UNIVERSITY OF SOUTHAMPTON

Faculty of Health Sciences

The use of Functional Electrical Stimulation as a treatment intervention to improve walking ability in a sub-acute stroke population

by

Anna Gould

Thesis for the degree of Clinical Doctorate in Clinical Practice

October 2015

UNIVERSITY OF SOUTHAMPTON

ABSTRACT

FACULTY OF HEALTH SCIENCES

Physiotherapy

Thesis for the degree of Doctorate in Clinical Practice

THE USE OF FUNCTIONAL ELECTRICAL STIMULATION AS A TREATMENT INTERVENTION TO IMPROVE WALKING ABILITY IN A SUB-ACUTE STROKE POPULATION

Anna Gould

To date, few authors have explored whether Functional Electrical Stimulation (FES) of the lower limb, can lead to improvements in gait parameters in a sub-acute stroke population using a randomised controlled study design. Addressing the limitations of previous studies and building on the current evidence to date, this study aims to explore the feasibility of conducting a two week gait training programme combined with FES (targeted to glutei and/or ankle dorsiflexor and evertor muscles) for people with sub-acute stroke, to inform the methodology of a larger randomised control trial.

Fifteen medically stable sub-acute stroke survivors were randomised into one of two groups; in addition to routine therapy one group received one hour of gait training four times a week for two weeks (n=7), and the other group received gait training at an identical level of intensity but combined with FES targeted to glutei and/or ankle dorsiflexor and evertor muscles (n=8). Outcome measures, including gait speed and quality of walking pattern, were measured prior to and post gait training intervention, and at six week follow-up.

All fifteen participants received the intended intensity of therapy and completed the trial. There were no drop outs during treatment or at follow-up. There was a significant improvement in gait speed and the quality of walking pattern between baseline assessment and immediately following both gait training programmes (week two). These improvements were maintained at six week follow-up. However, no trends were found in favour of either group.

The current methodological process proved a feasible approach and sub-acute stroke patients were able to tolerate the gait training interventions however, modifications to the protocol to enhance the success of a follow-on randomised controlled trial are suggested.

Contents

List of tables

List of figures

DECLARATION OF AUTHORSHIP

I, Anna Gould, declare that the thesis entitled:

The use of Functional Electrical Stimulation as a treatment intervention to improve walking ability in a sub-acute stroke population

and the work presented in the thesis are both my own, and have been generated by me as the result of my own original research. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
- where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
- where I have consulted the published work of others, this is always clearly attributed;
- where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- none of this work has been published before submission,

Signed: ……..

Date:……

Acknowledgements

With the oversight of my main supervisor, editorial advice has been sought. No changes of intellectual content were made as a result of this advice.

With particular thanks to the following:

Jo Molle for her assistance in proofreading this Thesis.

The Association of Chartered Physiotherapists in Neurology who have provided funds for the research to be completed.

Dr Fleur Kitsell and Health Education Wessex for having the foresight to develop the Trainee Consultant Practitioner programme giving me, and other aspiring leaders in healthcare like me, the opportunity to learn and grow as a thinker, a researcher and a leader.

My research supervisors, Professor Ann Ashburn and Dr Paul Taylor for their expert guidance advice and patience.

Last but not least I would like to thank my family for their support and looking after my son so well, allowing me to focus on writing these pages and my husband Paul, for providing a constant source of unwavering optimism and motivation.

Definitions and Abbreviations

Carry-over Effect: Operates on the principle that the movement deficit is restored without the use of FES immediately following its application. Short term gains are seen, which may wear off over time.

Chronic stroke: Commonly regarded as an open ended time period six months after development initial onset of stroke symptoms.

Foot drop: The inability to lift the foot and toes when walking.

Functional Electrical Stimulation (FES): FES uses small electrical impulses to activate muscles to supplement or replace function that is lost in neurologically impaired people. It involves stimulation of the peripheral nerves using electrodes.

Gait: A particular way or manner of walking.

Orthotic Effect: Where FES supports, aligns, prevents, or corrects deformities to improve function of movable parts of the body.

Prosthetic Effect: Where FES acts to replace a previously missing movement function.

Stroke: clinical syndrome consisting of 'rapidly developing clinical signs of focal (or at times global) neurological impairment of sudden onset and lasting more than 24 hours (or leading to death) and of presumed vascular origin' (WHO, 2006).

Sub-acute stroke: For the purposes of this study a sub-acute stroke is defined as the first six months following initial onset of the above signs and symptoms.

Therapeutic Effect/Training Effect: Operates on the principle that the deficit movement will be restored in the long term, no longer necessitating the device (Roche et al., 2009).

1. Chapter 1: Introduction

1.1 Stroke

Stroke has been defined as a clinical syndrome consisting of 'rapidly developing clinical signs of focal (or at times global) neurological impairment of sudden onset and lasting more than 24 hours (or leading to death) and of presumed vascular origin' (WHO, 2006). There are approximately 110,000 strokes per year in England alone, and around 1 in 4 people who have a stroke, die of it . It is the leading cause of serious long term disability in the UK with around half of all stroke survivors being dependent on others for activities related to daily living (DOH, 2010). The subsequent financial impact on the NHS and economy is substantial, in terms of direct costs to the NHS (at least £3 billion annually) and the wider economic expense (estimated at around £8 billion), not to mention the social and personal costs to the individual stroke survivor and their families (DOH, 2010).

The overall incidence of stroke has been documented to have fallen by 29% between 1999 and 2008 due to improved management of cardiovascular risk factors, such as high blood pressure and hypercholesterolaemia . However, with the rising prevalence of obesity it has been estimated that obesity attributable disease risks, will add an excess of 331,000 – 461,000 cases of coronary heart disease and stroke during the next 20 years (Wang et al., 2012). In addition, as the risk of stroke increases with age, the rapidly growing aging population is also linked to a predicted rise in stroke incidence (Di Carlo, 2009). It remains to be seen whether further efforts in the primary and secondary prevention of stroke will be sufficient to offset the predicted rise in stroke incidence.

1.2 Walking ability post stroke

Impaired mobility is a common disability following stroke, with 22% of stroke patients not regaining any walking function at the end of rehabilitation and 14% being able to walk, but only with assistance (Jørgensen et al., 1995). For the individual, walking ability following stroke can have significant consequences on length of hospital stay (RCP, 2011), discharge destination (Brosseau et al., 1996) and ultimately, independence in activities of daily living (Carod-Artal et al., 2002). It is unsurprising therefore that the most common rehabilitation goal for stroke survivors is regaining the ability to walk (Bohannon et al., 1988). In order to enable

patients to meet this rehabilitation goal, it is imperative that clinicians are able to select and implement effective and evidenced-based treatment programmes.

In the field of gait training, current evidence points towards the importance of task orientated, repetitive training programmes (Peurala et al., 2007, Pohl et al., 2007, Van Peppen et al., 2004). However, questions are still raised as to the optimal content, method of delivery and intensity of such interventions. Furthermore, the majority of studies investigating gait training in stroke patients relate to samples of chronic stroke survivors. This is in contrast to the evidence suggesting that most motor and functional recovery occurs within the first 3 months after stroke (Jørgensen et al., 1995, Wade and Hewer, 1987) and that intervening early can produce better outcomes in the long-term (Paolucci et al., 2000). Furthermore, recently published evidence has demonstrated that the level of functional and motor performance five years following stroke is comparable to the level achieved at two months, providing further support for the importance of intensive rehabilitation in the early stages of stroke (Meyer et al., 2015).

1.3 Gait training and Functional Electrical Stimulation

The specific use of Functional Electrical Stimulation (FES) to improve walking by addressing foot drop of central neurological origin has been well established in literature and is currently endorsed by national guidelines as safe and effective for use in routine clinical practice (NICE, 2009, NICE, 2013, RCP, 2012). However evidence on the use of FES as a therapeutic tool, used on multiple muscle groups and in combination with other treatment modalities to improve walking ability, is far less robust. Systematic reviews have shown that research in this field has largely focussed on chronic stroke populations, has insufficient sample sizes and demonstrates a great deal of heterogeneity in terms of treatment approaches. With the lack of high quality evidence from adequately powered randomised controlled trials in mind, current clinical guidelines for stroke advise that 'therapeutic electrical stimulation for the treatment of the upper and lower limbs following stroke should only be used in the context of a clinical trial' (RCP, 2012).

1.4 Purpose of this thesis

The purpose of this research is to investigate the combination of two treatment modalities; gait training and FES within a two week, intensive gait rehabilitation programme. Both

strategies are currently available in clinical practice but are used in isolation and in the chronic stages of rehabilitation. In view of the paucity of published research in this field and the use of the novel combination of treatment modalities in a sub-acute population, this primary aim of this study was to investigate whether the research protocol is feasible in the targeted population group.

The objectives of the study were to a) determine the proportion of eligible patients admitted to recruitment sites, b) to explore factors influencing eligibility and subsequent recruitment, c) to determine follow-up and retention rates, d) to determine whether patients were able to complete intervention schedule, e)to describe the variation in the content and intensity of the intervention delivered, f) to explore participant and staff perceptions of the acceptability of the intervention, g) to determine whether the selected outcome measures are suitable and can be carried out in clinical/home settings and h) to gain estimates required for a sample size calculation. The results of this study will then help inform the design of an adequately powered subsequent randomised controlled trial. From this, conclusions can be drawn to inform clinical decisions regarding choice of treatment programmes in the sub-acute phase of stroke aimed at maximising walking ability, and hence functional independence.

1.5 Thesis structure

This thesis has been divided into five main chapters. Following this introduction chapter, chapter two explores the background literature related to use of FES to improve gait in patients with stroke and uses a systematic approach to evaluate its use in a sub-acute stroke population. This chapter draws together the current knowledge and concludes that there is insufficient evidence from high quality trials into the efficacy of FES used with gait training in the population in question. It will be argued that prior to efficacy testing, research needs to first establish the feasibility of combining FES with a task specific gait training programme that is practical to complete in both hospital and community settings. The final section of this chapter highlights the research question and further clarifies the objectives of the study with regards to testing the feasibility of the research protocol.

Chapter three describes the methodology used to complete the experimental phase of this feasibility study, where 15 participants with sub-acute stroke were recruited over a 12 month period. Chapter four primarily contains the analysis of the data collected in order to meet the feasibility objectives of the study. Secondary to this, a preliminary analysis of the findings

related to outcome measures are also presented. Chapter five discusses these findings and places them within the context of other research. A critique of the research study is provided and a summary of learning to be taken forward to a subsequent larger scale randomised controlled trial is highlighted. Finally, the main conclusions are drawn together in relation to the extent to which the research aims and objectives were met.

2. Chapter 2 Part 1: Background

2.1 Chapter overview

This chapter is divided into three parts. Part 1 reviews the background literature around gait training and the use of FES to improve walking ability following stroke. Part 2 looks in further depth at the literature related to sub-acute stroke, identifies gaps in the knowledge base and justifies the need for further study and the rationale behind the formulation of the research question. Part 3 details the research question and the study's aims and objectives.

2.2 Gait training and stroke

There is now a growing body of evidence that suggests targeted and repetitive gait training early after stroke significantly improves motor outcomes and measures of functional independence (Peurala et al., 2007, Pohl et al., 2007, Van Peppen et al., 2004). These improvements have been shown to remain at six month follow-up (Peurala et al., 2007, Pohl et al., 2007). However, the components of the gait training packages offered by the literature vary significantly between studies, including the use of body weight supportive devices (Peurala et al., 2007, Pohl et al., 2007), treadmill training (McCain et al., 2008, Moseley et al., 2005), targeted land based exercise (Outermans et al., 2010, Richards et al., 1993), or a combination of these methods (da Cunha et al., 2002, Dean et al., 2010, Holleran et al., 2014). Clinicians are faced with the challenge to select the most effective, practicable and affordable training package from a wide ranging 'black box' of approaches. To help inform clinical decision making, research is needed to identify the individual key factors, or optimal combinations, that produce the best outcomes (Kwakkel et al., 1999).

In recent decades, rehabilitation following stroke has shifted from being mostly provided within a hospital setting to now being delivered at home or in care homes (RCP, 2014). Subsequently, hospital length of stay following stroke has dropped from to 25.4 days in 2006 to 19.5 days in 2010 (RCP, 2011), with stroke skilled Early Supported Discharge (ESD) services picking up ongoing rehabilitation needs in the community, most often in patient's homes. Bearing this in mind, access to clinic/gym based equipment such as treadmills and body weight support systems can be a real challenge in the sub-acute phase of stroke. Therefore, more practical and portable therapy methods are required that can be easily carried out within both a clinic and home setting.

2.3 Use of Functional Electrical Stimulation in gait training

One such portable treatment modality which can be used for targeted and repetitive gait training is Functional Electrical Stimulation (FES). Originally designed and used to correct foot drop by Liberson et al. (1961), FES has been used to replace or assist a functional movement that is lost after injury or disease of the central nervous system (Glanz et al., 1996). When used as a treatment aid, FES has the attraction over other assistive devices of being relatively inexpensive, portable and applicable to a large population of patients. Furthermore, there is some evidence to promote its clinical effectiveness, both in terms of its orthotic and training effects.

The orthotic effect of FES in the treatment of gait has been well established in research (Burridge et al., 1998, Burridge et al., 1997b, Burridge et al., 2007, Kottink et al., 2004). In these studies FES was controlled by a pressure switch worn in the shoe enabling appropriate muscle contraction activated in timing with gait cycle. Authors showed stimulation by this method improved gait parameters whilst wearing the device, often to a significantly greater degree than conventional physiotherapy alone (Bogataj et al., 1995, Burridge et al., 1997b). Due to significant evidence from sufficiently powered randomised controlled trials, the National Institute for Health and Clinical Excellence (NICE) have published guidance to support the use of FES for foot drop of central neurological origin in routine clinical practice (NICE, 2013).

FES has also been described as having a training effect (Glanz et al., 1996, Howlett et al., 2015, Robbins et al., 2006, Roche et al., 2009, Taylor et al., 1999b). This refers to the improvements to gait initially gained using FES remaining evident after the device has been removed. To date there have been four systematic reviews investigating the training effect of FES on activity measures post stroke and all have considered lower limb function (Howlett et al., 2015, Pereira et al., 2012, Robbins et al., 2006, Roche et al., 2009). Robbins et al. (2006) carried out a meta-analysis of eight articles, specifically examining the training effect of FES and transcutaneous electrical stimulation (TENS) on improving gait speed in stroke patients. Three of the trials that considered gait training with FES versus conventional therapy were entered into a fixed effects model (36 subjects in the treatment group and 35 subjects in the control group). Results showed a mean difference and 95% confidence intervals (mean, 0.18; 95% CI, 0.08 – 0.28) that were significant (p=0.01) for the effectiveness of FES treatment.

According to Perera et al. (2006), a small meaningful change in walking speed is 0.05m/sec whilst a substantial meaningful difference is 0.1m/s. However, this is based on meaningful changes associated with a decline in function. Tilson et al. (2010) investigated the meaningful clinically important differences in gait speed related to an improvement in function, which can be considered to be more relevant in rehabilitation trials. Authors used an anchor based analysis to estimate clinically meaningful change and compared change in gait speed with the modified Rankin Score, a measure with established clinical relevance and responsiveness to change. Results revealed that the estimate for clinically meaningful important difference in gait speed for people between 20 and 60 days after first-time stroke was 0.16 m/s. The mean difference in gait speed found in the meta-analysis by Robbins et al. (2006) can therefore be considered as reaching a clinically relevant threshold (mean, 0.18m/s).

In 2009, Roche et al. examined 30 trials ranging from case studies to controlled trials investigating the use of FES for foot drop (Roche et al., 2009). The authors concluded that there was inconclusive evidence to support the training effect of FES and highlighted the need for further research in this field, particularly in the earlier stages of stroke. In 2012, Pereira et al. carried out a systematic review of the effectiveness of FES on lower limb function in chronic stroke patients, including evidence from seven randomised controlled studies and 231 participants (Pereira et al., 2012). Authors here concluded that there was a small but significant positive impact of FES on walking ability, as measured by improvements in distance seen in the six minute walk test.

Finally, Howlett et al. (2015) carried out a systematic review with meta-analysis of 18 trials involving 485 patients to see whether incorporating FES into treatment was more effective than training alone. In their review of acute, sub-acute and chronic stroke participants, treatment included FES incorporated with upper limb (10 trials) and lower limb training (eight trials). Results showed that FES used with lower limb training resulted in a mean 0.08m/sec increase in walking speed compared with control groups (95% CI, 0.02-0.15). The authors concluded that FES moderately improves activity compared to no training or training alone.

On balance, in comparison to the body of evidence looking at the orthotic effect, the research to support FES as a training tool is far less robust. Results of these systematic reviews show that research has largely focussed on chronic stroke populations. Furthermore, trials have included small sample sizes ranging from as low as 12 (Daly et al., 2005) to 54 (Ng et al., 2008) participants. In view of the limited sample sizes and heterogeneity of treatment approaches, Howlett et al., (2015) document that there was insufficient data to warrant further subgroup

analysis and called for larger studies. In addition, other methodological flaws such as paucity in assessor blinding, adequate follow-up duration and concealed allocation suggest that the findings should be generalised with caution. It is clear that further adequately powered randomised controlled trials of high methodological quality are needed to firmly establish the training effects of FES.

2.4 Possible mechanisms underlying the training effect associated with FES

Despite the limited evidence to support the training benefits of FES, there does appear to be some biological plausibility to support its efficacy as a training aid. Several authors have offered neuroscience based explanations as to how FES may have a carryover and/or a training effect (Rushton, 2003, Sheffler and Chae, 2007).

2.4.1 Peripheral mechanisms

It is possible that FES may have an impact on improving gait through peripheral mechanisms. These include improving and/or maintaining muscle strength and endurance (Kimberley et al., 2004). In addition, using FES to improve and maintain muscle length and connective tissue elasticity can be achieved through stimulating antagonist muscles thus providing a mechanical stretch (Pandyan et al., 1997). There is also evidence to support FES having positive effects on oedema through stimulated contraction followed by full muscle relaxation, allowing interstitial fluid to be pumped out of the affected region (Faghri et al., 1998). This may in turn have an impact on range of movement and muscle activation.

Rushton (2003) further hypothesised that FES may facilitate motor learning via spinal mechanisms. According to Hebbian learning (Hebb, 2005) modifiable synapses can be strengthened if pre-synaptic firing is synchronised or shortly followed by post synaptic firing. Rushton suggested that the synapse between the pyramidal tract axon and the anterior horn cell may be a modifiable Hebb-type synapse. Under normal circumstances neural activity in the pyramidal tract is easily discharged to the anterior horn cell, thereby maintaining the strength of the presumed Hebb-type synapse. However, following stroke, neural activity in the pyramidal tract is significantly reduced and, if un-restored, 'decorrelation' of pre synaptic and post synaptic activities can weaken the synapse. FES uniquely generates an antidromic (centripetal) impulse, which depolarises as well as circumnavigates the anterior horn cell, so

that in some cases, the impulse travels down the motor axon. In this instance, FES may provide an artificial way of ensuring pre-synaptic and post -synaptic activity in affected anterior horn cells, thereby strengthening synapses and connectivity.

2.4.2 Reducing spasticity

It has been suggested that FES may have an impact on spasticity (Burridge et al., 1997a, Malezic et al., 1994, Yan et al., 2005). Burridge et al. (1997a) found that stimulation of the peroneal nerve in 32 chronic hemiplegic subjects significantly reduced spasticity in the quadriceps muscle, measured using the pendulum test. The authors hypothesised that the electrical stimulation triggered a reflex withdrawal response characterised by knee flexion with slight flexion, external rotation and abduction of the hip. Through generating activity of the hamstring muscle, it could be argued that a resultant activation of the 1a inhibitory neurones could therefore cause reciprocal inhibition in the quadriceps. Over time, spasticity of the muscle could be reduced through neuroplastic changes being facilitated by repeated inhibition.

Whilst this theory has also been described by other authors (Burridge and McLellan, 2000, Thompson et al., 2009, Weingarden et al., 1998), further research is required to prove the exact physiological mechanisms behind the reduction in spasticity seen following FES, and also to further identify the associated impact of reduced spasticity on walking ability.

2.4.3 Cortical influence

It has also been hypothesised that FES may have an influence at a cortical level. Everaert et al. (2010) showed that after three months of using FES, participants demonstrated a significant increase in motor evoked potential (MEP) of the tibialis anterior muscle from transcranial magnetic stimulation over the motor cortex. Authors attributed the large increases in MEP to a strengthening of activation of motor cortical areas and their residual descending connections. Analysis of the MEP mapping data showed that after use of the foot-drop stimulator, increased MEPs were generally measured at locations adjacent to damaged brain tissue. This remodelling of the motor map indicates that adjacent areas may “take over” to some extent to role of damaged area of brain. However, the exact physiological mechanism through which FES can influence this shift in cortical representation is not known.

FES may have an impact at a cortical level through influencing afferent impulses (Asanuma and Keller, 1991). Asanuma and Keller (1991) hypothesized that propioceptive and cutaneous impulses associated with repetitive movements induce long term potentiations in the motor cortex, which then modify the excitability of specific motor neurones and facilitate motor learning. Following this hypothesis, the proprioceptive and cutaneous impulses associated with FES induce repetitive movement training, thereby facilitating motor relearning through a similar pathway.

Animal studies have shown that after local damage to the motor cortex, goal orientated, active, repetitive movement of the paretic limb shapes subsequent cortical re-organisation (Nudo et al., 1996a, Plautz et al., 2000). To effect long-term plasticity in motor maps, training not only needs to be repetitive and task specific, but also requires adequate challenge, with new motor skills requiring cognitive effort to complete (Nudo et al., 1996a, Plautz et al., 2000, Nudo, 2006). It could be hypothesised that FES provides patients with the appropriate support to allow them to take part in gait training in positions and at an intensity that could not have been achieved without the FES. Therefore the indirect effects of FES in allowing patients a greater opportunity to practice, may facilitate motor learning, improve motor control and hence improve gait speed.

2.4.1 The use of FES in chronic versus sub-acute stroke

To date, the majority of authors have explored FES to the lower limb in a chronic stroke population. However the possible training effects linked with FES in the acute/sub-acute phase (less than six months post stroke) may also be clinically valuable. There is evidence to demonstrate that most post stroke recovery occurs in patients within the first 11 weeks after onset of stroke (Jørgensen et al., 1995). It could be argued that it is at this crucial time, when the surviving brain has shown its greatest potential for plasticity, FES integrated with high intensity, task specific physiotherapy may maximise the motor relearning of normal movement and appropriate muscle activation patterns. In addition, the effects of early stimulation may reduce the development of secondary compensations such as muscle atrophy through disuse, increased intrinsic muscle stiffness and abnormal compensatory patterns of movement.

Although these arguments to support the efficacy of FES in a sub-acute stroke population have not yet been fully established in the literature, there is some evidence to support that the training effect through the use of FES is greatest when used with a sub-acute stroke population. In the meta-analysis completed by Robbins et al. (2006) described in earlier

paragraphs, the single study that examined FES using subjects in the acute or sub-acute stage of recovery (Bogataj et al., 1995), had a larger effect size than the mean effect size of the studies examining FES using subjects with chronic stroke (Alon and Ring, 2003, Burridge et al., 1997b, Burridge and McLellan, 2000, Granat et al., 1996).

