. Transducer signals are produced by vertebral position and movement. The active subsystem consists of the muscles and tendons which generate the forces required for stability. The neural control subsystem determines the force required for stability and causes the active subsystem to adjust to achieve optimal stability (Panjabi, 1992).

Kibler et al describe core stability as “the ability to control the position and motion of the trunk over the pelvis and leg to allow optimum production, transfer and control of force and motion to the terminal segment in integrated kinetic chain activities” (Kibler et al., 2006).

Trunk stability is more complex than just trunk stiffness and the control mechanisms are extremely efficient (Thrasher et al., 2010). The muscles of the trunk contract in a coordinated manner (Thrasher et al., 2010) and this coordination of trunk muscle activation is one of the elements of trunk stability (McGill, 2000). The nervous system also plays an important role in the coordination of focal movement (Anderson and Behm, 2006). The feedback and feed forward systems from the somatosensory, vestibular and visual input systems achieve stability in postural equilibrium. The brainstem and cerebellum process information received and motor commands are then initiated to maintain balance (Anderson and Behm, 2006). The motor control system is needed to coordinate muscle co activation (McGill, 2000). The basal ganglia and cerebellar play a role in the planning of movement (Friedli et al., 1984)

Core stability is important for maintaining static and dynamic balance and is necessary to perform activities of daily living and sport (Anderson and Behm, 2006). When there is disruption of the neuromuscular system, core stability is affected which results in poor performance and injury (Anderson and Behm, 2006, Zazulak et al., 2007).

2.6.3 Trunk Kinematics:

The trunk muscles serve as prime movers, anticipatory postural adjustors during movement and automatically response to perturbations of the trunk or limbs in unexpected movement (Dickstein et al., 2004a). Thus, it also provides a stable anchor to allow movement of the upper and lower limbs (Davies, 1990).

According to Hodges and Richardson (1997), the contraction of IO and EO is not dependent on the change in movement direction and reactive forces produced by movement. This adds to the stability of the spine during movement irrespective of movement direction. The TrA first activates muscles to contract before any limb movement occurs, thereby preparing the body for movement. This is important as the feed forward mechanism for other trunk muscles is activated. The TrA activation assists in the production of rotation (Hodges and Richardson, 1997a). Rotation of the trunk is performed by the Oblique muscles (Davies, 1990). In gait the Oblique muscles perform a cyclic movement which requires stability of one side of the abdominal muscles in order for the opposite side to move. The twisting movement allows for the movement of the lower limb and the opposite upper limb in gait (Lee et al., 2010).

The muscle fibre arrangement of EO and Seratus Anterior allow for optimal counter fixation of the ribs. This results in a stable thorax which allows smooth movement of the scapular thereby allowing smooth shoulder movement for reaching (Davies, 1990). Co-ordination between the trunk and the arm is needed for reaching. This co-ordination is disrupted in stroke and results in the use of compensatory patterns to perform the task of reaching (Michaelsen et al., 2004) There is also greater trunk activity which results in trunk compensatory strategies in reaching after a stroke (Cirstea and Levin, 2000, Roby-Brami et al., 2003). Trunk recruitment and trunk rotation is significantly higher in stroke individuals than in healthy individuals when reaching (Cirstea and Levin, 2000).

2.7 IMPAIRMENTS OF TRUNK:

The most significant impairment after a stroke is the loss of motor control (Stein, 2004, Davies, 1990). This results in a loss of selective muscle activity in the trunk muscles which causes trunk muscle weakness (Davies, 1990). Poor recruitment of muscle motor units is one possible explanation for trunk weakness, while another explanation is that upper motor neurone lesions result in bilateral trunk weakness (Karatas et al., 2004). Trunk weakness results in poor trunk posture and asymmetry is noticeable (Chern et al., 2010, Karatas et al., 2004). Due to the lack of trunk stability, post stroke, upper and lower limb movements are affected and compensatory patterns are used to execute movements (Davies, 1990). The lack of trunk stability has far reaching effects on ADL and functional independence. Activities such as reaching and walking place demands on the trunk and this can

lead to injuries, for example falls (Chern et al., 2010). To perform functional activities when sitting or standing, it is necessary to maintain trunk stability (Karatas et al., 2004)

There is also a decrease in trunk muscle strength but this is difficult to measure. It is difficult to isolate individual trunk muscles and exclude limb movements when trying to measure trunk muscle strength (Tsuji et al., 2003)

There is a lack of research in the area of trunk muscle activity but recent studies on trunk muscle activation using electromyography post stroke indicate that there is a delay and lack of activation of trunk muscles on the affected side after stroke (Karatas et al., 2004, Tsuji et al., 2003, Pereira et al., 2010). Studies by Dickstein et al and Pereira et al have identified the poor motor control and motor unit recruitment of trunk muscles when performing an action (Pereira et al., 2010, Dickstein et al., 2004a, Dickstein et al., 2004b). Dickstein reports the malfunction of the EO muscle on the hemiparetic side post stroke and that the unaffected side EO overcompensates resulting in movement that is not beneficial to the patient after stroke (Dickstein et al., 2004b). These studies have helped to identify the pattern of muscle activation after a stroke. It also, helps the therapist to gain a better understanding of trunk impairments and therapeutic methods required to improve trunk function after stroke (Dickstein et al., 2004a).

2.8 METHODS OF PHYSIOTHERAPY INTERVENTION

The therapist requires a good evidence-based knowledge of recovery in order to plan a clinically effective, goal-orientated treatment program (Ashburn, 1997). The efficacy, effectiveness, efficiency and applicability of stroke interventions should be considered in evidence-based practice (Langhorne et al., 2009). There are, however, gaps in the research to assist clinicians in choosing and defining effective interventions, thus resulting in clinical practises which are based on the knowledge and experience of the individual clinician (Langhorne et al., 2011).

De Wit et al conducted a study to define the content of physiotherapy and occupational therapy session in the rehabilitation of stroke. A list of 12 categories (with 49 subcategories) consisting of mobilization, selective movement, lying and sitting balance, sitting and sitting balance, standing and standing balance, sensory and visual perception, transfers, ambulatory activities, personal activities of daily living, domestic activities of daily living, leisure and work related activities,

miscellaneous techniques(De Wit et al., 2007a). Using this list, De wit et al was able to distinguish between the content of physiotherapy and occupational therapy session in the rehabilitation of stroke across Europe. The study reported that the categories of selective movements, exercises and balance in sitting and standing and ambulatory exercises were mostly recorded in the physiotherapy sessions. Physiotherapists tend to focus on exercises and balance in lying and sitting to improve mobility in their treatment sessions (De Wit et al., 2006).

There are various physiotherapy approaches used in the treatment of stroke (Pollock et al., 2001). Examples of studies which compare different physiotherapy approaches to aid the recovery of postural control and lower limb function and their effects are listed in Table 1, below:

Table 1: Table of studies which compare physiotherapy approaches

Study	Bobath or motor relearning programme? A comparison of two different approaches of physiotherapy in stroke rehabilitation
Author	(Langhammer and Stanghelle, 2000)
Treatment Approach	Bobath and Motor learning
Participants	61 Participants with first time ever stroke randomised into two groups. 33 participants in Bobath group and 28 in the motor learning program
Results	Motor learning program is preferable to Bobath approach in the acute stage of rehabilitation.
Study	Randomised clinical trial of therapeutic exercise in sub-acute stroke
Author	(Duncan et al., 2003)
Treatment Approach	Exercise program designed to improve strength, balance and endurance (Mixed treatment methods). Usual care as prescribed

Participants	by physicians (placebo) 100 participants randomised into two groups with 50 participants in each group
Results	A structured exercise program proved more beneficial than usual care. This indicated that patients benefit substantially from a structured rehabilitation program. Exercise programs aimed at improving strength, balance and endurance in stroke is beneficial and does not increase spasticity
Study	Comparison of Bobath based and movement science based treatment for stroke
Author	(van Vliet et al., 2005)
Treatment Approach	Bobath and Motor learning
Participants	120 participants randomised into two groups. There were 60 participants in each group
Results	There was no significant difference between the two groups. Neither treatment approach was more effective than the other.
Study	Task-related circuit training improves performance of loco-motor tasks in chronic stroke: a randomised, controlled pilot trial
Author	(Dean et al., 2000)
Treatment Approach	Motor learning and Placebo (sham treatment)
Participants	12 participants first time ever stroke, three months post-stroke were randomised into groups. There were 6 participants in each group

Results	It is feasible to conduct a task specific exercise class with chronic stroke. The sample in this study was small and requires further investigation
Study	Training symmetry of weight distribution after stroke: a randomised controlled study comparing task-related reach, Bobath and feedback training approaches
Author	(Mudie et al., 2001)
Treatment Approach	Feedback, Motor learning, Bobath and No specific training
Participants	40 participants randomised into 4 groups. There were 10 participants in each group
Results	No significant difference in results was found. Finding suggest that treatment approaches that create awareness of body position can improve postural symmetry in early rehabilitation has better short and long term effects.
Study	Comparison of physio ball and plinth trunk exercises regimens on trunk control and functional balance in patients with acute stroke
Author	(Karthikbabu et al., 2011)
Treatment Approach	Motor learning
Participants	30 participants randomised into two groups. There were 15 participants in each group.
Results	Task specific trunk exercises performed with a physio ball were more beneficial than those performed on a plinth
Study	Does physiotherapy based on Bobath concept, in conjunction with task practice, achieve greater improvement in walking ability in

	people with stroke compared to physiotherapy focused on structured task practise alone?
Author	(Brock et al., 2011)
Treatment Approach	Bobath and Motor learning
Participants	26 participants randomised into two groups. There were 14 participants in the Bobath group and 15 in the Motor learning group.
Results	Rehabilitation program based a combination of Bobath and motor learning is more beneficial than motor learning alone.

No one treatment approach appears to be more beneficial than another. Using a mixture of approaches appears to be more beneficial in the treatment of stroke (Pollock et al., 2001). The addition of strengthening programmes in the treatment of stroke is also beneficial and does not increase spasticity as previously assumed (Ada et al., 2006).

Therapists need to shift from using specific approaches to using scientific, evidence-based treatment techniques in stroke rehabilitation (Pollock et al., 2001)

2.9 FUNCTIONAL ELECTRICAL STIMULATION:

Functional Electrical Stimulation can be described as the application of an electrical impulse to a muscle, at the point closest to the peripheral nerve or nerve root, which results in a muscle contraction that aids in both functional and beneficial movement in persons who have sustained an Upper Motor Neuron Lesion (Donovan-Hall et al., 2011, Thrasher and Popovic, 2008, Dimitrijevic, 2008). When a surface electrode is placed on the skin over the sensory-motor structures and a current is passed through it, it results in a formation of a magnetic field. This results in the flow of ions which create a current. This current creates action potentials, which propagate along the nerve and results in a muscle contraction. The electrical stimulation

provides restoration of movement and function as the electrodes are placed over a muscle with impaired function (Bajd and Munih, 2010).

The use of FES was first investigated by Lieberman et al in 1960 with the development of a device to correct dropped foot in hemiplegic gait (Lieberman et al., 1961). The device was a single channel stimulator. The electrodes were placed over the common peroneal nerve and the stimulation was controlled by a switch which was placed in the heel of a shoe. The dorsiflexors were stimulated each time the heel lost contact with the foot switch. This resulted in dorsiflexors activation during the swing phase of gait and a correction of hemiplegic gait (Lieberman et al., 1961).

There have been major advances in technology since the development of this first device (Dimitrijevic, 2008, Thrasher and Popovic, 2008). Electrode technology has also been developed and improved (Thrasher and Popovic, 2008). The devices have become smaller and more portable. There has also been development from single channel devices to multichannel devices. These devices can be used for therapeutic and home use (Thrasher and Popovic, 2008). Some of the devices available for everyday use in the correction of dropped foot are the WalkAide, the L300 Bioness and the Odstock Foot Drop Stimulator (ODFS) (Chae et al., 2008). In a study conducted by Taylor et al, which investigates the use of the ODFS, it was reported that walking speed improved in patients with stroke. Taylor et al also reported a carry-over effect when patients were not using the stimulator (Taylor et al., 1999).

There have also been developments in upper extremity devices. These devices aid grasping and reaching in persons with stroke and spinal cord injuries. These devices are multichannel systems. Some of the devices available are the NESS H200, Bionic glove, Belgrade Grasping reaching system and the FES system (Popovic et al., 2009, Chae et al., 2008). These systems were developed for patient use at home (Popovic et al., 2009).

2.9.1 Therapeutic Use of FES:

Some of the FES applications are for specific use in the clinical setting and are effective tools to use in the rehabilitation of persons with stroke (Thrasher and Popovic, 2008, Robbins et al., 2006). FES can be used on patients with impaired sensation and who present with cognitive and perceptual impairments (Limited,

2006a). Barsi et al suggests that the combination of FES and conventional therapy is more effective than FES alone or conventional therapy alone (Barsi et al., 2008).

One of the FES machines used in clinical practice is the Microstimulator. It has two channels which allow the stimulation of two groups of muscles at a time. Because of the pulse and intensity, the FES Microstimulator is ideal for use with regular exercise and can be used in the home environment. The Microstimulator has different modes which can be used to stimulate different muscles. Mode eight and nine allow for overlapping of two different muscles groups when stimulated. This mode is ideal for upper limb application. Mode zero and one of the Microstimulator are better suited for muscles that fatigue quickly. While modes two to seven are better suited for bigger muscles and should be used on fast twitch muscles (Limited, 2006b).

Application of FES in the clinical setting for the upper limb is aimed at retraining of the hemiplegic arm and hand and the treatment of shoulder subluxation (Durfee, 1999, Popovic et al., 2003). Popovic conducted a study to investigate the use of FES in the upper limbs. FES was applied to the muscles of the hand that controlled grasping, holding and releasing, using a multichannel FES system. Subjects who received FES and conventional therapy showed improvement in function of the hand as well as improvement in elbow and shoulder movements (Popovic et al., 2003) In a study conducted by Koyuncu et al, which investigates the effectiveness of functional electrical stimulation for the treatment of shoulder subluxation, it was found to be beneficial. The FES was applied to the supraspinatus and posterior deltoid five times a day and patients participated in the normal rehabilitation program of the hospital. There was a significant decrease in shoulder subluxation and pain in those participants who received FES and conventional therapy compared to those who received conventional therapy only (Koyuncu et al., 2010).

Clinical applications of FES in the lower limbs are to improve gait, balance and muscle strength in persons with stroke (Thrasher and Popovic, 2008). Yan et al conducted a study where the quadriceps, hamstring, tibialis anterior and gastromenuis muscles were stimulated with two dual channel stimulators. Participants were placed in side-lying with the affected leg supported by a sling and FES was delivered to mimic normal gait. Participants receiving FES in combination with conventional therapy walked two to three days earlier than the other groups and showed improvement in motor recovery and functional ability. In this study

84.6% of participants who received FES in combination with conventional therapy returned home. This percentage was significantly higher when compared to the other two groups (Yan et al., 2005). FES cycling is another method to improve lower limb strength to improve gait and balance. Quadriceps, hamstrings, gluteus maximus and tibialis anterior muscles are stimulated with a multichannel stimulator while cycling. In studies conducted by Ambrosini et al and Ferrante et al using FES cycling, the results have shown that these patients improve in muscle strength and functional ability. Both studies show an improvement in trunk control as well (Ambrosini et al., 2011, Ferrante et al., 2008) Ambrosini et al notes that trunk control is important and rehabilitation methods which enhance trunk control in the early stages of rehabilitation is essential for the recovery in performing functional tasks (Ambrosini et al., 2011).

The application of FES to the upper and lower limb in the clinical setting results in an improvement in function after stroke (Thrasher and Popovic, 2008, Koyuncu et al., 2010, Popovic et al., 2009). The EO after a stroke has a delayed activation and also poor muscle motor unit recruitment when performing an action (Pereira et al., 2010). The FES application to a muscle after stroke aids in the recruitment of muscle fibres of a paralysed or weak muscle resulting in a muscle contraction which results in functional movement (Donovan-Hall et al., 2011). Similarly it is hypothesised that the FES application to the abdominal muscles would aid in improved muscle contraction when stimulated resulting in improved function in patients with stroke.

To the knowledge of the researcher, there are no other published studies that have investigated the effect of FES on the abdominals in the treatment of stroke.

2.10 OUTCOME MEASURES:

Standardised clinical tools are a pre-requisite for both research and clinical practice (Verheyden et al., 2007). Outcome measures should be valid, reliable and responsive to clinical changes (Roberts and Counsell, 1998). These measurements should ideally also be linked to the International Classification of functioning, disability and health (ICF) as the evaluation will enable one to identify activity limitations and participation which is helpful in clinical practice and research (Schepers et al., 2007). In the most recent version of the ICF framework, three primary levels of human functioning were identified. The first is the body structure or body function (impairment). The second is the person's level of activity (disability)

and participation (handicap). The third level is the barriers caused by environment and personal factors which limit activity and participation (contextual factors) (Salter et al., 2005a, Salter et al., 2005c, Salter et al., 2005b).

Salter et al describes six commonly used outcomes measures used to assess impairment in those who have had strokes (Salter et al., 2005a, Salter et al., 2005b, Salter et al., 2005c). The Beck Depression Inventory was developed through clinical observation of depression and is used as an instrument for the detection and assessment of depression. The Fugl-Meyer Assessment of motor recovery after stroke was designed to assess motor function, balance, sensation and joint function in stroke. It is a disease specific impairment index. The Mini-mental state examination is a brief screening to assess cognitive impairment and to monitor changes in impairment over time. The Modified Ashworth scale developed from the Ashworth Scale which measures spasticity. Spasticity is graded on a scale from 0 to 4 using guidelines which describe the resistance perceived by the examiner. The Motor-free Visual Perception Test measures visual perceptual skills in five areas. It was originally designed for use with children. It tests spatial relation, visual discrimination, figure ground discrimination, visual closure and visual memory (Salter et al., 2005b). An outcome measure which was developed specifically to measure motor impairment of the trunk after stroke is the Trunk impairment Scale. It consist of 17 items which evaluates static and dynamic balance and the coordination of the trunk (Verheyden et al., 2002).

Salter et al also described nine popular outcome measures used to assess activity in patients with stroke. The BI and RMA are described later in detail. The Berg Balance scale is used to measure different aspects of balance. Subjects are asked to maintain positions or complete movements with different levels of difficulty, within a specific time period. The Chedoke-McMaster Stroke Assessment Scale is a two part assessment which looks at physical impairment and disability. It is able to classify a patient's stage of motor recovery and assess change in physical function. Functional Independence Scale (FIM) measures physical and cognitive disability in terms of the burden of care. The measure consists of 18 items which assess areas of function. The Frenchay activities Index measures actual ADL in persons with stroke and provide an objective assessment of activities conducted in three areas of domestic activities, leisure activities and outdoor activities. The Modified Rankin Handicap Scale is a rating scale measurement for stroke where pre-stroke activities are assessed on a scale of zero to five. The scale is based on the level of

independence of an individual with reference to pre-stroke activities. The Rivermead Mobility Index is an extension of the RMA gross motor function section. It focuses on the aspects of independent mobility in one's environment and provides assessment of mobility disability. The Timed-Up-and-Go Test provides an objective measure of mobility and balance as it assesses the sequential motor tasks related to walking and running (Salter et al., 2005c). An outcome measure designed to specifically measure motor performance of the trunk after stroke is the Trunk Control Test. It consists of a 4 item scale which measures rolling to both sides, sitting up from lying and maintaining sitting balance over the side of the bed. Total score ranges from zero to 100. A higher score would indicate better trunk performance (Verheyden et al., 2007).

Limitation in participation is influenced by quality of life and is more dependent on environmental factors. Salter et al (2005a) discuss six reliable outcome measures which assess participation. The EQ-5D is described in detail below. The Medical Outcome Study Short Form 36 assesses the health status of the general population. There are eight subscales and it includes questions which help determine changes in health status over a one year period. The Nottingham Health Profile is a short, subjective measure of perceived health which includes social and personal effects of illness. It does not measure quality of life nor does it identify a specific health condition. The Stroke-Adapted Sickness Impact Profile is a comprehensive measure in the assessment of health related quality of life. The Stroke Impact Scale is a stroke specific health status measure, which is patient-based and assesses a number of domains across the impairment-participation spectrum. The Stroke Specific Quality of Life Scale is used to assess the health related quality of life. It is stroke specific and patient-centred. It is a fairly new scale and has not been tested on severe strokes. This measure requires further studies. (Salter et al., 2005a)

The outcome measures used in the current study were chosen as they are valid, reliable, quick, easy outcome measurements which can be completed by any health professional and are frequently used in rehabilitative research studies (Salter et al., 2005a, Salter et al., 2005b, Fredrickson et al., 2007a). The outcome measures used in the study are described in the sections below.

2.10.1 The Barthel Index:

The BI was developed in 1955 and is still being used today. It is a simple, quick and useful evaluation used to measure independence (Mahoney and Barthel, 1965, Nakao et al., 2010). The assessment takes approximately 20 to 30 minutes to complete (Cole et al., 1995). The BI is a scale that measures 10 basic activities: grooming, toileting, feeding, dressing, transfers, mobility, stair climbing, bathing, dressing and bladder and bowel control. Each activity criteria is defined and the person is scored accordingly and is given 0 if unable to meet the criteria. The total score for the scale is 100 and this indicates total independence in the functional activities listed in the BI (Mahoney and Barthel, 1965). The lower a person scores on the BI the more dependent they are with functional activities. These persons often require full time care in the home or are institutionalised. Persons with stroke scoring ≥ 60 on the Bi are able to integrate into the community and home (Nakao et al., 2010). Persons scoring 100 on the Bi are independent in basic activities but may still require assistance in the home or community (Mahoney and Barthel, 1965).

The Bi is not a perfect assessment as it is a brief ordinal scale and the data is not normally distributed (Cummings et al., 2011). It is often criticised for the lack of comprehensiveness and sensitivity to change (Salter et al., 2005c). This is due to the ceiling effect, which makes it harder to discriminate between persons with moderate and high levels of function (Salter et al., 2005c, Cummings et al., 2011). It is not significant in the acute phase of stroke, that is, within first 24 hours and 3 days (Pan et al., 2007). The BI is appropriate for use during early inpatient rehabilitation (Houlden et al., 2006).

In a study completed by Hsueh et al, the reliability and validity of the BI when used in persons with stroke was confirmed. In this study, the BI had a high validity with Spearman's correlation coefficient of $r \geq 0.92$ and intraclass coefficient (ICC) ≥ 0.83 (Hsueh et al., 2002). This is in accordance with many other stroke studies where BI has been proven and accepted to be a reliable and valid measuring tool (Duncan et al., 1992, Cole et al., 1995, Sulter et al., 1999).

When the BI was compared to the FIM, the FIM showed no more advantage over the BI when evaluating changes in function during inpatient rehabilitation. The BI is quicker and simpler to score and can be used by any health professional. The FIM, in contrast, can only be rated by a multidisciplinary team who have been trained in its use, after a patient has been observed for up to 72 hours (Houlden et al., 2006).

2.10.2 The Rivermead Motor Assessment:

The RMA was developed specifically to assess and monitor motor recovery in persons with stroke and is based on the Bobath concept (Lincoln and Leadbitter, 1979). It consists of 3 subscales:

- gross function – deals with functional movement
- leg and trunk – deals with control of movement
- arm – deals with both control and functional movement of the arm

The items are scaled in order of hierarchy on the basis that stroke recovery follows a specific pattern. A person is given a score of 0 if unable to perform a task and 1 if able to perform the task. Where a person fails three consecutive items (given a score of 0) the test is stopped in that section (Lincoln and Leadbitter, 1979). The RMA is administered by physiotherapists and requires no training. It takes approximately 45 minutes to complete (Cole et al., 1995, Lincoln and Leadbitter, 1979).

Lincoln and Leadbitter proved validity using a scale as well as its reliability (Lincoln and Leadbitter, 1979). Some studies have shown shortcomings and found it to fail Guttman's scaling criteria (Kurtais et al., 2009). Kurtais et al conducted a study to test the reliability and validity by modern psychometric properties of the RMA, as the assessment is ideally used in the rehabilitation setting. In their study they proved that the RMA was valid. Both internal consistency and intraclass correlation coefficient indicated reliability of the scale. The RMA was also shown to be responsive to change. The study also showed that the RMA met Guttman's scaling criteria (Kurtais et al., 2009).

There are other assessments such as the Motricity Index and the Trunk Control Test which are shorter and easy to use. They are also valid and reliable outcome measurements of motor impairments. They are, however, not as detailed as the RMA and do not specifically look at the quality of movement (Collin and Wade, 1990). The Rivermead Mobility Index is a development from the RMA gross motor function section and is a good clinical tool (Collen et al., 1991). This assessment only focuses on mobility and does not cover control of movement or the functional movement of the arm (Collen et al., 1991, Salter et al., 2005c).

2.10.3 EQ-5D:

The EQ-5D was developed by a multi-national, multi-disciplinary team and has been in use since 1990. It is a generic assessment and can therefore be used across a range of diseases (Brooks and Group, 1996). The EQ-5D is a non disease specific measurement which aims at describing and evaluating Health Related Quality of Life (HRQoL) and is intended to complement other evaluation forms which serve the same purpose (Brooks and Group, 1996, Salter et al., 2005a). It is a quick assessment which takes approximately two to three minutes to complete and requires no special training. The initial aim of the EQ-5D was that the assessment be a self reporting tool but it can also be administered by an interviewer (Salter et al., 2005a, Brooks and Group, 1996).

The EQ-5D has five domains:

- mobility
- self care
- usual activities
- pain and discomfort
- anxiety and depression

Each of these domains can be scored according to three dimensions:

- no problems (1)
- some problems (2)
- confined to bed/extreme problems (3)

It also has a visual analogue scale (VAS) which patients use to quantify how they perceive their health status. Because a numerical number can be attached, there is a five digit expression of the state of health and the VAS makes it easy to scale (Brooks and Group, 1996, Salter et al., 2005a). The EQ-5D has distinct levels and any change in a level is important and significant (Dorman et al., 1998)

Dorman et al shows that the EQ-5D is a reliable measure when comparing groups of patients after stroke and that the reliability of the EQ-5D improves when the patients complete the tool themselves rather than by use of a proxy (Dorman et al., 1998).

2.10.4 Physiological Cost Index:

James Macgregor developed the PCI to help define the effort exerted during physical performance (Macgregor, 1981).

The following formula is used to calculate PCI:

$$PCI = WHR - RHR / speed \times 60$$

Walking Heart Rate (WHR) is the heart rate after walking. Resting Heart Rate is taken while sitting at rest for 3 minutes (RHR). Speed with is calculated in metres per second over a distance of 10m (Fredrickson et al., 2007b).

