THE EFFECT OF FUNCTIONAL ELECTRICAL STIMULATION OF THE ABDOMINAL MUSCLES ON MOTOR PERFORMANCE AND FUNCTIONAL ACTIVITY OF THE TRUNK IN PATIENTS WITH STROKE: A PILOT STUDY

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ABSTRACT

Background: Significant improvements in functioning in general, and in gait performance specifically, have been found following the application of Functional Electrical Stimulation (FES) in the lower limbs in patients with stroke (1,2). Theoretically, FES could confer the same benefits if utilised on the trunk to activate the abdominal muscles. However, this is not well researched. Thus, the primary aim of this study was to establish, in participants with stroke, the effect of FES application to the abdominals and conventional physiotherapy, on trunk performance, general motor impairments, performance in Activities of Daily Living, health related quality of life scores and Physiological Cost Index scores. The secondary aims were to describe the treatment techniques used by physiotherapists treating stroke patients at the site of the study and to determine the most suitable placement (bilateral vs unilateral) of FES electrodes to activate external obliques (EO) for use in combination with abdominal exercises. Ethical approval and permission for the study was obtained from the Human Research Ethics Committee at the University of Cape Town and the Western Cape Department of Health.

Study 1: Description of Conventional Physiotherapy Interventions for patients with Stroke admitted to a rehabilitation centre in the Western Cape

Methods: Cross-sectional descriptive study was conducted among 10 physiotherapists employed by the rehabilitation centre. There were no exclusion criteria. A questionnaire was purposively developed for this study, using physiotherapy intervention activities listed in studies by Veerbeek et al. (3) and De Wit et al. (4). Participants completed the questionnaire individually with assistance from the researcher. Frequency Tables were used to describe the techniques that were most and least used and their frequency of use in the last two weeks. Descriptive statistics were used to describe characteristics of participants.

Results: All physiotherapists (n=10) working at the centre participated. The mean number of years of experience was 11.3 years. The most used treatment activities for the upper limb and lower limb, were joint mobilisation (used 10 or more times by 5 out of 10 participants) and therapeutic positioning of the hemiplegic leg (used 10 or more times by 4 out of 10 participants) respectively. FES was only used by one physiotherapist in the upper and lower limb.

Study 2: Determination of best placement of FES to the abdominal muscles

Methods: An experimental study with a pre-test post-test design was conducted with 12 participants with stroke. Inclusion criteria. Inpatients between 21 and 70 years old, with first ever stroke in the last four months, who could sit independently, who could understand, read and speak English or Afrikaans and minimum level of education of Grade 10. Exclusion criteria: any other neurological conditions,

uncontrolled epilepsy, healing wounds/poor skin condition, pacemakers or other implants, abnormalities on an ECG, pregnant women, cognitive impairments, receptive and global aphasia that could not give informed consent and failed sensory screening. Four electrode placements with two positions, were tested: Placement A (Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space) and Placement B (two cm superior and two cm medial to ASIS (6) and the eighth intercostal space) as either a bilateral placement (A1, B1) over both external obliques (EO) muscles or unilateral (A2, B2) placement over hemiplegic EO only. A two-dimensional (2D) ultrasound image was used to measure muscle thickness of EO and Transversus abdominus (TrA) at rest and then at five seconds, 30 seconds, one minute and five minutes of stimulation. Participants also completed a VAS (range 0-10) to determine comfort level with stimulation (with and without exercise) and to measure perceived stability and effort exerted with completing the exercise (with and without FES stimulation).

Results: Average age was 50 years old, and two thirds of the participants had a right sided stroke. Of the four placements, placement A1 showed a significant difference for TrA at baseline, 5 seconds and 30 seconds (p=0.02). Placement B2 showed highest mean muscle thickness measurements for EO at 30 seconds (4.85mm) and one minute (4.76mm) but these were not significant (p=0.33). Placement A2 was most comfortable for use with exercise and stimulation (VAS= 7.75) and placement B2 provided most stability with exercise and stimulation (VAS= 7.92) and had the second highest median score (VAS= 7.6) for comfort with exercise combined with FES. Placement B1 was deemed the least comfortable to utilise with stimulation alone and when FES stimulation was combined with exercise.

Study 3: The effect of FES-abdominals on trunk performance, function, energy expenditure and HRQoL (a pilot study)

Methods: A Single blind experimental study with pre-test post- test design was used to assess the Impact of FES intervention. Inpatients at a state rehabilitation centre at time of the study who were between 21 and 70 years old, with first ever stroke in the last four months were included. The same exclusion criteria as Study 2 was used. Baseline measures included the Trunk impairment scale (TIS), Barthel index (BI), Rivermead Motor Assessment (RMA) and the European Quality of Life-5 Dimension questionnaire (EQ-5D-3L). The experimental group received conventional physiotherapy and FES applied to hemiplegic EO, for four weeks in week three of admission. The control group received conventional physiotherapy and placebo FES to their hemiplegic EO, for four weeks in total. from. A research assistant blinded to group allocation reassessed all participants at two-week intervals and four weeks post intervention (week 8) using the same outcome measures. An assessment of the physiological cost index of gait (PCI) was added at the end of the four-week intervention period and re-assessed again four weeks later.

Results: Twelve participants were enrolled in the study but ten completed the study because two participants did not arrive for the last assessment. The scores of all participants were included in the final analysis. No significant differences were found between the two groups for TIS, RMA, BI and EQ-5D-3L VAS at baseline, two weeks, four weeks and eight weeks. There was a significant difference found for PCI at four weeks (p=0.05) favouring the control group. No significant difference was found at eight weeks for PCI. Over time both groups improved with the intervention group showing higher increases in the TIS and RMA-LT over the intervention period within group, however this was not significant.

Discussion: The findings from the description of physiotherapy intervention are mostly in keeping with literature (4). Only one physiotherapist utilised FES in the upper limb and in the lower limb, which is aligned with findings from a survey completed with physiotherapists and occupational therapists about use of FES in post-stroke treatment (7), suggesting that physiotherapists do not commonly use FES.

Placement B2 was found to be the best position to utilise for the pilot study, based on change in muscle thickness measurements for both EO and TrA and VAS scores. Placement B2 was used in two other studies by Baek et al. (6) and Park et al. (8) however, unilateral placement was found to be preferable by the participants in these studies.

The pilot study showed both FES in combination with conventional therapy and conventional therapy improve outcomes in clients with stroke, but one is not superior to the other as no significant treatment effect was found. However, an appropriately powered study would need to be conducted to determine if it is more effective in improving outcomes than conventional therapy alone.

Conclusion: Our study provides a useful description of physiotherapy interventions, which is usually poorly described in the literature, and it was the first description of physiotherapy interventions provided to stroke clients in a South African context. Suitable electrode placement for FES application to be utilised in combination with abdominal exercises, was in keeping with previous studies using NMES application to the abdominals, however, participants in our study preferred a unilateral application. FES application to the abdominals used synchronously with physiotherapy intervention may be a promising intervention to improve trunk performance, motor impairments and ADL performance however the result of our small study suggests that this intervention is not better than conventional physiotherapy.

Keywords: Stroke, NMES, FES, physiotherapy, trunk control, abdominal muscles

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Glossary and Abbreviations

FES :	Functional Electrical Stimulation
BI:	Barthel Index
PCI:	Physiological Cost Index
TIS:	Trunk Impairment Scale
ADLs:	Activities of Daily Living
RA:	Rectus Abdominus
EO:	External Obliques
TrA:	Transversus Abdominus
NMES:	Neuromuscular Electrical Stimulation
TENS:	Transcutaneous Electrical Stimulation
ECG:	Electrocardiogram
MoCA:	Montreal Cognitive Assessment
ASIS:	Anterior Superior Iliac Spine
VAS:	Visual Analogue Scale
RMA:	Rivermead Motor Assessment
EQ-5D:	Euroqol-5 Dimension
RMA-Arm:	Rivermead Motor Assessment arm section
RMA-GF:	Rivermead Motor Assessment gross function section
RMA- LT:	Rivermead Motor Assessment leg and trunk section
CVA:	Cerebrovascular Accident
ICF:	International Classification of Function, Disability and Health
DALYs:	Disability-Adjusted Life Years
HIV:	Human Immunodeficiency Virus
HRQoL:	Health Related Quality of Life
COM:	Centre of Mass
APA:	Anticipatory Postural Adjustment
CPA:	Compensatory Postural Adjustments
TCT:	Trunk control Test
EMS:	Electrical Muscle Stimulation
K-BBS:	Korean Version of Berg Balance Scale
K-MBI:	Korean Version of Modified Barthel Index
IAP:	Intra-abdominal Pressure

Chapter 1. Introduction

1.1 Stroke

Cerebrovascular accident (CVA) or stroke is a disabling condition that results in hemiplegia or hemiparesis, spasticity and decreased control over and coordination of voluntary movements (9).. According to the Global Burden of Disease, Injuries and Risk Factors Study (2015), the age standardised death rates for stroke worldwide declined by 36.2.% (from -39.3% to -33.6%) from 1990 to 2016 (10). However, the overall burden has remained high: in 2016 the incidence of stroke was 13,676761 and the age standardised incidence rate had decreased by 8.1% from 1999 to 2016 (10).

Stroke is the second leading cause of global disability-adjusted life years (DALYs), showing an increase from 1990 (95,3 million years) to 2015 (116,4 million years) (10) and is fast becoming a major health problem in low and middle income countries (11,12). This could be due to low availability of preventative services in the primary healthcare sector (risk factor screening and access to medication and equipment) and there may not be rehabilitative services, follow up and secondary stroke prevention programmes available which could prevent further disability (13).

A standardised case control study comparing 22 countries investigating risk factors for stroke, found that participants in African countries (Mozambique, Nigeria, South Africa, Sudan and Uganda) are younger (mean age = 57.7 years) compared to stroke survivors living in high income countries (Australia, Canada, Croatia, Denmark, Germany, Iran, and Poland) (mean age = 66 years) (14–16). The difference in mean age of stroke survivors in low and high income countries could be due to many reasons such as the higher prevalence of non-communicable diseases in low- middle- income settings and the higher prevalence of HIV in Sub-Saharan countries (17,18). Additionally, low-income countries have limited resources to provide optimal healthcare services to all (19).

1.2 Impact

Following a stroke, motor impairments such as muscle weakness, impaired sensation and proprioception, including altered muscle tone, have a negative effect on stroke survivors activity levels and mobility (20,21). These functional limitations can result in disability and caregiver dependence (22). Mudzi et al. (23) found in their sample of stroke survivors (n=200) from Gauteng, South Africa, that at one-year post stroke, all participants described themselves as having mild to moderate difficulty performing activities such as preparing meals and completing housework independently, using part 2 of the ICF (International Classification of Function, Disability and Health Checklist: Activity limitations and Participation Restrictions). They also experienced mild difficulty with forming interpersonal and formal relationships, including being dependent on their caregivers (23). Haghgoo et al. (24) conducted a study in 2013 aiming to examine the relationship between the performance of activity of daily living (ADL) and degree of post-stroke depression and quality of life (QOL). They reported that 43% of stroke survivors were dependent on their caregivers and that difficulties performing ADL was strongly correlated (r=0.91,p<0.001) with QoL (24). Evidently, a reduction in functional ability is a huge burden to those affected by stroke (24).

1.3 Effect of stroke on trunk control

The trunk muscles maintain postural control by acting as a stabiliser to the spine and pelvis (25). These muscles contract *prior* to limb movement, known as anticipatory postural adjustments (APAs) (26,27), and also contract *during* limb movement, known as compensatory postural adjustments (CPAs) (28). However, the motor and sensory system impairments caused by stroke, results in reduced postural control (29,30).

Trunk control refers to "the ability of the trunk muscles to allow the body to remain upright, to adjust to weight shifts, and to perform selective movements of the trunk that maintain the base of support during static and dynamic postural adjustments." (31,32). Trunk control is reported to be associated with trunk performance after stroke (33) and is considered a functional predictor in determining post-stroke outcome (34).Trunk control performance and sitting balance have specifically been found to predict prognosis and length of hospital stay in stroke patients (35). A lower score for trunk control using the Trunk Control Test (TCT) predicts a poor functional prognosis (by 54%) on discharge using the Functional

Independence Measure (FIM) (r= 0.738) and a longer hospital admission (by 52%) (r= -0.722) (35).

Patients with stroke have trunk impairments that may include any combination of stiffness, muscle weakness, overactive muscles and poor segmental control (34,36). Since the trunk forms the stable base for movement of the limbs (37–40), any changes in trunk posture and alignment, such as the changes that occur during weight shift, will affect the ability of the limb to complete movements accurately (37). Furthermore, where superficial abdominal muscles have delayed latency of contraction and a poor recruitment level in preparation for a movement, the anticipatory activity of the trunk muscles may be impaired (41).

Yang et al. (27) found that clients with stroke tend to use compensatory movements of the trunk to assist in reaching tasks in standing by recruiting trunk and pelvic rotation earlier than individuals without stroke. Seo et al.(42) reported decreased abdominal muscle thickness and asymmetry in contraction on the paretic side in comparison to their non- hemiplegic side, using two-dimensional (2D) ultrasound imaging. These differences were potentially as a consequence of trunk muscle weakness seen in stroke which affects alignment of the trunk (42). Individuals with impaired trunk control therefore find it difficult to suitably prepare for movement, ultimately resulting in poor ADL performance (33).

1.4 Improving trunk control post stroke

Rehabilitation aimed at improving trunk control early after stroke is recommended to improve balance and trunk performance (38,43). Improving strength in muscles making up the trunk, is shown to improve dynamic sitting balance and gait in individuals with stroke (38,44–46).The addition of trunk exercises to a conventional physiotherapy programme to activate the core muscles (the superficial and deeper abdominal muscles, psoas major, intercostalis, erector spinae, quadratus lumborum, the diaphragm, multifidus and pelvic floor muscles)(47) has shown positive trends in improving trunk control (44). A randomized control trial (RCT) conducted by Cabanas-Valdes et al. (48). in 2016, demonstrated that the experimental group who received additional core stability exercises had a higher change in dynamic sitting balance scores and coordination scores measured by the Spanish Version of the Trunk Impairment Scale 2.0 (S-TIS 2.0)($p<0.01$) than those who received conventional therapy ("tone facilitation, stretching, passive mobilization and range of motion exercises for the hemiplegic side, walking between parallel bars, occupational therapy and nursing") only.

Trunk exercises commonly described in the literature include core stability exercises, weight shifting exercises, selective trunk movements, trunk stabilisation and balance exercises, as well as moving the limbs in task training (33). The role of the physiotherapist in improving trunk performance/control entails assessing and treating/managing (49) the poor trunk control to improve movement. This method requires a large amount of time from the physiotherapist interacting with the patient. For instance, Cabanas-Valdes et al. (44) conducted a systematic review of 11 studies in 2013, exploring the effect of additional truncal exercise (TTE) guided by a physiotherapist over and above a conventional physiotherapy programme. The authors defined TTE as trunk exercises performed in sitting or in supine position with the aim of improving trunk performance or functional sitting balance, performed on a stable or unstable base (44). This was measured primarily using the Trunk Impairment Scale (TIS) total score and coordination subscale to measure trunk performance (44). To measure functional sitting balance; TIS dynamic and static sitting balance subscale, the modified reach test (MRF), the reach movement time and peak vertical force (PVF) experienced by the affected leg during reaching and the balance performance measure (BPM) which measures the symmetry between weight distribution and dynamic reaching in sitting as percentage of body weight (% of body weight)(44). Secondary measures included outcomes measures related to standing balance (BPM in standing on the affected leg, Berg Balance Scale, Brunel Balance Assessment, subscale of Tinetti, Romberg's Test and four test balance scale) , gait (10 metre walk test, Dynamic Gait Index, Functional ambulation categories and sub scale of the Tinetti) and mobility outcomes (Rivermead Motor Assessment Battery, Barthel mobility sub-scale, quality of life assessed by stroke specific quality of life questionnaire (SS-QOL) and global dependency assessed by Barthel Index) (44). Each study in the systematic review had a specific duration of intervention that ranged from 20 minutes to 45 minutes, three to five days a week for two to eight weeks (44).
This may not be feasible in a South African context with shortage of both therapists and access to rehabilitative services in certain parts of the country (50).

1.5 Functional Electrical Stimulation

Neuromuscular electrical stimulation (NMES) refers to a form of electrical stimulation where the aim is to cause muscle tetany and contraction, that can be used for therapeutic or functional purposes i.e. Functional Electrical Stimulation (FES) (51). It requires an intact lower motor neuron system to produce a muscle contraction(52). It can be used for treatment of chronic lower back pain in individuals with an intact neurological system (53). It can also be used on paretic muscles in individuals with an upper motor lesion, such as spinal cord injuries and stroke, where the current produced by the device stimulates nerve fibres causing muscle contraction (54).

Functional Electrical Stimulation (FES) is a form of NMES that can be applied via superficial electrodes or subcutaneously through wiring to either a muscle or motor point on a muscle (55). FES is defined as NMES used in combination with voluntary movement (56,57) of the muscle or joint (58), so it is either paired simultaneously or intermittently with a functional task to achieve the best functional outcomes (51). It differs to other forms of electrical stimulation, such as transcutaneous electrical nerve stimulation (TENS), which provides stimulation to sensory fibres only (59), whereas FES stimulates motor fibres causing muscle contraction (60).

FES is widely used in rehabilitation for patients with neurological disorders, where lower limb application has been reported to elicit a safer gait pattern (1) and reduce the energy expenditure of walking (2). In the upper limb, FES can be used in patients with stroke to improve the positioning of a subluxed shoulder in stroke (61,62) or to augment hand function, such as grasping and releasing of objects, (63), in stroke and spinal cord injuries (60).

FES is used primarily to replace lost or to supplement weak movement, referred to as the *neuroprosthetic effect* (55). Repeated FES stimulation may result in a post-treatment effect seen as improved voluntary muscle activation of the stimulated muscle, which is known as the *therapeutic effect* (52). Besides improving strength of the applied muscles (64), other benefits of FES include improved perfusion, reduced spasticity and decreased disuse atrophy of a muscle (65). According to Bosch et al. (65) the application of FES promotes enhanced limb control through improving proprioception of the applied limb. This control is evident through better muscle activation and improved active and passive movement around the joint in the limb (66). This provides improved afferent feedback to potentially allow cortical changes and to enhance positioning while activation occurs (66).

From the literature, NMES is used to stimulate peripheral muscles through intact peripheral nerves either in static position or in combination with exercise (60). FES is electrical stimulation that is used to stimulate muscles to promote or as part of functional movement (61). For the purposes of this thesis, NMES will be referred to as electrical stimulation when used to stimulate muscles when in a static position or whilst completing exercises, FES will be referred to electrical stimulation used in combination with functional movements or to elicit functional movements.

1.5.1 NMES and FES application to the trunk

Coghlan et al. (67) explored the use of NMES in ten healthy individuals using an abdominal belt with three electrodes, one over the umbilicus, and two located superior to the iliac crests, applied to the trunk in supine lying. From resting to stimulated stated, they found that TrA thickness increased significantly ($p<0.01$) by 22.2%, EO thickness increased by 5.5% but this was not significant ($p=0.42$)(67). The findings suggest that anterior stimulation of the abdominal muscles using NMES, elicits contractions in the deep and superficial stabilising muscles TrA and EO, and may have potential to be used therapeutically to recruit dysfunctional stabilising muscles in lower back pain patients (67).

Coghlan et al. (68) completed another study in 2011 to explore the effect of NMES stimulation of deep lumbar stabilising muscles (TrA and multifidus(LM)) as part of a 6 week training programme with 13 participants with chronic lower back pain. Intervention was provided once or twice a day for 15 to 30 minutes and NMES was applied bilaterally to the anterolateral abdominal wall and paraspinals using hydrogel electrodes (68). Participants were measured for muscle thickness changes using RUSI at rest; with functional spinal loading tasks such as asymmetrical straight leg raise (ASLR) for TrA loading and single prone arm raise (SPAR) for LM loading at the beginning and end of the 6 weeks. Pain was measured at 2 week intervals using Visual Analogue Scale (VAS) (68). The authors found that there was a significant increase in percentage thickness change ($p\leq 0.05$) in TrA and IO during the ASLR test at 6 weeks compared to baseline; resting LM also showed significant increase in thickness ($p< 0.01$) after 6 weeks (68). Both these thickness changes were associated with significant improvements in pain ratings ($p<0.01$), which represented an approximate 50% reduction in pain and indicates that TrA performs better in spinal loading after abdominal NMES training (68).

Four studies, published between 2009 and 2018 explored the use of NMES or FES to the trunk in stroke survivors (8,69–71). Kim et al. (69) was the first published study to consider NMES on trunk muscles, they applied electrical stimulation to the posterior aspect of the trunk; bilaterally to thoracic and lumbar erector spinae muscles and lateral to the T6 and L5 spinous processes, in addition to receiving conventional therapy. In this study, they described conventional therapy as functional joint range of motion (ROM) exercises, functional mat exercises and gait training, and ADL training (69). They also applied NMES to the hip extensors, knees extensors and ankle dorsiflexors of the lower limbs passively in therapy if muscle power in these muscle groups was less than three out of five (69). Participants in the intervention group showed significantly higher scores ($p<0.05$) in trunk control as measured by the Trunk Control Test (TCT) than those in the control group, who received regular intervention only (69).

Moosajie (70) completed a feasibility study in 2012 exploring the use of FES applied to the external obliques (EO) muscle in 19 clients with subacute stroke, for the first two weeks of the participants' admission to a rehabilitation centre in South Africa. This single blinded randomised experimental study evaluated the effect of FES application on the EO in combination with conventional physiotherapy, using an experimental group receiving FES application to the abdominal muscles simultaneously with conventional physiotherapy, and a control group that only received conventional therapy (70). Functional Recovery was measured using the Barthel Index (BI), effort with walking using the physiological cost index of gait (PCI), and motor recovery using the Rivermead Motor Assessment (RMA)(70). The results showed significant improvements in BI scores in the intervention group from admission to discharge ($p=0.03$), with significant differences in PCI scores between intervention and control groups ($p=0.04$) (70). The research study centre closed early, limiting recruitment and thus the study was underpowered. However, the study found that FES application to the abdominals is feasible when used simultaneously with conventional therapy and shows that improvement in function (according to the Barthel Index and PCI results) is possible Moosajie (70) therefore recommended that further research should continue to determine if there would be a significant effect on trunk control, motor impairments and functional recovery in stroke by applying FES to the abdominals, as a pilot intervention study exploring the use of FES in this manner. While acknowledging that the previous study results were limited, it appeared that the methodological errors could be addressed in a follow up study.

When the current study was planned (2014), to our knowledge, one study by Kim et al. in 2009 (69) had been published regarding the use of NMES application to the trunk muscles in stroke. Subsequently, two published studies by Ko et al. (71) in 2016 and Park et al. (8) in 2018 have utilised NMES application to the trunk muscles in clients with stroke. In both these studies, the application of NMES were to the back muscles specifically erector spinae, with one study comparing application between back and abdominal muscles, specifically external obliques(8,71). In addition to regular therapy, both studies used NMES in combination with core muscle strengthening or in isolation (8,71).

The study by Ko et al. (71) in 2016 evaluated the additive effects of core trunk muscle strengthening and trunk NMES on trunk balance in stroke patients . The researchers enrolled patients within one month of stroke who were unable to maintain static sitting balance for more than five minutes (71). This study used three groups : 1) a group receiving NMES to the back muscles in combination with core muscle strengthening exercises in the intervention group, 2) a group receiving core muscle strengthening alone and 3) a group receiving additional NMES to the back muscles alone (71). All three groups received regular physiotherapy intervention, (71). These authors found significant improvements in the Korean version of the Berg balance scores (K-BBS) and the dynamic sitting balance scores of the Trunk Impairment Scale for the combination intervention group in comparison to the other two intervention groups (71).

The study by Park et al. (8) in 2018, combined NMES application to the abdominal muscles or to the back muscles with core muscle strengthening and compared it to core muscle strengthening alone in addition to regular therapy. These authors (8) found that those participants in the intervention groups that utilised either combination of NMES and core muscle strengthening exercises, had significantly higher Berg Balance Scale ($p< 0.02$) and Trunk Impairment Scale scores ($p< 0.02$), than those completing core muscle strengthening exercises alone, thus supporting the findings of Ko et al. (71) in 2016.

In summary, the studies by Kim et al. (69), Moosajie (70), Ko et al. (71) and Park et al. (8) demonstrate that application of FES or NMES to the trunk in patients with stroke is possible. They further demonstrate that NMES or FES used in combination with exercise (core exercises or conventional treatment) yields improvement in trunk performance and balance, as well as ADL performance and energy expenditure during gait (70). The study by Ko et al. (71) study suggests that NMES by itself, when applied to the back muscles, does not improve trunk control as much as NMES when it is combined with core strengthening exercises. Further, Park et al. (8) confirms this suggestion when comparing core exercise alone versus core exercise with NMES. Taken together, there is a positive additive effect of either using trunk exercise with NMES application to the trunk during conventional therapy or with trunk exercises to enhance trunk performance.

Only two (8,70) of the four studies evaluated the effect of NMES or FES applied directly to abdominals (external obliques) suggesting the need for further testing. Timing and dose of stimulation was an important factor in all studies, and this will be further examined below.

1.5.2 General recommendations regarding application of FES to trunk:

1.5.2.1 Timing and dosage of stimulation:

Thrasher and Popovic found that typical regimes in FES rehabilitation assisted walking studies with stroke and spinal cord injuries had stimulation periods of over at least four weeks, with three to five one hour sessions per week (72). The intervention period used by Moosajie (70) was only two weeks per participant and with varied application: In the first week it was 15 minutes per day and in the second week it was 20 minutes per day, with no reasoning given for the change in duration. Kim et al. (69) applied NMES for 30 minutes per day, five times a week for three weeks. Whereas Ko et al. (71) applied FES for 20 minutes a day, three times a week for three weeks and Park et al. (8) applied it for 30 minutes a day, five days a week for three weeks respectively. Neither author (8,71) provided reasoning for each of their choices for stimulation duration.

Time since stroke remains key in planning interventions (49). Langhorne et al. (49) hypothesized that spontaneous neurological recovery starts to occur within days of stroke incident and steadily increases, until plateauing after approximately six months. The appropriate time to conduct physical rehabilitation intervention would thus be before six months to best utilise spontaneous neural reorganisation. Many studies aim to supplement lost function with FES and therefore include chronic stroke participants in limb application of FES (73,74). However, multiple studies have shown promising rehabilitative results when FES is applied early after stroke (75,76) . With reference to the previous studies using NMES or FES, all the researchers used patients within six months of stroke. Kim et al. (69) and Ko et al. (71) completed their study with acute patients (within in one month of stroke), Park et al. (8) recruited subacute clients (within six months of stroke) and Moosajie (70) used subacute patients (within 3 months of stroke). All four studies showed promising effects when stimulation was used in the trunk in this period of up to 6 months, therefore applying FES within this stage can be recommended.

1.5.2.2 Stimulation parameters

Adjusting stimulating parameters, such as frequency, amplitude, pulse width, ramping, duty cycles, for NMES application can influence fatigue, comfort and force output (51).
In a review of 19 randomized control trials by De Kroon et al. (77) using electrical stimulation in the upper limb, the typical stimulation parameters found were 20-50 Hz for frequency, amplitude range was 0 – 100 mA and the typical pulse width was 0-300 µsec. Lower limb studies using FES report parameters for frequency 15-50Hz, amplitude 4-20mA and pulse width 1-50 µsec and 200-400µsec (78,79).

The four previous studies utilising NMES or FES to the trunk muscles applied stimulation with in the same parameters applied to the limbs as above; Kim et al. (69), Ko et al. (71) and Park. (8) utilised 30-70 mA, pulse width 250 µsec and 35 Hz frequency and Moosajie (70) used 100 mA amplitude, pulse width of 330µs and 40Hz frequency.

1.6 Methodological concerns in previous studies

1.6.1 Describing conventional therapy/usual care

Clinical trials usually assign participants to one of two or more groups. One (the experimental group) receiving the intervention that is being tested, and the other (the comparison group or control) receiving an alternative (conventional) intervention (80). Published intervention studies using FES often describe the control intervention as “usual care” or “conventional or regular physio- and/or occupational therapy". For reporting purposes, it is necessary that the control intervention is well described, and it is essential to identify the components of the control intervention that differ from the experimental intervention (81). In South Africa, there is currently limited literature regarding the content of conventional physiotherapy, within an inpatient rehabilitation setting, that can be used as a description of control intervention in a pilot intervention study. Before undertaking an intervention study using FES, a description of the control intervention should be determined as a basis for comparing the experimental intervention. One method to evaluate this would be to collate information from the therapists working in the area, where they describe their usual or conventional practices.

1.6.2 FES and electrode placement

The efficacy of FES to reach the underlying tissue is very dependent on electrode placement on the stimulating surface (82). Therapists commonly place electrodes over the muscle belly (83) or use the guideline provided by the manufacturer of the stimulation unit where these are included (51). Some manufacturers of stimulation devices provide an electrode placement guide however this is not available with trunk applications.

In unpublished studies by Moosajie (70) in 2012 and Joffe (5) in 2014, both researchers applied FES to the external obliques (EO) in adults with stroke and children with cerebral palsy respectively. Neither of these studies determined in advance, which electrode placement would provide the strongest and most comfortable muscle contraction. Neither did they provide a rationale for electrode placement. Both authors (5,70) used visual confirmation of muscle contraction for their theoretical placements and Moosajie (70) gave no clear indication of placement in adults. Moreover, neither study tested which electrode placement would be the most comfortable for participants when combined with exercises (5,70).

Using 2D ultrasound imaging on the anterior abdominal wall, Baek et al. (6) explored the best placement of electrodes for NMES application to illicit contraction of EO, internal obliques (IO), transversus abdominus (TrA) and multifidus, in healthy individuals. They identified a placement of two cm superior and two cm medial to the anterior superior iliac spine (ASIS), bilaterally on the abdominal wall, produced the largest changes in muscle thickness for TrA and multifidus (6). Of the three studies(8,69,71) utilising NMES to the trunk in stroke clients mentioned in 1.5.1., Park et al. (8) are the only authors that used this placement method in stroke clients to provide NMES to the abdominal musculature in combination with core exercises. The study by Park et al.(8) however, did not verify if this placement was the most suitable to be used in stroke clients, or if it would produce the same results in muscle thickness changes as in the Baek et al. study (6). Neither did they identify whether a unilateral or bilateral placement would be better in getting the maximal contraction (thickness change) in the abdominal muscles in stroke (8).

Before undertaking an intervention study using FES, a theoretical or clinical basis of the best anatomical placement of FES electrodes placement should be determined to provide the strongest and most comfortable muscle contraction to be used with exercise.
Real time 2D ultrasound imaging may present the best way to evaluate which point on the abdominal wall would be best suited to apply electrodes to, as the abdominal muscles are large, there are various muscles and each muscle has a different function. This would determine accurately whether the correct muscle is stimulated. Real time ultrasound images of muscle thickness are valid (84) and would be a useful way of determining if the electrical stimulation is reaching the deep abdominal muscles such as transversus abdominus.

1.6.3 Comfort with FES stimulation during exercise

One of the key limiting factors reported by patients using FES is discomfort with stimulation (85). This leads to either totally rejecting the modality or difficulty with tolerating the required stimulation intensity for optimal results (86). Lyons et al. (87) explored the effect of electrode size and placement on comfort with stimulation of the gastrocnemius muscle; the researchers compared four electrode placements on the gastrocnemius with two different electrode sizes, one of 38.48cm² and one of 19.63cm², by adjusting the stimulation intensity until the participant felt discomfort (pain threshold) and when discomfort could no longer be tolerated (pain tolerance) with muscle contraction. They found two positions, which were with the negative electrode positioned in the centre between muscle heads with the corresponding positive electrode placed either in the centre of the lateral or medial muscle belly, produced only one gastrocnemius head muscle contraction (87). Two positions 1) The negative electrode placed 1.25cm distally and below the proximal end of the muscle head and positive electrode was placed toward the end of the muscle belly just above the Achilles tendon and 2) both electrodes placed in the centre of the gastrocnemius heads, the negative electrode on the lateral head and the positive on the medial head were more comfortable and more tolerable (87). Smaller electrode size was more favourable and comfortable, and had higher pain thresholds and pain tolerance percentages (87). Forrester and Petrofsky also (88) found that placement of the electrode away from the motor point in any direction, resulted in an increase in pain as measured by visual analogue scale (VAS).

For NMES application to the trunk muscles, the studies by Kim et al. (69), Ko et al.(71) and Park et al. (8) did check for comfort with stimulation at the start of stimulation when determining the intensity of stimulation to be given. Only Kim et al (69) verified that the participants did not have pain for the 30 minutes of stimulation. It is unclear how the authors measured discomfort. For FES application to the abdominals, Moosajie (70) only tested for comfort when FES was first applied and when adjusting intensity for appropriate muscle contraction. Presently there is limited literature in describing if the stimulation continued to be comfortable while exercising.

1.7 Significance *and Hypothesis* of the study

Moosajie (70) completed a pragmatic study describing the effect of FES on the abdominals used simultaneously with regular physiotherapy in individuals with stroke in the context of an in-patient rehabilitation setting. Based on recommendations from this study by Moosajie (70), it was decided to improve upon the intervention protocol by addressing three key issues. First, the intervention period used by Moosajie (70) which was only two weeks per participant, whereas Thrasher and Popovic (72) indicate that most ambulation studies in stroke utilise a stimulation period of over at least four weeks. Second, the study did not utilise a placebo control group. Third, the placement of electrodes on the abdominal muscles was not practically explored in terms of defining the placement that yielded the strongest contraction and the placement which was most comfortable for the patient.

Therefore, we hypothesized that additive FES stimulation to the abdominal muscle combined with conventional physiotherapy, results in statistically significant improvement in motor performance and functional independence compared to conventional physiotherapy combined with placebo FES. This would provide stroke rehabilitation clinicians with a treatment method targeting the trunk which in turn may lead to improvement in patient performance of everyday functional activities. FES application to the abdominal muscles could be a relatively affordable and efficient way to assist with improving trunk stability by assisting with improving strength of the abdominal muscles and reducing the time to achieve sitting balance. There may also be potential to set up clients with an FES device to continue with conventional treatment activities with decreasing levels of input from the therapist. In a context where frequency of appointments at out- patient departments is poor (50,89), an intervention that can provide early activation of the abdominals or a more targeted approach to activate the abdominals, would be very useful.

1.8 Aim and Objectives

The aim of this study was to determine if the application of FES to one of the core stabilisers of the abdominals, the external obliques (EO) as the most superficial muscle, would yield positive results in trunk performance and functional independence in patients with stroke. EO was chosen as it was the most superficial muscle, and a contraction would be visible to the therapist when stimulated with FES.

1.8.1 Objectives

1. **To describe conventional physiotherapy treatment provided to stroke survivors by physiotherapists working in an inpatient stroke rehabilitation facility.** For this objective, we describe the most used physiotherapy interventions using a checklist containing commonly used treatment activities as described in the literature.

2. **To determine the most comfortable and effective anatomical placement of FES electrode placement on the abdominal muscles in stroke patients 4 months post stroke**. Two positions were evaluated: 1) electrodes placed bilaterally over the external oblique (EO) abdominal muscles and 2) electrodes placed over the EO muscles of the hemiplegic side only. Two conditions were examined: a) FES in combination with exercise, b) FES without exercise. Outcomes evaluated for this objective included determining:

2.1. The *most comfortable patient perceived contraction* of EO using a Visual Analogue Scale (VAS).

2.2. The *largest change in hemiplegic muscle thickness (EO and TrA)*, measured by 2D ultrasound imaging, between baseline (no FES stimulation) and contraction after five seconds, thirty seconds, one minute and five minutes with FES stimulation.

3. **To evaluate the impact of FES on trunk performance, motor impairments and ADL performance by comparing the change in scores between two groups, an experimental group receiving FES to the abdominals with simultaneous conventional physiotherapy and a control group receiving placebo FES to the abdominals with simultaneous conventional physiotherapy, in the following outcomes:**
    - Trunk performance using The Trunk Impairment Scale (TIS).
    - Motor impairments as measured by the Rivermead Motor Assessment (RMA).
    - Activities of Daily Living (ADLs) measured by the Barthel Index (BI).
    - Energy expenditure in gait measured using Physiological Cost index (PCI).
    - Health related quality of life (HRQOL) scores measured by the EQ-5D-3L

1.9 Study setting

The research setting, Western Cape Rehabilitation Centre (WCRC), is a 156 bedded facility providing specialised inpatient and outpatient rehabilitation services to privately funded, medical aid and state clientele from the Western Cape and neighbouring provinces. These individuals include survivors of CVA, head injury, Guillain Barre syndrome and other polyneuropathies, spinal cord injuries and amputees.

This facility utilises a multi-faced treatment approach which combines the Bobath treatment concept (90), the ICF, Community-Based rehabilitation philosophy and a client centred, outcome-based approach by Landrum and Schmidt (91) (personal communication with CEO at the time (2016), Jenny Hendry).

This is done through individualised treatment programmes providing therapy in functional activities and in various treatment activities or positions which are highlighted in sub study one e.g. sit to stand, standing weight shifts. The physiotherapists complete "hands on" treatment with in-patients diagnosed with CVA, head injury, Guillain Barre syndrome and other polyneuropathies, spinal cord injuries and amputees. Patients are treated, at least three times a week for approximately 30 to 45 minutes. They also draw up a programme of self exercises, incorporating the various treatment positions mentioned above to target their missing components of the required normal movement, with repetition for the patients to complete when not receiving "hands on" treatment.

1.10 Ethical approval and permission to conduct the study

The study was completed in three parts: the first part (chapter 3) involved therapist and the other two parts involved patients (chapter 4 and chapter 5). Ethical approval was obtained from Human Research Ethics Committee in the Faculty of Health Sciences at the University of Cape Town (434/2015) and from the Western Cape Department of Health (WC_2015RP37_153), to conduct these studies. This study complied with the Declaration of Helsinki (92) and participants in the study were covered under the UCT no fault insurance policy. All study participants provided informed consent to participate and could withdraw at any time with no consequence.

1.10.1 Ethical considerations for Chapter 3: Description of the physiotherapy treatment provided to stroke survivors by physiotherapists.

The therapist-participants received information sheets (Appendix VII) and verbal information sessions, explaining the study and its purpose. At any point during the study, the therapist-participants could request further information, or they could withdraw from the study with no consequences.

The data collection session was arranged in a time convenient for the therapist-participants and onsite, to ensure that no clinical time was taken away from their patients. The questionnaire took approximately twenty minutes to complete, which was worked into the information session of one hour. Two information and data collection sessions were arranged for participants to attend because not all consenting participants could attend the first organised session, therefore allowing all consenting therapist-participants equal opportunity to participate.

No personally identifiable data was collected from therapist-participants. However, we acknowledge that while every effort was made to ensure that the data was anonymised- there was a chance that due to the small number of therapist-participants, that individuals could be inadvertently identified. Questions and discussions from the information session were also kept confidential. All questionnaires were held in a secure location, which only the researcher had access to. The data from the questionnaires were entered onto an excel spreadsheet which was password protected and stored in a shared Drobox account with the supervisors only. Data was stored in accordance with the UCT data management policy (93,94).

1.10.2 Ethical Consideration for Chapter 4: Determination of best practice of FES application on the abdominals

The patient-participants received information sheets and introductory interviews were conducted; if requested by the patient-participants, the interview could be conducted in their preferred language to explain the study, procedure, and possible FES side effects for informed consent. The study protocol was discussed with the patient-participant. At the introductory interview, the patient-participant was given an information sheet and 24 hours to consider whether to participate or not. TS followed up with them the next day. Written and signed consent was obtained from the patient-participant. If the patient-participant wished for a family member or carer to be included in the discussion then TS would either arrange to come back in visiting hours and contact the nominated family member or carer to inform them of the request.

All patient-participants could at any time in the interview, information session and during the study request further information or withdraw from the study with no consequences.

To ensure anonymity patient-participants were given a code to be used on all data sheets. The data sheets were stored and locked away in a safe location that only the researcher could access. All patient-participants' details remained confidential. FES has few reported side effects; the most common being skin hypersensitivity to the electrodes, if this was to occur, hypoallergenic electrodes were used instead.

1.10.3 Ethical Considerations for Chapter 5: The effect of FES-abdominals on trunk performance, function, energy expenditure and HRQoL (a pilot study)

To ensure autonomy, all study participants received information sheets and introductory interviews. If requested by the patient-participant the interview could be conducted in their preferred language to explain the study, procedure, and possible FES side effects for informed consent. Informed consent forms were available in English and Afrikaans, but an interpreter was used for all other languages in the interviews. All participants could withdraw from the study at any stage with no consequences.

To ensure confidentiality of data, patient-participant codes were given such P1 or P2 as they entered the study and these codes were used on all data sheets. To demonstrate beneficence, all patient-participants received up to a R150 monetary contribution toward transport costs to attend the final (week eight) assessment, which is not a routine outpatient visit. The study results will be shared with all respective patient-participants when complete. Beneficence is further ensured, whereby if FES is found to be effective, the control subjects (patient-participants) will be referred for a short readmission as an inpatient to WCRC, if they chose to, to receive FES to their abdominals.

Randomisation was based on chance for all patient-participants to ensure justice. To further ensure justice, all study patient-participants received regular physiotherapy, patient - participants were referred appropriately for further management if they present with decreased functional ability or potential to gain function, at the final assessment.

Risk to patient-participant was managed where FES has few reported side effects; these include skin hypersensitivity to the electrodes, in the event that this occurred hypoallergenic electrodes were used instead. Participants were informed of all risks (see appendix X)

1.11 Data management

All paper questionnaires, outcome measures and consent forms were anonymised and stored in a safe location that only the researcher could access. The electronic data from these questionnaires and outcome measures was anonymised and entered onto an excel spreadsheet which was password protected and accessible to the researcher and supervisors only and stored using a Cloud-based system: a shared Dropbox account with the dissertation supervisor which was password protected. Dropbox has been found to be safe (95).

Participants were informed that publication of the thesis and any papers derived from it would not contain their names or reference to the institution, however the institutions could be inadvertently identified. According to UCT's Data Management policy (93,94), data (electronic copies) will be stored for approximately 10 years on Zivahub, an online open source data repository at UCT.

1.12 Format of the thesis

The thesis is presented in six chapters:

Chapter 1: Introduction

Chapter 2 Literature review

Chapter 3: Description of the physiotherapy treatment provided to stroke survivors by physiotherapists.

Chapter 4: Determination of the best anatomical placement of FES electrode placement on the abdominals in stroke patients.

Chapter 5: Intervention study: The Effect of FES-abdominals on trunk performance, function, energy expenditure and HRQoL (a pilot study)

Chapter 6: Conclusion

Chapter 2. Literature Review

2.1 Introduction

This literature review is presented as a narrative literature review, which will explore the impact of stroke as a disabling condition in terms of local epidemiology and resultant functional impairments. Thereafter the role and structure of the trunk, and how significant it is in achieving skilled movement as well as postural control and stability will also be discussed.

The next section will introduce how trunk control is emerging as a functional predictor in determining prognosis after stroke, and therefore it is highlighted as a priority for treatment in rehabilitation. Following on from that, different ways to target the trunk in rehabilitation will also be explored. Thereafter we will focus our attention on Functional Electrical Stimulation (FES) as a promising treatment tool to activate abdominal muscles and restore motor function in stroke. Its benefits and uses will be outlined as well as its feasibility for application to the trunk, notably the abdominal muscles. Previous intervention studies utilising Neuromuscular Electrical Stimulation (NMES) and FES to the trunk muscles will be highlighted, and critically reviewed, to identify areas in which clarity is needed, and to provide recommendations for future studies in this field.

Literature used for this review was sought by searching databases Pubmed, Medline, Cinahl, Science Direct using the search words, stroke, NMES, FES, physiotherapy, trunk control, abdominal muscles. Any further references that were cited in the searched articles were searched as above.
Articles used were limited to those freely available and full text.

2.1.1 Aetiology and epidemiology of stroke

In 2013, stroke or cerebrovascular accidents (CVA), was the second leading cause of death worldwide (11.8% of all deaths), ischaemic heart disease (14.8% of all deaths) being the first (96). CVA was also the third most common cause of disability (96). In 2017, an estimated 11.9 million people around the world were thought to have had a stroke, of which 52.1% (6.2 million) were fatal (97).

In 2000, stroke was the third leading cause of death in South Africa after HIV/AIDs and ischaemic heart disease (98). In 2009, stroke then ranked second to HIV/AIDs, with tuberculosis and ischaemic heart disease coming in third and fourth (99). In comparison to Sub-Saharan African, in 2016 South Africa had the highest number of stroke related deaths (approximately 23906 counts) (10). The death rate from stroke for South Africa decreased (-0.3%) from 1990 to 2016 (10). In the period between 1990 to 2016, South Africa showed an increase in incidence related to stroke (2.1%) and in 2016 had an estimated stroke incidence of 48260 counts (10).