2.4.2 Summary of background literature

Current evidence suggests that targeted and repetitive gait training early after stroke significantly improves motor outcomes and measures of functional independence. However, training approaches vary significantly between studies and can include the use of clinic based systems such as treadmills and body weight support equipment. In view of the fact that sub-acute stroke care is now often delivered within patients homes, evidence to support the efficacy of more practical therapeutic gait training methods is warranted. One such treatment modality is FES. It's use as an orthotic aid to improve foot drop after a central neurological injury is now well established, however systematic reviews of the evidence investigating the training effects of FES call for larger randomised controlled trials of high quality. Despite the limited evidence, there does appear to be some biological plausibility to support its value when used as a training aid. Neuroscience-based explanations as to how FES may have a 'carryover' and/or a training effect through both peripheral and central mechanisms, has been discussed. Furthermore, there is some evidence to support that the training effect through the use of FES is greatest when used with a sub-acute stroke population.

Chapter 2 Part 2: Literature Review

2.5 Introduction

A systematic literature search was completed in order to explore and evaluate the current available evidence regarding the use of FES to improve walking ability in the sub-acute stroke population. In Part 2, this literature will be critically reviewed and conclusions will be drawn, however the method of the literature review will first be detailed.

2.6 Method of Literature Review

The following electronic databases were searched using the search strategy outlined in Appendix 1; MEDLINE (1966 to April 2015), EMBASE (1980 to April 2015), CINAHL (1982 to April 2015) and AMED (1985 to April 2015). Abstracts were screened using the inclusion and exclusion criteria outlined in Appendix 2. Where abstracts did not give sufficient detail, full text articles were screened. A total of 23 articles were selected based on the outlined criteria (see Appendix 3).

The most common measure of walking ability was gait speed, captured in 21 of the 23 studies (Bogataj et al., 1995, Dunning et al., 2009, Granat et al., 1996, Lee et al., 2013, Malezic et al., 1987b, Malezic et al., 1987a, Malezic et al., 1994, Ng et al., 2008, Kim et al., 2013, Kojovic et al., 2009, Kojovic et al., 2011, Kunkel et al., 2013, Salisbury et al., 2013, Spaich et al., 2014, Tan et al., 2014, Tong et al., 2006a, Tong et al., 2006b, Wilkinson et al., 2014, Yamaguchi et al., 2012, Yan et al., 2005, Yavuzer et al., 2006). Since gait speed has been shown to be a useful and reliable measure of walking ability (Wade et al., 1987), a focus will be placed on the articles that identified speed as an outcome measure to allow for closer comparison. To add further clarity to the synthesis and appraisal of the identified articles, the studies have been grouped according to their design, namely case study, controlled single group and randomised controlled designs.

2.7 Case study design trials

Earlier studies of Malezic and colleagues (Malezic et al., 1987a, Malezic et al., 1994) show that FES can have a favourable effect on walking speed in sub-acute stroke. Malezic et al., (1987a) investigated the use of multichannel FES with 14 participants (mixture of stroke and head

injured patients) on average 3.8 months post injury. Participants practiced walking down a 50m or 90m runway with stimulation to muscles of the upper and lower limb and the assistance of therapists or crutches as appropriate. A mean increase in gait velocity at the end of therapy was noted to be 58%, although speed was only measured in five of the 14 participants. In a three case series study (Malezic et al., 1994), subjects with spastic hemiparesis (14, 17 and 33 weeks post stroke) were treated with multichannel FES. On this occasion, FES was applied to upper and lower limb muscles during 25 walking sessions. Gait velocity was measured in all three participants and an increase of 33% increase was noted.

In a two case series study (Dunning et al., 2009), subjects (10 and 9 days post stroke) received peroneal FES via a neuro-prosthesis during gait training. Patient 1 used the FES whilst walking during therapy for an average of 40 minutes per day for 7 days. Patient 2 used the FES during therapy for an average of 40 minutes for 4 weeks. Length of treatment time with the prosthesis was based on an observed return of active movement or the patient being discharged from the inpatient rehabilitation facility. Gait velocity was measured at baseline, at weekly intervals and at the end of treatment with and without the device in situ. Results showed that for both patients, gait speed improved with and without the prosthesis demonstrating both an orthotic and training effect.

The ability to generalise the results to a larger population is limited in view of the small sample size. With no control group in either study, it is not possible to attribute the results purely to the intervention. Natural recovery may have had a significant impact and in addition, as only one group was included, is not possible to make a judgement as to whether the walking practice alone or the FES incorporated walking practice, had an effect on gait speed.

2.8 Controlled single group design studies

Accommodating for the lack of control group, Granat et al. (1996) investigated the use of single channel FES for the correction of spastic foot drop using a two period, single group design study. Sixteen participants ranging from 3-24 months post stroke were included (11 of the 17 participants started the study within six months of their CVA). The control phase of the study consisted of the first four weeks, followed by a four week period of using the peroneal stimulator throughout the day. Results showed that the rate of increase of speed over the control period was significantly greater than that of the treatment period ($p<0.05$), indicating that FES produced a negative effect on walking speed. However, due to the high variability in time post stroke between participants, and between the two experimental periods, it could be

argued that the initial four weeks was not a true control phase. This is supported by other authors who have shown that time since stroke has a direct relationship with rate of recovery, with return of walking function occurring in 95% of the patients within the first 11 weeks after stroke (Jørgensen et al., 1995).

In contrast, Bogetaj et al. (1995) controlled for time since stroke as a potential variable by changing the treatment order in a cross over design study. Twenty participants, on average four months post stroke, were randomly assigned into two groups. Group 1 received conventional therapy for three weeks followed by three weeks of multichannel FES incorporated into gait training. Group 2 carried out the same programme but in the reverse order. Results showed a significant main effect for performance ($p=0.013$) determined by gait speed, stride length, gait cadence and Fugl Meyer score. Furthermore, there was a significant interaction between order of treatment and performance, with FES being applied first leading to greater improvement than when applied second. It is not clear whether statistical testing was carried out on gait speed in isolation, however from the individual data presented it appears that a trend towards an increase in gait speed, was seen after FES treatment in all but one participant in both groups. Conversely, only 10 out of 20 participants showed gains in gait speed following conventional therapy.

The content of conventional therapy was adapted to the individual needs of the participant, but in general terms was described to include either a passive or active approach, or a combination of both. The passive approach included icing, heating, brushing and placing patients in various positions (for example sitting or verticalisation on a tilt table). In contrast, the FES therapy consisted of participants mobilising with assistance from the therapists and/or a crutch on the non-affected side if needed. The authors have not provided a breakdown of the content of each therapy session and it could be possible that the FES sessions not only provided patients with electrical stimulation, but also contained a greater level of active, task specific gait training. The results can only be attributed to the package of FES with a more 'active' gait training programme, rather than the incorporation of FES into usual care alone.

2.9 Controlled multiple group studies

Controlling for the effects of time since stroke, Malezic et al. (1987b) incorporated a two group design where one group of sub-acute stroke patients (n=5) received multichannel FES during therapy whilst the other control group (n=5) received standard therapy alone. Results showed that average step length and gait velocity improved to a greater extent in the FES group,

compared with the control immediately following therapy although, these gains were not maintained at eight month follow-up.

Due to the lack of any randomisation process, the results should be interpreted with caution. Patients with extensive lesions and poor prospects of independent ambulation after regular treatment were included into the stimulation group. As they could not self ambulate at the beginning of treatment, their walking ability was instigated through the use of FES. Conversely the control patients were selected on being able to walk a short distance alone with assistive devices. It could be argued that since the control group started at a higher functional level, the room for making change in walking ability would have been less than the FES group regardless of the intervention applied. Therefore the two groups cannot be effectively compared.

2.10 Randomised Controlled Trials (RCTs)

The randomised controlled design adopted by other authors allow for changes in gait speed to be attributed to the use of FES with more confidence (Kojovic et al., 2009, Kunkel et al., 2013, Lee et al., 2013, Ng et al., 2008, Salisbury et al., 2013, Spaich et al., 2014, Tan et al., 2014, Tong et al., 2006b, Wilkinson et al., 2014, Yamaguchi et al., 2012, Yan et al., 2005, Yavuzer et al., 2006). These trials show a great deal of variety of treatment approaches, combining FES with traditional forms of physiotherapy as well as with more complex walking apparatus.

2.10.1 FES combined with passive exercise

Four of the RCTs have investigated the use of FES when combined with passive exercise (Tan et al., 2014, Yan et al., 2005, Yamaguchi et al., 2012, Yavuzer et al., 2006). Yan et al. (2005) applied FES to muscles in the lower limb in the side-lying position whilst the limb was suspended by a sling 'using an activation sequence that mimicked normal gait'. Authors found that the use of multichannel FES for three weeks in 46 acute stroke subjects had no significant impact on gait speed, as measured by Timed Get Up and Go (TUG). However, significant improvements were seen in composite spasticity score, ankle dorsiflexion torque and EMG co-contraction ratio ($p<0.05$) in the FES group compared to the control and placebo groups. Furthermore, 84.6% of patients in the FES group returned home, in comparison with the placebo (53.3%) and control (46.2%) groups. Another similar trial used cyclical FES on sub-acute participants in a supine position and also found no significant improvements in gait parameters (Yavuzer et al., 2006).

More recently, Tan et at (Tan et al., 2014) investigated the effect of four channel FES used with the affected lower limb supported sling and participants in a side lying position. Significant differences in favour of the four channels FES group were found in terms of Postural Assessment Score, Berg Balance Score, Modified Barthel Index and the Functional Ambulation Category compared with the placebo group. The Functional Ambulation Category is the only measure that directly relates to walking ability but it does not provide any specific information about changes in gait parameters.

Yamaguchi et al. (2012) used FES on tibialis anterior and soleus muscles in combination with a passive hip movement device applied to participants in a supine position. The gait velocity of the electrical stimulation combined with passive locomotion-like movement group, was significantly greater than the electrical stimulation only group and the passive locomotion only group. The change in gait speed in the electrical stimulation combined with passive locomotion group reached an average of 0.08m/s indicating that the change in speed was minimally clinically significant (Perera et al., 2006). However, a major flaw of this study relates to the fact that only the immediate effects of this treatment were considered, and it is unclear how long the improvement in gait velocity lasted after the intervention.

It could be argued that if electrical stimulation is applied within a weight bearing programme of gait training, a greater degree of carryover into changes in gait parameters may be seen. This would comply with the evidence supporting task specific training (Kwakkel et al., 1999, van de Port et al., 2007) and compliments Rushton's theory of the potential of FES to promote restorative synaptic modifications at the anterior horn cell level. The FES timed to activate muscles simultaneously with voluntary effort to produce a desired movement or reach a goal may have enhanced the synaptic strength at spinal level, leading improvements motor control and therefore gait speed. The theory that the integration of FES with an intensive, weight-bearing, gait training programme also compliments evidence from behavioural neuroscience, whereby FES enables patients to practice more challenging highly functional tasks at a greater intensity.

2.10.2 FES combined with treadmill training and electro mechanical gait trainers

This argument is further substantiated by randomised controlled trials which demonstrate improved gait outcomes following a combination of FES and training in upright, weight bearing positions. Two studies compared conventional over-ground gait training, use of an

Electromechanical Gait Trainer (EGT) and EGT coupled with simultaneous FES (Ng et al., 2008, Tong et al., 2006b), with intensity of training being standardised across all three groups. The EGT groups with and without FES had statistically significant improvements in walking speed compared with the conventional group. Furthermore, in the study conducted by Tong et al. (2006b) effect size calculations showed a medium strength difference in gait speed in favour of the FES group (effect size 0.55). However, the lack of a forth group receiving over-ground training integrated with FES restricts positive results to being attributable to FES only when used in conjunction with a Gait Trainer.

Another randomised controlled trial has considered the use of FES in combination with body weight support over a treadmill in a sub-acute stroke population (Lee et al., 2013). This study investigated the use of body weight support treadmill training with power-assisted functional electrical stimulation on balance and gait velocity in 30 stroke patients. The two groups received the same intensity of 30 minutes of body weight support treadmill training, five days a week for four weeks, however one group received stimulation to tibialis anterior during training. After four weeks of training, the body weight support treadmill training combined with FES showed greater improvements in gait speed, compared with the body weight support treadmill training only group ($F = 20.328$, $P = 0.000$). This study accounted for the limitations of other studies by standardising treatment intensity between groups and using a blinded assessor. However, the sample size was small with no evidence of a power calculation. In addition there was no long term follow-up and it is not possible to state whether the results were maintained following completion of the training programme.

2.10.3 FES combined with over ground gait training

Six of the randomised controlled trials have used more traditional over-ground based balance and walking training approaches combined with FES (Kojovic et al., 2009, Kojovic et al., 2011, Kunkel et al., 2013, Salisbury et al., 2013, Spaich et al., 2014, Wilkinson et al., 2014). These interventions have an obvious advantage of being more practical in today's clinical practice when more sub-acute patients are being treated in their own homes.

Due to the novel approach of such interventions a number of published studies have the primary aim of feasibility rather than hypothesis testing (Kunkel et al., 2013, Salisbury et al., 2013, Wilkinson et al., 2014). Both Salisbury et al., (2013) and Wilkinson et al., (2014) used stimulation for the correction of dropped foot combined with conventional physiotherapy

approaches for the improvement of walking ability and speed. These studies were underpowered for significance testing but showed promise in terms of the feasibility of combining FES with physiotherapy in a sub-acute population.

Kojovic et al. (2009) compared conventional over ground walking therapy with the equivalent amount of walking therapy with multichannel FES, using a randomised controlled research design. Although only minimal details of the contents of walking sessions were provided, authors describe that participants were encouraged to walk with physical assistance and instructions related to the quality of their walking pattern as appropriate five times a week, for four weeks. Thirteen stroke patients, no more than eight weeks post stroke were randomised into two groups; one of which received 45 minutes of daily walking practice and the other received 45 minutes of daily walking practice with multichannel FES. In the FES group, mean walking velocity was significantly improved at the end of the treatment intervention ($p<0.05$) whilst no significant differences were found in the conventional group ($p=0.13$).

The authors published a subsequent paper containing further details of muscle activation patterns and joint ankles whilst dorsi-flexing the foot in a seated position in the same sample group pre and post treatment (Kojovic et al., 2011). Authors then compared these results with a healthy population. Results showed that the functional electrical stimulation group produced significantly greater angles of dorsi-flexion that the conventional group following treatment. Furthermore, co-activation of the prime knee movers that did not exist in the healthy group, decreased and were somewhat modulated after FES treatment compared to the status prior to treatment.

However, significant methodological flaws in current randomised controlled trials exploring FES combined with over ground training, limit the generalisability of the results to a larger stroke population. Due to the small sample size the statistical strength of the studies described are low suggesting the need for larger randomised controlled trials. Kojovic et al., (2009) have not included a blinded assessor raising the potential for bias and there was no consideration as to whether the results were maintained at longer term follow-up. In addition, these authors failed to evaluate the quality of walking pattern and did not compare the activation patterns seen in the seated dorsi-flexion task with muscle activity and joint range changes during gait. There is no description of what constituted walking practice, therefore the authors are unable to explore the possibility of a difference between the two groups in terms of the content and intensity of practice within the gait training sessions.

Of the few studies that do provide details of the content of over ground gait training (Wilkinson et al., 2014), the amount of time spent completing each gait related activity has to date, never been measured. This raises questions as to whether the content and intensity of training between groups was standardised and hence whether any improvements seen can be truly attributable to the inclusion of FES rather than difference in the training intensity and/or content.

2.11 Number of electrical stimulation channels

The literature varies considerably with respect to stimulation sites from complex designs involving six muscle groups (Bogataj et al., 1995) to more simplistic single channel stimulators for ankle dorsi-flexion correction (Dunning et al., 2009). Of the studies that included multichannel stimulation, (Bogataj et al., 1995, Kojovic et al., 2009, Malezic et al., 1987a, Malezic et al., 1994, Ng et al., 2008, Tong et al., 2006a, Tong et al., 2006b, Yan et al., 2005), a number of different muscle groups were chosen for stimulation including peroneal nerve for ankle dorsiflexion, soleus, hamstrings, quadriceps femoris, gluteus maximus, gluteus medius and triceps brachii. When combined with a weight bearing exercise programme, studies using multichannel FES showed positive results. However, there are pragmatic drawbacks to the use of multichannel stimulation. Complex multichannel devices may involve the additional support of an engineer (Bogataj et al., 1995). Medical device engineers are not common place in the majority of clinical settings, thereby limiting the interventions applicability to common practice. In addition, setting up stimulation may detract from valuable and limited treatment time.

A dual channel stimulator, used with sub-acute stroke patients by several authors (Ng et al., 2008, Tong et al., 2006a, Tong et al., 2006b), may serve as an effective compromise. The device allows for the use of up to two channels (four electrode placements) and is therefore relatively quick and easy to set up, particularly in comparison to a multichannel device. In addition the device can be programmed to synchronise the gait phase and the timing of stimulation to the desired muscle groups.

2.12 Choice of muscle groups for stimulation

Of the studies that incorporated single channel stimulation, the dorsi-flexors and/or evertor of the ankle were targeted for stimulation (Dunning et al., 2009, Granat et al., 1996, Macdonell et

al., 1994, Yavuzer et al., 2006). This muscle group was likely to have been chosen in view of the high incidence of weakness in these muscles following stroke (Olney and Richards, 1996). Often seen in combination with reduced selectivity of hip and knee flexion during swing phase, weakness of the dorsi-flexors can result in an abnormal gait, consisting of hip hitching, circumduction and toe catch. Walking speed is impaired, walking effort is increased and there is a higher chance of stumbling and falling (Burridge et al., 1997b). Research has shown that electrical stimulation can be used to produce dorsiflexion and eversion at the ankle joint during the swing phase of the gait cycle to improve speed and reduce effort of walking (Burridge et al., 1997b).

Decreased hip extension of the affected leg has also been shown to be a common impairment following stroke (Olney and Richards, 1996). Restricted hip extension on the affected side leads to a reduction in contralateral step length, spatiotemporal asymmetry, and reduced walking speed (Hsu et al., 2003). Studies which have investigated gluteal taping, have found that improved gluteal activity can have an impact on hip extension angle, unaffected side step length (Kilbreath et al, 2006) and gait speed (Maguire et al., 2010). Furthermore Stanic et al., showed that through stimulation, hip extensors (including gluteus maximus) timed to activate during stance can help the hip to extend the hip, enable a better weight shift, and stabilise the pelvis. Hip abductors (including gluteus medius) stimulated during stance phase in the same way, can correct a pelvis drop (Stanic et al., 1991).

Another study showed stimulation of a combination of tibialis anterior and gluteal muscles (tibialis anterior during swing phase and gluteus medius during stance phase) produced significantly improved spatiotemporal gait parameters, compared with stimulation of tibialis anterior alone or no-FES conditions in chronic hemiparetic stroke patients (Kim et al., 2012). The study did not consider whether the benefits persisted once the electrical stimulation was removed and therefore the therapeutic gain of the intervention. As a potentially clinically practical treatment aid, further research is therefore warranted to evaluate the efficacy of dual channel stimulation to glutei, ankle dorsiflexion and evertor muscles to improve gait in sub-acute stroke patients.

2.13 Summary of the literature review

A number of randomised controlled trials have used FES combined with over ground gait training in a sub-acute stroke population. However to date, no literature has been published on the therapeutic effects of dual channel FES to stimulate glutei, dorsiflexor and evertor

muscles in combination with a gait training programme in patients less than six months post stroke. Feasibility studies have been advocated prior to large scale randomised controlled trials particularly when a novel package of intervention is the focus of investigation (Craig et al., 2011)

There is not enough evidence from high quality trials to fully support the use of FES integrated with gait training in sub-acute stroke. Whilst results from the few published studies suggest that FES may have positive effects on gait parameters in acute/sub-acute stroke patients, methodological flaws mean that findings cannot be easily generalised. Several authors failed to account for differences in components of standardised therapy (Bogataj et al., 1995, Newsam and Baker, 2004, Yavuzer et al., 2006) whilst others did not match training intensities between experimental and control groups (Yavuzer et al., 2006). Other studies have limited the electrical stimulation to passive exercise and did not integrate FES with more functional gait training in weight bearing positions. In light of the evidence to support task specific training, it could be argued that more significant improvements may have been observed had the FES been combined with a task specific gait training programme. Kojovic et al. (2009, 2011) failed to account for differences in the quality of walking pattern following treatment, measure whether the results were maintained at long term follow-up, and it is unclear whether assessors were blinded to treatment group.

Addressing these limitations and building on the current evidence to date, further research is needed to establish the efficacy of FES combined with gait training on walking ability in an acute/sub-acute stroke population. As an innovation in gait training rehabilitation in this phase of stroke, there are questions as to whether participants are able to tolerate the treatment. Judging from the low rate of drop outs described with the studies using sub-acute patients, it appears that patients within this group can tolerate stimulation during gait training; however patient perceptions of this kind of treatment have not yet been formally assessed. There are also questions around the optimal method of accurately recording content and intensity of treatment sessions, whether building in a follow-up period is feasible with this patient group and which outcome measures are most suitable.

Chapter 2: Part 3: Research Question

2.14 Research question

With so many feasibility questions unanswered, before a large scale multicentre RCT can be run, these issues need to be resolved. Therefore the purpose of the present study is to assess feasibility, reliability and validity of the proposed study design to help inform the methodology of a larger RCT.

Research Question

Is it feasible to conduct a two week gait training programme combined with FES (targeted to glutei and/or ankle dorsiflexor and evertor muscles) for people with a sub-acute stroke and reduced hip extensor and/or dorsiflexor activity?

2.15 Aims of the research

Until relatively recently there has been little guidance available related to the design and result analysis of feasibility studies. A recent publication by Thabane et al. (2010) offered a useful discussion around the purpose, design and reporting of pilot and feasibility studies. Building on this work, Arain et al. (2010) provided further evidence to recommend components of good quality pilot and feasibility studies. The authors collated 26 pilot studies and 28 feasibility studies to review how these studies are reported and in addition, conducted a survey to identify the methodological components in research studies, defined as pilot or feasibility studies. The article concluded that pilot and feasibility studies are generally poorly reported; a finding which has been documented by other authors (Lancaster et al., 2004). There is a tendency towards a lack of clarity around the purpose of the study, why it has been termed a pilot study or feasibility study and an inappropriate emphasis on hypothesis testing.

A strong case has now been put forwards that feasibility and studies trials should be designed to generate results that enable an informed decision to be made as to whether it is feasible to proceed to the main study (Arain et al., 2010, Thabane et al., 2010).

The authors further clarify that in general the results of a pilot or feasibility study direct the researcher to one of three main outcomes:

1. Stop – the main study is not feasible
2. Continue, but modify the protocol – the main study is feasible but the methodology required modifications to ensure its success
3. Continue with the main study following the same protocol, no modifications are necessary

To enable such informed decisions to be made objectively, authors prompted researchers involved in feasibility or pilot trials to consider in depth, the evidence needed to help inform decisions regarding next steps of the main study. The present feasibility study aims to test the feasibility of implementing methodological procedures which have not been used in this patient group before but also, to estimate important parameters that are needed to design the main study such as estimating sample size. These key areas of feasibility testing were identified in the protocol development stage in order to inform a decision as to whether the main study would be feasible or not, and whether any modifications need to be made to the methodology to ensure its success.