Since it's development, PCI has since been used by both researchers and clinicians alike (Ijzerman and Nene, 2002). PCI has a limited reliability and validity (Danielsson et al., 2007). It however, is an inexpensive tool which can be used by any clinician or researcher, does not require any specialised equipment or training and can be performed daily (Fredrickson et al., 2007a, Danielsson et al., 2007).

2.11 CONCLUSION TO THE LITERATURE REVIEW

The above review has discussed the considerable impact of stroke on both society and on the individual. The disability related to impairment, activity limitations and participation restrictions are considerable. Environmental factors were not discussed as monitoring the effect of the environment was beyond the scope of this study. (For studies related to the impact of the environment on stroke in the Western Cape refer to unpublished thesis by Rouillard and Rhoda (Rouillard, 2007, Rhoda, 2010))

The trunk clearly plays an essential role in providing a stable base from which the limbs can function and this role is dependent on the integrity of the motor control of the abdominal muscles. FES has been found to be a useful and effective adjunct to treatment but no studies report having tested the use of FES on the abdominal muscles in patients with stroke.

Although impairments such as abdominal muscle strength and ability to maintain sitting are clearly important to function, based on the findings that patients show

greater improvement in performing motor tasks in rehabilitation where implicit motor learning strategies are utilised, emphasis on functional gain would appear to be justified. Different outcome measures were presented and the BI, RMA and the EQ-5D were identified as being reliable and valid for use in people who have had strokes. These measures are reported to be relatively simple to administer and require no specialised training which makes them suitable for a pragmatic study embedded in daily clinical care. In addition, the impact of disturbed motor control on the physiological cost index of gait was discussed and found to be considerable.

This study therefore aimed to investigate the impact of FES of the abdominal muscles in patients with stroke on their functioning, using the functional measures of BI, RMA, EQ-5D and the PCI during gait. As other aspects, apart from the intervention that might impact on function, factors predictive of outcome are also discussed.

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3. METHODOLOGY:

3.1 RESEARCH DESIGN:

A pragmatic experimental, randomised controlled trial with single blinding was used. It was a pragmatic study in that it was an adjunct to routine therapy and took place within the context of ordinary clinical care (MacPherson, 2004). Participants were randomised into two groups. The experimental group received FES in addition to conventional physiotherapy. The control group received only conventional physiotherapy. The investigator who performed the standardised tests was blinded to the group membership of the participants. The investigators involved in the treatment of the participants did not perform any of the standardised tests.

3.2 NULL HYPOTHESIS:

The null hypothesis was that there would be no significant difference in ranking in the activities related to functional independence as measured by the BI and RMA when FES is applied to the abdominals as part of a physiotherapy treatment in stroke rehabilitation.

3.3 SAMPLE:

All patients admitted to the Rehabilitation Unit from 01 September 2010 to the 31 August 2011 were eligible for inclusion.

3.3.1 Inclusion Criteria for the Participants:

Participants were between the ages of 18 to 85 years of age who presented with a first time ever stroke, which was confirmed by an MRI or CT scan and a neurologist. The stroke had to have occurred within the past three months.

3.3.2 Exclusion Criteria for the Participants:

The following were excluded:

- Patients with pacemakers

- Patients whose length of stay in the unit was less than two weeks (note that the length of stay was based on an administrative rather than a therapeutic decision and that two weeks of care was the typical time period allowed by the fund providers, the medical aid societies).
- Patients with acute orthopaedic conditions where post operative precautions needed to be adhered to
- Pregnant females
- Patients with cancer
- Those with receptive aphasia

As conventional therapy started on admission, regardless of the mental state of the patient, FES was incorporated very early on, in treatment. As FES does not require any further co-operation on behalf of the participant, all patients regardless of mental status were included in the study. However, participation was restricted to those who were able to either give informed consent (verbally or through sign language – if the patient had an expressive aphasia) or in writing.

3.3.3 Sample Size Determination:

Sample size was based on the mean difference in BI score. A mean difference in BI score of 20 and SD =10 was used to calculate sample size. The difference of 20 points was obtained from two papers by Paolucci et al (2003) and Woldag et al (2006) and these two papers were used when calculating the sample size (Woldag et al., 2006, Paolucci et al., 2003). Using the Statistica power calculation function, it was estimated that the sample size of 16 per group was necessary to detect a difference between the two groups at a significant level of $p=0.05$ and a power level of 90%. In order to allow for attrition, a final sample size of 20 was to be recruited in each group.

The investigator was informed, during the data collection that the rehabilitation unit would be closing at the end of October 2011. The investigator approached other rehabilitation units in an attempt to ensure that the sample size for the study could be recruited. Unfortunately, approval to continue the study at other units was not given by the various institutions approached.

3.3.4 Therapist Participants

The four physiotherapists were employed in the Unit on a full-time basis to treat adults with neurological conditions. These four therapists conducted all the treatments. This was a sample of convenience.

3.3.5 Randomisation:

Randomisation was achieved by treating therapists' drawing cards out of an envelope. The envelope contained a total of 40 red and green circles which were mixed inside the envelope. A red circle signified the control group and the green circle signified the experimental group. The researcher was unaware of the group allocation of each participant. Allocation of a one to one basis for participants for randomisation was applied.

Randomisation of the treating therapist was achieved by placing four circles number one through to four in an envelope. Each therapist drew a circle and was allocated the number which appeared on the circle.

3.4 INSTRUMENTS:

Apart from the EQ-5D, the other instruments are based on observation of performance and do not require the participant to use language in responses.

3.4.1 Barthel Index:

The BI (appendix iv) was used to monitor changes in function. It was completed at inclusion to the study, at discharge and at the four- week follow- up.

3.4.2 Rivermead Motor Assessment:

The RMA (appendix v) was used to monitor change in motor recovery. The RMA was completed at inclusion to the study, the end of the first week, at discharge and at the four week follow-up.

3.4.3 Health Related Quality of Life (EQ-5D):

The EQ-5D (appendix vi and appendix vii) was completed at inclusion to the study, at discharge and at the four week follow-up.

3.4.4 Physiological Cost Index:

PCI (appendix viii) was conducted at discharge if the participant was able to walk (with the use of an aid or independently) and at the four week follow-up.

3.4.5 Functional Electrical Stimulation:

The FES Microstimulator was applied to the external oblique abdominal muscle on the affected side. The Microstimulator was set on mode one (simultaneous), which is best suited for muscles that fatigue quickly (Limited, 2006a). FES was applied from the first day of inclusion to the study. For the first week, Mode one was used during therapy for 15 minutes, once a day. For the second week, mode one was used for 20 minutes during therapy, once a day.

3.4.6 Therapy Planner

The therapy planner (appendix ix) was completed each day from the day of inclusion to the study till discharge and was used to indicate which group the participant was allocated. It was also used to identify the treating therapist. Therefore, the therapy planners were used to identify how many participants were treated by each physiotherapist. It also indicated the length of each treatment session and whether FES was applied and for what length of time it was applied for.

3.4.7 Treatment Activities Performed:

A self designed, check-list of the different type of treatment activities were drawn up using two studies completed by De Wit et al (De Wit et al., 2007a, De Wit et al., 2006). In these studies De Wit et al describes and defines the content of physiotherapy and occupational therapy programs in the inpatient rehabilitation centre in Europe. The list consisted of 12 categories with 49 subcategories. It was developed based on neurological textbooks, recorded therapy sessions and previous lists. The list is valid and reliable tool which can be used for describing the

content of physiotherapy and occupational therapy programs(De Wit et al., 2007a, De Wit et al., 2006). The following domains were taken from the two studies:

Balance activities, selective movements (hip and knee), transfers, strengthening exercises (upper and lower limb) and walking.

On examination of the daily notes of the physiotherapists the following domains were added:

Bed mobility, Posture re-education, weight shifts, mat work, sit-to-stand and FES lower limb application.

A self designed check-list (Table 13) was compiled containing the above domains. The check-list was used to identify the different treatment activities performed during the treatment sessions over the study period.

3.5 PROCEDURE:

Ethical approval was obtained from the Ethical and research Committee of the Faculty of Health Sciences (HRCF REF: 265/2010). Permission was obtained from the Hospital administration to conduct the study in the hospital rehabilitation unit.

3.5.1 Training of Investigators:

There were five collaborators who performed the treatments. These collaborators had previously been trained in the clinical use of FES and its application on the upper and lower limbs. A training session was arranged where the treatment protocol was explained and demonstrated. The training session also enabled the collaborators to familiarise themselves with the electrode placement on the abdominal muscles by practising on each other before testing the machines on patients.

The principal investigator (student) performed the assessments. It was necessary to establish the reliability of the administration of the BI and RMA instruments by the principal investigator in this context. Three participants with stroke were assessed, with a 15 minute break, by the principal investigator and one other assessor who has experience in the use of the instrument. This was to ensure the principal investigator was consistent in measurement and reliability. It was found that the principle investigator was consistent in measurement and reliable. There was no

difference in scoring of the BI and RMA instruments between the principle investigator and the other assessor.

3.5.2 Pilot Study:

A pilot study was carried out to pre-test the Instruments used to collect data as well as the patient information sheet and treatment planner. It was also used to test the accuracy of applying the FES to the abdominals by the collaborators. There were three patients who participated in the pilot study. It was determined during the pilot study that it was necessary to change a few of initial inclusion criteria to widen the participant pool of the study. The participants' age was adjusted to include participants between age 18 and 85 and the BI admission score of between 10 and 30 was changed so that all patients were eligible for inclusion irrespective of BI score on admission. There were no changes made to the patient information sheet.

3.5.3 Procedure for Data Collection:

The Rehabilitation unit was a private in-patient facility and all patients received pre-authorisation of length of stay including date of admission to discharge. The multi-disciplinary team met twice a week to discuss progress of patients as well as admissions and discharges from the unit. The collaborators informed the principle investigator of the admission and discharge dates as well as length of stay of possible candidates for the study. Therefore all possible participants were included into the study within the first week of admission to the unit and follow-up appointments were made with participants before discharge from the unit.

The BI was completed on all stroke patients who were admitted to the unit. Patients who met the inclusion and exclusion criteria were interviewed by the researcher and informed consent and permission to access medical information was obtained. This interview also gave candidates and family members an opportunity the chance to ask questions concerning the study. All participants were required to complete informed consent documents. Once a participant was accepted into the study, all the initial assessments were completed. The candidate was then randomly placed into a group by the collaborators and treatment then commenced. The collaborators completed the treatment planner each day. The planner indicated the total time of each treatment session as well as whether FES was applied. The treatment planner was only handed to the investigator at the end of the data collection period.

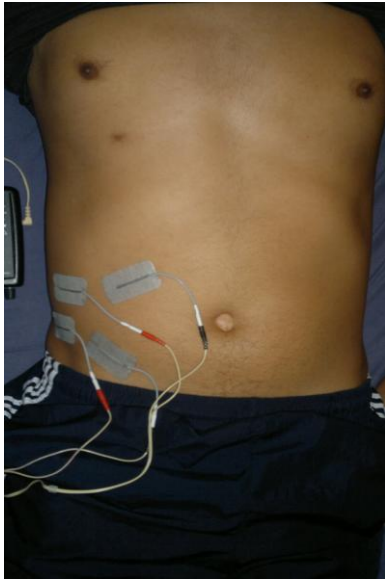


Figure 2: Placement of electrodes on the EO muscle on the affected side of the trunk

The experimental group received FES from the first day of inclusion to the study. FES was applied to the EO on the affected side of the trunk using both channels on the FES Microstimulator (refer to Figure 2 for exact placement of electrodes). The Microstimulator was set on mode one (simultaneous) which is best suited for muscles that fatigue quickly. The selected mode has a stimulation frequency of 40hz with an output amplitude of 100 mA. The pulse width was 330 μ s and had a ramp of 6 seconds (Limited, 2006b). The intensity of the machine was turned up to the point where a muscle contraction was clearly visible but still comfortable for the participants. FES was applied from the first day of inclusion into the study. For the first week, Mode 1 was used for 15 minutes, once a day, during therapy. For the second week, Mode 1 was used for 20 minutes. Conventional therapy continued in conjunction with the FES treatment.

The investigator conducted all interviews and assessments in the unit, outside of therapy hours, in a room separate to the treating therapists. This ensured reduced bias and confidentiality. A follow-up appointment, four weeks post discharge from the study, was arranged with the participants. All follow-up appointments were conducted in the unit.

The flow diagram (Figure 3) below demonstrates the progression of events from admission to four week follow-up assessments:

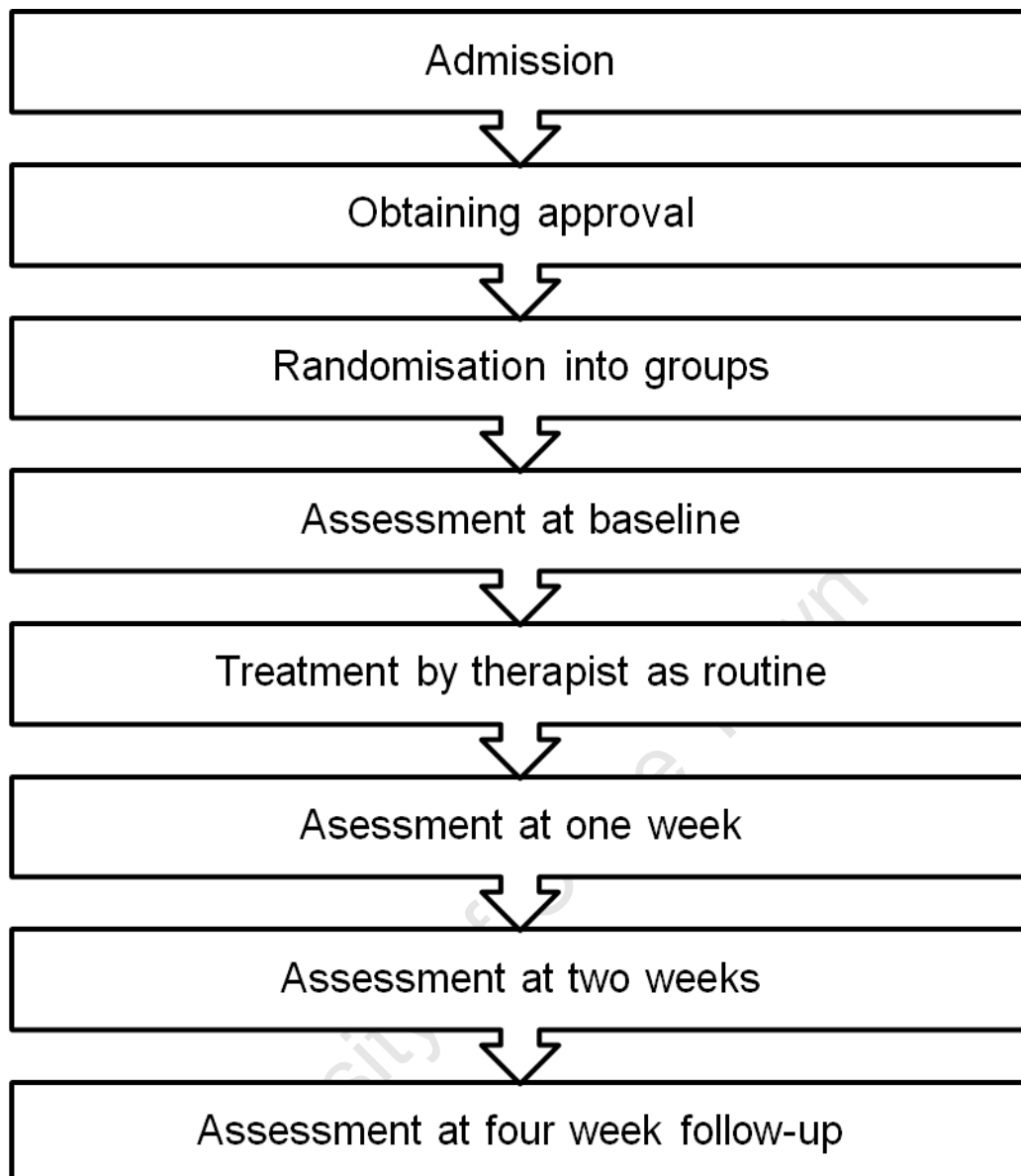


Figure 3: Flow diagram of progression of assessments from admission to discharge

3.5.4 Procedure for Collecting Data Regarding Intervention Modalities and Comparing to Current Literature

The therapy planner was completed for every participant at admission to the study by each physiotherapist. The therapy planner contained the name of each physiotherapist and the participant they treated as well as which group the participant was assigned to.

The therapist's daily treatment notes for all participants were assessed. The treatment activity check-list was completed for each participant and the physiotherapist identified on the list. The daily treatment notes were compared to the check-list of treatment activities that were compiled. When a participant received a treatment activity listed it was marked with a "Y". When the daily notes did not indicate that the treatment activity was performed it was marked with an "N". From this check-list, it could be assessed how many participants received the different treatment techniques by each physiotherapist. From this information a table was drawn up (see Table 13 in results section).

The principle investigator conducted searches on EBSCO, PUBMED and PEDRO databases for current literature on physiotherapy intervention modalities in treatment of in-patient stroke. Relevant peer-reviewed studies were compared to the content of the physiotherapy intervention modalities used in this study.

3.6 DATA ANALYSIS:

Statistical analysis using Stastica version 10 was done to analyse data. Analysis was based on the type of data, the BI and RMA yield ordinal data whereas the EQ-5D-Y VAS and tariff and the PCI are numeric in nature.

Due to the small sample sizes and ordinal nature of the data, non-parametric statistics were used in most cases. The median and quartile ranges were plotted for the BI and RMA whereas means and standard deviations (SD) were calculated for the EQ-5D VAS and tariff and the PCI. The ANOVA were used to compare the scores of the whole group at different points in time.

The Chi-square and Mann-Whitney U tests were used to ensure the demographic and hemiplegic related variables were equally distributed between groups. Variables such as age, gender, side of lesion and type of lesion of the two groups were compared to ensure that they were equivalent on entry. The Mann-Whitney U was used to compare the scores of two groups after the intervention on the ordinal outcome measures as well as the change in scores. The effect sizes were calculated for the primary outcome variables of BI, RMA Gross Function, the EQ-5DY tariff and the PCI. "Sample-based effect sizes are distinguished from test statistics used in hypothesis testing, in that they estimate the strength of an apparent relationship, rather than assigning a significance level reflecting whether the relationship could be due to "chance" (Nakagawa and Cuthill, 2007, Wikipedia,

2012). As the sample size was smaller than anticipated, it was expected that the power of this study to detect differences would be inadequate and consequently Cohen's d was used to calculate the effect size.

$$d = \frac{\bar{x}_1 - \bar{x}_2}{s},$$

Cohen's d is equal to the difference between the means of the two groups divided by the standard deviation of the whole group. For Cohen's d an effect size of 0.2 to 0.3 might be a "small" effect, around 0.5 a "medium" effect and 0.8 to infinity, a "large" effect (Coe, 2002).

The 95% Confidence Intervals (CIs) were calculated with the following formula:

$$\sigma[d] = \sqrt{\frac{N_E + N_C}{N_E \times N_C} + \frac{d^2}{2(N_E + N_C)}}$$

Where (Where N_E and N_C are the numbers in the experimental and control groups, respectively) (Coe, 2002).

On calculation, it was apparent that the CIs of the change in score from admission to discharge were so large (due to the small number n each sample) as to meaningless and these were excluded.

Although some authors do not recommend that the effect size should be calculated for ordinal data and argue that Cliff's Delta would be a better statistic (Romano et al., 2006, Hobart et al., 2010) in practice several researchers have calculated the effect size when using the Barthel Index and other functional outcome measures such as the FIMS (Houlden et al., 2006, Galvin et al., 2008, Schepers et al., 2006). It was decided to use the effect size for this study, provided both the control and experimental data sets were normally distributed, as tested using the Shapiro-Wilk's test. This would allow for comparison with other studies.

The five domains in the EQ-5D descriptor domains were transformed into a QALY (quality adjusted life year) value based on the EQ-5D tariff of values which were

derived by the EuroQoL foundation by determining the relative societal value of each health state. (See Appendix X)

Analysis was by intention to treat. That means, that, all participants who might have withdrawn from the study or those who did not complete the treatment for whatever reason, that the assessments already taken were included in the analysis of their original group. Where there were incomplete assessments, these fields were left blank in the analysis to avoid altering data or results of their interpretation.

Spearman correlation coefficients were calculated and visually presented using Scatterplots. These were created to depict the relationship between admission and discharge BI score and the change in score.

The median change in score from admission to discharge was plotted for each therapist and a Median Test was undertaken to establish if any therapist performed significantly better in terms of participant improvement compared to others.

The content of the physiotherapy interventions was compiled and compared to current available literature on physiotherapy interventions in stroke rehabilitation.

3.7 ETHICAL CONSIDERATIONS:

A research proposal was submitted to the Ethics and Research Committee of the Faculty of Health Sciences, UCT, for approval. Permission to carry out the study was also obtained from the Hospital Manager of the hospital. An information sheet was provided to the patients, which provided all the relevant information regarding the purpose of the study and testing procedures. Informed consent was obtained prior to involvement in the study. The patient's information was kept strictly confidential and only used for research purposes. This was indicated in the information sheet and explained by the investigator. Participation was completely voluntary and patients were free to refuse participation or withdraw from the study at any time without questions asked. A decision not to participate did not affect their treatment in any way.

Patients were given a coding number in order to identify the participants and to protect their autonomy:

Patient	Coding Number
Mrs A	P1

Mr B	P2
Mr C	P3
.....
.....
Miss S	P19

When entering the data into the computerised data base programme, the participants were given a coding number as shown above.

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4. RESULTS

As the number of participants in each group was relatively small, non-parametric tests were used to compare all the parameters between the two groups.

4.1 SAMPLE:

There were 29 subjects assessed before being entered into the study. There were 16 subjects excluded from the study as they did not meet the inclusion and exclusion criteria. There were four subjects who refused to participate in the study. A final total of 19 subjects were entered into the study. Of the 19, only one person indicated that they did not want a follow-up assessment. There were seven participants who did not have follow-up assessments due to medical complications post discharge. The follow-up results of one participant were excluded as she had suffered a second stroke since discharge from the unit.

The flow diagram (Figure 4) below demonstrates the progression of events from initial assessment, admission, discharge to follow-up and exclusion of participants:

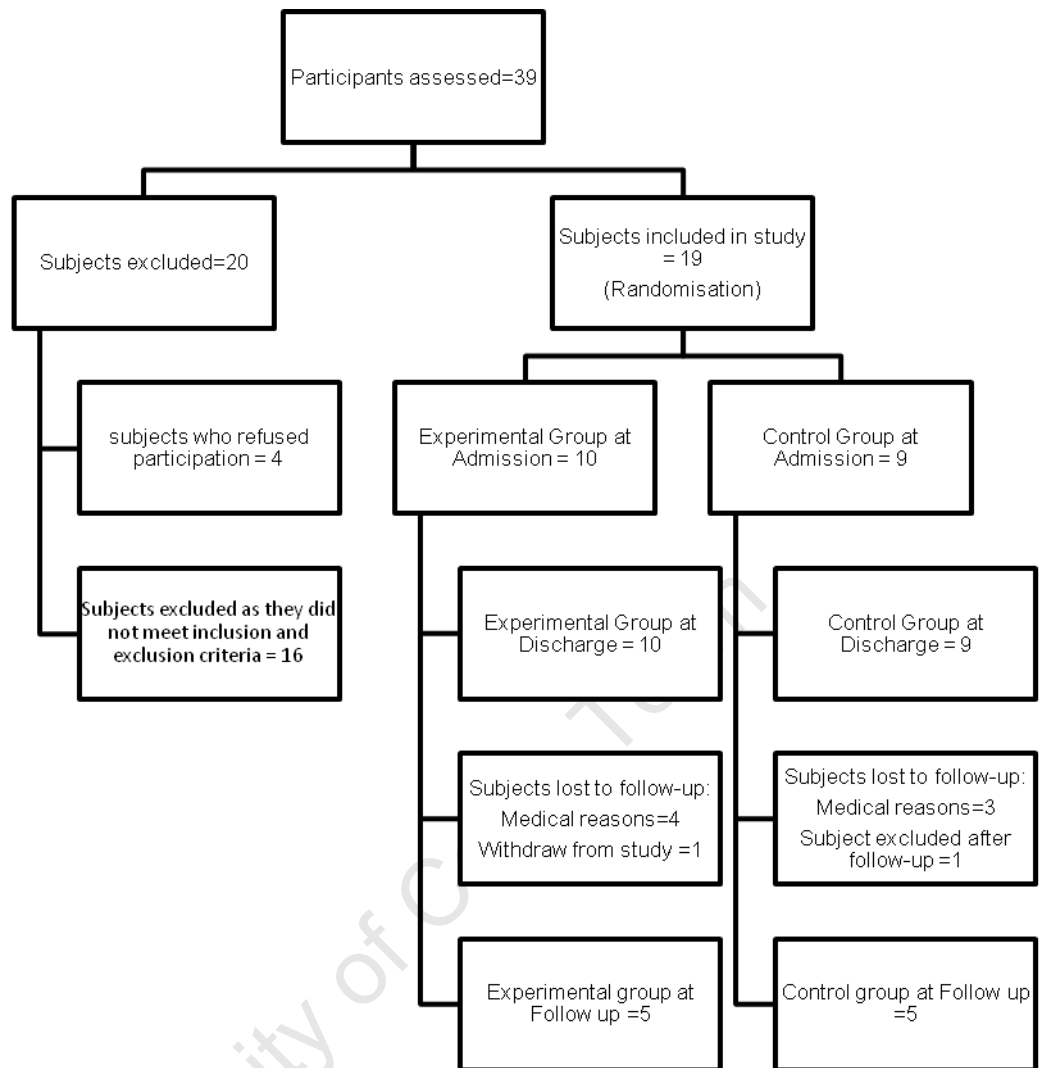


Figure 4: Progression of events for participants

4.1.1 Demographic Characteristics

Recruitment took place over one year from October 2010 to October 2011. There were 19 participants of which 8 were male. The demographic details and the comparison between the two groups are presented below. Nine were allocated to the control group and ten to the experimental. Table 2 indicates that the gender distribution was equivalent across the two groups.

Table 2: Gender distribution across the two groups

	Male	Female	Totals
Control (n=9)	3	6	9
Experimental (n=10)	5	5	10
Totals (n=19)	8	11	19

ChiSq=0.54, df=1, p=.463

The mean age of the participants was 65 years (SD=16.04). As can be seen in Figure 5, there was a wide range of ages, from a minimum of 31 to a maximum of 85.