Disability Adjusted Life Years (DALYs) is a statistic used to measure the burden of disability (13). It is used to determine life years lost due to premature death (YLL or years of life lost) and years of life lost due to living in a state of less than good health (YLD or years lost to disability), where one DALY is equal to one lost year of life living with full health (100,101). Approximately 90% of the stroke burden measured in DALY's globally, are due to modifiable risk factors, such as behavioural (smoking, diet, lack of exercise) and metabolic (High BMI, diabetes, hypercholesterolaemia, hypertension) (102). Obesity is increasing in developing countries and is linked with increased hypertension and stroke (103). Uncontrolled hypertension has been linked to the incidence of haemorrhagic stroke (14,16) and was found to be the most prevalent risk factor in stroke incidence in sub-Saharan African countries (104).

In South Africa, there is a higher incidence rate of stroke at a younger age in comparison to their regional neighbours (98). Mudzi, Stewart and Musenge's (2013) study conducted in Johannesburg, South Africa, explored community participation 12 months after stroke. They found that of the 200 participants, the mean age for male participants was 52.1 years (87 participants) and 54.1 years for females (113 participants) (23).

The presence of HIV infection may be a major risk factor for stroke in younger patients, in whom traditional risk factors for stroke are not usually present at time of stroke (105–108). HIV can cause stroke via opportunistic infections, vasculopathy, cardioembolism and coagulopathy (108). In a case series study between 1999 to 2000, completed in a hospital in Johannesburg, South Africa, by Mochan et al. (109), they found that the mean age in their sample of 35 patients with HIV to be 32.1 years. A similar age range was found in another hospital study in Cape Town, South Africa, where 61 (91%) of the 67 HIV positive clients stroke clients admitted from 2000-2006 (n=1087), were younger than 46 years old (110). The presence of HIV infection at time of stroke, however, was not found to influence stroke severity and outcome (104). Overall, the burden of HIV is high in rural South Africa (108). While stroke occurs in a younger age group in South Africa (98), the stroke survivors who have HIV positive are reported to be younger than stroke survivors who are HIV negative (111).

2.1.2 Motor Impairments and functional limitations in stroke

Common impairments post stroke include impairments of mobility and function as a result of motor, somatosensory, speech and cognitive impairments (44,112–114). The functional activity limitations that affect stroke survivors' daily lives include manipulating eating utensils, effectively gripping objects, washing, dressing and basic mobility (89,115). Therefore, they may be functionally dependent on others (89). Poor performance in ADLs have been linked to sensory, motor and cognitive impairments (21,116).

Motor impairment post stroke has varying degrees of severity from paresis to paralysis, affecting the control of movement in the face, arm, leg and trunk on both the hemiplegic and non-hemiplegic sides of the body (117). Motor impairments are caused by central and peripheral factors. Central factors arise from ischaemic damage to the corticospinal tracts, resulting in decreased descending neural drive and post stroke cortical reorganisation (118). Peripheral factors, known as adaptive changes, occur at the level of the muscles and joints due to the central manifestations (119).

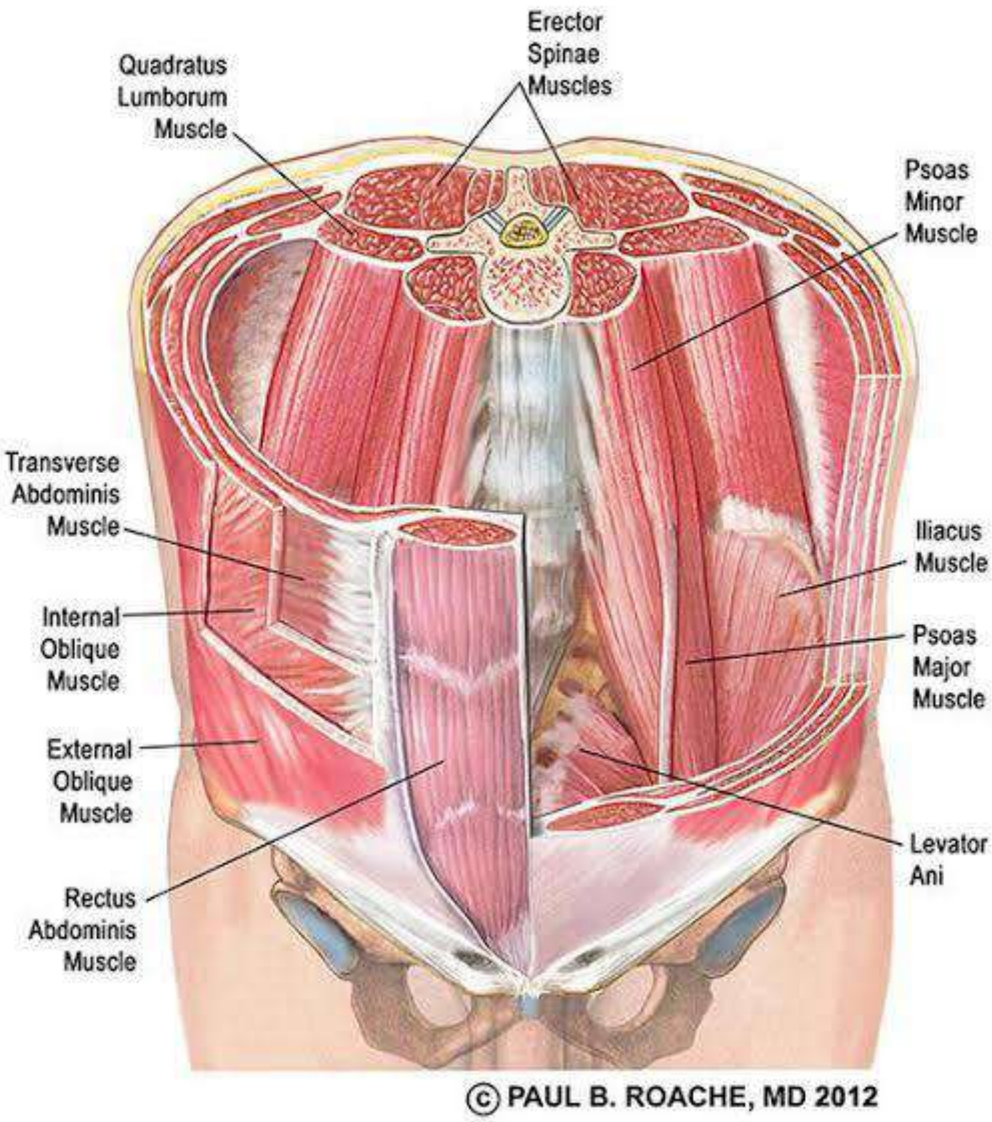
After stroke, central factors manifest as altered muscle tone, altered motor unit firing rates and altered firing patterns in skeletal muscles, causing altered muscle recruitment patterns and variable contractility (120). This results in poor force generation in the muscles impaired by stroke (118), which leads to poor voluntary muscle activation, poor selective activation of muscles and decreased dexterity (119,121). Tonal changes (121) and poor voluntary activation of the muscles leads to adaptive changes (peripheral factors) such as muscle and joint immobility, resulting in decreased joint range of motion, reduced flexibility (122) and muscle atrophy, commonly seen post stroke (123,124).

Somatosensory impairment is a pre-cursor for motor function and new skill acquisition and has shown significant association with muscle weakness after stroke (125). Furthermore, somatosensory impairments can also contribute to immobility, most evident in the upper limb where stroke survivors with sensory impairments do not spontaneously use their hemiplegic arm despite having sufficient movement (115,126).

2.2 The role of the Trunk in Function

2.2.1 Structure of the trunk

The general muscles of the trunk anteriorly and anterolaterally are the abdominal muscle wall and posteriorly, the trunk extensors. Bergmark in 1989, classified the core musculature of the trunk as either global or local muscles (47).



The global muscles of the trunk act as the prime movers of the trunk and comprise of rectus abdominus, lateral fibres of external obliques, psoas major and erector spinae, and the thoracic portion of intercostalis (47,127). These are thought of as "slings" with multiple bony attachments-(the ribcage, vertebrae, humerus and pelvis) and are able to generate speed and torque (47). The local muscles of the trunk directly affect the segmental levels of the spine and are the multifidus, transversus abdominus (TrA), quadratus lumborum, internal oblique (IO), middle fibres of external obliques (EO), the diaphragm and the pelvic floor muscles. They have direct attachments to the vertebrae and are shorter in length, allowing them to create enough tension and force within a very short reaction time (47,127).

The anterior abdominal wall consists of five muscles. Superficially, there are the rectus abdominus(RA), pyramidalis and external obliques (EO), and the deep layers are made up of transversus abdominus (TrA) and internal oblique (IO) (128). During an anterior posterior adjustment (APA) in voluntary movement, the IO and TrA muscles have been found to activate first (129–131). The orientation of the TrA fibres in a corset like fashion (127), allow it to increase the tension in the thoracolumbar fascia and as a result, increase the intra-abdominal pressure (IAP) when it contracts, thus creating stability around the spine to guard against forces acting on it (129) and to reduce the movement of the centre of mass (COM) (132). The centre of mass (COM) is defined as "a point that is at the centre of the total body mass" and "is determined by the weighted average of the COM of each body segment". The COM is displaced when a disturbance or perturbation occurs which destabilizes posture e.g. moving the limbs when completing a task (133) and is therefore the main variable to be manipulated for postural control (36,134).

The oblique muscles, EO and IO, mostly contribute to gross movement such as flexion, side flexion and rotation of the spine (135–137) but also contribute to IAP (129). While TrA is always found to contract prior to movement, the superficial muscles, like the obliques and RA, may play a larger a role in providing stability as a response to the movement (26,138,139).

The external obliques muscle is the most superficial of the abdominal muscles; the fibres for EO run inferomedial from the outer surface of the lower ribs to the iliac crest bilaterally (128). The EO has been shown to have multiple roles in its interaction with the Centre of Mass (COM) in voluntary movement. In previous studies exploring activation timing in upper and lower limb movement, EO has been shown to act as a stabiliser of the COM in response to the perturbations from voluntary movements (132). It directly activates after the prime mover of the arm (deltoid) (140) or of the lower limb (rectus femoris, gluteus maximus, tensor fascia latae) (135). Whereas these previous studies confirmed the role of EO in a position where the COM remained in the base of support, Stamenkovic and Stapley (132) found that the EO increases activity when the target is out of the base of support and the COM needs to shift in order to complete the movement. For example, in their study with the participant standing, when the target was ipsilateral to the moving arm, and within the base of support, the EO contracted prior to movement with TrA, IO and RA to slow down movement of the COM and provide stability. When the target required the moving arm to go beyond midline and cross over to the contralateral side and reach beyond outside the base of support, EO and gluteus max of the contralateral leg increased in activating, essentially helping to shift the COM and establish a new point of equilibrium (132).

2.2.2 Postural control

To complete activities of daily living and to decrease dependence, stroke survivors need adequate postural control. Decreased motor force, poor motor coordination, decreased range of motion and somatosensory impairment all negatively affect postural control (141,142). Pollock and colleagues (2000) define postural control as *"… the act of maintaining, achieving or restoring a state of balance during any posture or activity"* (143). Shumway-Cook and Woollacott (36) further defines postural control as "*the ability to control the body's position in space for the dual purposes of stability and orientation".* Postural control is thus a necessary feature to maintain an upright orientation and is essential to complete several physical tasks associated with activities of daily living efficiently and safely (144).

Shumway-Cook and Woollacott (36) identify two requirements for postural control: postural orientation and postural stability. Postural orientation is the organisation of the body segments in relation to each other and the relationship between the environment and the body for a task (36). Postural stability refers to controlling the centre of mass (COM) over the base of support (134). The COM is displaced when a disturbance or perturbation occurs which destabilises posture e.g. moving the limbs when completing a task (133), and is therefore the main variable to be manipulated for postural control (134).

The trunk has a unique role in postural control as its musculature provides stability to the spine, pelvic and shoulder girdles during functional tasks. Trunk control refers to “the ability of the trunk muscles to allow the body to remain upright, to adjust to weight shifts, and to perform selective movements of the trunk that maintain the base of support during static and dynamic postural adjustments.” (31,32). To achieve trunk control, trunk muscles are known to contract prior to movement (anticipatory postural adjustments or APAs) (26,145) to maintain the COM over the base of support and react to or adjust (compensatory postural adjustments or CPAs) to exertional movements from the limbs (28). APAs have been widely researched and are seen not just as a strategy to reduce movement of the COM but also as a method to regulate postural orientation (140).

2.2.3 How the trunk is affected by stroke

Stroke causes hemiplegia and resultant muscle weakness on the affected side (146). However, investigation into trunk muscle activity post stroke shows that after stroke both sides of the trunk have been found to be weak, and this may be due to bilateral innervation of the trunk by both sides of the brain (41,147,148).

Kim et al. (147) completed ultrasound imaging of abdominal muscles in people with stroke; They found no significant differences between hemiplegic and non-hemiplegic side muscle thickness measurements for EO, IO and TrA at rest, and found significantly ($p<0.05$) thicker measurements in the healthy age matched controls. Their study also found that the contraction ratio of TrA (1.14) was less on the hemiplegic side than the non-hemiplegic side (1.40), and when compared to the same side in the control group (right side = 1.85 and left = 1.92) (147). The left and right side in this study refer to the corresponding left and right side in healthy matched controls, which are unaffected. The researchers hypothesized that, considering the decreased muscle thickness measurements, disuse atrophy may be another possible cause for weakness of the non-hemiplegic side in stroke clients (147).

Post stroke, the trunk muscles show poor coordination between communicating bilateral and ipsilateral abdominal muscles (149). Dickstein et al. (149) found in a sample of 50 stroke patients and 30 healthy age matched controls, a reversal in recruitment of rectus abdominus muscle (RA) and EO muscles using a modified sit up position. EO activated first in the stroke group on the hemiplegic side, whereas in the control group, RA activated first on both sides

(149). Furthermore, the authors found in the stroke patients that there was reduced recruitment speed, activation magnitude, and poor synchronised activity of the bilateral RA muscles and there was poor synchronised activity between hemiplegic RA and EO, when compared to the control (149). This recruitment reversal and poor synchronisation of abdominal muscles indicates a general inability to recruit motor units effectively (149).

The trunk has altered kinematics and altered APAs due to muscle weakness post stroke (27,150). During lateral reaching activities, in healthy individuals the head moves to the target first, then the trunk and pelvis. However, Verheyden et al. (150) found that in post stroke survivors the pelvis is recruited first, then the trunk and head and that the onset of head (approximately 0.02 sec delay ($p<0.01$)) and trunk activation (0.18 sec delay ($p<0.03$)) is delayed. Yang et al. (145) also explored reaching of the hemiplegic and non-hemiplegic arm in patients with stroke compared to healthy matched controls. They found that when the stroke survivor reached using the hemiplegic arm, prior to this movement of the hemiplegic arm they recruited a larger trunk and pelvic rotation and the trunk rotation was recruited sooner than if they carried out reaching using the non-hemiplegic arm (145). Additionally, they found that APAs were affected when comparing reaching with the non-hemiplegic arm in the stroke group versus reaching with healthy arm in the healthy control group. There was a significant delay in onset of APA ($p< 0.04$) and altered APA in the stroke group (145).

Furthermore, the trunk muscles have been shown to adopt compensatory strategies in response to trunk muscle weakness, where movement of the hemiplegic lower limb causes increased activity of bilateral TrA and IO compared to ipsilateral trunk activity only preceding the movement of the non-hemiplegic limb (151). Trunk weakness could affect the individual's balance (144) and thus limit performance in activities of daily living such as dressing, toileting and transfers (152), which require postural control (153). Fujita et al. (152) found in their group of 24 subacute stroke survivors, divided into a weakness and a non-weakness group according to abdominal muscle weakness using the abdominal strength score of the Stroke Impairment Assessment Set (SIAS), that those in the weakness group scored significantly lower ($p<0.05$) for the Function Independence Measure (FIM) motor domain score (median:66; range:50-91), total FIM score (median:100; range:78-125) and for performance of dressing the upper (median:5; range:3-7) and lower body (median:5; range:2-7), toilet use (median:6 ; range:4-6), walk/wheelchair items (median:5 ; range:1-7), transfer to bed/chair/wheelchair (median: 6; range:5-7) items of the FIM. The weakness group also had significantly lower SIAS abdominal strength scores (median:2; range:1-2) and Berg Balance Scale (BBS) total scores (median:41.2), than the non-weakness group (152).These findings have also been used to predict prognosis in terms of functional outcome in stroke survivors (153).

2.3 Importance of evaluating Trunk control

The ability to predict prognosis to improve in terms of functional outcome after stroke has become important in planning rehabilitation programmes (154). Understanding the prognosis to improve post stroke assists with discharge planning, and overall efficiency of stroke management in terms of appropriate rehabilitation goal setting and provision of needed services (155).

As described in 2.2.2., postural control is necessary to perform daily tasks successfully, therefore it is seen as an important activity to assess early after stroke to assist with planning treatment (156).

Regaining the ability to walk independently is a key goal in stroke rehabilitation (155). Achieving sitting balance is a requirement for standing balance, therefore regaining initial control of sitting balance is an important factor in determining gait at six months (157). Furthermore, sitting balance scores along with muscle strength measurements in the hemiplegic leg between the second and fourth week after stroke, have shown a significant association with improvement in walking at six months (157–162).

Persson et al. (156) reported that patients who demonstrate good postural control of their trunk in the first week after stroke were able to perform more intense physical activity within the first year, using the Physical Activity Score for the Elderly (PASE), than those who showed poor postural control of their trunk, measured by the modified version of the Postural Assessment Scale for Stroke (SwePASS) (156,163). However, the participants were found to have high PASE and SWEPASS scores at baseline so it could be that they were less affected, and this may have impacted the results.

Measuring trunk control has been widely used to predict functional outcome in stroke survivors. Several studies (34,35,153) have used different outcome measures, such as the trunk control test and the trunk impairment scale, to evaluate trunk control. Duarte et al. (35) found in their 2002 study of 28 stroke survivors that were undergoing subacute rehabilitation, that admission Trunk Control Test (TCT) score positively correlated (r=0.72) with the motor Functional Independence Measure (FIM) score at discharge, indicating that stroke clients with good trunk control on admission would have a higher motor FIM score on discharge (35). The TCT score also had a negative correlation (r = - 0.72) with length of stay, therefore stroke clients with poor trunk control scores on admission remained longer in the rehabilitation ward than those with higher trunk control scores (35). Verheyden et al. (34) showed that the static sitting balance score at admission using the Trunk Impairment Scale (TIS), was significantly correlated with the Barthel Index (BI) score at six months (R= 0.71, (p<0.0001)), therefore indicating that the TIS score on admission is predictive of the BI score and functional ability at six months. In 2010, Di Monaco et al. (164), assessed 60 stroke survivors at admission to rehabilitation unit using the Trunk Impairment Scale (TIS) and the Postural Assessment scale for Stroke Patients. They found that both the TIS and Postural Assessment Scale for Stroke Patients were significantly associated with a higher FIM at discharge (p =0.01 and p=0.04 respectively).

2.4 Measuring Trunk impairment/control/performance

Researchers and clinicians have a wide range of specific, validated trunk assessment tools to choose from to measure trunk performance (165). Given the importance of trunk control and the role it plays in function and in predicting prognosis, validated outcome measures are needed to assess trunk control (166). A systematic review of clinical measurement tools to assess trunk performance after stroke by Sorrentino et al. (165) evaluated ten trunk related outcome measures: the Trunk Control Test (TCT), Trunk Impairment Scale (TIS), Postural Assessment Scale for Stroke (PASS), Ottawa Sitting Scale (OSS), Modified Functional Reach Test (MFRT), Function In Sitting Test (FIST), Physical Ability Scale (PAS), Trunk Recovery Scale (TRS), Balance Assessment in Sitting and Standing Positions (BASSP), and Sitting- Rising Test (SRT). The review concluded that while each test was valid for measuring trunk performance in stroke, the TIS, was most preferable, because it has consistently demonstrated validity, good test re-test reliability responsiveness. A criticism of the TIS is that it has not undergone modern evaluation under Rasch Analysis, unlike later versions of the TIS (TIS 2.0 and Fujiwara TIS version) and therefore may not be considered as robust as other trunk measurement tools such as SWePASS and BASSP (166).

Trunk control can be measured as part of larger, comprehensive motor assessment batteries, such as the balanced sitting subtest of the Motor Assessment Scale (MAS) or the postural control subtest of the Chedoke- McMaster Stroke Assessment (165). In addition, trunk control and performance can also be assessed using specially designed tools e.g. TCT and TIS focused only on the trunk. There is also a large variety of tools suited for the varying abilities of stroke clients; for instance, sitting only scales (e.g. OSS or MFRT), tools that measure performance across lying, sitting and standing (e.g. PASS or BASSP). Verheyden et al. (167) however, advised against using the subscales approach as they lack validated statistical quality. .

2.4.1 The Trunk Control Test and Trunk Impairment Scale

Two trunk performance measurements were chosen for further discussion for this thesis, the TCT and the TIS. These outcome measures were selected as their psychometric properties were sound and they had been used in previous NMES and FES studies (abdominal application)(see section 2.7).

The Trunk Control Test (TCT), first developed by Collin and Wade in 1990, is seen as the first scale to measure trunk control independently of and not part of a larger functional scale (32,165,167,168). It measures trunk function rather than trunk impairment (169) and has demonstrated good predictive validity (r=0.71) when used to predict discharge FIM scores and strong concurrent validity, with the TIS (168). Duarte et al. (35) went on to show the good predictive value of the TCT when used with the FIM; good correlation (r=0.72) with length of stay of stroke patients, as previously described in 2.3. The TCT evaluates four aspects of trunk function: 1) rolling to the hemiplegic side and 2) to the non-hemiplegic side from supine, 3) sitting up from lying down, 4) sitting over the edge of the bed with feet without making contact with the ground for at least 30 seconds (170). Scoring is by three categories on a three-point ordinal scale; a score of zero is given if unable to perform the movement without assistance, a score of twelve if able to perform the movement but in a non-prescribed manner and a score of twenty five if able to complete the movement normally (170). The final TCT score will range from 0-100 (169), a higher score indicating better trunk control.

In 2007, Verheyden et al. (167) proposed that the term '*sitting balance'* to measure trunk control was no longer fitting. This was because trunk control and trunk performance is more than just being able to maintain or obtain a position, as it also encompasses stability and selective movement of the trunk. Verheyden' s original trunk impairment scale (TIS) was a 23-point ordinal scale (scored as 0,1,2 or 3 points for each item, please refer appendix XII for the instrument), where a higher score indicates better trunk control and 17 items consisting of three categories are used to measure trunk performance: 1) Static sitting balance, 2) dynamic sitting balance and 3) trunk coordination, with the aim to evaluate the quality of trunk movement and motor impairment of the trunk (32). The TIS rates good-very good in terms of test-retest and interobserver reliability (intraclass correlations (ICC) 0.85 to 0.99) for static and dynamic sitting balance, trunk coordination and total TIS scores (32). For internal consistency, it scored a Cronbach's alpha score of 0.89 for the total TIS score (32) and in terms of validity, the TIS reported Spearman Rank correlations coefficients of 0.86 with the Barthel Index (BI) for construct validity and 0.83 with the TCT for concurrent validity (32). Initially in 2006, Verheyden (165) reported that the original TIS had no ceiling effect. However, it has shown that the static sitting component had a ceiling effect, with many participants scoring the full seven points, and therefore a TIS 2.0 version was developed in 2010, which excluded this component. Both the dynamic sitting balance and coordination subscales of the TIS 2.0 are validated measures of trunk performance (165).

2.5 Physiotherapy treatment of the Stroke-impaired trunk

Motor impairment and function have a direct, bidirectional relationship and physiotherapists and occupational therapists focus their efforts on improving either or both aspects in rehabilitation programmes (171). Since trunk control is required for better limb skill acquisition in stroke and is a known predictor for functional outcome, growing attention has been given to improving trunk control to effect postural control or function in stroke (44).

Intervention aimed at improving trunk control in stroke and other health conditions generally incorporate exercise and movement targeting the core muscles (171). Other approaches include neurodevelopmental therapy (172) and task specific training (44).
Kim et al. (173) added task specific training (step-ups, balance beam, kicking a ball, standing up and walking , obstacle course, treadmill walking, walking and carrying an object, speed walking, walking backwards and climbing stairs) for one hour per day, three days a week for

four weeks in addition to regular physiotherapy treatment in the experimental group (n=10) and compared it to conventional therapy alone (n=10) and found significant improvements ($p<0.05$) in TIS scores between the two groups in favour of the experimental group. Individualised trunk training programmes based on neurodevelopmental (Bobath) principles, have been shown to improve TIS scores post treatment (174).

Several studies have incorporated the use of movements of the trunk in tasks (e.g. reaching and weight-shifting), trunk stabilisation exercises and exercises targeting the core as focused exercise programmes, to improve trunk performance and general function (38,44,175,176). Cabanas-Valdés et al. (44) systematic review in 2013 of 11 studies with 317 participants, showed moderate evidence that specific trunk training exercises improved trunk performance and dynamic sitting balance in sub-acute and chronic stroke clients. Also, Verheyden et al. (38) showed in a study in 2009 that additional trunk exercises such as side flexion, flexion and extension, rotation, in supine and sitting, bridging and shuffling forwards and backwards in sitting used in combination with regular intervention based on neuro developmental principles and motor relearning principles, resulted in a significant improvement in dynamic sitting balance post treatment when measured with the TIS.

Jung et al. (177) incorporated additional weight shifting exercises while sitting on an unstable surface, in addition to regular physiotherapy (patient specific programme of stretching, strengthening and stationary cycling) in chronic stroke to improve trunk control, proprioception and balance. In their sample of 18 participants, those in the weight shifting group who had the intervention daily for 30 minutes, in addition to 30 minutes of regular physiotherapy, showed significant improvements in trunk reposition error ($p<0.03$), TIS total score ($p<0.01$) and dynamic sitting balance score ($p<0.03$) and Timed Up and Go (TUG) score ($p<0.02$) than those in the control group who had just 60 minutes of daily conventional physiotherapy (177).

Utilising an unstable base with exercise has been shown to provide even better improvement in trunk stability and balance (31,176). In a study by Bae et al. (176) in 2013, both groups improved in the TIS with sitting and supine exercises, but the unstable base group had a larger improvement ($t= -3.83$ ($p<0.05$) vs $t=-2.65$ ($p<0.05$). Similarly, Karthikbabu et al. (178) used a physio ball in trunk exercise as an unstable surface, with participants in the physio ball group (experimental group) showed greater and significant improvement ($p<0.01$) in change in total TIS scores from pre to post treatment (7.93 ($p<0.05$) vs 4.87 ($p<0.05$)) and Brunel Balance Assessment scores (6.2 ($p<0.05$) vs 4.4 ($p<0.05$)), than those who performed the same exercises on a table surface i.e. plinth (control group).

Targeting core muscles has had recent increasing focus from various authors, e.g. Haruyama, et al. (179) and Cabanas-Valdés et al. (48), who have incorporated core stability exercises to improve trunk control in stroke. Haruyama et al. (179) combined 20 minutes of core stability exercises with 40 minutes of regular conventional physiotherapy daily, for four weeks(179). The core exercise programme consisted of the anterior draw-in manoeuvre (ADIM) method to contract Transverse Abdominals, selective pelvic movements and pelvic movements with ADIM. The group that complete the core exercises, showed a significant improvement in total TIS score and the dynamic balance component of the TIS, compared to the those in the control or regular physiotherapy group with a between group effect size of 1.58 and 1.18 respectively (179).

Cabanas-Valdés et al. (48) completed an RCT exploring the effect of adding core stability exercises to a conventional therapy programme on trunk performance and dynamic sitting balance using the Spanish version of the trunk impairment scale (S-TIS 2.0), and then on standing balance, gait and activities of daily living in sub-acute stroke clients. The intervention was provided for five weeks, with 15 minutes of core stability exercise added to daily one hr conventional therapy five days a week (48). Both experimental and control groups showed improvement in TIS, where the mean change in scores were 5.88 and 2.48 respectively, the difference between the improvement in these two groups was significant ($p<0.01$) with the experimental group showing the greatest change (48). The experimental group showed greater change in scores with 23 % ($p<0.01$) improvement in the dynamic sitting balance sub-scale of the TIS, 24% ($p<0.01$) in Tinetti gait sub-scale and the mean changes in experimental and control groups was almost triple for the Berg Balance Scale (23.02 vs ± 8.48 points respectively) ($p<0.01$) (48). Cabanas-Valdés et al. (180) completed a three month follow up of the aforementioned 2016 RCT, with 68 of the original 80 participants to ascertain if the positive improvements of the RCT were maintained(180). They found significant differences in the change scores between the two groups trunk impairment scale (dynamic sitting balance score $p<0.03$; total TIS score $p<0.01$), the Function in Sitting Test ($p<0.01$), the Brunel Balance Assessment (stepping component $p<0.01$; total score $p<0.02$), Berg Balance Scale ($p<0.01$) and Tinetti Gait ($p<0.05$) (180). These significant change scores resulted from adding

6.5 hours of core stability exercise in the 2016 study to regular physiotherapy, and its effectiveness appeared to be maintained three months after completing the intervention (180).

Taken together, it is evident that conventional physiotherapy incorporating trunk specific exercises appears to improve trunk control. Gross task specific exercise programmes (step ups, walking and carrying objects etc) that require trunk control has been shown to improve trunk performance using the TIS ($p<0.05$)(173).Specific trunk training programmes which incorporate trunk movements(reaching, side flexion, flexion, bridging etc) have been shown to significantly ($p<0.05$) (38) improve trunk performance and if provided on an unstable base can provide even greater improvement in not only TIS scores ($P<0.01$) but also in balance measured by the TUG ($p<0.02$) (177).Specifically, the addition of core stability exercises (48,179) improves performance on measures of trunk performance such as the TIS and function in sitting test , as well measures in balance such as the Berg Balance Scale and Brunel Balance Assessment and associated gait items as measured by tests such as such as the Tinetti Test. Core stability exercises known to improve performance includes ADIM method to contract Transverse Abdominals and selective pelvic movements and pelvic movements with ADIM (179). Duration, 15 minutes daily for five weeks (48) and 20 minutes for four weeks (179), is varied across studies suggesting an area requiring further research.

The next section examines the effect of functional electrical stimulation on improving outcomes in stroke in general and with respect to trunk control specifically.

2.6 Functional Electrical Stimulation

FES is a form of neuromuscular electrical stimulation (NMES) that can be applied to the peripheral muscles to stimulate contraction or enhance movement around a joint (181), for a voluntary movement (51) within a functional activity. TENS is another form of electrical stimulation, applied to skeletal muscle, that delivers a low frequency stimulus and is intended for pain relief (52). FES is aimed at improving motor function in hemiplegic muscles in upper motor neuron lesions, known as the therapeutic effect, and it can also be used to replace voluntary movement needed to complete certain functional activities, known as the neuroprosthetic effect (52) as mentioned in 1.5.

FES is only effective in upper motor neuron injuries, as an intact motor neuron is required to cause contraction of a muscle.(55) Thus, application is usually directly on the motor end point of the skeletal muscle or directly on the peripheral nerve, via electrodes or implanted needles or device (52,60). The wave form for FES are biphasic rectangular waves and treatment parameters include frequencies between 20 – 50Hs, 30-500 us and <100mA amplitude (73,76,77,182).

FES stimulates both the sensory and motor systems (183). The afferent input (cutaneous, motor and proprioceptive) (184) from repetitive movement and sensory input from the electrical stimulation as part of FES stimulation (185), helps with reorganisation of neuromuscular activity and increases neuronal excitability of the sensorimotor cortex (186). Stimulating the sensory system peripherally has been found to enhance excitability in the motor cortex (187) and cortical representation of specific muscles (188). Multiple authors have found increased perfusion to the ipsilesional sensory motor cortex and increased cortical excitability when electrical stimulation is applied to the upper limb in conjunction with voluntary movement (63,189,190). Cortical changes could lead to long term changes, such as motor activation, decreased spasticity and increased joint range of movement (ROM) (75,183).

2.6.1 Use of FES in stroke (Limb application)

FES application is recommended by many best practice guidelines for stroke rehabilitation (191). Liberson et al. developed the first documented FES system in 1961 (192). It was a hard wired single channel drop foot stimulator to correct dropped foot in hemiplegic individuals through peroneal nerve stimulation on the hemiplegic side (193). It was intended to be used as an alternative to ankle foot orthosis (AFO) (193). This single channel system still exists today, and contraction is triggered via mechanical switch mechanism usually on the ipsilateral side to the hemiplegic side. Newer studies have also demonstrated how single channel stimulation of the peroneal nerve on the hemiplegic side, in subjects with upper motor neuron lesion including stroke or multiple sclerosis can improve foot clearance in gait, helping to reduce falls (194). It is equal to the AFO in achieving clinically significant improvement in gait speed and functional gait (195). While it has not been found to be superior to the AFO for drop foot, patients found it more preferable as it is more socially acceptable (196).

FES devices have evolved into multichannel devices allowing multiple anatomical application sites, these can be used for muscle contractions in specific sequence to result in the desired functional movement (61) or in various therapeutic activities such as rowing or cycling. FES applied in a stationary cycling system, with electrode application to the hamstrings and quadriceps on the hemiplegic side, has been shown to reduce muscle tone in the lower limbs in persons with hypertonia after stroke (197,198). The contralateral system of triggering contraction in the hemiplegic limb, has recently been developed for use in the upper limb (199). A randomised control trial (RCT) by Zheng et al. (199) in 2019 compared contralaterally controlled FES (experimental) versus passive NMES in combination with regular therapy for wrist extension and upper limb function. The experimental group showed significant decrease time to onset of wrist extension, and significant improvements in upper extremity function ($p<0.01$), extensor carpi strength ($p<0.01$), active range of motion of wrist extension ($p<0.01$), Modified Barthel Index score ($p<0.03$) and International Classification of Function Generic Set score ($p<0.01$).

While FES is well established for use in the lower limb, systematic reviews regarding its effectiveness for application in the upper limb remain conflicting. A systematic review by Eraifej et al. (58) found significant improvement in ADLs if utilised within the first two months post stroke, but no clear optimal treatment window time frame and effectiveness in terms of motor restoration could be concluded, as various outcome measures were used. This was echoed in a previous review by Howlett et al. (79), which noted that all the lower limb studies (seven of the total eighteen studies) used walking speed as an outcome measure, whereas the upper limb studies showed more variability. Only six of the ten upper limb studies used three similar outcome measures (box and block test, action research arm test and upper extremity function test) (79).

FES is more commonly used in the upper limb in treating and preventing shoulder subluxation, as it can be applied directly to the muscles that are responsible for keeping the head of the humerus in the glenoid fossa (61). A systematic review in 2015 by Vafadar, Côté and Archambault (61), found that FES in combination with conventional therapy is superior to conventional therapy alone, in prevention or treatment of shoulder subluxation within six months post stroke. In the same systematic review, FES was found to have no effect on pain in comparison to conventional therapy (61), but an RCT combining upper limb FES with a motorised cycling ergometer as an adjunct to conventional therapy, showed significant improvements in shoulder pain (p<0.02) in comparison to the control group (186). The participants in this RCT were asked to not voluntarily move the arm to use the ergometer but to concentrate on the overall exercise while receiving FES via an automated duty cycle as the cycle moved (186). This type of FES is known as cyclic-FES which is a passive application of FES, but it still allows for repetitive movement within a meaningful and functional context (60). Cyclic-FES has also been used as an adjunct to regular therapy in the lower limb, where simple stimulation of the desired movement e.g. ankle dorsiflexion, has been found to improve lower limb mobility, because it reduces the onset of spasticity and this then carries over to improving mobility in ADLs and balance (75).

With so many therapeutic benefits, an FES application to the trunk to improve trunk muscle activation may yield promising improvements in motor function of the trunk, trunk control and in mobility and ADLs.

2.6.2 FES feasibility in application to the abdominals

The concept of activating the core muscles has emerged as a large contributor to trunk control in sports rehabilitation and in managing lower back pain as the core musculature is responsible for improving stability of the spine and maintaining the correct alignment of the lumbar and pelvic areas during sporting activities (200). There are few published studies that have utilised NMES application to the trunk muscles in clients with stroke. Three studies applied passive NMES to the trunk, these were to the back muscles, specifically erector spinae (8,69,71), with one study comparing application between back and abdominal muscles, specifically external obliques (8). In addition to regular therapy, all three studies utilised NMES either simultaneously with exercise (core muscle strengthening) or without exercise, but the participants all received conventional therapy outside of the NMES treatment (8,69,71).

Kim et al. (69) applied NMES bilaterally to the erector spinae muscles, at T6 and L5 level for 30 minutes once a day, five times a week for three weeks, in addition to receiving conventional therapy. Conventional therapy consisted of functional joint range of motion exercises, mat exercises and gait training as physiotherapy, and occupational therapy consisting of upper limb joint ROM ex and ADL training as well lower limb FES (hip extensors, knee extensors, dorsiflexors). NMES stimulation was provided as additional sessions separate to conventional therapy and patients were kept in a static sitting position for the passive stimulation period. The participants in the intervention group showed significantly higher scores in the trunk control items of the postural assessment scale for stroke (PASS-TC) ($p<0.05$) and the TCT ($p<0.05$) than those in the control group, who received regular intervention only (69).

In 2016, Ko et al. (71) used the same electrode placement to the bilateral erector spinae muscles as Kim et al. (69) in 2009, to apply NMES to the posterior back muscles simultaneously with core muscle strengthening exercises (CMS) in the combination intervention group. They compared the combination intervention to two other groups, CMS alone and NMES to the back muscles without exercise (t-NMES), all three groups received conventional rehabilitation interventions. Sessions where NMES was provided (in the combination group) and NMES were provided (t-NMES group) were for 20 minutes a day, three days a week for three weeks separate to the regular physiotherapy received. The CMS group also received their intervention for the same time period and separate from regular physiotherapy sessions. Core muscle strengthening consisted of various core strengthening exercises in supine, prone and side lying, and conventional rehabilitation interventions consisted of range of motion exercises, aerobic exercise, strengthening exercise, balance exercises in sitting and standing using mirror or balance board, ADL training, gradual gait and functional ambulation training. These authors found significant improvements in the Korean Berg balance scores ($P<0.05$) and the dynamic sitting balance scores ($p<0.05$) of the Trunk Impairment Scale for the combination intervention group in comparison to the other CMS group and the t-NMES group (71).

In 2018, Park et al. (8) combined NMES application to the abdominal muscles (a-NMES) or to the back muscles (b-NMES), used simultaneously with core muscle strengthening (CMS) and compared it to core muscle strengthening alone in addition to regular therapy, for 30 minutes a day at five days a week for three weeks . All three groups, (group A = a-NMES+ CMS, Group B =b-NMES +CMS and Group C= CMS alone) received regular therapy intervention described as balance activities, selective hip and knee movements, transfers, strengthening exercises, walking, bed mobility, posture re-education, weight shifts, mat work, sit-to-stand and FES to the lower limb. The abdominals application for a-NMES was, according to the findings from the study by Baek et al. (6), the placement of 1cm superior to iliac crest along mid-axillary line and 2cm superior and 2cm medial to ASIS bilaterally. The electrode placement for the b-NMES was the same as Kim et al. (69) and Ko et al. (71). The CMS intervention was the same intervention used in Ko et al. (71) . These authors found that those participants in the intervention groups (Group A and Group B) that utilised either combination of FES and core muscle strengthening exercises, in addition to regular therapy, resulted in significantly higher Berg Balance Scale and Trunk Impairment Scale scores, than those completing core muscle strengthening exercises alone, in addition to regular therapy (Group C) (8) . This demonstrates that application to the abdominals in stroke is possible and would be best placed to be used in combination with treatment.

Whereas the previous studies explored FES while doing specific core exercises to improve trunk control, one study by Jung et al. in 2016 (201) has combined TENS with functional trunk movement and weight shifting. Jung et al. (201) utilised TENS applied to the erector spinae muscles and external oblique muscles, to explore muscle activity and trunk control in patients with stroke. The exact placement on these two muscles was not given. The sample included sixty stroke patients divided into three groups, weight shifting exercises combined with TENs (intervention group), weight shifting exercises combined with placebo TENS (placebo group) and the control group (stretching exercises of trunk and limbs and stationary bicycle exercises) (201). All three groups received a conventional exercise therapy programme, consisting of exercises based on the Bobath technique e.g. tone facilitation and range of movement exercises for one hour per day, five days a week over six weeks (201). The intervention, placebo and control interventions were given over thirty sessions, thirty minutes per session over the six weeks (201). The intervention group showed significant increase in the EO activity ($p<0.01$), maximum reaching distance ($p<0.01$) and trunk impairment scale scores ($p<0.01$) compared with the placebo and control groups (201).

Where TENS is used to stimulate the sensory system and not the motor end point, the improved results in the afore mentioned study could show that utilising FES while completing a functional movement of the trunk would be worthwhile to explore in future research. FES application to abdominal muscles may be appropriate because the abdominal muscles are the first muscles to contact in APAs in preparation before a movement of an upper or lower limb. This may ultimately lead to improving trunk control and ultimately ADL performance and motor function.

2.7 Methodological concerns with previous FES-abdominals studies:

There are four previous studies which have utilised NMES or FES application to the abdominal muscles in stroke (please see Table 1). There are differences between these four studies with regards to location of electrode placement on the trunk or abdominals, whether comfort was tested with stimulation, and the description of control intervention or conventional physiotherapy that was used. The differences and why they are a concern for future study will be discussed below:

Table 1: Description of methodologies used in previous studies with NMES and FES application to the abdominal muscles studies in adults with stroke

Author	Electrode Placement	Duration of stimulation	Comfort tested	Groups	Description of control intervention/conventional therapy (CPT)	Outcome measures	Core exercises	Stimulation during exercise	Subjects
Kim et al .2009 (69)	Bilaterally over the thoracic erector spinae (5cm lateral to T6 spinous process) and lumbar Erector Spinae (2cm lateral to L5 spinous process)	30 minutes once, 5 times a week, for 3 weeks	Yes, at start of stimulation researcher checked that patients did not feel contraction that would cause muscle pain or fatigue	**2 groups:** NMES group and control group (CPT only)	Physical therapy: functional joint Rom exercises, functional mat exercises and gait training. Occupational therapy: joint ROM of the upper limb and ADL training. FES to the lower limbs eg. hip extensors knees extensors and ankle dorsiflexors) if MP was less than 3/5	TCT, K-MBI, K-BBS, PASS, MI. Measurements taken at Baseline and at 3 weeks	nil	No. Patient completed stimulation in sitting	Acute and sub-acute stroke patients. Patients could maintain sitting for more than 2 minutes
Ko et al. 2016 (71)	Bilaterally over the thoracic erector spinae (5cm lateral to T6 spinous process) and lumbar Erector Spinae (2cm lateral to L5 spinous process)	20 minutes a day, 3 times a week for 3 weeks	Yes, Intensity was set until when patient could feel muscle contraction without pain sensation or tiredness (muscle fatigue)	**3 groups: Experimental Group: CME alone** (CPT +CME) **Group 2: tNMES group** (CPT+ tNMES) **Group 3: Combination group** (CPT + CME + tNMES)	Physiotherapy, occupational therapy which consisted of range of motion exercises, tone facilitation, strengthening, balancing, ADL training, and postural control exercises (eg. standing weight shifts) and gait.	K-BBs, PASS, TIS, KMBI. Measurements taken at baseline and then at 3 weeks.	Supine position: bridge position, segmental rotation and dead bug exercise. Prone position: plank, belly blaster, bird dog exercise. Lateral position: side plank exercise, side bridge exercise.	Experimental Group: No Group 2: No Group 3: Yes, with CME	Patients within 1 month of stroke Patients couldn't maintain sitting for more than 5 minutes

Author	Electrode Placement	Duration of stimulation	Comfort tested	Groups	Description of control intervention or conventional therapy	Outcome measures	Core exercises	Stimulation during exercise	Subjects
Park et al. 2018 (8)	1cm superior to iliac crest along mid-axillary line and 2cm superior and 2cm medial to ASIS bilaterally	30 minutes, 5 days a week for 3 weeks	Yes, intensity set until patient could feel maximal amount of contraction without pain sensation or fatigue at start of stimulation.	**3 Groups: Experimental Group: abdominal tNMES + CME** (CPT + abdo. tNMES +CME) **Group 2: Back tNMES + CME** (CPT+ back tNMES +CME) **Group 3: CME alone** (CPT +CME)	Physiotherapy and Occupational therapy made up of range of motion exercises, aerobic exercise, strengthening exercise, balance exercises in sitting and standing using mirror or balance board, ADL training, gradual gait and functional ambulation training.	K-BBS. TIS, K-MBI, WDI, SI. Measurements taken at baseline and then at 3 weeks	Supine position: bridge position, segmental rotation, and dead bug ex. Prone position: plank, belly blaster, bird dog exercise. Lateral position: side plank ex, side bridge ex.	Experimental Group: Yes, with CME group 2: Yes, with CME Group 3: No	Within 6 months stroke and participants needed to sit for more than 5 minutes
Moosajie 2012 (70)	Photograph as reference. On EO on hemiplegic side only	Stimulation applied at start of daily physiotherapy treatment sessions of 1 hour, for 15minutes in the first week and for 20minutes in second week. 5 days a week for 2 weeks.	Yes, checked at start of stimulation an intensity was increased until contraction was seen and was not uncomfortable for the patient.	**2 Groups: Experimental group:** FES and conventional intervention. **Control group:** Conventional therapy only.	Balance activities, selective movements (hip and knee), transfers, strengthening exercises (upper and lower limb) and walking. Bed mobility, Posture re-education, weight shifts, mat work, sit-to-stand and FES lower limb application.	BI, RMA, EQ-5D, PCI. Measurements taken at baseline, 1 week, 2 weeks and then 4 weeks follow up.	N/A	Yes: Experimental group. Stimulation applied while completing regular therapy.	Within 3 months of stroke

TCT = Trunk Control Test, K-MBI = Korean version of the Modified Barthel Scale, K-BBS= Korean version of the Berg Balance Scale ,PASS=Postural Assessment Scale for Stroke, MI= Motricty Index, BI= Barthel Index, RMA = Rivermead Motor Assessment Scale,EQ-5D-3L= European Quality of Life five domain three level , PCI= Physiological Cost Index of Gait, TIS= Trunk Impairment scale, WDI=Weight Distribution Index, SI= Stability Index, ADL= Activities of Daily Living, FES= Functional Electrical Stimulation, NMES = Neuromuscular Electrical Stimulation, tNMES = Trunk Neuromuscular Electrical Stimulation, abdo = abdominal muscles , CME = Core muscle exercises

2.7.1 Electrode Placement

Baek et al. (6) completed a study exploring which anatomical area on the abdominal muscle would be best to provide NMES via electrodes to stimulate the lumbar stabilising muscles or core muscles within in the context of improving lower back pain. They verified and measured thickness changes (i.e. the thicker the muscle, the greater the contraction) using real time ultrasound imaging across the external obliques (EO), internal obliques (IO) and transversus abdominus (TrA) muscles, as well as the deep multifidus (DM) and superficial multifidus muscles (SM), in three possible electrode placement positions on the abdominal wall (6). One position was found to elicit the greatest change in muscle thickness change from resting state to contraction with NMES: 2 cm superior and 2 cm medial to anterior superior iliac spine, and 1cm superior to the iliac crest and on the midaxillary line (6). This was mirrored on the other side of the abdominal wall and placement was therefore bilateral, with electrodes placement on either side of the umbilicus (6).