2.16 Research objectives

The following research objectives were identified to establish the feasibility of the study in preparation for a larger RCT:

1. To determine the proportion of eligible patients admitted to recruitment sites
2. To explore factors influencing eligibility and subsequent recruitment
3. To determine follow-up and retention rates
4. To determine whether patients were able to complete intervention schedule
5. To describe the variation in the content and intensity of the intervention delivered in order to determine the extent to which these elements can be standardised without the loss of an individualised, patient centred approach
6. To explore participant and staff perceptions of the acceptability of the intervention (gait training and gait training and FES)

7. To determine whether the selected outcome measures are suitable and can be carried out in clinical/home settings

8. To gain estimates required for a sample size calculation

3. Chapter 3: Research Methodology

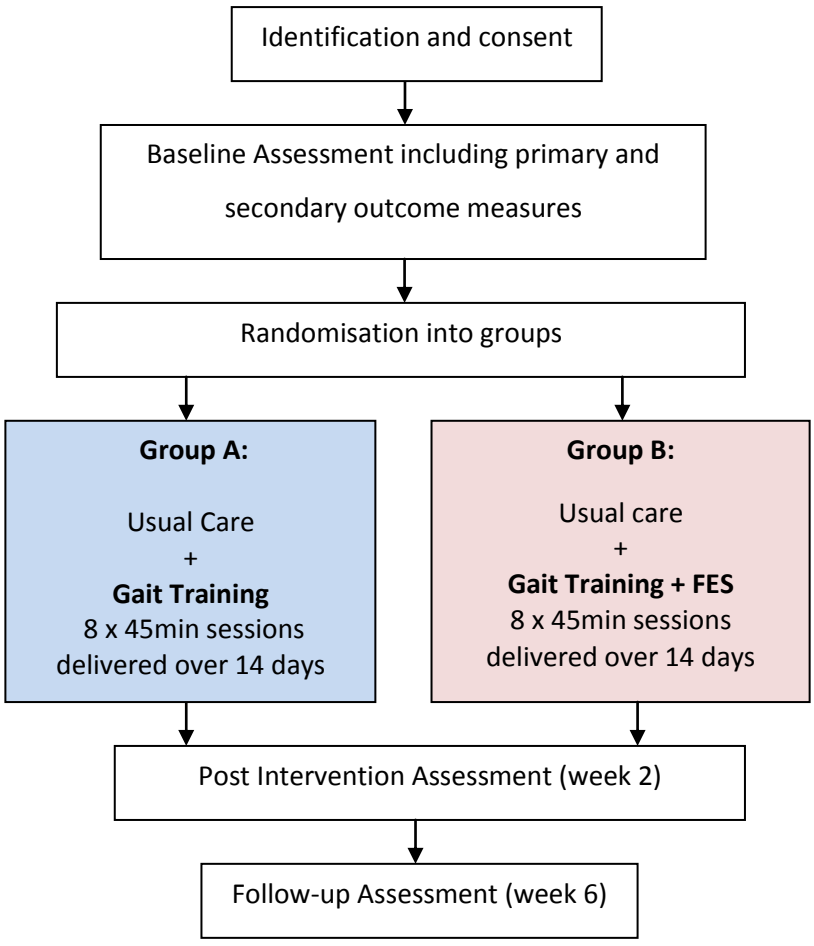
3.1 Introduction

The purpose of this study is to answer the question: Is it feasible to conduct a two week gait training programme combined with FES (targeted to glutei and/or ankle dorsiflexor and evertor muscles) for people with a sub-acute stroke and reduced hip extensor and/or dorsiflexor activity? The aim of this chapter is to describe the research methodology used to answer the research question including providing an explanation of the study design, recruitment and methods, interventions and outcome assessments. Finally this chapter will provide an explanation of the analysis methods and statistical procedures used to examine the data.

3.2 Research design

The participant journey is summarised in Figure 1. There were two groups; Group A received intensive gait training and Group B received intensive gait training and FES.

Figure 1: Participant journey through the study



Inclusion of a third group receiving usual care only was considered, however as the aim of this feasibility study is to test the appropriateness of the intervention, it was felt that a control group was not needed. For the larger, adequately powered RCT a control group receiving usual care alone would be included. This would determine whether a statistically significant difference in outcomes exists following intensive gait training, intensive gait training and FES and usual care alone, thereby establishing a cause and effect relationship between the intervention and outcome.

3.3 Ethical approval

Ethical approval was obtained from the South West 4 Research Ethics Committee. The study was granted NHS permission to proceed by the South Wiltshire Research and Development Consortium and the Dorset Research Consortium.

3.4 Sample size

The focus of this study is to explore the feasibility of carrying out research using a novel package of interventions. As it is not to evaluate the efficacy of the interventions the sample size is based on pragmatic reasoning rather than on statistical sample size calculations. In this early stage study, it has been proposed to recruit 16 stroke survivors. This number is based on the maximum number of assessments and interventions practicable within the twelve month data collection time scale.

One of the objectives of the study is to use the data generated to estimate the sample size needed for a subsequent RCT to have sufficient power to test the hypothesis and minimise the likelihood of Type I and Type II errors. The methods used to calculate the sample size calculation are discussed in further depth in section 4.5 of the Results Chapter.

3.5 Recruitment methods

Three separate sites were involved in the study; Salisbury District General Hospital, the Royal Bournemouth Hospital and Christchurch Hospital. The researcher met with each of the therapy teams working across the three sites to describe the research study. Team leads at each site were given an information pack containing details of the study which included an inclusion/exclusion checklist, details of how to contact the researcher and participant information sheets. The clinicians at each site were asked to identify potential participants

according to the information provided. The researcher kept in regular contact with the clinicians at each of the three sites, though email and where possible, face to face contact through weekly visits.

Once identified by the clinical staff, patient suitability was discussed with the researcher based on the inclusion and exclusion criteria listed below. Potential participants were then approached by clinical staff in each of the stroke units, who then outlined the key aspects of the study to patients and relatives if appropriate. If the patients expressed an interest in taking part in the study, the clinician informed the researcher. Those patients were then seen by the researcher who discussed the trial with them in more depth and provided them with a study information sheet (see Appendix 4).

3.6 Inclusion criteria

All patients who met the following criteria were invited to participate in the study:

- First stroke according to the WHO definition (WHO, 2006) less than 6 months ago (see Definitions and Abbreviations section). Commonly, old infarcts are seen on CT imaging without the patient having experienced any pre-existing neurological deficits. In the absence of pre-morbid impairment, these patients were deemed appropriate for the study.
- Medically stable, willing and able to take part in the study
- Sufficient cognitive and language skills to give informed consent and follow simple instructions, as determined by the clinical staff
- Previously independently mobile with or without aids
- Able to stand for 10 seconds unsupported
- Able to safely take part in a gait training programme with the assistance of one person
- Demonstrate a need for physiotherapy targeted at improving gait by showing reduced walking speed compared with age matched healthy controls, which has been documented to be 1.15 m/sec (Friedman et al., 1988, Goldie et al., 1996). Therefore patients who walk 5m in more than 5.75 seconds were eligible for the study. This was screened by the clinicians.

- Demonstrate one or more of the following clinically observable deficits based on the clinician and researchers joint observational assessment:
    - Reduced dorsiflexion during swing phase
    - Reduced hip extension during stance phase

    This was based on the clinician and researchers joint observational assessment. Where impairments were mild and the patient's quality of movement varied over a set walking distance, if the patient demonstrated either reduced dorsiflexon and/or reduced hip extension more than once during gait cycle over a 5m distance, and they met the other criteria, they were deemed appropriate for the study.
- Respond to stimulation to dorsiflex the foot and/or extend the hip. There are patients who do not respond to stimulation due to oedema, fixed contractures and lower motor neurone lesions and therefore these patients would need to be excluded. This was screened by the researcher.

3.7 Exclusion criteria

Patients with the following were not eligible to take part in the study:

- Had a pacemaker or other active implanted medical devices
- Uncontrolled epilepsy
- Poor skin condition or those allergic to wipes or adhesive tape
- Other medical conditions that might be negatively affected by electrical stimulation
- Do not demonstrate a need for gait training
- Pregnancy – if participants were female and of childbearing age, and they expressed an interest in taking part of the study, they were asked to undertake a pregnancy test (see Appendix 6).

3.8 Cognitive and language skills

In order to mirror clinical practice as closely as possible, all patients who were able to follow simple instructions and who were able to give informed consent were eligible to take part in

the study. This was determined by the clinical staff working with the patients. In addition, a Mini Mental State Examination (MMSE) was included in the baseline measures to allow for a more in depth description of the participants' impairments.

3.9 Randomisation

Patients who met the inclusion and exclusion criteria were then asked to sign a consent form (see Appendix 5). Following written consent, participants were randomly allocated to one of two groups. Randomisation for feasibility studies is not essential as they are not designed to evaluate the outcome of interest (Arain et al., 2010). However exploring the participants' willingness to be randomised (as evidenced by dropout rates) would provide further information to inform the design of a further trial. Therefore participants were randomised using the method described below.

The first four participants were randomised separately to guarantee a balance of selection into the two intervention groups. This was so that in this initial phase, the protocol could be trialled equally for both intervention arms. In advance of the commencing recruitment, the research supervisor numbered 16 envelopes. 'FES' was written on eight separate pieces of paper and 'Physio' on another eight separate pieces of paper and folded the paper so that the writing was covered. Two of the 'FES' allocation papers and two of the 'Physio' papers were put in a box, which was then shaken. The research supervisor picked out the papers in turn, keeping them covered and placed them individually in the first four envelopes at random and sealed them.

The research supervisor then went on to put the remaining 12 folded allocation papers in the box, which was shaken. The papers where then picked at random, placed in the remaining twelve envelopes and sealed. Following gaining consent, participants were given sequential recruitment numbers which correlated to an envelope. The researcher and the participant opened the corresponding envelopes together to find out their allocation. This procedure provided some reassurance to the participants that the researcher had not chosen their allocated group for them, and that the process was truly random.

This simple method of randomisation was chosen as the focus of the study was to assess feasibility of the interventions, which due to the small sample size could only be achieved with relatively equal amounts of data on each group. In addition, using this method the researcher had limited involvement in the randomisation process. For a follow-on RCT, where formal

randomisation with a transparent audit trail is key to reduce the risk of bias, a computer software program that generates a random sequence would be used.

3.10 Usual care

Both groups received usual care delivered by ward and outpatient clinicians (occupational therapists and physiotherapists). The treating therapists documented frequency, duration and content of their contact sessions (see Appendix 7). The researcher arranged intervention sessions to fit around their usual care. It is possible that the participant's involvement in the study may have an impact on normal care. To monitor this, a questionnaire was administered to the treating therapist to explore whether health professionals felt that the intervention had an impact on delivering usual care (see Appendix 8).

3.11 Subject groups

3.11.1 Intervention schedule

All participants received additional gait training therapy, either with FES or without it, in addition to their usual care. The researcher delivered this in the form of eight one to one sessions in total, delivered four times a week, over a period of two weeks. The researcher aimed for each session to last between 45 to 60 minutes depending on the fatigue levels of the individual participant.

3.11.2 Content of gait training programme

The gait training programme was based on exercises shown to be effective in research (Cheng et al., 2004, Pomeroy et al., 2005, Winstein et al., 1989) and those used in current clinical practice. Table 1 provides a summary of the components of the gait training programme and gives examples of how each exercise may have been progressed.

The combination of exercises, intensity and progression of the gait training programme was individually tailored to the needs of each participant. However, in order to establish whether the content and intensity of the gait training programme had an impact on the results, details of the exercise performed, number of repetitions, and time spent on the exercise were recorded during the sessions using a treatment log (see Appendix 9 and 10).

Table 1: Components and progressions of the gait training programme

Components of the gait training programme	**Details**
Lower limb muscle, soft tissue stretching and mobilisation	Specific soft tissue mobilisations provided by therapists Soft tissue stretches provided by therapist Soft tissue stretches achieved by patient in non weight bearing positions in including foot mobilisation Soft tissue stretches achieved by patient in weight bearing functional positions
Core and Lower limb strengthening	Resistance from therapist Resistance from patient's body weight Resistance from equipment (e.g. theraband, cycle resistance)
Sit to stand and stand to sit practice	PT 'hand on' techniques to re-education posture and movement patterns Changing height of sitting surface or base of support
Standing towards walking	PT 'hands on' techniques to re-education posture and movement patterns Static standing in stride and step standing Reducing the amount of support from upper limbs With and without visual feedback from the mirror, eyes open and eyes closed Reducing base of support for example tandem standing, one leg standing activities Dynamic standing balance training including reaching out of base of support, catching ball Reducing the amount of support from upper limbs Reducing base of support for example tandem standing, one leg standing activities
Stepping practice (stepping with hemiplegic and non hemiplegic lower limbs)	PT 'hand on' techniques to re-education posture and movement patterns Stepping forwards, backwards and sideways Flat surface to on and off blocks Stepping up, down and over blocks Increasing height and width of blocks Reducing the amount of support through the upper limbs
Walking practice	PT 'hand on' techniques to re-education posture and movement patterns Walking forwards, backwards and sideways, fast and slow walking Reducing the amount of support through the upper limbs Outdoor walking Obstacle negotiation training Dual task e.g. talking, counting whilst walking
Climbing stairs	Increasing number of steps Increasing step height Reducing the amount of support through the upper limbs

3.11.3 Functional Electrical Stimulation integrated with gait training

The Dual Channel Stimulator was used to stimulate gluteus maximus or medius muscles and/or dorsiflexor and evertor muscles during the gait training programme in participants randomised to Group B. The decision of whether to stimulate one or both sets of muscle groups was based upon the individual needs of participants and where clinically observable deficits were seen (see 3.6 Inclusion criteria).

3.11.3.1 Positioning of the electrodes

The exact positioning of the electrodes varied between participants and was adjusted to stimulate the desired muscle contraction. However, in general the positioning of the electrodes was as follows:

- Channel 1: Dorsiflexor and evertor muscles: active electrode over common peroneal nerve at the neck of the fibula and indifferent electrode at the motor point of the tibialis anterior muscle. The electrode positioning and stimulation level was adjusted to achieve the optimal desired movement pattern of ankle of dorsiflexion with a small degree of eversion.

- Channel 2: Gluteus Maximus/medius: active electrode placed below the posterior superior iliac crest and the indifferent electrode was placed approximately one hands breath below the active electrode. Again electrode positioning and stimulation levels were adjusted to produce a visible contraction of the gluteus maximus muscle in standing and assisted hip extension when taking a step forwards with the opposite leg. For participants who demonstrated evidence of a pelvic drop during gait, the indifferent electrode was placed more laterally to bias stimulation of gluteus medius.

3.11.3.2 Trigger mechanism

The electrodes related to channel one were applied and movement tested in sitting, whereas electrodes pertaining to channel two were applied in standing. The setup of the stimulation and trigger mechanism were also adjusted to meet the demands of task. This included varying between the heel switch and manual switch as demonstrated in Table 2. The heel and manual switches proved to be reliable with participants in triggering stimulation at an appropriate time within each exercise.

Table 2: Summary of stimulation set up with each exercise

Components of the gait training programme	Electrode positioning	Trigger Method
Lower limb stretching	FES not used	
Lower limb strengthening	Channel 2: for standing exercises including squats (bilateral and single leg).	Heel switch trigger
Sit to stand practice	Channel 1: on tibialis anterior during forward progression phase of sit to stand (at low intensity) Channel 2: used on during extension phase of sit to stand.	Hand held switch (by researcher) – delay between channel 1 & 2
Standing towards walking	Channel 2: on weight transfer to hemi-paretic leg.	Heel switch
Stepping practice	Channel 1&2: Channel 1 activated on stepping with hemi paretic leg and channel 2 activated during stepping with non hemiplegic leg.	Heel switch
Walking practice	Channel 1&2: Channel 1 activated on stepping with hemi paretic leg and channel 2 activated during stepping with non hemiplegic leg.	Heel switch
Climbing stairs	Channel 1&2: Channel 1 activated on stepping with hemi paretic leg and channel 2 activated during stepping with non hemiplegic leg.	Heel switch

3.12 Baseline assessment

All assessments took place in the clinical setting (Salisbury District General Hospital, the Royal Bournemouth Hospital, or Christchurch Hospital) and were carried out by the researcher. The following information was collected at baseline assessment to allow for an accurate description of the sample population:

- Participants demographic details
- Time since stroke (days)
- Type and location of Stroke according to the Oxford Stroke Classification (Bamford et al., 1991)
- Length of hospital stay (days)

- Pre stroke level of independence and mobility level

- Mini Mental Sate Examination (MMSE). This Impairment measure to assess cognitive function. It consists of a brief 30 point questionnaire that takes 10 minutes to complete. The lower the score the greater the degree of cognitive impairment (see Appendix 15).

3.13 Outcome measures

In this exploratory stage of the study measurements of both gait speed and quality were considered to give an indication of overall walking ability (see Table 3).

Table 3: Outcome measures for assessment of walking ability

Component of gait	**Outcome measure**	**Description and supporting evidence**
Gait speed	5m walk test (see Appendix 11)	Recommended as the most responsive method of measuring gait speed in acute stroke patients (Salbach et al., 2001).
Quality of gait	Wisconsin Gait Scale (WGS) (Rodriquez et al., 1996) (see Appendix 12 and 13)	To allow for the visual quantification of gait quality. The maximum score achieved on the scale is 42 and the higher the score the more seriously affected the gait. Since its original development the WGS has been used in acute and sub-acute stroke patients (Turani et al., 2004) and has been shown to have high inter and intra-rater reliability when administered by physiotherapists (Wellmon et al., 2003).

A standard protocol of instructions and set up of the 5m walking test was used in each assessment. During the test, participants were timed and videotaped. Participants were advised to wear appropriate clothing and the same foot wear for all walk tests. They completed the 5m walk test a total of three times. This was to enable an average of three time scores to be taken but also allowed video footage to be recorded from anterior, posterior and side views (see Appendix 11).

As described in the 5m walk test protocol (Appendix 11), walking speed was assessed at a self selected 'comfortable walking pace'. The researcher used a stop watch to time the walk test, starting the stopwatch as the participant's leg (or assistive device) crossed the first marker and stopping the stopwatch when the participant's leg (or assistive device) crossed the second marker. The same researcher performed all walk tests to prevent introducing inter-rater variability. This method was selected in the absence of more advanced technology available at the clinical sites. In addition, studies have shown excellent agreement between stopwatch and automatic timer assessments in patient groups and older adults (Karpman et al., 2014, Peters et al., 2013).

Quality of gait was scored by a blinded assessor using the videotape of the walking test which included instructions given during the test. The blinded assessor was therefore able to verify whether the researcher had followed the standardised protocol (Appendix 12). The blinded assessor had no prior knowledge of the participant or their allocated group. They were asked to watch the video of participants completing the walk test at baseline, week two and week six and analyse the gait pattern using the WGS. Video of the participants was given to the blinded assessor in a random order. The blinded assessor was provided with a recording sheet (Appendix 12) and an instruction sheet giving guidance of which aspects of gait to focus on in each view (Appendix 13). They were able to zoom in on specific joints, freeze frames at set points in the gait cycle, slow down movements and play back footage as many times as necessary.

Other measures were used to identify changes other than speed and quality of gait, as shown in Table 4. These measures were also carried out by the researcher. Due to the nature of the feasibility study, using a blinded assessor for scoring of the WGS is considered acceptable. For a subsequent larger randomised controlled trial, a blinded assessor would be used for all outcome measures.

Table 4: Other outcome measures

Component to be measured	Tool for measurement	Brief description of measure
Tone	Modified Ashworth scale (Bohannon and Smith, 1987) (see Appendix 16)	Impairment measure used to gain a measure of muscle tone and spasticity in the lower limb.
Motor Skills	Motricity Index (Demeurisse et al., 1980) (see Appendix 17)	Impairment measure to assess motor skills. This information may give an indication of the feasibility of the proposed intervention with participants with differing levels of motor impairment Brief assessment that will give an indication of the motor impairment of the upper and lower limbs and the trunk. Scores range from 0-100, lower scores indicating greater motor impairment.
Mobility	Rivermead Mobility Index (Collen et al., 1991) (see Appendix 18)	Activity measure to assess what the patient can and cannot do in terms of general mobility. Staff completed questionnaire used to measure mobility disability after head injury and stroke. It comprises of 14 questions (activities scored range from turning over in bed to running) and one direct observation of standing for 10 seconds. Scores range from 0-15. Lower scores indicate greater mobility deficits.
Balance	Berg Balance Test (Berg, 1989) (see Appendix 19)	Activity measure consists of 14 observable tasks common to everyday life measured on a 5 point ordinal scale. The maximum score is 56, with higher scores indicating better balance.
Health related quality of life	Stroke Impact Scale (Duncan et al., 1999) (see Appendix 20)	Questionnaire to evaluate how stroke has impacted on health and life.

All outcome measures were recorded at baseline assessment; one to four days post two week intervention and at six week follow-up assessment (see Figure 1). To ensure standardisation of outcome measures at each assessment point, all outcome measures were carried out in the clinical setting (Salisbury District General Hospital, the Royal Bournemouth Hospital, or Christchurch Hospital) apart from the Stroke Impact Scale, which was completed in the clinical

setting or participants' homes depending on the length of time taken to complete the physical measurements and what was most convenient for the participants.

At the end of the intervention period participants were left with a questionnaire to evaluate their experiences of the gait training programme. Participants were asked to comment on how they found the intensity, use and application of the treatment and assessment methods (see Appendix 14). Therapists were also asked to give their opinions as to how the study impacted on their everyday practice (see Appendix 8). Both questionnaires were anonymous.

3.14 Analysis of the results

The methodology described above was designed to explore the feasibility of conducting a two week gait training programme combined with FES (targeted to glutei and/or ankle dorsiflexor and evertor muscles) for people with a sub-acute stroke and reduced hip extensor and dorsiflexor activity. The main focus of the study was therefore to assess the feasibility of various methodological components in a sub-acute stroke population. Therefore analysis of the results is primarily based on the use of descriptive statistics. Table 5 reviews the data collected to meet the key feasibility objectives described in previous paragraphs and summarises how the data was analysed.

Although testing efficacy of the intervention was not a primary aim of the study, results were analysed to see whether there was any possibility of an effect. In particular, results were analysed to see whether trends existed in outcome measures pre and post intervention and at six week follow-up. In addition comparisons of outcomes were made between groups. Interferential statistics were used for these analyses however, as the study was not adequately powered to detect statistically significant differences and therefore these were not expected. A significance level of 0.05 was used in all the tests. SPSS 21 software was used for the statistical analysis.

Table 5: Table to summarise the data collected and method of analysis

Objectives of the study	Data collected	Methods of analysis
a. To determine the proportion of eligible patients admitted to recruitment sites	Stroke Unit total admission numbers, stroke admission numbers.	Descriptive
b. To explore factors influencing eligibility and subsequent recruitment	Reasons for ineligibility Proportion of eligible patients that consented	Descriptive
c. To determine follow-up and retention rates	Number of drop outs at week two and week six assessment	Descriptive
d. To determine whether patients were able to complete intervention schedule	Number of intervention sessions missed	Descriptive
e. To describe the variation in the content and intensity of the intervention delivered	Duration and content of interventions, number of repetitions completed.	Individuals: Descriptive Comparisons between groups: Interferential Statistics
f. To explore participant and staff perceptions of the acceptability of the intervention (gait training and gait training and FES)	Quantitative and qualitative data gathered through questionnaires	Descriptive
g. To determine whether the selected outcome measures are suitable and can be carried out in clinical/home settings	Results of outcome measures at taken at baseline, week two and week six – reasons related to missing data noted	Descriptive
h. To gain estimates required for a sample size calculation	Gait speed at baseline, week two and week six	Interferential Statistics: Correlation of speed at baseline and week six. Sample size calculation using standard deviation of speed data.