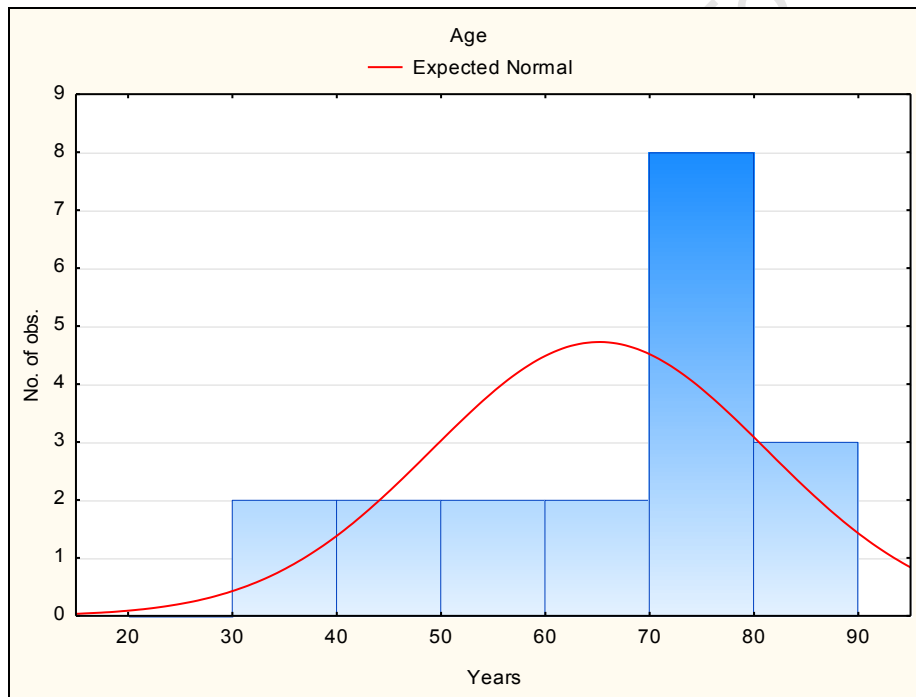
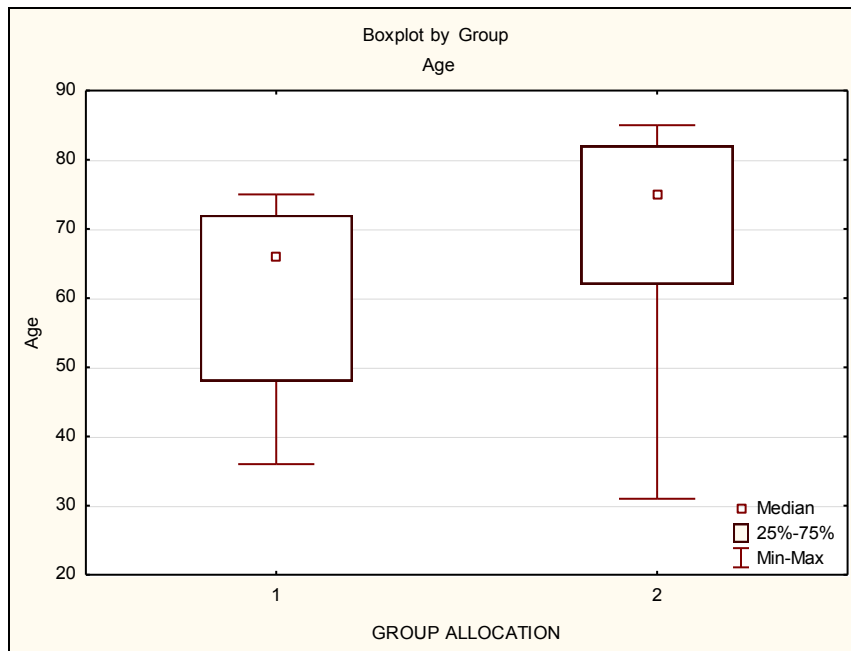


Figure 5: Histogram of ages of the participants (n=19)

The mean age of the control group was 60 years (SD= 14.45) and the mean age of the experimental groups was 69.7 years (SD= 16.75).

The Mann-Whitney U test indicated that the difference in the ranking of the age of the two groups approached significance, with the control being younger than the experimental group (U=21, Z adjusted -1.92, p=0.054) as indicated in Figure 6.



Group Allocation: 1= Control group (n=9), 2= Experimental group (n=10)

Figure 6: Box and Whisker plot of Age

4.1.2 Associated Risk Factors and Medical Condition:

The Chi- Square test indicated that there was no association between group allocation and risk factors Table 3).

Table 3: Associated risk factors

	Control n=9	Experimental n=10	Chi-Square
Smoking (yes)	4	3	0.42, df=1, p=.514
Alcohol (yes)	5	5	0.50, df=a, p=.808
Diabetes (yes)	1	5	3.32, df=1, p=.069
Hypertension (yes)	5	7	0.42, df=1, p=.514
Cardiac conditions (yes)	3	4	0.42, df=1, p=.514

This increased the risk profile of the experimental group. There was no significant difference between the groups with regards to smoking and alcohol consumption (Table 3).

Although not found to be significantly different on testing, the experimental group was older and five had diabetes, as opposed to only one in the control group.

4.1.3 Medical Factors Relating to the Stroke:

The Chi-Square test indicated that there was no association between group allocation and medical condition (Table 4). Only one participant was admitted to the unit from home (in the control group). All the other participants were transferred directly from the various acute hospitals to the rehabilitation unit.

Table 4: Medical Condition

	Control n=9	Experimental n=10	Chi-Square
Right hemiparesis	4	4	0.38, df=1, p=0.845
Ischemic Stroke	5	6	0.58, df=1, p=0.808
Surgery (yes)	2	1	0.53, df=1, p=0.466
Diagnostic test (MRI)	9	9	0.95, df=1, p=0.329

4.1.4 Length of Stay in Acute Hospital:

The Mann-Whitney U test indicated that there was no significant difference in ranking of the two groups in the length of stay at an acute hospital before admission to the rehabilitation unit (U=45.0, Z adjusted=0, p=1.0).. The mean length of stay in the acute hospital was 13.42 days (SD= 5.44, range =2-25).

4.2 COMPARISON OF FUNCTIONING OF THE TWO GROUPS

4.2.1 Barthel Index Scores:

The mean BI scores of participants was 35.7 (SD=19.87) at admission (n=19), 76.6 (SD=26.6) at discharge (n=19) and 84.0 (SD=22.335) at follow-up (n=10) (Figure 7).

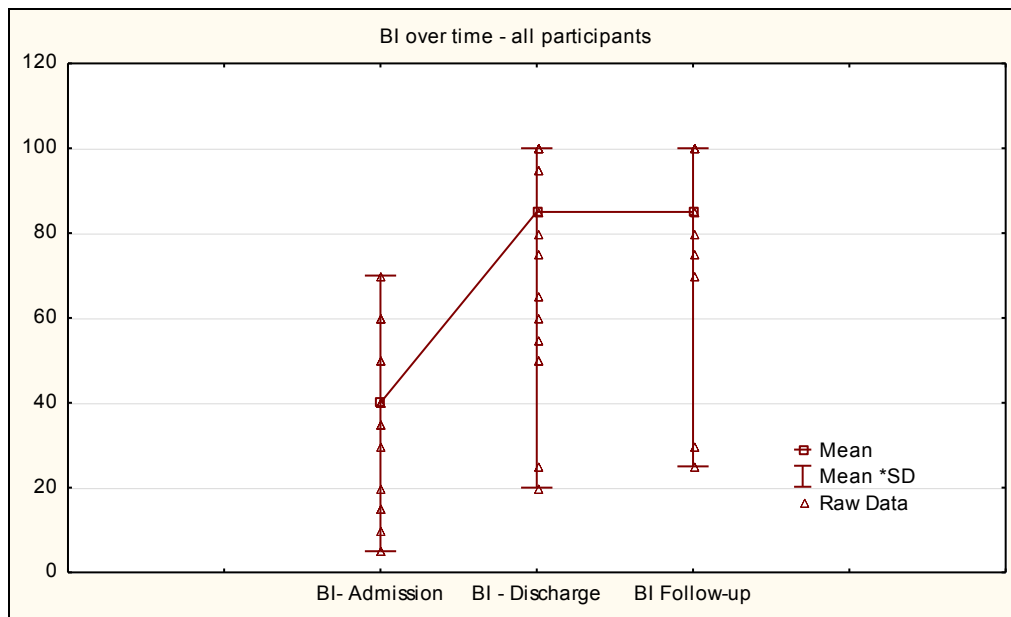
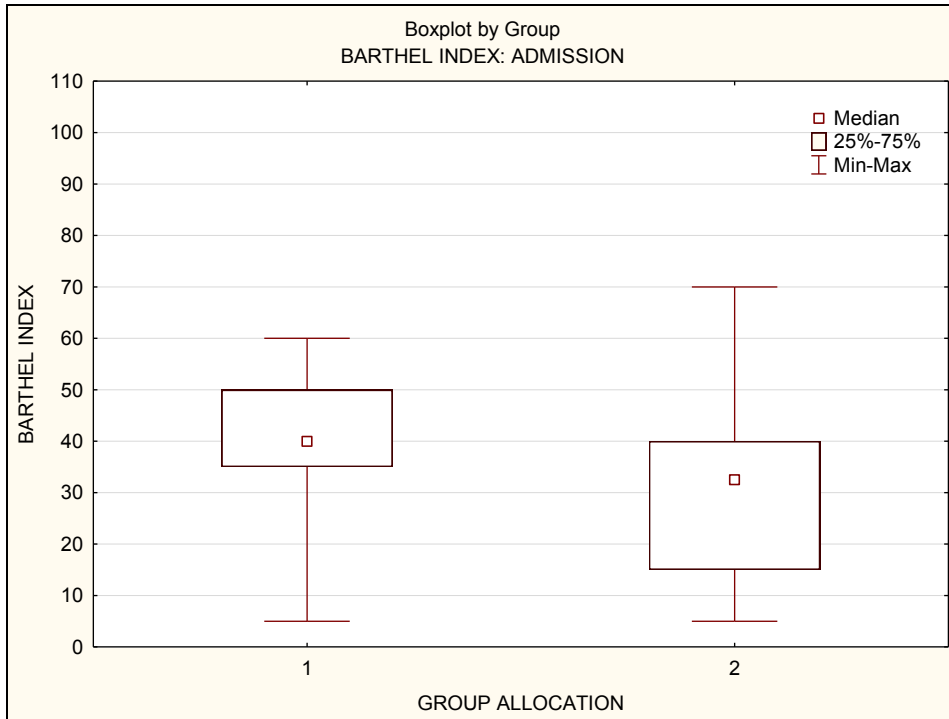


Figure 7: BI at admission (n=19), discharge (n=19) and follow-up (n=10). Raw scores are included

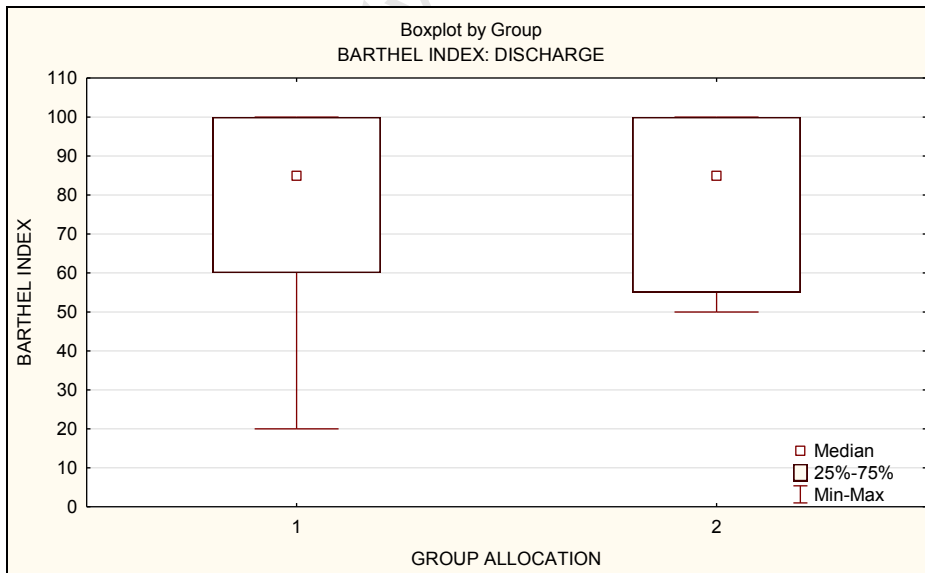
The Mann-Whiney U indicated that there was no significant difference in ranking between the BI admission score of the two groups ($U=33.5$, Z adjusted= 0.91, $p=0.364$). However, as indicated in Figure 8, the median BI score of the control group was higher than the control group.



Group Allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 8: Box and Whisker Plot of BI at Admission

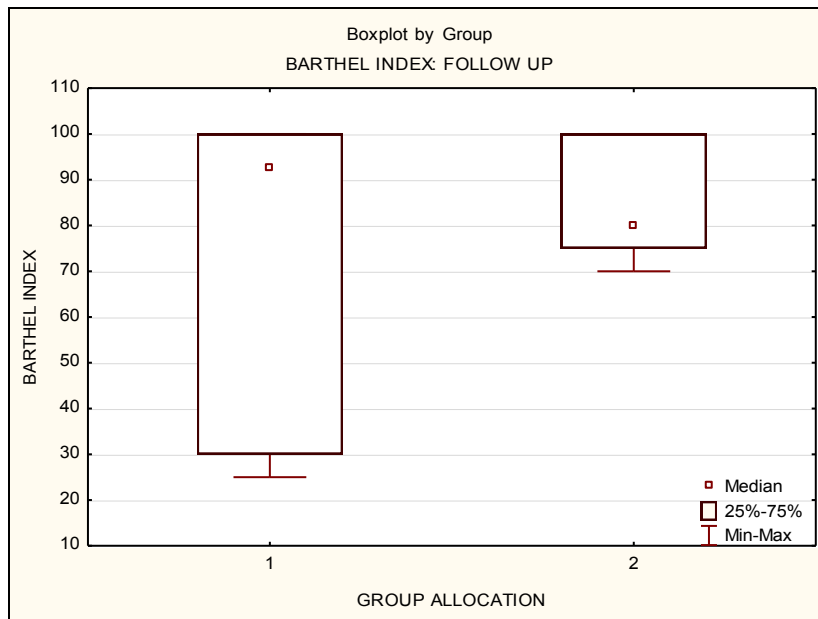
The Mann-Whiney U indicated that there was no significant difference in ranking between the BI scores at discharge of the two groups ($U=42.5$, Z adjusted= -0.17 , $p=0.867$). The BI scores for each group are indicated in Figure 9.



Group Allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 9: Box and Whisker plot of BI at discharge

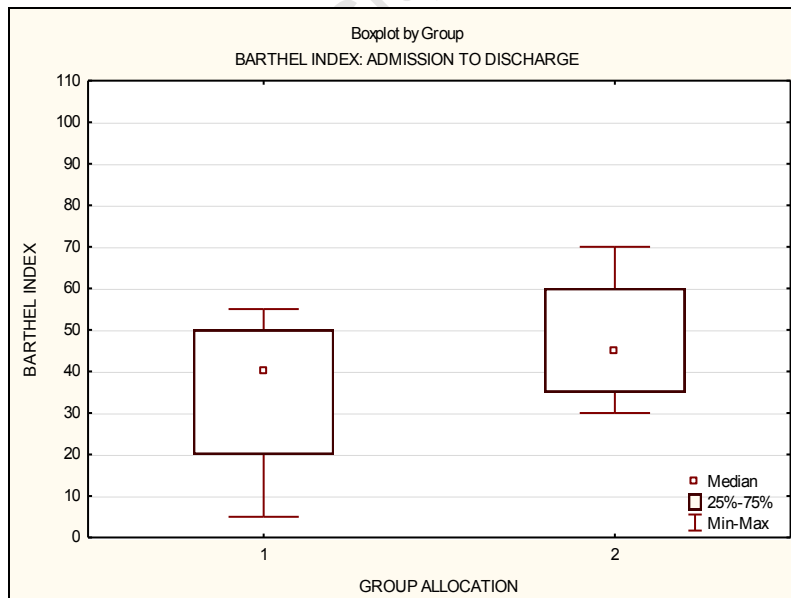
The Mann-Whitney U indicated that there was no significant difference in ranking between the BI scores at follow-up of the two groups ($U=10.0$, Z adjusted= -0.45 , $p=0.656$). The BI scores for each group are indicated in Figure 10.



Group Allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 10: Box and Whisker of BI at Follow-up

The Mann-Whitney U indicated that there was no significant difference in ranking the difference between admission to discharge BI scores between the two groups ($U=28.0$, Z adjusted= -1.36 , $p=0.175$). The BI scores from admission to discharge between the two groups are indicated in Figure 11.

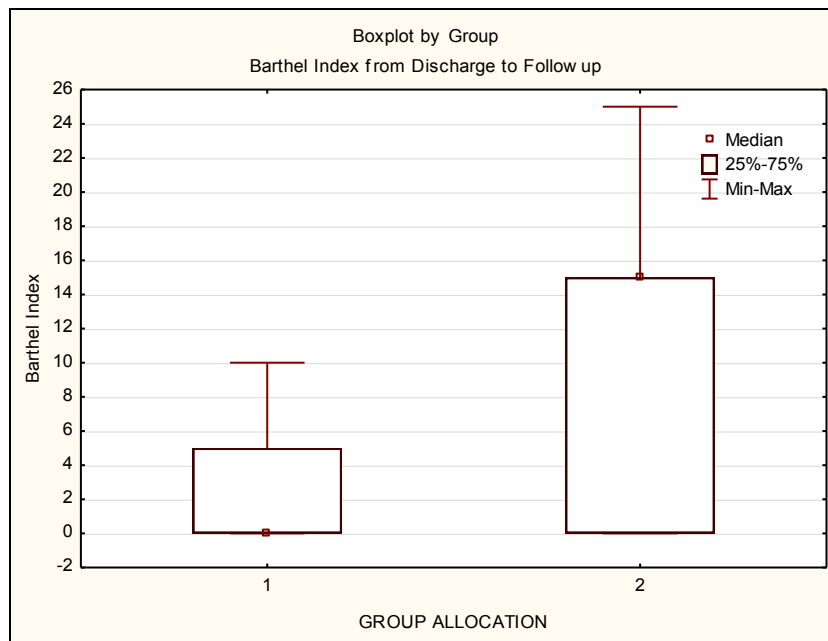


Group Allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 11: Box and Whisker of BI from Admission to Discharge

Although not significant on testing, the size of the effect of treatment on the difference in scores from admission to discharge was 0.75 (CIs 0.52-0.98) a medium effect size (mean control=difference of 34.4, SD=17.4, experimental 46.5 SD=13.5, SD of whole sample=16.27).

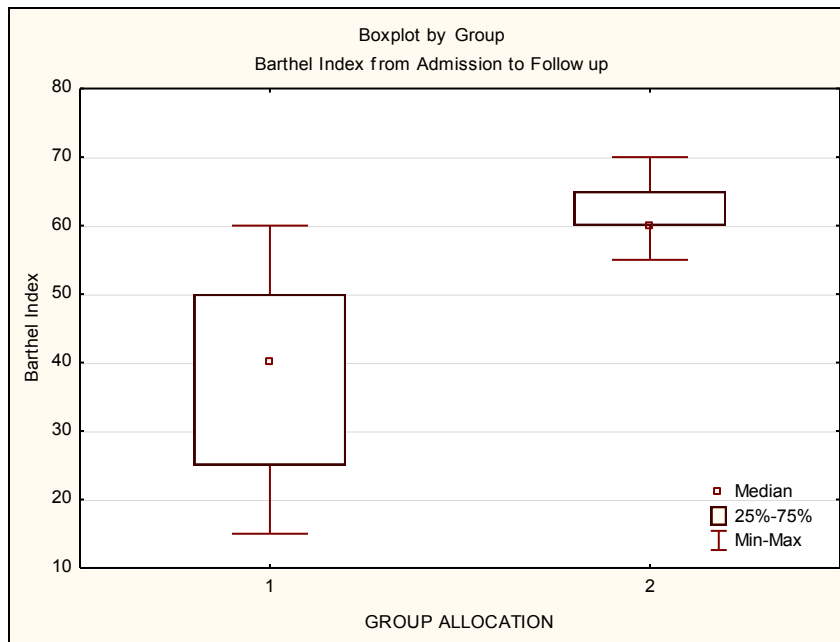
One subject in the control group suffered a second stroke and was excluded from analysis of the follow-up BI score. There was no significant difference in ranking between BI scores difference from discharge to follow-up between the two groups (U=7.00, Z adjusted= -1.12, p=0.264). The BI scores from discharge to follow-up are indicated in Figure 12.



Group allocation: 1= Control group (n=5); 2= Experimental group (n=5)

Figure 12: Box and Whisker of BI from Discharge to Follow-up

There was a significant difference in ranking between the two groups BI scores from admission to follow-up, with the experimental group showing the most improvement in BI score (U=2.0, Z adjusted= -2.09, p=0.034). The BI score from admission to follow-up are indicated in Figure 13.



Group allocation: 1= Control group (n=5); 2= Experimental group (n=5)

Figure 13: Box and Whisker plot of BI from Admission to Follow-up

4.2.2 The Rivermead Motor Assessment:

One subject in the control group suffered a second stroke and was excluded from analysis of the RMA at follow-up.

The mean RMA Gross Function Subscale of participants at admission, discharge and follow-up are listed in Table 5.

Table 5: Rivermead Motor Assessment Gross Function

Gross Function	Median	Lower Quartile	Upper Quartile	Standard Deviation	Minimum Score	Maximum Score	Total Score for Subscale
Admission (n=19)	2.00	1.00	5.0	2.19	0	7	13
Discharge (n=19)	9.00	3.0	11.0	3.65	1	11	13
Follow-up (n=10)	10.00	4.0	12.0	4.10	1	12	13

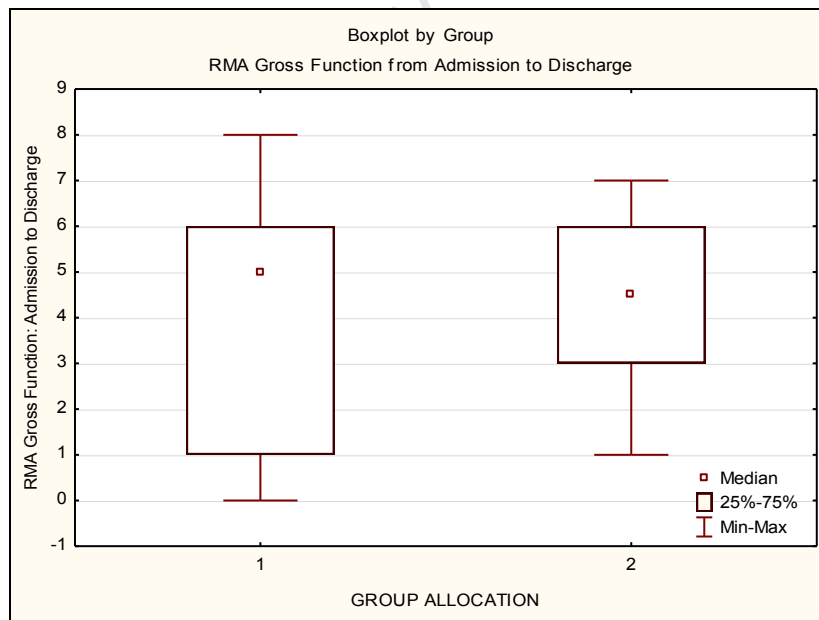
The Mann-Whitney U indicated that there was no significant difference in ranking between the two groups scores of the RMA Gross Function Subscale at admission, discharge and follow-up. These values are indicated in Table 6.

Table 6: RMA Gross Function Section

Gross Function	U- value	Z adjusted	p-value
Admission (n=19)	38.0	0.53	0.592
Discharge (n=19)	43.50	0.08	0.932
Follow-up (n=10)	9.5	0.53	0.595

The Box and Whisker plot for the RMA Gross function are listed in Appendix I

There was no significant difference in ranking between the two groups gain in score for the RMA Gross Function Subscale from admission to discharge (U= 44.0, Z adjusted= -0.04, p=0.967). The RMA Gross Function Subscale scores from admission to discharge are indicated in Figure 14.

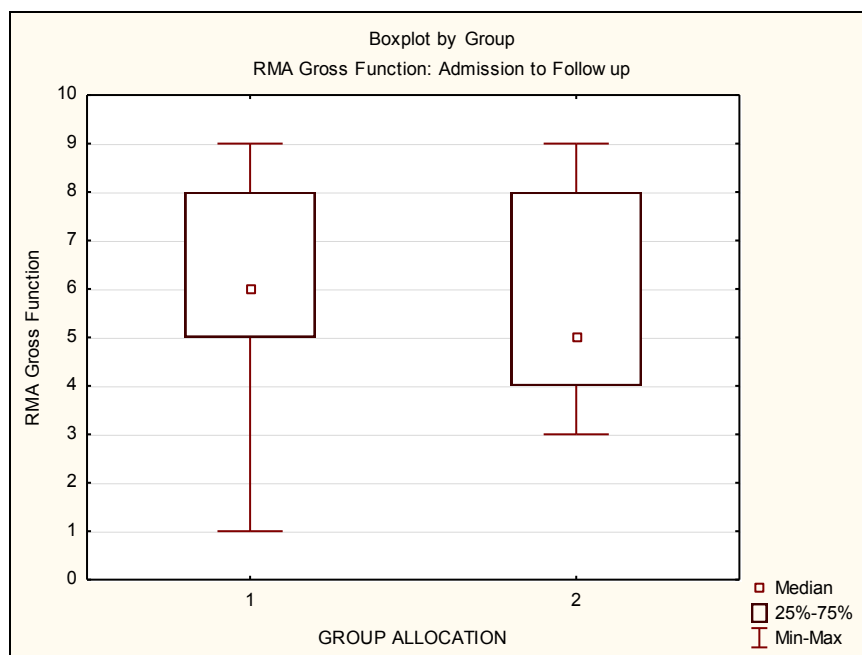


Group Allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 14: Box and Whisker plot of RMA Gross Function from Admission to Discharge

The difference between the two means was 0.22, the SD of the total group was 2.72 and the effect size was very small, 0.08 (CIs 0.13-0.29), indicating that there was no impact of treatment on the change in the RMA Gross Function scores between admission and discharge.