Moosajie (70) utilised unilateral placement of four electrode on the hemiplegic side stimulating EO. A picture is provided of stimulation points, but a descriptor of the location points is not given for reproduction(70). Joffe et al's study in 2014 also explored stimulating the EO in children with cerebral palsy to improve balance and trunk muscle strength (5). The author used bilateral placement of the EO with two electrodes on either side of the umbilicus and described placement at two points(5). Superolateral to the umbilicus above the eleventh rib and superior to this below the fifth rib (5). Both authors used visual inspection when verifying EO contractions with FES applied to the EO (5,70). However, neither author (5,70) used an objective measure, such as electromyography (EMG) or 2D ultrasound, to verify contraction, which may introduce observer bias (202) when observing and verifying EO contraction.

Because the success of FES being able to reach and stimulate the underlying muscle is in large part influenced by the electrode placement and size (51), the following questions therefore arise: 1) Should unilateral or bilateral placement be used patients with hemiplegia? and 2) Which anatomical placement would best be used in clients with stroke in conjunction with conventional therapy?
This is unclear from previous studies. Baek et al. (53) provides a good theoretical basis within the healthy individual to start from, but it is not clear whether clients with stroke would be able to utilise the same settings considering the change in sensation and muscles changes seen in the abdominal muscles post stroke (see 2.3.4.).

2D real time ultrasound imaging, a similar method used by Baek et al.(6), may be best placed to determine effective placement as it has been shown to have good reliability, (ICC = 0.77(hemiplegic side) and 0.81 (non-hemiplegic side), in measuring muscle thickness of the abdominal muscles in stroke clients (203). In previous studies, assessing activity of the lumbopelvic area (deep abdominal muscles and pelvic muscles) in healthy individuals' movements, such as the AIDM and fine wire EMG have been used, but these are usually only available in a laboratory setting. 2D ultrasound is less invasive and less complex (204).

2.7.2 Comfort with electrical stimulation:

Discomfort with stimulation is common with transcutaneous and surface electrical stimulation because cutaneous sensory fibres are also stimulated, which often leads to clients being discouraged from using it (87). Comfort with stimulation is influenced by electrode size, electrode placement and treatment parameters such as frequency, stimulus waveform, pulse duration, pulse frequency, pulse amplitude, ramp up time, ramp down time and on-off time (87)

The previous studies utilising either NMES to the abdomen in clients with stroke have utilised the recommended treatment parameters but comfort with stimulation was only checked with initial application and intensity of setting was checked to see if contraction was elicited and the client didn't experience "burning sensation" or discomfort (8,70,205). Furthermore, the two studies by Park et al. (8) and Moosajie (70) that incorporated stimulation to the abdomen with exercises or with regular physiotherapy, did not report on comfort of stimulation with exercise and movement.
Therefore, clients' perceived comfort with electrode placement to the abdominal muscles at rest and during exercise should be actively explored before undertaking a pilot intervention study where FES will be used in conjunction with regular physiotherapy.

2.7.3 Description of Control Intervention:

Lohse et al. (206) found that there is more underreporting of control group intervention than for experimental groups interventions within randomised control trials (RCTs), with more words and references (almost double in both categories) devoted to the description of experimental interventions than the control intervention. The description of the control intervention is usually termed "conventional" therapy in rehabilitation trials but across various trials the content of conventional therapy differs in frequency, intensity, timing and type of therapy (207). This confuses the reader and makes it difficult to analyse what exactly happens in control groups (206). Accurate and complete reporting is therefore essential in control interventions, to ascertain the internal validity of the study and to compare interventions across many studies (206).

Park et al. (8) described the control intervention utilised in their study with NMES applied to the abdominals in one group, and to the back muscles in another group, as "conventional stroke rehabilitation program consisting of physical and occupational therapy including range of motion exercises, aerobic exercise, strengthening exercise, sitting and standing balance training using mirror or balance board, basic and instrumental ADL training, progressive gait and functional ambulation training". However, the frequency of control treatment was not given (8). Cognitive or speech therapy was added as needed (8).

Moosajie (70) used a self-designed checklist to describe and quantify the different treatment activities completed in the study. The checklist consisted of designated categories of treatment activities described in two previous studies by De Wit et al. (4). The classification by De Wit et al. (4) organised and described the content of physiotherapy and occupational therapy across 12 categories with 49 subcategories of treatment activities used by physiotherapists and occupational therapists in inpatient rehabilitation centres in Europe. The checklist by Moosajie (70) contained balance activities, selective movements (hip and knee), transfers, strengthening exercises (upper and lower limb), walking, bed mobility, posture re-education, weight shifts, mat work, sit-to-stand and FES lower limb application . The participants in both the experimental and control groups received conventional treatment daily for one hour during the intervention period (two weeks) and up until their discharge. The average length of stay for participants in the study was 13.42 days (70).

There is currently limited literature that describes physiotherapy intervention provided in inpatient stroke rehabilitation within a South African setting. Therefore, a baseline of regular or conventional physiotherapy interventions within a South African inpatient rehabilitation needs to be explained in detail in any study comparing experimental and "regular" intervention.

2.8 Recommendations for future application of FES to the abdominals:

2.8.1 Dosage:

Clear indication of duration or dosage of treatment is not evident within the literature. Within in upper limb studies that utilise FES, overall treatment period ranges from two weeks to three months, with treatment sessions prescribed from 30 minutes once daily to one hour three times daily and no reasoning why that duration was chosen (51,77) . In ambulation studies, treatment periods have been recorded as four weeks, consisting of three to five hours per week for lower limb stimulation (72). It is commonly thought that more stimulation sessions leads to improvement; however a review of upper limb stimulation by de Kroon et al. (77) in 2005 suggested the contrary. The authors found that participants who had had a stroke within 10 days showed improvement with 2.5 hours of stimulation per week whereas another study (utilising chronic stroke survivors) did not show improvement with 21 hours of stimulation per week (77). A multicentre trial by Sota et al. (208) of eight centres determined that approximately 17.5 hours of FES is recommended to achieve a minimally clinically important difference of 0.1m/s of walking speed in the 10 metre walk test.

In previous studies that utilise NMES on the abdominals, there is also a difference in treatment dosage allocated to participants. In 2016 , Ko et al. (71) applied NMES for 20 minutes, three days per week for 3 weeks and in 2018, Park et al. (8) utilised 30 minute sessions, five days a week for three weeks. Both authors did not provide rationale for choosing their treatment dosages, although Park et al. (8) did hypothesize that the difference in dosage of 10 minutes extra stimulation and daily stimulation for five days per week, was the reason that there was a significant difference between the total TIS score.

In the study by Moosajie (70) in 2012, they utilised FES applied to the abdominals during physiotherapy treatment for a two week period, in daily sessions of 15 minutes over the first week and then increased it to 20 minutes daily in the second week. Joffe (5) utilised FES in cerebral palsy for a six week period, as part of weekly or biweekly physiotherapy sessions and an additional passive session twice per week.

2.8.2 Timing

When best to apply FES also varies in literature. FES can be utilised in both acute, subacute and chronic phases (>six months post stroke) post stroke (8,61,69,71,196,209).

Vafadar et al. (61) completed a systematic review of 10 studies outlining the use of electrical stimulation in the upper limb in addition to conventional therapy and found in the pooled data from six studies where FES was applied within six months post stroke, there was a collective 4.9 mm reduction in shoulder subluxation as compared to the 2.0 mm reduction in the pooled data from the four studies, where FES was applied after six months post stroke. Within the majority of the lower limb studies (209–212) exploring the therapeutic effect of FES versus an AFO on dropped foot, most of the participants enrolled in the studies were in the chronic phase, but this could be because more stroke survivors are ambulant and walking at this stage post stroke.

With reference to stimulation of the abdominals with FES or NMES post stroke, authors have mainly recruited participants from either acute or subacute phase post stroke. Ko et al. (71)) recruited stroke survivors within one month post stroke for NMES application and Park et al. (8) applied NMES to the abdominals in stroke survivors within six months since stroke onset. Moosajie (70) recruited participants who had a stroke within three months of entry into the study in their abdominal application of FES

Neuroplastic research has hypothesized that cortical reorganisation starts to occur spontaneously within days after stroke and then increases consistently until six months when a plateau is reached (49). It has been shown that rehabilitation interventions that cause synchronised pre and postsynaptic neural activity within the motor and sensory pathways, could enable synaptic remodelling and could lead to neural reorganisation and eventually motor recovery (213) and FES provides peripheral motor output as efferent activation, and the resultant muscle and joint activity provides proprioceptive feedback or afferent activation (214). It may be best to provide FES intervention before six months post stroke to best take advantage of cortical reorganisation.

2.8.3 Stimulation Parameters

Manipulation of stimulation parameters such as frequency, amplitude, pulse width, ramping of stimulation and duty cycles influences strength of contraction, recruitment of muscle fibres, comfort with stimulation and muscle fatigue (51).

Frequency refers to the number of pulses delivered in one second and is measured in Hertz (Hz). The choice of frequency to deliver FES depends on the goal of the intervention, where lower frequencies prevent muscle fatigue and high frequencies are more comfortable (51). Most clinical regimes in upper limb studies utilise 20-50 Hz (77). Cho et al. (215) compared 20 Hz, 50 Hz and 80Hz stimulation frequencies in superficial NMES application in 20 healthy volunteers between ages 24 years old to 32 years old, to determine which frequency would best activate transversus obliques TrA, Internal Oblique (IO) and External Obliques (EO) muscles. The authors used real time RUSI to determine muscle thickness changes and found significant muscle thickness changes during all frequencies (p=0.001), but 50 Hz provided the largest mean muscle thickness for E0 (1.39mm), IO (1.22mm) and TrA (1.33mm) (215).

Ramp time is the time from when stimulation is initiated until when stimulation is delivered, and is used to modulate comfort when the client has hypersensitivity and when increased tone may cause resistance to movement (51,216). Ramp times can also be adjusted when trying to modulate movements such as walking or standing, using multiple muscle applications of FES to allow smooth transitions of individual muscles so movements appear more realistic (217). Kim et al. (69) , Ko et al. (71) and Park et al. (8) didn't ramp stimulation but Moosajie et al (70) utilised six seconds ramp up and two seconds ramp down which may assist with increased sensitivity in the abdominal muscles.

The strength of a muscle contraction is usually modulated using amplitude or pulse width. Amplitude (reported in miliampules or mA) refers to intensity of the stimulation provided, higher intensities will provide a stronger contraction but are usually not well tolerated (51). It isn't clear from literature which range is best, but typical amplitudes used in upper limb studies are between 0-100 mA (77). Frequency can influence intensity, in that decreased frequency decreases amplitude (51). Previous studies with application to trunk muscles (69,71) and abdominal muscles (8) utilised 30- 70mA and Moosajie (70) utilised a 100mA amplitude, in their application of FES to the abdominal muscles.

Pulse width is the period of time for a single pulse to be delivered (218) and encompasses both alternating and direct current (51). Short pulse widths (10µs - 50µs) can influence muscle fibre recruitment to generate contraction (219) and wider pulse widths (200µs - 1000µs), resulting in stronger contractions (220).Upper limb studies have been shown to utilise 0-300µsec pulse width (77) and lower limb studies utilised pulse widths of 1-50µsec and 200-400µsec (78,79). In the three studies utilising NMES to the trunk muscles by Kim et al. (69) , Ko et al. (71) and Park et al. (8) 250 µsec was utilised and Moosajie (70) used 330µs in their FES application to the abdominal muscles; these were similar to the pulse width used in upper limb and lower limb studies (217).

2.9 Summary/Conclusion of Literature review:

Stroke incidence is increasing in developing countries (221). In South Africa, the age of the stroke survivor is younger (23,98), even more so in HIV infected stroke survivors (111). Disability resulting from stroke at such a young age has profound effect on the individual's employment and productivity for the remainder of their lives (50).

Stroke causes hemiplegia, which affects balance and postural control (141,142). Balance and postural control are pivotal in completing smooth and controlled movements of the upper and lower limbs in self-care activities or voluntary movements (27,28,37,135). As a result, many stroke survivors show poor performance in ADLs and many are dependent on caregivers for assistance to complete daily tasks for extended periods post stroke(23).

The trunk and the trunk musculature, has been shown to contribute postural control in the form of trunk control (31,32). The abdominal muscles of the trunk , play a unique role in the kinematics and strategies of the trunk to adjust to change in posture and ultimately trunk control (47,127,130,132,135,136). In the stroke survivor the return, or lack of return, of trunk control early after stroke, has been shown to be a significant predictor of discharge outcome and prognosis (156,163). Multiple studies have shown correlation between trunk performance scores on trunk performance scales e.g. TIS with scores on functional assessments such as FIM and BI (34,164). It is also assessed by clinicians early after stroke to assist with treatment planning and rehabilitation goal setting (222). Therefore, improving trunk performance or control should be an early goal in rehabilitation after stroke. We know that physiotherapy interventions or exercises that target the trunk, improve trunk control and trunk impairments such as muscle weakness (44,174). Recent studies have focused on targeting the core musculature of the trunk as part of their exercise intervention, in addition to conventional physiotherapy, with positive results (48,179).

FES is known to improve the activation of paralysed muscles and is used to aid return of movement in limbs after stroke (55). FES is a form of NMES and three published studies showed that NMES applied to the trunk muscles, in addition to conventional therapy and used simultaneously with core strengthening exercise in stroke survivors, has shown positive results in improving trunk performance, balance and performance in ADLs (8,69,71). An unpublished feasibility study by Moosajie (70) has shown that FES applied to the abdominal muscles after stroke and used simultaneously with conventional physiotherapy is also a promising treatment resulting in in improvements in ADL performance, HRQOL and energy expenditure in gait.

Previous studies by Kim et al. (69) in 2009, Ko et al. (71) in 2016 utilised NMES application to the trunk. Studies by Park et al. (8) in 2018 applied NMES to the abdominal muscles and Moosajie (70) in 2012 used FES application to the abdominals. All four studies have methodological concerns which need to be explored before a pilot study using FES application to the abdominal muscles in stroke can be undertaken. First, which anatomical site for electrode placement would be best to use in application to best stimulate the abdominal muscles; two of the four studies which utilised abdominal application have used two different anatomical placements. Second, all four studies have not indicated clearly if electrical stimulation was comfortable with exercise and well tolerated throughout the exercise period. Third, previous studies do provide a description of conventional treatment or conventional physiotherapy, but a more detailed description is needed in order to determine if FES used in combination with conventional therapy is better than the conventional therapy alone.

Furthermore, there is no clear understanding from the literature of when best to utilise FES post stroke in order to capitalise on neuroplastic change after stroke, so as to promote best possible outcome in function. Dosage of FES stimulation in terms of frequency of application is also unclear from the literature in FES application in limbs, and from the three studies utilising NMES application to the abdominals and the one study using FES application to the abdominals.

In conclusion, further research is needed to determine if FES applied to the abdominals after stroke, when used simultaneously with conventional physiotherapy treatment, will improve trunk performance, ADL performance and motor impairments after stroke. Further research is also needed to clarify best placement of electrodes to the abdominals, which electrode application is the most comfortable with stimulation when used simultaneously with exercise, to describe what physiotherapy interventions are provided in conventional physiotherapy as a control intervention, to provide an understanding of what frequency or dosage of application would be needed to see improvement within a pragmatic setting and last, if starting FES stimulation to the abdominals earlier would make a difference in outcome.

Chapter 3. Conventional physiotherapy interventions for stroke (a case study of the Western Cape Rehab Centre Physiotherapy Department)

3.1 Background

Clinical trials of FES have usually assigned participants to one of two groups: the experimental group receiving the FES intervention and the comparison group or control receiving usual care (223,224) or no intervention (185,195,199). Sharif et al. (223) and Tan et al. (224) described the control intervention as exercise therapy that consisted of “neurodevelopmental techniques, physiotherapy and occupational therapy” (223) or conventional physiotherapy treatment according to the neurofacilitation approach and occupational therapy focused on ADLs (224).

In the literature review, we summarised the interventions and control interventions used in recent studies reporting the effect of NMES or FES application on abdominal muscles in stroke patients (See Table 1 in section 2.7). The findings suggest that while a description of conventional therapy is provided, it needs to be more detailed.

A descriptor of control interventions is required in experimental studies (81). In South Africa, limited studies describe current physiotherapy practice in stroke rehabilitation within an inpatient rehabilitation centre. Ntsiea et al. (50) completed a narrative review of 39 studies on interventions to improve impairments and participation restrictions within a South African context between 2008-018. The review explored studies outlining interventions in upper limb rehabilitation, balance, gait, unilateral spatial neglect, caregiver training, home exercise programmes and return to work in South Africa (50). Most interventions reviewed were provided in an outpatient setting, either at a community clinic or via an outpatient department at an acute hospital (50).

Thus, the aim of this sub-study was to describe physiotherapy interventions to be used as the control intervention in the pilot study. The specific objective was to describe the current physiotherapy intervention used by physiotherapists in stroke rehabilitation at Western Cape Rehabilitation Centre (WCRC), using a checklist containing the most and least used treatment activities.

3.2 Methodology

3.2.1 Research Design:

A cross-sectional descriptive design was used.

3.2.2 Participants

Convenient sampling was used to recruit consenting physiotherapists working at a state-funded rehabilitation centre providing stroke rehabilitation in Cape Town. There are 15 physiotherapy staff in the centre, consisting of 11 clinical physiotherapists (of whom 10 work with stroke clients as inpatients), two physiotherapy assistants and two supervisory chief physiotherapists. All ten inpatient clinical physiotherapists consented.

3.2.3 Instrumentation: Physiotherapy Intervention Checklist

A questionnaire, in the form of a checklist (Appendix VIII), was developed by the researcher and the two supervisors for this study, containing treatment activities listed in the studies by Veerbeek et al. (3) and De Wit et al. (4). Veerbeek et al. (3) completed a systematic review of 467 RCTs of physiotherapy post-stroke, subcategorising physical treatments into specific treatment activities such as sit-to-stand. De Wit et al. (4) developed a validated and reliable checklist to define what physiotherapists and occupational therapists do in stroke rehabilitation in four European centres.

The questionnaire developed by the researcher required participants to complete a section on their demographic, education, and career experience. To complete the questionnaire, the participants had to state their highest qualification, description of postgraduate courses and years of experience working in stroke rehabilitation.

The content of the checklist was reviewed for face validity by two physiotherapists in Cape Town with extensive clinical experience in stroke rehabilitation one month before data collection via email, and changes were recommended and implemented. These changes included grouping treatment activities according to activity limitations (bed mobility, gait, balance activities) and body impairments (upper and lower limb treatment activities) rather than position-specific activities, e.g., activities in standing and sitting. The measurement of the frequency of treatment provided over two weeks was also changed to numerical categories rather than Likert scale categories (not used, rarely used, used often, used very often).

3.2.4 Procedure

An email was sent to all identified physiotherapists two weeks prior, explaining the details of the study and inviting interested parties to attend an information session and to complete the checklist (questionnaire). The researcher met with participants to explain the study, gain written consent, and complete data collection. Each questionnaire was coded to ensure anonymity and was completed by the therapist-participants after consent. The questionnaire took approximately twenty minutes and was returned to the researcher in the information session.

3.3 Statistical Analysis

Statistica version 13.5 was used to complete the analysis. Frequency Tables were used to describe the most and least used techniques and their frequency of use in the last two weeks. Descriptive statistics such as mean, median, and interquartile range were used to describe the years of experience working in stroke rehabilitation, years since qualification, and years worked at the rehabilitation centre.

3.4 Results:

3.4.1 Demographics

Ten physiotherapists working at the state-funded rehabilitation centre participated in the study. The median number of years since qualification with a BSc Physiotherapy was 11.3 years (range: 5-19 years). In addition, one physiotherapist had a master's degree (focusing on rehabilitation), and one had a postgraduate diploma in rehabilitation studies. Nine physiotherapists completed the Basic Bobath course, five completed advanced Bobath training (including the Ataxia and Upper limb courses), and one completed three Bobath courses (Table 2).

Table 2: Participant (Physiotherapists) Demographics (n=10)

Undergraduate Qualification	**BSc Physiotherapy (n=10)**
Post Graduate Qualification	Masters (n=2) (in rehabilitation) Postgraduate diploma (n=1) (in rehabilitation)
Years working since undergraduate qualification	Mean= 11.2 years (SD= 5.10; range= 5-19) Median=10,5 years (IQR=8.25)
Time working in stroke rehabilitation:	Mean = 100.4 months (SD=56.990; Range=170) Median =73.5 months (IQR=71.75)
Time working at Facility	Mean= 87.8 months (SD=74.805, Range=204) Median= 68 months (IQR=82)
Clinical Courses in Stroke completed	Basic Bobath (n=9) Advanced Bobath (n=5)

Therapists were asked to report the number of patients seen in the last two weeks (29 October 2018 and 09 November 2018). The mean number of stroke patients seen by the group was eight over the two weeks (range: 4 to 12).

3.4.2 Most used treatment techniques identified as per the checklist

The techniques were categorised as follows: upper limb techniques, lower limb techniques, bed mobility and mat work techniques, balance techniques, gait techniques and assistance in other therapies. This is reported in terms of the number of therapists, from the sample of ten, who used the techniques and how frequently a technique was used.

3.4.2.1 Upper limb techniques

Table 3 describes how many physiotherapists used a specific upper limb technique and how frequently they chose to use them in a consecutive two-week period, consisting of a five-day week. All the physiotherapists used bilateral arm training, therapeutic positioning of the arm and palpation (including pain assessment). None of the physiotherapists used the following techniques in the upper limb: Water-based, constraint-induced movement therapy (CIMT), virtual reality, mirror therapy, air splints of the arm, other NMES and TENS.

Table 3: Frequency of use of upper limb techniques by physiotherapists (n=10) over two weeks

	Physiotherapists grouped by times of technique use n(%)			
Techniques	**No use**	**1-4 times**	**5-9 times**	**>=10 times**
Joint Mobilisation	0 (0.0)	3 (30.0)	2 (20.0)	5 (50.0)
Palpation (including pain assessment)	0 (0.0)	5 (50.0)	1 (10.0)	4 (40.0)
Massage, including soft tissue mobilisation and trigger point release	0 (0.0)	6 (60.0)	3 (30.0)	1 (10.0)
Therapeutic positioning of the arm	0 (0.0)	4 (40.0)	2 (20.0)	4 (40.0)
Bilateral arm training	0 (0.0)	3 (30.0)	3 (30.0)	4 (40.0)
Stretching of shortened muscles	1 (10.0)	2 (20.0)	3 (30.0)	4 (40.0)
Passive relaxation, including positioning	1 (10.0)	3 (30.0)	4 (40.0)	2 (20.0)
Caregiver Training	1 (10.0)	7 (70.0)	2 (20.0)	0 (0.0)
Sensory stimulation/training	2 (20.0)	5 (50.0)	2 (20.0)	1 (10.0)
Reflex inhibition/immobilisation of the arm	6 (60.0)	2 (20.0)	2 (20.0)	0 (0.0)
Circuit Class Training	6 (60.0)	3 (30.0)	0 (0.0)	1 (10.0)
Upper Limb- Group Classes	6 (60.0)	3 (30.0)	1 (10.0)	0 (0.0)
Mental practice with motor imagery of the other arm	8 (80.0)	2 (20.0)	0 (0.0)	0 (0.0)
FES of the arm	9 (90.0)	0 (0.0)	0 (0.0)	1 (10.0)
Other NMES of the arm	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Air splints of the arm	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mirror therapy	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Virtual reality training of the arm	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
CIMT	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Water based Exercises	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)

NMES = Neuromuscular Electrical Stimulation, FES= Functional Electrical Stimulation, CIMT= Constraint Induced Movement Therapy

3.4.2.2 Lower Limb Techniques

Below, Table 4 displays the number of physiotherapists who used the specified lower limb techniques and how frequently the physiotherapists chose to use them in two weeks. All physiotherapists used therapeutic positioning and stretching of shortened muscles utilised the hemiplegic leg. Each of the following modalities was only used by one physiotherapist: Mental practice with motor imagery, TENS of the hemiplegic leg and FES of the hemiplegic leg. The following techniques were not used in the lower limb: Other neuromuscular electrical stimulation (NMES), virtual reality training, mirror and water-based therapy.

Table 4: Frequency of use of lower limb techniques by physiotherapists (n=10) over two weeks

Techniques	Physiotherapists grouped by times of technique use n(%)			
	No use	**1-4 times**	**5-9 times**	**>=10 times**
Stretching of shortened muscles	0 (0.0)	4 (40.0)	3 (30.0)	3 (30.0)
Therapeutic positioning of hemi leg	0 (0.0)	4 (40.0)	4 (40.0)	2 (20.0)
Joint mobilisation	1 (10.0)	4 (40.0)	2 (20.0)	3 (30.0)
Caregiver training	1 (10.0)	8 (80.0)	1 (10.0)	0 (0.0)
Passive relaxation, including positioning of hemi leg	2 (20.0)	5 (50.0)	2 (20.0)	1 (10.0)
Palpation (incl. pain assessment) of muscles or joints in hemi leg	3 (30.0)	2 (20.0)	4 (40.0)	1 (10.0)
Massage, including soft tissue mobilisation and trigger point release	3 (30.0)	3 (30.0)	2 (20.0)	2 (20.0)
Sensory stimulation/training	3 (30.0)	4 (40.0)	1 (10.0)	2 (20.0)
Group classes	5 (50.0)	4 (40.0)	1 (10.0)	0 (0.0)
Splinting of hemi leg	6 (60.0)	2 (20.0)	2 (20.0)	0 (0.0)
Circuit class training	6 (60.0)	2 (20.0)	2 (20.0)	0 (0.0)
Reflex Inhibition/immobilisation of hemi leg	7 (70.0)	1 (10.0)	1 (10.0)	1 (10.0)
FES of hemi leg	9 (90.0)	0 (0.0)	1 (10.0)	0 (0.0)
TENS of hemi Leg	9 (90.0)	1 (10.0)	0 (0.0)	0 (0.0)
Mental practice with Motor imagery of hemi leg	9 (90.0)	1 (10.0)	0 (0.0)	0 (0.0)
Water-based exercises	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mirror Therapy of hemiparetic leg	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Other NMES of the hemi leg	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Virtual Reality training	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)

NMES = Neuromuscular Electrical Stimulation, FES= Functional Electrical Stimulation, TENS = Transcutaneous Electrical Stimulation

3.4.2.3 Bed mobility and mat work techniques

All bed mobility treatment techniques (rolling, moving along the bed in sitting, lying to sitting and bridging) were used by all physiotherapists (Table 5). The most used mat work techniques were half (1/2) kneeling, two-point kneeling activities, four-point activities and moving into other positions. The least used mat work techniques were side sitting activities, with only 50% of physiotherapists using it in two weeks.

Table 5: Frequency of use of bed mobility techniques used by physiotherapists (n=10) over two weeks

	Physiotherapists grouped by times of technique use n (%)			
Techniques	**No use**	**1-4 times**	**5-9 times**	**>=10 times**
Bed mobility - Bridging	0 (0.0)	2 (20.0)	4 (40.0)	4 (40.0)
Bed Mobility - Lying to sitting	0 (0.0)	1 (10.0)	6 (60.0)	2 (20.0)
Bed Mobility - Moving along the bed in sitting	0 (0.0)	5 (50.0)	3 (30.0)	2 (20.0)
Bed Mobility - Rolling	0 (0.0)	4 (40.0)	3 (30.0)	3 (30.0)
Matwork Activities - Moving into other positions	2 (20.0)	2 (20.0)	3 (30.0)	3 (30.0)
Matwork Activities - 4-point activities	2 (20.0)	3 (30.0)	2 (20.0)	3 (30.0)
Matwork Activities- 2-point kneeling activities	2 (20.0)	3 (30.0)	3 (30.0)	2 (20.0)
Matwork Activities - 1/2 kneeling activities	2 (20.0)	4 (40.0)	3 (30.0)	1 (10.0)
Matwork Activities - Getting onto the floor and up again	3 (30.0)	2 (20.0)	4 (40.0)	1 (10.0)
Matwork Activities - Side-sitting activities	5(50.0)	1(10.0)	3(30.0)	1(10.0)

3.4.2.4 Balance Techniques

Below, Table 6 displays the number of physiotherapists who used the specified balance techniques and how frequently the physiotherapists chose to use them in two weeks.
All physiotherapists used all balance techniques: sitting balance - weight shift, dynamic standing exercises - transfer training, sit-to-stand training and weight shift exercises.

Table 6: Frequency of use of balance techniques by physiotherapists (n=10) over two weeks

	Physiotherapists grouped by times of technique use n (%)			
Categories	**No use**	**1-4 times**	**5-9 times**	**>=10 times**
Sitting balance- weight shifting	0 (0.0)	1 (10.0)	5 (50.0)	4 (40.0)
Dynamic Standing Exercises- Transfer Training	0 (0.0)	2 (20.0)	1 (10.0)	7 (70.0)
Dynamic Standing Exercises - Sit to stand training	0 (0.0)	2 (20.0)	1 (10.0)	7 (70.0)
Dynamic Standing Exercises - Weight shifting Exercises	0 (0.0)	0 (0.0)	4 (40.0)	6 (60.0)
Sitting Balance- Reaching exercises	1 (10.0)	2 (20.0)	2 (20.0)	5 (50.0)
Static Standing Exercises - Standing in a standing frame	2 (20.0)	5 (50.0)	1 (10.0)	2 (20.0)
Dynamic Standing Exercises - Standing and retrieving objects from the floor	2 (20.0)	5 (50.0)	3 (30.0)	0 (0.0)
Dynamic Standing Exercises - Reaching exercises	2 (20.0)	3 (30.0)	3 (30.0)	2 (20.0)
Sitting Balance- Righting reactions	3 (30.0)	3 (30.0)	2 (20.0)	2 (20.0)
Static Standing Exercises - Standing and looking behind	3 (30.0)	4 (40.0)	2 (20.0)	1 (10.0)
Static Standing Exercises - Reaching Exercises	3 (30.0)	3 (30.0)	1 (10.0)	2 (20.0)
Sitting Balance Training - Protective Reactions	4 (40.0)	1 (10.0)	3 (30.0)	2 (20.0)
Static Standing Exercises - Righting reactions	4 (40.0)	2 (20.0)	2 (20.0)	2 (20.0)
Dynamic Standing Exercises - Protective Reactions	4 (40.0)	3 (30.0)	2 (20.0)	1 (10.0)
Dynamic Standing Exercises - Walking on the spot	4 (40.0)	3 (30.0)	2 (20.0)	1 (10.0)

3.4.2.5 Gait Techniques

Table 7 displays the number of physiotherapists who used the specified gait techniques and how frequently the physiotherapists chose to use them in two weeks.

Walking forwards, swing phase training and stance phase training were used by all physiotherapists (n=10). No physiotherapists used speed-dependent treadmill walking, electromechanically assisted gait training, and body weight-supported treadmill walking.

Table 7: Frequency of use of gait techniques by physiotherapists (n=10) over two weeks

categories	Physiotherapists grouped by times of technique use n(%)			
	No use	**1-4 times**	**5-9 times**	**>=10 times**
Gait training - stance phase training for hemi leg	0 (0.0)	3 (30.0)	2 (20.0)	5 (50.0)
Gait Training - Swing phase training for hemi leg	0 (0.0)	4 (40.0)	3 (30.0)	3 (30.0)
Gait training - walking forwards	0 (0.0)	2 (20.0)	4 (40.0)	4 (40.0)
Gait training - sideways walking	1 (10.0)	4 (40.0)	3 (30.0)	2 (20.0)
Gait training - Overground walking	1 (10.0)	5 (50.0)	1 (10.0)	3 (30.0)
Gait training - issue assistive device for walking	2 (20.0)	6 (60.0)	1 (10.0)	1 (10.0)
Gait Training - Issue orthoses for walking	2 (20.0)	6 (60.0)	2 (20.0)	0 (0.0)
Gait Training - Rhythmic Gait cueing	3 (30.0)	6 (60.0)	1 (10.0)	0 (0.0)
Gait training - walking backwards -	4 (40.0)	2 (20.0)	3 (30.0)	1 (10.0)
Gait Training - Community walking	6 (60.0)	4 (40.0)	0 (0.0)	0 (0.0)
Gait Training - Tiptoe walking	8 (80.0)	0 (0.0)	1 (10.0)	0 (0.0)
Gait Training - walking on heels	9 (90.0)	0 (0.0)	1 (10.0)	0 (0.0)
Gait training - Electromechanically assisted gait training	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gait training - Speed-dependent treadmill walking	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gait Training - body weight supported treadmill training	10 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)

*BWS = Body weight Support

3.4.2.6 Assistance in therapy related to other professions and wheelchair-related activities

Table 8 below displays the number of physiotherapists who used therapy related to other professions and wheelchair-related activities, and of the techniques used, how frequently the physiotherapists (n=10) chose to use them in two weeks. The most used technique was wheelchair handling, and the least used techniques were wheelchair skills training and visual perceptual training.

Table 8: Frequency of use of wheelchair-related activities and assistance in other related therapies used by physiotherapists (n=10) in a two-week

	Physiotherapists grouped by times of technique use n (%)			
Categories	**No use**	**1-4 times**	**5-9 times**	**>=10 times**
Wheelchair Related Activities - Wheelchair handling	2 (10.0)	3 (30.0)	2 (20.0)	3 (30.0)
Assistance in therapy related to other professions - Other neuropsychological training	2 (10.0)	6 (60.0)	1 (10.0)	1 (10.0)
Wheelchair-related activities - wheelchair driving by the patient	3 (30.0)	4 (40.0)	1 (10.0)	2 (20.0)
Wheelchair Related activities - wheelchair skills training	4 (40.0)	4 (40.0)	1 (10.0)	1 (10.0)
Assistance in therapy related to other professions - Visual Perceptual training	4 (40.0)	4 (40.0)	1 (10.0)	1 (10.0)

3.5 Discussion

The physiotherapists who completed the questionnaire had years of experience ranging from 5 to 19 years. This differed from the experience range in a study by Kimberley et al. (225), which compared the amounts and types of practice given to traumatic brain injury clients and stroke clients with 50 therapists (17 physiotherapists, seven physiotherapy assistants, 13 occupational therapists and three occupational therapy assistants). The experience range was wider, starting at less than a year and reaching over 15 years (225).

De Wit et al. (4) recorded over 60 treatment sessions across the four centres. They found that in one hour of physiotherapy, the most recorded activities were selective movements, ambulatory exercises, and exercises and balance in sitting and standing. When comparing content between physiotherapy and occupational therapy sessions, the authors also found that ambulatory exercises, transfers, exercises, and balance in standing and lying occurred significantly more often in the physiotherapy sessions. This study also found similar results where all physiotherapists (n=10) mostly used ambulatory exercises in gait training, exercises in lying in bed mobility and balance in sitting and standing exercises. Moosajie (70) also found similar results in their unpublished study in recording the control intervention utilised in her feasibility work using the same tool from De Wit et al. (4).

In this study, joint mobilisation was the most frequently used upper limb technique by all ten physiotherapists, in keeping with findings from Garcia-Vega et al. (226): a retrospective clinical notes audit in Western Australian physiotherapists. Here, they identified that shoulder mobilisations were used in all 16 cases (226). Conversely, an online survey about the management of hemiplegic shoulder pain, completed by Kumar et al. (227) with 66 United Kingdom physiotherapists and occupational therapists, found that 67% used palpation as an assessment technique, 45% used soft tissue techniques, such as trigger point release, joint mobilisation and spasticity, and 26% utilised manual joint mobilisations (227). Bobath training emphasises a “preparatory" phase before active treatment; joint mobilisations are one manual technique that falls in this category (228). As most of the physiotherapists were Bobath-trained, it is to be expected that joint mobilisation was used to improve the joint's alignment in preparation for complete selective movement (223). Therefore, it comes as no surprise that this technique was widely used. There is sparse evidence around the effectiveness of this specific technique within the context of neurophysiotherapy (229).

This study found that all physiotherapists (n=10) used more passive lower limb techniques, such as stretching lower limb muscles and therapeutic positioning of the hemi leg. However, an observational study Hendrey et al. (230) recording the usual activities conducted with 20 patients found that lower limb strength training (median = 8.5), along with gait training (median = 10.8) and balance exercise (median=6.2) were the most recorded activities. This difference could be explained by the different study design used by Hendrey et al. (230) where they completed an observational study, and the inclusion criteria for patients recruited included patients observed to be mobile: they had to score three or more on Functional Activity Category and already be ambulating up to 14 meters.

As Hendrey et al. (230) described, balance activities and gait training were among the most recorded activities. This was found to be true in this study, with more than 60% of the physiotherapists using balance and gait techniques in this sample. Improving mobility is one of the two top goals stroke patients would like to achieve, ranked second after improving hand function (231). It is unsurprising, then, that physiotherapists in this institution would spend a large portion of a treatment session focusing on ambulation exercises and gait training.

Notably, FES was only used by one therapist in the sample in the upper limb and lower limb and was used frequently by this one therapist (more than ten times in the two weeks) in both the upper and lower limb. This is in keeping with current findings in physiotherapy research where FES is not a routine intervention chosen by physiotherapists or occupational therapists (7). Auchstaetter et al. (191) found in a survey of 298 Canadian therapists, 38.85% to 70.21% reported never using FES to achieve specific therapeutic goals such as improving walking function, muscle strength or endurance, preventing or improving shoulder subluxation, improve arm function, improve hypertonia or spasticity and improving sensation. This is also consistent with the findings from Moosajie (70), where only one out of ten therapists used FES on the lower limb with two patients.

Trunk activities were not itemised in this study. However, trunk activation is incorporated as part of bridging (8,71), reaching in standing and sitting (150), and weight shifts in sitting and standing (177). This study showed that these techniques were used by at least 80% of the physiotherapists. Moosajie et al.(70) found that all five therapists used trunk-strengthening exercises, consistent with this study's findings.

Gait activities utilising a treadmill, such as speed-dependent treadmill walking and body weight-supported treadmill walking, were not used as there was no treadmill at the rehabilitation centre. Most rehabilitation centres in South Africa have treadmills but do not have the body weight support harness (50).

In this current study, physiotherapists do not use lower limb techniques, including water-based activities (hydrotherapy), neuromuscular electrical stimulation (NMES), virtual reality training and mirror therapy. The rehabilitation centre did not have an NMES or virtual reality device to utilise. While a pool was available for therapy, water restrictions were present in the Cape Town City metropole at the time of the study. Therefore, water-based treatments were limited. These activities, along with air splints of the arm, TENS and constraint-induced movement therapy, were not used by any physiotherapists in this study. The rehabilitation centre does not have air splints for use with patients. This is a true representation of rehabilitation services in South Africa, a developing country mostly reliant on the limited availability of physical and human resources (50,232). This facility had a large patient-to-physiotherapist ratio (approximately one therapist to 18 patients), resulting in clients being seen for about 30 to 45 minutes, up to 3 times a week for individual sessions, therefore limiting the ability to use interventions with or without equipment (air splints, virtual reality) that require extensive one-on-one therapy (50)). In developed countries, patients can receive daily physiotherapy, usually in 1-hour sessions (4,233). Therefore, these interventions would be more appropriate.

3.6 Limitations and Recommendations

While the findings of most and least used techniques align with similar results in the literature (4,7,70,226,234), a limitation of this study was that it did not report on patient profiles. Specifically, the level of impairment of the clients that the physiotherapists reported about their treatment for the two weeks. While this was not the aim of the study, it may be useful in future studies to add a section which asks why the physiotherapist chose the particular treatment or what the aim of treatment was. This could have provided valuable information about why a specific treatment was selected at a particular frequency. While adding this question could make the questionnaire time-consuming, this rich information may help future studies and aid the continual professional development of course content.

While the instrument was based on defined categories from literature, it did not include a distinct category for the trunk, like for the upper limb and lower limb. Trunk training was embedded within other categories, such as bed mobility, sitting, and standing activities. A specific trunk category should be included for future studies to gain more accurate reporting on treatment activities targeting the trunk, such as core stability exercises and so on. Other instruments, such as the Stroke Physiotherapy Intervention Recording Tool (SPIRIT) and the treatment schedule by Donalson et al. (235) in 2009, which records treatment activities completed by physiotherapists with stroke patients, were not considered during the study. The SPIRIT is reported to be easy for physiotherapists to use. It has similar treatment categories to the checklist used in this study, with some differences where some activities are grouped as practising whole or part of activities, facilitation of whole or part of activities (235). However, it, too, does not have a defined category for trunk treatment activities, and this would need to be addressed (235). The SPIRIT focuses on the upper limb and does not include activities directed at the trunk (235).

Another limitation is the sample size, which was small; it was a sample of convenience, and the study was completed in one centre, although all physiotherapists working with patients, excluding the researcher, consented to participate. The South African health system is two-tiered, with at least four privately run rehabilitation units in the Cape Town metropole. In contrast, there is only one government-funded tertiary rehabilitation unit, the WCRC. Furthermore, the results describe inpatient rehabilitation in a specialised rehabilitation unit in South Africa; the other government-funded rehabilitation facility based in Tshwane in Gauteng is smaller, with fewer beds and manages children and adults with physical disabilities. The two government rehabilitation facilities share similar treatment approaches and patient-to-therapist ratios. This would also allow the results to be compared across centres.

A further recommendation would be to use a combination of instruments to record sessions, a questionnaire and video recording sessions. The questionnaire from this study can be expanded to incorporate an additional section asking what the aim of treatment was to understand better why a particular technique was chosen, e.g., the aim of treatment. This would have been beneficial to determine why a specific treatment was chosen. A category for trunk training should be added to the instrument. Video recording of sessions would allow a more accurate method of determining the frequency of treatment techniques used and provide an additional descriptor for treatment techniques used (4).