4. Chapter 4: Results

4.1 Introduction

The purpose of this chapter is to summarise the data collected in order to answer the question: Is it feasible to conduct a two week gait training programme combined with FES (targeted to glutei and/or ankle dorsiflexor and evertor muscles) for people with a sub-acute stroke and reduced hip extensor and/or dorsiflexor activity? Section 1 of this chapter will first describe the data collected to meet the key feasibility objectives. This will include demonstrating recruitment and retention to the study. The participants enrolled in the study will be described in terms of their baseline characteristics. The location, content and intensity of the interventions provided will be explicitly described, including exploration of the intensity and content of usual care provided by the therapy teams. Participant and staff perceptions of how manageable they found the study interventions, and their feelings related to its impact on their walking ability will then be demonstrated.

Secondary to this, Section 2 of this chapter will explore results of the primary outcomes; gait speed and quality of walking as measured by the Wisconsin Gait Scale. Section 3 will describe the results related to the secondary outcomes. Finally, Section 4 of this chapter will consider whether it is possible to use the current data to estimate a sample size for a follow-on randomised controlled trial.

4.2 Section 1: Feasibility of methodological processes

4.2.1 Recruitment

Fifteen research participants were recruited during the 12 month recruitment period. This was one participant less than was originally proposed due to the 12 month data collection period coming to an end before the final participant could be recruited. This is a feasibility study and the sample size is based on pragmatic reasoning rather robust hypothesis testing. It was therefore felt that the data collected from fifteen participants was enough to meet the feasibility objectives.

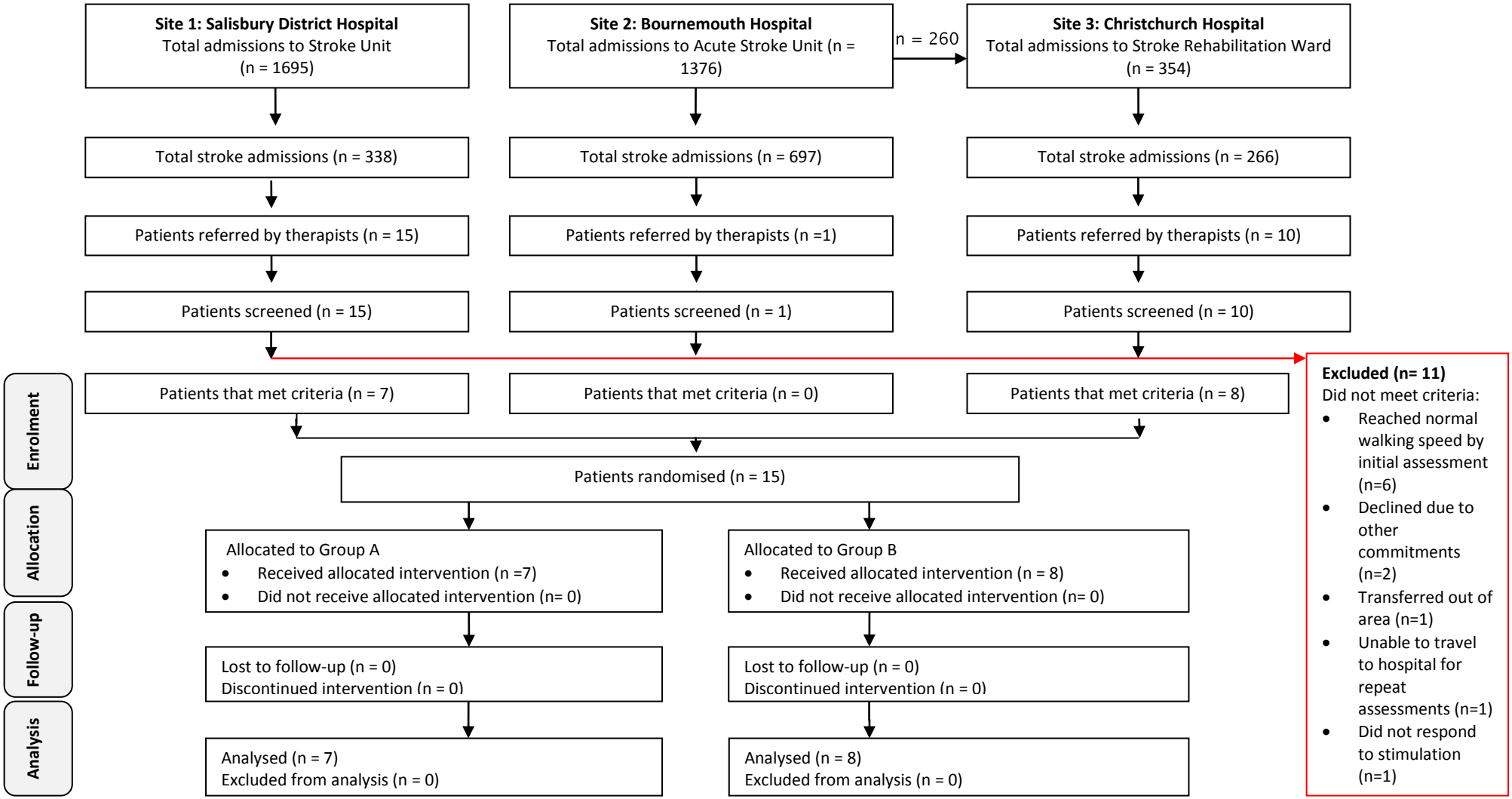
The first study objective was to determine the proportion of eligible patients admitted to recruitment sites. Figure 2 shows the flow of patients through the study with numbers and reasons for exclusion at each step. Stroke Data Analysts at Bournemouth and Christchurch Hospitals and Salisbury Hospital provided information regarding the total number of admissions to each stroke ward and those diagnosed with stroke from the period of August 2010 to August 2011. As Figure 2 demonstrates, not all patients admitted to stroke wards were diagnosed with stroke. At Salisbury Hospital, 19% of all admissions to the stroke ward had a stroke diagnosis; at Bournemouth Hospital 51% of all admissions to the Stroke Unit were diagnosed as stroke and at Christchurch Hospital 75% of patients admitted to the Stroke Rehabilitation Ward were diagnosed as stroke, with 98% of those having been transferred directly from Bournemouth Acute Stroke Unit. Six patients admitted to Christchurch Stroke Rehabilitation Ward were stroke transfers from other hospitals.

The information gathered from the Stroke Data Analysts showed that in total 1041 new stroke patients were admitted to the stroke unit sites during the period of recruitment. Only 26 of those were identified by the therapists and referred to the researcher (2.5%) which was a much lower number than expected. It was not possible for the researcher to screen all new stroke admissions and therefore therapists working on the wards were asked to refer patients who met the eligibility criteria. It could be that the eligibility criteria was too narrow and only allowed for small recruitment rates but it could also be possible that a higher proportion of patients were eligible but, were not referred to the researcher by the therapists. Of the 26 patients that were referred, 11 were excluded. The most common reason for exclusion (55%) was patients having reached normal walking speed by their initial assessment.

4.2.2 Retention

All fifteen participants completed the trial and there were no drop outs during treatment or at follow-up. There was 100% attendance at all assessment and treatment sessions. Appointments needed to be flexible around the participants' availability and transport arrangements however, all assessments and all eight intervention sessions for all fifteen participants were administered within the identified time frame.

Figure 2: Consort diagram during study period from August 2010 to August 2011



4.2.3 Participant characteristics

The baseline characteristics of the participants are presented in Table 6.

Table 6: Baseline characteristics of each participant

Group	Subject No.	Age (years)	Gender	Time since stroke (days)	Type of stroke	Side of hemiplegia	Length of stay (days)	MMSE Score	Pre - Mobility
A *(Gait Training only group)*	1	78	F	64	LACI	Right	91	29	Ind
	4	59	M	18	PACI	Left	25	28	Ind
	5	81	F	26	LACI	Right	32	28	Ind
	8	51	M	42	PACI	Right	47	20	Ind
	9	76	M	15	PACI	Left	15	28	Ind
	12	66	F	106	PACI	Left	44	28	Ind
	14	87	F	53	PACI	Right	60	28	Ind
B *(Gait Training and FES group)*	2	63	M	70	TACI	Left	70	30	Ind
	3	79	F	53	PACI	Right	23	28	Ind
	6	81	F	31	PACI	Left	38	30	Ltd (2 sticks outdoors)
	7	75	F	62	PACI	Left	66	30	Ind
	10	85	M	15	PACI	Left	22	29	Ltd (1 Stick outdoors)
	11	63	M	10	LACI	Left	14	27	Ind
	13	68	M	18	PACI	Left	12	29	Ind
	15	75	F	42	PACI	Left	43	25	Ind

Type of stroke: See Appendix 21 for details of stroke classification
Pre-Mobility: Ind=independently mobile indoors and outdoors without assistance or aids. Ltd=Limited outdoor mobility needing aids for support

The average age of the sample was 77.8 (range 66–87, SD = 6.11) years in women (n=8) and 66.4 (range 51-85, SD = 11.22) in men (n=7). Participants were recruited on average 41.8 days post stroke (range 10-106, SD = 26.75). All participants recruited had an infarct rather than a haemorrhagic stroke, the majority of infarcts being Partial Anterior Circulatory Infarcts (PACI). Ten participants had a left-sided hemiplegia and five participants had a right-sided hemiplegia. Length of in-patient hospital stay varied from 12 days to 91 days. All participants were independently mobile indoors prior to the stroke.

4.2.4 Demographic comparisons between groups

Groups A and B were not statistically different in terms of age, gender, time since stroke, length of inpatient stay and cognitive function as measured by MMSE scores (see Table 7). Group B included a participant who was diagnosed with a Total Anterior Circulatory Infarct (TACI) and two participants who required an aid to mobilise outdoors prior to their stroke.

Table 7: Comparisons between participant characteristics in Group A and B

	Group A: Gait Training only group	Group B: FES with Gait Training	P value
Age			
Average (mean)	71.1	73.6	0.660*
Range	36 (51 - 87)	22 (63 - 85)	
SD	12.9	8.2	
Gender			
No. of Males	3	4	
No. of Females	4	4	
Time since stroke (days)			
Average (mean)	46.3	37.6	0.551*
Range	91 (15 – 106)	60 (10 – 70)	
SD	32.0	22.7	
Side of hemiplegia			
Right	4	1	
Left	3	7	
Type of stroke			
TACI	0	1	
PACI	5	6	
POCI	0	0	
LACI	2	1	
Length of stay			
Average (mean)	44.9	36	0.484*
Range	76 (15 – 91)	58 (12 – 70)	
SD	25.2	22.5	
MMSE score			
Average (mean)	27	28.5	0.288*
Range	9 (20 – 29)	5 (25 - 30)	
SD	3.1	1.8	
Pre-stroke level of mobility			
Description	All participants were independent	All patients were independent except 2 patients, who mobilised with one or two sticks outdoors	

**No significant difference between groups according to the independent t test*

4.2.5 Description of the Intervention

The interventions were designed to be clinically relevant and compatible with current resources available in clinical settings and in patients' homes. The location, combination of exercises, intensity and progression of the gait training programme were individually tailored to the needs of each participant. It is possible that these individual factors may have an influence on outcomes. Therefore, an objective of the current study was to describe the variation in the intervention delivered, in order to determine the extent to which these elements can be standardised without the loss of an individualised, patient centred approach. The following paragraphs describe the results related to the variability in these aspects of the intervention.

4.2.5.1 Location of the intervention

The interventions were carried out either in a clinical inpatient setting or in the participants' homes, depending on their location at the time. Appendix 22 illustrates the location of the intervention sessions. Of the 120 treatment sessions performed, 24 (20%) were performed in clinical settings as participants were still inpatients, whilst 96 sessions (80%) were performed in participants' homes. The Mann-Whitney *U* Test revealed that the location of treatment (home or clinic setting) was not significantly different between the two groups ($U = 28$, $p = 1.00$).

4.2.5.2 Duration of intervention

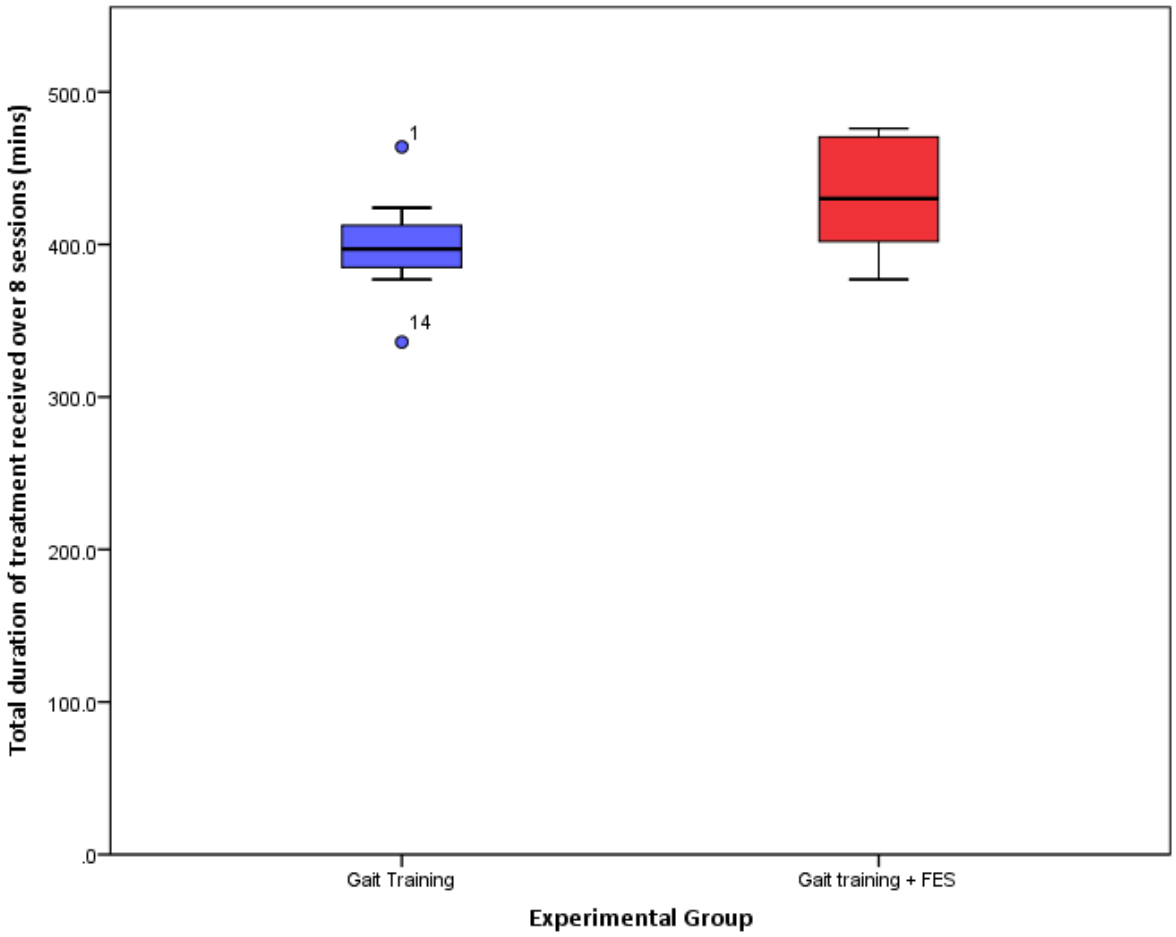
Appendix 23 shows the total treatment duration received by participants over all eight sessions. The average total treatment time was 417 minutes (S.D 41.2) which ranged from 336 to 476 minutes. The average duration of each individual treatment session was 52 minutes (S.D 5.2) ranging from 42 to 60 minutes. The target of an average of 45 minutes for each treatment session (360 minutes for all eight sessions) was achieved by all but one participant (participant 14).

Figure 3 shows the results related to average treatment times for each group in the form of box and whisker plots, where the median value is given as a horizontal line and the interquartile ranges are represented by the box. The whiskers show the minimum and maximum values, with asterisks used to highlight outlier values.

Inspection of Q-Q Plots revealed that treatment time was equally distributed for both groups and that there was homogeneity of variance as assessed by Levene's Test for Equality of

Variances. Therefore an independent t-test was run on the data. It was found that there was no significant difference in treatment times for the Gait Training only group (M=398.9, SD=39.5) and the Gait and FES group (M= 432.3, SD=38.4); t(13)=-1.659, p=0.121.

Figure 3: Box plot graph to show the total duration of treatment received over eight treatment sessions in each group



4.2.5.3 Amount of time spent setting up stimulation

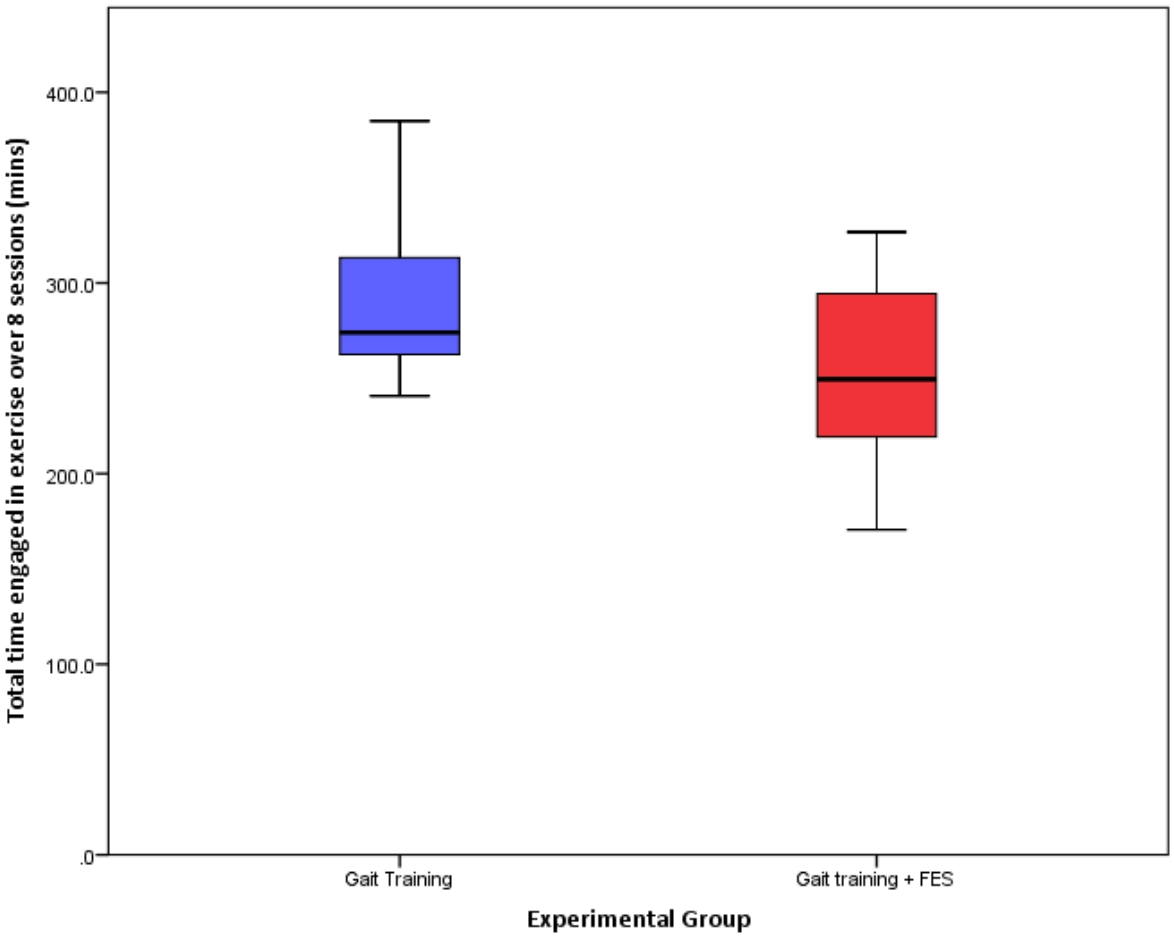
The amount of time spent setting up the stimulation during each treatment session was also recorded in the treatment log. As Appendix 24 demonstrates, the time taken to set up stimulation in total varied between the participants ranging from 57 to 113 minutes and averaged 79 minutes. This equated to an average setup time per session ranging from 7 minutes to 14 minutes. The average percent of the total treatment session taken up by setting up stimulation ranged between 10.7% and 23.6%.

4.2.5.4 Amount of time physically engaged in exercise

The amount of time physically engaged in exercise was also calculated from the treatment log (Appendix 25). This included the time participants spent physically engaged in the task related training activities (see Table 1). The remaining session time was spent setting up stimulation with participants in Group B as described above, resting, describing and demonstrating the exercise or general discussions about progress. The amount of time physically engaged in training tasks varied between participants and ranged from a total of 171 to 385 minutes and averaged at 272 minutes. This equated to an average of 65.83% of the total treatment duration spent physically engaged in exercise (SD = 14.15, median = 64.73).

Figure 4 shows the difference in the average amount of time engaged in exercise between the two groups. An independent t-test found that there was no significant difference in the amount of time physically engaged in task related exercises for the Gait and FES group (M= 253.0 SD=51.4) and the Gait Training only group (M=293.0, SD=49.6); t(13)=1.53, p=0.150. However, when comparing the proportion of treatment time spent actively exercising there was a significant difference, with a greater percentage of time spent actively exercising in the Gait Training only group (M=74%, SD=11.6) compared with the Gait Training and FES group (M=59%, SD=13.0); t(13)=2.3, p=0.038).