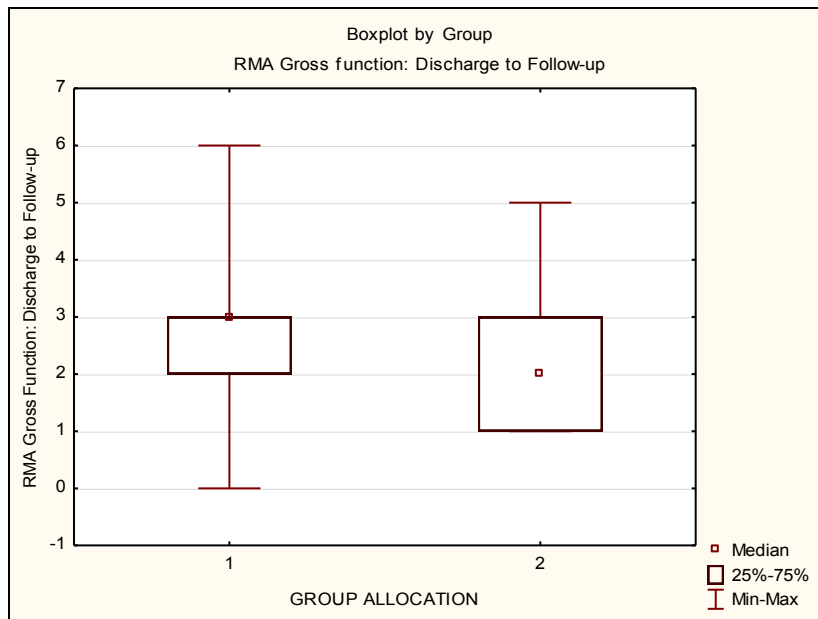
There was no significant difference in ranking between the two groups gain in score for the RMA Gross Function Subscale from admission to follow-up ($U=11.50$, Z adjusted= 0.10 , $p=0.916$).). The RMA Gross Function Subscale scores from admission to follow-up are indicated in Figure 15.



Group allocation: 1= Control group (n=5); 2= Experimental group (n=5)

Figure 15: Box and Whisker plot of RMA Gross Function gain from Admission to Follow-up

There was no significant difference in ranking between the two groups gain in score for the RMA Gross Function Subscale from discharge to follow-up ($U=10.50$, Z adjusted= -0.32 , $p=0.750$). The RMA Gross Function Subscale scores from discharge to follow-up are indicated in Figure 16.



Group allocation: 1= Control group (n=5); 2= Experimental group (n=5)

Figure 16: Box and Whisker plot of RMA Gross Function gain from Discharge to Follow-up

The mean RMA Leg and Trunk scores of participants at admission, discharge and follow-up are listed in Table 7.

Table 7: RMA Leg and Trunk Section

Leg and Trunk	Median	Lower Quartile	Upper Quartile	Standard Deviation	Minimum Score	Maximum Score	Total Score for Subscale
Admission (n=19)	5.00	2.00	6.00	2.56	0	9	10
Discharge (n=19)	8.00	6.00	10.00	2.03	4	10	10
Follow-up (n=10)	8.50	6.00	10.0	1.91	6	10	10

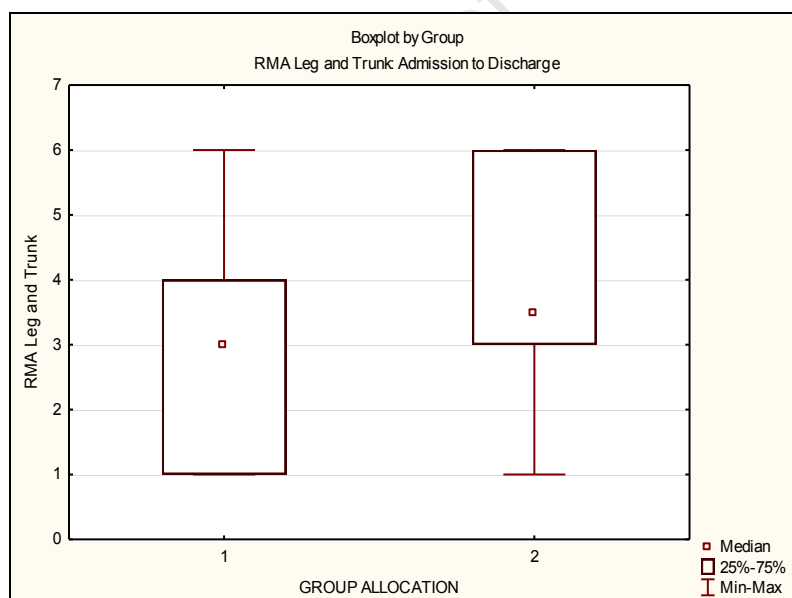
The Mann-Whitney U indicated that there was no significant difference in ranking between the two groups gain in scores of RMA Leg and Trunk Subscale at admission, discharge and follow-up. These values are indicated in Table 8.

Table 8: RMA Leg and Trunk

Leg and Trunk	U- value	Z adjusted	p-value
Admission (n=19)	44.0	0.04	0.967
Discharge (n=19)	36.0	-0.72	0.471
Follow-up (n=10)	12.0	0.00	1.00

The Box and Whisker plot of RMA Leg and Trunk for admission, discharge and follow-up are listed in Appendix I

There was no significant difference in ranking between the two groups gain in score for the RMA Leg and Trunk Subscale from admission to discharge (U=35.50, Z adjusted=-0.75, p=0.452). The RMA Leg and Trunk Subscale scores from admission to discharge are indicated in Figure 17. The effect size was 0.11 (CIs 0.1-0.32), which indicates that there was no treatment effect.



Group Allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 17: Box and Whisker plot of RMA Leg and Trunk gain from Admission to Discharge

There was no significant difference in ranking between the two groups gain in score for the RMA Leg and Trunk Subscale from admission to follow-up (U=11.50, Z

adjusted=-0.11, $p=0.915$). The RMA Leg and Trunk Subscale scores from admission to follow-up are indicated in Figure 18.

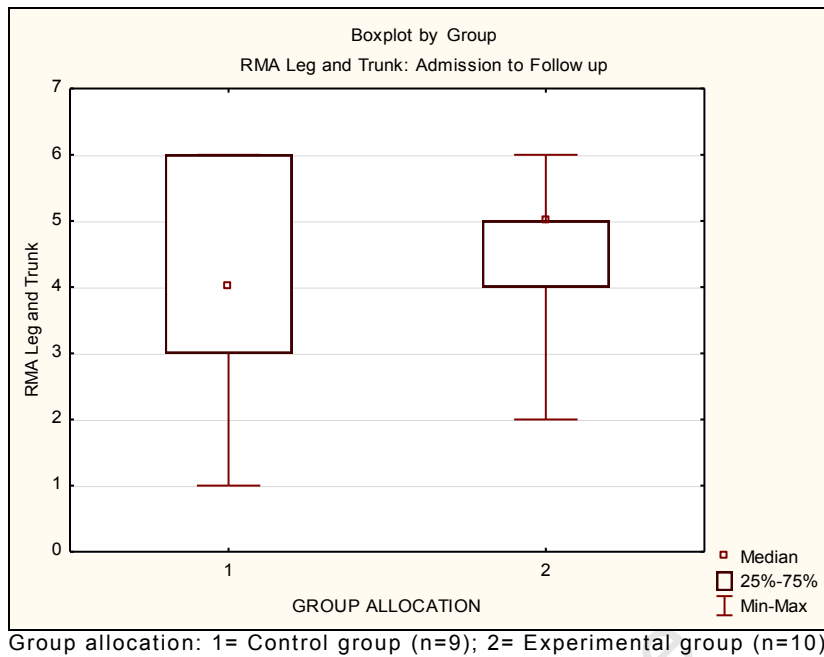


Figure 18: Box and Whisker plot of RMA Leg and Trunk gain from Admission to Follow-up

There was no significant difference in ranking between the two groups gain in score for the RMA Leg and Trunk Subscale from discharge to follow-up ($U=10.50$, Z adjusted=-0.39, $p=0.699$). The RMA Leg and Trunk Subscale scores from discharge to follow-up are indicated in Figure 19.

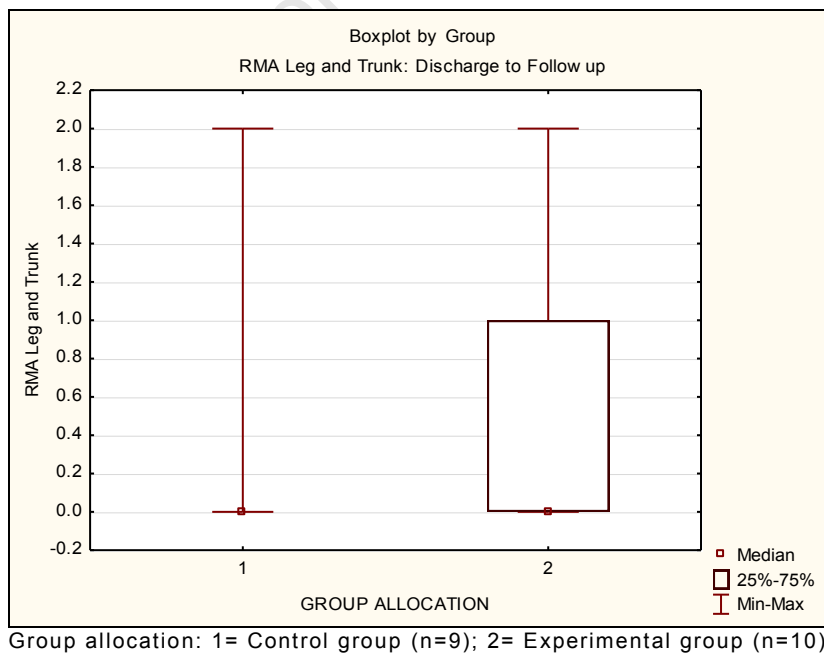


Figure 19: Box and Whisker plot of RMA Leg and Trunk gain from Discharge to Follow-up

The mean RMA Arm Section scores of participants at admission, discharge and follow-up are listed in Table 9.

Table 9: RMA Arm Section

Arm	Median	Lower Quartile	Upper Quartile	Standard Deviation	Minimum Score	Maximum Score	Total Score of Subscale
Admission (n=19)	3.00	0.00	7.00	3.31	0	8	15
Discharge (n=19)	8.00	4.00	10.00	3.79	0	15	15
Follow-up (n=10)	10.0	5.00	11.0	3.59	3	13	15

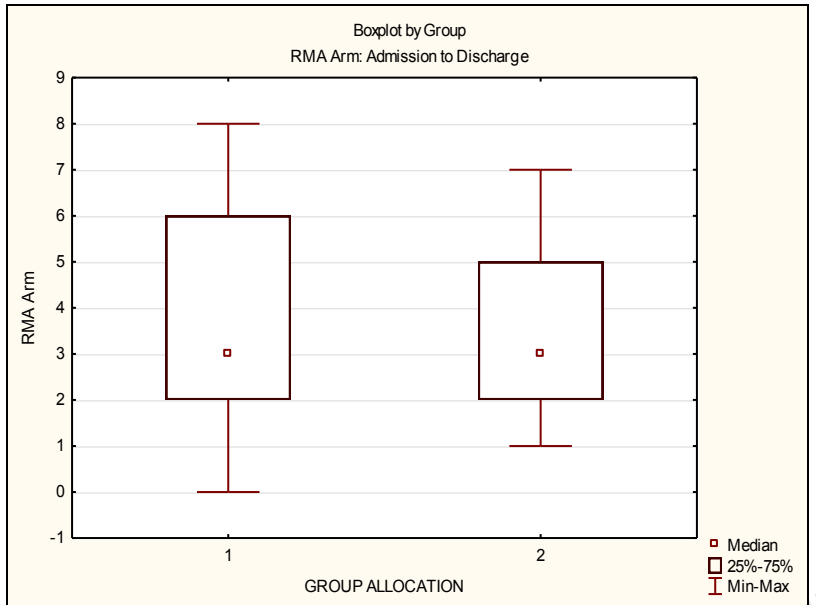
The Box and Whisker plot for the RMA Arm for admission, discharge and follow-up are listed in Appendix I.

The Mann-Whitney U indicated that there was no significant difference in ranking between the two groups gain in scores of the RMA Arm subscale at admission, discharge and follow-up. These values are indicated in Table 10.

Table 10: RMA Arm Subscale

Arm	U- value	Z adjusted	p-value
Admission (n=19)	33.0	0.96	0.337
Discharge (n=19)	37.0	0.62	0.533
Follow-up (n=10)	12.5	0.00	1.000

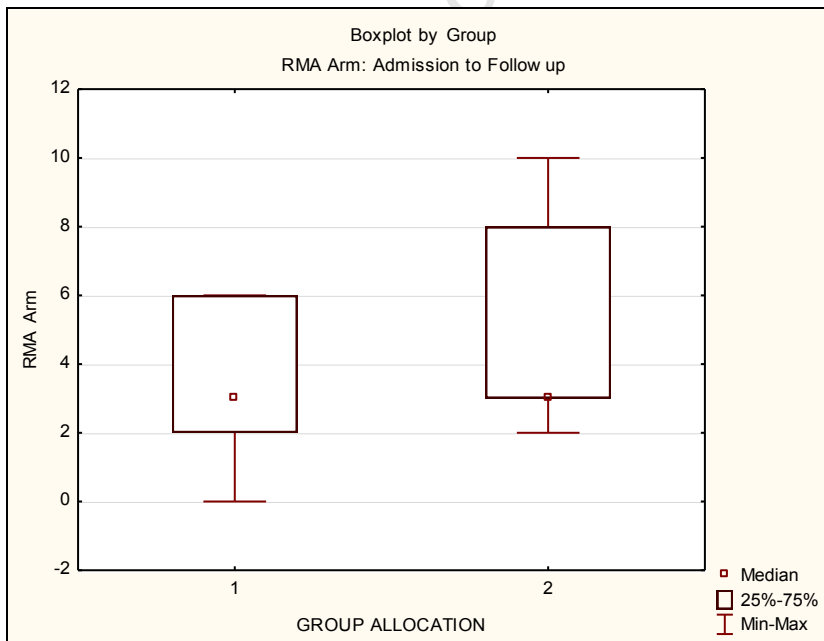
There was no significant difference in ranking between the two groups gain in scores of the RMA Arm Subscale from admission to discharge (U=42.50, Z adjusted=-0.17, p=0.868). The effect size was 0.30 (CIs 0.11-0.51), a small effect size. The RMA Arm section scores from admission to discharge are indicated in Figure 20.



Group allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 20: Box and Whisker plot of RMA Arm gain from Admission to Discharge

There was no significant difference in ranking between the two groups gain in scores of the RMA Arm Section from admission to follow-up ($U=8.50$, Z adjusted= -0.74 , $p=0.456$). The RMA Arm sections from admission to follow-up are indicated in Figure 21.



Group allocation: 1= Control group (n=5); 2= Experimental group (n=5)

Figure 21: Box and Whisker plot of RMA Arm gain from Admission to Follow-up

There was no significant difference in ranking between the two groups gain in scores of the RMA Arm Section from discharge to follow-up ($U=5.50$, Z adjusted=-1.46, $p=0.145$). The RMA Arm sections from discharge to follow-up are indicated in Figure 22.

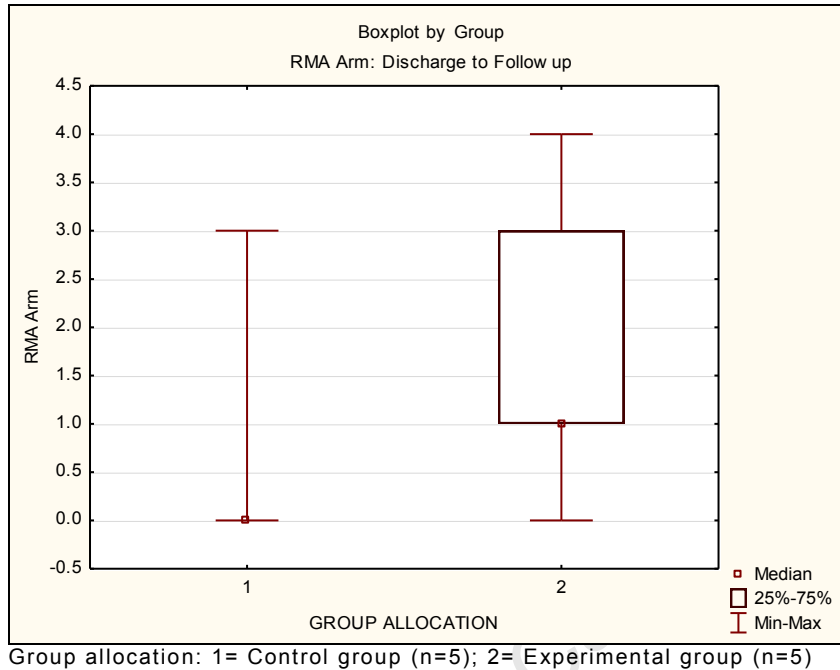


Figure 22: Box and Whisker plot of RMA Arm gain from Discharge to Follow-up

In summary, there was no significant difference in ranking in the gain in scores between the two groups of the RMA Gross Function, Leg and Trunk and the Arm Subscales.

4.3 COMPARISON OF HEALTH RELATED QUALITY OF LIFE OF THE TWO GROUPS

4.3.1 EQ-5D: VAS

The values of the EQ-5D Vas for the all participants are shown in Figure 23. The mean EQ-5D: VAS on admission is 55.79 (SD=15.12, range). Values ranged from 10 to 80 as indicated Figure 23. The mean EQ-5D: VAS on discharge was 68.95 (SD=16.46).The values ranged from 40 to 95 as indicated in Figure 23. The mean EQ-5D: VAS at follow-up is 71.00 (SD=15.60).The values ranged from 50 to 95 as indicated in Figure 23.

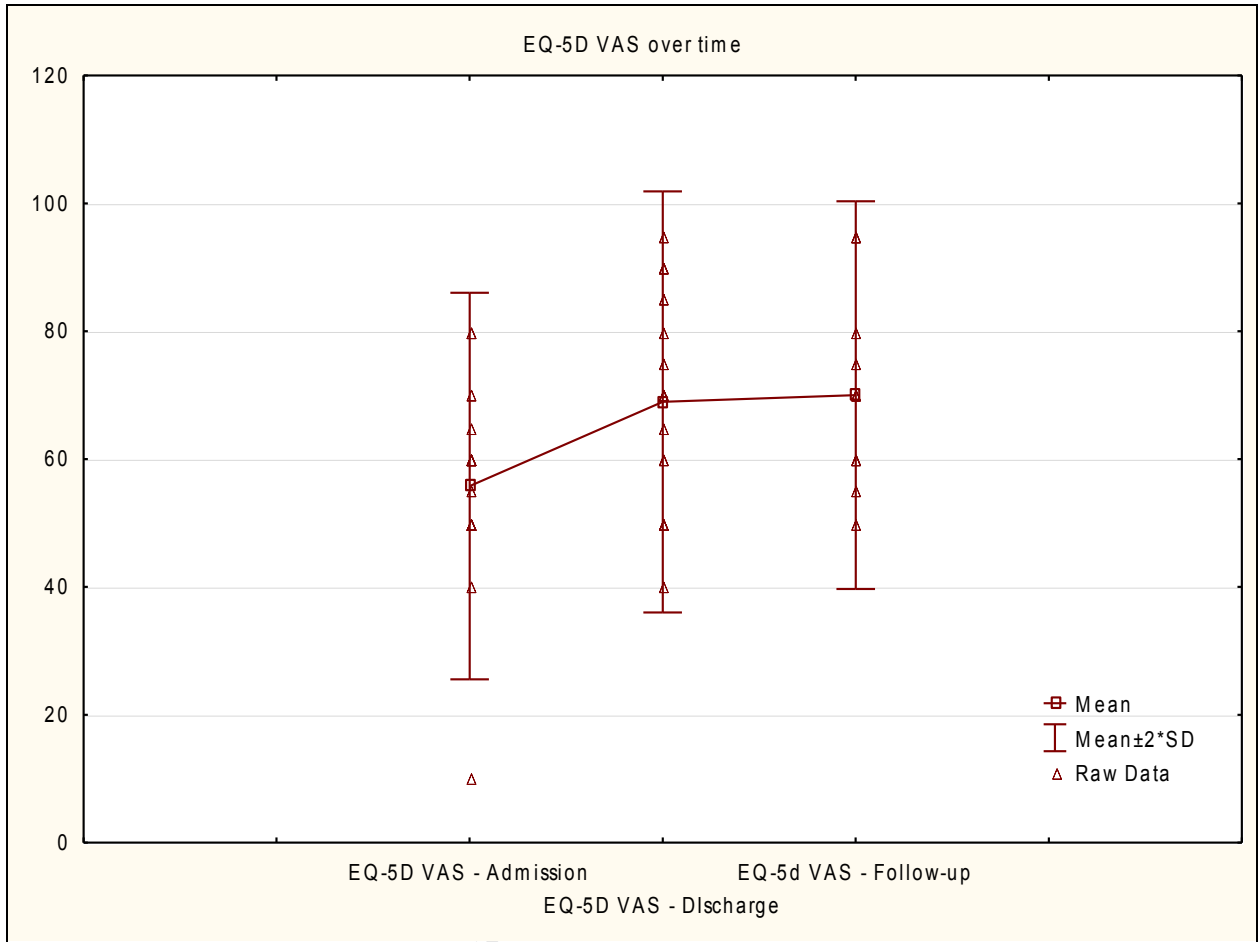
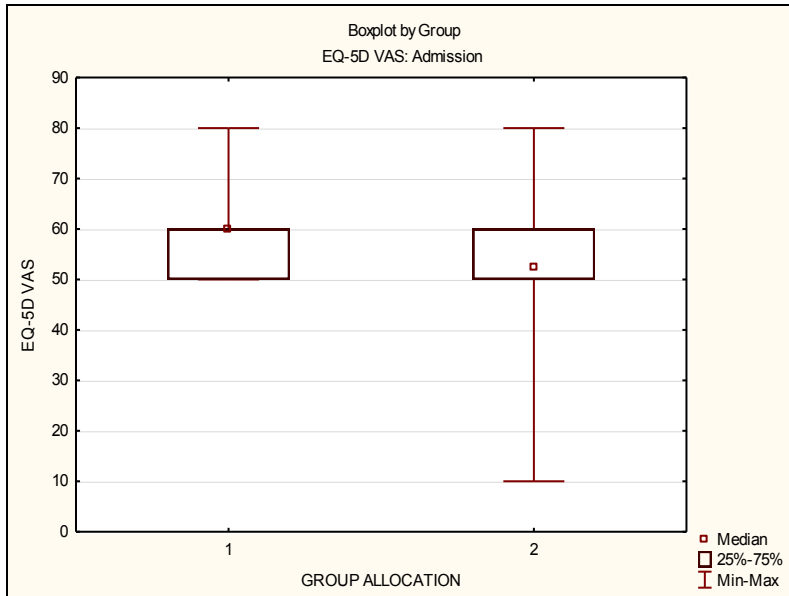


Figure 23: Change in EQ-5D Vas overtime (n=19 for admission and discharge, 11 at follow-up)

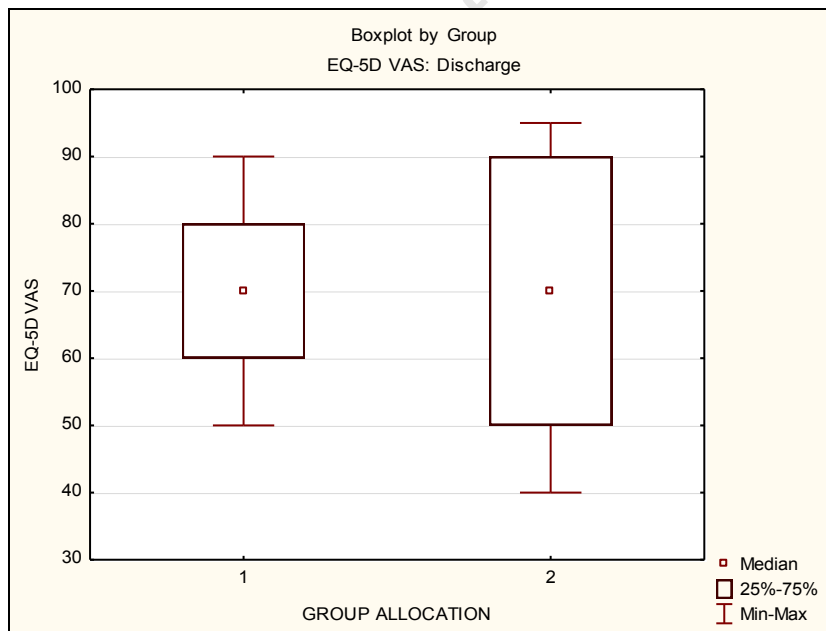
The Mann-Whitney U indicated that there was no significant difference in ranking between the two groups EQ-5D VAS values at admission (U= 34.0, Z adjusted=0.89, p=0.376) as indicated in Figure 24 .



Group allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 24: Box and Whisker plot of EQ-5D VAS at Admission

The Mann-Whitney U indicated that there was no significant difference in ranking between the two groups EQ-5D VAS values at discharge ($U= 44.0$, Z adjusted=0.04, $p=0.967$) as indicated in Figure 25.