3.7 Conclusion

In conclusion, a checklist that could be used in a South African context for a future study would include the above categories as the checklist used in this study, with additional sections for reasons for choosing a treatment technique, a category for specific trunk training techniques and more categories for frequency of techniques used. This study provided content about physiotherapy practices in the participant’s environment in South Africa and how it compares to international practices.

Chapter 4. Determination of best practice of FES application on the abdominals

4.1 Background

Before undertaking an intervention study using FES, a theoretical or clinical basis of the best anatomical placement of FES electrodes on the abdominals should be determined. The electrode placement for electrical stimulation greatly affects muscle response and should therefore should be scrutinised when applying stimulation (51). Specifically, placement of electrodes when used synchronously with exercise requires investigation into which position yields optimal results.

Four studies have utilised neuromuscular electrical stimulation on the abdominal or back muscles in stroke clients to determine the effect on postural control and balance (8,69–71). One study (8) utilised NMES applied to the abdominals in stroke clients, while doing core training exercises, to compare the difference in abdominal application versus back application on trunk control and balance. In unpublished studies by Moosajie (70) and Joffe (5), both researchers applied FES to the EO in adults with stroke and children with cerebral palsy respectively, to evaluate the effect on ADLs, motor impairment, gait performance and health related quality of life in stroke and abdominal strength and gross motor function in children.

In healthy individuals, Baek et al. (6) explored the best placement of electrode application for NMES on the abdominal wall to get the best contraction of EO, internal obliques, transversus abdominus (TrA) and multifidus. They tested three positions, with the participant supine with a pillow under the knees and head for comfort (6). Muscle contraction and muscle thickness changes were measured using real-time ultrasound imaging (6). An electrode placement of two cm superior and two cm medial to ASIS, bilaterally on the abdominal wall, produced the largest change in muscle thickness in TrA and multifidus (6). Park et al. (8) reproduced this electrode placement in their study to provide NMES to the abdominals in combination with core exercises, added to a conventional physiotherapy programme. However, the authors (8) didn't verify if this placement was the most suitable to be used in stroke clients: Would it confer the same results in muscle thickness changes as Baek et al. (6), would it be best suited as a unilateral or bilateral placement for use in stroke clients and would it be comfortable to use with exercises?

Moosajie (70) in 2012 applied FES to the abdominals in stroke clients as a unilateral placement on the hemiplegic EO placement; they provided a photograph of placement but not a description. Joffe (5) in 2014 applied FES to the abdominals in children with Cerebral Palsy (CP) as a bilateral placement over both EO muscles: superior-laterally from the umbilicus above the eleventh rib and superior to this below the fifth rib. Part of Moosajie (70) placement from the photograph looks similar to Joffe's description, the location superior-laterally from the umbilicus above the eleventh rib. Neither Moosajie (70) nor Joffe (5) determined in advance which electrode placement would provide the best/strongest muscle contraction but followed the theoretical advice of the supplier of the FES device. Both authors used visual confirmation to determine if muscle contraction of EO was produced with electrical stimulation; without objective confirmation, this could introduce observer bias (202).

Limited data exists on the comfortability of FES on the trunk muscles when combined with exercise in stroke patients. Although the benefit of FES is well established (1,2,61,63,65), the discomfort experienced by patients using these devices has been identified as a limiting factor (87). Lyons et al . (87) investigated the effect of electrode size and location on comfort during stimulation of the gastrocnemius muscle. Their findings suggest that changing the electrode site or area (size) can influence pain tolerance and threshold. Moosajie (70), Joffe (5), and Park et al. (8) did not test which electrode placement would be *the most comfortable* for participants when combined with trunk exercises; intensity was checked and modulated for comfort with stimulation once the device was applied, but not when exercises were being performed with stimulation applied.

In summary, neither Moosajie (70) in 2012, Joffe (5) in 2014 nor Park et al. (8) in 2018 determined in advance *which electrode placement would provide the strongest and most comfortable muscle contraction*. Furthermore, there is uncertainty about whether unilateral or bilateral placement would be best for adult stroke clients. Moosajie (70) used unilateral electrode placement on EO, and Park et al. (8) used bilateral placement over both EO muscles. Last, none of the aforementioned authors (5,8,70) ascertained the participants' comfort with electrical stimulation to the trunk while they performed exercises.

Thus, the aim of this study was to determine the electrode placement to be used in the intervention arm of the study.

To achieve this aim, we set out to answer the following research questions:

Which anatomical electrode placement, placed either *bilaterally over both EO muscles* or *only over the hemiplegic side*, would:

- result in the most comfortable patient perceived contraction of EO using a Visual Analogue Scale (VAS)?
- cause the largest difference in hemiplegic EO muscle thickness, measured by 2D ultrasound imaging, between baseline (no FES stimulation) and contraction after five seconds, thirty seconds, one minute and five minutes[1] with FES stimulation?
- cause the largest difference in hemiplegic transversus abdominus (TrA) muscle thickness measured by 2D ultrasound imaging between baseline (no FES stimulation) and contraction after five seconds, thirty seconds, one minute and five minutes with FES stimulation[1]?
- result in the largest difference in visual analogue scale (VAS) scores relating to comfort, stability, and effort when performing abdominal strengthening exercises with and without FES application?

4.2 Methodology:

4.2.1 Research design

This was a pre-experimental study with a pre-test post-test design, a form of feasibility study (236) as part of planning for the upcoming pilot study (237). The aim of this study was 1) to determine which electrode placement would be best to provide stimulation and 2) to determine whether it would be comfortable to exercise with stimulation as part of therapeutic activities; therefore, it can be considered a form of feasibility study according to the definition by Eldridge et al. (236) in 2016. According to Eldridge et al. (236) any study that is part of the *"preparation for a main study may be classified as a "feasibility study*" and a "*pilot study*" is a subtype of feasibility study which "*specifically looks at a design feature proposed for the main trial, whether in part or in full, is being conducted on a smaller scale*" (238).

4.2.2 Participants

Inclusion Criteria:

Patients 18 years and older, with first-ever stroke in the last four months, admitted to a state rehabilitation centre at the time of this study, could read and speak English or Afrikaans and consented to participate.

[1] These timepoints were used to prevent the muscle from experiencing possible fatigue with stimulation.

Exclusion Criteria:

Individuals excluded were those:

- With the highest education level less than Grade 10
- Unable to sit independently without a backrest.
- With any other neurological conditions
- With uncontrolled epilepsy
- With healing wounds/poor skin condition
- With pacemakers or other implants or had abnormalities on an ECG
- Pregnant individuals.
- Individuals with cognitive impairments that failed the Montreal Cognitive Assessment (MOCA) (score less than 26/30 or less than 25/30 if level of education less than Grade 12) conducted by their occupational therapist and individuals with receptive and global aphasia (as assessed by a speech therapist)(239). If patients couldn't fully comprehend the concepts in the informed consent process or didn't pass the MOCA, then the researcher contacted their family members to attend a meeting to discuss consent by proxy. This was to ensure that patients with some cognitive impairments were not excluded. The family member was provided with an information sheet in the patient's presence, and the study protocol was explained. The patient and family members were then given at least 24 hours to decide whether to consent by proxy. The patient was excluded if the family could not provide consent by proxy.
- Individuals who did not pass the sensory screening. The participants underwent a sensory screening that consisted of the electrodes placed on both sides of the trunk initially; the researcher tested the non-hemiplegic side first to determine the patient's stimulus level (intensity measured out of eight) for sensation and then tested the hemiplegic side to determine if they could sense the stimulus and at which intensity. If the participant did not feel the stimulus or have a visible muscle contraction before the intensity setting on the machine reached four (50%), they were excluded from the study.

4.2.2.1 Sample size estimation

Therefore, a similar sample size to a pilot or feasibility study was used. Based on recommendations from Julious et al. in 2005 (240) regarding a suitable sample size estimation for pilot studies, a sample size of 12 was chosen for this study. Julious et al. (238) recommends that a sample size of 12 per group in pilot studies would be best regarding feasibility and precision around the variance and mean.

However, this study was a pre-experimental study with only one group, which was an experimental group (240).

4.2.2.2 Enrolment

The researcher obtained informed consent from patients who passed the MOCA assessment. Patients with expressive aphasia underwent the consent process with the researcher, and the speech therapist was present to verify that the patient could grasp the information discussed, to guide the best way to facilitate true informed consent with the patient and to prevent therapeutic misconception by the patient (239).

4.2.3 Instrumentation

4.2.3.1 Visual Analogue Scale (VAS)

The VAS is widely used in medical research. In people with stroke, to account for visual-spatial deficits, a vertical VAS is better than a horizontal VAS to measure pain (241). All participants in this study completed questionnaires containing vertical VAS scales measuring comfort, stability felt, and effort exerted in completing the exercise with the FES application.

A 10-point vertical VAS defined the level of comfort individuals experienced when they felt the FES stimulation. A scale measuring levels of comfort/discomfort rather than no pain/pain was chosen, where one indicated not comfortable and ten was very comfortable. The word comfort was deemed appropriate because stimulation may result in discomfort but not pain. Pain may cause discomfort, but not all discomfort is due to pain (242). Stability was defined as the participant feeling stable in maintaining their sitting balance while completing the exercise and receiving stimulation, where one equalled not stable and ten was very stable. Effort level or effort exerted was defined as how much energy or effort ("was it tiring or easy") did it take to complete the exercises while receiving FES stimulation, where one was no effort and 10 was high effort.

4.2.3.2 Two-Dimensional (2D) Ultrasound Imaging

To determine which electrode placement would result in the most effective muscle contraction of EO and TrA, 2D real-time ultrasound was chosen to measure thickness changes in these abdominal muscles when contracted during FES stimulation. Muscle thickness was measured using the built-in software callipers of the machine and transcribed onto a data sheet.

2D ultrasound imaging provides a non-invasive way of observing muscle structure and thickness changes (84). It has good intra-rater reliability (hemiplegic side ICC =0.77 and non-hemiplegic ICC =0.81) when used in abdominal muscle thickness measurement in acute stroke patients (203).
Real-time 2D ultrasound imaging is safe when used with electrical stimulation in healthy individuals in the abdominals and lumbar paraspinal (6,205) and was used to confirm an EO and a resultant TrA contraction and to measure muscle thickness changes of TrA and EO. At the same time, FES is applied to EO on the hemiplegic side.

The researcher underwent training by a qualified radiographer who assisted with ultrasound imaging and was employed full-time at the facility where the study occurred. Training took place one day before data collection, for approximately two hours, and it consisted of one-on-one practice outlining where to place the transducer head for measurement and how to operate the machine. The radiographer and another staff member volunteered for the researcher to practice the above. The radiographer also verified the correct transducer placement and how to utilise the machine with the first two participants who were imaged the following day. The ultrasound machine used in this study was a Siemens Diagnostic Ultrasound System Acuson X150 (model no. 10131661).

The positioning for measuring EO/TrA using real-time ultrasound was in supine with hips and knees at 90 degrees, resting on a stool on the bed to allow a neutral pelvis and to support the hemiplegic leg. The researcher positioned herself on the hemiplegic side of the patient. The transducer head was placed along the mid-axillary line, halfway between the anterior superior iliac spine and the inferior border of the last rib. The three layers of abdominal muscles were visualised on the ultrasound, separated by intermuscular fascial layer viewed as white lines. Digital callipers were placed on each line perpendicular to each other; the distance was measured digitally to determine muscle thickness.

Images were taken at rest, then five seconds, 30 seconds, one minute and five minutes to determine if the muscles may fatigue over time. Images were taken at the end of a breath, and participants were instructed to hold their breath when the image was taken as recommended by the radiographer who gave the training. Holding breathing during image capture or taking an image at the end of breathing is standard practice and creates a still image with less distortion (84,204).

4.2.3.3 FES Electrode placement:

The description of electrode positioning from Joffe (5) and Baek et al. (6) was tested to determine the best electrode application areas on one of two points on EO. The other electrode was placed in the eighth intercostal space over the eighth intercostal nerve, one of the nerves supplying EO. Bilateral (A1, B1) or unilateral (A2, B2) placement of each position was also tested, therefore FOUR electrode placements were tested:

Figure 1: Position A2 Electrode Position

Figure 2: Position B2 Electrode Position

1) Placement A1: Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space, as bilateral placement over both EOs.

2) Placement A2: Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space, with placement over the hemiplegic EO only.

3) Placement B1: Two cm superior and two cm medial to ASIS (6) and the eighth intercostal space, as bilateral placement over both Eos.

4)Placement B2: Two cm superior and two cm medial to ASIS (6) and the eighth intercostal space, with placement over the hemiplegic EO only.

When testing of electrode position was completed, the allocation of placements was randomised to allow for an equal spread of testing of placement positions per day. Randomisation was conducted using four cards, numbered from one to four, each card representing each of the allocated electrode placements, placed in individual unmarked envelopes.

The description in each card is described below:

- Card 1 = placement A1
- Card 2 = placement A2
- Card 3 = placement B1
- Card 4 = placement B2

The participant consecutively drew all four cards one at a time to determine their sequence for stimulation across the four days, i.e., if the sequence is 1-2-4-3, then on day one, only placement A1 was tested, day two, placement A2 was tested, on day three placement B2 was tested and on day four placement B1 was tested.

4.2.3.4 FES stimulation mode and setting - stimulation protocol.

An electrical stimulation device, the Microstim 2(v2) (Odstock Medical Limited, Salisbury, Wiltshire), was used for this study. Mode one (simultaneous) was used on the microstimulator; it has a frequency of 40Hs, output amplitude of 100mA, pulse width of 330µs and a ramp of 6 seconds (216). Simultaneous mode indicates that two outputs via two channels run simultaneously, so two muscle groups can be stimulated simultaneously. As per Figure 3 (216), the output has a gradual two-second ramp-up in intensity, then remains at that intensity for 10 seconds and then ramps down for two seconds to zero intensity. Zero output is then provided for two seconds. After that, there is a two-second delay before the next stimulation cycle begins in the same manner. With the gradual ramp-up and down of output, this mode accommodates any spasticity that occurs when activating movement (216).

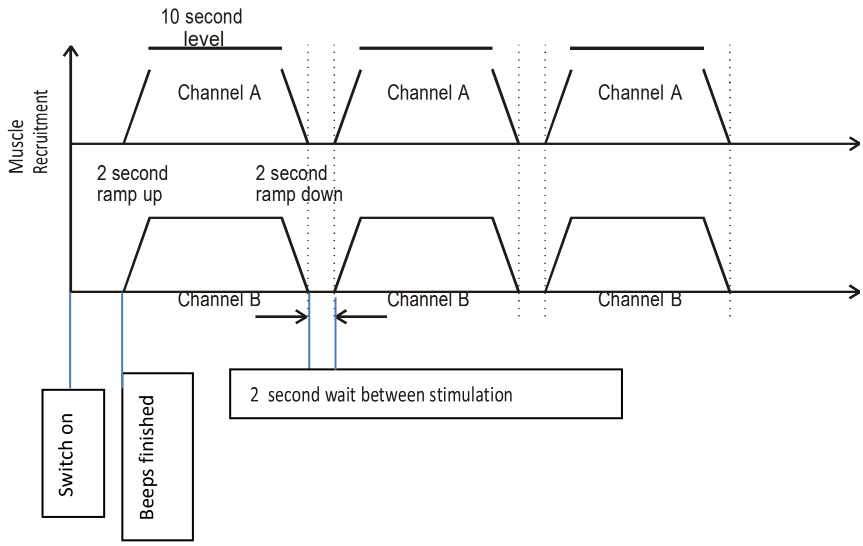


Figure 3: How electrical current is delivered in simultaneous mode on Odstock Microstim machine

These parameters were chosen based on typical parameters used in recommendations from studies using electrical stimulation in upper limbs (77) and FES in lower limb studies (78,79) as described in the literature review (2.8.3). Moosajie (70) also used the same parameters proposed for this pilot study in their study. Previous NMES studies with NMES application to the back muscles of the trunk and abdominals utilised 30-70 mA, pulse width 250 µsec and 35 Hs frequency (8,69,71). The device used in this study has fixed settings as described, and at the time that data collection was completed in 2016, the study by Park et al. (8) in 2018 had not yet been published. The study by Park et al. (8) was the only one that applied NMES to the abdominals. We used the same parameters as Moosajie (70), as the study provided stimulation similarly to how we intended to provide stimulation with physiotherapy treatment.

Stimulation was applied using 5 X 5 cm electrodes, and the intensity of the machine was increased until a contraction of the EO was visible to the examiner and on the ultrasound machine. The machine's intensity settings are built in from notches one to eight. The intensity was increased until the patient was comfortable with the stimulation level. If the participant reported discomfort, stimulation was stopped or turned down until comfortable.

4.2.4 Procedure

The researcher approached physiotherapists and occupational therapists working at the centre approximately three weeks before data collection. They were asked to identify any patients who fit the eligibility criteria and would still be at the centre for one week to complete data collection. The researcher met with these patients identified by the therapists one week before data collection and explained the study, obtained written consent and completed the various screenings (see section 4.2.1. and 4.2.2.2), coded the participants using participant numbers from F1 to F12 and randomised the electrode placement for stimulation as described in section 4.2.3.3.

A height-adjustable plinth was used in all sessions in a room separate from the general physiotherapy gyms. As described in 4.2.4.1., there were two phases for testing over four days. Phase one determined which FES electrode placement position provides the most comfortable and best EO and TrA contraction. Phase two determined the suitability of combining FES with abdominal exercises in terms of stability felt and effort exerted in completing the exercise with FES application. Four FES electrode placement tests per phase were conducted per day.

4.2.4.1 Positioning

Participants were tested supine on a height-adjustable plinth when measuring muscle thickness changes. A stool was placed on the plinth, and participants were instructed to put their calves on it. This ensured that their hips and knees were at 90 degrees, the pelvis was maintained in neutral, and the hemiplegic leg was supported; angles and adjustments to the stool position on the plinth were made to ensure this was the case. A baseline ultrasound image of the EO and TrA muscles (at rest) was taken before stimulation to measure the thickness of each muscle.

After that, FES abdominal stimulation was started, and the participants confirmed the first muscle contraction when they felt it. Real-time ultrasound images were taken when contraction occurred at five seconds, thirty seconds, one minute and five minutes, as seen on the ultrasound imaging. Each ultrasound image was taken at the pause at the end of expiration. Afterwards, the participant completed a VAS to determine their comfort level with FES after the five minutes of stimulation. Total stimulation time was approximately five minutes for phase one.

In phase two, assessment of comfort during exercise or movement, patients were positioned sitting over the edge of the plinth, hips and knees at 90 degrees, thighs fully supported, feet resting flat on the floor. Sitting is a functional position for many day-to-day activities. Physiotherapists are often encouraged to include functional exercises in therapy, and thus, sitting is often used as the starting position for trunk exercises.

The participants performed five repetitions each of two abdominal exercises: trunk rotation and flexion in sitting (38) and completed a VAS afterwards to determine their comfort, effort and stability while doing the exercises without FES applied. Flexion and extension of the trunk were described as the patient flexing and extending the lower trunk without moving the trunk forward or backwards while sitting upright (like an anterior and posterior pelvic tilt in sitting). Trunk rotation exercises were described as the patient moving each shoulder forward and backward for upper trunk rotation in a seated position. The researcher facilitated the exercises and guided the correct technique, preventing overshooting or undershooting. Each exercise was limited to five repetitions to ensure that patients were not fatigued at the end of the testing session. Fatigue may have compromised their perceived notion of comfort, and thus, only five repetitions were used. There is no clear guideline on the number of repetitions to use. Therefore, five repetitions were hypothesised to be favourable. The participants completed the same exercises again, with FES applied to their abdominals and a follow-up VAS after each application to determine the level of comfort, stability, and effort with combining FES with the exercises. The stimulation regime therefore included one minute of stimulation with no exercise, two minutes of stimulation for the first exercise with five repetitions and two minutes of stimulation for the second exercise with five repetitions. The stimulation was not timed to overlap with exercises, i.e., it was not timed to coincide with each repetition in an on/off manner (pause while returning to the starting position and reactivate when performing the next repetition). The stimulation was constant while the participants exercised. The aim was to allow stimulation to continue while the patient exercised for five minutes to simulate what would happen in therapy.

Total stimulation time was approximately five minutes for phase two. Five minutes was given as a rest period between phases one and two.

4.3 Statistical Analysis

The purpose of the study was to determine which electrode placement, using the patient's self-reported VAS scores and muscle thickness measurements from 2D real-time ultrasound images, would be most suitable for the pilot study. Statistica version 13.5 and Microsoft Excel were used to complete the analysis. The data for each electrode position for each timepoint for both EO and TrA was tested for normality using a Shapiro-Wilks test. If the data was normally distributed, means and standard deviations were used. If the data was determined to be non-normally distributed, medians with interquartile range were presented to describe the following parameters:

1) Muscle thickness measurements for EO and TrA were calculated for each electrode placement at each measurement (time) point for the participants.
2) The change in muscle thickness for EO and TrA was determined by the difference between the mean/average scores for EO and TrA for each placement at each measurement point and the baseline measurement.
3) Mean scores for VAS scores per electrode placement measured at each time point were calculated and compared.

A Friedman ANOVA tests whether two or more related groups differ and are conducted to test if the mean muscle thickness (mm) was different across the five-time points. The null hypothesis is that the thickness across the populations is equal (H0): $\mu1 = \mu2 = \mu3$). The alternative hypothesis (Ha) is that at least one population mean differs from the rest. The cut-off value for statistical significance was $p \leq 0.05$.

4.4 Results

4.4.1 Patient Demographics

The sample consisted of 12 participants, 11 male and one female. Two thirds (eight participants) had a right sided CVA, and 10 participants had a stroke as a result of an infarct. The mean age was 50.33 years (SD =8.97), the mean time from stroke was 48.5 days (SD= 29.69) and mean BMI 28.5 kg/m^2 (SD=5.87). Five participants were able to walk, with two participants walking indoors with an assistive device greater than 10m and three walking with assistance from a person and a device indoors for less than 10m. Table 9 outlines the participant risk factors and figure 3 describes the recruitment and screening process for the participants.

Table 9: Participant risk factors for stroke (n=12)

Risk factor	Count (n=12)
Diabetes	5
High blood pressure	10
Hypercholesterolaemia	1
Smoker	4

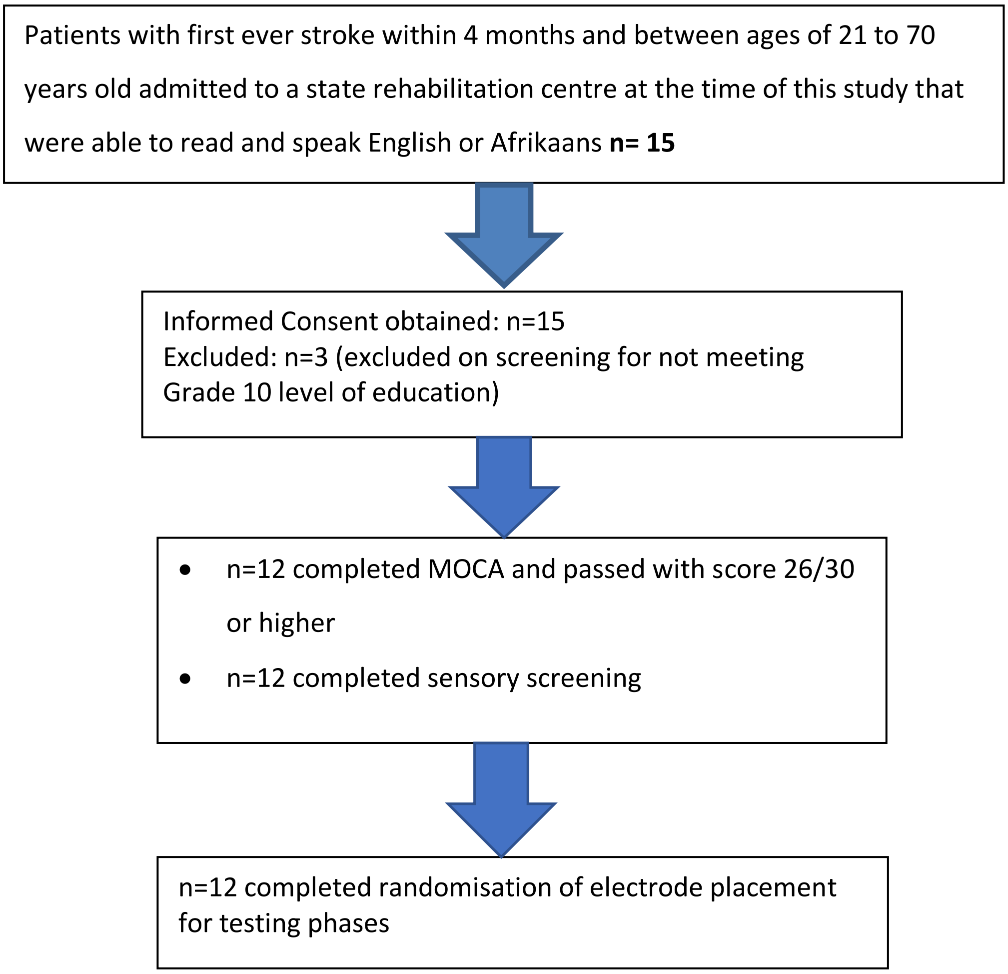


Figure 4: Flow Diagram outlining participant (n=12) recruitment and screening process

4.4.2 Muscle thickness changes

Mean and median muscle thickness measurements for each electrode placement for EO and TrA muscles from rest and at each measured timepoint (five seconds, 30 seconds, one minute and five minutes) as the difference between means for EO and TrA will be presented first. Thereafter, the change (differences) in muscle thickness for each electrode placement from rest to each timepoint (five seconds, 30 seconds, one minute and five minutes) will be presented.

4.4.2.1 Relative muscle thickness measurements

Tables 10 and 11 below show the muscle thickness measurements from 2D ultrasound scans for EO and TrA at each time point: baseline, five seconds, 30 seconds, one minute and five minutes. The results are reported as mean (standard deviation).

Table 10: Muscle thickness measurements (in mm) for EO at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes for each electrode position: Position A1, Position A2, Position B1 and Position B2)

Electrode Position	Measurement	Baseline	5 Seconds	30 Seconds	1 minute	5 minutes
Position A1	Mean (SD)	4.66 (0.83)	4.28 (0.94)	4.41 (0.78)	4.16 (1.24)	4.36 (0.95)
	Median (range)	4.40 (4.25-4.85)	4 (3.58 -5.0)	4.55 (3.95-5.10)	4.10 (3.3-5.13)	4.15 (3.60-4.78)
	Shapiro Wilks W	*0.85 (p=0.04)	0.94 (p=0.37)	*0.83 (p=0.01)	0.98 (p=0.96)	0.92 (p=0.19)
Position A2	Mean (SD)	**4.88 (1.08)**	**4.59 (1.01)**	4.48 (1.07)	4.51 (0.96)	4.53 (0.92)
	Median (range)	**5.30 (4.15-5.7)**	**4.6 (3.75-5.08)**	4.6 (3.68-5.33)	4.40 (3.83-5.23)	**4.75 (3.85-5.15)**
	Shapiro Wilks W	*0.85 (p=0.03)	0.93 (p=0.31)	0.91 (p=0.18)	0.93 (p= 0.33)	*0.85 (p=0.03)
Position B1	Mean (SD)	4.73 (0.54)	4.51 (0.73)	4.31 (0.72)	4.50 (0.71)	**4.56 (0.86)**
	Median (range)	4.95 (4.3-5.1)	4.45 (4.05-4.95)	4.35 (3.80-4.80)	4.55 (3.95-4.70)	4.55 (4.08-4.95)
	Shapiro Wilks W	0.89 (p=0.13)	*0.84 (p=0.01)	*0.85 (p=0.02)	*0.81 (p=0.01)	0.88 (p=0.06)
Position B2	Mean (SD)	4.42 (1.20)	4.47 (1.18)	**4.85 (0.97)**	**4.76 (1.07)**	4.23 (1.09)
	Median (range)	4.50 (3.45-5.13)	4.30 (3.58-5.10)	**4.90 (4.45-5.35)**	**4.80 (4.33-5.18)**	4.50 (3.85-4.98)
	Shapiro Wilks W	0.75 (p=0.75)	0.97 (p=0.84)	*0.86 (p=0.03)	0.91 (p=0.18)	0.88 (p=0.06)

*Results reported as mean (standard deviation), median (range) and Shapiro Wilks W score with P=<0.05 indicating statistical significance.

Bolded text in the tables indicates the highest muscle thickness measurement (mean and median) during stimulation at each timepoint.

Position A1: Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space, as bilateral placement over both EOs.) Position A2: Superior-laterally from the umbilicus above the eleventh rib(5) and the eighth intercostal space, with placement over the hemiplegic EO only. Position B1: Two cm superior and two cm medial to ASIS (6) and the eighth intercostal space, as bilateral placement over both EOs. Position B2: Two cm superior and two cm medial to ASIS (6) and the eighth intercostal space, with placement over the hemiplegic EO only

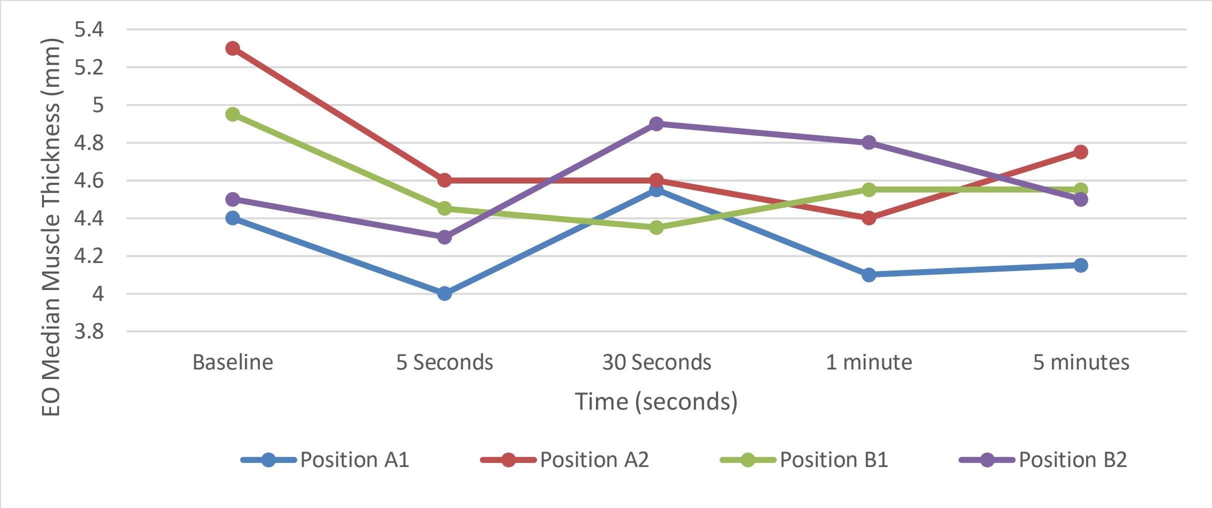


Figure 5: Median muscle thickness measurements (in mm) for EO at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes for each electrode position: Position A1, Position A2, Position B1 and Position B2).

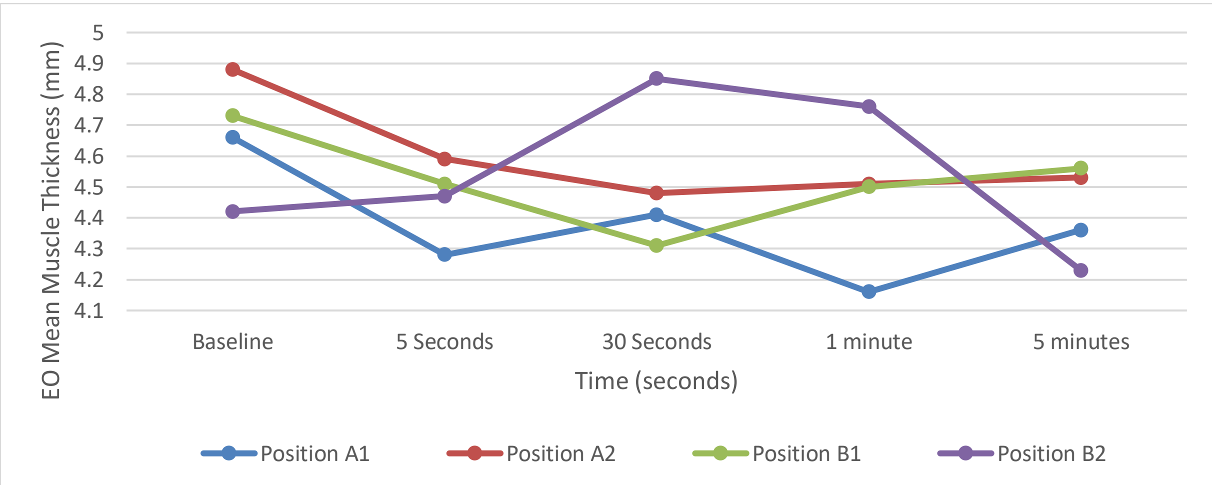


Figure 6: Mean muscle thickness measurements (in mm) for EO at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes for each electrode position: Position A1, Position A2, Position B1 and Position B2).

From Table 10, Figure 5, and Figure 6, at baseline position A2 had the highest mean thickness (4.88 mm (SD = 1.08)) and the highest median thickness (5.30mm (Range = 4.15mm - 5.7mm)) for EO. It was found that at 5 seconds, position A2 had the highest mean thickness (4.59 mm (SD = 1.01mm)) and highest median thickness (4.6mm (Range = 3.75mm - 5.08mm)) in EO.

At 30 seconds, position B2 had the highest mean for muscle thickness measurement (4.85mm (SD = 0.97mm)) and highest median thickness measurement (4.90mm (Range = 4.45mm - 5.35mm) for EO. At one minute, position B2 had the highest mean muscle thickness measurement for EO (4.76mm (SD = 1.07mm)) and the highest median muscle thickness measurement (4.80mm (Range = 4.33mm - 5.18mm)) for EO.

At five minutes, highest mean for muscle thickness measurement came from position B1 for EO (4.56mm (SD = 0.86mm)) and position A2 had the highest median thickness (4.75mm (Range = 3.85mm -5.15mm)) for EC.

Table 11: Muscle thickness measurements (in mm) for TrA at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes for each electrode position: Position A1, Position A2, Position B1 and Position B2)

Electrode Position	measurement	Baseline	5 Seconds	30 Seconds	1 minute	5 minutes
Position A1	Mean (SD)	3.08 (1.18)	3.17 (1.49)	3.10 (0.79)	3.27 (1.02)	2.98 (1.05)
	Median(range)	2.7 (2.25 - 3.55)	2.40 (2.08-4.2)	2.95 (2.55-3.60)	2.80 (2.40-4.08)	2.95 (2.08-3.70)
	Shapiro wilks W	*0.82 (p=0.02)	0.89 (p=0.09)	0.96 (p=0.76)	0.97 (p=0.82)	0.97 (p=0.91)
Position A2	Mean (SD)	2.88 (0.68)	2.96 (1.24)	**3.50 (0.98)**	3.20 (0.92)	3.03 (1.09)
	Median(range)	2.7 (2.6-3.08)	2.45 (2.15-3.33)	3.35 (2.7-4.25)	3.15 (2.48-3.43)	2.65 (2.25-4.03)
	Shapiro wilks W	0.88 (p=0.08)	*0.87 (0.04)	0.98 (p=0.99)	0.96 (p=0.67)	0.95 (p=0.59)
Position B1	Mean (SD)	**3.12 (0.88)**	3.18 (1.24)	3.16 (0.88)	3.41 (0.97)	**3.14 (1.22)**
	Median(range)	3.05 (2.45-4)	2.45 (2.15-3.33)	3.05 (2.50-3.80)	3.40 (2.48-3.43)	**3 (2.08-4.18)**
	Shapiro wilks W	0.92 (p=0.32)	0.97 (p=0.89)	0.98 (p=0.95)	0.95 (p=0.63)	0.93 (p=0.31)
Position B2	Mean (SD)	**3.12 (0.97)**	**3.53 (1.11)**	3.20 (0.77)	**3.61 (1.15)**	2.93 (0.79)
	Median(range)	**3.2 (2.4 - 3.9)**	**3.30 (2.75-3.98)**	**3.45 (2.60-3.55)**	**3.45 (3.08-3.85)**	2.70 (2.38-3.43)
	Shapiro wilks W	0.98 (p=0.97)	0.98 (p=0.98)	0.94 (p=0.38)	0.91 (p=0.17)	0.96 (p=0.80)

*Results reported as mean (standard deviation), median (range) and Shapiro wilks W score with P=<0.05 indicating statistical significance.

***Bolded text in the tables indicates the highest muscle thickness measurement (mean and median) during stimulation at each timepoint.**

*Position A1: Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space, as bilateral placement over both EOs.) Position A2 : Superior-laterally from the umbilicus above the eleventh rib(5) and the eighth intercostal space, with placement over the hemiplegic EO only. Position B1: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, as bilateral placement over both EOs. Position B2: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, with placement over the hemiplegic EO only.

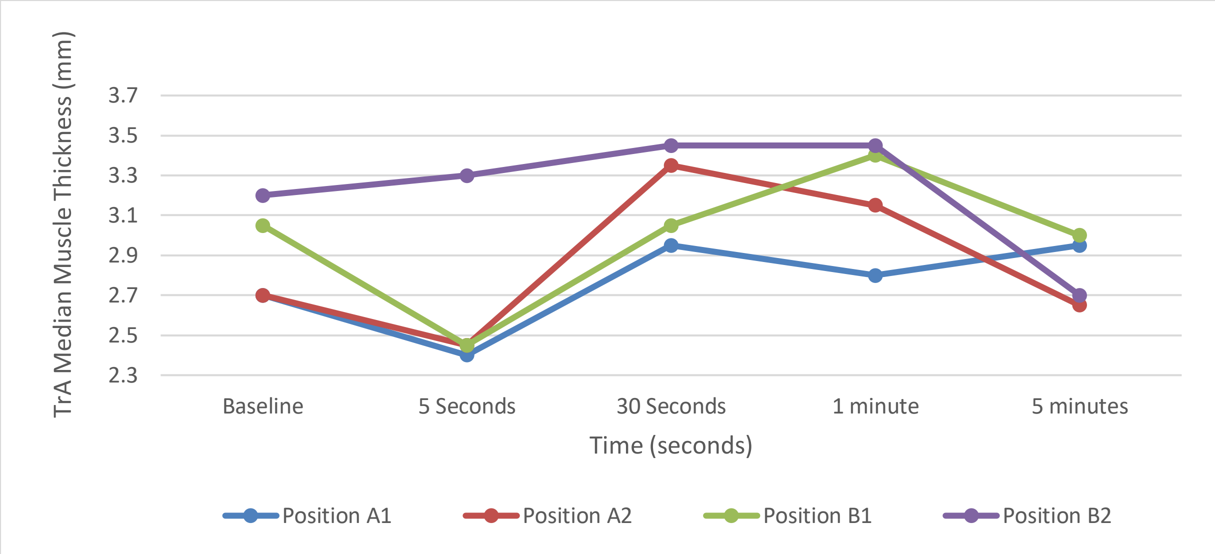


Figure 7: Median muscle thickness measurements (in mm) for TrA at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes for each electrode position: Position A1, Position A2, Position B1 and Position B2).

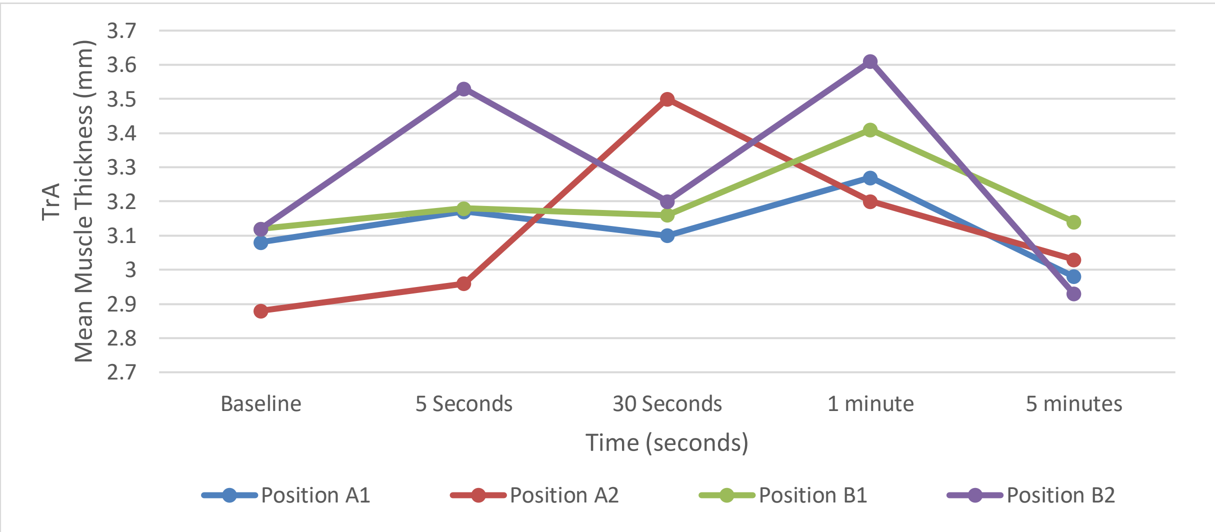


Figure 8: Mean muscle thickness measurements (in mm) for TrA at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes for each electrode position: Position A1, Position A2, Position B1 and Position B2).

According to table 11, figure 7 and figure 8 at baseline, position B1 and position B2 had the highest mean muscle thickness measurements (3.12mm (SD = 0.97)) and (3.12mm (SD = 088)) respectively for TrA. At baseline position B2 had the highest median muscle thickness measurement (3.2mm (Range = 2.4mm - 3.9mm)) for TrA.

At 5 seconds, position B2 had both the highest mean thickness measurement (3.53mm (SD=1.11mm)) and the highest median muscle thickness measurement (3.30mm (Range = 2.75mm- 3.98mm) in TrA.

At 30 seconds, position A2 had the highest mean for muscle thickness measurement for TrA (3.5mm (SD=0.98mm)) and position B2 had the highest median muscle thickness measurement (3.45mm (Range= 2.60mm - 3.55mm)) for TrA.

At one minute, the highest mean muscle thickness measurement for TrA was from position B2 (3.61mm (SD =1.15mm)) as well as the highest median muscle thickness measurement (3.45mm (Range = 3.08mm -3.85mm)).

At five minutes, both the highest mean for muscle thickness measurement (3.14mm (SD=1.22mm)) and highest median muscle thickness (3.0mm (Range = 2.08mm – 4.18mm) came from position B1 for TrA.

Table 12: Friedman ANOVA test for Position A2 for TrA muscle at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes

	Average Rank	Sum of Ranks	Mean	SD
Position A2 U/S baseline TrA	2583333	3100000	2875000	0.68
Position A2 U/S 5sec TrA	2208333	2650000	2958333	1239104
Position A2 U/S 30 sec TrA	4208333	5050000	3500000	0.98
Position A2 U/S 1min TrA	3125000	3750000	3200000	0.92
Position A2 U/S 5min TrA	2875000	3450000	3025000	1094719

* Friedman ANOVA and Kendall Coeff. of Concordance ANOVA Chi Sqr. (N = 12, df = 4) = 11.48 **p = 0.02** Coeff. of Concordance = 0.24 Aver. rank r = 0.17

*Position A2 : Superior-laterally from the umbilicus above the eleventh rib (5) and the eighth intercostal space, with placement over the hemiplegic EO only

Table 12 shows that the ANOVA Chi Square=1,48, and p=0,022 for TrA muscle thickness measurements and position A2. Since p<0.05, we can reject the null hypothesis and we conclude that time point leads to a statistically significant difference in thickness.

No significant differences were found for the positions A1, B1 and B2 f or TrA and for positions A1, B1. A2 and B2 for EO (appendix XVIII)

4.4.2.2 Change in Thickness

Tables 13 and 14 refers to change or difference in muscle thickness (in mm) from rest measurement (baseline) mean to the mean muscle thickness at timepoints at 5 seconds,30 seconds, one minute and five minutes of FES stimulation for EO and TrA. The results are reported as mean (standard deviation) Bolded text in the tables indicates the highest change in muscle thickness measurement from baseline at each timepoint.

Table 13: Change in muscle thickness in mm (mean with (SD)) from rest to 5 seconds, 30 seconds, 1 minute and 5 minutes for EO with FES stimulation to EO at position A1, A2, B1 and B2

Electrode position	Time			
	5 Sec	30 sec	1 min	5 min
Position A1, mean(SD)	-0.38 (0.67)	-0.25 (0.78)	-0.5 (0.87)	**-0.12 (0.98)**
Position A2 mean(SD)	-0.28 (0.82)	-0.4 (1.02)	-0.37 (0.80)	-0.35 (0.60)
Position B1 mean(SD)	-0.23 (0.63)	-0.43 (0.41)	-0.23 (0.62)	-0.18 (0.73)
Position B2 mean(SD)	**0.05 (0.82)**	**0.43 (0.99)**	**0.34 (1.15)**	-0.18 (1.39)

***Bolded text in the tables indicates the highest muscle thickness measurement (mean) during stimulation at each timepoint.**

* Position A1: Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space, as bilateral placement over both EOs.) Position A2 : Superior-laterally from the umbilicus above the eleventh rib(5) and the eighth intercostal space, with placement over the hemiplegic EO only. Position B1: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, as bilateral placement over both EOs. Position B2: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, with placement over the hemiplegic EO only.