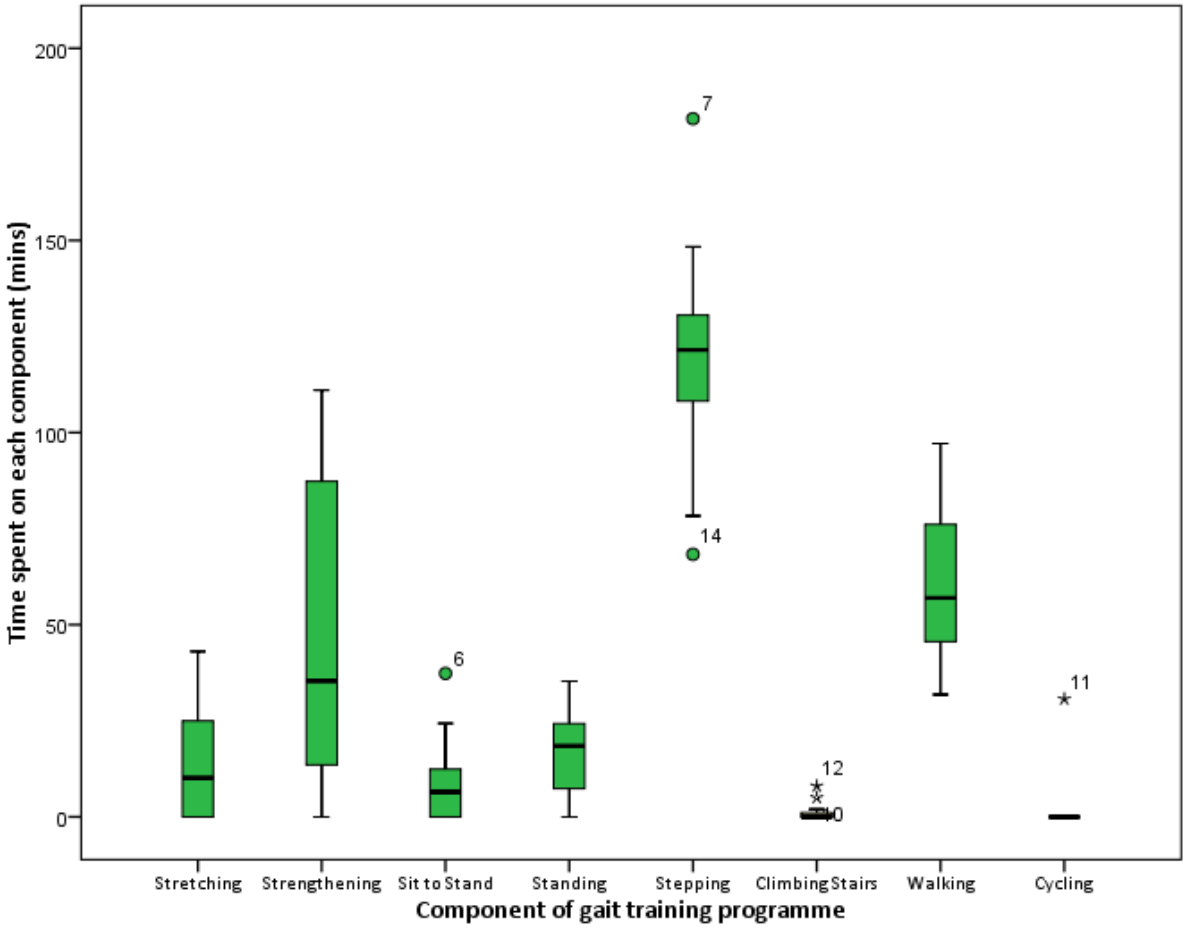
Figure 4: Box plot graph to show the total time participants were engaged in physical task practice over eight treatment sessions in each group



4.2.5.5 Content of Intervention

The components of the gait training programme completed by each participant were also documented within the treatment log. These were selected by the therapist based on the assessment findings and the individual needs of each participant. Figure 5 shows the amount of time (mins) spent on each component of the gait training programme in total across the eight treatment sessions. The amount of time varied considerably between components (see Appendix 26). The largest amount of time was spent on stepping practice, walking and on strengthening work. The least amount of time was spent climbing stairs and cycling.

Figure 5: Box plot graph to show the amount of time spent on each of the gait training components across all eight sessions



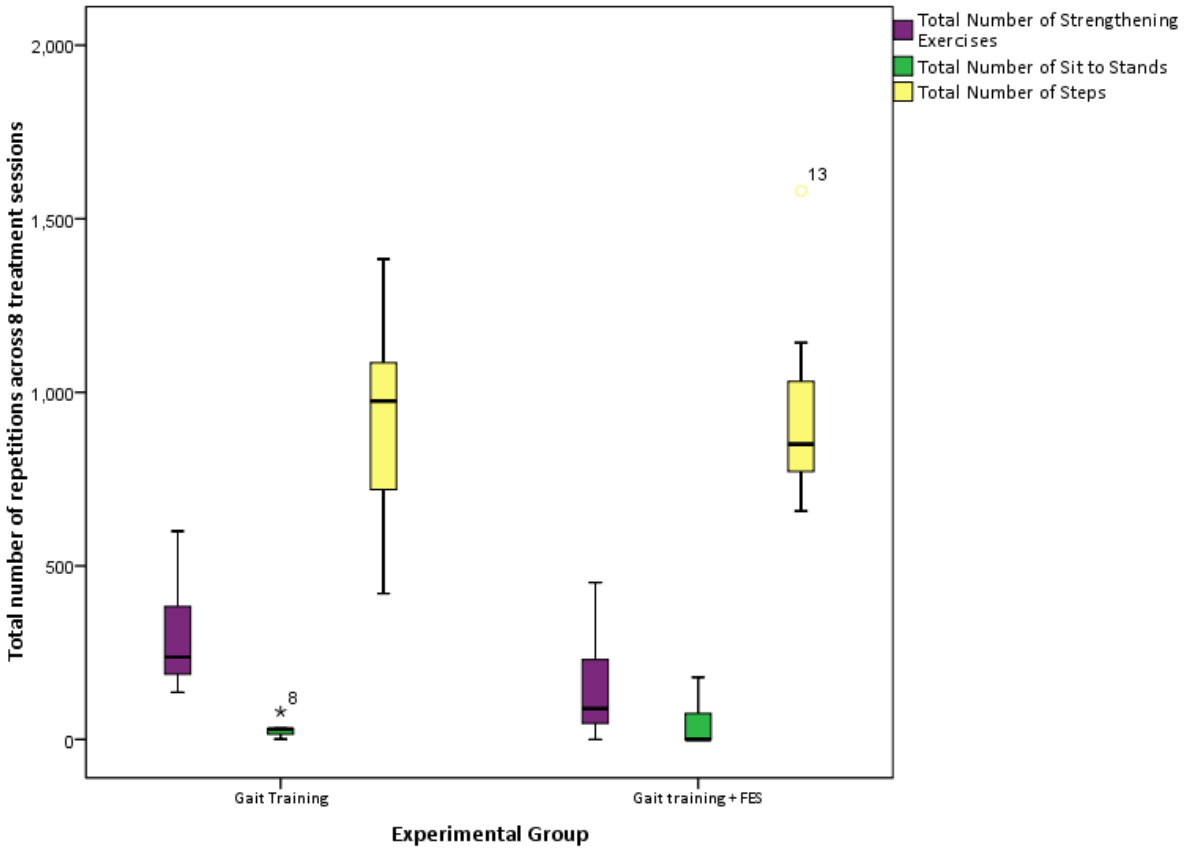
4.2.5.6 Number of repetitions

It was feasible to record number of repetitions for several of the gait training components within the programme. This included counting the number of strengthening exercises, sit to stand repetitions and steps completed within each session. Appendix 27 shows the total number of repetitions for each of these three components across all eight treatment sessions. The number of repetitions varied greatly between the type of exercise being performed and between participants. The highest number of repetitions was found with the stepping component of the gait training programme with a minimum of 420 and a maximum of 1580 steps being performed over all eight treatment sessions. This equates to an average of 116 steps being performed during each treatment session.

Figure 6 compares the number of repetitions across all eight treatment sessions in the three gait training components between the two groups. An independent t-test was run on the data to compare repetitions of steps between the two groups. It was found that there was no significant difference in the number of steps taken in the gait training group (M=913, SD=321) and the gait training and FES group (M=943, S.D=295); t (13)= - 0.191, p = 0.851.

The data related to the number of repetitions of strengthening exercise was not normally distributed. Therefore a Mann-Whitney *U* test was run to compare the repetitions of sit to stand and strengthening exercises between the two groups. It was found that there was no significant difference in the number of sit to stand exercises completed in the gait training and FES group and the gait training only group (U = 20, p=0.345). It was also found that there was no significant difference in the number of strengthening exercises completed in the gait training and FES group and the gait training only group (U =12, p=0.064).

Figure 6: Box plot graph to compare the number of repetitions in three components of the gait training programme between the groups



4.2.5.7 Summary of the components of the intervention

The intervention for the gait training and gait training and FES groups provided by the researcher has been described. The components of the intervention including location, duration, intensity, content and number of repetitions, were all designed to be clinically relevant and to meet the individual needs of patients. An objective of the current study was to describe the variation in the intervention delivered. This information could then be used to inform decisions about the extent to which elements can be standardised for a follow-on randomised controlled trial.

Results revealed that 80% of the intervention was provided in patients homes as opposed to a clinical/inpatient setting. All participants, apart from participant 14, received at least 45 minutes of gait training per session. The average duration of each individual treatment session was 52 (S.D 5.2) ranging from 42 to 60 minutes. The amount of time spent setting up stimulation ranged from 7-14 minutes with an average set up time of 10 minutes (SD 2.2). The average amount of time spent actively exercising per session was 34 minutes (SD 6.62) ranging

from 21 to 48 minutes. The content of each session varied considerably across the sample, in response to the individual needs of the participant. The largest amount of time was spent on stepping practice, walking and on strengthening work. The least amount of time was spent climbing stairs and cycling. The results relating to the intervention provided will be reflected upon in the Discussion Chapter and methods of standardisation of duration, intensity, content and repetitions will be explored.

4.2.6 Routine care charts

The healthcare professionals involved in the participants' routine care were also asked to document frequency, duration and content of their usual contact sessions during the two week intervention period (see Appendix 7). Records from three participants were returned; relating to participants 2, 3 and 12. The following paragraphs demonstrate their responses in relation to frequency, duration and content of routine care.

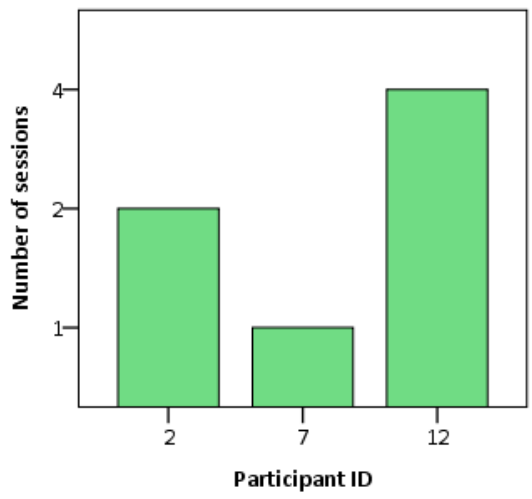
4.2.6.1 Routine care chart response rate

The response received from therapists related to routine care was lower than expected. It is not possible to calculate response rates as routine therapy was not explicitly monitored. It may have been that participants did not receive additional routine therapy in addition to the intervention during the intervention period, or it may have been the case that they did, but the routine care charts were not completed and/or returned to the researcher.

4.2.6.2 Frequency of routine care

Figure 7 shows the number of sessions of routine therapy documented during the intervention period. Of the three participants for whom a record was completed, frequency of routine care ranged from one session to four sessions. This was considerably less than the eight sessions all participants received during the intervention phase of the study, regardless of which group they were in.

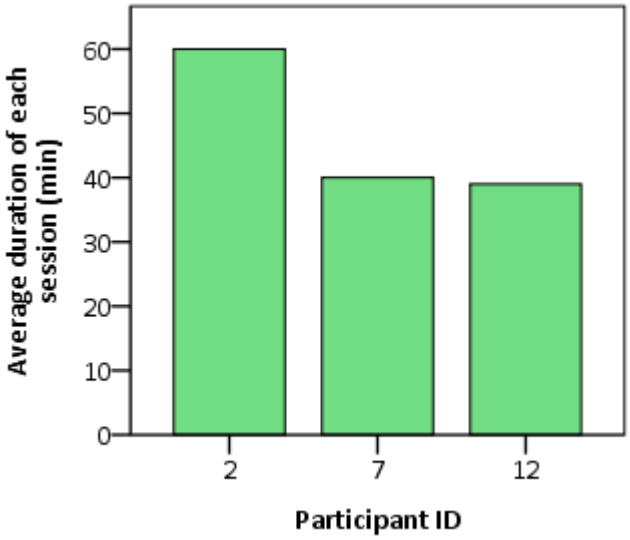
Figure 7: Bar chart to show the number of routine therapy sessions during the study intervention period



4.2.6.3 Duration of routine therapy

Figure 8 shows the average duration of routine therapy sessions documented during the intervention period. This ranged from 39 to 60 minutes and was similar to the average duration of individual gait training sessions. Shorter sessions of routine therapy were attributed to hydrotherapy treatment, where service parameters rather than individual patient tolerance levels may have limited therapy duration.

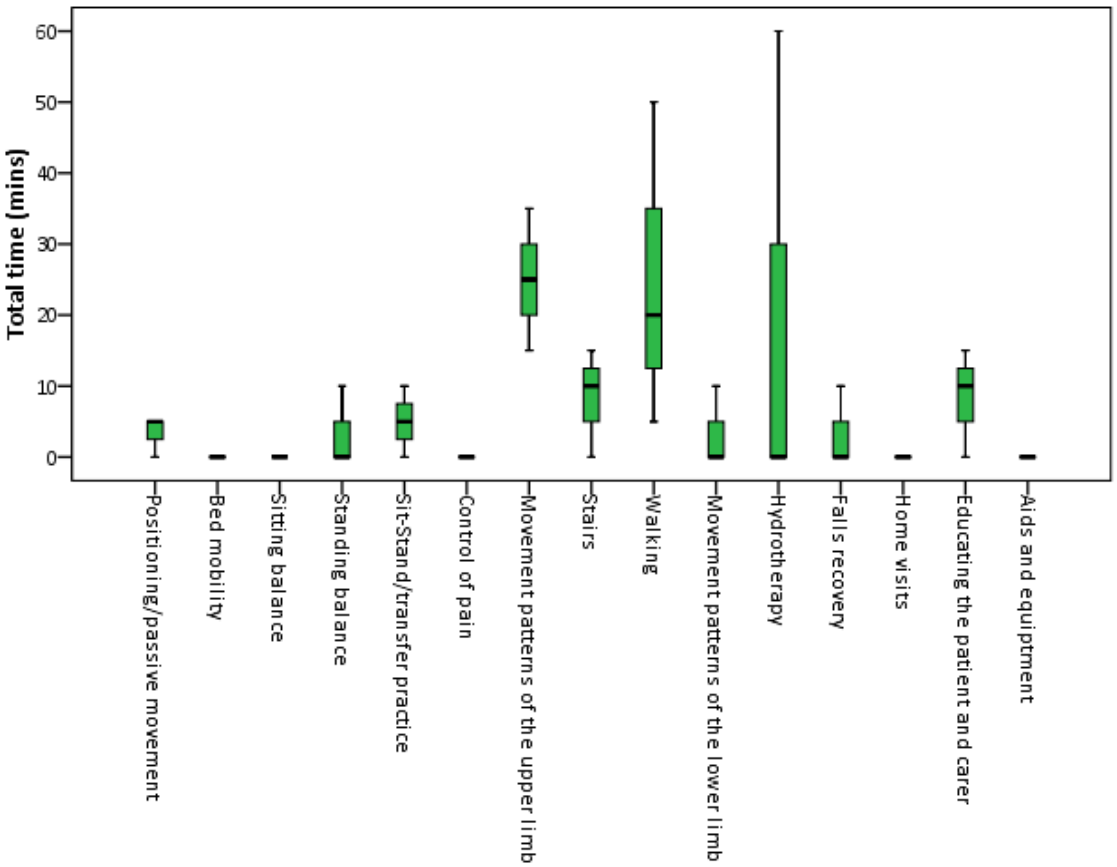
Figure 8: Bar chart to show the average duration of routine therapy session during the study intervention period



4.2.6.4 Content of routine therapy

Figure 9 shows the content of the routine therapy sessions and the amount of time spent on each activity. Participant 12 had two sessions in hydrotherapy, totaling 60 minutes. The most frequently occuring intervention was walking practice, carried out by all three patients. The total length of time spent on walking across the two weeks was 5 minutes for participant 2, 45 minutes for participant 3 and 20 minutes for participant 12. Therapy targeted to the upper limb was also common for all three participants with the amount of time spent on this rangeing from 15 to 35 minutes across a two week period.

Figure 9: Box plot graph to show total amount of time spent on aspects of routine therapy during intervention phase



4.2.7 Participant questionnaire responses

At the end of the intervention period participants were left with a questionnaire to evaluate their experiences of the gait training programme (see Appendix 14). Participants were asked to comment on how acceptable they found the intensity, use and application of the assessment and treatment methods. They were instructed to return the completed anonymised forms in addressed and prepaid envelopes.

4.2.7.1 Participant questionnaire response rates

Twelve of the 15 participants returned completed questionnaires, demonstrating an 80% response rate. Five of these were from participants in the gait training only group and seven were gait training and FES group. The following paragraphs describe the responses gained from the completed questionnaires and have been summarised into the following themes; overall experience of being involved in the study, quantity of treatment, impact of treatment, experiences of electrical stimulation and other comments.

4.2.7.2 Overall experience of being involved in the study

The majority of participants gave positive responses to questions related to their overall experience of taking part in the study. All enjoyed taking part in the study, 11 reported that trial procedures were easy to fit in, one participant did not complete this section of the questionnaire. Ten of the participants reported that they did not find the study too tiring, one reported that they did, and one did not complete this section. None of the participants thought about leaving the study.

4.2.7.3 Quantity

Participants were asked questions related to how appropriate they found the quantity of the exercise programme. The majority of participants in both groups found that the quantity was sufficient. One participant in the gait training only group felt there was too little exercise and they could have done more. Another participant, also in the gait training only group felt that the exercise was ‘Just about enough’ although reported in their comments that they would have liked more. Details of the comments received related to quantity are described in Figure 10.

Figure 10: Comments related to the quality of the intervention

"It helped me to understand how to stretch and retrain myself, how much I could and should do."
"Just about cope with the exercise as training was quite intense"
"Worked hard for full hour and although a bit tiring very productive. Was able to do short exercises myself whenever I could."
"At that stage of recovery the concentration needed to do the exercises was quite tiring."
"Because I was still physically weak and tired during the trial."
"It was more about quality than quantity. I was very happy with the physio I received"
"I had to be satisfied but then I wanted more. It boosted my mood. What happened to people who did not have this offered - not good enough NHS "
"I felt I could have done more."
"I was aware of the lessons, it taught me aware of the left foot's tendency. I think the programme impressed this upon me incredibly."
"I felt I could cope."

4.2.7.4 Impact of treatment

Participants were asked to score on a scale of 0-10 the impact of the two week walking training programme on walking ability. Scores were similar between groups; participants in the gait training only group gave a mean score of 8.4 whereas the participants in the gait training and FES group had a mean score of 8.57.

4.2.7.5 Experiences of electrical stimulation

Participants were asked how they felt about the electrical stimulation, in particular the time required to apply the electrodes, whether they found it comfortable to exercise with the electrical stimulation on and whether they found the electrical stimulation itself comfortable. The six responses of participants in the Gait and FES arm of the study indicated that FES was

tolerated well. All participants found the time required to apply the electrodes acceptable and that they found the stimulation comfortable.

4.2.7.6 Other comments

At the end of the questionnaire participants were given the opportunity to write any additional comments about taking part in the study (see Figure 11). Their feedback from both groups was largely positive with participants commenting on the quality of the additional exercise and the impact it had on their recovery. One participant wrote that they may have made even more progress with more therapy.

Figure 11: Additional comments from participants

Additional comments from participants in the gait training only group
"It was very positive - I looked forward to the sessions - physically and psychologically worthwhile. I am grateful for the opportunity to have shared in the programme."
"Anna has the rare ability of offering hope and purpose..... Thanks for what I received."
"I think that if I had more exercise I might have made even better progress."
Additional comments from participants in the gait training and FES group
"The programme was made easier at a difficult time with the lovely Anna"
"Excellent programme carried out by an excellent physiotherapist."
"The extra physiotherapy together with electrical stimulation undoubtedly helped my walking to improve more quickly. Thank you Anna for all your help and good luck with the study."
"I felt pleased to think that through participating in this research it might help someone in the future struggling to move."
"Very useful, helpful and well thought out"
"The two weeks of intensive therapy helped me to make more rapid progress"

4.2.8 Healthcare professionals' opinions

Healthcare professionals involved in routine treatment whilst participants were in the treatment phase of the study were provided with a questionnaire to complete. The questionnaire was designed to gain an insight into their opinions about the intervention and assessment procedures used and how they felt the study affected their daily routine (see Appendix 8).

4.2.8.1 Healthcare professional questionnaire response rates

Only two healthcare professionals returned completed questionnaires. It is not possible to calculate response rates, as routine care was not explicitly monitored and it is unclear how many participants received routine therapy in addition to the study. The following paragraphs describe the responses gained from the completed questionnaires. The healthcare professionals' opinions have been summarised into three main themes; the study's impact on their ability to deliver usual care, demands on the study's participants and their willingness to contribute to a similar study.

4.2.8.2 Ability to deliver usual care

As demonstrated in Table 8 the completed questionnaires showed that the study has little impact on the healthcare professionals' ability to deliver usual care. One healthcare professional felt that the study competed with space to deliver usual care, although they responded that his did not change their delivery of usual care in any way.

Table 8: Healthcare professionals' feedback on ability to deliver usual care

Questions related to ability to deliver usual care	Healthcare Professional 1	Healthcare Professional 2
Did you find it difficult to continue usual care with people who received the intervention?	No	No
Did the study make it more difficult for you to organise your day?	No	No
Did the study compete with space to deliver usual care?	No	Yes
Did you find it difficult to continue usual care with people who did not receive the intervention?	No	No
Did you change your usual care in any way as a result of the study?	No	No
Did you feel that taking part in the study interfered with the ward/community team's routine?	No	No

4.2.8.3 Impact of the study on the participants

Table 9 demonstrates that healthcare professionals felt that the study had a positive impact on participants and that they benefitted from additional treatment.

Table 9: Healthcare professional feedback on impact of the study on the participants

Questions related impact of the study on the participants	**Healthcare Professional 1**	**Healthcare Professional 2**
Do you think that the study participants enjoyed being part of the study?	Yes	Yes
Did you find the demands of the study on the participants acceptable?	Yes	Yes
Did you find that the intervention was helpful?	Yes	Yes
Can you explain why you think that? Healthcare Professional 1: "Increased input" Healthcare Professional 2: "I think that the patient benefitted from having extra sessions as he was very motivated. It was also good for him to have lots of practice walking during the intervention."		

4.2.8.4 Willingness to contribute to a similar study

The final question related to whether healthcare professionals would be prepared to contribute to a similar study. Both healthcare professionals replied that they would.

4.2.9 Summary of Section 1: Feasibility of methodological processes

Section 1 of this chapter has described findings in relation to the key feasibility objectives. The results relating to each objective are summarised in Table 10.

Eligibility: In total 1041 new patients were admitted with stroke to the three hospital sites during the 12 month data collection period. Only 26 were identified to the researcher as having met the eligibility criteria. It is unclear whether this gives a true picture of the proportion of eligible patients as it cannot be ruled out that more patients were appropriate, and not identified to the researcher. The potential reasons for this are described in the Discussion Chapter.

Recruitment: Of the 26 patients identified by the therapists, 15 were recruited. The most frequent reason for exclusion related to the fact that patients had reached normal walking speed by the initial assessment. Of the 15 participants recruited, female participants had an average age of 77.8 years (n=8) and male participants had an average age of 66.4 years (n=7). They were recruited on average 42 days post stroke.

Retention: Retention rates for the study were good. All fifteen participants attended all eight treatment sessions and completed baseline, week two and week six outcome measures. There was no missing data.

Variability of the Intervention: The intervention in terms of the location, duration, intensity, content and number of repetitions have been described in order to explore variability across the participants. There was relative consistency in the location of the intervention with 80% of the interventions taking place in participants' home. The average duration of each session was 53 minutes (SD 5.2, range 42 – 59.5). Only one participant tolerated sessions lasting less than 45 minutes (42 minutes). The amount of time engaged in active exercise based on the researcher's perception of the participants' fatigue levels averaged 34 minutes, however ranged from 21 to 48 minutes (SD 6.62). Stepping and walking activities were common gait programme components however all other activities varied greatly between participants. The number of repetitions also varied for example, numbers of total steps completed over the eight treatment sessions ranged from 420 to 1580. Analysis of these preliminary results shows no significant difference between the groups in terms of location, duration, intensity, content and number of repetitions.

Variability of routine care: To explore the intensity and content of routine care received in addition to the study intervention, healthcare professional were asked to complete questionnaires. Information on the routine care of three of the fifteen participants was returned, which was fewer than expected. This ranged from one to four sessions across the two week intervention period, with each session ranging from 39-60 minutes in duration. Walking practice and upper limb exercises were a common element of the routine care sessions.