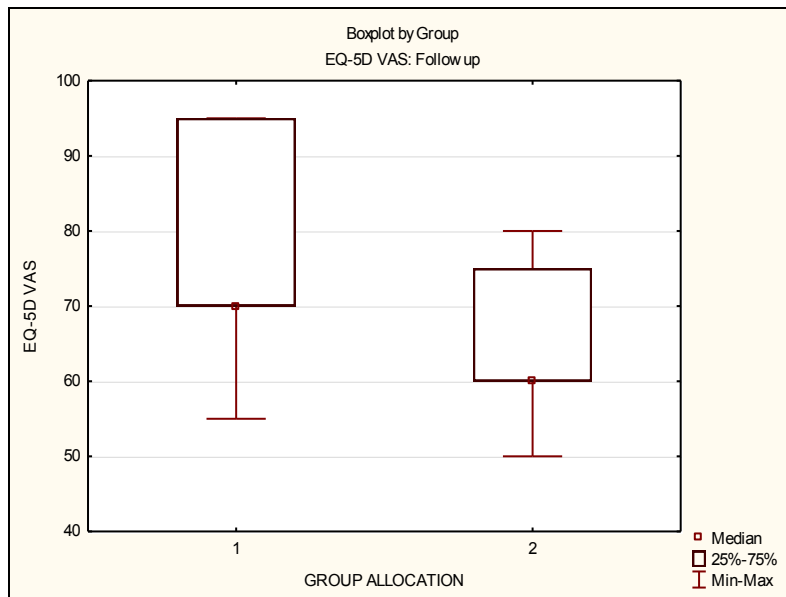


Group Allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 25: Box and Whisker plot of EQ-5D VAS at Discharge

One subject in the control group suffered a second stroke and was excluded from analysis of the EQ-5D at follow-up. The Mann-Whitney U indicated that there was

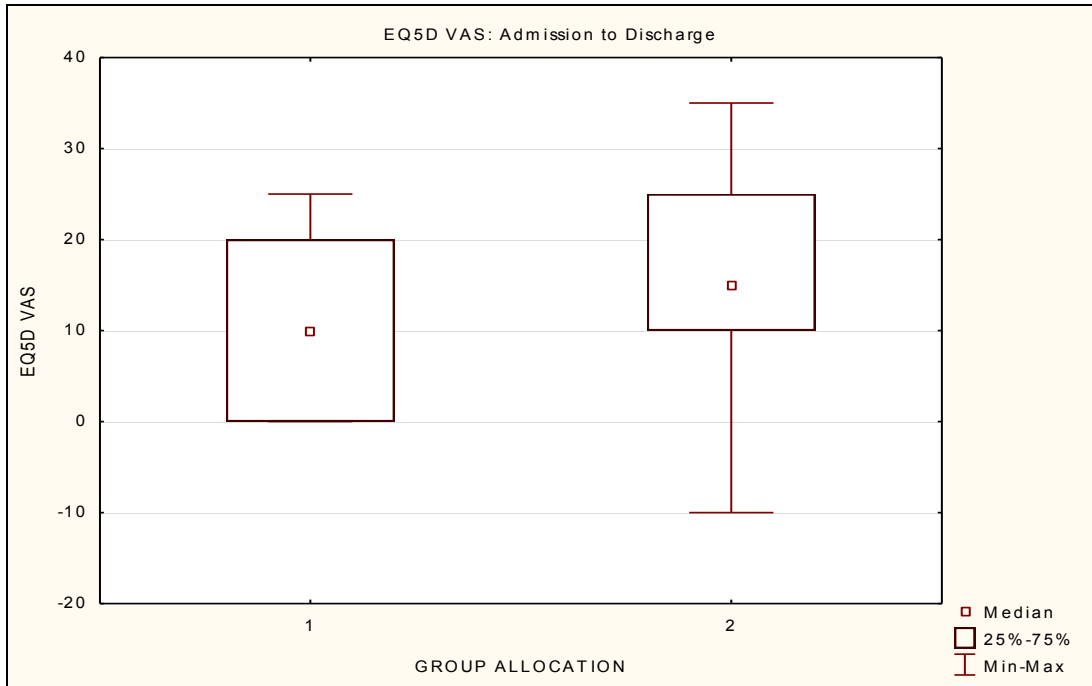
no significant difference in ranking between the two groups EQ-5D VAS values at follow-up ($U= 8.0$, Z adjusted= 0.84 , $p=0.399$) as indicated in Figure 26.



Group allocation: 1= Control group (n=5); 2= Experimental group (n=5)

Figure 26: Box and Whisker plot of EQ-5D VAS at Follow-up

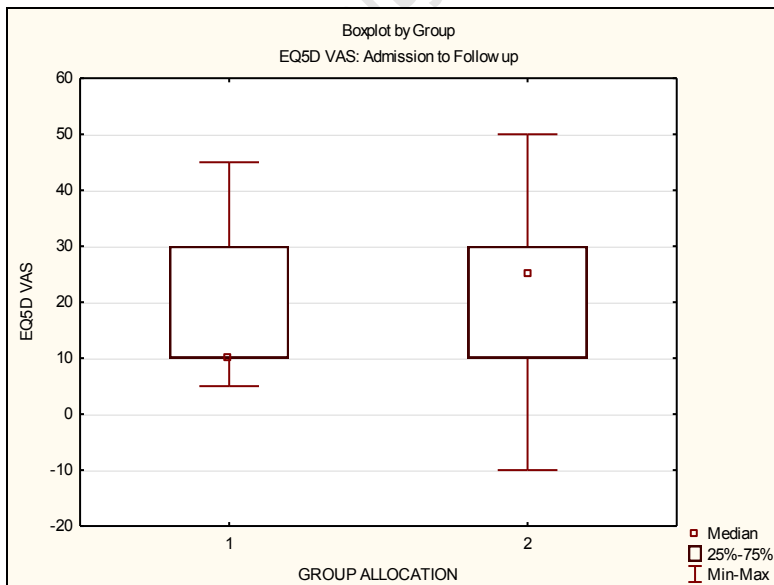
There was no significant difference in ranking between the two groups EQ-5D VAS change in score from admission to discharge ($U=29.50$, Z adjusted= -1.25 , $p=0.210$). The changes in VAS EQ-5D scores from admission to discharge are indicated in Figure 27. However, based on a mean difference between admission and discharge of 6 (control group mean 10.0, SD 9.68; experimental group 16.0 SD 12.86) and a SD of 11.57 for the combined group, the effect size was 0.52 (CIs 0.30-0.74), a medium treatment effect.



Group Allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 27: Box and Whisker plot of EQ-5D change from Admission to Discharge Scores

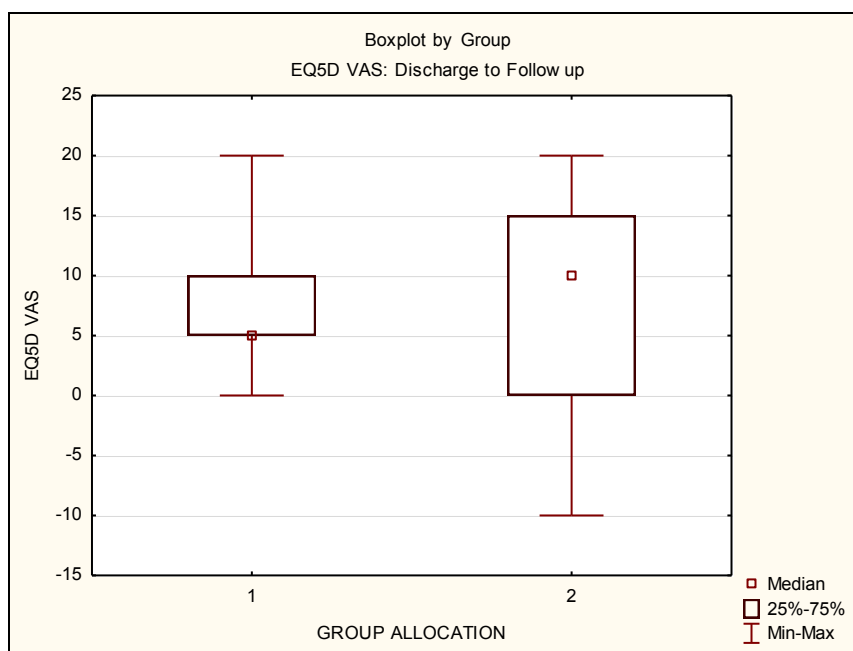
There was no significant difference in ranking between the two groups EQ-5D VAS from admission to follow-up ($U=11.50$, Z adjusted=-0.11, $p=0.916$). The EQ-5D scores between the two groups from admission to follow-up are indicated in Figure 28.



Group allocation: 1= Control group (n=5); 2= Experimental group (n=5)

Figure 28: Box and Whisker plot of EQ-5D from Admission to Follow-up

The EQ-5D VAS scores between the two groups from discharge to follow-up are indicated in Figure 29.



Group allocation: 1= Control group (n=5); 2= Experimental group (n=5)

Figure 29: Box and Whisker plot of EQ-5D VAS from Discharge to Follow-up

4.3.2 EQ-5D domains and QALY tariff

The Chi- Square test indicated that there was no association between group allocation and the EQ-5D domain as indicated in Table 11 apart from the domain of Usual Activities at discharge which indicated a significant difference between group association ($p=0.015$). In this domain the experimental group were able to perform more usual activities than the control group.

Table 11: EQ-5D Variables

	Domain	No Problems	Some Problems	Severe Problems	Total	Chi-square p-value between groups
Admission	Mobility					0.782
	Control	1	4	4	9	
	Experimental	1	3	6	10	

Discharge						0.971
	Control	4	4	1	9	
	Experimental	5	4	1	10	
Follow-up						0.333
	Control	3	1	1	5	
	Experimental	2	3	0	5	
Self-care						
Admission						0.988
	Control	1	6	2	9	
	Experimental	1	7	2	10	
Discharge						0.259
	Control	4	5	0	9	
	Experimental	7	3	0	10	
Follow-up						0.527
	Control	3	2	0	5	
	Experimental	2	3	0	5	
Usual Activities						
Admission						0.844
	Control	0	4	5	9	
	Experimental	0	4	6	10	
Discharge						0.015
	Control	0	4	5	9	
	Experimental	2	8	0	10	

Follow-up						0.178
	Control	2	2	1	5	
	Experimental	0	4	1	5	
Pain/Discomfort						
Admission						0.484
	Control	5	3	1	9	
	Experimental	5	5	0	10	
Discharge						0.252
	Control	5	4	0	9	
	Experimental	8	2	0	10	
Follow-up						1.0
	Control	4	1	0	5	
	Experimental	4	1	0	5	
Anxiety/Depression						
Admission						0.445
	Control	1	7	1	9	
	Experimental	3	5	2	10	
Discharge						0.498
	Control	4	5	0	9	
	Experimental	6	4	0	10	
Follow-up						0.766
	Control	2	2	1	5	
	Experimental	3	1	1	5	

The application of the York Tariff of values for each state and testing for the scores of the whole group over time using the ANOVA indicated that there was a significant difference between the scores of the entire group over time as indicated in Figure 30.

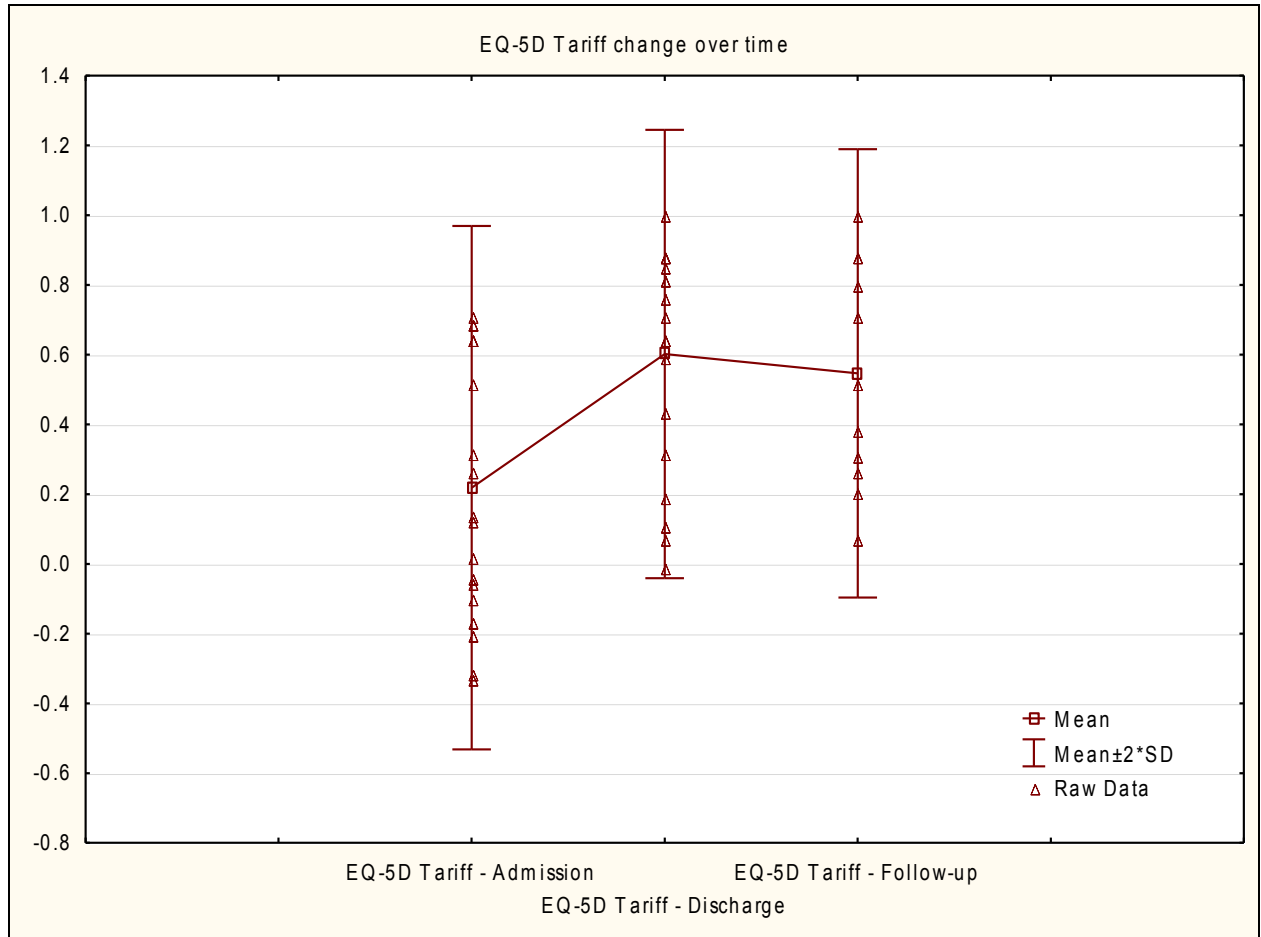
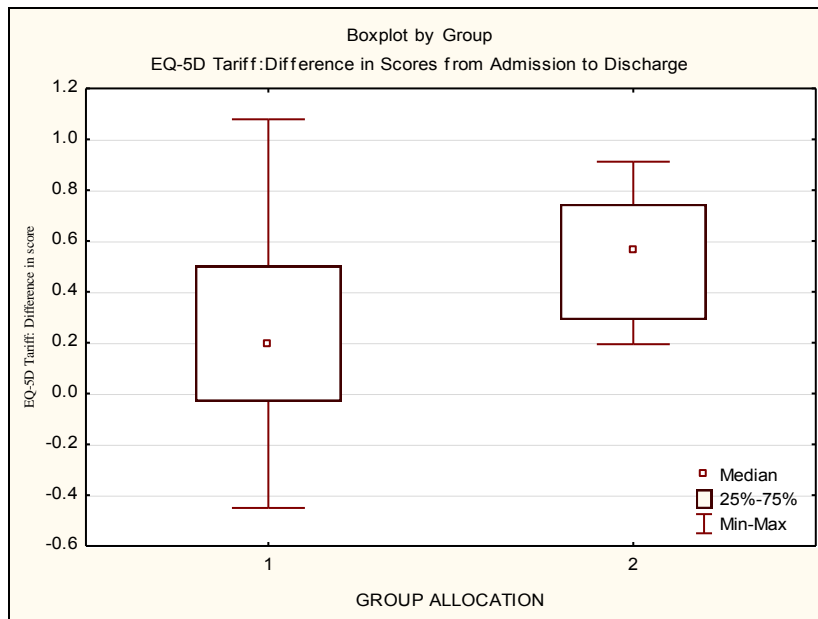


Figure 30: EQ-5D Tariff at Admission (n=19), Discharge (n=19) and Follow-up (n=10)

The Mann Whitney U revealed that there was no significant difference between the two groups in the rank ordering of the difference in scores from admission to discharge, although the exact p value approached significance at 0.053 (U=21.5, Z=1.88, exact p=0.053) as indicated in Figure 31.



Group allocation: 1= Control group (n=9); 2= Experimental group (n=10)

Figure 31: Box and Whisker of EQ-5D Tariff Change in Scores from Admission to Discharge

The mean value of the change in control group was 0.21(0.46) and that in the experimental was 0.54 (0.27). This implies that the quality of life in the experimental group was 0.33 better than the control group on discharge which equates to a gain in QALYs (quality adjusted life year) equivalent to 3.9 months over one year (0.325*12)

The treatment effect size was 0.83 (CIs 0.6-1.06), a large effect, based on a difference between the gains in score of 0.33 and a SD of the total group of 0.39. (Mean control group = 0.21, SD=0.46, mean experimental group =0.54, SD=.27).

4.4 COMPARISON OF THE EFFORT OF WALKING OF THE TWO GROUPS

4.4.1 Physiological Cost Index:

Eleven patients were walking on discharge, six in the control group and five in the experimental group. The mean PCI value at discharge was 0.91 (SD=1.02). The values ranged from 0.17 to 3.54 as indicated in Figure 32.

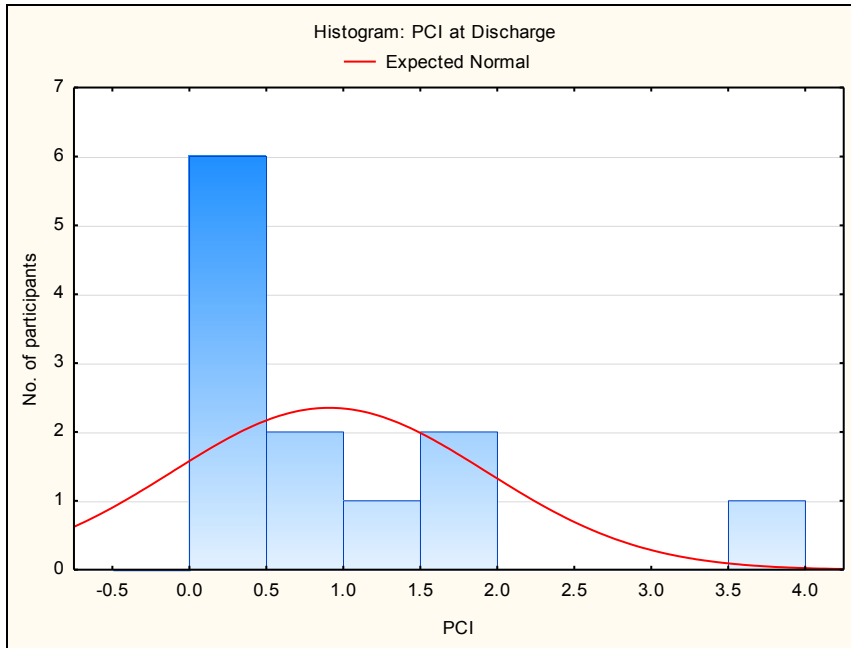
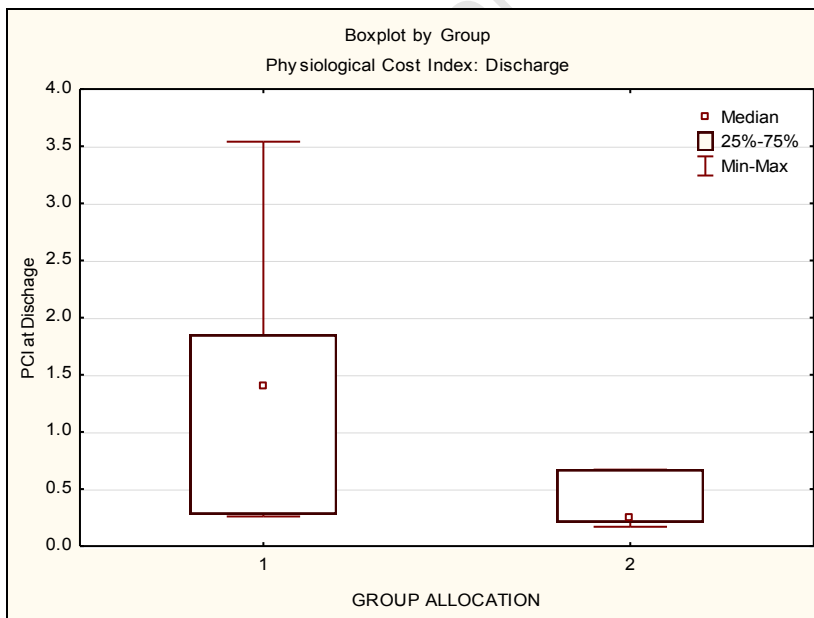


Figure 32: Histogram of PCI at discharge (n=12)

The Mann-Whitney U indicated that there was a significant difference in the effort of walking between the two groups PCI at discharge ($U=4.5$, Z adjusted=2.09, $p=0.037$). The difference in PCI between the two groups are indicated in Figure 33.



Group allocation: 1= Control group (n=6); 2= Experimental group (n=6)

Figure 33: Box and Whisker plot of PCI at Discharge (Note that the higher the score the more energy required to walk).

The mean of the control group was 1.45 (SD=1.23) and that of the experimental group was 0.41 (SD=0.24). The effect size was not calculated as the data sets of the two groups were not normally distributed (Shapiro-Wilk's $W=0.76749$, $p=0.004$ for the control and Shapiro-Wilk's $W=0.78491$, $p=0.01$ for the intervention groups).

One subject in the experimental group started walking after discharge. One subject in the control group suffered a second stroke and was excluded from analysis of the PCI at follow-up. The mean PCI value at follow-up was 0.49 (SD=0.51). The values ranged from 0.05 to 1.25 as indicated in Figure 34.

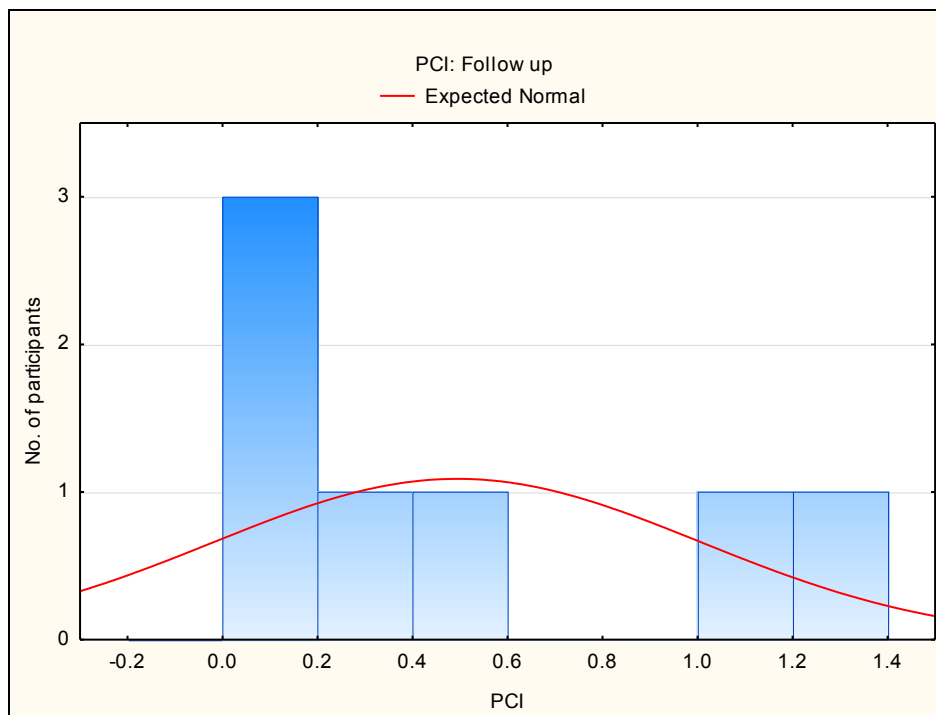
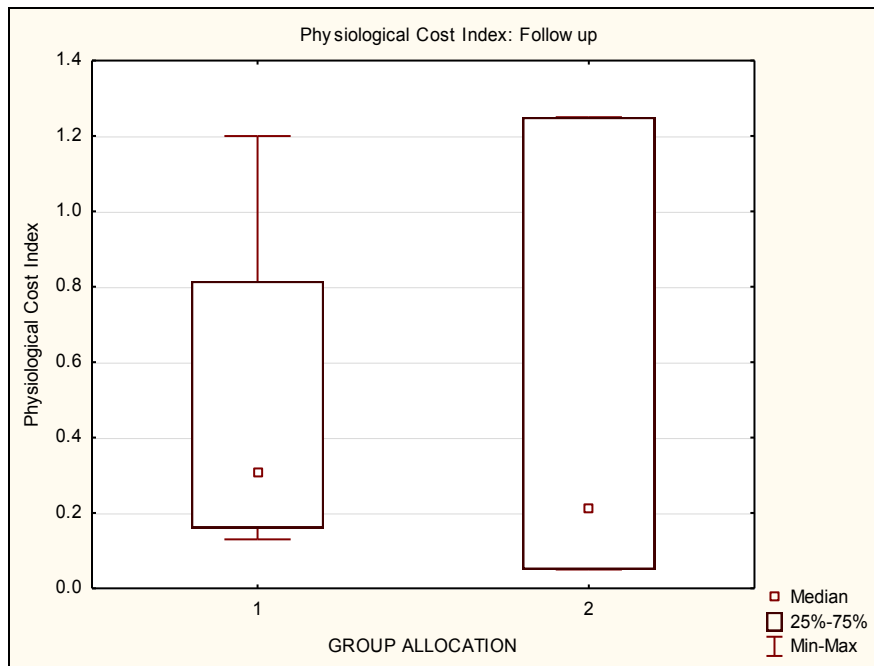


Figure 34: Histogram of PCI at follow-up (n=7)

The Mann-Whitney U indicated that there was no significant difference in the effort of walking between the two groups PCI at follow-up ($U=6.0$, Z adjusted=-0.177, $p=0.860$) as indicated in Figure 35.



Group allocation: 1=Control group (n=4); 2= Experimental group (n=3)

Figure 35: Box and Whisker plot of PCI at Follow-up

4.5 POWER ANALYSIS:

The study was underpowered. Using the means of 34.4 and 46.5 on the BI, the sample sizes of nine and ten respectively and a SD of 13.5, it was calculated in Statistica that the power of the t-test to detect a significant difference, was only 45%. Using the same figures, it was calculated that a sample size of 12 in each group would have picked up a significant difference with an 80% power level.

4.6 INTERVENTION DESCRIPTION:

The distribution of control and experimental participants treated by each therapist is represented in Table 12 below:

Table 12: Distribution of groups between therapists

	Control (n=9)	Experimental (n=10)	Total (n=19)
Therapist 1	1	4	5
Therapist 2	3	0	3
Therapist 3	2	4	6
Therapist 4	2	3	5

Chi-Square=5.63, df=3, p=0.131

Each participant received one hour of physiotherapy a day, five days a week. The number of participants who received specific treatment activities, performed by the therapists irrespective of group allocation, is represented in Table 13.

Table 13: Check-list of treatment activities performed on participants by therapists

	Therapist 1 (n=5)	Therapist 2 (n=3)	Therapist 3 (n=6)	Therapist 4 (n=5)	Total (n=19)
Bed Mobility	5	3	5	4	17
Transfers	5	3	6	5	19
Weight Shifts	5	1	1	4	11
Postural Re-education	5	1	0	3	9
Walking	4	2	5	1	12
Sit-to-stand	4	3	3	3	13
Upper Limb Strengthening	5	3	6	5	19
Lower Limb Strengthening	5	3	6	5	19
Trunk Strengthening	5	3	4	4	16
Balance Activities	5	3	6	5	19
Selective hip exercises	5	2	3	4	14
Selective knee exercises	5	2	3	4	14
Mat work	4	0	1	0	5
FES: lower limb	2	0	0	0	2

Upper and lower limb strengthening was performed with the use of suspension, weights and springs. Trunk strengthening was performed with the physio ball and plinth exercises.