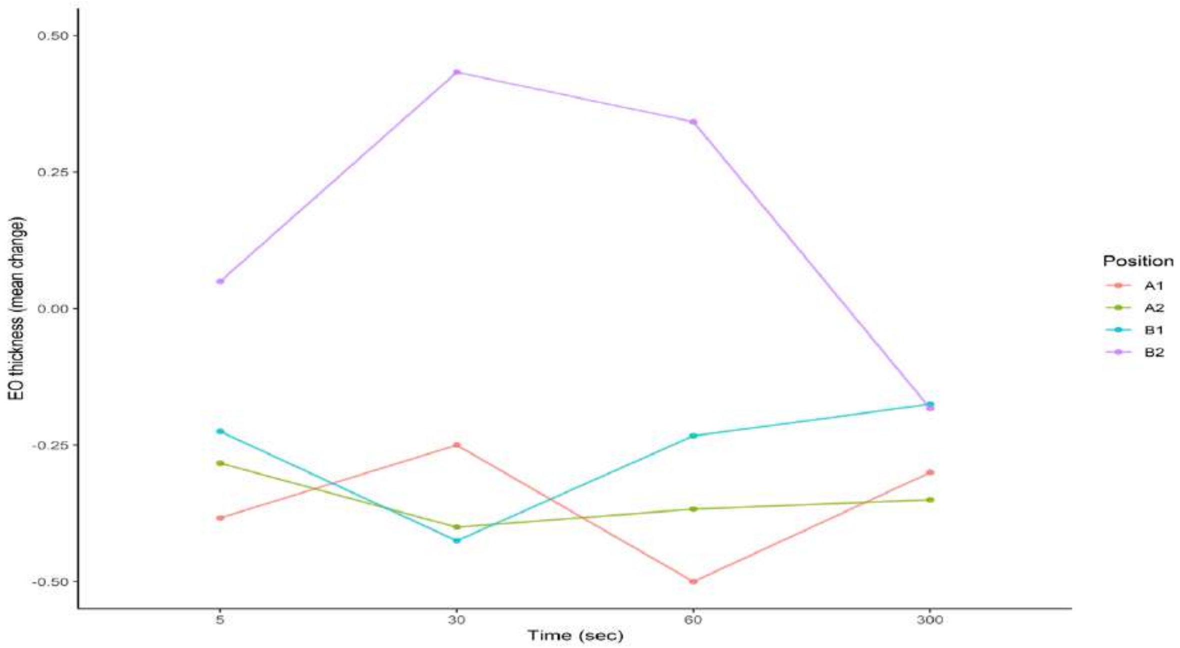


Figure 9: Change in muscle thickness in mm (mean with (SD)) from rest to 5 seconds, 30 seconds, 1 minute and 5 minutes for EO with FES stimulation to EO at position A1, A2, B1 and B2

According to Table 13 and Figure 9, at five seconds of stimulation, position B2 had the highest mean change for EO (0.05mm (SD=0.82)).

At 30 seconds of stimulation, placement B2 had the highest mean change for EO (0.43mm (SD=0.99)).

At one minute of stimulation, placement B2 had the highest mean for E0 (0.34mm (SD =1.15))

At five minutes of stimulation, placement A1 had the highest mean change in muscle thickness for EO (-0.12mm (SD=0.98))

Table 14: Change in muscle thickness in mm (mean with (SD)) from rest to 5 seconds, 30 seconds, 1 minute and 5 minutes for TrA with FES stimulation to EO at position A1, A2, B1 and B2 ($p<0.05$)

Electrode position	Time			
	5 Sec	30 sec	1 min	5 min
Position A1, mean(SD)	0.08 (1.06)	0.02 (0.69)	0.18 (0.86)	-0,1 (0.73)
Position A2 mean(SD)	0.08 (0.85)	**0.63(0.66)**	0.33 (0.72)	**0.15 (0.66)**
Position B1 mean(SD)	0.07 (0.70)	0.04 (0.51)	0.29 (0.59)	0.03 (1.24)
Position B2 mean(SD)	**0.42 (1.00)**	0.08 (0.73)	**0.5 (1.02)**	-0.18 (0.71)

***Bolded text in the tables indicates the highest muscle thickness measurement (mean) during stimulation at each timepoint.**
* Position A1: Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space, as bilateral placement over both EOs.) Position A2 : Superior-laterally from the umbilicus above the eleventh rib(5) and the eighth intercostal space, with placement over the hemiplegic EO only. Position B1: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, as bilateral placement over both EOs. Position B2: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, with placement over the hemiplegic EO only.

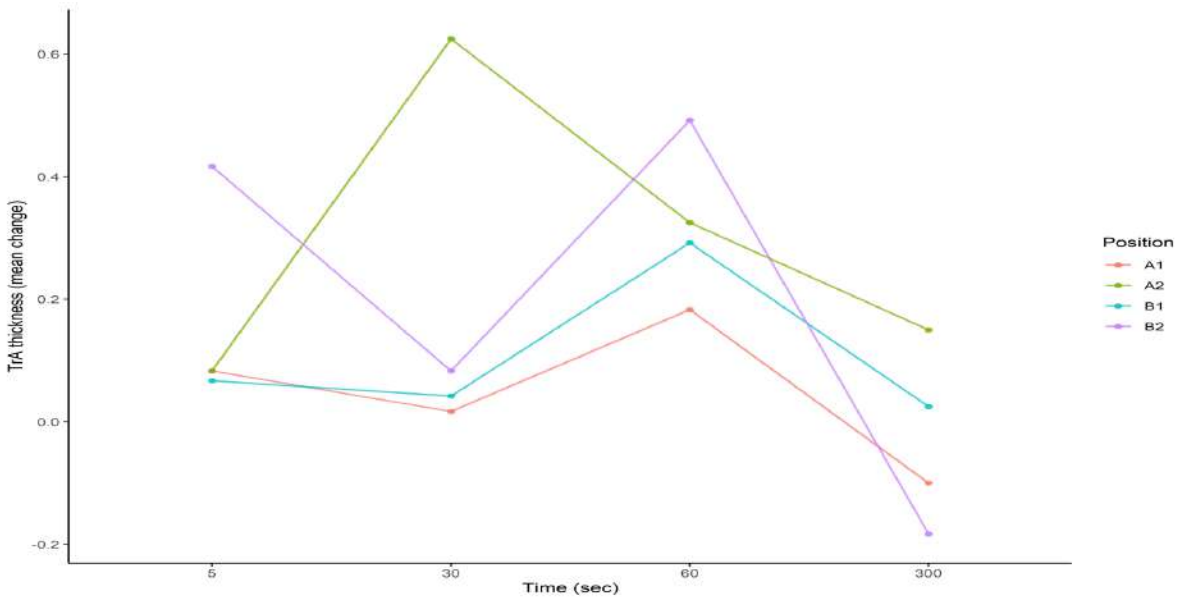


Figure 10: Change in muscle thickness in mm (mean with (SD)) from rest to 5 seconds, 30 seconds, 1 minute and 5 minutes for TrA with FES stimulation to TrA at position A1, A2, B1 and B2 ($p<0.05$).

According to Table 14 and Figure 10, at five seconds of stimulation, position B2 had the highest mean change for TrA (0.42mm (SD=1.0)).
At 30 seconds of stimulation, placement A2 had the highest mean change for TrA (0.63mm (SD=0.66)). At one minute of stimulation, placement B2 had the highest mean change for TrA (0.49mm (SD= 1.02)). At five minutes of stimulation, placement A2 had the highest mean change for TrA (0.15mm (SD=0.66)).

4.4.3 VAS Changes

To determine comfort with FES application, within two scenarios – FES stimulation provided in a static position and FES stimulation provided with exercise, are presented first (Table 14). This is followed by VAS scores for effort experienced when completing the abdominal exercises with and without FES stimulation to the abdominal muscles for each electrode position (Table 15). Lastly, VAS scores for stability felt when completing the abdominal exercises with and without FES stimulation to the abdominal muscles and for each electrode position (Table 16). Bolded text in the tables indicates which position achieved the highest score (mean) for that rating (comfort, effort, stability).

4.4.3.1 Comfort rating

Table 15 represents the mean VAS scores out of ten for comfort with FES stimulation in two cases (FES applied to the abdominals at rest and FES applied to the abdominals in combination with abdominal exercises), where one is rated not comfortable and ten is the most comfortable each electrode placement.

Placement A2 was found to have the highest mean VAS score for both cases of FES stimulation, at rest and no exercise (6.92 and SD=1.93) and with abdominal exercises (7.75 and SD=1.96). Placement B1 had the lowest the mean scores for both EO (3.63 and SD= 1.07) and TrA (6.92 and SD=1.78).
Notably, positions B1 and B2 were more comfortable when applied during exercise compared to no exercise.

Table 15: Mean VAS scores (out of 10) for comfort with FES stimulation in a static position and FES stimulation with and without exercise. (p<0.05)

		Position A1	Position A2	Position B1	Position B2
FES application with no ex	Mean	6.58	**6.92**	3.63	3.71
	SD	2.02	1.93	1.07	0.92

	Range	7.00	6.00	4.00	3.00
	Median	7.00	8.00	3.25	4.00
	IQR	3.00	3.00	5.25	1.00
FES application with ex	Mean	7.67	**7.75**	6.92	7.67
	SD	1.50	1.96	1.78	1.83
	Range	5.00	7.00	5.00	5.00
	Median	8.00	8.00	7.00	8.00
	IQR	2.25	2.00	3.25	3.00

*** Bold numbers in the table indicate the highest mean VAS score for either FES application with no exercises and FES application with exercises**

*Position A1: Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space, as bilateral placement over both EOs.) Position A2 : Superolateral from the umbilicus above the eleventh rib(5) and the eighth intercostal space, with placement over the hemiplegic EO only. Position B1: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, as bilateral placement over both EO muscles. Position B2: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, with placement over the hemiplegic EO only

4.4.3.2 Effort rating

Table 16 shows the VAS scores for effort exerted, where one equalled no effort and 10 indicated high effort, and stability felt with performing the exercise with no FES stimulation to the abdominals and for each electrode position when performing the same abdominal exercises with FES stimulation.

Position B2 had the highest mean (6.58 and SD=3.48) for effort exerted and position A1 had the lowest mean (3.08 and SD=2.28) for effort exerted and scored the same as if the exercise were performed with no FES stimulation. Notably, position B1 and B2 were found to have more effort when combined with exercise compared to no exercise, but this was only for position B.

Table 16: Mean VAS scores (out of 10) for Effort exerted when completing abdominal exercises without FES and when completing abdominal exercise with FES stimulation for each electrode position

	No FES stimulation and Exercise	Position A1: FES stimulation and exercise VAS	Position A2: FES stimulation and exercise	Position B1: FES stimulation and exercise	Position B2: FES stimulation and exercise
Mean	3.08	**3.08**	3.25	6.08	6.58
SD	2.47	2.27	2.63	3.29	3.48
Range	8.00	8.00	8.00	9.00	9.00
Median	2.50	2.50	2.50	6.50	7.00
IQR	2.00	1.00	1.50	4.50	5.50

*** Bold numbers in the table indicate the highest mean VAS score for the electrode position with FES application with exercises**

* Position A1: Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space, as bilateral placement over both EOs.) Position A2 : Superior-laterally from the umbilicus above the eleventh rib (5) and the eighth intercostal space, with placement over the hemiplegic EO only. Position B1: Two cm superior and two cm medial to ASIS (6) and the eighth intercostal space, as bilateral placement over both Eos. Position B2: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, with placement over the hemiplegic EO only.

4.4.4 Stability rating

Table 17 depicts the mean VAS scores for stability felt by participants while completing abdominal exercises with no FES stimulation to the abdominals and for each electrode placement, that provided FES stimulation synchronously while the participant completed abdominal exercises. One equalled not stable and 10 equalled very stable.

Placement B2 scored the highest for stability (7.92 and SD= 1.88) and position B1 scored the lowest for stability (7.00 and SD=2.63).

Table 17: Mean VAS scores (out of 10) for stability felt while performing abdominal exercises with no FES stimulation and with FES stimulation for each electrode position.

	Performing exercises with no FES stimulation	Position A1: performing exercises with FES stimulation.	Position A2: performing exercises with FES stimulation.	Position B1: performing exercises with FES stimulation.	Position B2: performing exercises with FES stimulation.
Mean	6.33	7.50	7.25	7.00	**7.92**
SD	2.71	1.78	2.18	2.63	1.88
range	8.00	5.00	6.00	8.00	6.00
Median	6.00	7.50	8.00	6.50	8.00
IQR	3.50	3.00	3.25	5.00	2.50

*** Bold numbers in the table indicate the highest mean VAS score for the electrode position with FES application with exercises**

*Position A1: Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space, as bilateral placement over both EOs.) Position A2: Superior-laterally from the umbilicus above the eleventh rib(5) and the eighth intercostal space, with placement over the hemiplegic EO only. Position B1: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, as bilateral placement over both Eos. Position B2: Two cm superior and two cm medial to ASIS(6) and the eighth intercostal space, with placement over the hemiplegic EO only

4.5 Discussion

The aim of this sub-study was to determine the most comfortable and effective placement of FES on EO in stroke survivors; this placement will be used to provide stimulation in the pilot study to follow (Chapter 5). This was done by evaluating muscle thickness changes in EO TrA and VAS scores for stimulation combined with abdominal exercises for comfort, effort, and stability with exercise across four positions, as described above.

Both unilateral electrode placements, position A2 (Superior-laterally from the umbilicus above the eleventh rib (5) and the eighth intercostal space) and position B2 (Two cm superior and two cm medial to ASIS (6) and the eighth intercostal space), performed better in terms of muscle thickness changes. Regarding the VAS rating, positions A2 and B2 performed better than the bilateral placements. Position A2 scored the highest VAS rating for comfort when exercise was combined with FES, and position B2 was second. Position A2 had the lowest VAS for effort exerted with FES combined with exercise, which was the same rating score as when the exercises were performed with FES. Position B2 scored the highest VAS rating for stability when FES is combined with exercise. This is not in keeping with the literature, where most studies utilise bilateral placements on the abdominal muscles, whether in healthy individuals (215) or individuals post-stroke (8). Moosajie. (70) are the only author known to date who has utilised unilateral placement for stimulation without reasoning why it was chosen over bilateral placement.

Unilateral placement may have produced better results in this study than bilateral placement because only the hemiplegic side was activated with stimulation. In a stroke, there is delayed response to the abdominal muscles' anticipatory postural activation (APA) on the hemiplegic side (243). Abdominal muscles are meant to contract synchronously, and since the non-hemiplegic side reacts faster and with greater intensity (151), there is impaired coordination between the two sides. When EMS is applied bilaterally, both sides of the trunk are activated; notably, Dickstein et al. (41) have reported poor coordination and activation between bilateral muscle groups in stroke. This could interfere with the contraction of the hemiplegic muscles in this bilateral placement and could explain why there may be slightly lower muscle thickness changes measured at the time points. Therefore, possibly by only stimulating the hemiplegic side alone, the hemiplegic abdominal muscles may have been allowed to contract without synchronising with the non-hemiplegic side.

An interesting finding was that placement B2 was the only electrode position to show positive changes or increase in thickness measurement from baseline measurement for both EO and TrA at all time points except for five minutes. This could be because it had the lowest baseline measurements; therefore, an increase in muscle thickness was more likely. Placement B2 was based on the findings from Baek et al.(6), which the authors hypothesised was the most suitable position between the three tested positions because of the anatomical location. Baek et al.(6) found this position was where EO was thinnest at rest, similar to our findings. The authors also hypothesised that this thinness was associated with a more efficient and stronger contraction of TrA. This hypothesis was not consistent with the conclusions of this study. However, this could be because Baek et al.(6) conducted their study with only healthy individuals.

Literature regarding electrical stimulation is usually for a limb muscle group, and the trunk presents a unique situation where two identical sides (muscles) can be stimulated as one unit in healthy individuals. In the case of stroke clients, one side of the unit is weaker and has less sensation than the other. This discrepancy in sensation could have resulted in the level of stimulus being well tolerated on the hemiplegic side but uncomfortable on the non-hemiplegic side in a bilateral placement, and therefore, why a unilateral placement on only the hemiplegic side (placement A2) was found more comfortable.

Compared to Baek et al. (6) baseline measurements of EO and TrA in 20 healthy individuals, our study measured the muscle thickness for these respective muscles less. Baek reported 8.11mm and 4.9mm as the mean resting state measurements (6), whereas this study reported 4.67mm for EO and 3.05mm for TrA as the median baseline measurements. This is in keeping with findings from a study by Kim et al. (147), where the authors compared muscle thickness changes between healthy individuals and those with stroke using real-time ultrasound; the resting thickness in individuals with stroke was lower than the healthy individuals for EO, Internal obliques (IO) and TrA and the difference was significant ($p<0.5$) (147). In Kim et al. (147), the mean EO thickness measurement at baseline on the hemiplegic side was 6mm (SD=1.8mm), and the mean TrA thickness was 2.8mm (SD =0.8mm). There was no significant difference between the resting state of the hemiplegic and non-hemiplegic side in stroke patients. This study's mean muscle thickness measurement for EO is smaller (1.13-1.58mm less) compared to Kim et al. (147). However, the mean TrA measurements are larger (0.08-0.28mm) in this study compared to the mean TrA measurements in the Kim et al. (147) study.
The mean age (healthy = 49.48 years and stroke participants = 50.79 to 52.22 years) of the participants in Kim et al. (147) study was similar to the mean age of participants in this study (50.33 years).

The aim of determining which electrode position would be best in practice was to find a suitable placement for the pilot study in Chapter 5. Based on the above findings, there is no clear indicator between the two placements A2 (Superolateral from the umbilicus above the eleventh rib (5) and the eighth intercostal space) and B2 (Two cm superior and two cm medial to ASIS (6) and the eighth intercostal space), as to what the preferred placement in muscle thickness changes and VAS changes.

Position A2 scored the highest VAS for comfort and had the lowest VAS for effort with exercise. It also had all positive changes for thickness from baseline measurements for TrA but showed less change for EO than position B2.

However, Placement B2 may be more preferrable as it produced the largest change in EO muscle thickness change from rest at three-time points (five seconds, 30 seconds and one minute) and the highest change in TrA muscle thickness from rest at two time points (five seconds and one minute). Furthermore, it was the only electrode placement to show positive changes for EO muscle thickness change from baseline to five seconds, 30 seconds and one minute for EO compared to the other placements. It also had the second-highest VAS score for comfort during exercise, and the participants found it provided the most stability when combined with stimulation and exercises compared to the other electrode placements.

4.6 Limitations and Recommendations

A limitation of this study is that only the hemiplegic side was measured to determine if there would be a difference in contraction and muscle thickness between the two sides, as there is poor coordination of contraction between abdominal muscles in stroke clients. This would have allowed us to determine if there was as large a difference in muscle thickness change on the non-hemiplegic compared to the hemiplegic side with stimulation. Furthermore, we could observe if these changes are comparable to the Baek et al. (6) study results, which explored the effect of NMES application on abdominal muscles in individuals without stroke.

Another limitation of the study is that the mean BMI of the participants (mean = 28.5kg/m^2) was higher than the recommended BMI for ultrasound imaging, which is 25kg/m^2 (244). Higher BMI affects image quality (245). Individuals with larger BMIs have large amounts of body fat. Fat increases the attenuation or weakening of the ultrasound wave, which affects image quality. This may have affected the clarity of the muscle layers (246). At the time of the study, the sample of convenience of many stroke clients at the facility had a high BMI; for example, only three of the 12 participants had a BMI under 25 and four had a BMI greater than 30. This is fitting as high BMI is a risk factor for stroke (102) and is linked to stroke in developing counties (103). Therefore, pragmatically, due to the availability of participants at the time of the study, larger clients with higher BMI were included in the data collection. Therefore, a recommendation for a future study would be to recruit participants, where possible, with a BMI of 25g/m² or less. The researcher who completed the ultrasound imaging may not have adequately interpreted the ultrasound images, which may have affected her ability to identify the muscle groups efficiently and effectively. The researcher did not complete inter-rater reliability testing of the ultrasound imaging measurements with the radiographer. This may have further affected the researcher's measurements in terms of being consistently reliable and accurate.

While 2D ultrasound is a valid measurement tool to determine muscle changes, EMG recordings are another tool to assess muscle activation. A future study using EMG recordings in combination with ultrasound imaging may be a more accurate method to measure muscle activation and change in activation.

We acknowledge that decreased sensation on the hemiplegic side may have influenced the results related to comfort perception. However, sensation was not tested in this study. We recommend that future studies incorporate cutaneous sensation testing of the abdominal muscles when evaluating the comfort of NMES application.

We recognize that the study excluded isiXhosa only speakers, as isiXhosa speakers were included if they were only able to speak Afrikaans or English. The diversity and representation in the sample was therefore limited. For future studies we recommend that patient participants that are able to speak English or Afrikaans or isiXhosa be included and that a translator be used for isiXhosa only speakers where necessary.

4.7 Conclusion

In conclusion, the results from this study will assist in determining an electrode position that is best for the pilot study. Placement B2 was chosen to be the most suitable to be used for the pilot study in Chapter 5 because it produced the largest change in EO muscle thickness change from rest at three time points (five seconds, 30 seconds and one minute) and the highest change in TrA muscle thickness from rest at two time points (five seconds and one minute). Furthermore, it was the only electrode placement to show positive changes for EO muscle thickness change from baseline to five seconds, 30 seconds and one minute compared to the other placements. It also had the second-highest VAS score for comfort during exercise, and the participants found it provided the most stability when combined with stimulation and exercises compared to the other electrode placements.

Chapter 5. The effect of FES-abdominals on trunk performance, function, energy expenditure and HRQoL (a pilot study)

5.1 Background

The trunk muscles play a pivotal role in trunk control, influencing the alignment of the trunk and creating stability around the spine in preparation for movement and after performing movement of the limbs (47,127,131,136,247). Stroke results in weakness of trunk muscles (146), impaired contraction timing between muscles on both sides of the trunk (147,149,248) and altered kinematics (150). Together, these impairments (along with environmental constraints and possible cognitive impairments) can result in poor performance in activities of daily living such as walking about, bathing and toileting (152) and can ultimately contribute to poorer quality of life (24). Therefore, feasible and effective interventions to improve outcomes for stroke patients are needed to address the impact of activity limitations and participation restrictions.

In resource-constrained countries, such as South Africa, the frequency of treatment sessions for patients is limited (232). The limitation of services requires interventions that can effectively achieve positive outcomes for stroke survivors in this short period. Neuromuscular Electrical Stimulation (NMES) applied to the abdominals has shown positive outcomes, such as improved balance, ADL performance and trunk performance, when combined with trunk strengthening exercises (8,69,71). Studies reporting positive outcomes for stroke patients using NMES applied to the trunk typically ranged from twenty to thirty minutes per session daily or three times a week for three weeks (8,69,71).

As described in the literature review, applying FES within the first six months post-stroke may be best to take advantage of neuroplastic changes after stroke (49). Studies investigating the use of NMES on the trunk have generally included participants from acute or sub-acute settings. For instance, Ko et al. recruited stroke survivors within one month post-stroke for NMES application (71), and Park et al. (8) applied NMES to the abdominals in stroke survivors within six months from stroke onset. Moosajie (70) recruited participants who had a stroke within three months of entry into the study. To date, it is unclear whether initiating electrical stimulation treatment influences outcome.

Moosajie et al. (70) combined FES application to the abdominal muscles (hemiplegic external obliques (EO)) with conventional physiotherapy in an experimental group. They compared their functional outcomes to participants in a control group who received conventional physiotherapy only (70). In that study, the experimental group showed improvements in ADL performance (as measured by the Barthel Index) and the physiological cost index (PCI) of gait (70). These findings indicate that combining FES application to the EO with simultaneous physiotherapy intervention is a promising, feasible treatment that should be further explored.

However, a few methodological concerns were identified in the study by Moosajie (70). These included vague reporting on the exact electrode position, no reasoning for the position, and no reporting on the dosage of FES application were provided. Moosajie (70) only provided FES for two weeks in the experimental group. In contrast, three to four weeks of FES application is more commonly found in FES application to the limbs (72) and abdominals (8). A pilot study was proposed to replicate and improve the research study conducted by Moosajie (70). Thus, the aim and objectives of this pilot study were:

- To determine if there was a significant difference between participants receiving FES on the EO in addition to conventional physiotherapy in the experimental group and participants receiving placebo FES to the EO with conventional physiotherapy in the placebo control group, by comparing the **c**hange over time in:
    1. Motor performance and coordination of the trunk using The Trunk Impairment Scale (TIS).
    2. Impairments as measured by the Rivermead Motor Assessment (RMA).
    3. Functional independence and performance in Activities of Daily Living (ADLs) measured by the Barthel Index (BI).
    4. The Physiological Cost Index (PCI) measures energy expenditure in gait).
    5. Health-related quality of life (HRQoL) scores measured by the EQ-5D 3L health-related quality of life measure.

5.2 Methodology

5.2.1 Research design

A single-blinded, pilot experimental study with a repeated measures design was utilised to evaluate the effect of FES on trunk performance, motor impairment, activities of daily living (ADL) performance, energy expenditure with gait and health-related quality of life (HRQOL). Pilot studies consider if an intervention is feasible and what aspects of the study design, such as recruitment, assessment, and randomisation, should be addressed before undertaking a larger clinical trial. Furthermore, pilot studies are also conducted to assess the sample size required for future appropriately powered studies (236). The experimental group received FES with conventional physiotherapy, and the control group received placebo FES with conventional physiotherapy.

5.2.2 Null Hypothesis

In stroke survivors, there will be no significant difference in motor performance of the trunk, motor impairments, performance of ADLs, energy expenditure with gait and health-related quality of life between those receiving FES to the EO while completing regular physiotherapy in the experimental group and those receiving placebo FES when completing regular physiotherapy in the placebo control group.

5.2.3 Sample

The sampling frame consisted of patients with stroke admitted in the time frame from 15 August 2016 to 15 November 2016 to Western Cape Rehabilitation Centre (inpatient rehabilitation centre) in Cape Town.

5.2.3.1 Eligibility Criteria:

Inclusion criteria

- Residing in the Cape Town metropole to ensure that participants could easily return to the centre for the 8-week follow-up assessment.
- Patients 18 years and older, admitted to the state rehabilitation centre at the time of this study, who could read and speak English or Afrikaans and consented to participate.
- First-ever stroke in the last four months, confirmed by a medical professional. Four months was chosen to capitalise on increased neuroplastic changes within the first six months post-stroke (49).

Exclusion Criteria:

- any other neurological conditions
- uncontrolled epilepsy
- healing wounds/poor skin condition
- pacemakers or other implants
- pregnancy
- cognitive impairments defined as a Montreal Cognitive Assessment (MoCA) score less than 26/30
- receptive and global aphasia (assessed by a speech therapist) that prevented giving informed consent, and their family members could not provide consent on their behalf
- sensory impairments are defined as a score of four out of eight or lower for stimulus intensity on the sensory screening at the initial screening

5.2.3.2 Sample Size Calculation

Table 18: Sample size calculation for pilot study Two Means, t-Test, Ind. Samples H0: Mu1 = Mu2

Parameter	**Value**
Population Mean Mu1	37.0
Population Mean Mu2	76.0
Population S.D. (Sigma)	23.0
Standardised Effect (Es)	-1.70
Type I Error Rate (Alpha)	0.05
Critical Value of t	2.18
Power Goal	0.80
Actual Power for Required N	0.83
Required N (per group)	**7**

The means and standard deviations of the BI post-intervention in the study by Moosajie (70) were used to determine the sample size because an equivalent study using the TIS was not available to reference. For an 80% power goal, seven individuals needed to be recruited in each group. The following parameters (table 18) were entered into the sample size calculator in Statistica version 13.5.

5.2.4 Instrumentation and intervention:

The following instruments were selected because they were used in previous studies (8,70,71) where the outcome of FES or NMES applied to the trunk muscles was evaluated. The chosen instruments were accessible to the researcher at the time of the study and were considered to have good psychometric properties.

5.2.4.1 Trunk Impairment Scale (TIS)

The TIS was used to assess the trunk performance of the two groups at four time points (baseline, two weeks, four weeks, and eight weeks). Specifically, the total TIS score was used to evaluate the effect of the intervention. The TIS was chosen as it had been used in two previous studies utilising NMES by Park et al. (8) and Ko et al. (71); both studies reported positive TIS findings (refer to 1.5.1.). Moosajie (70) did not measure trunk performance or control in their study.

Developed in 2004 by Verheyden (167), the TIS is a 17-item ordinal scale that measures sitting balance and trunk coordination. Each item is scored on a two to three- or four-point ordinal scale, and the total score ranges from zero to 23, with a higher score indicating better trunk control. It has good test-retest reliability, inter-rater reliability, and construct validity with the BI and Trunk Control Test (167). The TIS has a high discriminate validity between healthy individuals and stroke survivors (167). Further information regarding the TIS can be found in the literature review (Section 2.4.1.), and please refer to Appendix XIII for the instrument.

5.2.4.2 Rivermead Motor Assessment (RMA)

The Rivermead Motor Assessment (RMA) was used to measure motor impairment at four time points: Baseline, two weeks, four weeks, and eight weeks. It was developed by Lincoln and Leadbitter in 1979; the RMA measures motor impairments in three sections: gross function (RMA-GF), arm function

(RMA-Arm) and leg and trunk function (RMA-LT)(170). The maximum score for RMA-GF is thirteen, fifteen for RMA-Arm, and ten for RMA-LT; a higher score indicates better motor return. The three sections are not summed together to report a final score but rather reported individually. Items are scored: one if the task is completed and zero if not completed. The items are arranged hierarchically; testing is stopped if the participant fails an item three consecutive times.

The RMA was chosen as it was previously used in the Moosajie et al. (70) study to measure motor impairment . Studies providing NMES to the abdominals or trunk in stroke by Ko et al. (71)and Park et al.(8) did not measure motor impairment(8,71).

The RMA-Arm is valid and reliable (249). The RMA has shown validity with high coefficient correlation (r=0.79 -0.98) for reproducibility and scalability, moderate to good interrater reliability and test-retest reliability (r=0.66-0.88) (250). The RMA-GF and RMA LT were found to have moderate to high correlations with the FIM motor subscale (RMA GF r=0.865; RMA LT r= 0.784), FIM self-care subscale (RMA GF r=0.815; RMA LT r = 0.726) and FIM mobility subscale (RMA GF r=0.844; RMA LT r = 0.782) for external construct validity. The RMA-LT and RMA-GF have shown internal consistency with Cronbach's Alpha coefficients and intra-class correlation values of 0.88 and 0.84 for RMA-LT and 0.93 and 0.88 for RMA-GF, respectively. According to Guttman Scaling requirements, the RMA-LT was also found to have good scalability with a Loevinger coefficient of 0.723 (251). Please refer to the Appendix XIV for the instrument.

5.2.4.3 Barthel Index (BI)

The ten-item Barthel Index (BI) was used to assess change in ADL performance at baseline, two weeks, four weeks, and eight weeks in both the intervention and control groups. The BI was chosen as both studies that previously used NMES application to the trunk in clients with stroke had used a Korean version of the Modified Barthel Index to measure ADL performance. Moosajie (70) used the BI to measure ADL performance in their sample of stroke that had FES applied to the abdominal muscles.

The BI, first developed in 1965 by Mahoney and Barthel, measures functional independence in ADLs across ten items, such as feeding, wheelchair and bed transfers, personal toilet (personal care), toilet transfer, bathing, walking, stair climbing, dressing, and bladder and bowel control (252–254). Each item is scored out of ten, with three increments: zero score if unable to perform the activity, a score of five if able to perform the activity with assistance and ten if able to perform the task independently. The highest score can reach 100; a higher score indicates better independence in ADLs.

The BI is widely cited and used in stroke trials (255,256), including prognostic studies to determine ADL outcomes (222,257). The BI is known to have good convergent validity with the Modified Rankin Scale (MRS) (253,258). It has good inter-rater reliability (Kendall's coefficient of concordance =0.93), test-retest reliability (259), and concurrent validity with the Frenchay Activities Index (FAI) (260).

For more information, please refer to the instrument in Appendix XV.

5.2.4.4 EQ-5D-3L

The European Quality of Life Five domain three-level (EQ-5D-3L) was used to assess health-related quality of life in the intervention and control groups at baseline, two weeks, four weeks, and eight weeks.

The EuroQol EQ-5D-3L consists of 5 domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each with three levels of severity (no problems, moderate problems and severe problems) for rank ordering to describe their health state in each domain (261). It contains a Visual Analogue Scale (VAS) (measured out of 100), which measures the subjective description of the participant's health state, ranging from zero or "worst imaginable health state" to 100 or "best imaginable health state" (261). A higher VAS score, therefore, indicates a better health state (261).

The EQ-5D-3L shows good concurrent validity with modified single questions in the FAI, Hospital Anxiety and Depression Scale (HADS) and a VAS pain scale when patients could complete questionnaires themselves and by patients assessed by an interviewer (262). Please refer to the instrument in Appendix XVII for more information.

5.2.4.5 Physiological Cost Index (PCI)

The physiological cost index of gait (PCI) was used to measure all participants' energy expenditure with gait at four weeks and eight weeks. These time points were chosen as it was predicted that all the participants would be able to start walking at this point of the study compared to a baseline or after two weeks. Developed in 1979 by MacGregor, it is calculated as follows (263):

$$PCI = \frac{\text{walking heart rate (beats/minute)} - \text{resting heart rate (beats/minute)}}{\text{Walking speed (metres/minute)}}$$

Study participants walked a distance of 10m from a static start, with or without an assistive device, depending on the patient's functional ability, to complete the PCI. Using a heart rate monitor, the participant's heart rate was taken at baseline (resting heart rate) and immediately after they completed the 10m distance (walking heart rate), the 10m walk was also timed in seconds. The baseline was from standing, with or without an assistive device.

A higher score means more energy is utilised when walking or walking is more effortful, and a lower score indicates less energy expenditure.

The PCI is valid when used in stroke patients (264), has a good correlation with oxygen cost and thus can be used as an oxygen cost index (263). It showed limited reliability and validity compared to VO2 measurements in stroke survivors but may be useful in clinical situations (265) as it is simpler and inexpensive (266).

5.2.4.6 Functional Electrical Stimulation (FES) and Placebo FES

The Microstim 2 (v2) (Odstock Medical Limited, Salisbury, Wiltshire was utilised. Stimulation settings are pre-programmed into the machine; therefore, settings such as frequency ramping up or down cannot be manually adjusted, and the user would need to choose the preprogrammed settings. Stimulation is provided once the intensity dial is moved manually from zero to one; intensity increases to increment eight. The machine also makes an audible beep once switched on.

Settings: 40Hz frequency on simultaneous mode (mode one on the stimulator). Simultaneous mode means two outputs via two channels run simultaneously, so two muscle groups can be stimulated simultaneously. For this study, only one output was chosen to stimulate the hemiplegic EO only. As per Figure 3 in section 4.2.3.4., the output in the mode has a gradual increase of intensity with a two-second ramp-up. The output then remains at this intensity for 10 seconds, and then there is a gradual decrease for two seconds to no output (zero output) provided for two seconds before the same cycle repeats itself. With the gradual ramp-up and down of output, this mode accommodates any spasticity that occurs when activating movement.

Electrode placement: As determined in chapter four, two cm superior and two cm medial to ASIS (42) and the eighth intercostal space on the hemiplegic EO only.

Placebo FES: Stimulation is provided from intensity increments (via a manual dial) numbers from zero to eight; the machine rests at increment zero when not used. When the device is turned on, the dial must be moved from increment zero to increment no. one to provide stimulation. Therefore, placebo FES was defined as switching the machine on, but stimulation was not provided: the dial was not turned up from increment zero to increment one.

5.2.5 Procedure

5.2.5.1 Study Personnel

The MSc student researcher (TS) was employed at the facility, was formally trained in FES use, and used FES routinely in treatment as part of her work in treating clients. TS would be part of the cohort of physiotherapists (therapist-participants) that would be treating the patient-participants in the pilot study. Therefore, TS was responsible for baseline assessments and randomising the patient-participants. A blind research assistant (a qualified physiotherapist – (MSM)) who didn't work at the facility was recruited as part of the study personnel to conduct all assessments at week two, week four and week eight. The research assistant was blinded to participant allocation. To determine agreement in the scoring of the outcome measures between TS and MSM, TS and MSM scored three patients not involved in the study two weeks before the start of the study, using all the outcome measures described in 5.2.4. except for PCI, 100% agreement was reached in all scores.

The patient-participants were assigned to the respective physiotherapists according to the processes at the facility so as not to disrupt operations. Therefore, a physiotherapist (therapist-participants) could have a patient-participant in the control group and/or a patient-participant in the experimental group as part of the group of patients they would be managing.

The physiotherapists (therapist-participants) who consented to be part of the study received basic training from the researcher on applying FES to the abdominals. The day before the first patient-participant was seen, TS provided one-on-one training with the physiotherapist (therapist-participant) using another physiotherapist (therapist-participant) as a model. TS went through electrode placement, how to operate the machine and the difference between applying FES for intervention and control patient-participants. Therapist-participants were instructed to use the FES throughout the intervention session, remove the electrodes, and monitor the patient-participant for any reactions or adverse events. The researcher observed the first intervention with the patient-participant and gave feedback to the therapist-participant to ensure that the interventions were applied consistently with the instructions. A written description of correct placement was placed in each patient participant's electrode pack for the therapist-participants to use as a reference for placement throughout data collection.

For experimental group patient-participants, the therapist-participants were instructed to turn on the machine to increase intensity by turning the dial past increment number one until increment number two or three, at a maximum of four. For placebo group participants, the therapist-participants were instructed to turn the machine on but not to turn the dial for intensity past increment number one, therefore not providing stimulation.

5.2.5.2 Data Collection Period

The average length of stay for stroke patients at the rehabilitation centre was six to eight weeks. To ensure patient participants were available for the entire intervention period, the first seven weeks of admission and approximately one month post-discharge (for the follow-up assessment) was identified as the data collection period. Patients are admitted every day of the week, and during the first three weeks at the facility from admission, patients are assessed by their therapists and a comprehensive rehabilitation plan is drawn up based on these assessments and discussed with the patient in a goal discussion meeting, after that a discharge date is set. To accommodate these processes, patient recruitment and baseline measurement took place at the end of the third week of admission to the facility.

The researcher (TS) contacted the physiotherapist who assigned patients to the relevant therapy team (physiotherapist, occupational therapist, speech therapist) on a Friday of every week to find new recruitment participants. TS then contacted the relevant treating physiotherapist, occupational therapist, and, if necessary, the speech therapist to determine if the newly admitted participant met the inclusion and exclusion criteria. If the patient-participant met the inclusion criteria, TS then met with the patient-participant to obtain informed consent. The study protocol was discussed with the patient-participant. The patient-participant was given an information sheet and a minimum of 24 hours to consider whether to participate. TS followed up with them the next day. Written and signed consent was obtained from the patient-participant. If the patient-participant wished for a family member or carer to be included in the discussion, TS would arrange to come back during visiting hours and contact the nominated family member or carer to inform them of the request.

Assessments were conducted at baseline (enrolment into the study), two weeks into the intervention, and four weeks. The final assessment was at eight weeks of enrolment (after discharge) to explore if there was any long-term effect (refer to Figure 1 below). It is unclear what the recommended typical intervention period is for FES-assisted gait; from the literature, FES stimulation can range between two weeks and three months (267). Pragmatically, four weeks of intervention was chosen for this study because the WCRC has a seven to eight-week admission period for patients, ensuring that as many patient-participants as possible remain in the study for the intervention period.

If patient-participants were discharged, transferred, or passed away before seven weeks (to accommodate for the facility admission period of eight weeks) or transferred to another facility before week four, they were excluded from the study because they would not complete the stipulated intervention period of four weeks for FES or placebo FES.

5.2.5.3 Informed Consent

The researcher obtained informed consent from patient-participants who passed the MOCA assessment. Patient-participants with expressive aphasia underwent the consent process with the researcher and the speech therapist present to verify that the patients could grasp the information discussed, guide the best way to facilitate true informed consent with the patient and prevent therapeutic misconception by the patient-participants (239). If patient-participants could not fully comprehend the concepts in the informed consent process or did not pass the MOCA, their family member was contacted to meet with the researcher and provide consent by proxy.

5.2.5.4 Screening

A sensory screening assessment was conducted before enrolment. The FES electrodes were placed on both sides of the trunk initially; the researcher tested the non-hemiplegic side first to determine the patient-participant's stimulus level (intensity measured out of eight as there are eight intensity settings on the stimulator) for sensation and then tested the non-hemiplegic side to determine if they could sense the stimulus and at which intensity. If the patient-participant only sensed the stimulus at an intensity greater than four on either side, they were excluded from the study. Patient-participants who sensed the stimulation only past intensity four were deemed poor or had no sensation, and stimulation may be harmful.

5.2.5.5 Stratification and Randomisation

The researcher stratified patient-participants into three groups according to their baseline RMA gross function (RMA-GF) score to prevent unequal allocation of mildly impaired or severely impaired patient-participants into either group. The three groups were 1) the low-functioning group, those who scored between one and five; 2) the middle-functioning group, those who scored between six and nine; and 3) the patient-participants were assigned to the high-functioning group if they scored between ten and thirteen.

Each patient-participant in each category received a random number, using the rand between function on EXCEL, between one and forty. A staff member working at the centre who was not involved in the study completed the randomisation. According to this random number, patient-participants were then placed into experimental or control groups, where the experimental group was from numbers one to twenty, and the placebo group was from twenty-one to forty. This process resulted in an unequal distribution of patient-participants between the two groups, with seven patient-participants allocated to the experimental group and five to the control group.

5.2.5.6 Baseline assessment

In session 1, the researcher completed the baseline assessments of the participants using the above outcome measures (TIS, RMA, BI and EQ-5D). PCI was not completed as none of the participants could walk on admission.

5.2.5.7 Experimental and Placebo Intervention

Four weeks of stimulation were provided. Treatment session lengths were between 30 to 45 minutes each, completed an average of three times a week, within a range of twice to four times a week. The physiotherapist attached electrodes to the patient's hemiplegic EO at the start of the treatment session.

If the patient was in the experimental group, the machine was turned on, and the intensity increased until the patient could feel a stimulation and was comfortable. The machine was left on while they completed their conventional physiotherapy treatment activities (described in Chapter 3.) with their physiotherapist. At the end of the session, the physiotherapist switched off the machine and removed the electrodes.

If the patient was in the control group, the same process was followed per experimental group participants, except the machine was turned on. Still, the intensity was not turned up, so stimulation was not provided. Both groups received conventional physiotherapy (as described in Chapter 3).

5.2.5.8 Re-Assessments

A research assistant (blinded to participant group) reassessed all participants at two-week intervals. The TIS, RMA, BI and EQ-5D were completed at week two of the study, which was the end of week five of the patient-particpant's admission. The TIS, RMA, BI, EQ5D and PCI were completed at week four (end of week seven of admission) and week eight of the study. The PCI was incorporated at weeks four and eight because most patient-participants could start walking. All baseline and reassessments were completed in a separate gym, away from the therapy areas.