Participant perceptions of the intervention: Participants were asked for their feedback in relation to their perceptions of the study intervention via questionnaires. Twelve of the 15 participants responded giving mostly positive feedback. All participants enjoyed being part of the study, one participant found the intervention 'too tiring' and one participant felt they 'could have done more'. All participants in the Gait Training and FES group found the electrical stimulation acceptable and comfortable.

Staff perceptions of the intervention: Healthcare professionals were also asked for their feedback relating to their perceptions of the study. Two healthcare professionals returned the questionnaire. In the main, responses indicated that the study did not interfere with routine care. One healthcare professional reported that they felt the study did take up space that may have otherwise been used for routine care. Both healthcare professionals found the demands of the study on the research participants acceptable and helpful reporting that they felt it had a positive impact on their walking ability.

This section of the results chapter has considered the data in relation to the methodological feasibility of the study. The following section considers the results of the primary outcomes; gait speed and quality of walking as measured by the Wisconsin Gait Scale.

Table 10: Summary of findings against key feasibility objectives

Objectives of the study	Findings
a. To determine the proportion of eligible patients admitted to recruitment sites	• 1041 new patients were admitted with stroke to three hospital sites during the 12 month recruitment phase. • 26 of those patients were identified by the therapists as meeting the eligibility criteria and referred to the researcher. • 15 of those were subsequently recruited.
b. To explore factors influencing eligibility and subsequent recruitment	• Reasons why patients not identified as having met eligibility criteria by therapists not directly measured. Of the patients identified to the researcher the predominant reason for exclusion was patients had reached normal walking speed by initial assessment (54.5%).
c. To determine follow-up and retention rates	• Once recruited, retention to the study was good. 100% of patients completed all assessments at follow-up.
d. To determine whether patients were able to complete intervention schedule	• All 15 participants were able to complete all eight-treatment sessions. • 14 participants tolerated intervention sessions lasting 45 – 60 minutes. One participant averaged 42 minutes.
e. To describe the variation in the content and intensity of the intervention delivered	• 80% of interventions took place in participants' homes. • Average duration of each session was 53 minutes (SD 5.2, range 42 – 59.5). • Average amount of time engaged in active exercise was 34 minutes (SD 6.6, range 21.3 – 48.1). • Amount of time setting up stimulation was 10 minutes (SD 2.2, range 7.1-14.1). • Stepping and walking activities were common gait programme components to all participants however all other activities varied greatly between participants. • Number of repetitions also varied, for example numbers of total steps completed over the eight treatment sessions ranged from 420 – 1580. • Analysis of preliminary results shows no significant difference between the groups in terms of location, duration, content and repetitions. The Gait Training only group spent a significantly greater percentage of their treatment time actively engaged in exercise compared with the Gait Training and FES group.
f. To explore participant and staff perceptions of the acceptability of the intervention (gait training and gait training and FES)	• Positive feedback from participants (12 responses to questionnaires). All participants enjoyed taking part, one found the intervention "too tiring", one felt they "received too little exercise" whilst all others felt that the quantity of the exercise programme was "just about enough". All participants who received FES found it comfortable and the set up time acceptable. • Positive feedback from staff (2 responses to questionnaires). They felt that the study did not interfere with their routine practice and would be willing to contribute to a similar study again.
g. To determine whether the selected outcome measures are suitable and can be carried out in clinical/home settings	• All outcome measures completed. No missing data.
h. To gain estimates required for a sample size calculation	• See section 4 of the Results Chapter. Based on standard deviations from gait speed data, a total of 138 participants would be needed for a follow on randomised controlled trial in order to detect the effect of interest.

4.3 Section 2: Preliminary analysis of results of gait related outcome measures

The primary aim of the study was to determine the feasibility of a novel treatment approach in a sub-acute stroke population, which has been explored in Section 1 of this chapter. Section 2 will now focus on describing the results of the outcomes directly related to gait, namely gait speed and Wisconsin Gait Scale Scores. The results relating to these measures will be examined to explore whether participants responded to the intensive gait training programme (either with FES or without it). Preliminary analysis will also consider whether there are any differences in gait performance between the two intervention groups. As this is a feasibility study with a small sample size, statistically significant differences were not expected however statistical testing was carried out to identify any preliminary trends. The results are presented below.

4.3.1 Gait Speed

Gait speed was measured using the 5m walk test (see Appendix 11). Participants were timed walking 5m according to the protocol, a total of 3 times at each assessment. The three time scores were noted and an average taken. This was then converted into a value for their speed (meters per second).

The following figures demonstrate the speed for each participant at baseline, week two and week six in the Gait Training group (Figure 12) and the Gait Training and FES group (Figure 13). Numerical values for each participant are demonstrated in Appendix 28.

Figure 12: Line graph to show gait speed at baseline assessment, following the intervention (week 2) and at final follow-up (week 6) in the Gait Training group

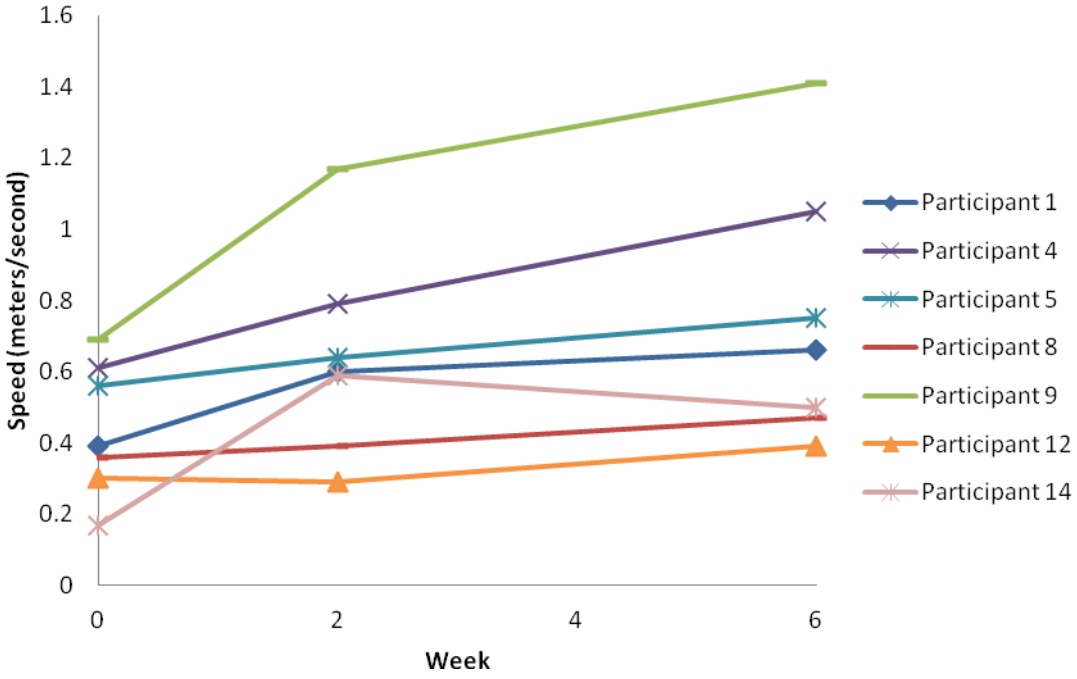
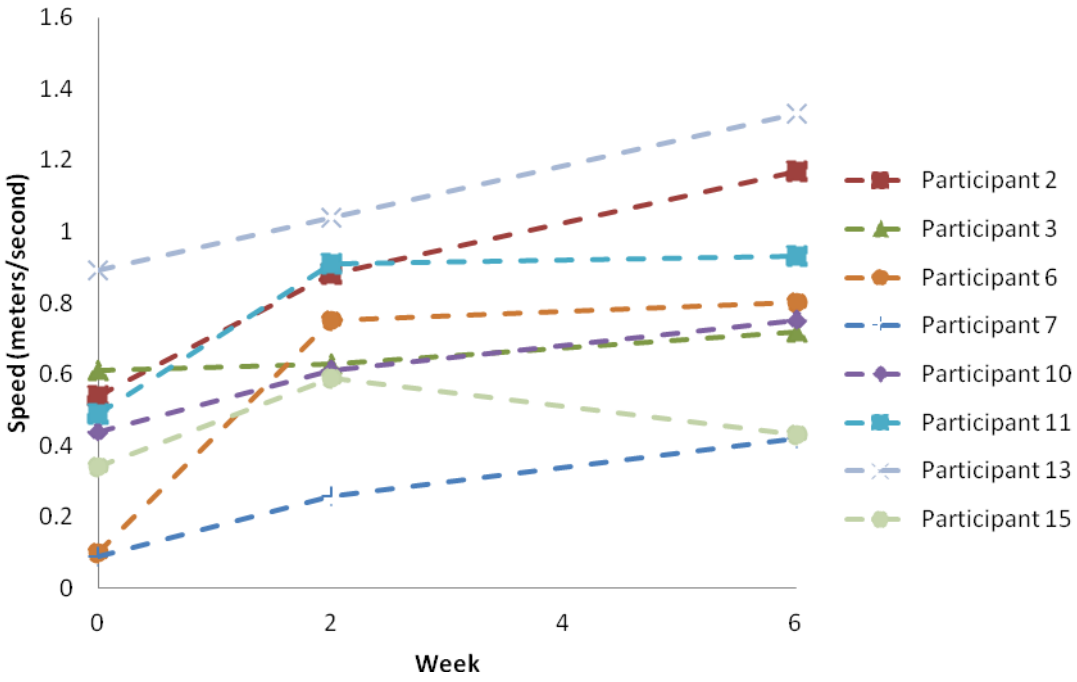


Figure 13: Line graph to show gait speed at baseline assessment, following the intervention (week 2) and at final follow-up (week 6) in the Gait Training and FES group



4.3.1.1 Changes in gait speed between assessment points

All participants apart from one (participant 12) showed an improvement in gait speed from their baseline assessment (M = 0.44 meters/sec, SD = 0.22, range 0.09 – 0.89) to following the intervention at week two (M = 0.66 meters/sec, SD = 0.27, range 0.26 -1.17). All participants apart from one (participant 14) showed an improvement from week two to week six. All participants without exception showed an improvement in their walking speed from baseline to follow-up at week six (M = 0.79 meters/sec, SD = 0.33, range 0.39 – 1.41).

To test whether these improvements were statistically significant, dependent samples t-tests were performed. Prior to conducting the analysis, the assumption of normally distributed difference was examined. Inspection of histograms, normal Q-Q Plots and box plots revealed that gait speed was approximately normally distributed at each of the assessment points. The dependent samples t-tests confirmed that there was a significant improvement in gait speed from baseline to week two; $t(14)= 4.350$, $p= 0.001$, from week two to week six; $t(14)=4.494$, $p=0.001$ and from baseline to week six; $t(14)= 6.247$, $p= 0.0005$.

Numerically, average change in gait speed appeared marginally larger in the first two weeks of the study following the intervention (M = 0.22 m/sec, SD = 0.20) compared with the change in speed in the follow-up period between weeks two and six (M= 0.12m/sec, SD=0.11). To test whether this was statistically significant, a dependent samples t-test was conducted on rate of change scores (change in speed divided by number of weeks). This accounted for the fact that the intervention phase was two weeks in duration, whereas the follow-up period was four weeks. Results showed that the rate of improvement in speed was greatest immediately following the intervention (baseline to week two) compared with during the follow-up period (between weeks two and six); $t(14)=2.942$, $p=0.011$.

4.3.1.2 Comparison of changes in gait speed between groups

Changes in gait speed between the two groups were compared to explore whether there was a greater trend towards gait speed improvement in either group. Figures 14, 15 and 16 show the spread of change in gait speed from baseline to week two, week two to week six and baseline to week six in each intervention group.

Figure 14: Box plot graph to show change in gait speed between baseline assessment and week 2 in the Gait Training and Gait Training and FES groups

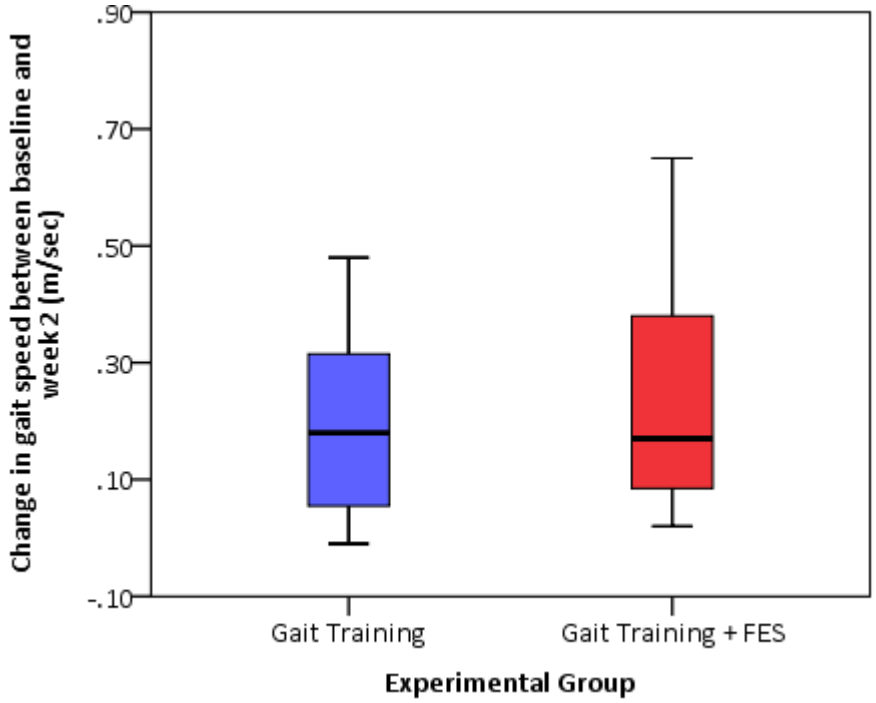


Figure 15: Box plot graph to show change in gait speed between week 2 and 6 week follow-up in the Gait Training and Gait Training and FES groups

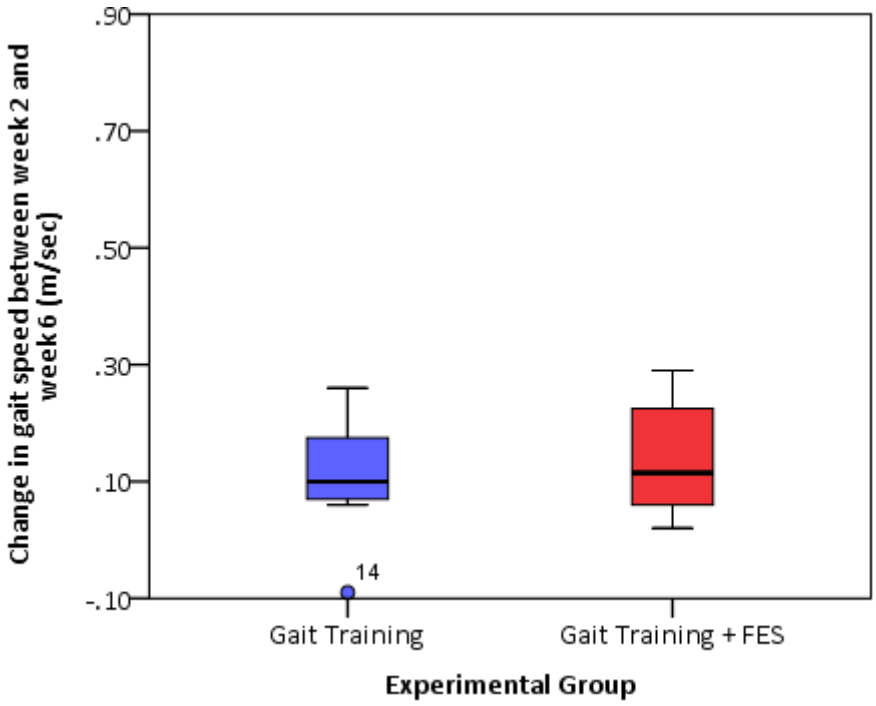
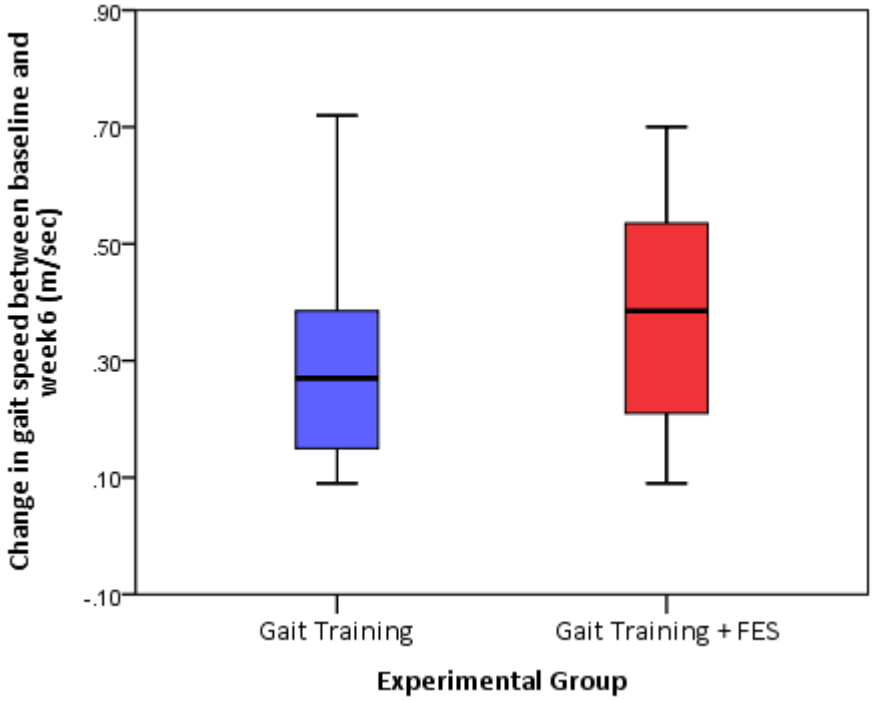


Figure 16: Box plot graph to show change in between baseline and 6 week follow-up in the Gait Training and Gait Training and FES groups



The mean change in speed was marginally larger in the Gait Training and FES Group at all assessment points (see Table 11). To examine whether this was statistically significant, an independent t-test was conducted. Results show that at this preliminary stage, there was no significant difference in changes in walking speed between the Gait Training Group and the Gait Training and FES Group from baseline assessment to week two, week two to week six and baseline to week six.

Table 11: Comparison of the change in speed between the two groups between assessments

	Gait Training Only Group		**Gait Training and FES Group**		**df**	**t**	**Sig. (2 tailed)**
	Mean (SD) Change in speed	**Median (IQR) Change in speed**	**Mean (SD) Change in speed**	**Median (IQR) Change in speed**			
Change in walking speed during intervention phase (baseline and week two)	0.20 (0.19)	0.18 (0.26)	0.24 (0.22)	0.17 (0.24)	13	-0.42	0.684
Change in walking speed during follow-up phase (week two to week six)	0.11 (0.12)	0.10 (0.11)	0.14 (0.10)	0.12 (0.13)	13	-0.529	0.606
Change in walking speed from baseline to follow-up (baseline to week six)	0.31 (0.22)	0.27 (0.24)	0.38 (0.22)	0.39 (0.23)	13	-0.652	0.526

4.3.1.3 Correlation between gait speed and time delay from stroke onset

The participants' mean speed at baseline was 0.44 meters/sec (SD = 0.22, range 0.09 – 0.89), although gait speeds varied considerably between participants. To examine whether any of the variability in gait speed at baseline was associated with the variability in time delay from stroke onset to baseline assessment, a correlation was conducted between these two variables. The Pearson r correlation coefficient confirmed that no systematic relationship was detected between these two variables ($r = -0.44$, $p = 0.101$).

4.3.2 Wisconsin Gait Analysis

To measure the quality of gait, the participants were videotaped whilst walking. An independent assessor watched the videotape and scored each participant using the Wisconsin Gait Scale. The tape, including the walking instructions given during the test, was shown to the blinded assessor who had no knowledge of which group the participants were in. Furthermore, the videotape of walking tests was shown to the blinded assessor in a random order, so that they had no knowledge of the assessment point at which the walking test was taken. The Wisconsin Gait Scale observed 14 variables related to the hemiplegic gait deviations (see Appendix 12). The maximum score is 42, higher scores indicate a greater degree of abnormality of gait pattern. Figures 17 and 18 show the results for each participant at baseline, week two and week six in each of the intervention groups. Numerical values for each participant are demonstrated in Appendix 29.