Treatment was task-specific and goal orientated.

The therapy intervention was compared to a study conducted by De Wit et al which compared physiotherapy interventions across four in-patient European rehabilitation Centres. The physiotherapy intervention received at the unit can be compared to that received internationally

4.6.1 Therapeutic Predictors of Change

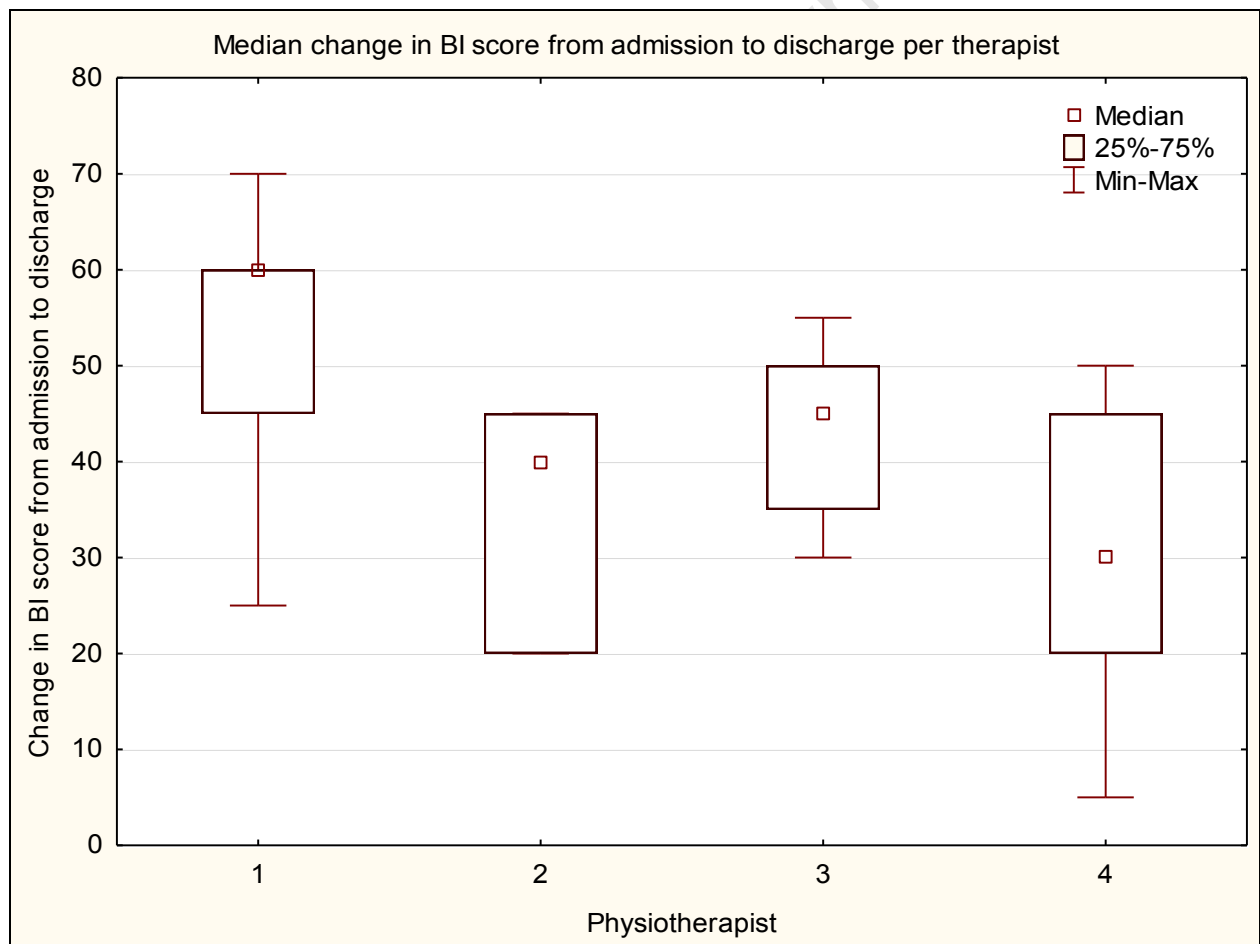


Figure 36: Box and Whisker plot of change in score for each therapist

As depicted in Figure 36 depicts the median change in score and 95% CIs for each therapist. As can be seen, the CIs for each therapist and for each condition (control

or experimental) overlap and there is no significant difference between them. This was confirmed by a Median test (Chi-Square=3.95, df=3, p=0.266) as indicated in Table 14 below.

Table 14: Median Test for the change in score for each therapist

	Therapist 1	Therapist 2	Therapist 3	Therapist 4	Total
<= Median: observed	2	3	3	4	12
Expected	3	2	4	3	
Obs.-exp.	-1	1	-1	1	
> Median: observed	3	0	3	1	7
Expected	2	1	2	2	
Obs.-exp.	1	-1	1	-1	
Total: observed	5	3	6	5	19

4.7 SUMMARY:

There are no adverse effects reported in the Odstock Manual. There are however precautions and warning which need to be adhered to and these were used as exclusion criteria for the study. Odstock Medical request that any adverse effects be reported immediately. No adverse effects were recorded during the data collection of this study.

Although not tested due to the large number of dropouts at follow-up, the means of the scores of all the variables increased steeply from admission to discharge and the improvement then continued at a much slower pace between discharge and follow-up. The exception was the EQ-5D tariff in which the mean score decreased from discharge to follow-up.

Only the change in BI scores from admission to follow-up (p=0.034), the EQ-5D usual activities at discharge (p=0.015) and the PCI at discharge (p=0.037) were found to be significantly different in favour of the intervention group. As the sample

size was smaller than anticipated, the study was found to be underpowered (45%). There was a medium treatment effect for the change in BI from admission to discharge, a small to medium effect on the VAS change and a large effect for the EQ-5D tariff. The effect size of the PCI was not calculated as the two data sets were not normally distributed. There was no effect detected on any of the RMA data sets.

The therapy intervention received included a large range of what would appear to be appropriate interventions. No one therapist's treatment was superior to another.

University of Cape Town

5. DISCUSSION:

The primary aim of the study was to determine whether FES of the abdominal muscles would result in improved function. Post-hoc analysis indicated that the study was underpowered and the sample size was too small to determine whether FES as part of a physiotherapy treatment had any significant effect on the abdominal strength and independence, as measured by the BI and the RMA. Significant differences were however, found between the gain in score of the EQ-5D tariffs between admission and discharge and the PCI at discharge. The effect size calculation was utilised as it is aimed at determining the size of the difference between the scores of the two groups, and is not dependent, as significance testing is, on the sample size. The effect size in favour of the intervention group ranged from medium to large in all parameters from admission to discharge, apart from the RMA. It can therefore be concluded that the intervention had a positive effect on function but that this could have been due to chance as the p values did not reach significance.

This section will discuss the above results in detail. First the generalisability of the results will be examined by comparing the demographic details of the participants with the general population for stroke survivors. The implication of the findings of each parameter will be discussed and the results pertaining to therapy intervention will then be discussed. The limitations of the study will be identified.

5.1 DEMOGRAPHIC CHARACTERISTICS OF THE SAMPLE:

The small participant pool in this study limits comparability to most studies in the literature.

The mean age of the participants in this study was 65 years (SD=16.04) which is somewhat younger than that of patients in developed countries. De wit et al conducted a study comparing four European rehabilitation centres. This article has a participant pool of 500 participants compared to the 19 participants in the current study. The article by De wit et al was however chosen because the study participant pool could be compared more than one inpatient rehabilitation unit in Europe. The mean age of participants at the United Kingdom centre was 67.8 years, the Belgian Centre was 72 years, the Swiss Centre was 71.7 years and the German Centre was 66.5 years. The mean ages of the United Kingdom centre and the German centre

was similar to the mean age of all the participants in the present study. (De Wit et al., 2007b). It would appear that the age of stroke onset is younger in South Africa. In a study conducted in rural South Africa, it was reported that the mean age for participants was 60 years ((SASPI), 2004b). In two studies conducted in Cape Town, it was reported that the mean age of participants was 61 years and 59 years (Rhoda and Hendry, 2003, Rhoda et al., 2011) The Johannesburg Stroke register recorded the mean age of patients admitted to the Johannesburg Hospital after a stroke was 53 years(Connor et al., 2009). The mean age of the present study was older than the participants in the Johannesburg Hospital but was similar to studies conducted in rural South Africa and Cape Town. The Johannesburg Hospital was an acute hospital and not a rehabilitation centre. Participants were therefore representative of SA stroke survivors, but would seem to be younger than other samples of people with stroke internationally.

The gender distribution, in the current study, was similar to those reported at the United Kingdom, Belgian, and Swiss Rehabilitation Centres in that there were equal numbers of males and females. (De Wit et al., 2007b). It was also similar to the gender distribution in the Johannesburg hospital Stroke Register which recorded no significant difference between male and female participants (Connor et al., 2009).The gender distribution of the present study is, however, different to that of a study conducted in rural South Africa where the majority of the participants were female (64%) ((SASPI), 2004b). The latter study might have reflected the general demography of rural areas, rather than the demography of stroke, in South Africa as many men will leave rural areas to move to work in urban areas.

De wit et al and Connor et al also recorded equivalent numbers in terms of type of stroke and the side of impairment in participants in their studies (De Wit et al., 2007b, Connor et al., 2009). This was a similar finding in the present study.

The Johannesburg Stroke Register recorded 70% of the participants were hypertensive, 30% were current smokers, 26% consumed alcohol, 14% were diabetic and 9% had cardiac conditions (Connor et al., 2009). When compared to the current study the results for alcohol consumption, diabetes and hypertension are similar to the results of the Johannesburg Stroke Register.

In general, the sample appears to be similar to stroke populations described in South Africa and it is likely that the results can be generalised to the South African

population but might need to be applied with caution to populations in the higher income countries.

The mean length of stay in studies conducted by Woldag et al and Karthikbabu et al were similar to the length of stay at the acute hospital reported in this study (Karthikbabu et al., 2011, Woldag et al., 2006). Unfortunately, however, the length of stay was not determined by functional level at discharge in the current participants but rather by the dictates of the funding authorities (medical aid societies). Direct comparison with other studies is therefore not possible.

5.2 FUNCTIONAL INDEPENDENCE MEASURES:

5.2.1 Barthel Index:

Improvement in BI scores over time indicates an improvement in ADL and the overall function of a person following stroke. Monitoring of BI scores throughout the acute rehabilitation phase can serve as a functional outcome indicator for post discharged from acute rehabilitation after a stroke (Nakao et al., 2010).

The BI scores at admission to rehabilitation can aid the therapist in identifying and gaining a better understanding of problems with ADL. The BI scores can help indicate patients who are dependent with ADL compared to those requiring assistance or are independent with ADL at admission (Nakao et al., 2010). Many of the participants were severely limited in ADL on admission with nine scoring below 40 at admission (dependent with ADL), while none were independent.

The BI scores at admission was compared to a study conducted by De Wit et al, who compared the BI admission scores between four European rehabilitation centres in a study which investigated motor and functional recovery after stroke (De Wit et al., 2007b). The median of 40 was similar to those of the patients admitted to the United Kingdom Rehabilitation Centre (median =45) and Belgian Rehabilitation Centre (median =40). In contrast, the BI admission scores for the Swiss and German rehabilitation centres are much higher with a median of 70 and 75 respectively (De Wit et al., 2007b). Similarities of the BI score of the United Kingdom Centres and this study could be attributed to similarities in the length of stay at an acute hospital before admission to the rehabilitation centre which is average of 12 days for the United Kingdom and an average of 13 days in this study.

The German and Swiss centres have an average length of stay in an acute hospital of three weeks before admission to the rehabilitation centres. Patients are thus more mobile and less dependent with ADL in the German and Swiss Centres (De Wit et al., 2007b).

BI scores at discharge from rehabilitation can provide a good functional long term predictor of stroke as most recovery after stroke occurs within the first three months. This is as a result of spontaneous recovery and treatment interventions. The big limitation of the BI is its ceiling effect. A patient can reach the ceiling effect and still make significant recovery as the BI does not specifically monitor the quality of movement performed (O'Connor et al., 2004). Many studies report on the ceiling effect of the BI in monitoring functional recovery (O'Connor et al., 2004, Nakao et al., 2010, Kasner, 2006). At discharge, seven participants had reached the ceiling effect.

The BI scores can help determine the amount of assistance required on discharge and who is independent with ADL once discharged from rehabilitation. Patients who score more than 60 at discharge are more functional in the home and community environments. They are also more likely to still show improvement six months after stroke (Nakao et al., 2010). The mean BI score at discharge (mean 76.6) indicates that the participants were more functional at discharge. Only five participants scored less than 60 at discharge and would therefore require the assistance of caregivers in the home environment. This can place financial and emotional strain on the family who are often the primary caregivers (Hassan et al., 2011).

The BI scores from admission, discharge and follow-up were compared to a study conducted by Nakao et al. In the study, Nakao et al investigated the relationship between BI scores during acute rehabilitation of stroke patients, the BI scores at admission and at discharge were compared between participants. The BI scores in that study were much lower and had a bigger standard deviation compared to the present study. When BI scores of 40 or higher are recorded at discharge from rehabilitation, improvement in BI scores can still be expected at three and six month follow-up (Nakao et al., 2010). This is evident in the present study as the mean BI score at follow-up did increase in the four weeks since discharge, but only by 7.4 points (84.0, SD=22.335). There were only ten participants who had follow-up appointments. Only one participant BI score was less than 40 at follow-up and therefore still requires the assistance of a caregiver in the home environment. The

other nine participants' BI score was more than 60 at follow-up and were more functional in the home environment.

The effect of the application of FES on the abdominals was indicated to have a significant effect on the change in BI from admission to discharge as measured by effect size. It was indicated to have a large effect size on the sample. This indicated that the FES does help to improve the functional outcome of patients with stroke as measured by the BI. A possible explanation for the improvement is that the FES application to the abdominals aided the better recruitment of muscle motor units. Any therapy intervention which improves activation of trunk muscles especially EO will result in better trunk muscle activation (Dickstein et al., 2004a, Dickstein et al., 2004b). This results in better trunk stabilization and improves functional movement (Winzeler-Mercay and Mudie, 2002, Mudie et al., 2001). The re-enforcement of functional tasks from therapy into the wards also contributes to the improvement of BI (De Wit et al., 2007b).

5.2.2 The Rivermead Motor Assessment:

The RMA is specifically used to assess motor deficit and the quality of movement after stroke (Collin and Wade, 1990, De Wit et al., 2007b).

5.2.3 Gross Function:

This subscale of the RMA assesses mobility with regards to balance, transfers and walking. The gross motor function subscale consists of high level items of mobility such as walking, climbing stairs, running and hopping. It follows the expected pattern of motor recovery after stroke (Lincoln and Leadbitter, 1979). Some of the items in the subscale such as running and hopping are difficult for patients to achieve in the rehabilitative phase as these are very high level mobility activities (Kurtais et al., 2009).

All the participants demonstrated improvement in the gross function subscale from admission to follow-up but the amount of improvement was less than that recorded by the BI. In addition, the application of FES to the abdominals indicated no effect on RMA Gross Function subscale as measured by the effect size.

The mean admission score for this subscale was very low, with three of the participants unable to sit unsupported on admission. This had dropped to one on

discharge and 12 of the participants were able to walk 10m with no standby help on discharge. This indicated that ten of the participants would be capable of safely mobilising within the home environment. Only ten participants could safely climb a full flight of stairs. None of the participants scored a maximum score of 13 for this subscale on discharge or follow-up.

The experimental group performed poorer than the control group in this subscale from admission to discharge and follow-up. This was an unexpected result as the experimental group performed much better in the BI. One explanation for this is that stroke patients develop compensatory strategies to perform ADL tasks and still present with major motor impairments. Therefore, patients present with a low RMA score (De Wit et al., 2007b) while still able to achieve function.

In a study by De Wit et al which compared four European rehabilitation centres, the score for the RMA gross function for the United Kingdom and Belgian Centres were similar to that of the participants in the present study at admission to rehabilitation (De Wit et al., 2007b). When the results of the current study were compared to a study conducted by Jones, only the gross functional section of the RMA was similar at admission((Jones, 1998).

5.2.3.1 Leg and Trunk:

Some of the items in the leg and trunk subscale are activities (rolling and bridging exercises) which are initiated by therapists during the acute phase after stroke and continued during rehabilitation. This provides on possible explanation for the high scoring of participants for this subscale. All the participants indicated improvement in the Leg and Trunk subscale from admission through to follow-up. Seven of the participants reached a maximum score of ten for this subscale at discharge.

5.2.3.2 Arm:

At discharge, 12 participants were able to reach for a tennis ball from a table. Only one participant had regained full functional upper limb movement at discharge. There was one participant who still had no movement in the upper limb at discharge.

Motor recovery of the arm after stroke is known to be a slow process with some patients not regaining any arm functional after stroke (Woldag et al., 2006). This was evident in this study in that six participants who had no upper limb movement at admission. However, considerable progress was made and only one had no

movement at discharge with seven of the ten participants seen at follow-up demonstrating functional movement of the upper limb. There have been many advances in therapy to attempt to improve hand function but often patients are not able to use the arm functionally despite the ability to contract some upper limb muscles. Patients often benefit from compensatory strategies while working on functional improvement of the upper limb (Woldag et al., 2006).

5.2.4 Lack of responsiveness of RMA to treatment effect

It is puzzling as to why the RMA did not detect any difference in outcome between the two groups. All the participants improved in score for all three subscales of the RMA. Lincoln and Leadbitter recommended that the RMA be used at four week intervals as the reliability of the measure when used at more frequent intervals may be lower (Lincoln and Leadbitter, 1979). As the intervention and outcome measures were administered over a two week period during in-patient rehabilitation, the RMA may not have been reliable in detecting the differences in outcome between the two groups change in score from admission to discharge as the time period may be too short to detect major change in motor recovery. It may also not have detected any major change in score from admission to follow-up and discharge to follow-up as the most recovery was detected during inpatient rehabilitation as indicated by the BI scores.

Another reason for the RMA not detecting any difference in outcome might be that all subjects were able to achieve the simpler tasks but that the more difficult tasks required a greater 'leap' in terms of ability. Participants therefore reached a plateau in score and were unable to perform with a much greater improvement in motor control than is required by the BI to progress from one score to the next. However, as the SD of scores at admission were relatively high, indicating a wide spread of scores, this may not be the correct explanation.

5.3 HEALTH RELATED QUALITY OF LIFE MEASUREMENT:

5.3.1.1 The EQ-5D

The measurement of patient and family perception of health related quality of life after stroke is an important aspect of recovery after a stroke (Pickard et al., 2004).

The results of the EQ-5D VAS indicate that the experimental group perceived their general health to be poorer than the control group. This perception did improve by discharge but dropped again on follow-up. As the VAS score is based on a general perception of the participants' state of health, rather than specifically targeted at functional activities, it is influenced by several other factors and it may not be a suitable outcome measure for a trial of this nature.

The admission score for the EQ-5D VAS of the present study were compared to two studies conducted by Pickard et al and were much lower than those reported in the two studies (Pickard et al., 2005, Pickard et al., 2004). The participants in the present study perceived their general health as measured by the EQ-5D VAS at admission to the study to be poorer than those participants in studies conducted by Pickard et al at baseline. In the studies conducted by Pickard et al, the sample size was larger than the present study. Pickard et al recorded that the majority of participants reported problems within all five domains of the EQ-5D at baseline and is similar to the results in the present study. However, by discharge and follow-up the participants in the present study reported a higher EQ-5D VAS mean score compared to the studies by Pickard et al (Pickard et al., 2005, Pickard et al., 2004).

Any improvement noted in the domains of the EQ-5D and EQ-5D VAS is important and meaningful to the patient as it reflects an improvement in ADL and health status (Pickard et al., 2005). In the present study the experimental group indicated that they were more likely to improve and have no problems in each domain of the EQ-5D and EQ-5D VAS.

The effect of the application of FES on the abdominals was indicated to have a significant effect on the EQ-5D tariff as measured by effect size. It was indicated to have a large effect size on the sample. This indicated that the FES does help to improve the health related quality of life as perceived by patients with stroke. This information can be used in cost-utility analysis to determine the cost of the QALYs gained through intervention (3.9 months).

5.4 PHYSIOLOGICAL COST INDEX:

Most patients reported walking as a goal for in-patient rehabilitation. Most patients are unable to walk at admission (Jorgensen et al., 1995a). There is an increase in the effort in walking of patients, post stroke. When compared to healthy individuals, the effort of walking in stroke is higher (Fredrickson et al., 2007a).

Studies conducted by Sabut et al and Taylor et al investigate the use of FES to correct dropped foot in stroke and the effect it has on the effort of walking. These studies report an improvement in PCI in stroke patients using FES on the lower limb. However, none of the studies consider the impact of trunk stability when walking and assess the strength or function of the trunk (Sabut et al., 2010a, Sabut et al., 2010b, Taylor et al., 1999). In the present study, FES was only applied to the trunk and a decrease in the PCI value was recorded. The PCI value at discharge was significantly better in the experimental group, despite the small sample size ($p=0.037$). This improvement indicates improvement in trunk stability when walking, which results in a decrease in the effort of walking. This highlights the importance of trunk stability and strength in decreasing the effort of walking.

5.5 THERAPY INTERVENTION AND IMPACT ON FUNCTIONAL RECOVERY:

The main aim of rehabilitation is to assist a patient in achieving the highest possible functional ability (Kwakkel et al., 1999). Several studies report that most functional gains occur within the first three months of stroke (Jorgensen et al., 1995b, Cramer, 2008, Verheyden et al., 2008).

In a study by De Wit et al which compares physiotherapy and occupational therapy sessions across four European Rehabilitation Centres, the mean treatment time recorded in these centres was less than that reported in this study. The German Centre recorded the shortest treatment session times (mean= 35.2), while the United Kingdom, Switzerland and Belgium Centres recorded similar times to each other (mean= 43.0; 44.8; 46.0 respectively). The physiotherapy treatment times at the Rehabilitation Unit in this study was reported to be one hour.

Ada et al recommends that strength training be incorporated into stroke rehabilitation. Strength training within the first six months of stroke is beneficial and has an effect on functional activity. Strength training does increase muscle strength in stroke without increasing spasticity (Ada et al., 2006). In this study, all the participants received upper and lower limb strength training.

The content of the physiotherapy treatment sessions at the Rehabilitation Unit was compared to a study conducted by De Wit et al. In this study, the content of physiotherapy and occupational therapy sessions in four European rehabilitation units were compared to and found to be consistent between the four units.

Categories most recorded in the physiotherapy sessions were selective movements, exercises and balance in sitting and standing, and ambulatory exercises. De Wit et al also reports that physiotherapists tend to focus their treatments more on mobility(De Wit et al., 2006). The content of the physiotherapy sessions at the Rehabilitation Unit recorded was similar to the findings in De Wit et al as the physiotherapists most recorded categories are similar to the content of the physiotherapy sessions in the study. These categories are selective movements, lying and lying balance, sitting and sitting balance, standing and standing balance, transfers and ambulatory activities. Therefore, physiotherapy treatment at Rehabilitation Unit was consistent with physiotherapy treatment performed in European rehabilitation units and was effective.

It was interesting to note that in the present study, most of the recovery as indicated by the BI score was made during the rehabilitation stay. There was a significant difference in BI scores from admission to discharge. Although not tested, the BI showed far less improvement in the four weeks from discharge to follow-up. This indicates that the therapy intervention was effective. The therapy received at the Rehabilitation Unit demonstrated a significant impact on patient recovery. Therefore, the effect of the FES intervention would yield marginal results between the control and experimental groups.

5.6 LIMITATIONS TO THE STUDY:

The impacts of therapy interventions in stroke trials are difficult to measure. This is partly due to small sample sizes in stroke trials and a loss of participants due to follow-up visits. Results with trials which have small sample sizes need to be interpreted with care as the statistical power of the results are affected. Studies like those conducted by Brock et al, Mudie et al, Dean et al all reported small sample sizes in the trials which they conducted and recommended larger sample sizes for future studies (Mudie et al., 2001, Brock et al., 2011, Dean et al., 2000)The study similarly had a small sample size. The Rehabilitation Unit is dependent on medical aid approval of length of stay prior to admission for patients. Most medical aids had limited funding for stroke patients to less than two weeks. This limited the number of patients eligible for admission to the study. Unfortunately the rehabilitation unit closed on 30 October 2011. The unit decreased the number of admissions two months before closure of the unit. Thus, although the researcher set out to recruit an adequate number of participants, she was unable to do so due to circumstances

beyond her control and the research questions have not been satisfactorily answered.

Many studies report loss of participants at follow-up for various reasons. This study was no different as there were a large number of patients lost to follow-up due to medical complications (cancer, hospitalisation due to orthopaedic procedures or second stroke) and patient refusal of follow-ups. Roth et al reports that patients with stroke have a high rate of pre-existing medical conditions (Roth et al., 2001) Only ten participants (five in each group) had follow-up sessions.

The study required an estimated a sample size of 12 in each group would have picked up a significant difference with an 80% power level. Unfortunately, the study was underpowered and the sample size was nine in the control group and ten in the experimental group picked up a significant difference at a power level of 45%.

The internal validity was acceptable in that all aspects of the protocol were observed. Single blinding was maintained throughout, and the collaborating therapist performed the intervention treatment as prescribed. No participants were lost from the hospital based part of the study.