5.2.5.9 Follow-up

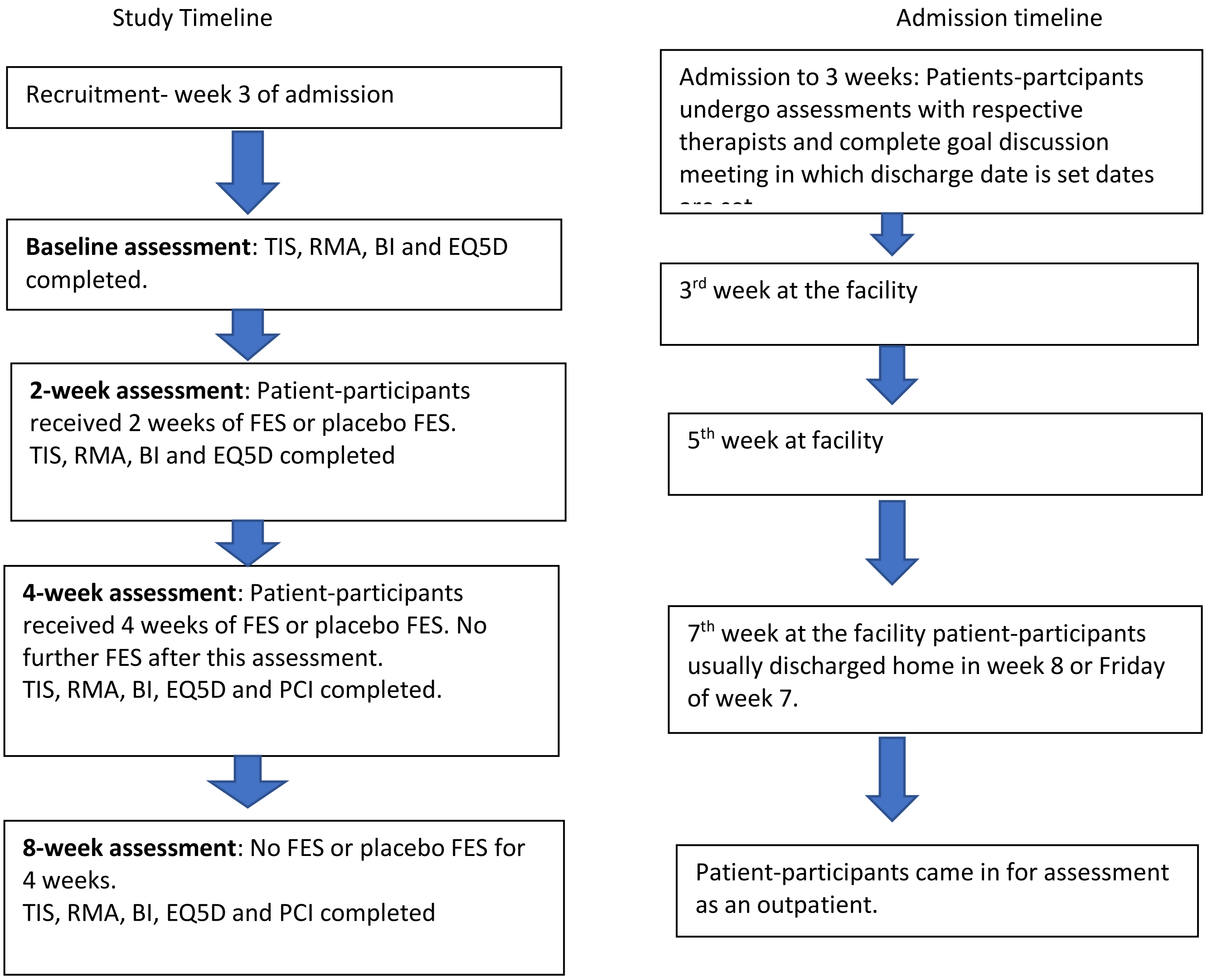


Figure 11: Study Timeline and Admission timeline for participants in control and intervention groups.

Please refer to Figure 11 above to represent the study timeline during the participants' admission. No FES or placebo FES was provided from week four to week eight. The week eight assessment was approximately one-month post-discharge; therefore, patient-participants would be at home. At the week four assessment, the researcher (TS) provided a date and time for the patient-participants to follow up for the week eight assessment. The eight-week follow-up appointment was conducted at the rehabilitation centre. TS phoned the patient-participants one week before the week eight assessment to remind them of the date and time.

5.3 Statistical Analysis

Statistica version 13.5 was used to complete data analysis. Analysis was focused on two components: The profile of experimental and control groups and the impact of the intervention.

5.3.1 Profile of experimental and control groups

Descriptive statistics (means, SD, frequencies) were used to summarise the data related to patient characteristics. Pearson's Chi-square test was used to examine group differences concerning gender and side of hemiplegia. The data related to the intervention was first checked for normality by conducting the Shapiro Wilks test. If the p value was ≤ 0.05 for the test , we treated the dataset as not normally distributed. Following the check for normality, we used the t-test for normally distributed data and non-parametric equivalents for not-normally distributed data. Medians and IQR were used to describe non-normally distributed data. The t-test was used to compare groups with normally distributed data and was described as means with standard deviations.

5.3.2 Impact of Intervention

Data was first checked for normality using the Shapiro-Wilks test. Non-parametric statistics were used to compare groups and test associations between variables where data was not normally distributed.

Summary statistics of the outcomes of interest were described and presented as mean and standard deviation (SD) or median and interquartile range (IQR) depending on the distribution of the variable. The departure from normality among the outcome variables was tested using the Shapiro-Wilks test (the null hypothesis of normality was rejected when the p-value ≤ 0.05). The Mann-Whitney U test was used to compare the differences between two groups in cases where the sample distributions were not normally distributed. The two-sample independent t-test was used to compare groups when the data set under study was normally distributed. These analyses are useful to report on as they give the mean difference in the rank sum of the two groups at specific time points (baseline, two weeks, four weeks, and eight weeks). The cut-off value for statistical significance was $p \leq 0.05$. Treatment effect sizes between the experimental and control groups were calculated using Cohen's d statistic for normally distributed data and calculating for r ($r = z/\sqrt{N}$) using the Mann-Whitney U test. A small effect size was interpreted at ≤0.2, a medium effect size was understood at 0.5 (between 0.2 and 0.5) and a large effect size was taken at 0.8 (268).

Linear models using Generalized Estimating Equations (GEE) with a first-order auto-regressive (AR1) correlation structure were fitted to estimate the effect of time and intervention on the outcomes of interest. The approach was used because the outcome variables were repeated measurements; hence, the estimates were adjusted for clustering due to the study participants. Both univariable and multivariable GEE were used to estimate the effect of the intervention and time on the outcomes of interest. An interaction term between the intervention and time was added to the multivariable model to determine how the outcomes change with time in the two experimental groups. All the estimates were presented with a 95 % confidence interval, and the statistical significance cut-off value was $p \leq 0.05$. The GEE is useful with repeated measures like our study, where the interaction between group and time can be reported.

5.4 Results

5.4.1 Recruitment and Patient Characteristics

32 patients met the inclusion criteria. The enrolment details are given in the flow chart, figure 12 below.

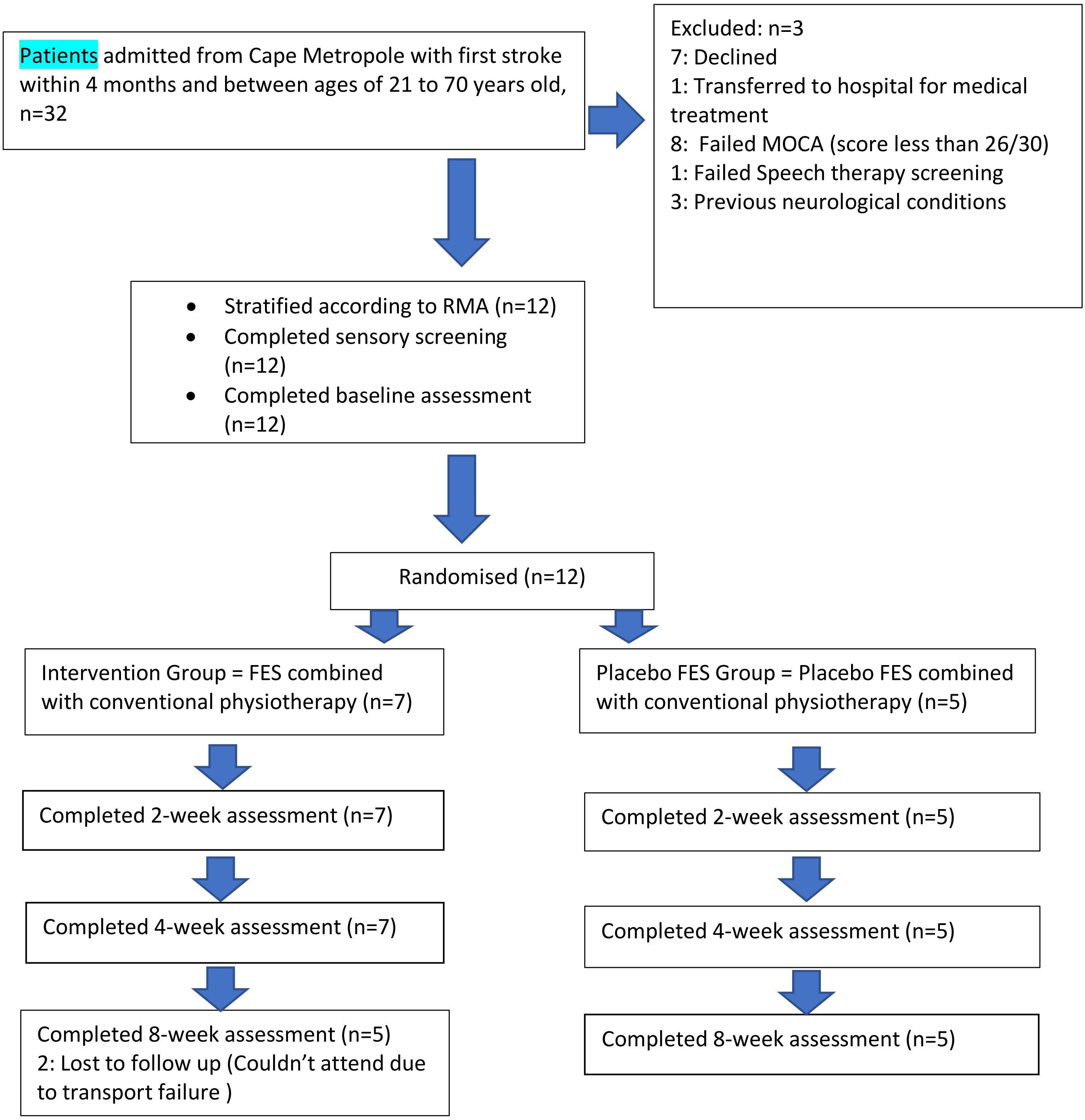


Figure 12: Patient recruitment

5.4.2 Profile of experimental and control groups

The Shapiro-Wilks test showed that age was normally distributed (W=0.92; p=0.29). The Experimental (EXP) group consisted of seven participants (five female), mean age 41.71 years (SD=9.63), and the Control group (CON) consisted of five participants (two female), mean age 50,80 years (SD=14.13). No significant differences were found between groups regarding mean age at baseline (t=-1.33; d=10;

p=0.21) or gender distribution (Chi^2=1.18; df=1, p=0.28). Four participants in the experimental group had right-sided hemiplegia and three in the control group. No significant differences were found with regard to hemiplegic side (Chi^2 =0.34; p=0.56).

In terms of stratification according to the RMA-GF, the experimental group (n=7) had four participants in the low functioning group, two in the middle functioning group and one in the high functioning group. The control group (n=5) had two participants in the low functioning group, two in the middle-functioning group and one in the high-functioning group.

5.4.3 Impact of the Intervention

Six outcomes were evaluated: the TIS total score, the RMA GF, RMA LT and RMA-Arm, the BI Total score, the EQ-5D-3L VAS score, PCI Gait and PCI total score. For more information on subcomponent scores (e.g. TIS static, dynamic and coordination; EQ-5D-3L domain scores and BI items etc- see Appendix x).

The differences between the control and experimental groups per outcome are presented first (table 18). The effect of time and intervention on each outcome will be presented (table 19 with Figure 4 and Table 20 with figure 5).

5.4.3.1 Between Group Differences

Table 19 below shows the difference between means and medians for TIS total, RMA-GF, RMA LT, RMA Arm, BI Total and EQ-5D-3L VAS, and PCI Gait Speed and PCI total at four and eight weeks for the intervention and control groups.

Table 19: Difference between control and intervention group at baseline, two weeks, four weeks and eight weeks (means and medians) p≤0.05 for TIS total using the two-sample t-test for parametric data , and the Mann Whitney U test for non-parametric data for RMA-GF, RMA LT, RMA Arm, BI Total and EQ-5D-3L VAS, and PCI Gait Speed and PCI total at four and eight weeks.

		Baseline	2 weeks	4 weeks	8 weeks
TIS total		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
	Control Group (n=5)	14.80 (0.84)	15.8 (4.55)	17.6 (1.82)	18 (1.73)
	Experimental Group (n=7)	12.57 (3.31)	15.57 (3.69)	16.14 (4.22)	16.14 (4.34)
	p value	0.18	0.93	0.49	0.39
	t value	1.45	0.1	0.72	0.9
	Effect size	0.85	0.06	0.42	0.53
RMA GF		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
	Control Group (n=5)	8 (3.32)	10 (3.32)	10.8 (2.39)	11.6 (1.14)
	Experimental Group (n=7)	5.71 (2.29)	6.29 (2.98)	7.86 (2.73)	9 (2.38)
	p value	0.19	0.07	0.08	**0.05**
	t value	1.42	2.03	1.93	2.24
	Effect size	0.83	1.19	1.13	1.31
RMA LT		Mean (SD)	Mean (SD)	Median (IQR)	Mean (SD)
	Control Group (n=5)	8.2 (1.3)	7.2 (2.68)	9 (6)	9.2 (1.1)
	Experimental Group (n=7)	5.43 (2.07)	6.86 (2.55)	8 (6)	7.14 (3.24)
	p value	**0.03**	0.83	0.64	0.21
	t value or z value	t= 2.63	t= 0.13	z=-0.58	t= 1.35
	Effect Size	1.54	0.132	-0.17	0.79
RMA Arm		Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)

	Control Group (n=5)	0 (7)	3 (7)	4 (9)	11 (10)
	Experimental Group (n=7)	3 (13)	8 (12)	11 (12)	10 (11)
	p value	0.27	0.53	0.88	0.88
	z value	-1.28	-0.73	-0.25	-0.25
	Effect Size	-0.37	-0.21	-0.07	-0.07
BI total		Mean (SD)	Mean (SD)	Median (IQR)	Median (IQR)
	Control Group (n=5)	76 (16.36)	91 (7.42)	100 (13)	100 (5)
	Experimental Group (n=7)	70 (20.41)	77.86 (17.53)	85 (30)	95 (25)
	p value	0.6	0.15	0.15	0.43
	t value or z value	t= 0.54	t= 1.56	z= -1.5	z= -0.89
	Effect size	0.32	0.92	-0.43	-0.26
EQ5D VAS		Median (IQR)	Median (IQR)	Mean (SD)	Mean (SD)
	Control Group (n=5)	50 (45)	95 (35)	82 (19.24)	81 (19.49)
	Experimental Group (n=7)	80 (30)	80 (30)	80.71 (18.8)	82.86 (14.96)
	p value	0.53	0.64	0.91	0.86
	t value or z value	z= -0.67	z= -0.5	t= 0.12	t= -0.19
	Effect size	-0.19	-0.14	0.07	-0.11
PCI Gait Speed (metres per minute)				Mean (SD)	Mean (SD)
	Control Group (n=5)			0.91 (0.25)	0.92 (0.2)
	Experimental Group (n=7)			0.49 (0.36)	0.61 (0.42)
	p value			0.05	0.12
	t value			2.26	-1.73

	Effect Size			1.32	0.89
PCI Total (beats per minute/metres per minute)				Median (IQR)	Median (IQR)
	Control Group (n=5)			0.91 (9.02)	8.16 (12.52)
	Experimental Group (n=7)			17.79 (47.56)	21.48 (32.21)
	p value			**0.02**	**0.03**
	z value			-2.36	-2.19
	Effect Size			-0.68	-0.63

TIS = Trunk Impairment Scale, RMA-GF = Rivermead Motor Assessment Scale Gross Function, RMA LT= Rivermead Motor Assessment Scale Leg and Trunk section, RMA Arm = Rivermead Motor Assessment Scale Arm section , BI = Barthel Index, EQ-5D-3L VAS= European Quality of Life five domain three level Visual Analogue Scale, PCI= Physiological Cost Index of Gait, PCI Gait Speed= Physiological Cost Index of Gait – gait speed component

5.4.3.1.1 Trunk Impairment Scale (TIS)

TIS scores over the intervention period were identified to be normally distributed using the Shapiro Wilks Test, please see results in table 23 in Appendix I. At baseline the total TIS mean scores were different between the intervention group and the control group, but this difference was not statistically significant (p=0.18) Overall, the mean total TIS score showed improvement in both the control group and the intervention group across all time intervals from baseline (week two, four and eight), however the difference between groups at each time point was not statistically significant (Table 19).The effect size between groups started with a large effect size at baseline (Cohen's d=0.85), however as the study continued the treatment effect tapered off to a small effect size at two weeks (Cohen's d=0.06) and a medium effect size at four weeks (Cohen's d=0.42) and eight weeks (Cohen's d=0.53) (Table 19).

5.4.3.1.2 Rivermead Motor Assessment Scale (RMA)

The Rivermead Motor Assessment Score – Gross Function (RMA-GF) scores GF scores were normally distributed at all time intervals. The Rivermead Motor Assessment Score – Leg and Trunk (LT) were normally distributed at baseline, two weeks and eight weeks but not normally distributed at four weeks. The Rivermead Motor Assessment Scores for Arm (RMA Arm) were not normally distributed at all time intervals (table 23 in Appendix I.)

The mean RMA-GF scores in the experimental and control groups were different at baseline, however this difference was not statistically significant (p=0.19). The control group and the intervention group showed improvement at week two and four, however the difference between groups at each timepoint was not statistically significant (Table 19). A significant difference was found between groups at week eight, where the control group mean (mean=11.60(SD=1.14)) was higher than the experimental group mean(mean=9.00(SD=2.38)) (t=2.24;p=0.05) with a large effect size (Cohen's d=1.31). The effect size between groups started with a large effect size at baseline (Cohen's d=0.83) and remained large at each timepoint as the study continued (Table 19).

At baseline the RMA Arm scores were different between the intervention group and the control group, but this difference was not statistically significant (p=0.27). The median RMA Arm scores showed improvement in both the control group and the intervention group across all time intervals from baseline (week two, four and eight), however the difference between groups at each time point was not statistically significant and the effect size was small (r= -0.07)(table 19).

There was a significant difference between groups at baseline between the RMA LT control group mean (mean=8.20(SD=1.30)) and the experimental group mean (mean=5.43(SD= 2.07)). The control group started with a better RMA LT score than the experimental group (t=2.63; p=0.03). There was a large effect size was (Cohen's d=1.54) at baseline. The effect size then tapered down to small at week two and week four and then at eight week it was large again (Cohen's d=0.79), although this was less than at baseline (table 19).When comparing total RMA-LT scores at two weeks, four weeks and eight weeks, there was improvement in both the control group and the intervention group across all time intervals (week two, four and eight), however the differences between groups at each time point was not statistically significant (table 19).

5.4.3.1.3 Barthel Index (BI)

The BI total scores were normally distributed at baseline and week two, but were not normally distributed at week four and eight (table 22 in Appendix I). There was no significant different between the control and intervention group at baseline (p=0.6). The mean BI total scores showed improvement in both the control group and the intervention group between baseline and week two, but this was not significant, and the effect size was initially medium (Cohen's d= 0.32) at increased to large at week two (Cohen's d= 0.92). The median BI scores remained the same at week four and week eight in the control group and the experimental group BI scores showed an improvement, however the differences between scores at these time points were not significant and the effect sizes remained small (table 18).

5.4.3.1.4 EQ-5D-3L VAS

EQ-5D-3L VAS scores were not normally distributed at baseline and week two, but were normally distributed at week four and eight (table 22 in Appendix I). Analysis at domain level was completed (see Appendix V). At baseline the median EQ-5D-3L VAS score was not significantly different between groups (p=0.53). The control group showed improvement in scores over the time intervals while the experimental group showed a stabilisation of scores, however the differences at these time intervals (two weeks, four weeks, and eight weeks) were not statistically significant between the two groups with small treatment effect sizes (table 18) .

5.4.3.1.5 Physiological Cost Index of Gait (PCI)

The PCI gait scores were normally distributed at week four and week eight and the PCI total scores were not normally distributed at these two time points (table 22 in Appendix I)

There was a significant difference between groups in PCI gait speed scores at week four where the control group (mean =0.91 (SD=0.25) had a higher mean score then the experimental group (mean =0.49 (SD=0.36))(t=2.26;p=0.05) with a large effect size (Cohen's d= 1.32).At eight weeks, the control group had a higher mean score then the experimental group, but this was not significant and the effect size remained large (table 18).

There was a significant difference between groups in PCI total scores at week four and week eight, where the experimental group had a higher median score compared to the control group (17.79 (IQR=9.02) vs 0.91 (IQR=47.56)) (z=-2.36,p=0.02) at week four and (21.48 (IQR=12.52) vs 8.16 (IQR=8.16))(z=-2.19;p=0.03)) at week eight . The effect was r= 0.68 and r=0.63 respectively meaning that there was a medium effective size (table 18).

5.4.3.2 *The Impact of Time and Intervention Within Each Group*

From baseline to four weeks:

Table 20 and Figure 13. below demonstrates using a generalized linear model (GLM) the effect of time and the intervention on both control and intervention groups from baseline to four weeks (the four weeks of intervention).

Table 20: GLM of control (group 0) and intervention groups (group 1) for all outcome measures for TIS Total, RMA GF, RMA LT, RMA Arm, BI and EQ5D VAS for the intervention period (from baseline until four weeks) p≤0.05

		Univariate model (Unadjusted)		Multivariate model (Adjusted)	
		estimate (95% CI)	**p.value**	**estimate (95% CI)**	**p.value**
TIS total					
Intervention	Group 0	1.00	-	1.00	-
	Group 1	-1.48 (-4.05,1.09)	0.26	-2.33 (-5.15,0.49)	0.11
Time	Time (weeks)	1.63 (1.01,2.24)	<0.01	1.40 (0.46,2.34)	<0.01
Interaction	Group 1*Time	-	-	0.39 (-0.84,1.61)	0.54
RMA GF					
Intervention	Group 0	1.00	-	1.00	-
	Group 1	-2.76 (-5.48,-0.04)	0.05	-2.04 (-5.67,1.58)	0.28
Time	Time (weeks)	1.21 (0.73,1.69)	<0.01	1.40 (0.65,2.15)	<0.01
Interaction	Group 1*Time	-	-	-0.33 (-1.30,0.64)	0.51
RMA LT					
Intervention	Group 0	1.00	-	1.00	-
	Group 1	-1.53 (-4.04,0.97)	0.02	-3.73 (-5.29,-2.17)	<0.01
Time	Time (weeks)	0.33 (-0.29,0.96)	0.3	-0.30 (-1.28,0.68)	0.55
Interaction	Group 1*Time	-	-	1.09 (-0.08,2.25)	0.07
RMA Arm					
Intervention	Group 0	1.00	-	1.00	-
	Group 1	2.76 (-2.57,8.80)	0.31	4.35 (-1.43,10.1)	0.14
Time	Time (weeks)	1.33 (0.52,2.14)	0.001	1.80 (0.64,2.96)	<0.02

Interaction	Group 1*Time	-	-	-0.80 (-2.37,0.77)	0.32
BI					
Intervention	Group 0	1.00	-	1.00	-
	Group 1	-9.20 (-22.3,3.94)	0.17	-4.12 (-29.7,21.5)	0.75
Time	Time (weeks)	8.13 (4.38,11.9)	<0.001	9.50 (2.38,16.6)	<0.01
Interaction	Group 1*Time	-	-	-2.36 (-10.4,5.70)	0.57
EQ5D VAS					
Intervention	Group 0	1.00	-	1.00	-
	Group 1	1.64 (-17.20,20.4)	0.86	9.36 (-21.00,39.8)	0.55
Time	Time (weeks)	4.79 (0.08, 9.50)	0.05	7.00 (-3.22,17.2)	0.18
Interaction	Group 1*Time	-	-	-3.79 (-14.4,6.85)	0.49

*TIS = Trunk Impairment Scale, RMA-GF = Rivermead Motor Assessment Scale Gross Function, RMA LT= Rivermead Motor Assessment Scale Leg and Trunk section, RMA Arm = Rivermead Motor Assessment Scale Arm section , BI = Barthel Index, EQ-5D-3L VAS= European Quality of Life five domain three level Visual Analogue Scale.

Footnote

Estimate: change in mean of the outcome variable

95% CI: 95% confidence interval

Univariable models were bivariate models between main outcome and independent variables (intervention and time)

Multivariate models included the intervention variable, the time (weeks) and the interaction between the intervention and time variables

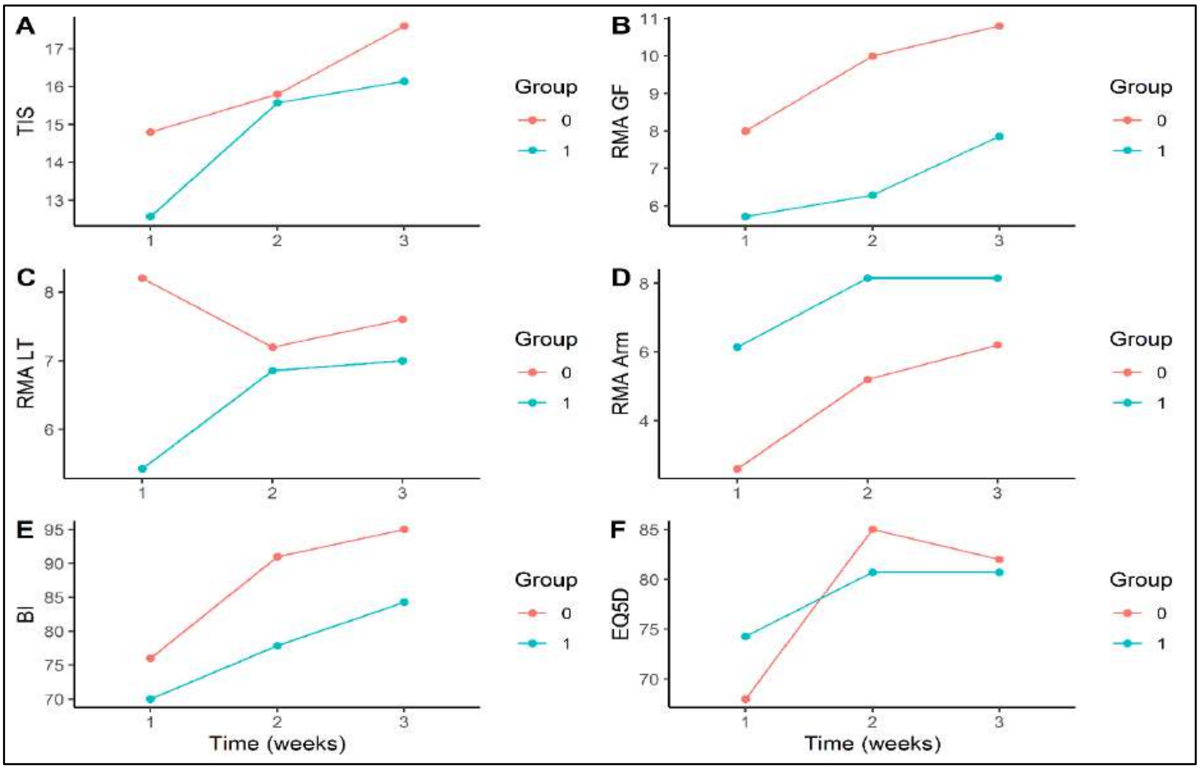


Figure 13 : Change in the outcomes between baseline (1), two weeks (2) and four weeks (3) within the experimental (group 1) and control (group 0) groups.

***TIS** = Trunk Impairment Scale, RMA-GF = Rivermead Motor Assessment Scale Gross Function, RMA LT= Rivermead Motor Assessment Scale Leg and Trunk section, RMA Arm = Rivermead Motor Assessment Scale Arm section, BI = Barthel Index, EQ-5D-3L = European Quality of Life five domain three level

From four weeks to eight weeks (no intervention was provided):

Table 21 and Figure 14. below demonstrate using a generalized linear model (GLM) the effect of time and the intervention on both control and intervention groups from four weeks baseline to eight weeks (the period when no intervention was provided).

Table 21: GLM to examine the effect of group, time, and group x time from four weeks (end of intervention) to eight weeks for all outcome measures (TIS Total, RMA GF, RMA LT, RMA Arm, BI, EQ5D VAS and PCI gait speed and total PCI)(p ≤0.05)

		Univariate model		Multivariate model	
		estimate (95% CI)	p.value	estimate (95% CI)	p.value
TIS total					
Intervention	Group 0	-	-	-	-
	Group 1	-1.66 (-4.59,1.27)	0.27	-0.257 (-10.4,9.91)	0.96
Time	Time (weeks)	0.17 (-1.33,1.66)	0.83	0.40 (-1.23,2.03)	0.63
Interaction	Group 1*Time	-	-	-0.40 (-3.20,2.40)	0.78
RMA GF					
Intervention	Group 0	-	-	-	-
	Group 1	-2.77 (-4.95,-0.60)	0.01	-3.97 (-10.5,2.53)	0.23
Time	Time (weeks)	1.0 (0.27,1.73)	0.01	0.80 (-0.22,1.82)	0.13
Interaction	Group 1*Time	-	-	0.34 (-1.09,1.78)	0.64
RMA LT					
Intervention	Group 0	-	-	-	-
	Group 1	-1.33 (-4.01,1.35)	0.33	3.77 (-7.22,14.80)	0.50
Time	Time (weeks)	0.75 (-0.56,2.06)	0.26	1.6 (-0.79,3.99)	0.19
Interaction	Group 1*Time	-	-	-1.46 (-4.17,1.25)	0.29
RMA Arm					
Intervention	Group 0	-	-	-	-
	Group 1	1.46 (-4.03,6.95)	0.60	4.86 (-8.07,17.8)	0.46
Time	Time (weeks)	1.83 (0.19,3.48)	0.03	2.40 (-0.24,5.04)	0.08
Interaction	Group 1*Time			-0.97 (-4.31,2.37)	0.57
BI					
Intervention	Group 0	-	-	-	-
	Group 1	-9.00 (-18.6, 0.65)	0.07	-21.0 (-48.8,6.75)	0.14

Time	Time (weeks)	5.00 (1.73,8.27)	0.003	3.00 (-2.26,8.26)	0.26
Interaction	Group 1*Time	-	-	3.43 (-3.07,9.93)	0.30
EQ5D VAS					
Intervention	Group 0	-	-	-	-
	Group 1	0.29 (-18.4,18.9)	0.98	-10.70 (-48.5,27.1)	0.60
Time	Time (weeks)	0.83 (-3.91,5.57)	0.73	-1.00 (-5.29,3.29)	0.65
Interaction	Group 1*Time	-	-	3.14 (-5.39,11.7)	0.47
PCI Gait					
Intervention	Group 0	-	-	-	-
	Group 1	-0.37 (-0.68, -0.06)	0.02	-0.79 (-1.44, -0.14)	0.02
Time	Time (weeks)	0.08 (-0.006,0.163)	0.07	0.008 (-0.14,0.15)	0.91
Interaction	Group 1*Time	-	-	0.12 (-0.05,0.29)	0.16
PCI Total					
Intervention	Group 0	-	-	-	-
	Group 1	30.1 (8.31,51.90)	0.01	23.5 (-117.0,164.0)	0.74
Time	Time (weeks)	6.75 (-17.3,30.8)	0.58	5.65 (0.42,10.9)	0.03
Interaction	Group 1*Time	-	-	1.90 (-39.0,43.3)	0.93

*TIS = Trunk Impairment Scale, RMA-GF = Rivermead Motor Assessment Scale Gross Function, RMA LT= Rivermead Motor Assessment Scale Leg and Trunk section, RMA Arm = Rivermead Motor Assessment Scale Arm section , BI = Barthel Index, EQ-5D-3L VAS= European Quality of Life five domain three level Visual Analogue Scale, PCI= Physiological Cost Index of Gait, PCI Gait Speed= Physiological Cost Index of Gait – gait speed component

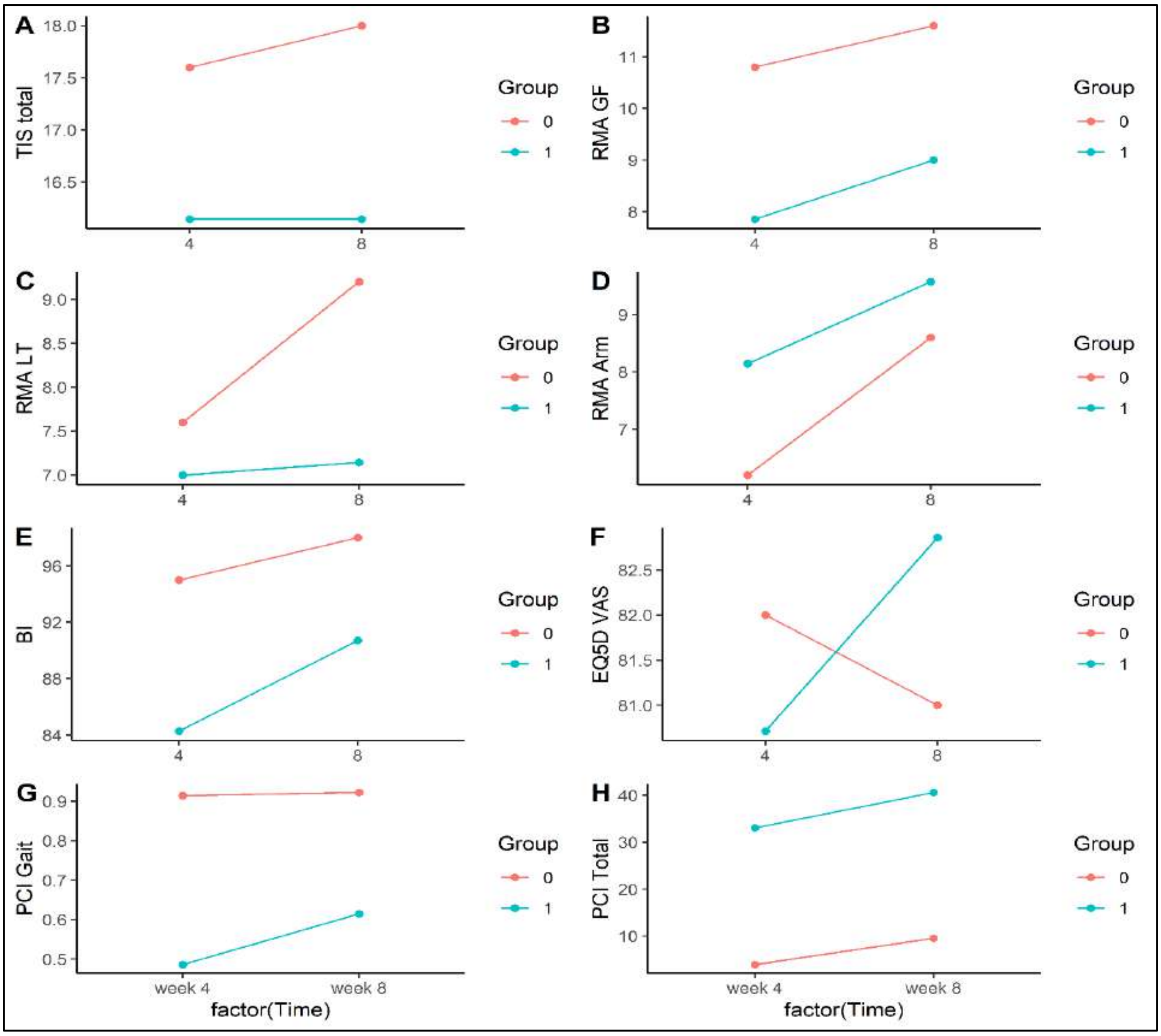


Figure 1413: Change in outcomes between 4th and 8th week with the intervention group (group 1) and control group (group 0)

*TIS = Trunk Impairment Scale, RMA-GF = Rivermead Motor Assessment Scale Gross Function, RMA LT= Rivermead Motor Assessment Scale Leg and Trunk section, RMA Arm = Rivermead Motor Assessment Scale Arm section , BI = Barthel Index, EQ-5D-3L VAS= European Quality of Life five domain three level Visual Analogue Scale, PCI= Physiological Cost Index of Gait, PCI Gait Speed= Physiological Cost Index of Gait – gait speed component

5.4.3.2.1 Trunk Impairment Scale (TIS) Total Score

From baseline to four weeks (when intervention was provided), both groups demonstrated a significant improvement in TIS (1.40; 95% CI: 0.46,2.34; $p<0.01$). The control group showed increase of an average of 1.4 units for every unit increase in time. The experimental group scores increased by an average of 1.79 units for every unit increase in time, however, the interaction (group*time) was not statistically significant ($p=0.54$) (Table 20), indicating that one group did not change more than another. At the end of four weeks, the TIS of those in the experimental group was 2.33 units (-5.15,0.49) less than for those in the control group, however this was not significant ($p=0.11$).

From four weeks to eight weeks (when no intervention was provided), the improvement over time was not significant (0.40; -95% CI: 1.23,2.03; $p=0.63$). In the control group, the total TIS increased by an average of 0.4 units for every unit increase in time. In contrast, within the experimental group, there was no change for every unit increase in time. This interaction was not statistically significant ($p=0.78$) Table 20). At the end of eight weeks the mean TIS was 0.26 units less in the experimental group, however this was not significant ($p=0.96$) (Table 21).

5.4.3.2.2 Rivermead Motor Assessment Scale

5.4.3.2.2.1 RMA-GF

Both control and intervention group demonstrated a significant improvement over the four weeks ($p<0.01$) (table 19). The total RMA-GF in the experimental group increased by an average of 1.07 units for every unit increase in time and the control group, increased by an average of 1.4 units for every unit increase in time. However, the interaction (group*time) was not statistically significant ($p=0.51$) (table 20), indicating that one group did not improve more than the other. At the end of the intervention period the RMA-GF of the experimental group was 2.04 (-5.67,1.58) units less than for the control group, but this difference was not significant ($p=0.28$) (Table 20).

From four to eight weeks, (when no intervention was provided), the improvement over time was not significant (0.80; -95% CI: -0.22,1.82; $p=0.13$). The total RMA-GF increased by 0.8 units within the control group and by 1.14 units within the experimental group, but the interaction was not statistically significant ($p=0.64$)(Table 21). At the end of eight weeks the mean RMA-GF was 3.97 units less in the experimental group than for the control group, however this was not significant ($p=0.23$) (Table 21).

5.4.3.2.2.2 RMA-Arm

From baseline to four weeks, both groups demonstrated a significant improvement over time (1.80; 95% CI:0.64, 2.96) (p<0.02). The total RMA-Arm in the experimental group increased 1 unit for every unit increase in time, and by 1.8 units for every unit increase in time in the control group. The interaction of group*time was however not significant(p=0.32) (table 20), indicating that one group did not improve more than the other. At the end of the intervention period (four weeks), the RMA-Arm of those in the experimental group was 4.35 (-1.43,10.1) units more than those in the control group, but this was not statistically significant (p=0.14)(table 20).

When comparing the change from four weeks to eight weeks (when no intervention was provided), the improvement over time, (2.40; 95% CI: 0.24, 5.04; p=0.08) was not significant (Table 21). Within the control group, the total RMA-Arm increased by 2.4 units for every unit increase in time on average. Within the intervention group, the total RMA-Arm increased by 1.43 units for every unit increase in time, however this interaction was however not significant (p=0.57) (Table 21).

5.4.3.2.2.3 RMA-LT

During the intervention period, both groups demonstrated deterioration in the RMA-LT (-0.30, 95% CI: -1.28, 0.68) which was significant (p< 0.01). During the intervention period, the total RMA-LT decreased by 0.3 units for every unit increase in time within the control group and increased by 0.79 units for every unit increase in time within the experimental group, however the interaction effect was not significant (p=0.07) (table 20). This was likely due to the differential starting scores between the groups (Table 18). At the end of the intervention period, the RMA-LT of those in the experimental group was 3.73 (-5.29, -2.17) units less than those in the control group, which was significant (p<0.01) (table 20), indicating that the experimental group showed less improvement than the control group at the end of the intervention period.

When comparing the change from four weeks to eight weeks (when no intervention was provided), the increase in RMA-LT over time was not significant (1.6; 95% CI: -0.79, 3.99, p=0.19). At the end of the eight weeks, the RMA-LT of those in the experimental group decreased by 0.14 units and increased by 1.6 units within the control group. This interaction effect (group*time) however was not significant (p=0.29) (Table 21).

5.4.3.2.3 Barthel Index (BI)

During the intervention period, both groups demonstrated an improvement over time (9.50; 95% CI: 2.38, 16.6) (p<0.01) which was significant. Within the control group, the total BI score increased by 9.5 units on average for every unit increase in time and increased by 7.14 units in the experimental group. The interaction of group*time was not significant (p=0.57). At the end of intervention, BI of those in the experimental group was 4.12 (-29.7,21.5) units less than those in the control group, however this was not significant (p=0.75)(Table 20).

When comparing the change from four weeks to eight weeks (when no intervention was provided), the improvement seen in both groups was not significant (3.00; 95% CI: -2.26, 8.26, p=0.26). Within the control group, the total BI score increased by 3 units for every unit increase in time on average. Among those in the experimental group, BI score increased by 6.43. units for every unit increase in time), however this interaction was not significant (p=0.30). At eight weeks, the BI Total score of those in the experimental group was 21 units less than those in the control group, however this was not significant (Table 21).

5.4.3.2.4 EQ-5D-3L VAS

During the intervention period, both groups improved over time (7.00; 95% CI: -3.22, 17.2, however this was not significant (p=0.18). Within the control group, the total EQ-5D-3L VAS score increased by 7 units on average for every unit increase in time. Among those in the experimental group, the total EQ-5D-3L VAS score increased by 3.21 units for every unit increase in time. The interaction was not significant (p=0.49) (table 20). At the end of the intervention period, the EQ-5D-3L VAS score in the experimental group was 9.36 (-21.00, 39.8) more than those in the control group, but this was not significant (table 20).

From four to eight weeks (when no intervention was provided), both groups dropped scores by 1 unit (-5.29; 3.29, p=0.65), this was not significant. Among those in the experimental group, the total EQ-5D-3L VAS increased by 2.14 units for every unit increase in time, and the control group decreased by 1 unit. The interaction effect (group*time) was however not significant (p=0.47)(table 21). At the end of the eight weeks, the EQ-5D-3L VAS for those in the experimental group was 10.70 units less than those in the control group (table 21), this was however not significant (p=0.60).

5.4.3.2.5 Physiological Cost Index of Gait (PCI)

5.4.3.2.5.1 PCI Gait Speed

When comparing the change from four weeks to eight weeks (when no intervention was provided), improvement in PCI gait speed (0.01;95% CI:-0.14,0.15) was not significant (p=0.91). Among the control group, the mean PCI Gait speed increased by 0.01 unit for every unit increase in time on average, and for those in the experimental group, the total PCI Gait score increased by 0.13 units for every unit increase in time. The interaction effect was not significant (p=0.16) (Table 21).

At the end of eight weeks, the mean PCI Gait speed for those in the intervention group was 0.79 units less than those in the control group and this was significant (p=0.02)(table 21).

5.4.3.2.5.2 PCI Total

From four to eight weeks, both groups significantly improved in time (5.65; 95% CI: 0.42,10.9, p=0.03). Within the control group the mean PCI total score increased by 5.65 units on average for every unit of time. The experimental group PCI total scores increased by 7.55 units on average for every unit of time, The interaction effect was not significant (p=0.93) (Table 21).

At the end of eight weeks, the PCI total score in the intervention group was 23.5 units more than the control group, but this was not significant (table 21).

5.5 Discussion

The aim of this pilot study was to determine if FES applied to the abdominal muscles on the hemiplegic side during routine physiotherapy sessions in stroke clients, specifically EO, would result in improvements in trunk performance, motor impairments and activities of daily living and PCI of gait.

5.5.1 Summary of Main Findings

The results from this pilot study showed that there was an improvement in all scores for both groups except the RMA-LT which showed deterioration in scores. However, these improvements in scores between groups were not statistically significant (table 19). Change over time for both groups was shown to be significant for all outcome measures except the EQ-5D VAS (table 20).

This may be due to more participants in the experimental group vs. the control group; this could have affected weighting in the lower functioning group. However, the small sample size was not conducive to stratification.

According to the GLM, during the four-week intervention period, the experimental group indicated improvement in median and mean scores over time in all the outcome measures except for BI and EQ5D-VAS. However, these were not significant. Whereas the control group indicated significant improvement over unit of time for all the outcome measures except EQ5D- VAS, PCI Gait and PCI total. This suggests that the treatment effect over time of FES with conventional therapy was not significantly greater than that of conventional therapy with placebo FES.

From four weeks to eight weeks, when neither group received conventional therapy of FES in combination with conventional treatment, and participants were discharged home, the median and mean scores were mostly maintained.

The main findings for each of these categories, as measured by their respective outcome measures, will be discussed, as well as the results for HRQOL as measured by the EQ5D.