Figure 17: Line graph to show Wisconsin Gait scores at baseline assessment, following the intervention (week 2) and at final follow-up (week 6) in the Gait Training group

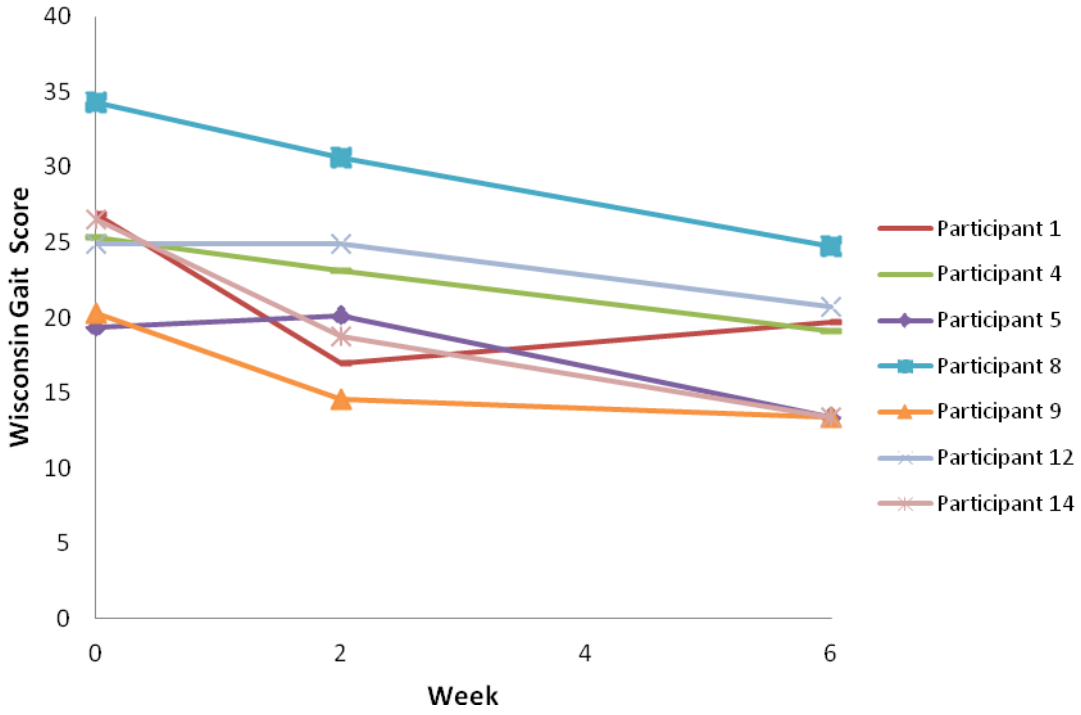
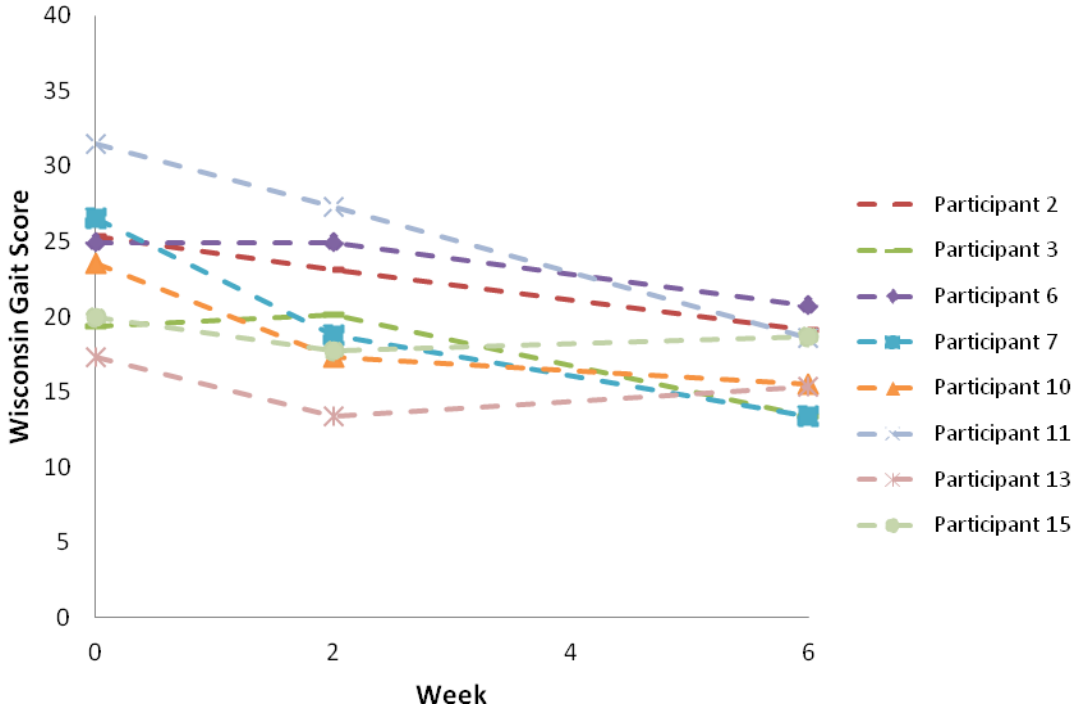


Figure 18: Line graph to show Wisconsin Gait scores at baseline assessment, following the intervention (week 2) and at final follow-up (week 6) in the Gait Training and FES group



4.3.2.1 Changes in Wisconsin Gait Scores between assessment points

Twelve of the 15 participants made an improvement in the quality of gait as assessed by the Wisconsin Gait Scale from baseline (M = 23.32, SD = 5.07, range 16.30 – 34.25) to week two (M = 19.29, SD = 5.23, range 13.35 - 30.65). Participant 3 and 5 showed a slight deterioration in their Wisconsin Gait Scores and participant 12 remained the same. At six week follow-up 10 of the participants made further improvements in the quality of their walking pattern compared with week two. Participants 1,10,11,13 and 15 showed deterioration at week six compared with week two. However, all participants without exception showed an improvement in the quality of their walking from baseline to follow-up at week six (M = 16.99, SD = 3.24, range 13.35 – 24.70).

To test whether these results were statistically significant, a Wilcoxon Signed Ranks Test was performed. This statistical test was selected as the data was ordinal. Results showed that there was a significant difference in Wisconsin Gait scores between baseline and two weeks ($z = -3.107$, $p = 0.02$), between week two and week six ($z = -2.046$, $p = 0.041$) and between baseline and six weeks ($z = -3.408$, $p = 0.001$).

In keeping with the gait speed data, average change in Wisconsin appeared larger in the first two weeks of the study following the intervention (M = -4.03, SD = 0.82), compared with the change in speed in the follow-up period between weeks two and six (M= -2.30, SD = 0.91). To test whether this was statistically significant a Wilcoxon Signed Ranks Test was conducted on rate of change scores. Similar to the results seen with gait speed data, analysis showed that the rate of improvement in Wisconsin Gait scores was greatest immediately following the intervention (baseline to week two), compared with during the follow-up period (between weeks two and six); $z = -2.385$, $p=0.017$.

4.3.2.2 Comparison of Wisconsin Gait Scores between groups

Figures 19, 20 and 21 show the spread of change in Wisconsin Gait scores from baseline to week two, week two to week six and baseline to week six in each of the two intervention groups.

Figure 19: Box plot graph to show change in Wisconsin Gait score between baseline assessment and week 2 in the Gait Training and Gait Training and FES groups

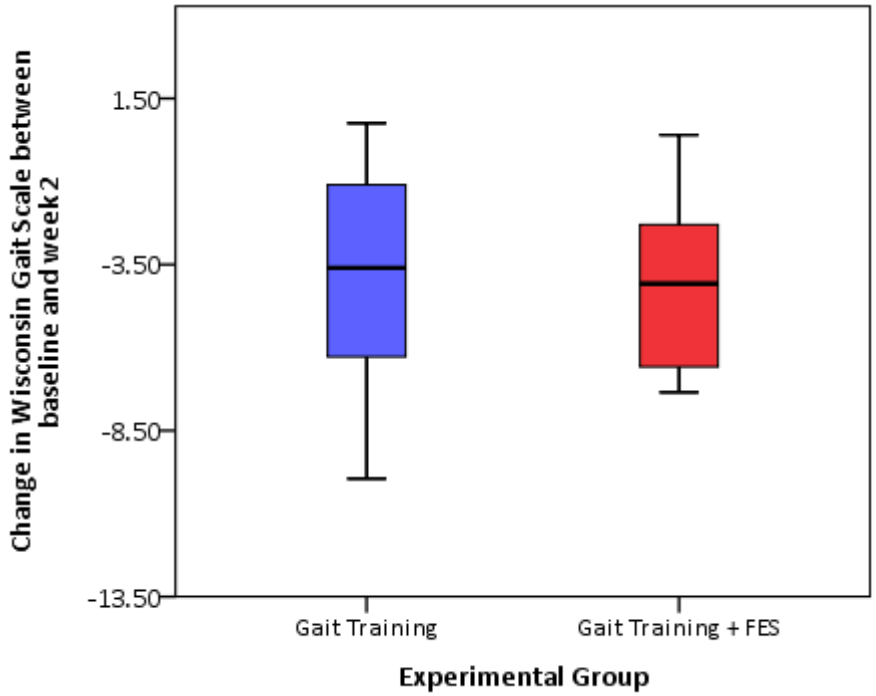


Figure 20: Box plot graph to show change in Wisconsin Gait score between week 2 and 6 week follow-up in the Gait Training and Gait Training and FES groups

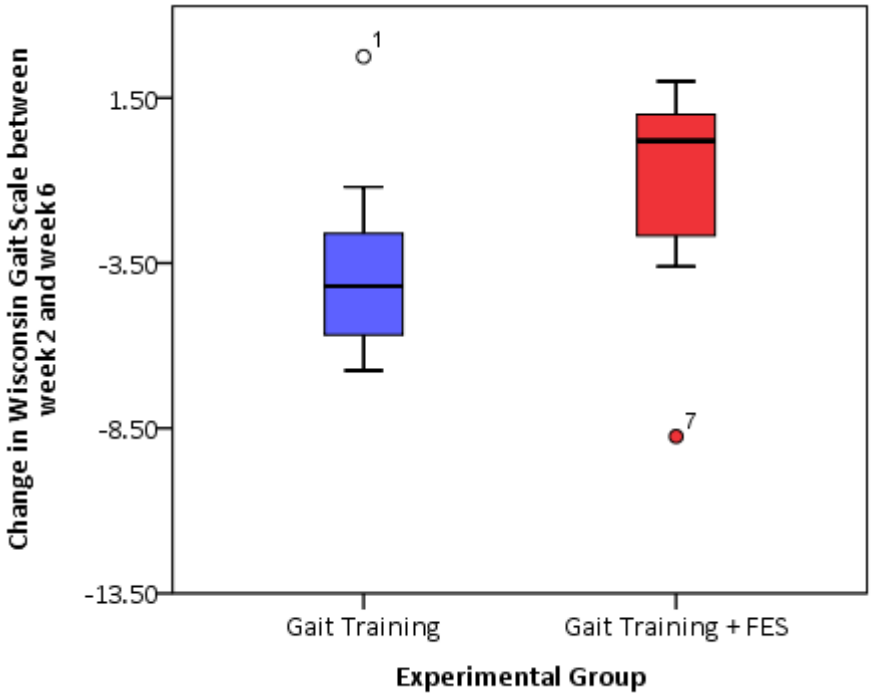
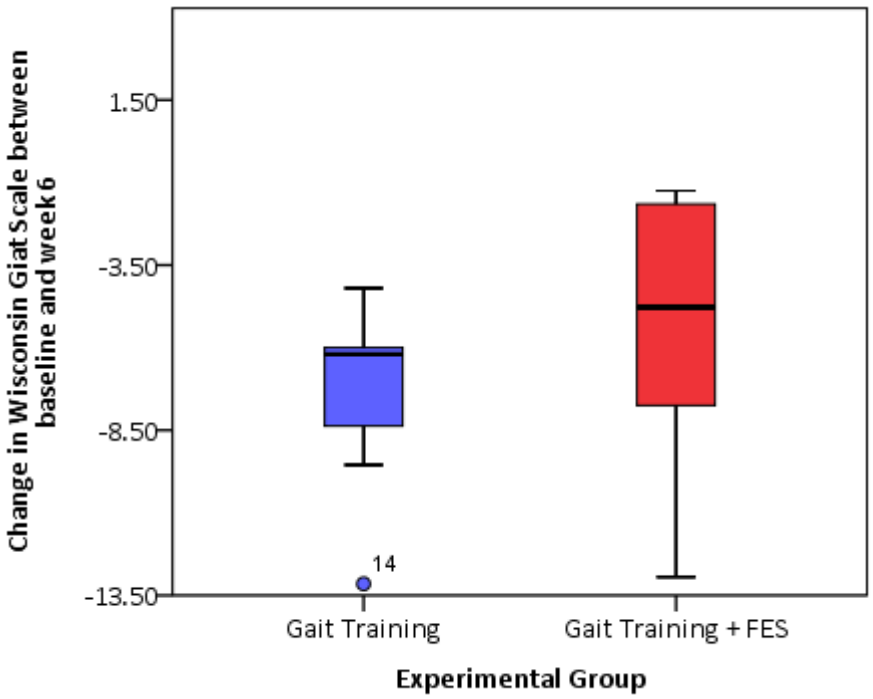


Figure 21: Box plot graph to show change in Wisconsin Gait score between baseline and 6 week follow-up in the Gait Training and Gait Training and FES groups



The mean change in Wisconsin Gait Scale was larger in the Gait Training and FES Group from baseline to week two (see Table 12) but lower for this group from weeks two to six and from baseline to week six. To examine whether there was a significant difference between the groups, a Mann Whitney U test was performed. Results indicate that at this preliminary stage, there was no significant difference in changes in quality of walking as measured by the Wisconsin Gait Scale between the Gait Training Group and the Gait Training and FES Group at any of the assessment points.

Table 12: Comparison of the change in speed between the two groups

	Gait Training Only Group		**Gait Training and FES Group**		**z**	**Sig. (2 tailed)**
	Mean (SD) Change in Wisconsin	**Median (IQR) Change in Wisconsin**	**Mean (SD) Change in Wisconsin**	**Median (IQR) Change in Wisconsin**		
Change in Wisconsin Gait Scale score during intervention phase (baseline and week two)	-3.94 (3.92)	-3.60 (5.18)	-4.11 (2.67)	-4.08 (4.06)	-0.231	0.817
Change in Wisconsin Gait Scale score during follow-up phase (week two to week six)	-3.54 (3.30)	-4.20 (3.08)	-1.21 (3.55)	0.20 (3.21)	-1.394	0.163
Change in Wisconsin Gait Scale score from baseline to follow-up (baseline to week six)	-7.47 (2.98)	-6.20 (2.38)	-5.32 (4.13)	-4.78 (5.85)	-0.927	0.354

4.3.2.3 Correlation between change in Wisconsin Gait scores and Gait Speed

To test whether there was a correlation between gait speed and the Wisconsin Gait score scatterplots of the data were studied (see Figures 22, 23 and 24). In addition a Spearman's correlation coefficient was used to investigate the relationship between the two outcome measures. There was a positive correlation between the change in gait speed and the change in Wisconsin Gait score between baseline and week two, which was statistically significant (r_s = 0.652, p = 0.008). There was however no significant correlation between the two variables between week two and week six (r_s = 0.083, p = 0.770) and between baseline and week six (r_s = 0.342, p = 0.239).

Figure 22: Scatter plot graph to show the relationship between change in gait speed and change in Wisconsin Gait Scale between baseline and week 2

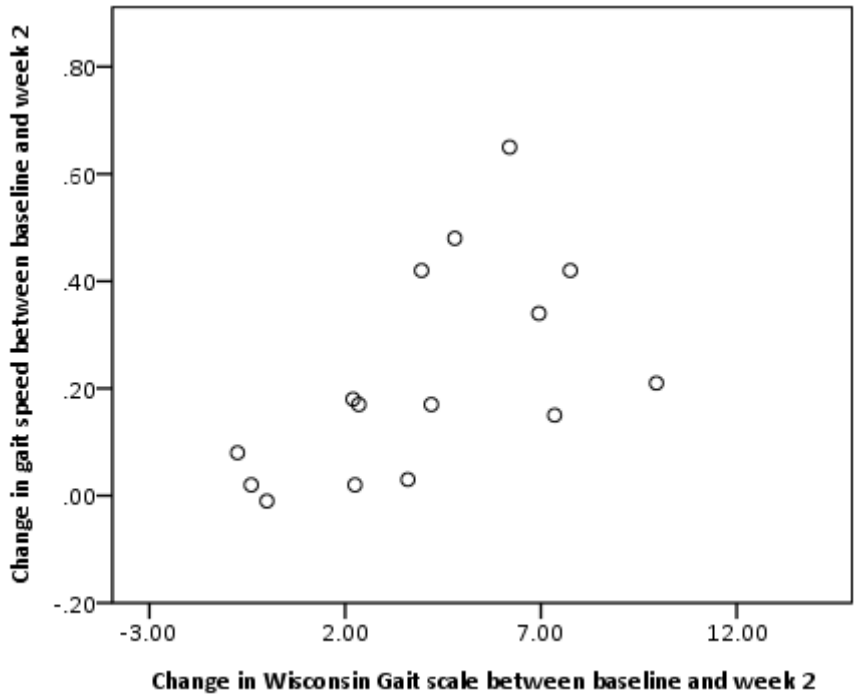


Figure 23: Scatter plot graph to show the relationship between change in gait speed and change in Wisconsin Gait Scale between week 2 and week 6

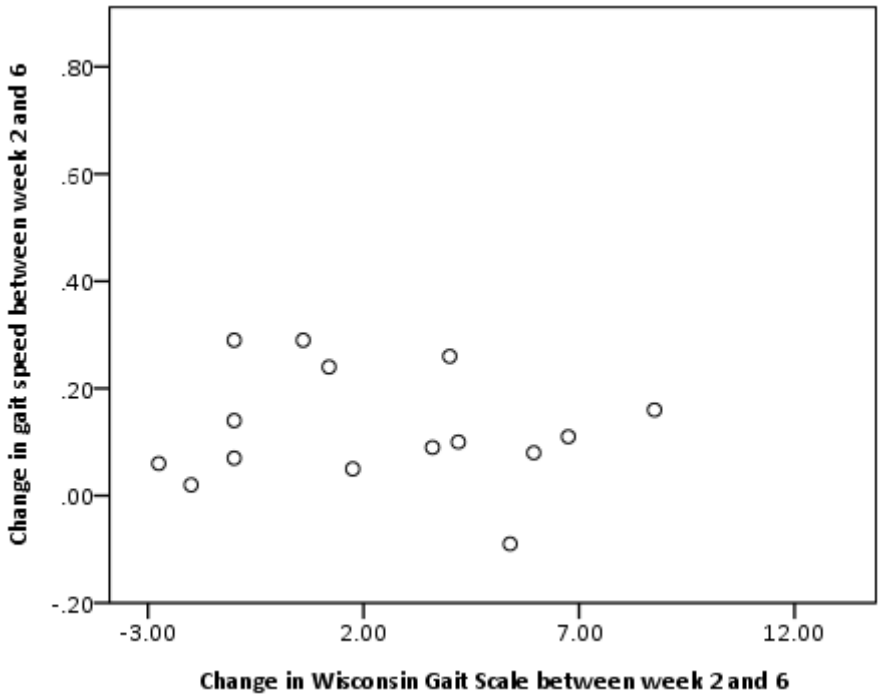
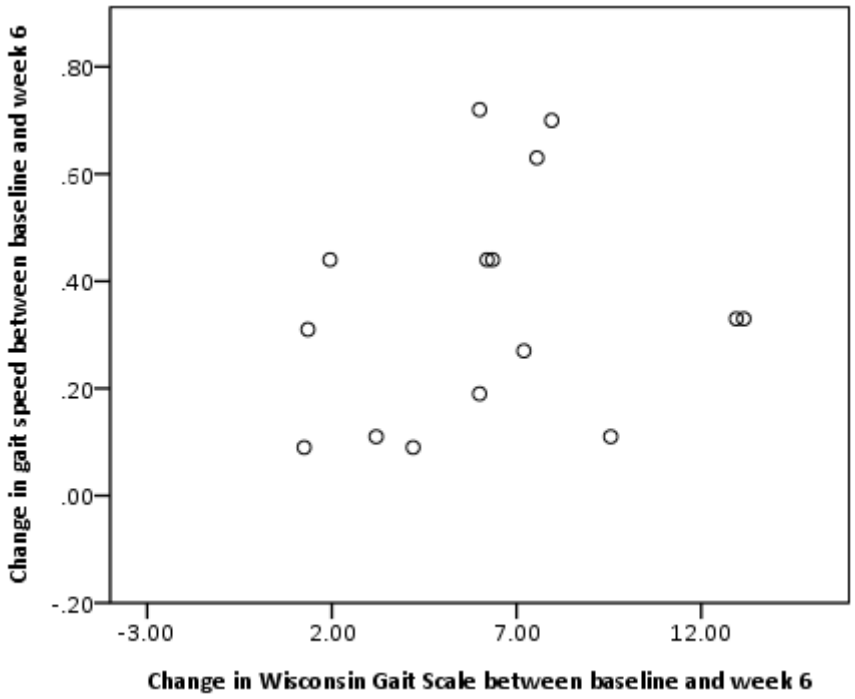


Figure 24: Scatter plot graph to show the relationship between change in gait speed and change in Wisconsin Gait Scale between baseline and week 6



4.3.3 Summary of section 2: Results of gait related outcome measures

This section of the results chapter focused on exploring whether participants responded to the intensive gait training programmes in terms of changes to their gait speed and quality as measured using the Wisconsin Gait Scale. Gait speed was measured using the 5m walk test. The quality of gait was assessed by an independent assessor scoring videotape of the participants walking, using the Wisconsin Gait Scale.

Similar trends were seen in both these outcomes in relation to changes between baseline and week two, week two and week six and baseline and week six (see Table 13). For the majority of participants both gait speed and quality of gait improved following the intervention (week two) and during the follow-up period (between weeks two and six). All participants without exception, showed an improvement in both outcome measures from baseline assessment to week six follow-up. Results showed that the rate of improvement in both outcome measures was greatest following the two week intervention phase compared with the follow-up phase.

Table 13: Table comparing results of gait outcomes between assessment points

	Speed of Gait (5m walk test)	**Quality of Gait (Wisconsin Gait Scale)**
Change in outcome measure between baseline assessment and week two	14/15 participants improved (p= 0.001)	12/15 participants improved (p = 0.02)
Change in outcome measure between week two and week six	14/15 participants improved (p=0.001)	10/15 participants improved (p = 0.041)
Change in outcome measure between baseline assessment and week six	15/15 participants improved (p= 0.0005)	15/15 participants improved (p = 0.001)

Results related to changes in speed and quality of gait within each group were analysed and comparisons made between groups. Preliminary statistical analysis showed that there were no significant differences between groups at any of the assessment points for both gait speed and Wisconsin Gait Scale scores.

Several correlation analyses were carried out to see if there were any relationships between outcome measures. Firstly, to examine whether any of the variability in gait speed at baseline was associated with time delay from stroke onset to baseline assessment, a correlation was conducted between these two variables. The Pearson r correlation coefficient confirmed that no systematic relationship was detected between these two variables ($r = -0.44$, $p = 0.101$).

Secondly, the Spearman's correlation coefficient was used to look for a relationship between gait speed and Wisconsin Gait Scale results. Analysis showed that there was a positive correlation between the change in gait speed and the change in Wisconsin Gait score between baseline and week two, which was statistically significant ($r_s = 0.652$, $p = 0.008$). There was however no significant correlation between the two variables between week two and week six ($r_s = 0.083$, $p = 0.770$) and between baseline and week six ($r_s = 0.342$, $p = 0.239$).

The following section of the results chapter will now explore whether participants responded to the intensive gait training programme as demonstrated by secondary outcome measures including the Modified Ashworth Scale (muscle tone), Motricity Index (motor impairment), Rivermead Mobility Index (mobility activity), Berg Balance Assessment (balance) and Stroke Impact Scale (health related quality of life).

4.4 Section 3: Preliminary analysis of secondary outcomes

4.4.1.1 Muscle Tone

Additional measures were used to identify changes other than speed and quality of gait and were recorded at baseline assessment, following the intervention (week two) and at follow-up assessment (week six). Muscle tone was measured using the Modified Ashworth Scale (see Appendix 16).

No increased muscle tone was detected in the following muscle groups in any of the participants at any of the assessment points:

- Hip Flexors
- Hip internal rotators
- Hip external rotators
- Hip adductors
- Hip abductors
- Knee flexors
- Ankle dorsiflexors
- Ankle invertors
- Ankle evertors

Increased tone was found in the hip extensors, biceps and planar flexors in at least one participant and at least one assessment point. The following paragraphs will explore these results in more depth using descriptive analysis.

4.4.1.1.1 Hip Extensors

Only participant 7 (Gait and FES Group) demonstrated increased muscle tone in their hip extensors. They scored 1 at baseline; demonstrating a slight increase in muscle tone, 0 at week two (no increase in muscle tone) and 1 again at week six.

4.4.1.1.2 Biceps

Increased muscle tone in the biceps muscle of the affected side was present in six participants (40%) during at least one of the three assessments (participants 1,2,7,8,11 and 12), as shown in Figures 24, 24 and 26. Table 14 summarises these results in terms of the numbers of

participants that showed an increase, decrease or maintenance of muscle tone in the affected biceps at week two and week six. The groups were relatively comparable with changes in tone at each of the assessment points (Figures 25, 26 and 27).