The Consort statement was used to assess the validity of the study (CONSORT, 2010), see Table 15 below:

Table 15: Consort 2010 checklist of information to include when reporting a randomised trial

Section/Topic	Item No	Checklist Item	Reported on Page
Title and Abstract	1a	Identification as a randomised trial in the title	I
	1b	Structured summary of trial design, methods, results, and conclusion	II
Introduction Background and objectives	2a	Scientific background and explanation of rationale	1
	2b	Specific objectives or hypotheses	2

Methods			
Trial design	3a	Description of trial design(such as parallel, factorial) including allocation ratio	31
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	35-36
Participants	4a	Eligibility criteria for participants	31
	4b	Setting and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	36-38
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	33-35
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	32
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation			
Sequence	8a	Method used to generate the random allocation sequence	33
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	33
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	36

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	31
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	38-40
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	38-40
Results			
Participants flow(a diagram is strongly recommended)	13a	For each group, the number of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	42-43
	13b	For each group, losses and exclusions after randomisation, together with reasons	43
Recruitment	14a	Dates defining the periods of recruitment and follow-up	31
	14b	Why the trial ended or was stopped	4
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	43-46
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analyses was by original assigned groups	43-79
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group and the estimated effect size and it's precision (such as 95% confidence interval)	72-79
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from	72-79

		exploratory	
Harms	19	All important harms or unintended effects in each group	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	92
Generalisability	21	Generalisability (external validity, applicability) of the findings	81
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	81-92
Other information			
Registration	23	Registration number and name of trial registry	35, 40
Protocol	24	Where the full trial protocol can be accessed, if available	40
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	xvi

6. CONCLUSION:

The purpose of the study was to investigate the effect of FES on abdominal muscle strength and function when applied to the abdominal muscles in stroke patients, combined with conventional therapy. The primary aim of the study was to determine if there was a significant difference in mean score and ranking of the control and experimental groups in functional independence, health related quality of life and the effort of walking at discharge. The second aim of the study was to document the content of physiotherapy intervention and compare it to published literature.

All the participants demonstrated improvement during their stay at the rehabilitation unit. The gains in functional and motor improvement after discharge to follow-up were less than that achieved during the rehabilitation stay.

There were no significant differences detected between the experimental and control group apart from the change in BI score from admission to follow-up and the EQ-5D domain of Usual Activities at discharge. The PCI at discharge was significantly less in the experimental group. There was thus a trend towards gains in function and strength by the experimental group. However, as discussed above, the study was underpowered and did not detect other differences.

The FES constituted only one component of the treatment. It was therefore necessary to evaluate the type of intervention the participants received by the individual therapists. By assessing the intervention, one can ascertain whether the individual therapist's treatment varied from therapist to therapist and assess the role their intervention played in the improvement of each participant. In the research setting, the control treatment is considered to be the conventional treatment given by therapists. The experimental treatment is an adjunct to the conventional therapy. This is conducted for ethical reasons. When the conventional therapy received in a study is effective and an experimental treatment is introduced as well, marginal results are expected. The treatment programme provided by the physiotherapists at Rehabilitation Unit appears to be of a standard comparable with other international centres. The therapy intervention had an impact on the participants' recovery and no one therapist treatment was superior to another. This provides an explanation as to why the control and experimental group results of the outcome measures were so closely related.

There was a trend towards gains in functional ability as measured by the BI and RMA in the experimental group when compared to the control group. There was also a trend towards gain in health related quality of life as measured by the EQ-5D in the experimental group when compared to the control group. There was a trend towards a decrease in the effort of walking as measured by the PCI in ambulant participants in the experimental group when compared to the control group.

Interestingly, although the sample size was smaller than anticipated and resulted in non-significant probability values on testing, the effect size for most outcome parameters were medium to large (change in BI indicated a medium effect size and the EQ-5D tariff and PCI indicated a large effect size). This indicates that it is feasible to apply FES to the abdominals in stroke patients and is a clear indication that the use of the FES might be beneficial in improving function in patients with stroke. The researcher cannot therefore conclude that the results found were not by chance, but can conclude that the intervention was associated with an improvement in all parameters, apart from the RMA.

This indicates that it is feasible to apply FES to the abdominals in stroke patients and that the use of the FES might be beneficial in improving function in patients with stroke. The FES is also an inexpensive method of treatment. It is easy to incorporate into a physiotherapy treatment programme.

6.1 RECOMMENDATIONS:

In the light of the feasibility of the application of FES of the abdominal muscles in patients with stroke, it is recommended that therapists can introduce the intervention and need to monitor its effect closely. It is a non-invasive, relatively inexpensive intervention which may be beneficial.

It is recommended that future studies involving FES to the abdominal muscles include a larger sample size in order to detect significant differences in the results. Recommendations for future randomised control trials are listed in the section below.

6.1.1 Recommendations for a Randomised Control Trial:

It is recommended that future studies involving FES to the abdominal muscles include a larger sample size in order to detect significant differences in results. A

sample size of 40 participants (20 per group) for the randomised control trial is recommended. This sample size was calculated based on the BI score (the mean is expected to be approximately 20 and the SD 10). A difference in score between the control group and the experimental score of 12 will be regarded as being of clinical significance. Using Statistica power calculation function, it was estimated that a sample size of 16 per group would be necessary to detect a difference between the two groups at a significant level of $p=.05$ and a power level of 90%. In order to allow for attrition, a final sample size of 20 should be recruited in each group.

The protocol used in the present study for placement and treatment time of the FES is recommended.

It is also recommended that the BI be used as an outcome measure as this measure is effective in monitoring functional outcome in stroke. The use of the Trunk Impairment Scale as an outcome measure instead of the RMA is also recommended. The Trunk Impairment Scale can be used to measure both the motor recovery and abdominal strength in patients with stroke

It is also recommended that a multi-centre trial be undertaken to ensure access to a large sample pool and various therapy interventions.

This study is feasible, inexpensive and easy to reproduce. It is also recommended that measures be implemented to ensure compliance with regard to follow-up with patients after discharge.

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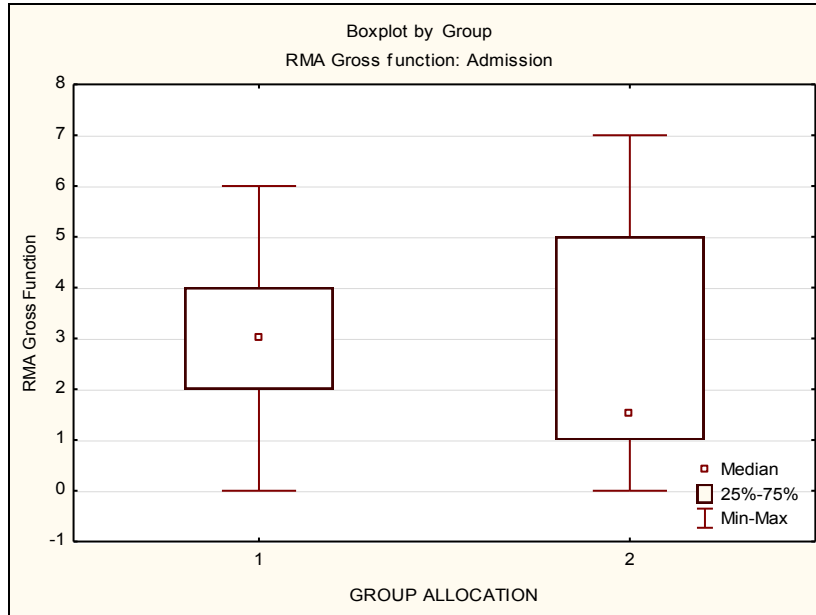
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APPENDIX I:

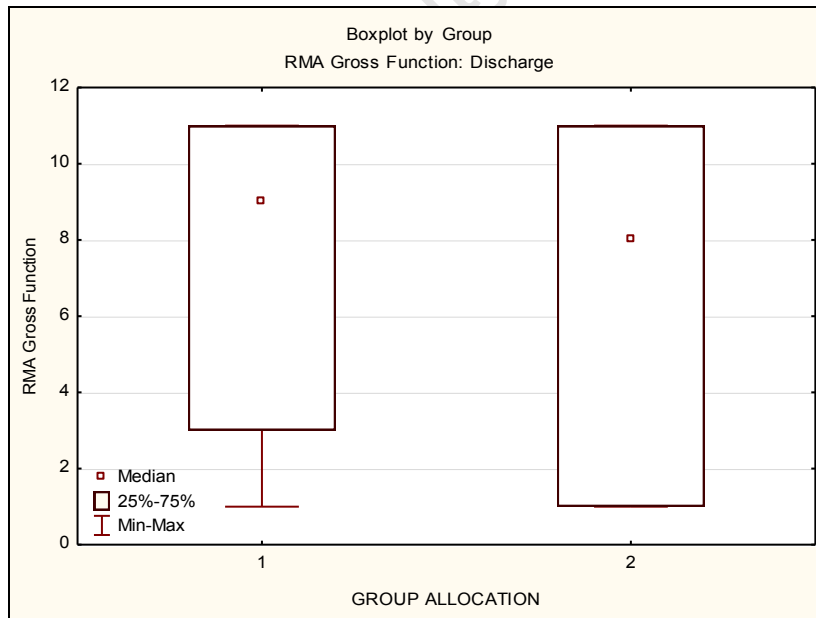
RIVERMEAD MOTOR ASSESSMENT:

RMA Gross Function:



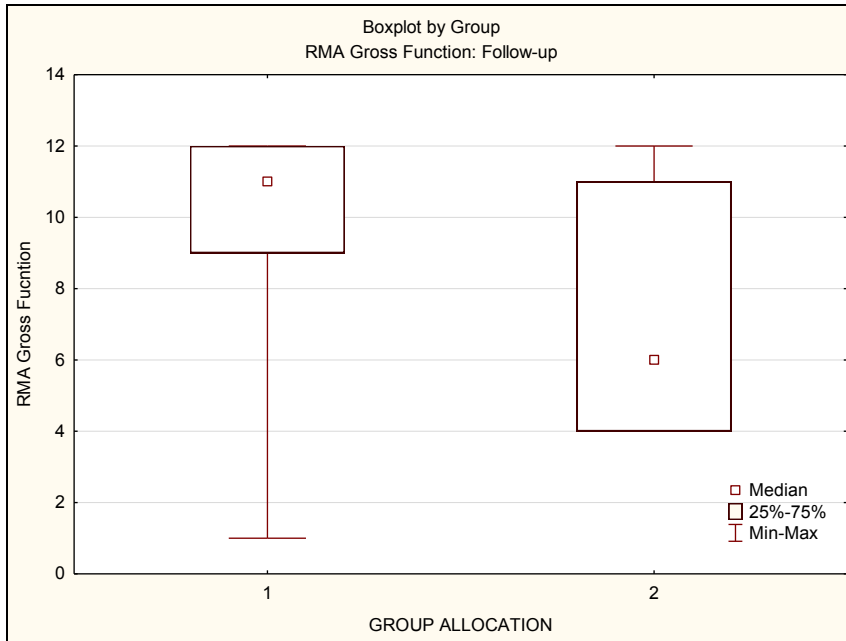
Group allocation: 1= Control group (n=9); 2=Experimental group (n=10)

Figure 37: RMA Gross Function at admission



Group allocation: 1= Control group (n=9); 2=Experimental group (n=10)

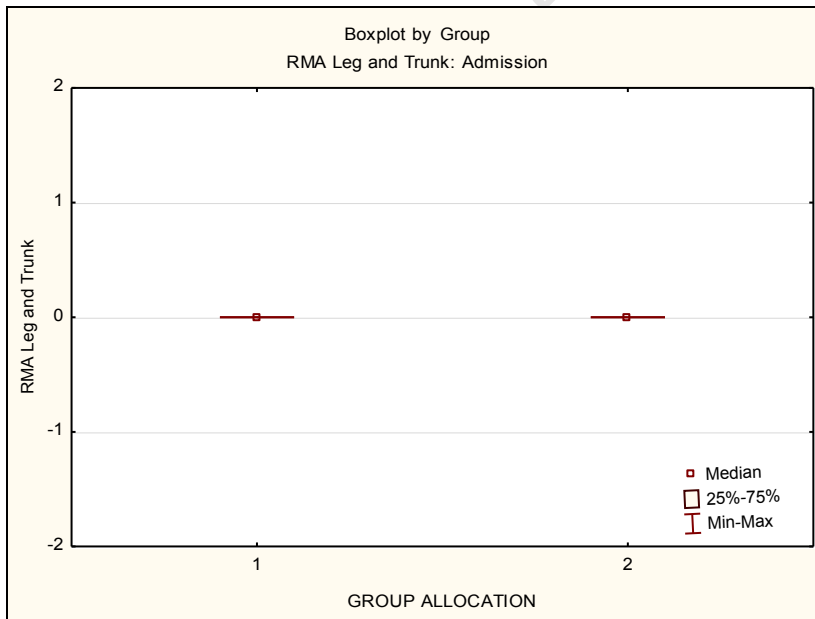
Figure 38: RMA Gross Function at discharge



Group allocation: 1= Control group (n=5); 2=Experimental group (n=5)

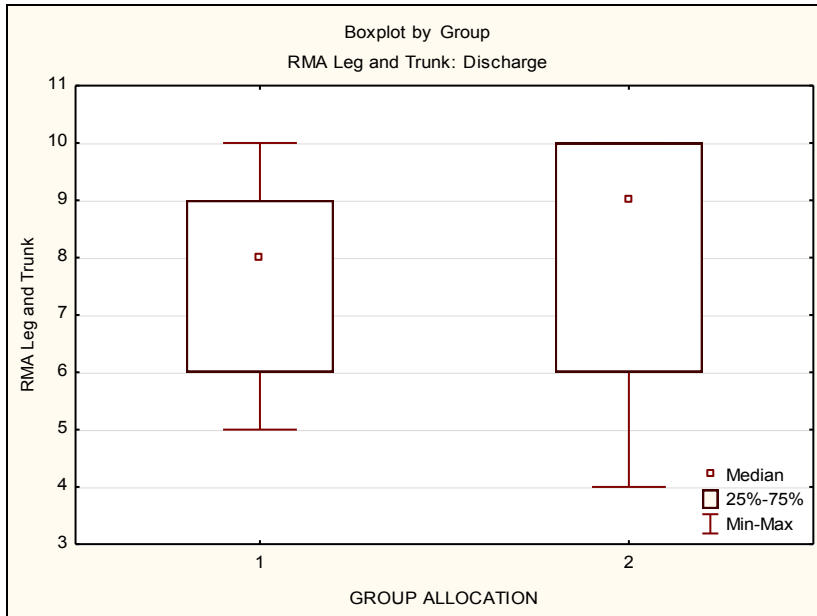
Figure 39: RMA Gross Function at follow-up

RMA Leg and Trunk:



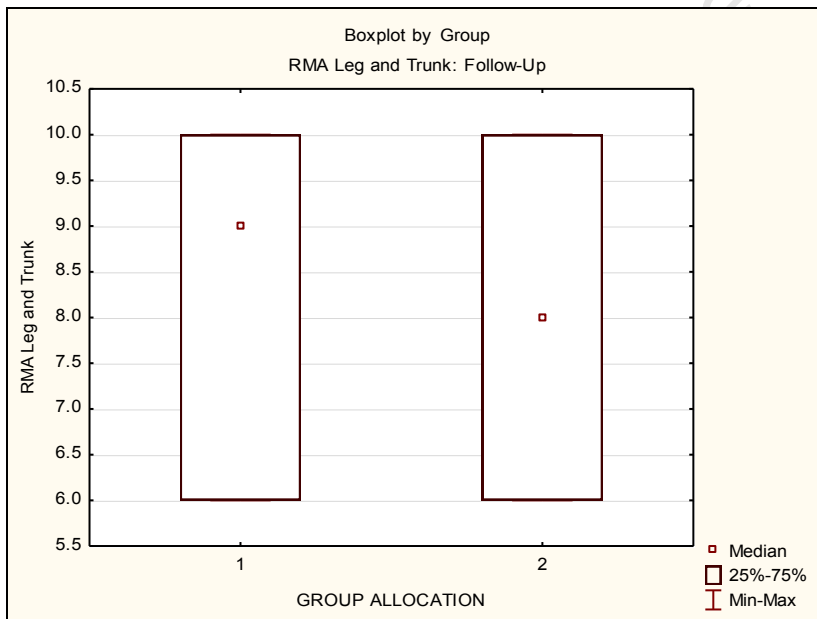
Group allocation: 1= Control group (n=9); 2=Experimental group(n=10)

Figure 40: RMA Leg and Trunk at admission



Group allocation: 1= Control group (n=9); 2=Experimental group (n=10)

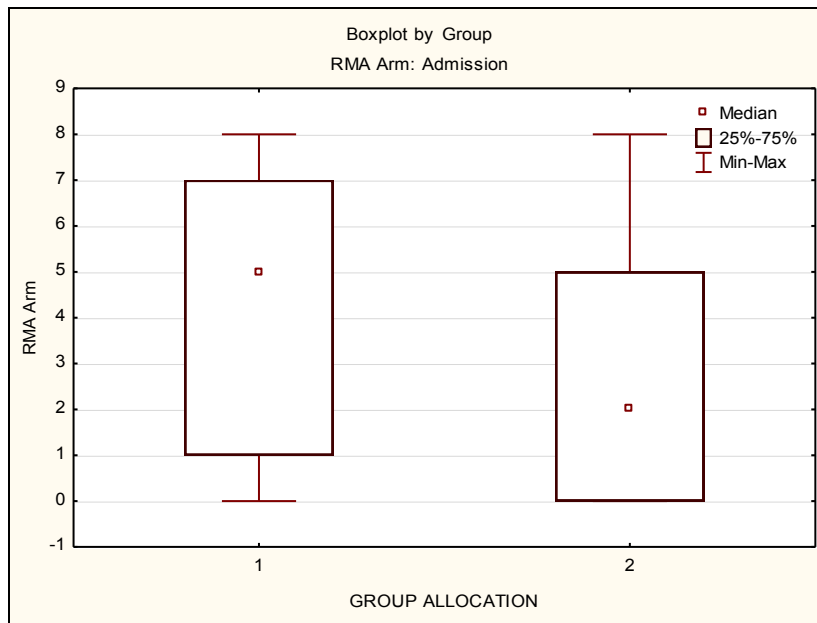
Figure 41: RMA Leg and Trunk at discharge



Group allocation: 1= Control group (n=5); 2=Experimental group(n=5)

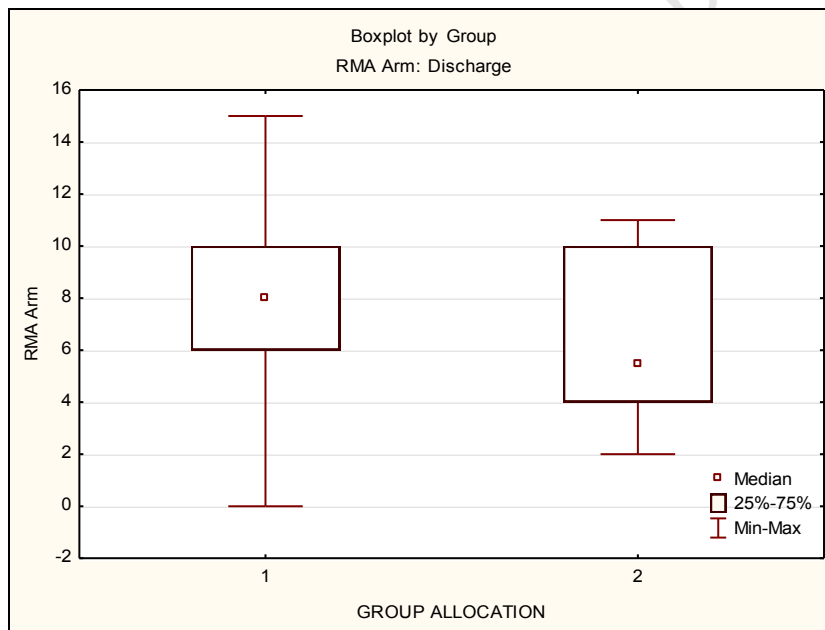
Figure 42: RMA Leg and Trunk at follow-up

RMA Arm:



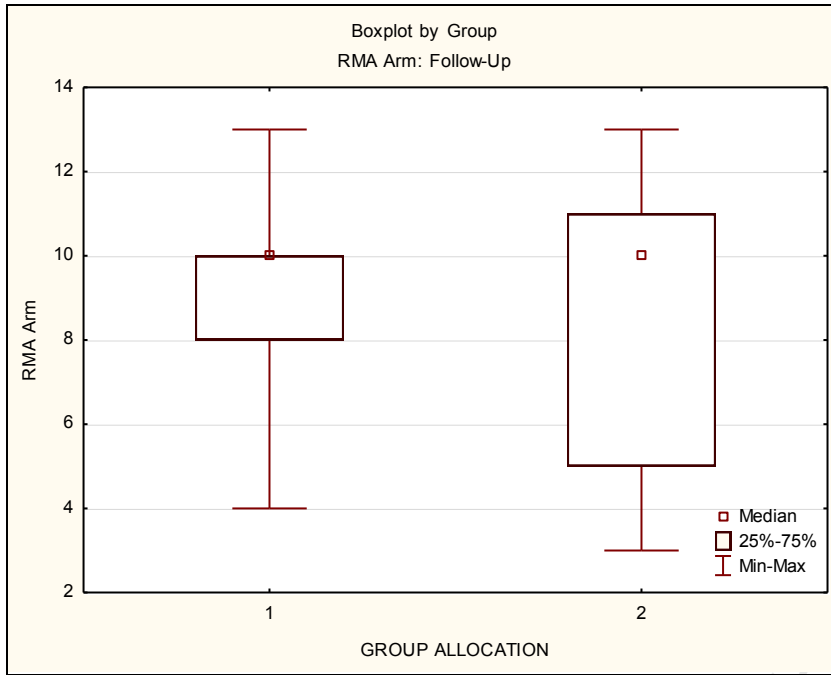
Group allocation: 1= Control group (n=9); 2=Experimental group (n=10)

Figure 43: RMA Arm at admission



Group allocation: 1= Control group (n=9); 2=Experimental group (n=10)

Figure 44: RMA Arm at discharge



Group allocation: 1= Control group (n=9); 2=Experimental group (n=10)

Figure 45: RMA Arm at follow-up

University of Cape Town

APPENDIX II:

CONSENT FORM

The Effect of Functional Electrical Stimulation on Abdominal Muscles and Functional Independence in Patients with Stroke.

Dear Participant

I, Crystal Moosajie, am currently conducting a research project as part of my Master's Degree in Physiotherapy at the University of Cape Town.

The aim of the study is to find out whether Functional Electrical stimulation (FES) will improve abdominal muscle strength and everyday activities (activities of daily living) when used as part of physiotherapy treatment in patients with stroke. Information obtained in this study will help to improve physiotherapy treatment in patients with stroke.

This study has been given ethical approval by the Research and Ethics Committee, Faculty of Health Sciences, University of Cape Town. (265/2010)

Participants will be divided into two groups. Both groups will receive usual physiotherapy on a daily basis. Only one group will receive FES to the abdominals as part of their physiotherapy treatment. You will be randomly placed into a group by the therapist who will pick a card from an envelope. There will be two colour cards in the envelope. The colour of the card will decide if you receive FES or not. As FES has not been proven to work, if you do not take part in the study, you will not receive the FES. The FES is applied to the abdominal muscle (external oblique) on the weak side of the abdomen. During the first week of treatment FES will be applied for 15 minutes during the treatment session. During the second week, FES will be applied for 20 minutes during the session. Your physiotherapist will apply and remove the machine.

There is a patient information sheet which gives general information about you and your stroke. This needs to be filled in. I (Crystal Moosajie) will also need to look at your medical records. There will be assessments, which will be conducted throughout your length of stay and participation in the study. These assessments are:

- The Barthel index, which measures the ability to perform everyday tasks such as feeding, personal hygiene, transfers etc. It takes 30 minutes to complete this assessment.
- The Rivermead Motor Assessment, which measures physical recovery and progress following a stroke. It takes 30 minutes to complete this assessment.
- Physiological Cost Index, which measures the amount of energy a person uses when walking a distance of 10 meters. It takes 10 minutes to complete this assessment.
- EQ-5D is a health related quality of life questionnaire, which assesses your perception of quality of life since the stroke. It takes 10 minutes to complete the assessment.

The Barthel Index, Rivermead Motor Assessment and the EQ-5D will be completed when you are included into the study and after the first and second week of the study. The Physiological Cost Index will be completed at discharge. An appointment will be arranged for six weeks after discharge, for you to come to the unit to repeat all the assessments named above.

These assessments will help keep a record of your improvement during the time of the study. These assessments will be conducted by me, Crystal Moosajie. They will be done outside of the normal therapy hours and will not affect your therapy in any way. All these assessments and information sheets are confidential. These assessments and information sheets will be kept in a safe and confidential file. Only I (Crystal Moosajie) and my supervisor (Prof Jennifer Jelsma) will have access to these files. If necessary, the head of the UCT Research ethics Committee might also be able to see them. The treating therapists will not have access or know the results of the assessments. The information gathered from these assessments will be analysed at the end of the study. All information gathered is strictly confidential and at no point will any names of participants be revealed or mentioned in the write up of the findings of this study.

POTENTIAL RISKS TO THE PARTICIPANT ARE:

- Current can pass through the rest of your body and could cause a slight shock if the electrodes are handled while the machine is still on. The machine should always be switched off when handling the electrodes.

- There is some reddening of the skin under the electrode after use. This is normal and should fade after an hour after the electrodes have been removed. The electrodes should not be placed over broken skin as this will cause skin irritation.
- The participant may find FES treatment not tolerable. The intervention will stop should the participant indicate this or wish to withdraw at any time.
- The participant will experience some tingling or “pins and needles” sensation. You should not experience any pain when the FES is applied. Should you feel any pain, the FES will be removed immediately.

BENEFITS TO THE PARTICIPANT:

Participation in the study will enrich the ongoing research in the field of stroke treatment. The aim of the study is to evaluate whether there is any benefit in the use of FES to the abdominal muscles after stroke. You will not benefit from participation in the study. Unfortunately there is no financial compensation (participants will not be paid to take part in the study) available for the participation in this study.

PAYMENT:

You will need to pay for the physiotherapy sessions as per normal. However, you will not have to pay for the added assessments. You will also not be paid to take part in these assessments. There will be no extra charge for the application of FES to the abdominals during the treatment session.

INSURANCE:

Please note that UCT does offer a no-fault insurance that will cover all participants in the event that something may go wrong. This insurance will provide prompt payment of compensation for any trial-related injury according to the Association of the British Pharmaceutical Industry (ABPI) guidelines (1991). These guidelines recommend that UCT, without any legal commitment, should compensate you without you having to prove that UCT is at fault. An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study investigators immediately of any injuries during the trial, whether they are research-related or other related complications. UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions that you were given while taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected

QUESTIONS AND CONCERNS:

Should you have any questions or concerns about the study, please feel free to contact any of the individuals listed below:

Crystal Moosajie (Researcher)

11 Vaal Avenue

Belthorn Estate

Crawford, 7780

Cell: 0835117265

Email: cmoosajie@yahoo.co.uk

Professor Jennifer Jelsma (PhD)

Head, Division of Physiotherapy

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University of Cape Town

Anzio Road

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Fax: 27-21-4066323

e-mail Jennifer.jelsma@uct.ac.za

Professor Marc Blockman

Chairperson

Faculty of Health Sciences Research and Ethics Committee

Tel: 021 406 6492

E-mail: marc.blockman@uct.ac.za

INFORMED CONSENT:

Title of Study: The Effect of Functional Electrical Stimulation on Abdominal Muscle Strength and Functional Independence in Patients with Stroke.