5.5.2 Sample

The sample was well matched with no significant differences in profile between the groups regarding gender, age, and hemiplegic side. Sample size calculation before the start of the study determined that seven participants per group would be necessary for adequate power. This was fulfilled in the intervention group (n=7) but not in the control group (n=5). Furthermore, two clients in the experimental group were lost to follow-up at week eight due to transport challenges. As per Table 22, however, the post hoc power analysis at week eight showed that the study was underpowered and therefore limited any conclusions on the differences between the groups because of lack of statistical power. However, we are still able to compare groups.

Table 22: Post hoc power analysis based on means and standard deviation of both groups, a sample size of n=5 (control group) and n= 7 (experimental group), at Week 8 for all outcome measures

Outcome measure	week 8 post hoc power	week 8 post hoc power (%)
TIS total	0.15	15%
RMA GF	0.61	61%
RMA LT	0.28	28%
RMA Arm	0.06	6%
BI Total	0.24	24%
EQ5D VAS	0.05	5%
PCI gait speed	0.33	33%
PCI Total	0.29	29%

In this study, female participants slightly outnumber male participants (seven vs. five). This is similar to findings by Matizirofa and Chikobvu (269) in their public health study analysing costs of stroke in South Africa from 2014 to 2018, where females (50.8%) outnumbered males (49.2%) with N= 35. 730. Moosajie (70) also reported similar gender distribution with more females (11) than males (eight), with a sample of 19 in their study exploring FES application to abdominals in stroke clients in South Africa. However, due to the small sample size in this study this does not really bear impact on the results of each group.

The average age of the participants in both the control (41.71 years) and intervention groups (50.8 years) in this study was slightly less than the average age in previous studies in South Africa by Mudzi et al. (23) (52.1 to 54.1 years) and Matizirofa and Chikobvu (269) (54.3 years). It was also less than the average age reported of participants in studies using NMES to the abdominals by Park et al. (8) , with an average age of 57.8 to 68.7 years and Ko et al. (71) with an average age of 58.5 to 65.5 years. Compared to Moosajie's (70) study, the average age of this sample is lower than the participants in their research (65 years). Younger patients are expected to show greater improvement in scores in outcome measures because the brain of a younger stroke survivor has the capacity for quicker neuroplastic changes (270). However, the TIS and BI used by Park et al. (8) and Moosajie (70) in 2012 showed significant improvement in post-experimental intervention. This could be because the participants in these two studies received experimental intervention at least daily or five times a week compared to a maximum of three times a week in this study (8,70).

The hemiplegic side distribution in this sample was similar to Moosajie's (70) study, with more participants with right hemiplegia than left hemiplegia. This was not in agreement when compared to studies by Park et al. (8) and Ko et al.(71), where there were more participants with left hemiplegia than right hemiplegia or equal distribution of hemiplegic side, respectively. However, due to the small sample size in this study this does not really bear impact on the results of each group.

5.5.3 TIS

No significant difference was found between the experimental and control groups for TIS total scores at any time point. This was inconsistent with findings from Park et al. (8), where NMES stimulation to the abdominals was used in combination with core muscle strengthening exercises (CME), in addition to conventional physiotherapy while the control group received CME and conventional physiotherapy only; there was a significant difference between the groups in TIS scores. The NMES in the study by Park et al. (8) was intended to strengthen or increase the effect of the CME to target the core muscles more, as previous studies have shown that a CME programme alone added to a physiotherapy treatment programme can improve dynamic sitting balance and trunk control (48,200). This compounding effect of electrical stimulation on top of strengthening the core muscles may be superior to stimulation alone with regular therapy to illicit a difference between groups.

While there was improvement in trunk performance for both groups over time, one group did not improve more than the other, and the improvements were not significant. This is in agreement with findings from Park et al. (8) where the experimental and control groups showed significant improvements within each group ($p=0.05$). This indicates that conventional physiotherapy does also improve trunk performance. However, we cannot exclude that stroke patients will also experience natural recovery in the acute and sub-acute phase (270).

5.5.4 RMA

No significant difference was found between the experimental and control groups for the RMA gross function (RMA-GF), RMA-leg and Trunk (RMA -LT) and RMA-Arm at baseline, two weeks, four weeks, or eight weeks. This was in agreement with findings by Moosajie (70), where no significant differences were found between groups at admission, discharge (two weeks) and follow-up (six weeks) for the subscales.

The experimental and control groups improved total scores over time within the group for RMA-GF, RMA-Arm and RMA-LT during the intervention period. However, the control group showed significant improvement (increase in average unit score over time) over time for the RMA-GF and the RMA-Arm and the experimental group showed non-significant improvement in comparison. These within-group results are consistent with findings from Moosajie (70) for RMA-Arm and RMA-GF. Moosajie (70) found very little or no treatment effect in the experimental groups and that the scores for the subscales were higher for the control group.

Both experimental and control groups showed improvement with scores over time, although not significant, between four and eight weeks. This indicates that despite not having intervention, the effects from the intervention continue post-discharge, showing that conventional therapy and FES used in combination with conventional therapy are both effective. However, we cannot exclude that the stroke patient will also experience natural recovery in the acute and sub-acute phase (270). Furthermore, all the participants returned home during this period, and we cannot exclude the recovery from continuing with activity at home.

5.5.5 BI

No significant differences were found between groups for BI total scores in this study. Moosajie (70) also reported no significant differences between groups for total BI scores. In Park et al.'s (8) study using NMES, the authors utilised the Korean version of the Modified Barthel Index (K-MBI); their findings also showed no significant differences between groups for K-MBI.

In the GLM during the intervention period, both groups showed a significant improvement in BI total ($p<0.01$), but the group*time interaction was not significant ($p=0.57$). When no intervention was provided between four weeks and eight weeks, the control and the intervention group showed improvement. However, this was not significant ($p=0.26$). This was inconsistent with findings from Moosajie (70) and Park et al. (8). Moosajie (70) found a significant difference in Total BI scores within the experimental group only between admission to discharge at two weeks (total time of intervention), which was found to have a moderate effect size. Park et al. (8). however, found significant differences from the start to end of intervention in the K-MBI scores for the experimental and control groups for the intervention period This may be because both groups in each of these studies received control or experimental intervention daily or five times a week. In contrast, our study's participants only received intervention two to three times a week. Furthermore, the lack of significant improvement in scores in the study may be due to the high baseline BI scores for both groups indicating that the participants were high functioning, which leaves little room for significant change, leading to a ceiling effect (271).

5.5.6 EQ-5D-3L

There were no significant differences between groups for EQ-5D-3L at the domain level, and no significant differences were found between groups at the domain level (Appendix IV).

Regarding VAS, both groups improved scores during the intervention period. Post-intervention, the scores either decreased or remained the same for eight weeks. This increase in scoring during the intervention could be due to participants still being admitted and receiving therapy and seeing other improvements in BI, RMA-GF, and RMA-LT. A decrease in quality of life scores is not unexpected when patients go home, as studies have demonstrated patients reporting a reduction in quality of life with time, where patients report a decrease in autonomy, ADL independence and social activities (91). There are many determinants for decreased quality of life after stroke. A study by Jonsson et al. (272) explored the quality of life with 304 stroke survivors and their 234 caregivers after stroke, 4 months after stroke, using the Short Form 36 (SF-36) questionnaire. The SF-36 is a subjective quality of health questionnaire comprising 36 questions about limitations in social and usual activities due to physical or emotional problems, limitations in physical activities of health problems, general health problems, bodily pain, general mental health, and vitality (272). The SF-36 has a score range from 0-100, with 100 being the highest score attainable. They found that stroke survivors with lower depressive scores using the Swedish adapted Geriatric Depression Scale (GDS-20) reported higher quality of life scores and higher Barthel Index scores (272).In our study, we noted that BI, RMA-Arm and RMA-GF scores had plateaued at week 8 and there was no improvement in TIS and RMA-LT scores for the experimental group at week eight. This occurred when the patients were at home and were not receiving any therapy. As they plateaued in function, their levels of anxiety/depression about the rate of recovery may have affected QoL VAS scores (272). This was also found in a pilot study by Smout et al. (273); the authors explored the quality of life and coping mechanisms between eight younger stroke patients (mean age =47.6 years) within one to three years of stroke and spouses (n=4). They found that the patients reported a decrease in Quality of life by 20% using the Schedule for the Evaluation of Individual Quality of Life (SEIQoL) despite a high BI score (mean =19.25). An interesting finding from this study was that the partners did not report decreased quality of life(273). The authors hypothesised this could be because the patient and their partner could have grown closer with the patient returning home (273).

The intervention group maintained a consistent score from baseline to eight weeks. This agrees with Moosajie (70) findings, where no significant differences were found between groups for all the domains, including VAS.

5.5.7 PCI

The PCI measures energy expenditure with gait, where a higher score indicates higher energy expenditure. A significant difference between groups was found for total PCI score at four weeks. Four weeks also signalled the end of the experimental FES intervention; it essentially was the baseline for the PCI. The experimental group had the higher expenditure, and therefore, gait was not as energy efficient for the experimental group participants compared to the control group at four weeks and eight weeks. Moreover, at four weeks, the control group had significantly higher gait speed scores when compared to the intervention group, indicating that, once the intervention was complete, those in the control group walked faster than those in the intervention group. Despite the control groups' gait speed decreasing over time with an increase in energy expenditure (i.e. slower walking and using more energy) and the intervention group showing an increase in gait speed and energy expenditure over time, the control group's gait was still more energy efficient and faster than the intervention group, although not significantly. This could be because the experimental group within the group showed no increase in TIS score and a very small increase in score in the RMA-LT compared to the control group for this period. Furthermore, despite having fewer patient-participants (n=5) in the control group than the experimental group (n=7), the patient-participants in the control group had higher mean scores for TIS, RMA GF, RMA LT and BI at four weeks and eight weeks. This indicates that the control group performed better than the experimental group at four weeks and eight weeks in trunk control, which may have improved mobility.

This is in keeping with the findings from Karthikbabu et al. (55), where stroke patients who had performed trunk exercises on a ball versus on a stable surface had significantly improved selective trunk control as measured by the TIS (p=0.0001) had significantly higher scores in the stepping aspect of the Brunel Balance assessment(p=0.0001) indicating better mobility as a result of improved trunk control. Furthermore, Lee et al. (274) found that stroke patients who had completed a treatment regime of abdominal hollowing or bracing as a method to improve trunk stability resulted in significantly improved gait as measured by the 10-metre walk test. This was similar to the findings in the control and intervention groups at baseline, which could be because the control group had fewer patient-participants in the low-functioning group (two) than in the intervention group (four) after stratification. However, with the small sample size, it is unclear if the stratification could have impacted the findings at four weeks.

5.6 Limitations and Recommendations:

5.6.1 Study Procedures

In this study, no participants dropped out (declined participation or transferred to another facility) during the intervention, and all patients were still inpatients during the intervention period. However, when participants were discharged home and expected to return as an outpatient for the final assessment, two participants could not attend due to transport challenges despite a R150 transport allowance. Therefore, The WCRC would be a suitable site for a larger study as stroke patients are admitted for approximately seven weeks, and there are few cases where patients are discharged earlier. Moreover, the risk of transfer to another facility during the admission is also low as patients are required to be medically stable when admitted per the facility's admission guidelines. Therefore, medical complications requiring transfer to another facility are unlikely and infrequent. For future studies, other options for transport access should be considered to ensure patients return for the follow-up assessment as an outpatient, for example, e-hailing services or arranged transport services.

The intervention, FES abdominal application during exercise, was tested with two patients one month prior to starting the study in one session per patient. TS observed both treatment sessions with these patients, which included FES applied to the abdominals in both patients. Patient one performed trunk exercises in supine and sitting, bed mobility exercises (rolling, bridging) and standing exercises next to the bed for one session. Patient Two performed matwork activities (four-point kneeling, transitions between two-point and half kneeling) and gait training indoors with an assistive device. Both patients reported the FES was comfortable to use during exercise and reported no residual discomfort on follow-up the following day. The physiotherapists managing these patients advised that application during treatment sessions would be possible with minimal disruption to the treatment sessions: the electrodes only needed to be applied at the beginning of therapy sessions, removed at the end of the session, and they would adjust the device (move or hold the physical device) when the patient was transitioning between positions. During the study, TS followed up informally with physiotherapists to understand if they or the participants had any complaints or concerns regarding the FES application during the intervention period. One physiotherapist expressed that a holder or bag to hold the device while completing gait training may be useful. This was, however, not standardised, and there wasn't equal opportunity given to the participants for feedback; therefore, for future studies, the research assistant could assess the participants using a VAS scale, like the scale used in Chapter 4, to measure comfort, effort, and assistance with application during treatment at the week two and week four assessments to measure the participants' acceptability of the intervention. The researcher could also email the participating physiotherapists at week two and week four and ask if there were any concerns or suggestions regarding the intervention to allow for more standardised intervals.

Recruiting patients suitable for the study was challenging as the combination of inclusion criteria and recruitment period limited the number of participants to be recruited. The study could only include patients from the Cape Town metropole to enable patients to return for the last assessment. The WCRC admits patients from all over the Western Province, and the facility admission guidelines prioritise admissions from outside of the metropole as there are limited resources in that part of the province, which may have reduced the number of patients for recruitment. This, coupled with a short recruitment period of three months, reduced the number of patients to be recruited. Should the inclusion criteria remain the same for a larger study, the recruitment period should be increased to at least six months to accommodate the facility admission guidelines.

5.6.2 Instrument versions

A limitation of this study was not using the TIS 2.0, Modified Barthel index (MBI)and the EQ-5D-5L, updated versions of the original scales.

The BI has been found to have reduced reliability due to ceiling and floor effect (275), mainly due to the lack of sensitivity to change in each item, which is a limitation of the BI, so the Modified Barthel Index (MBI) was developed by Shah, Vanclay and Cooper in 1989 (259). For future studies, the MBI should be used because it could show more responsiveness as its categories are more sensitive to change.

In this study, the TIS showed little change in score between the four measurement points, with no significant change in between groups statistics. Using the TIS 2.0 may have shown more discriminatory power and prevented a ceiling effect so that discriminatory power could be noted (166). Both the TIS and BI are commonly used by the therapists at the research site, and many published studies still use these instruments.

The EQ-5D-5L has a five-point ordinal scale per domain, which could have been better at picking up change when compared to the three-point ordinal level scale used in the EQ-5D-3L, and it may have more discriminatory power(276).

The literature does not indicate whether the PCI is valid over 10 metres. Patients should walk for at least four minutes at their own pace (277). To obtain a valid PCI measurement, subjects must walk at least 80 meters (278). We opted for the 10-metre walk test, a valid and reliable measure of gait among stroke patients within the first 12 weeks after stroke (60, 61, 62). Conducting the PCI using a longer distance would be recommended for future studies.

5.6.3 Electrode Application

While previous NMES studies utilised the posterior application to the trunk in combination with core muscle strengthening or an abdominal application in combination with core strengthening exercise, the effect of both applications sites used simultaneously has not been explored. When used with conventional therapy, this may have a positive impact.

The placement was determined in Chapter 4 before commencing the pilot study. The focus was determining the best placement on the abdominal muscle belly, specifically the EO. However, in literature, clinicians have debated whether the best location for electrical stimulation should be over the muscle belly or over the motor point (85,86). Therefore, application over a motor point may yield different results. McCaughey et al. (279) determined the motor points stimulation sited for FES stimulation on the RA and EO muscles in tetraplegia to improve respiratory function. Therefore, a future study utilising these motor points is recommended.

5.6.4 Intervention variation

In previous studies using NMES by Ko et al. (71) and Park et al. (8), the NMES was applied within structured and standardised circumstances, i.e., set times, with set stimulation duration and within a standard content of exercises. The FES stimulation period in this study was very dependent on the content of conventional therapy. The treating therapist decided on treatment time with the participant and the content of activities (exercises) when FES was to be applied. Therefore, stimulation time per session varied from 30 minutes to 45 minutes. The activities (exercises) that combined FES with trunk activation were not consistent or structured when compared to the structure of the NMES application period in studies by Park et al. (8) and Ko et al. (71). This study did provide treatment within a more pragmatic and realistic treatment setting when compared to studies by Park et al.(8) and Ko et al. (71). While these authors explored if this intervention was possible in their studies, this study looked at how effective would it be in routine practice. This study allowed the researcher to test the hypothesis in a real life clinical setting. In doing so, the findings are made more applicable to everyday practice where there is more variability in the clinicians and delivery of the control intervention. However, the small sample limited the external validity and the ability to generalise the results to other rehabilitation settings (280).

Furthermore, compared to the structured, targeted core exercises in the NMES studies by Park et al. (8) and Ko et al.(71) , which provide a direct double method to activate the trunk when combined with NMES, the content of regular physiotherapy treatment intervention doesn't target the trunk muscles directly. Still, the premise is that the trunk is activated indirectly through movement, and the FES provides the direct activation (8,71) . This double-targeted activation may be more beneficial; therefore, for a future study, adding a small period of targeted core exercises, approximately ten minutes, at the start of the conventional therapy session is recommended. This will allow the stimulation to still be part of the conventional therapy session (truer to a pragmatic treatment setting) but add more targeted core strengthening.

The training programme on how to use the FES device was provided to the researcher. However, the researcher was not a licenced trainer in FES but underwent formal training from PROFESSA (supplier of Odstock medical FES devices in South Africa) in 2012 over two days. In a future study, the participants providing stimulation (physiotherapists) should undergo similar formal training for FES from a supplier and licenced trainer before participating.

5.6.5 Assessors

Two assessors were used in this study: the researcher and a blinded research assistant completed follow-up assessments. At the time of the study, the researcher was part of the cohort of physiotherapists who would provide FES or placebo FES as part of the intervention to patients. Therefore, to allow for the blinding of the assessor for follow-up assessments, a research assistant was tasked to complete follow-up assessments. Using two assessors pragmatically helped with doing all assessments (baseline and follow-up assessments) on Friday mornings before the participants (patients) went home for the weekend on Friday afternoons.

This could have allowed for differences in assessment results between the two assessors or observer bias.

5.6.6 Stratification of participants

The patient-participants were stratified into three groups according to the impairment level according to their scores on the RMA on baseline. The three groups were low-functioning, middle, and high-functioning. Initially, the researcher had hoped to recruit more patient-participants, which could have made the stratification of patient-participants into three functioning groups more effective. We acknowledge now that stratification was not as effective as we had hoped.

5.6.7 Recommendations for future studies

Therefore, if a future study should be explored, the following is recommended:

- Consider using more sensitive instruments to measure ADL performance, trunk performance and health-related quality of life, such as MBI, TIS 2.0 and EQ-5D -5L
- If it is to remain a pragmatic trial, then adding in 15 minutes with prescribed core exercises similar to those in studies by Park et al. (8) and Ko et al. (71) before starting their physiotherapy treatment session where the FES will be applied to the abdominals. It will also increase FES stimulation time (15 minutes and 30 minutes thrice weekly within treatment sessions). This will also help to standardise the application.
- It will need to be carried out in an inpatient or outpatient setting where regular attendance can be guaranteed for three to four weeks.
- All physiotherapists applying to the FES will need formal training from a licenced FES trainer.
- The recruitment period should be at least six months to enable more suitable patient recruitment to meet the inclusion criteria to ensure an adequately powered study.
- Consider using e-hailing transport services or arranged transport for participants who struggle to come to the final assessment as an outpatient.
- Consider using a standardised VAS scale to measure the acceptability of the intervention with patients during the study assessment time point.

Chapter 6. Conclusion:

The purpose and primary aim of this study was to determine the effect of FES application to the abdominal muscles in stroke clients when used simultaneously in conventional physiotherapy treatment on trunk performance, motor impairments, ADL performance and health-related quality of life. The secondary and third aims included describing physiotherapy interventions as a description of the control intervention to be used in the pilot study as a sub-study one and determining the best electrode position on the abdominal muscles to provide the stimulation in the pilot study as sub-study two.

Regarding study one and study aim two, the results suggest that physiotherapists maintain treatment based on positional activities and not functional ADLs, keeping with literature from De Wit et al.(4). This study is the first to describe physiotherapy interventions within a specialised inpatient rehabilitation setting in South Africa. However, as the sample size was small and the study was only conducted in one centre, the results are not generalizable. Therefore, a multicentre study is recommended for future research.

In study two, the most suitable electrode position was 2 cm above and medial to the iliac crest and on the eighth intercostal space as a unilateral placement. This placement was in keeping with NMES abdominal stimulation done by Baek et al. (6); however, unilateral placement was found to be preferable by the participants, contradictory to Baek et al. (6) and Park et al. (8), who both utilised bilateral placement over both EO muscles. While ultrasound imaging was used to determine muscle thickness changes, EMG recording may be an additional method to determine muscle contraction better.

The pilot study explored the primary aim but did not find that adding FES application to the abdominals in combination with conventional therapy was more effective than conventional therapy with placebo FES. A treatment effect within the intervention group was present but not significant. While the study had many limitations, recommendations to improve the protocol of a future study may be able to address these.

The results showed that both the control group and the intervention improved over time, but neither group improved more than the other; this strongly confirms that conventional physiotherapy is effective without the “enhancement” of FES to the programme. Whether therapists utilise FES in practice should consider their work environment. Resource constraints related to physiotherapy services within South African public service institutions suggest that (50) adding an FES device may not be financially possible. Moreover, trained physiotherapists may not be available to apply the FES consistently. To effectively see a positive impact from the use of FES in the abdominals, it would require patients to attend regular therapy sessions to adhere to a protocol of potentially one hourly session, daily for at least three to four weeks, which may not be possible considering that most physiotherapy services are provided on an outpatient basis in South Africa. Transport challenges are a hindrance to attendance. It is encouraging to note that conventional therapy achieves similar outcomes and can continue to be applied within settings like the Western Cape Rehabilitation Centre.

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Appendix I

Normality Test for all outcome measures (Shapiro Wilk Test)

Table 23: Shapiro Wilks Test for normality for all Variables

	Shapiro-Wilk				Shapiro-Wilk		
	Statistic	df	Sig.		Statistic	df	Sig.
Baseline TIS TOTAL	.882	12	.094	Baseline BI Total	.911	12	.221
2-week TIS TOTAL	.986	12	.998	2-week BI Total	.862	12	.051
4-week TIS TOTAL	.962	12	.814	4-week BI Total	.813	12	.013
8-week TIS TOTAL	.893	12	.130	8-week BI Total	.645	12	<,001
Basline RMA GF Total	.913	12	.235	Baseline EQ5D VAS	.847	12	.034
Baseline RMA LT Total	.885	12	.101	2-week EQ5D VAS	.836	12	.025
Baseline RMA Arm Total	.777	12	.005	4-week EQ5D VAS	.877	12	.080
Week 2 RMA GF Total	.866	12	.059	8-week EQ5D VAS	.906	12	.190
Week 2 RMA LT Total	.917	12	.261	4-week PCI Gait speed	.932	12	.401
Week 2 RMA Arm Total	.853	12	.039	4-week Total PCI score	.682	12	<,001
Week 4 RMA GF Total	.874	12	.074	8-week PCI Gait speed	.957	12	.738
Week 4 RMA LT Total	.846	12	.033	8-week Total PCI score	.621	12	<,001
Week 4 RMA Arm Total	.845	12	.032				
Week 8 RMA GF Total	.881	12	.091				
Week 8 RMA LT Total	.775	12	.005				
Week 8 RMA Arm Total	.855	12	.043				

If the W value of the Shapiro-Wilk Test is greater than or equal to 0.05, the data is normal.

If it is below 0.05, the data significantly deviate from a normal distribution

Appendix II

Trunk Impairment Scale (TIS) Results

Table 24: : TIS normality testing results

TIS subscale	W	p
Baseline TIS total	0.88	0.09
2-week TIS total	0.99	0.1
4 weeks	0.96	0.81
8 weeks	0.91	0.26

The Shapiro-Wilk W test is used in testing for normality. If the W statistic is significant, the hypothesis that the respective distribution is normal should be rejected.

Additional exploratory analysis was completed per sub-category of the TIS to explore the difference between the experimental and control groups at each time point (table 22) as well to explore within group differences per sub-category (Table 22) for the control group and experimental group.

Table 25: Mann Whitney U Test between experimental and control groups for total scores for Stattic sitting balance, dynamic sitting balance and Coordination for the TIS ($p \leq 0.05$)

TIS Subcategory	timepoint	Rank Sum Experimental group n=7	Rank Sum Control group n=5	U	S	p-value
Static Sitting Balance total scores	Baseline	37.5	40.5	9.5	-1.22	0.22
	2 weeks	41.5	36.5	13.5	-0.57	0.57
	4 weeks	43	35	15	-0.33	0.75
	8 weeks	32.5	22.5	11.5	0	1
Dynamic Sitting Balance Total scores	Baseline	34.5	43.5	6.5	-1.71	0.09
	2 weeks	40.5	37.5	12.5	-0.73	0.46
	4 weeks	38	40	10	-1.14	0.26
	8 weeks	32	23	11	-0.11	0.92
Coordination Total scores	Baseline	42	36	14	-0.49	0.63
	2 weeks	51.5	26.5	11.5	0.89	0.37
	4 weeks	50.5	27.5	12.5	0.73	0.47
	8 weeks	30.5	24.5	9.5	-0.43	0.67

Further Mann Whitney U tests were conducted for each item under static sitting balance, dynamic sitting balance, and coordination categories of the TIS to determine a significant difference between the experimental and control groups at baseline, two weeks, four weeks, and eight weeks. No significant differences were found for each item.

Table 26: Friedman's ANOVA for all participants (n=12) for the TIS total scores and TIS subcategories

TIS Scores	Chi square	Df	P value
TIS Dynamic Sitting Balance score	4.93	3	0.17
TIS Static Sitting Balance Score	5.68	3	0.13
TIS Coordination score	1.70	3	0.60

No significant associations were found for the subcategories (Dynamic sitting balance, static sitting balance, and coordination) of the TIS for all participants using the Friedman's ANOVA

Appendix III

<u>**Rivermead Motor Assessment Scale (RMA) results**</u>

Additional exploratory analysis was completed per sub-category of the RMA to explore the between and within group differences per sub-category for the control and experimental groups.

A Friedman's ANOVA and chi-square for RMA-GF, RMA-LT and RMA Arm total scores showed a significant association was found in both groups for RMA-GF (p<0.01) and RMA Arm (p<0.01), but no significance was found for RMA –LT (p=0.16) (Table 24).

Table 27: Friedman's ANOVA and Chi square for total scores for RMA-GF, RMA-LT, and RMA Arm for entire sample (n=12)

RMA	Chi square	Df	P-value
Gross Function (RMA- Gf)	23.05	3	<0.01
Upper limb (RMA arm)	16.06	3	<0.01
Lower limb (RMA Lt)	5.20	3	0.16

Further Wilcoxon matched paired tests of the experimental and control groups for the RMA- GF and RMA Arm are depicted in Table 26 and Table 27. Significant associations were found for all time points for the RMA-GF totals in the experimental group, except between baseline and two weeks (p=0.27) and week four and week eight (p=0.07) No significant associations were found for the control group for RMA-GF totals (Table 26).

Table 28: Wilcoxon Matched Pair Tests for experimental and control groups for RMA- Gf Totals (p ≤ 0.05)

Group	Variable	Valid N	T	S	p-value
Experimental group	Baseline RMA GF Total & Week 2 RMA GF Total	4	2.00	1.10	0.27
	Baseline RMA GF Total & Week 4 RMA GF Total	5	0.00	2.02	0.04
	Baseline RMA GF Total & Week 8 RMA GF Total	6	0.00	2.20	0.03
	Week 2 RMA GF Total & Week 4 RMA GF Total	5	0.00	2.02	0.04
	Week 2 RMA GF Total & Week 8 RMA GF Total	6	0.00	2.20	0.03

	Week 4 RMA GF Total & Week 8 RMA GF Total	4	0.00	1.83	0.07
Control Group	Baseline RMA GF Total & Week 2 RMA GF Total	3	0.00	1.60	0.11
	Baseline RMA GF Total & Week 4 RMA GF Total	4	0.00	1.83	0.07
	Baseline RMA GF Total & Week 8 RMA GF Total	3	0.00	1.60	0.11
	Week 2 RMA GF Total & Week 4 RMA GF Total	4	1.50	1.28	0.20
	Week 2 RMA GF Total & Week 8 RMA GF Total	3	0.00	1.60	0.11
	Week 4 RMA GF Total & Week 8 RMA GF Total	2	0.00	1.34	0.18

A significant association for RMA Arm totals were found between baseline and two weeks (p=0.04) in the experimental group). A significant association was further found between baseline and eight weeks (p=0.04) for RMA-Arm totals in the experimental group. No other significant associations were found at any other time points in either group (Table 27).

Table 29: Wilcoxon Matched Pair Tests for experimental and control groups for RMA Arm totals (n=10)

Group	Pair of Variables	Valid N	T	S	p-value
Experimental group	Baseline RMA Arm Total & Week 2 RMA Arm Total	5	0.00	2.02	0.043
	Baseline RMA Arm Total & Week 4 RMA Arm Total	5	1.50	1.62	0.106
	Baseline RMA Arm Total & Week 8 RMA Arm Total	5	0.00	2.02	0.043
	Week 2 RMA Arm Total & Week 4 RMA Arm Total	4	5.00	0.00	1.000
	Week 2 RMA Arm Total & Week 8 RMA Arm Total	4	1.50	1.28	0.201
	Week 4 RMA Arm Total & Week 8 RMA Arm Total	2	0.00	1.34	0.180
Control group	Baseline RMA Arm Total & Week 2 RMA Arm Total	4	0.00	1.83	0.068
	Baseline RMA Arm Total & Week 4 RMA Arm Total	4	0.00	1.83	0.068
	Baseline RMA Arm Total & Week 8 RMA Arm Total	3	0.00	1.60	0.109
	Week 2 RMA Arm Total & Week 4 RMA Arm Total	1			
	Week 2 RMA Arm Total & Week 8 RMA Arm Total	3	0.00	1.60	0.109
	Week 4 RMA Arm Total & Week 8 RMA Arm Total	3	0.00	1.60	0.109

Appendix IV

Barthel Index (BI) Results

Additional exploratory analysis was completed per individual items (10) of the BI between groups. Within group exploratory analysis was also completed to determine if their associations at each time point for the BI

Between group Effect

Mann Whitney-U tests for total BI scores showed no significant difference between the experimental and control groups for BI individual items at any time point in the study (Table 27).

Table 30: Mann-Whitney U test for individual BI items (Mobility, Feeding, Bathing, Grooming, Bowels, Bladder, Toilet, Transfers, Stairs) scores between the experimental and control groups (n=12)

BI Category	Variable	Rank Sum Experimental group	Rank Sum Control group	U	S	p-value
Mobility	Baseline BI Mobility	37.5	40.5	9.5	-1.22	0.22
	4-week BI Mobility	41.5	36.5	13.5	-0.57	0.57
	8-week BI Mobility	29	26	8	-0.75	0.46
Feeding	Baseline BI Feeding	53	25	10	1.14	0.26
	4-week BI Feeding	44	34	16	-0.16	0.87
	8-week BI Feeding	35	20	10	0.32	0.76
Bathing	Baseline BI Bathing	41.5	36.5	13.5	-0.57	0.57
	4-week BI Bathing	43	35	15	-0.32	0.75
	8-week BI Bathing	31	24	10	-0.32	0.75
Grooming	Baseline BI Grooming	41.5	36.5	13.5	-0.57	0.57
	4-week BI Grooming	43	35	15	-0.32	0.75
	8-week BI Grooming	31	24	10	-0.32	0.75
Dressing	Baseline BI Dressing	49.5	28.5	13.5	0.57	0.57
	4-week BI Dressing	44	34	16	-0.16	0.87
	8-week BI Dressing	32	23	11	-0.11	0.92
Bowels	Baseline BI Bowels	45.5	32.5	17.5	0.00	1.00
	4-week BI Bowels	45.5	32.5	17.5	0.00	1.00
	8-week BI Bowels	33	22	12	0.00	1.00
Bladder	Baseline BI Bladder	45.5	32.5	17.5	0.00	1.00
	4-week BI Bladder	45.5	32.5	17.5	-0.08	0.94

	8-week BI Bladder	33	22	12	-0.11	0.92
Toilet	Baseline BI toilet	41.5	36.5	13.5	-0.57	0.57
	4-week BI toilet	45.5	32.5	17.5	0.08	0.94
	8-week BI toilet	33	22	12	0.11	0.92
Transfers	Baseline BI transfers	44	34	16	-0.16	0.87
	4-week BI transfers	45.5	32.5	17.5	0.08	0.94
	8-week BI transfers	33	22	12	0.11	0.92
Stairs	Baseline BI Stairs	44	34	16	-0.16	0.87
	4-week BI Stairs	34.5	43.5	6.5	-1.71	0.09
	8-week BI Stairs	29	26	8	-0.75	0.46

Within Group Effect

Significant associations using the Friedman's ANOVA were found between BI totals for all groups (p=0.0001), in the experimental group (p=0.004) and in the control group (p=0.035)[Table 29).

Table 31: Friedman's ANOVA scores for BI total scores for both groups, experimental group, and control group (n=12)

BI Totals	Chi-square	Df	P-value
All groups	20.97	3	0.0001
Experimental group	13.29	3	0.004
Control group	8.56	3	0.04

Wilcoxon Matched Pair Test for BI Totals for experimental and control groups also yielded significant associations between baseline and two weeks (p=0.03), baseline and four weeks (p=0.04), baseline and eight weeks (p=0.04), two weeks and eight weeks (p=0.04) and four weeks and eight weeks (p=0.04) for the experimental group In the placebo-control group the only significant association was found at baseline and four weeks (p=0.04), and baseline and two weeks was approaching significance (p=0.07) (Table 30)

Table 32: Wilcoxon Matched Pair Test for BI Totals for experimental and control groups (p=0.05)

Group	BI Totals Variables	Valid N	T	S	p-value
Experimental Group	Baseline & 2 weeks	6	0	2.20	0.03
	Baseline & 4 weeks	5	0	2.02	0.04
	Baseline & 8 weeks	5	0	2.02	0.04

	2 weeks & 4 weeks	6	2	1.78	0.08
	2 weeks & 8 weeks	5	0	2.02	0.04
	4 weeks & 8 weeks	5	0	2.02	0.04
Control Group	Baseline & 2 weeks	4	0	1.83	0.07
	Baseline & 4 weeks	5	0	2.02	0.04
	Baseline & 8 weeks	3	0	1.60	0.11
	2 weeks & 4 weeks	3	0	1.60	0.11
	2 weeks & 8 weeks	3	0	1.60	0.11
	4 weeks & 8 weeks	3	1	1.07	0.29

Further Wilcoxon Matched Pair Tests were conducted for each item for the Barthel Index (ten in total). No significant associations were found within each group at any time point.

Appendix V

EQ-5D-3L Results

Additional exploratory analysis was completed per domain of the EQ-5D-3L between and within group to determine if there are any associations at each time point.

Between Group effect

No significant differences were found for between groups in any of the other domains

Table 33: Mann Whitney U test results for individual EQ-5D domains between experimental and control groups (n=12)

EQ-5D Domain	Timepoint/variable	Rank Sum Experimental group	Rank Sum Control group	U	S	p-value
Mobility	Baseline	53.5	24.5	9.5	1.22	0.22
	4 weeks	49.5	28.5	13.5	0.57	0.57
	8 weeks	37	18	8	0.75	0.46
Self-Care	Baseline	51	27	12	0.81	0.42
	4 weeks	50.5	27.5	12.5	0.73	0.47
	8 weeks	37	18	8	0.75	0.46
Usual Activities	Baseline	46	32	17	0.00	1
	4 weeks	52	26	11	0.97	0.33
	8 weeks	38	17	7	0.96	0.34
Pain/Discomfort	Baseline	58	20	5	1.95	0.05
	4 weeks	47	31	16	0.16	0.87
	8 weeks	34	21	11	0.11	0.92
Anxiety/Depression	Baseline	41	37	13	-0.65	0.52
	4 weeks	44.5	33.5	16.5	-0.08	0.94
	8 weeks	32	23	11	-0.11	0.92
VAS	Baseline	49.5	28.5	13.5	0.57	0.57
	2 weeks	42.5	35.5	14.5	-0.41	0.69
	4 weeks	45	33	17	0.00	1
	8 weeks	34	21	11	0.11	0.92

Within Group Effect

Significant associations were found within both groups using the Friedman's ANOVA and chi-square for the following domains: Mobility (p=0.015) and Self-Care (p=0.019)[Table 32]

Table 34: Friedman ANOVA for EQ-5D for all domains for both groups (n=12)

EQ-5D Domain total	Chi-square	Df	P-value
VAS	2.41	3	0.49
Mobility	10.41	3	0.02
Self-Care	9.92	3	0.02
Usual Activities	5.67	3	0.13
Pain/ Discomfort	0.55	3	0.91
Anxiety/Depression	1.71	3	0.634

No significant differences were found from Wilcoxon Matched Pairs Test within the experimental and control groups for the mobility and self-care (domains despite showing significance in the Friedmans ANOVA and chi square.

Table 35: Wilcoxon Matched Pairs Tests for EQ-5D domain mobility for the experimental and control groups

Group	EQ-5D Mobility Variable	Valid N	T	S	p-value
Experimental Group	Baseline & 4 weeks	3	0.00	1.60	0.11
	Baseline & 8 weeks	3	0.00	1.60	0.11
	4 weeks & 8 weeks	1			
Control Group	Baseline & 4 weeks	1			
	Baseline & 8 weeks	2	0.00	1.34	0.18
	4 weeks & 8 weeks	1			

Table 36: Wilcoxon Matched Pairs Tests for EQ-5D domain Self-Care for the experimental and control groups

Group	EQ-5D Self-care Variable	Valid N	T	S	p-value
Experimental group	Baseline & 4 weeks	3	0.00	1.60	0.11
	Baseline & 8 weeks	2	0.00	1.34	0.18
	4 weeks & 8 weeks	0			
Control Group	Baseline & 4 weeks	2	0.00	1.34	0.18
	Baseline & 8 weeks	2	0.00	1.34	0.18
	4 weeks & 8 weeks	0			

Table 37: Wilcoxon Matched Pairs Tests for EQ-5D VAS for the experimental and control groups

Group	EQ-5D Domain Variable	Valid N	T	S	p-value
Experimental Group	Baseline EQ5D VAS & 2-week EQ5D VAS	6	4	1.36	0.17
	Baseline EQ5D VAS & 4-week EQ5D VAS	5	1	1.75	0.08
	Baseline EQ5D VAS & 8-week EQ5D VAS	2	0	1.34	0.18
	4-week EQ5D VAS & 8-week EQ5D VAS	5	6	0.40	0.69
	Baseline EQ5D VAS & 4-week EQ5D VAS	4	2	1.1	0.27

Control Group	Baseline EQ5D VAS & 8-week EQ5D VAS	3	1	1.07	0.29
	4-week EQ5D VAS & 8-week EQ5D VAS	2	1	0.45	0.65

Appendix VI

<u>Physiological Cost Index of Gait (PCI) Results:</u>

Additional exploratory analysis was completed per component of the PCI within group to determine if there are any associations at each time point.

Within Group effect

The experimental group showed no significant association between four weeks and eight weeks for total PCI scores (p= 0.753) and for resting HR (p=0.249). Significant associations were found for HR after 10m (p= 0.046) and gait speed (p= 0.046) for Wilcoxon Matched Pair Tests.

Table 38: Wilcoxon Matched Pair Test for PCI variables for the experimental group (n=7)

PCI Variable	Pair of Variables	Valid N	T	S	p-value
Total PCI	4-week Total PCI score & 8-week Total PCI score	6	9	0,31	0,75
Rest HR	4-week PCI rest HR & 8-week PCI rest HR	6	5	1,15	0,25
HR 10min	4-week PCI HR 10m & 8-week PCI HR 10m	6	1	1,99	0,05
Gait speed	4-week PCI Gait speed & 8-week PCI Gait speed	6	1	1,99	0,05

Table 39: Wilcoxon Matched Pair Test for PCI variables for the control group (n=5)

PCI Variable	Pair of Variables	Valid N	T	S	p-value
Total PCI	4-week Total PCI score & 8-week Total PCI score	4	1	1,46	0,14
Rest HR	4-week PCI rest HR & 8-week PCI rest HR	4	4	0,37	0,72

HR 10min	4-week PCI HR 10m & 8-week PCI HR 10m	4	4	0,37	0,72
Gait speed	4-week PCI Gait speed & 8-week PCI Gait speed	4	4	0,37	0,72

No significant associations were found in the control group between four weeks and eight weeks for total PCI (p=0.144), resting HR (p=0.715), HR after 10m (p=0.715) and gait speed (p=0.715) for Wilcoxon Match Pair Test.

Appendix VII

Conventional physiotherapy interventions for stroke (a case study of the Western Cape Rehab Centre Physiotherapy Department)

Participant (physiotherapist) Information sheet and Consent form

Thank you for your time and for considering participating in this study.

Please read the information below and you can only be part of the study if you agree to be part of it.

My name is Tarryn Barry, I am a physiotherapist and physiotherapy masters student at the University of Cape Town (UCT). My topic of research is:

"THE EFFECT OF FUNCTIONAL ELECTRICAL STIMULATION OF THE ABDOMINAL MUSCLES ON MOTOR PERFORMANCE AND FUNCTIONAL ACTIVITY OF THE TRUNK IN STROKE PATIENTS: A RANDOMISED CONTROL TRIAL "

As part of this study I need to describe what is regular physiotherapy intervention used in stroke rehabilitation in a South African context. This will provide more information about what the physiotherapy treatment that will be provided to the patients (as the control intervention) in the randomised controlled trial, that will compare the use of functional electrical stimulation (FES) combined with regular physiotherapy in stroke clients in the experimental group, to placebo FES combined with regular physiotherapy in the control group.

There are many studies explaining treatments used by physiotherapists in stroke rehabilitation internationally but there are currently no studies that provide information describing what treatments physiotherapists use with stroke clients in stroke rehabilitation in the context of a South African rehabilitation setting. This study would help provide such information and if you consent to be part of this study, you could be part of providing such information.

Procedure:

I have developed a questionnaire (using information from literature) of the most common activities used by physiotherapists in treating patients with stroke. The questionnaire will be provided today for you to complete if you wish to participate. It has been laid out in a survey format and you would need to choose yes or no (by marking off your answer with a cross or tick) if you have completed the activity and how often in the last two weeks (not at all, rarely, most of the time) . It will take about twenty minutes to complete the questionnaire and when you have you will need to return it back to me at the end of the information session today.

You do not need to write your name on the form and your answers will remain anonymous, as each questionnaire is coded. You will need to provide your highest level of qualification, the year you qualified as a physiotherapist, name of the centre you work in, how long you have worked at your current facility, years of experience working in the field of stroke rehabilitation and names of post graduate courses you have completed. This information will help determine if all physiotherapist in the study are similar and if it may have an association with answers/ treatments that physiotherapists have chosen.

All physiotherapists (approximately 24 in total) working with stroke clients at inpatient rehabilitation centres (approximately seven) in the Cape Town metro pole, will be approached to be part of this study.

Your participation in this study is voluntary and you can at any time while filling in the questionnaire stop and choose not to continue, with no consequences.

If you have any questions, please feel free to ask me now or at a later date. My details are attached to the end of this form. The UCT FHS Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any questions about your rights and welfare as research subjects on the study.

All completed questionnaires will be locked away and stored in a safe place that only I can access, for one year.

The results of the study will be available in October 2017, and I will email them to your various centres.

Kind Regards

Tarryn Barry
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Head of Human Research and Ethics Committee- UCT Faculty of Health Sciences

Old Main Building of Groote Schuur Hospital,

Floor E52, Room 23,

Observatory, 7925.

Tel: 021 406 6338

See more at: http://www.health.uct.ac.sa/fhs/research/humanethics/about

CONSENT FORM.

I ___________________________ have read 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 this study, and I am doing so of my own free will. I know that I can withdraw at any time if I so wish and that it without any consequences for myself.

Signed:

____ ___________________

Participant Date and place

____ ___________________

Researcher Date and place

Appendix VIII

Conventional physiotherapy interventions for stroke (a case study of the Western Cape Rehab Centre Physiotherapy Department)

Instrument: Questionnaire and covering data sheet

Data sheet: sub study 1 description of physiotherapy interventions:

Type of Institution/facility where you work	State or Private
How long have you worked at your current facility?	_______years ____months
When did you qualify as a physiotherapist?	Year _____
How many years have you worked in the field of stroke rehabilitation?	_____years _____months
What is your highest qualification? Eg. Bsc degree or diploma or masters degree etc. (if masters or PHD degree, please name area of specialisation)	
Have you completed any post-graduate courses related to stroke rehabilitation?	Yes / No
Please name the post graduate courses related to stroke rehabilitation that you have completed and the year in which you completed it	
Approximately how many stroke patients with stroke did you see in the previous two weeks?	