Principle Investigator: Crystal Moosajie

I, (participant), have read (or had read to me by)
the Information Sheet. I understand what is required of me and I have had all my
questions answered. I do not feel that I am forced to take part in the study and I am
doing this of my own free will. I know that I can withdraw at anytime should I wish to
and that withdrawing from the study will not affect my treatment in any way.

Signed at:.....on.....

Signature:..... (Participant)

Signature:..... (Witness)

Signature :.....(Principle Investigator: Crystal
Moosajie)

APPENDIX III:

PATIENT INFORMATION:

Name and Surname:.....

Age:.....

Gender: M / F

Marital status:.....No. of children:.....

Highest level of Education:.....

Employment:.....

Total Monthly Household Income:

R0 – R3000.....

R3001 – R6000.....

R6001 – R10000.....

R10001 – R15000.....

>R15000.....

Smoker: Y / N

How many a day:.....

Drink: Y / N

How many glasses a week:.....

Diabetes: Y / N

On Medication: Y / N

Hypertension: Y / N

On Medication: Y / N

Cardiac Condition:.....

Other Medical conditions:.....

Onset of Stroke:.....

Type of Stroke:.....

Side of Stroke:.....

Diagnosis made by (Neurologist, GP, etc):.....

Diagnostic Test: MRI

CT Scan

Surgery: Y / N

If yes, What type of surgery:.....

Date of surgery:.....

Which Hospital Admitted to:.....

Date of admission to Hospital:.....

No. of days spent in Hospital:.....

Were you discharged home/care facility before admission to Rehabilitation
Centre:.....

If so, time at home/care facility:.....

University of Cape Town

APPENDIX IV:

BARTHEL INDEX

1. Bowels

0= incontinent (or needs to be given enema)

5= occasional accident (once a week)

10= continent

2. Bladder

0= incontinent, or catheterized and unable to manage alone

5= occasional accident (maximum once per 24 hours)

10= continent

3. Grooming

0= needs help with personal care

5= independent face/hair/teeth/shaving (implements provided)

4. Toilet use

0= dependent

5= needs some help, but can do something alone

10= independent (on and off, dressing, wiping)

5. Feeding

0= unable

5= needs help cutting, spreading butter, etc.

10= independent

6. Transfer (bed to chair and back)

0= unable, no sitting balance

5= major help (one or two people, physical), can sit

10= minor help (verbal or physical)

15= independent

7. Mobility

0= immobile

5= wheelchair independent, including corners

10= walks with help of one person (verbal or physical)

15= independent (but may use any aid; for example, stick)

8. Dressing

0= dependent

5= needs help but can do about half unaided

10= independent (including buttons, zips, laces, etc.)

9. Stairs

0= unable

5= needs help (verbal, physical, carrying aid)

10=independent

10. Bathing

0= dependent

5= independent

TOTAL SCORE

University of Cape Town

APPENDIX V:

Rivermead Motor Assessment

General instructions: Go through the items in order of difficulty. Score '1' if patient can perform activity, '0' if he cannot. In the 'Gross function' and 'Arm' section you may stop that the test after 3 consecutive '0' scores. In the 'Leg and Trunk' section all actions should be tested, even if there are three consecutive '0' scores.

Give no feed-back of whether correct or incorrect, just give general encouragement. Repeat instructions and demonstrate them to the patient if necessary. All exercises to be carried out independently unless otherwise stated. All armtests refer to the affected side unless otherwise stated. 'Gross function' section can be assessed simply by asking, which makes it a rapid measure.

Section Item	Score
A. Gross function	
1. Sit unsupported <i>Without holding on, on edge of bed, feet unsupported.</i>	<input type="text"/>
2. Lying to sitting on side of bed <i>Using any method.</i>	<input type="text"/>
3. Sitting to standing <i>May use hands to push up. Must stand up in 15 sec and stand for 15 sec, with an aid if necessary</i>	<input type="text"/>
4. Transfer from wheelchair to chair towards unaffected side <i>May use hands.</i>	<input type="text"/>
5. Transfer from wheelchair to chair towards affected side <i>May use hands.</i>	<input type="text"/>
6. Walk 10 m indoors with an aid <i>Any walking aid. No stand-by help.</i>	<input type="text"/>
7. Climb stairs independently <i>Any method. May use bannister and aid--must be a full flight of stairs.</i>	<input type="text"/>
8. Walk 10 m indoors without an aid <i>No stand-by help. No caliper, splint or walking aid.</i>	<input type="text"/>
9. Walk 10m , pick up bean bag from floor, turn and carry back <i>Bend down any way, may use aid to walk if necessary. No stand-by help. May use either hand to pick up bean bag.</i>	<input type="text"/>
10. Walk outside 40 m <i>May use walking aid, caliper or splint. No stand-by help.</i>	<input type="text"/>
11.Walk up and down four steps	<input type="text"/>

Patient may use an aid if he would normally use one, but may not hold on to rail. This is included to test ability to negotiate curb or stairs without a rail.

12. Run 10 m
Must be symmetrical.

13. Hop on affected leg five times on the spot
Must hop on ball of foot without stopping to regain balance. No help with arms.

Gross function Total

Section Item	Score
--------------	-------

B. Leg and trunk

1. Roll to affected side
Starting position should be lying, not crook lying.

2. Roll to unaffected side
Starting position should be lying, not crook lying.

3. Half-bridging
Starting position -- half-crook lying. Patient must put some weight through affected leg to lift hip on affected side. Therapist may position leg, but patient must maintain position even after movement is completed.

4. Sitting to standing
May not use arms-- feet must be flat on floor--must put weight through both feet.

5. Half-crook lying: lift affected leg over side of bed and return it to the same position.
Affected leg in half-crook position. Lift leg off bed on to support; for example, box, stool, floor, so that hip is in neutral and knee at 90 degrees while resting on support. Must keep affected knee flexed throughout movement. Do not allow external rotation at hip. This tests control of hip and knee.

6. Standing, step unaffected leg on and off block
Without retraction of pelvis or hyperextension of knee. This tests knee and hip control while weight bearing through the affected leg.

7. Standing, tap ground lightly five times with unaffected foot
Without retraction of pelvis or hyperextension of knee. Weight must stay on leg. This again tests knee and hip control while weight bearing through the affected leg but is more difficult than in 6.

8. Lying, dorsiflex affected ankle with leg flexed
Physiotherapist may hold affected leg in position, knee at 90 degrees. Do not allow

inversion. Must have half range of movement of unaffected foot.

9. Lying, dorsiflex affected ankle with leg extended

Same conditions as in 8, with leg extended. Do not allow inversion or knee flexion. Foot must reach plantigrade (90°).

10. Stand with affected hip in neutral position, flex affected knee

Therapist may not position leg. This is extremely difficult for most hemiplegic patients, but is included to assess minimal dysfunction.

Leg and trunk function total

Section Item

Score

C. Arm

1. Lying, protract shoulder girdle with arm in elevation

Arm may be supported.

2. Lying, hold extended arm in elevation (some external rotation) for at least 2 sec

Therapist should place arm in position and patient must maintain position with some external rotation. Do not allow pronation. Elbow must be held within 30 degrees of full extension.

3. Flexion and extension of elbow, with arm as in 2 above

Elbow must extend to at least 20 degrees full extension. Palm should not face out during any part of movement.

4. Sitting, elbow into side, pronation and supination

Three-quarters range is acceptable, with elbow unsupported and at right angles.

5. Reach forward, pick up large ball with both hands and place down again

Ball should be on table so far in front of patient that he has to extend arms fully to reach it. Shoulders must be protracted, elbows extended, wrist neutral or extended, and fingers extended throughout movement. Palms should be kept in contact with the ball.

6. Stretch arm forward, pick up tennis ball from table, release on affected side, return to table, then release again on table. Repeat five times

Shoulder must be protracted, elbow extended and wrist neutral or extended during each phase.

7. Same exercise as in 6 above with pencil

Patients must use thumb and fingers to grip.

8. Pick up a piece of paper from table in front and release five times

Patient must use thumb and fingers to pick up paper and not to pull it to edge of table. Arm position as in 6 above.

<p>9. Cut putty with a knife and fork on plate with non-slip mat and put pieces into container at side of plate <i>Bite-size pieces.</i></p>	<input type="text"/>
<p>10. Stand on spot, maintain upright position, pat large ball on floor with palm of hand for 5 continuous bounces</p>	<input type="text"/>
<p>11. Continuous opposition of thumb and each finger more than 14 times in 10 sec <i>Must do movement in consistent sequence. Do not allow thumb to slide from one finger to the other.</i></p>	<input type="text"/>
<p>12. Supination and pronation on to palm of unaffected hand 20 times in 10 sec <i>Arm must be away from body, the palm and dorsum of hand must touch palm of good hand. Each tap counts as one. This is similar to 4 above, but introduces speed.</i></p>	<input type="text"/>
<p>13. Standing, with affected arm abducted to 90 degrees with palm flat against wall. Maintain arm in position. Turn body towards wall and as far as possible towards arm, i.e. rotate body beyond 90 degrees <i>Do not allow flexion at elbow, and wrist must be extended with palm of hand fully in contact with wall.</i></p>	<input type="text"/>
<p>14. Place string around head and tie bow at back <i>Do not allow neck to flex. Affected hand must be used for more than just supporting string. This tests function of hand without help of sight.</i></p>	<input type="text"/>
<p>15. 'Pat- a-cake' seven times in 15 sec <i>Mark crosses on wall at shoulder level. Clap both hands together (both hands touch crosses.) Each sentence counts as one. Give patients three tries. This is a complex pattern which involves co-ordination, speed, and memory, as well as good arm function.</i></p>	<input type="text"/>
<p>Arm function total</p>	<input type="text"/>

APPENDIX VI:

EQ - 5D

Health Questionnaire

South African English version

University of Cape Town

By placing a tick in one box in each group below, please indicate which statements best describe your own state of health TODAY.

Mobility

I have no problems in walking about

I have some problems in walking about

I am confined to bed

Self-Care

I have no problems with self-care

I have some problems washing or dressing myself

I am unable to wash or dress myself

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

Pain/Discomfort

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

Anxiety/Depression

I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale, in your opinion, how good or bad your own health is today. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

Your own
state of health
today

Best
imaginable



0
Worst
imaginable

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

1. Have you experienced serious illness? Yes No
- | | | | |
|-------------------------|--------------------------|--------------------------|-----------------------------|
| yourself | <input type="checkbox"/> | <input type="checkbox"/> | please tick appropriate box |
| in your family | <input type="checkbox"/> | <input type="checkbox"/> | |
| while caring for others | <input type="checkbox"/> | <input type="checkbox"/> | |

2. What is your age in years ?

3. Are you: Male Female
- | | | |
|--------------------------|--------------------------|-----------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | please tick appropriate box |
|--------------------------|--------------------------|-----------------------------|

4. Are you:
- | | | |
|-------------------------------|--------------------------|-----------------------------|
| a current smoker | <input type="checkbox"/> | please tick appropriate box |
| an ex-smoker | <input type="checkbox"/> | |
| a person who has never smoked | <input type="checkbox"/> | |

5. Do you now, or did you ever, work in health services or social welfare? Yes No
- | | | |
|--------------------------|--------------------------|-----------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | please tick appropriate box |
|--------------------------|--------------------------|-----------------------------|
- If so, in what capacity?

6. Which of the following best describes your main activity?

- | | | |
|----------------------------------|--------------------------|-------------|
| in employment or self employment | <input type="checkbox"/> | please tick |
| retired | <input type="checkbox"/> | appropriate |
| housework | <input type="checkbox"/> | boxes |
| student | <input type="checkbox"/> | |
| seeking work | <input type="checkbox"/> | |
| other (please specify) | <input type="checkbox"/> | |

7. Did your education continue after

the minimum school leaving age	Yes	No	please tick
(15 years / grade 9 / standard 7)?	<input type="checkbox"/>	<input type="checkbox"/>	appropriate

8. Do you have a degree or a diploma?

<input type="checkbox"/>	<input type="checkbox"/>	please tick
		appropriate
		box

9. If you know your postal code, would you please write it here

appendix VII:

EQ - 5D

Gesondheidsvraelys

Afrikaanse weergawe

(Afrikaans version)

University of Cape Town

Dui asseblief aan watter stellings u eie gesondheidstoestand vandag die beste beskryf deur 'n regmerk in een blokkie by elkeen van die onderstaande groepe te maak.

Beweeglikheid

Ek het geen probleme om rond te loop nie

Ek het sommige probleme om rond te loop

Ek is beperk tot die bed

Selfversorging

Ek het geen probleme om myself te versorg nie

Ek het sommige probleme om myself te was of aan te trek

Ek is nie in staat om myself te was of aan te trek nie

Gewone Aktiwiteite (bv. werk, studeer, huiswerk, familie- of ontspanningsaktiwiteite)

Ek het geen probleme om my gewone aktiwiteite uit te voer nie

Ek het sommige probleme om my gewone aktiwiteite uit te voer

Ek is nie in staat om my gewone aktiwiteite uit te voer nie

Pyn/ Ongemak

Ek het geen pyn of ongemak nie

Ek het matige pyn of ongemak

Ek het uiterste pyn of ongemak

Angstigheid/ Neerslagtigheid

Ek is nie angstig of neerslagtig nie

Ek is matig angstig of neerslagtig

Ek is uiters angstig of neerslagtig

Om mense te help om te sê hoe goed of sleg hul gesondheidstoestand is, het ons 'n skaal (baie soos 'n termometer) geteken waarop die beste gesondheidstoestand wat u u kan verbeel, gemerk is met 100 en die slegste gesondheidstoestand wat u u kan verbeel, gemerk is met 0.

Ons wil graag hê dat u op hierdie skaal aandui hoe goed of sleg u eie gesondheid vandag na u mening is. Doen dit asseblief deur 'n streep te trek vanaf die blokkie hieronder (waar dit sê: "u eie gesondheidstoestand vandag") tot by enige punt op die skaal wat aandui hoe goed of sleg u gesondheidstoestand vandag is.

U eie
gesondheids-
toestand

Beste
denkbare



0
Slegste
denkbare

Omdat alle antwoorde naamloos is, sal dit ons help om u antwoorde beter te verstaan indien ons 'n bietjie agtergrondinligting oor almal het, soos in die volgende vrae gedek.

Het u ernstige siekte ondervind?	Ja	Nee	
<i>in uself</i>	<input type="checkbox"/>	<input type="checkbox"/>	merk
in u familie	<input type="checkbox"/>	<input type="checkbox"/>	asseblief
in die versorging van andere	<input type="checkbox"/>	<input type="checkbox"/>	

Wat is u ouderdom in jare?

Is u:	Manlik	Vroulik	merk
	<input type="checkbox"/>	<input type="checkbox"/>	asseblief

Is u:			
'n huidige roker	<input type="checkbox"/>		merk
'n voormalige roker	<input type="checkbox"/>		asseblief
iemand wat nog nooit gerook het nie	<input type="checkbox"/>		

Werk u nou, of het u ooit in die	Ja	Nee	
gesondheids- of maatskaplike dienste gewerk?	<input type="checkbox"/>	<input type="checkbox"/>	merk
Indien wel, in watter hoedanigheid?			asseblief

Watter van die volgende beskryf u hoofaktiwiteit die beste?

in diens wees of vir uself werk	<input type="checkbox"/>	
afgetree	<input type="checkbox"/>	merk
huiswerk	<input type="checkbox"/>	asseblief
student	<input type="checkbox"/>	
soek werk	<input type="checkbox"/>	
ander (spesifiseer asseblief)	<input type="checkbox"/>

Het u onderwys voortgegaan na die
minimum skoolverlatersouderdom
(15 jaar oud / Graad 9 / Standaard 7)?

Ja

Nee

merk
asseblief

Het u 'n graad of 'n diploma?

Ja

Nee

merk
asseblief

Indien u u poskode ken, sal u dit asseblief hier neerskryf

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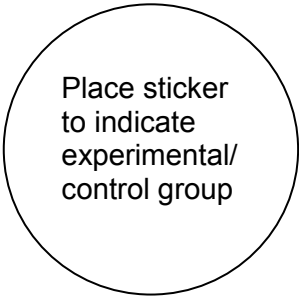
APPENDIX VIII:

PCI:

$$PCI = HR - RHR / speed \times 60$$

Date	Time Taken to walk 10m	Resting HR	WalkingHR	Walking speed	PCI
Discharge:					
Six week post discharge:					

APPENDIX IX:



Planner for treating therapists:

Therapist Name:

Patient name:

	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5
WEEK 1: DATE: TREATMENT TIME: FES :					
WEEK 2: DATE: TREATMENT TIME: FES :					

In each column indicate date, duration of treatment session and tick if FES was applied.

Red sticker: control group (placebo FES applied)

Green sticker: experimental group (FES applied)

APPENDIX X:

SCORING EQ-5D HEALTH STATES

Values for the 243 health states defined by the EuroQoL classification have been calculated using a regression model. The following worked example indicates how these coefficients are to be used so as to compute the estimated values for each state.

Calculating EQ-5D state scores - a worked example

EuroQoL dimension	Level 2	Level 3
Mobility	0.069	0.314
Self-care	0.104	0.214
Usual activity	0.036	0.094
Pain / discomfort	0.123	0.386
Anxiety / depression	0.071	0.236
	Constant = 0.081	N3 = 0.269

The arithmetic needed to recover the estimated value for any health state from this table of decrements is given by the following example:

Taking health state 1 1 2 2 3

Full health (1 1 1 1 1) = 1.0

Constant term (for any dysfunctional state)(subtract 0.081)

Mobility.. level 1(subtract 0)

Self-care.. level 1(subtract 0)

Usual activity.. level 2(subtract 0.036)

Pain / discomfort.. level 2(subtract 0.123)

Anxiety / depression.. level 3(subtract 0.236)

Level 3 occurs within at least 1 dimension(subtract N3 parameter 0.269)

Hence the estimated value for state 1 1 2 3 3 is given by

$$1.0 - 0.081 - 0.036 - 0.123 - 0.236 - 0.269 = \mathbf{0.255}$$

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Estimated weights for EQ-5D health states

1 1 1 1 1	1.000
1 1 1 1 2	0.848
1 1 1 1 3	0.414
1 1 1 2 1	0.796
1 1 1 2 2	0.725
1 1 1 2 3	0.291
1 1 1 3 1	0.264
1 1 1 3 2	0.193
1 1 1 3 3	0.028
1 1 2 1 1	0.883
1 1 2 1 2	0.812
1 1 2 1 3	0.378
1 1 2 2 1	0.760
1 1 2 2 2	0.689
1 1 2 2 3	0.255
1 1 2 3 1	0.228
1 1 2 3 2	0.157
1 1 2 3 3	-0.008
1 1 3 1 1	0.556
1 1 3 1 2	0.485
1 1 3 1 3	0.320

1 1 3 2 1	0.433
1 1 3 2 2	0.362
1 1 3 2 3	0.197
1 1 3 3 1	0.170
1 1 3 3 2	0.099
1 1 3 3 3	-0.066
1 2 1 1 1	0.815
1 2 1 1 2	0.744
1 2 1 1 3	0.310
1 2 1 2 1	0.692
1 2 1 2 2	0.621
1 2 1 2 3	0.187
1 2 1 3 1	0.160
1 2 1 3 2	0.089
1 2 1 3 3	-0.076
1 2 2 1 1	0.779
1 2 2 1 2	0.708
1 2 2 1 3	0.274
1 2 2 2 1	0.656
1 2 2 2 2	0.585
1 2 2 2 3	0.151
1 2 2 3 1	0.124
1 2 2 3 2	0.053
1 2 2 3 3	-0.112

1 2 3 1 1	0.452
1 2 3 1 2	0.381
1 2 3 1 3	0.216
1 2 3 2 1	0.329
1 2 3 2 2	0.258
1 2 3 2 3	0.093
1 2 3 3 1	0.066
1 2 3 3 2	-0.005
1 2 3 3 3	-0.170
1 3 1 1 1	0.436
1 3 1 1 2	0.365
1 3 1 1 3	0.200
1 3 1 2 1	0.313
1 3 1 2 2	0.242
1 3 1 2 3	0.077
1 3 1 3 1	0.050
1 3 1 3 2	-0.021
1 3 1 3 3	-0.186
1 3 2 1 1	0.400
1 3 2 1 2	0.329
1 3 2 1 3	0.164
1 3 2 2 1	0.277
1 3 2 2 2	0.206
1 3 2 2 3	0.041

1 3 2 3 1	0.014
1 3 2 3 2	-0.057
1 3 2 3 3	-0.222
1 3 3 1 1	0.342
1 3 3 1 2	0.271
1 3 3 1 3	0.106
1 3 3 2 1	0.219
1 3 3 2 2	0.148
1 3 3 2 3	-0.017
1 3 3 3 1	-0.044
1 3 3 3 2	-0.115
1 3 3 3 3	-0.280
2 1 1 1 1	0.850
2 1 1 1 2	0.779
2 1 1 1 3	0.345
2 1 1 2 1	0.727
2 1 1 2 2	0.656
2 1 1 2 3	0.222
2 1 1 3 1	0.195
2 1 1 3 2	0.124
2 1 1 3 3	-0.041
2 1 2 1 1	0.814
2 1 2 1 2	0.743
2 1 2 1 3	0.309

2 1 2 2 1	0.691
2 1 2 2 2	0.620
2 1 2 2 3	0.186
2 1 2 3 1	0.159
2 1 2 3 2	0.088
2 1 2 3 3	-0.077
2 1 3 1 1	0.487
2 1 3 1 2	0.416
2 1 3 1 3	0.251
2 1 3 2 1	0.364
2 1 3 2 2	0.293
2 1 3 2 3	0.128
2 1 3 3 1	0.101
2 1 3 3 2	0.030
2 1 3 3 3	-0.135
2 2 1 1 1	0.746
2 2 1 1 2	0.675
2 2 1 1 3	0.241
2 2 1 2 1	0.623
2 2 1 2 2	0.552
2 2 1 2 3	0.118
2 2 1 3 1	0.091
2 2 1 3 2	0.020
2 2 1 3 3	-0.145

2 2 2 1 1	0.710
2 2 2 1 2	0.639
2 2 2 1 3	0.205
2 2 2 2 1	0.587
2 2 2 2 2	0.516
2 2 2 2 3	0.082
2 2 2 3 1	0.055
2 2 2 3 2	-0.016
2 2 2 3 3	-0.181
2 2 3 1 1	0.383
2 2 3 1 2	0.312
2 2 3 1 3	0.147
2 2 3 2 1	0.260
2 2 3 2 2	0.189
2 2 3 2 3	0.024
2 2 3 3 1	-0.003
2 2 3 3 2	-0.074
2 2 3 3 3	-0.239
2 3 1 1 1	0.367
2 3 1 1 2	0.296
2 3 1 1 3	0.131
2 3 1 2 1	0.244
2 3 1 2 2	0.173
2 3 1 2 3	0.008

2 3 1 3 1 -0.019
2 3 1 3 2 -0.090
2 3 1 3 3 -0.255
2 3 2 1 1 0.331
2 3 2 1 2 0.260
2 3 2 1 3 0.095
2 3 2 2 1 0.208
2 3 2 2 2 0.137
2 3 2 2 3 -0.028
2 3 2 3 1 -0.055
2 3 2 3 2 -0.126
2 3 2 3 3 -0.291
2 3 3 1 1 0.273
2 3 3 1 2 0.202
2 3 3 1 3 0.037
2 3 3 2 1 0.150
2 3 3 2 2 0.079
2 3 3 2 3 -0.086
2 3 3 3 1 -0.113
2 3 3 3 2 -0.184
2 3 3 3 3 -0.349
3 1 1 1 1 0.336
3 1 1 1 2 0.265
3 1 1 1 3 0.100

3 1 1 2 1	0.213
3 1 1 2 2	0.142
3 1 1 2 3	-0.023
3 1 1 3 1	-0.050
3 1 1 3 2	-0.121
3 1 1 3 3	-0.286
3 1 2 1 1	0.300
3 1 2 1 2	0.229
3 1 2 1 3	0.064
3 1 2 2 1	0.177
3 1 2 2 2	0.106
3 1 2 2 3	-0.059
3 1 2 3 1	-0.086
3 1 2 3 2	-0.157
3 1 2 3 3	-0.322
3 1 3 1 1	0.242
3 1 3 1 2	0.171
3 1 3 1 3	0.006
3 1 3 2 1	0.119
3 1 3 2 2	0.048
3 1 3 2 3	-0.117
3 1 3 3 1	-0.144
3 1 3 3 2	-0.215
3 1 3 3 3	-0.380

3 2 1 1 1 0.232
3 2 1 1 2 0.161
3 2 1 1 3 -0.004
3 2 1 2 1 0.109
3 2 1 2 2 0.038
3 2 1 2 3 -0.127
3 2 1 3 1 -0.154
3 2 1 3 2 -0.225
3 2 1 3 3 -0.390
3 2 2 1 1 0.196
3 2 2 1 2 0.125
3 2 2 1 3 -0.040
3 2 2 2 1 0.073
3 2 2 2 2 0.002
3 2 2 2 3 -0.163
3 2 2 3 1 -0.190
3 2 2 3 2 -0.261
3 2 2 3 3 -0.426
3 2 3 1 1 0.138
3 2 3 1 2 0.067
3 2 3 1 3 -0.098
3 2 3 2 1 0.015
3 2 3 2 2 -0.056
3 2 3 2 3 -0.221

3 2 3 3 1 -0.248
3 2 3 3 2 -0.319
3 2 3 3 3 -0.484
3 3 1 1 1 0.122
3 3 1 1 2 0.051
3 3 1 1 3 -0.114
3 3 1 2 1 -0.001
3 3 1 2 2 -0.072
3 3 1 2 3 -0.237
3 3 1 3 1 -0.264
3 3 1 3 2 -0.335
3 3 1 3 3 -0.500
3 3 2 1 1 0.086
3 3 2 1 2 0.015
3 3 2 1 3 -0.150
3 3 2 2 1 -0.037
3 3 2 2 2 -0.108
3 3 2 2 3 -0.273
3 3 2 3 1 -0.300
3 3 2 3 2 -0.371
3 3 2 3 3 -0.536
3 3 3 1 1 0.028
3 3 3 1 2 -0.043
3 3 3 1 3 -0.208

3 3 3 2 1	-0.095
3 3 3 2 2	-0.166
3 3 3 2 3	-0.331
3 3 3 3 1	-0.358
3 3 3 3 2	-0.429
3 3 3 3 3	-0.594

Source : A1 TARIFF BASED ON UK SURVEY (1993)

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