Name of Activity		Have you used this activity in treatment sessions with your clients in the last 2 weeks?		If **yes**, how often have you applied it? Please circle the closest appropriate number of times
Activity Group	Subgroup	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
1. Upper Limb Activities				
1.1. Manual techniques	a)Joint mobilisation, including accessory/passive/active, of shoulder complex?	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)Stretching of shortened muscle groups	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)Palpation (including pain assessment) of shoulder, elbow, or wrist	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	d)Passive relaxation including positioning	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)Reflex inhibition/immobilization of the arm	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	e)Massage including soft tissue mobilisation and trigger point release.	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
1.2. Electrotherapy/Electrical stimulation	a)FES of the arm eg: FES of deltoids or triceps or wrist extensors	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)TENS of arm	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+

	c) Other NMS of the arm eg. Biphasic Stimulation e.g. Russian stimulation	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
1.3. Other therapeutic interventions	a)Therapeutic positioning of arm	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)Air splints of arm	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)Reflex inhibition/immobilization of the arm	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	d)Bilateral arm training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	e)Mental practice with motor imagery of arm	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	f)Mirror therapy of arm	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	g)Virtual reality training of arm eg. Nintendo Wii	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	h)Constraint Induced movement therapy (CIMT) of arm	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	i)Circuit class training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	j)Group classes	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	k)Caregiver training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	l)Water based exercises (hydrotherapy)	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	m) Sensory stimulation/training E.g. tapping, icing, brushing	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
2. Lower Limb Activities				
2.1. Manual techniques of the lower limb	a)Joint mobilisation, including accessory/passive/active, of hip or ankle complex?	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+

2.1. Manual techniques of the lower limb	b)Stretching of shortened muscles in leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)Palpation (including pain assessment) of muscles or joints in leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	d)Passive relaxation including positioning of hemiparetic leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	e)Reflex inhibition/immobilization of the hemiparetic leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	f)Massage including soft tissue mobilisation and trigger point release of tight/shortened muscles on hemiparetic leg.	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
2.2. Electrotherapy/ Electrical stimulation of the lower limb	a)FES of the hemiparetic leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)TENS of hemiparetic leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c) Other NMS of the hemiparetic leg e.g. Biphasic Stimulation e.g. Russian stimulation	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
2.3. Other therapeutic interventions of the lower limb	a)Therapeutic positioning of hemiparetic leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)Splinting of hemiparetic leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)Reflex inhibition/immobilization of the hemiparetic leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	e)Mental practice with motor imagery of hemiparetic leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	f)Mirror therapy of hemiparetic leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	g)Virtual reality training of hemiparetic leg. Weightbearing exercises using Nintendo Wii	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	h)Circuit class training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+

	i)Group classes	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	j)Caregiver training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	k)Water based exercises (hydrotherapy)	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	l) Sensory stimulation/training e.g. tapping, icing, brushing	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
3. Bed Mobility	a)Bridging	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)Lying to Sitting	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)Moving along bed in sitting	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	d)Rolling	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
4. Sitting Balance Training	a)Protective Reactions	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b) Weight shifting exercises	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c) Reaching exercises	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	d) Righting reactions	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
5. Standing and standing balance exercises				
5.1. Static Standing Exercises	a) Standing in standing frame	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)Standing and looking behind	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)Righting reactions	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+

	d)Reaching exercises	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
5.2. Dynamic Standing Exercises	a)Transfer training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)Sit to stand training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)Standing and retrieving object from floor	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	d)Protective reactions	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	e)Walking on the spot	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
5.2. Dynamic Standing Exercises	f)Weight shifting exercises	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	g)Reaching exercises	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
6. Matwork activities	a)Getting onto the floor and up again	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)Moving into other positions	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)4-point activities	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	d)2 point kneeling activities	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	e)1/2 kneeling activities	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	f)Side sitting activities	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
7. Wheelchair related activities	a)Wheelchair handling e.g. Removing or replacing cushions or repositioning affected arm or leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)Wheelchair skills training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+

	c)Wheelchair driving by patient	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
8. Gait Training	a)Stance phase training for the affected leg e.g. weight shifts	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b)Swing phase training for affected leg	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	c)Sideways walking	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	d)Tiptoe walking	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	e)Walking on heels	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	f)Walking backwards	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
8. Gait Training	g)Walking forwards	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	h)Body-weight supported treadmill training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	i) Issue assistive device for walking e.g. stick, crutch etc.	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	j)Issue orthosis for walking including AFO, knee braces	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	k) Electromechanically assisted gait training (FES)	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	l)Speed dependent treadmill training	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	m)Overground Walking	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	n)Rhythmic gait cueing	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	o)Community walking	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+

9. Assistance in therapy related to other professions	a) Other neuropsychological training's e.g. training of memory, language, orientation, space, body, gestures, planning	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+
	b) Visual perceptual training e.g. recognise objects, neglect and /or hemianopia treatment	Yes	No	0 1 2 3 4 5 6 7 8 9 10 10+

Appendix IX

<u>Determination of best practice of FES application on the abdominals: Participant Information Sheet and Consent Form</u>

<u>Information Sheet</u>

Thank you for your time and considering participating in this study.
My name is Tarryn Barry, I am a physiotherapist completing my masters at the University of Cape Town (UCT). My supervisor is Professor Jennifer Jelsma .

The topic I am researching is the effect of functional electrical stimulation (FES) on the abdominal (stomach) muscles in patients with stroke.
FES helps a muscle to contract or activate by giving it an electric current. This current doesn't cause pain but can be an uncomfortable sensation that some people says feels like" pins and needles".

Please read the information below and you can only be part of the study if you want to be and if agree to be part of it. The **purpose** of the study is to find out :
1. Where is the most comfortable and best place on the abdominal (stomach) muscles to place functional electrical stimulation (FES) electrodes, when providing a stimulus that will cause the abdominal muscle to contract
2. Which of the tested electrode placements is the best to be used when you do abdominal (stomach exercises).

<u>Procedure:</u>
Twelve patients will be asked to take part in this study. It will be conducted over a period of approximately five days. If you take part in this study, it will not interfere with your normal therapy schedule and will be able to receive all your therapy. Every person in this study will receive FES to their abdominal muscles. FES helps a muscle to contract or activate by applying an electric current.

In the beginning I will first check if you can feel the FES on both sides of your abdominal muscles. I will do a test where the machine will be turned on and the current will first be given to the non-affected side and then to your affected (weak) side. If you can't fell the current when the machine is turned up higher than a setting of 4, then you may not be able to be part of this study.

The order in which you receive FES stimulus and what position the electrode will be placed in will be random, and you will decide the order by drawing cards out of an envelope. At the beginning of the study, I will assess you using one tool that will take a two-dimensional (2D) image of your abdominal muscles using an ultrasound machine.

This study is divided into two parts. In the first part I will try to determine where the electrode pads should be placed on the abdominal muscles. I will use two points on the abdominal muscle to work from. Both points will be tested in bilateral placement (over both stomach muscles) of electrodes and single placement (on the stomach muscles on your weak side). This means that you will receive stimulation 4 times overall in this phase. You will receive FES each of the 4 times for 5 minutes while you lay on your back and your knees and hips are bent and resting on a stool. I will check to see if you have an abdominal muscle contraction while you receive stimulus and ask you if you can feel any contraction. I will then take further ultrasound images at 5 seconds, 30 seconds, 1 minute and then at 5 minutes when you receive FES stimulation to your abdominal muscles. After each stimulation you will be asked to rate how comfortable you felt the FES was, using a questionnaire that has a scale from numbers 1 to 10.

In the second part I will be testing how you comfortable and stable you feel having FES stimulus on the abdominal muscles, while doing two exercises. Again you will receive FES 4 times over all in this phase. The same points in phase 1 will be used for testing in this phase and both bilateral and single placement of the electrodes will be used with testing with exercises. First you will be asked to do the exercises without FES applied to the stomach and then you will complete a questionnaire that has a scale of numbers from 1 to 10 asking you to rate how much effort you needed to do the exercise and how sTable you felt doing the exercises. You will then do the same two exercises while having FES applied to the stomach muscles, using both electrode placement positions and treatment stimulus settings. After stimulation I will ask you again, using the questionnaire that has a scale of numbers from 1 to 10 , to rate how much effort you need to do the exercises, how sTable you felt, did the FES assist you to do the exercises, how comforable you felt and how much support you think the FES gave you while doing the exercises.

Side Effects / Risks:

FES has very few side effects that have been reported, these are only related to skin sensitivity to the pads that will be placed on your skin. If you have a rash, or the skin is red then you need to inform me, and you will receive different pads to use that will not give you a rash. I will then inform your managing doctor at WCRC, and he will provide you with medical treatment for the rash.

This current doesn't cause pain but can be an uncomforTable sensation that some people says feels like " pins and needles".

How do you benefit:

If you participate in this study, you may not directly benefit, but you will help us as clinicians to help other patients with stroke, if we find the best place to place the FES on the stomach muscles to work and that it can be possible and comfortable to be used while doing exercises.

This is the first ever study to determine where and how to use FES on the abdominals in people with stroke, and your participation will be appreciated.

At any time, you can choose to leave the study and not participate if you want to. If you leave the study, it will not affect your treatment until your discharge or any other future admissions to WCRC.

Your name and other details will remain anonymous and only I, the researcher, will know these details.

What if you are injured during the study

Any research-related injuries to any participants, will be compensated according to the provisions of the SA Department of Health's 2006 SA GCP guidelines (based on the Association of the British Pharmaceutical Industry (ABPI) Clinical Trial Compensation Guidelines).

The University of Cape Town (UCT) has insurance cover for the event that research-related injury or harm results from your participation in the trial. The insurer will pay all reasonable medical expenses in accordance with the South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines

(ABPI) in the event of an injury or side effect resulting directly from your participation in the trial. You will not be required to prove fault on the part of the University.
The University will not be liable for any loss, injuries and/or harm that you may sustain where the loss is caused by

- The use of unauthorised medicine or substances during the study
- Any injury that results from you not following the protocol requirements or the instructions that the study doctor may give you
- Any injury that arises from inadequate action or lack of action to deal adequately with a side effect or reaction to the study medication
- An injury that results from negligence on your part

"By agreeing to participate in this study, you do not give up your right to claim compensation for injury where you can prove negligence, in separate litigation. In particular, your right to pursue such a claim in a South African court in terms of South African law must be ensured. Note, however, that you will usually be requested to accept that payment made by the University under the SA GCP guideline 4.11 is in full settlement of the claim relating to the medical expenses. "

An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study doctor immediately of any side effects and/or 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 you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.
Please feel free to ask me any questions at any time. The UCT FHS Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any questions about your rights and welfare as research subjects on the study

The results of the study will be available in June 2016. Your data sheets and ultrasound images will be stored for up to one year in a locked cupboard that I will only have access to for up to one year. After that all data will be destroyed.

Kind Regards

Tarryn Barry

(researcher)

Email: tarryn603@gmail.com

Tel no: 021 370 2456/2354

Professor Jennifer Jelsma

(Supervisor)

Division of Physiotherapy

University of Cape Town

Email: jennifer.jelsma@uct.ac.sa

Tel. no. 021 406 6401/ 6595

Professor Marc Blockman

Head of Human Research and Ethics Committee- UCT Faculty of Health Sciences

Old Main Building of Groote Schuur Hospital,

Floor E52, Room 23,

Observatory, 7925.

Tel: 021 406 6338

See more at: http://www.health.uct.ac.sa/fhs/research/humanethics/about

CONSENT FORM)

I have read the information and understand the purpose of this study and what is expected of me. I have had all my questions answered.

Please circle the correct answer below:

If I choose to be part of this study, I will definitely receive FES …… YES or NO

My personal details will be available for everyone to see…. YES or NO

I can leave the study and choose not to be part of it at any time if I don't want to….YES or NO

There is a risk of getting a skin rash from the pads on my skin and this means I need different pads….YES or NO

I (participant)………………………………………………………… agree to be part of this study.

Participant signature: ………………………………

Researcher signature: …………………………….

Date: ……………………………………………

CONSENT FORM (WITH WITNESS SIGNATURE)

I have read the information and understand the purpose of this study and what is expected of me. I have had all my questions answered.

Please circle the correct answer below:

If I choose to be part of this study, I will definitely receive FES …… YES or NO

My personal details will be available for everyone to see…. YES or NO

I can leave the study and choose not to be part of it at any time if I don't want to….YES or NO

There is a risk of getting a skin rash from the pads on my skin and this means I need different pads….YES or NO

I (participant)……………………………………………………… agree to be part of this study.

Participant signature: ………………………………

Researcher signature: …………………………….

Witness Signature…………………

Date: ……………………………………………

Appendix X

Determination of best practice of FES application on the abdominals: Instrument:

VAS Questionnaire

1. How **comfortable** was it to have FES applied to your stomach muscles? On a scale of 1 to 10, with 1 meaning very uncomfortable and 10 meaning very comfortable, please circle your answer.

_1 = not comfortable

_ 2

_ 3

_ 4

_ 5

_ 6

_ 7

_ 8

_ 9

_ 10 = very comfortable

Exercises without FES applied:

1. How much **effort** did it take to perform the exercises? On a scale of 1 to 10, with 1 meaning no effort and 10 meaning high effort, please circle your answer

_1 = no effort

_ 2

_ 3

_ 4

_ 5

_ 6

_ 7

_ 8

_ 9

_ 10 = high effort

2. How **stable** did you feel performing the exercises? On a scale of 1 to 10, with 1 meaning not stable and 10 meaning very stable, please circle your answer.

_1 = not stable

_ 2

_ 3

_ 4

_ 5

_ 6

_ 7

_ 8

_ 9

_ 10 = very stable

FES applied when doing exercises:

1. How **comfortable** did you feel doing the exercises with FES applied to your abdominals? On a scale of 1 to 10, with 1 meaning not comfortable and 10 indicating very comfortable, please circle you answer.

_1 = not comfortable

_ 2

_ 3

_ 4

_ 5

_ 6

_ 7

_ 8

_ 9

_ 10 = very comfortable

2. How **sTable** did you feel doing the exercises with FES applied to your abdominals? On a scale of 1 to 10, with 1 meaning not sTable and 10 meaning very sTable, please circle you answer.

1 = not sTable

_1

_ 2

_ 3

_ 4

_ 5

_ 6

_ 7

_ 8

_ 9

_ 10 = very sTable

3. How much **effort** did it take to do the exercises while having FES? On a scale of 1 to 10, with 1 meaning no effort and 10 meaning very high effort, please circle you answer.

_1 = no effort

_ 2

_ 3

_ 4

_ 5

_ 6

_ 7

_ 8

_ 9

_ 10 = very high effort

Patient Data Sheet for all measurements

Phase 1															
Electrode position and placement		Contraction													VAS questionnaire Score out of 10
Position	Placement	Contraction seen	Patient perceived contraction	Ultrasound image and muscle thickness measurement on hemiplegic side											
				Baseline		5sec		30 sec		1 minute		5 minutes		contraction time for max TrA contraction	
				EO	TrA	EO	TrA	EO	TrA	EO	TrA	EO	TrA		
Position A	Bilateral	Y/N	Y/N												
	Hemiplegic side														
Position B	Bilateral														
	Hemiplegic side														

Phase 2								
Electrode positioning and frequency		VAS questionnaires score out of 10						
		No FES: Question 1	No FES: Question 2	With FES: Question 1	With FES: Question 2	With FES : Question 3	With FES: Question 4	With FES: Question 5
Position 1	Bilateral							
	Hemiplegic side							
Position 2	Bilateral							
	Hemiplegic side							

Appendix XI

Pilot Study : Participant information sheet and consent form:

Information Sheet:

Thank you for your time and considering to be part of this study.

My name is Tarryn Barry, I am a physiotherapist completing my masters at the University of Cape Town (UCT). My supervisor is Professor Jennifer Jelsma . My topic of research is:

"THE EFFECT OF FUNCTIONAL ELECTRICAL STIMULATION OF THE ABDOMINAL MUSCLES ON MOTOR PERFORMANCE AND FUNCTIONAL ACTIVITY OF THE TRUNK IN STROKE PATIENTS: A RANDOMISED CONTROL TRIAL "

What is FES:

Functional electrical stimulation or FES helps a paralysed muscle to contract or activate by applying an electric current. This current doesn't cause pain but can be an uncomforTable sensation that some people says feels like" pins and needles". It mostly used by physiotherapists and occupational therapists in the weak arm and leg in stroke patients, to help with moving the arm and walking. There hasn't been a lot of testing of FES on the stomach muscles in stroke to see if it works in this area.

Please read the information below and you can only be part of the study if you agree to be part of it.

Purpose of Study:

The purpose of this study is to find out if using FES on the abdominal (stomach) muscles ,while patients are doing their treatment at the same time in physiotherapy, will help patients with stroke with doing everyday activities like washing and dressing easier . We would also like to see if other functions such as walking and doing activities in standing will be easier.

Procedure:

Patients in this study will have an FES machine applied to the stomach muscles, using small sticky electrode pads. In the beginning I will first check if you can feel the FES on both sides of your abdominal muscles. I will do a test where the machine will be turned on and the current will first be given to the non-affected side and then to your affected (weak)side. If you can't fell the current when the machine is turned up higher than a setting of 4, then you may not be able to be part of this study.

This machine will only be applied to the stomach muscles during physiotherapy sessions by your physiotherapist, at the start of your session. It will remain applied for the entire treatment session where you will do your normal therapy exercises with your physiotherapist, and it will be removed by your physiotherapist when your treatment session is finished. The physiotherapist will apply the FES to your stomach muscles on the weak side.
At the beginning of the study and your admission I will do four assessments with you as, this will be your first study measurement session. Every patient that is part of the study will be part of these study measurement sessions. These assessments will not take much time. Every two weeks from week three to week seven or the first five weeks, while you are admitted here at WCRC you will have a study measurement session, and this will be done by another therapist using the same four assessments. This will be done to see if you have scored better or worse on the assessments as you continue with therapy. At the last study measurement session,(this is the third study measurement session) we will add another assessment, this assessment will measure your number of heart beats when you walk, so we can see how much energy you use when walking.

We will also ask if you could please come back to the state rehabilitation centre , one month after this last study measurement session so we can see if you are still doing the same functional activities you could do for yourself when you were discharged from the rehabilitation centre. You will be assessed using the same four assessments again and the one we added at the last study measurement session that measures your heart beats with walking, for the last time, at this session. We will assist you with transport costs (if you have to pay for a car or for petrol to a family member, or take a bus or train) to come to this last session, with a cash donation of up to R150.

Please note If you are discharged from WCRC or transferred to another hospital , during your admission to WCRC before the first ~~five~~ **seven** weeks of your admission, you will no longer be part of this study.

Number of patients needed:
The research will involve approximately 60 patients. The patients will be divided into two groups.

Patient groups:
One group will get full FES treatment to their stomach muscles. This FES will only be applied in physiotherapy sessions while you are doing your normal therapy exercises with your

physiotherapist. The physiotherapist will apply the FES to your stomach muscles on the weak side. You will only have the machine on for your whole treatment session and it will be removed when you finish the session.

The other group will receive placebo (not full) FES treatment to their stomach muscles. This means the FES machine will be applied to your stomach muscles, but it may not be switched on or may not be as strong a setting used in the other group. This group will receive your normal exercises you would get in physiotherapy treatment sessions as well. **This means that NOT everyone included in the study will receive the full tested FES.**

How patients will be placed into the groups:

The patients will randomly be placed into each group and patients will not be chosen to be in either group. I will use a computer programme to give you a random number, and depending on where this number falls between one and forty will decide which group you are placed in. But you will not know which number you are given, and this means you won't know which group you are placed in, only I will know which group you are in. The kind of stroke, how severe your stroke is, where you live or how old you are will not decide which group you will be placed into.

Side effects:

FES has very few side effects that have been reported, these are only related to skin sensitivity to the pads that will be placed on your skin. If you have a rash, or the skin is red then you need to tell your physiotherapist and you will receive different pads to use that will not give you a rash.
This FES current doesn't cause pain but can be an uncomfortable sensation that some people says feels like" pins and needles"

How do you benefit:

If you participate in this study, you may not directly benefit, but you will help us as clinicians to help other patients with stroke if we find that FES used in physiotherapy treatment sessions does help with doing functional activities.
You will however receive regular physiotherapy by your physiotherapist, as if there was no study taking place, no matter which group you are placed in.
You can at any time choose to leave the study and not be part of it if you want to. If you leave the study, it will not affect your treatment until your discharge or for any future admissions to WCRC.

Your details eg. Name, address etc will remain anonymous and only I the researcher, will know these details and which group you have been placed in.
You will receive a contribution towards transport costs of up to R150 to assist with paying for your transport to WCRC for the last assessment which will be 1 month after your last assessment.

If you are placed into the placebo group (the group that doesn't receive full FES) and we find at the end of the study that FES did help those patients that were placed in the full FES group then we can offer you another short admission (+-4 weeks) to WCRC to do therapy with full FES, if you would like to stay for another admission.
What happens if I get hurt taking part in this study:

The University of Cape Town (UCT) has insurance cover for the event that research-related injury or harm results from your participation in the trial. The insurer will pay all reasonable medical expenses in accordance with the South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI) in the event of an injury or side effect resulting directly from your participation in the trial. You will not be required to prove fault on the part of the University.
The University will not be liable for any loss, injuries and/or harm that you may sustain where the loss is caused by

- The use of unauthorised medicine or substances during the study
- Any injury that results from you not following the protocol requirements or the instructions that the researcher may give you
- Any injury that arises from inadequate action or lack of action to deal adequately with a side effect or reaction to the FES electrodes.
- An injury that results from negligence on your part

"By agreeing to participate in this study, you do not give up your right to claim compensation for injury where you can prove negligence, in separate litigation. In particular, your right to pursue such a claim in a South African court in terms of South African law must be ensured. Note, however, that you will usually be requested to accept that payment made by the University under the SA GCP guideline 4.11 is in full settlement of the claim relating to the medical expenses. "
An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study doctor immediately of any side effects and/or 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 you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.
Your participation in this study will be appreciated.

Please feel free to ask me any questions at any time. The UCT FHS Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any questions about your rights and welfare as research subjects on this study.

The results of the study will be available in June 2016 and all completed data sheets will be locked away and stored in a safe location that only I can access, for one year. I will let you know what the results are if you provide me with your address or telephone number.

Kind Regards

Tarryn Barry

(researcher)

Email: tarryn603@gmail.com

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(Supervisor)

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Professor Marc Blockman

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Floor E52, Room 23,

Observatory, 7925.

Tel: 021 406 6338

See more at: http://www.health.uct.ac.sa/fhs/research/humanethics/about

Intervention study

CONSENT FORM)

I have read the information and understand the purpose of this study and what is expected of me. I have had all my questions answered.

Please circle the correct answer below:

If I choose to be part of this study, I will definitely receive FES …… YES or NO

My personal details will be available for everyone to see…. YES or NO

I can leave the study and choose not to be part of it at any time if I don't want to….YES or NO

There is a risk of getting a skin rash from the pads on my skin and this means I need different pads….YES or NO

I (participant)………………………………………………………… agree to be part of this study.

Participant signature: ………………………………

Researcher signature: ……………………………

Date: ……………………………………………

CONSENT FORM. (WITH WITNESS SIGNATURE)

I have read or have been explained to the information in this study and understand the purpose of this study and what is expected of me if I take part in the study.

Please circle the correct answer below:

If I choose to be part of this study, I will definitely receive full tested FES …… YES or NO

My personal details will be available for everyone to see…. YES or NO

I can leave the study and choose not to be part of it at any time if I don't want to….YES or NO

There is a risk of getting a skin rash from the pads on my skin and this means I need different pads….YES or NO

I (participant)………………………………………………………… agree to be part of this study.

Participant signature: ………………………………

Researcher signature: ……………………………

Witness: …………………………….

Date: ……………………………………

Appendix XII

<u>Pilot Study: Physiotherapist information sheet and consent form</u>

Intervention study

<u>Physiotherapist Information Sheet:</u>

Thank you for your time and for considering to be part of this study.
Please read the information below and you can only be part of the study if you agree to be part of it.

My name is Tarryn Barry, I am a physiotherapist and physiotherapy masters student at the University of Cape Town (UCT). My topic of research is:
"THE EFFECT OF FUNCTIONAL ELECTRICAL STIMULATION OF THE ABDOMINAL MUSCLES ON MOTOR PERFORMANCE AND FUNCTIONAL ACTIVITY OF THE TRUNK IN STROKE PATIENTS: A PILOT STUDY

Functional Electrical stimulation (FES) is the application of electrical current to via superficial electrodes to the nerves of paralysed muscles in individuals with upper motor neuron lesions eg. Stroke or traumatic brain injuries. It is widely used clinically and in stroke research, but is mostly utilised in the upper limb and lower to restore function eg. Improved dropped foot in gait. There is no published literature of the use in FES in the trunk (abdominal muscles) in stroke despite trunk treatment being so important in stroke rehabilitation.

<u>Aims and objectives:</u>

To determine if there is a significant difference between participants who have had a stroke within the previous three four months, receiving FES on the EO in addition to conventional physiotherapy in the experimental group and participants receiving placebo FES to the EO and conventional physiotherapy in the FES placebo control group, by comparing the :

1. change in motor performance and coordination of the trunk using The Trunk Impairment Scale (TIS)
2. change in impairments as measured by the Rivermead Motor Assessment (RMA)
3. change in functional independence and performance in ADLs measured by the Barthel Index (BI)
4. change in energy expenditure in gait measured using Physiological Cost index (PCI).
5. Health related quality of life scores measured by the EQ-5D health related quality of life measure.

To determine if the timing of when FES is first used in physiotherapy treatment after the onset of stroke, makes a significant difference in scores in the above-mentioned outcome measures in the experimental group.

To determine if the following patient characteristics age, gender, and side of stroke, determine a change in score in the above outcome measures, from admission to follow up in the control placebo and treatment groups.

Sample:

Approximately 60 stroke survivors admitted consecutively over five months at your centre will be recruited. These participants must reside in the Cape Town metro pole, be between 18 to 70 years old, have had their first ever and only stroke in the last three four months, confirmed by a medical professional.

These individuals must not have any other neurological conditions, uncontrolled epilepsy, healing wounds/poor skin condition, pacemakers, or other implants, have abnormalities on an ECG and or be pregnant. They may also not have cognitive (they must pass the MOCA) and language impairments (Only expressive aphasics will be included and will be screened by the speech therapist for suitability to provide consent) that prevent giving informed consent. and if they are found unsuitable to provide consent then their family member must come in to provide consent on their behalf. They may not fail the sensory screening using the FES machine in the initial screening.

Methodology:

I, the researcher will assess all participants on admission for eligibility and obtain written consent. Each participant will be provided with a code as they enter the study to ensure anonymity. I will then randomise and assess the participants, using the above outcome measures, except PCI. All participants will be part of the study from week three to week seven of their admission, which is six- to eight weeks approximately. The experimental group will receive conventional physiotherapy and FES to their external obliques (EO) on their hemiplegic side. The control group will receive conventional physiotherapy and placebo FES to their EO on their hemiplegic side, by applying FES just below intensity threshold for contraction or not switching on the machine

A research assistant will reassess all participants using the above outcome measures at two-week intervals during their admission, except for the PCI which will first be measured at discharge, and four weeks post their last inpatient measurements. All assessments will take place in the afternoon in a room separate from the therapy/treatment area. The research assistant will be tested for inter-rater and intra-rater reliability in outcome measure scoring by the researcher before data collection starts. You will not be involved with assessment or randomisation, but will know which group they are placed into. The patient will not know which group they are placed into.

FES application will therefore occur in all physiotherapy sessions. This would require you to be able to apply the electrode pads on a certain area of the EO at the start of your treatment session and to turn it up to the correct setting to provide the correct stimulation. This should be quick and easy. FES must be applied for your whole session no matter what activity you wish to do with the patient and for all physiotherapy sessions the patient has for their entire admission. Therefore some of your clients will be part of the experimental group and some clients will be part of the control group.

The electrode placement and treatment setting will be determined after a feasibility study has been completed a month prior to this study, which I have completed. You will receive training on how to use the FES machine and where to place the electrodes on the EO and which setting to use to get a contraction for the experimental group based on the feasibility study results, by myself. You will also receive training on how you should apply FES for the control placebo group, as they will not be stimulated to get a contraction.

I will supply three FES machines for this study, and I will require the use of the facility's other FES machines. I will supply all batteries and electrodes pads for the clients. Each client will get a set of pads.

<u>How do you benefit:</u>

You will receive training on how to use the devices. If some of the physiotherapists would like to receive further training using FES, I can assist with providing further motivation to get this training. There should be no further load placed on you and your sessions as FES should just be applied quickly, to be in the background of your treatment session and you can continue with regular therapy.

Data collection will continue over five months from July 2016- December 2016. You may at any time in this period choose to no longer participate with no consequences or penalties.

All completed data sheets will be locked away and stored in a safe location that only the researcher can access for one year. I will make the results of the study available to you in October 2017 when my thesis is completed.

What happens if I get hurt taking part in this study:

The University of Cape Town (UCT) has insurance cover for the event that research-related injury or harm results from your participation in the trial. The insurer will pay all reasonable medical expenses in accordance with the South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI) in the event of an injury or side effect resulting directly from your participation in the trial. You will not be required to prove fault on the part of the University.

The University will not be liable for any loss, injuries and/or harm that you may sustain where the loss is caused by

- The use of unauthorised medicine or substances during the study
- Any injury that results from you not following the protocol requirements or the instructions that the researcher may give you
- Any injury that arises from inadequate action or lack of action to deal adequately with a side effect or reaction to the FES electrodes.
- An injury that results from negligence on your part

Please feel free to ask me any questions at any time The UCT FHS Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any questions about your rights and welfare as research subjects on the study

Kind Regards

Tarryn Barry
(researcher)
Email: tarryn603@gmail.com
Tel no: 021 370 2456/2354

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(Supervisor)
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Professor Marc Blockman

Head of Human Research and Ethics Committee- UCT Faculty of Health Sciences

Old Main Building of Groote Schuur Hospital,

Floor E52, Room 23,

Observatory, 7925.

Tel: 021 406 6338

See more at: http://www.health.uct.ac.sa/fhs/research/humanethics/about

Intervention study:

CONSENT FORM.

I ___________________________ have read 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 this study, and I am doing so of my own free will. I know that I can withdraw at any time if I so wish and that it without any consequences for myself.

Signed:

____ ___________________

Participant Date and place

____ ___________________

Researcher Date and place

Appendix XIII

APPENDIX 1: THE TRUNK IMPAIRMENT SCALE FOR TBI PATIENTS.

Starting position for all items: sitting, thighs horizontal and feet flat on support, knees 90 ° flexed, no back support, hands and forearms resting on the thighs. The subject gets three attempts for each item. The best performance is scored. The observer may give feedback between the tests. Instructions can be verbal and non verbal (demonstration).

Item	Task description	Score description	Score	Remarks
1.	Keep starting position for 10 sec	Falls or needs arm support Maintains position for 10 sec	0 2	If 0, total TIS score is 0
2.	Therapist crosses strongest leg over weakest leg, keep position for 10 sec	Falls or needs arm support Maintains position for 10 sec	0 2	
3.	Patient crosses strongest leg over weakest leg	Falls Needs arm support Displaces trunk > 10 cm / assists with arm Moves without trunk / arm compensation	0 1 2 3	
		Total Static Sitting Balance		/7
1.	Touch seat with elbow on weakest, side, return to starting position (task achieved or not)	Doesn't reach seat / falls / uses arm Touches seat without help	0 1	If 0, items 2 + 3 are also 0
2.	Repeat item 1 (evaluate trunk movement)	No appropriate trunk movement Appropriate trunk movement (shortening weak side, lengthening strong side)	0 1	If 0, item 3 is also 0
3.	Repeat item 1 (compensation strategies used or not)	Compensation used (arm, hip, knee, foot) No compensation strategy used	0 1	
4.	Touch seat with elbow on strongest side, return to starting position (task achieved or not)	Doesn't reach seat / falls / uses arm Touches seat without help	0 1	If 0, items 5+6 are also 0
5.	Repeat item 4 (evaluate trunk movement)	No appropriate trunk movement Appropriate trunk movement (shortening strong side, lengthening weak side)	0 1	If 0, item 6 is also 0
6.	Repeat item 4 (compensation strategies used or not)	Compensation used (arm, hip, knee, foot) No compensatory strategy used	0 1	
7.	Lift pelvis on weakest side from seating, return to starting position (evaluate trunk movement)	No appropriate trunk movement Appropriate trunk movement (shortening weak side, lengthening strong side)	0 1	If 0, item 8 is also 0
8.	Repeat item 7 (compensation strategies used or not)	Compensation used (arm, hip, knee, foot) No compensation strategy used	0 1	
9.	Lift pelvis on strongest side from seating, return to starting position (evaluate trunk movement)	No appropriate trunk movement Appropriate trunk movement (shortening strong side, lengthening weak side)	0 1	If 0, item 10 is also 0
10.	Repeat item 9 (compensation strategies used or not)	Compensation used (arm, hip, knee, foot) No compensation strategy used	0 1	
		Total Dynamic Sitting Balance	/10	
1.	Rotate shoulder girdle 6 times (move each shoulder 3 times forward, start with weakest side)	Doesn't move weak side 3 times Asymmetric rotation Symmetric rotation	0 1 2	If 0, item 2 is also 0
2.	Repeat item 1, perform within 6 sec	Asymmetric rotation Symmetric rotation	0 1	
3.	Rotate pelvis girdle 6 times (move each knee 3 times forward, start with weakest side)	Doesn't move weak side 3 times Asymmetric rotation Symmetric rotation	0 1 2	If 0, item 4 is also 0
4.	Repeat item 3, perform within 6 sec	Asymmetric rotation Symmetric rotation	0 1	
		Total Co-ordination	/6	
		TOTAL TRUNK IMPAIRMENT SCALE	/23	

Appendix XIV

Rivermead Motor Assessment

'Gross function' section can be assessed simply by asking, which makes it a rapid measure.

Repeat instructions and demonstrate them to the patient if necessary. All exercises to be carried out independently unless otherwise stated. All arm tests refer to the affected side unless otherwise stated. In the 'Leg and Trunk' section all items should be tested, even if there are three consecutives '0' scores. Give no feed-back of whether correct or incorrect, just give general encouragement.

General instructions: Go through the items in order of difficulty. Score '1' if patient can perform activity, ' 0' if he cannot. Three tries are allowed for each item. You may stop the 'Gross function' section and 'Arm' section after 3 consecutives '0' scores for 3 consecutive items.

Section Item Score

A. Gross function

1. Sit unsupported

Without holding on, on edge of bed, feet unsupported.

----

2. Lying to sitting on side of bed

Using any method.

----

3. Sitting to standing

May use hands to push up. Must stand up in 15 sec

and stand for 15 sec, with an aid if necessary

----

4. Transfer from wheelchair to chair towards unaffected side

May use hands.

----

5. Transfer from wheelchair to chair towards affected side

May use hands.

----

6. Walk 10 m indoors with an aid

Any walking aid. No stand-by help.

----

7. Climb stairs independently

Any method. May use bannister and aid--must be a full flight of stairs.

----

8. Walk 10 m indoors without an aid

No stand-by help. No calliper, splint or walking aid.

----

9. Walk 10m , pick up bean bag from floor, turn and carry back

Bend down any way, may use aid to walk if necessary. No stand-by help. May use either hand to pick up bean bag.

----

10. Walk outside 40 m

May use walking aid, calliper, or splint. No stand-by help.

11.Walk up and down four steps

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.

----

9. Cut putty with a knife and fork on plate with non-slip mat and put pieces into container at side of plate

Bite-size pieces.

----

10. Stand on spot, maintain upright position, pat large ball on floor with palm of hand for 5 continuous bounces

-----

11. Continuous opposition of thumb and each finger more than 14 times in 10 sec

Must do movement in consistent sequence. Do not allow thumb to slide from one finger to the other.

----

12. Supination and pronation on to palm of unaffected hand 20 times in 10 sec

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.

----

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

Do not allow flexion at elbow, and wrist must be extended with palm of hand fully in contact with wall.

----

14. Place string around head and tie bow at back

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.

______

15. 'Pat- a-cake' seven times in 15 sec

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.

______

Arm function total

0

CERISE/QLRT-2001-00170 5

Appendix XV

THE BARTHEL INDEX

Patient Name: ____________________________

Rater Name: ____________________________

Date: ____________________________

Activity Score

____

____

FEEDING

0 = unable

5 = needs help cutting, spreading butter, etc., or requires modified diet

10 = independent

______

BATHING

0 = dependent

5 = independent (or in shower) ` ______

GROOMING

0 = needs to help with personal care

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

______

DRESSING

0 = dependent

5 = needs help but can do about half unaided

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

______

BOWELS

0 = incontinent (or needs to be given enemas)

5 = occasional accident

10 = continent ______

BLADDER

0 = incontinent, or catheterised and unable to manage alone

5 = occasional accident

10 = continent _______

TOILET USE

0 = dependent

5 = needs some help, but can do something alone

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

TRANSFERS (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 _______

MOBILITY (ON LEVEL SURFACES)

0 = immobile or < 50 yards

5 = wheelchair independent, including corners, > 50 yards

10 = walks with help of one person (verbal or physical) > 50 yards

15 = independent (but may use any aid; for example, stick) > 50 yards

____

STAIRS

0 = unable

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

10 = independent _______

TOTAL (0–100):_____

Provided by the Internet Stroke Centre — www.strokecenter.org

The Barthel ADL Index: Guidelines

1. The index should be used as a record of what a patient does, not as a record of what a patient could do.

2. The main aim is to establish degree of independence from any help, physical or verbal, however minor

and for whatever reason.

3. The need for supervision renders the patient not independent.

4. A patient's performance should be established using the best available evidence. Asking the patient,

friends/relatives and nurses are the usual sources, but direct observation and common sense are also

important. However direct testing is not needed.

5. Usually the patient's performance over the preceding 24-48 hours is important, but occasionally longer

periods will be relevant.

6. Middle categories imply that the patient supplies over 50 per cent of the effort.

7. Use of aids to be independent is allowed.

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Copyright Information

Appendix XVI

Physiological Cost Index

$$PCI = \frac{\text{walking heart rate (beats/minute)} - \text{resting heart rate (beats/minute)}}{\text{Walking speed (metres/minute)}}$$

Appendix XVII

EQ-5D-3L

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

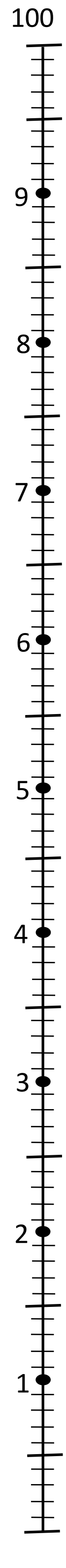
I have extreme pain or discomfort ☐

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

Appendix XVIII

Friedman ANOVA results for muscle thickness measurements for Position A1. A2, B1 and B2. For transversus abdominus (TrA) and external obliques (EO) muscles.

A Friedman ANOVA was conducted to test if the mean muscle thickness (mm) was different across five time points. Position A2 for TrA was the only placement that showed a significant difference for muscle thickness (section 4.4.2.1. and table 12).

Friedman ANOVA results for EO:

No significant difference was found for position A1 (p= 0.62), position A2 (p= 0.74), position B1 (p=0.18) and position B2 (p = 0.33)

Table 40: Friedman ANOVA test for Position A1 for EO muscle at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes

	Average Rank	Sum of Ranks	Mean	Std.Dev.
Position A1 U/S baseline EO	3583333	4300000	4658333	0.83
Position A1 U/S 5sec EO	2791667	3350000	4275000	0.94
Position A1 U/S 30sec EO	3125000	3750000	4408333	0.78
Position A1 U/S 1min EO	2666667	3200000	4158333	1241303
Position A1 U/S 5min EO	2833333	3400000	4358333	0.95

Friedman ANOVA and Kendall Coeff. of Concordance ANOVA Chi Sqr. (N = 12, df = 4) = 2.65 p = 0.62
Coeff. of Concordance = 0.06 Aver. rank r = -0.03

Table 41: Friedman ANOVA test for Position A2 for EO muscle at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes

	Average Rank	Sum of Ranks	Mean	Std.Dev.
Position A2 U/S baseline EO	3541667	4250000	4875000	1078825
Position A2 U/S 5sec EO	2958333	3550000	4591667	1013956
Position A2 U/S 30sec EO	2916667	3500000	4475000	1073757
Position A2 U/S 1min EO	2875000	3450000	4508333	0.96
Position A2 U/S 5min EO	2708333	3250000	4525000	0.92

Friedman ANOVA and Kendall Coeff. of Concordance ANOVA Chi Sqr. (N = 12, df = 4) = 1.99 p = 0.74
Coeff. of Concordance = 0.04 Aver. rank r = -0.05

Table 42: Friedman ANOVA test for Position B1 for EO muscle at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes

	Average Rank	Sum of Ranks	Mean	Std.Dev.
Position B1 U/S baseline EO	3666667	4400000	4733333	0.54
Position B1 U/S FES 5sec EO	2958333	3550000	4508333	0.73

Position B1 U/S FES 30 sec EO	2125000	2550000	4308333	0.72
Position B1 U/S FES 1 min EO	3041667	3650000	4500000	0.71
Position B1 U/S FES 5 min EO	3208333	3850000	4558333	0.86

Friedman ANOVA and Kendall Coeff. of Concordance ANOVA Chi Sqr. (N = 12, df = 4) = 6.3 p = 0.18 Coeff. of Concordance = 0.13 Aver. rank r = 0.05

Table 43: Friedman ANOVA test for Position B2 for EO muscle at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes

	Average Rank	Sum of Ranks	Mean	Std.Dev.
Position B2 U/S baseline EO	2875000	3450000	4416667	1199116
Position B2 U/S FES 5sec EO	2958333	3550000	4466667	1184240
Position B2 U/S FES 30 sec EO	3541667	4250000	4850000	0.97
Position B2 U/S FES 1 min EO	3333333	4000000	4758333	1072345
Position B2 U/S FES 5 min EO	2291667	2750000	4233333	1087393

Friedman ANOVA and Kendall Coeff. of Concordance ANOVA Chi Sqr. (N = 12, df = 4) = 4.61 p = 0.33 Coeff. of Concordance = 0.1 Aver. rank r = 0.01

Friedman ANOVA results for TrA:

No significant difference was found for position A1 (p= 0.58), position B1 (p=0.49) and position B2 (p = 0.1)

Table 44: Friedman ANOVA test for Position A1 for TrA muscle at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes

	Average Rank	Sum of Ranks	Mean	Std.Dev.
Position A1 U/S baseline TrA	3041667	3650000	3083333	1176152
Position A1 U/S 5sec TrA	2666667	3200000	3166667	1488339
Position A1 U/S 30 sec TrA	2750000	3300000	3100000	0.79
Position A1 U/S 1min TrA	3625000	4350000	3266667	1017424
Position A1 U/S 5min TrA	2916667	3500000	2983333	1046929

Friedman ANOVA and Kendall Coeff. of Concordance ANOVA Chi Sqr. (N = 12, df = 4) = 2.86 p = 0.58 Coeff. of Concordance =0.06 Aver. rank r = -0.03

Table 45: Friedman ANOVA test for Position B1 for TrA muscle at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes

	Average Rank	Sum of Ranks	Mean	Std.Dev.
Position B1 U/S Baseline TrA	2500000	3000000	3116667	0.88
Position B1 U/S FES 5sec TrA	3250000	3900000	3183333	0.84
Position B1 U/S FES 30 sec TrA	2666667	3200000	3158333	0.88
Position B1 U/S FES 1 min TrA	3500000	4200000	3408333	0.97
Position B1 U/S FES 5 min TrA	3083333	3700000	3141667	1218388

Friedman ANOVA and Kendall Coeff. of Concordance ANOVA Chi Sqr. (N = 12, df = 4) = 3.47 p = 0.49 Coeff. of Concordance = 0.07 Aver. rank r = -0.01

Table 46: Friedman ANOVA test for Position B2 for TrA muscle at each time point: Baseline, 5 seconds, 30 seconds, one minute and 5 minutes

	Average Rank	Sum of Ranks	Mean	Std.Dev.
Position B2 U/S Baseline TrA	2333333	2800000	3116667	0974057
Position B2 U/S FES 5sec TrA	3541667	4250000	3533333	1108097
Position B2 U/S FES 30sec TrA	3000000	3600000	3200000	0.77
Position B2 U/S FES 1 min TrA	3708333	4450000	3608333	1150066
Position B2 U/S FES 5 min TrA	2416667	2900000	2933333	0.79

Friedman ANOVA and Kendall Coeff. of Concordance ANOVA Chi Sqr. (N = 12, df = 4) = 7.74 p = 0.1 Coeff. of Concordance = 0.16 Aver. rank r = 0.09