Table 14: Table to summarise the number of participants that showed an increase, decrease or maintenance of muscle tone in the biceps muscle group at weeks two and six

		Tone remained the same	**Tone increased**	**Tone decreased**
Week 2	Gait Training only group	5	2	0
	Gait Training and FES group	7	1	0
Week 6	Gait Training only group	6	0	1
	Gait Training and FES group	8	0	0

Figure 25: Bar chart to show MAS for Biceps at baseline

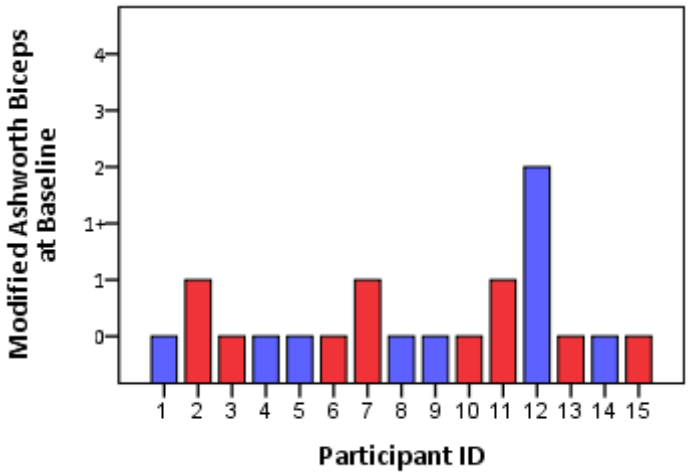


Figure 26: Bar chart to show MAS for Biceps at week two

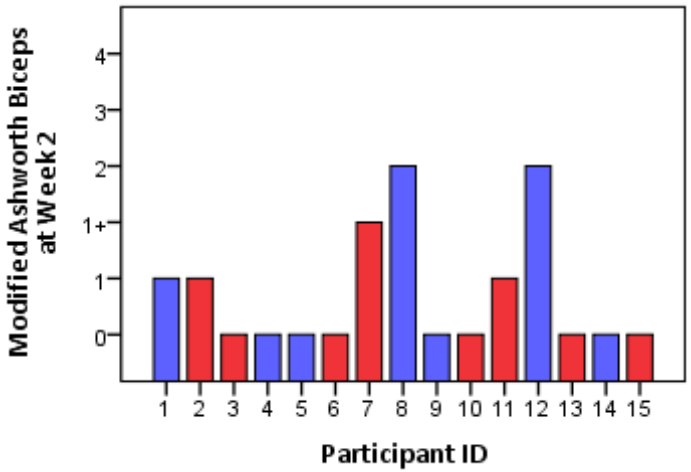
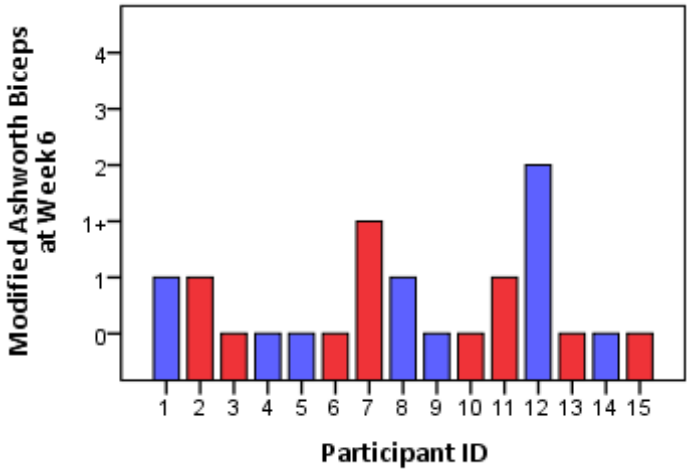


Figure 27: Bar chart to show MAS for Biceps at week six



Modified Ashworth Scale (MAS)

0 No increase in muscle tone

1 Slight increase in muscle tone

1+ Slight increase in muscle tone with resistance

2 More marked increase in tone

3 Considerable increased in tone

4 Affected part rigid

Gait Training Group

Gait Training and FES Group

4.4.1.1.3 Plantar flexors

Nine out of the fifteen participants (60%) demonstrated increased tone in the affected plantar flexors at one or more assessment points (participants 1, 2, 3, 4, 6, 7, 8, 12 and 13), as shown in Figures 27, 28 and 29.

Table 15 summarises these results in terms of the numbers of participants that showed an increase, decrease or maintenance of muscle tone in the affected plantar flexors at week two and week six. Again, the groups were relatively comparable with changes in tone at each of the assessment points (Figures 28, 29 and 30).

Table 15: Table to summarise the number of participants that showed an increase, decrease or maintenance of muscle tone in the plantar flexor muscle group at weeks two and six

		Tone remained the same	**Tone increased**	**Tone decreased**
Week 2	Gait Training only group	4	1	2
	Gait Training and FES group	5	1	2
Week 6	Gait Training only group	5	1	1
	Gait Training and FES group	6	1	1

Figure 28: Bar chart to MAS for Plantar Flexors at baseline

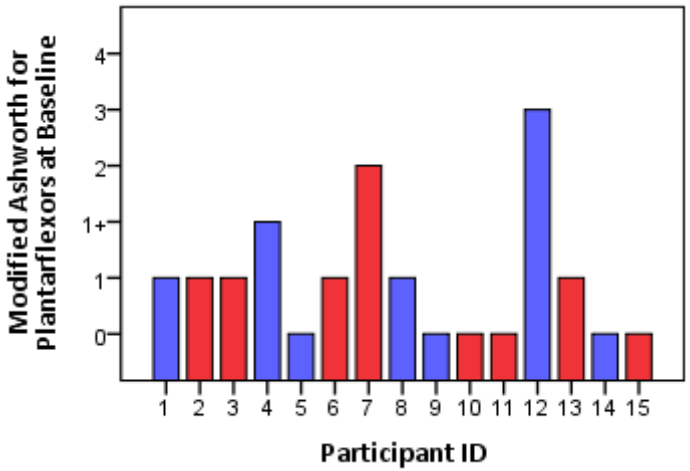
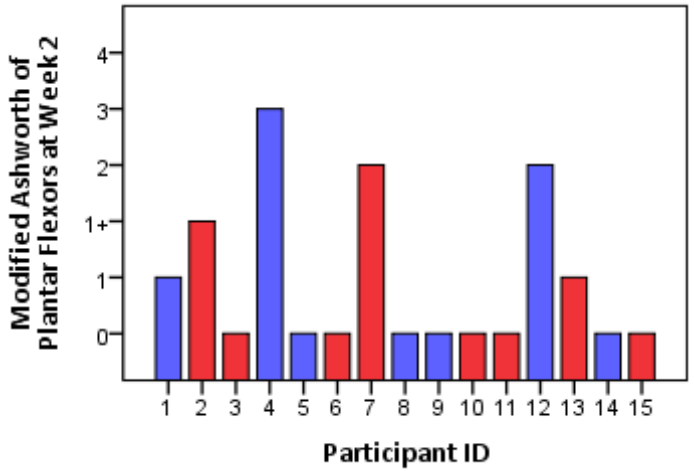


Figure 29: Bar chart to show MAS for Plantar Flexors at week two



Modified Ashworth Scale (MAS)

0 No increase in muscle tone

1 Slight increase in muscle tone

1+ Slight increase in muscle tone with resistance

2 More marked increase in tone

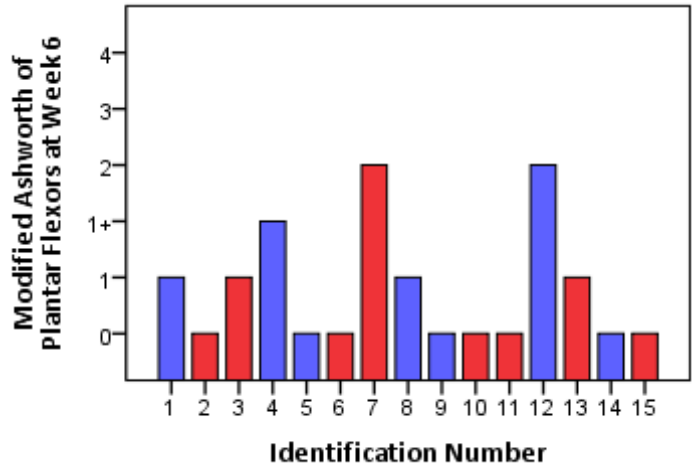
3 Considerable increased in tone

4 Affected part rigid

Gait Training Group

Gait Training and FES Group

Figure 30: Bar chart to show MAS for Plantar Flexors at week six



4.4.1.2 Motricity Index

The Motricity Index was used to assess motor impairment in the upper limb, lower limb and trunk at baseline, week two and week six. The scores can range from 0 – 100 with lower scores indicating greater motor impairment. Motricity Index scores for the upper limb, lower limb and truck will now be considered in turn.

4.4.1.2.1 Upper Limb Motricity Index

Upper limb Motricity Index scores varied considerably between participants (see Appendix 30). This highlighted the range of upper limb impairment across the sample at baseline assessment, from no detected weakness (maximum score of 100) to a moderate degree of weakness in the upper limb (score of 30). Three participants (participants 4, 12 and 15) showed a reduction in the upper limb section of the Motricity index after the two week intervention. All other participants either remained the same or made an improvement at two weeks. At six week follow-up, two participants (6 and 12) showed a reduction in the upper limb Motricity Index compared with week two. All other participants remained the same or improved at six weeks. Participant 14 showed the greatest improvement achieving a score of 39 at baseline, 92 at week two and 100 at week six.

The Wilcoxon Signed Ranks Test was performed on the data to look for significant differences in upper limb Motricity Index scores between baseline and week two, week two and week six and baseline and week six. This statistical test was selected as the data did not show normal distribution and Motricity Index is an ordinal scale. Results showed that there was no significant difference between baseline and two weeks ($z = -1.483$, $p = 0.138$). There was a trend towards improvement between week two and week six ($z = -1.848$, $p = 0.065$). There was however a significant difference between baseline and week six ($z = -2.296$, $p = 0.022$) indicating that motor impairment of the upper limb improved by six week follow-up.

The data was then analysed to compare changes in upper limb Motricity Index scores between the groups. Figures 31, 32 and 33 compare the spread of data related to changes in upper limb Motricity Index between the groups from baseline to week two, week two to week six and baseline to week six. Mann-Whitney U tests revealed that there were no significant differences between the groups in the change in upper limb Motricity Index scores from baseline to week two, week two to week six and from baseline to week six (table 16).

Table 16: Comparison of the change in upper limb Motricity Index scores between the two groups

	Gait Training Only Group		**Gait Training and FES Group**		**U**	**Sig. (2 tailed)**
	Mean (SD) Change in upper limb Motricity Index	**Median (IQR) Change in upper limb Motricity Index**	**Mean (SD) Change in upper limb Motricity Index**	**Median (IQR Change in upper limb Motricity Index)**		
Change in upper limb Motricity Index score during intervention phase (baseline and week two)	8.00 (20.31)	0 (6)	2.63 (6.48)	0 (8.5)	26.000	0.811
Change in upper limb Motricity Index score during follow-up phase (week two to week six)	5.00 (9.36)	5 (12)	5.13 (8.77)	4 (9.5)	28.000	1.000
Change in upper limb Motricity Index score from baseline to follow-up (baseline to week six)	13.00 (22.83)	9 (9)	7.75 (10.83)	1.5 (14.5)	24.500	0.679

Figure 31: Box plot graph to show change in upper limb (UL) Motricity Index scores between baseline and week two

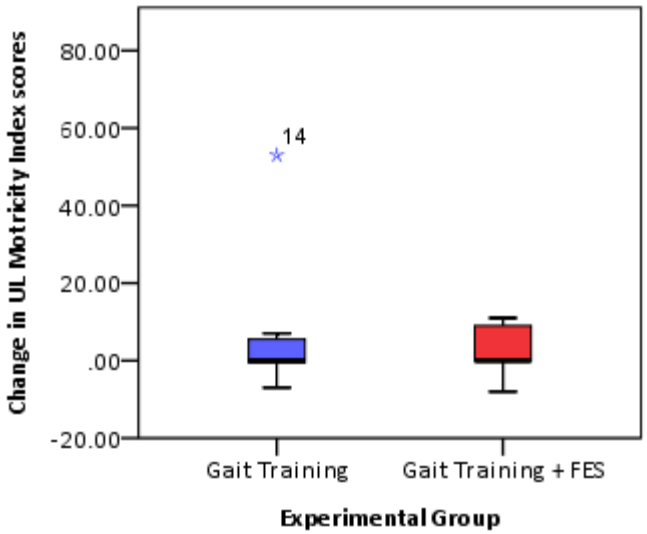


Figure 32: Box plot graph to show change in upper limb (UL) Motricity Index scores between week two and week six

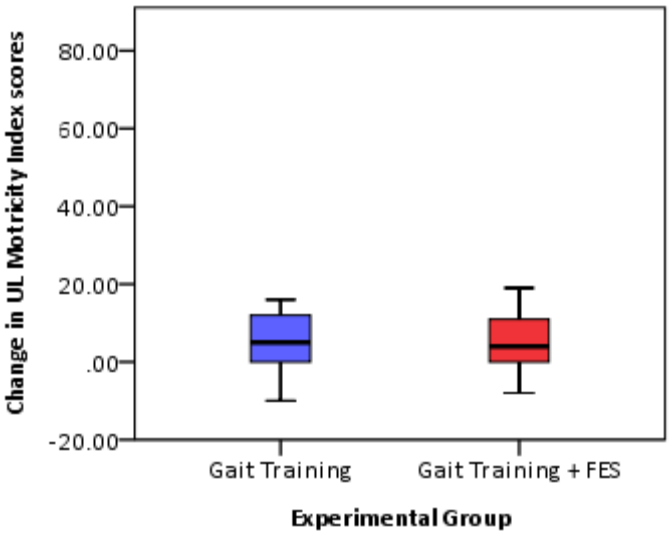
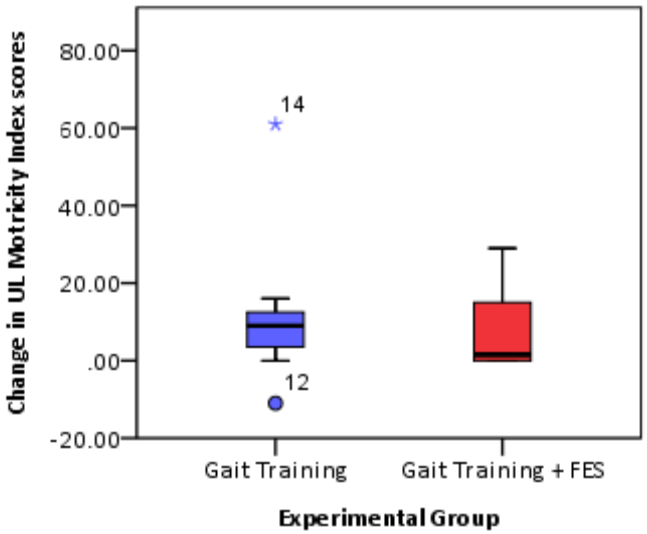


Figure 33: Box plot graph to show change in upper limb (UL) Motricity Index scores between baseline and week six



4.4.1.2.2 Lower Limb Motricity Index

In contrast to the Upper Limb Motricity Index scores, all participants either maintained (participants 2,4,11,12 and 13) or improved (participants 1,3,5,6,7,8,9,10,14 and 15) their lower limb Motricity Index scores by week two directly following the intervention (see Appendix 31). By week six, four participants showed a reduction in Motricity Index scores for the lower limb (participants 6, 9, 10 and 12). Three participants maintained their scores (participants 2, 13 and 14) and eight participants improved their scores (participants 1, 3, 4, 5, 7, 8, 11 and 15). Mirroring results seen in the upper limb, participant 14 showed the greatest improvement in the lower limb Motricity Index achieving a score of 39 at baseline, 76 at week two which was maintained at week six.

To see whether there was a significant difference between lower limb Motricity Index scores at assessment points, Wilcoxon Signed Ranks Tests were performed on the data. Results showed that there was a significant difference between baseline and two weeks ($z = -2.805$, $p = 0.005$) and between baseline and six weeks ($z = -2.986$, $p = 0.003$) but not between week two and week six ($z = -1.656$, $p = 0.098$).

The data was then analysed to investigate for differences between changes in lower limb Motricity Index scores between the two groups (Figures 34, 35 and 36). Mann-Whitney U tests were performed. It can be concluded that there was no significant difference between the groups in the change in lower limb Motricity Index scores from baseline to week two, week two to week six and from baseline to week six (Table 17).

Table 17: Comparison of the change in lower limb Motricity Index scores between the two groups

	Gait Training Only Group		Gait Training and FES Group		U	Sig. (2 tailed)
	Mean (SD) Change in lower limb Motricity Index	**Median (IQR) Change in lower limb Motricity Index**	**Mean (SD) Change in lower limb Motricity Index**	**Median (IQR Change in lower limb Motricity Index)**		
Change in lower limb Motricity Index score during intervention phase (baseline and week two)	13.43 (13.97)	8 (19.5)	9.25 (9.33)	9 (13.75)	24.500	0.680
Change in lower limb Motricity Index score during follow-up phase (week two to week six)	4.71 (9.59)	1 (15)	3.44 (9.51)	1.25 (12.75)	26.000	0.814
Change in lower limb Motricity Index score from baseline to follow-up (baseline to week six)	18.14 (13.90)	16 (16.5)	12.69 (12.27)	15.25 (17.5)	22.000	0.484

Figure 34: Box plot graph to show change in lower limb (LL) Motricity Index scores between baseline and week two

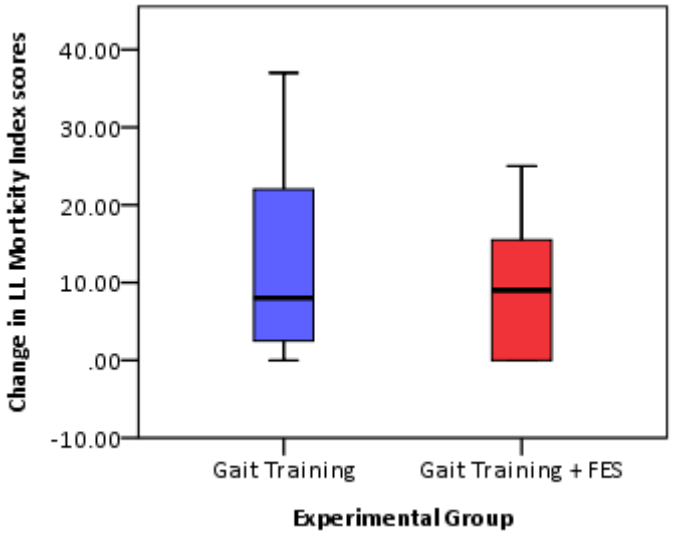


Figure 35: Box plot graph to show change in lower limb (LL) Motricity Index scores between week two and week six

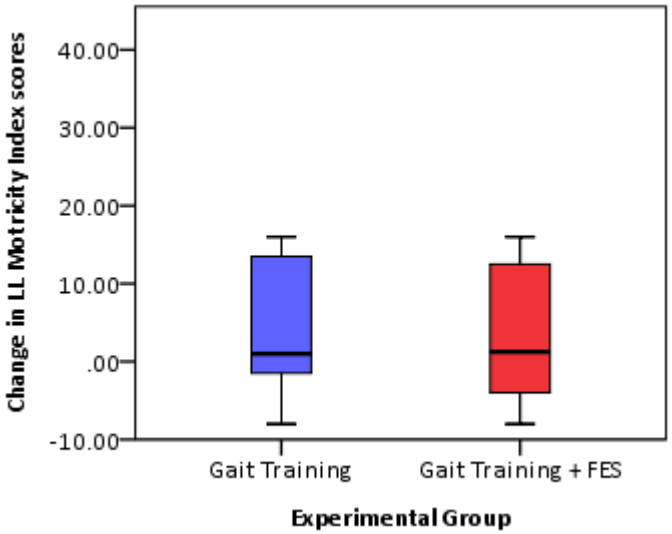
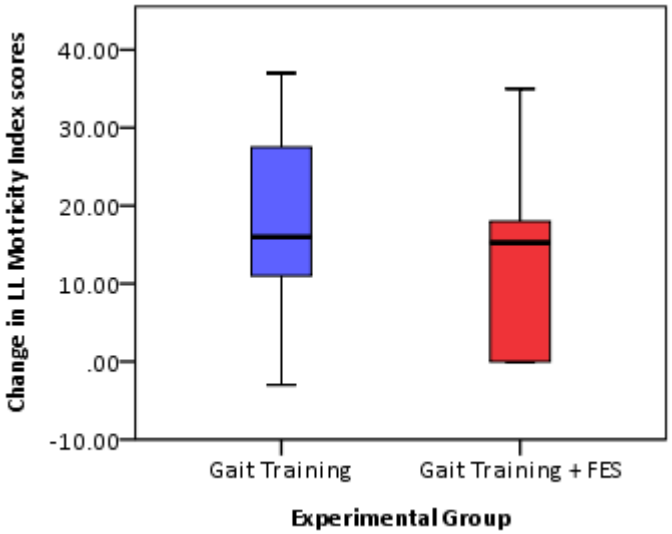


Figure 36: Box plot graph to show change in lower limb (LL) Motricity Index scores between baseline and week six



4.4.1.2.3 Trunk Motricity Index

The trunk section of the Motricity index assessed four specific movement tests: rolling to the weak side, rolling to the strong side, sitting up from lying and balancing sitting (see Appendix 17). Scores of 100 indicted that participants were able to complete these tasks normally, scores under 100 showed an element of needing help from the environment (for example pulling on bed clothes, using arms to steady themselves when sitting up).

Seven out of the fifteen participants (47%) were able to complete all trunk activities normally. All participants either maintained their trunk scores (participants 3,4,5,8,9,10,11,12 and 13) or improved their trunk scores (participants 1,2,6,7,14 and 15) following the two week intervention. At six week follow-up, one participant (participant 8) showed a reduction in trunk score, all others either maintained their score (participants 3,4,5,9,10,11,13 and 14) or showed an improvement (participants 1,2,6,7,12 and 15). Again, participant 14 showed a marked improvement in score from baseline to week two, in keeping with the pattern of improvement shown in both upper limb and lower limb subsections of the Motricity Index. All participants who scored 100 at baseline, maintained this level at each assessment point. By six week follow-up, 12 of the 15 participants (80%) had achieved a maximum trunk score of 100 (see Appendix 32).

To see whether there was a significant difference between trunk Motricity Index scores at baseline and week two, week two and week six and baseline and week six, a Wilcoxon Signed Ranks Test was performed. Results showed that there was a significant difference between baseline and two weeks ($z = -2.214$, $p = 0.027$), baseline and week six ($z= -2.410$, $p = 0.016$) and a trend towards significance between week two and week six ($z = -1.933$, $p = 0.053$).

To test whether there was a significant difference in trunk Motricity Index Scores between the Gait training only and Gait Training and FES group, Mann-Whitney U tests were performed (Table 18). It can be concluded that there was no significant difference in the change in Trunk Motricity Index scores from baseline to week two, week two to week six and baseline to week six between the gait training only group and the gait training and FES group (see Figures 37, 38 and 39).

Table 18: Comparison of the change in trunk Motricity Index scores between the two groups

	Gait Training Only Group		**Gait Training and FES Group**		**U**	**Sig. (2 tailed)**
	Mean (SD) Change in trunk Motricity Index score	**Median (IQR) Change in trunk Motricity Index score**	**Mean (SD) Change in trunk Motricity Index score**	**Median (IQR) Change in trunk Motricity Index score**		
Change in trunk Motricity Index score during intervention phase (baseline and week two)	9.29 (16.30)	0 (13)	8.00 (9.61)	6 (13)	25.500	0.744
Change in trunk Motricity Index score during follow-up phase (week two to week six)	5.57 (16.54)	0 (6.5)	9.75 (13.46)	6.5 (13)	21.000	0.374
Change in trunk Motricity Index score from baseline to follow-up (baseline to week six)	14.86 (23.05)	0 (39)	17.75 (20.72)	12.5 (29.25)	25.500	0.758

Figure 37: Box plot graph to show change in Trunk Motricity Index scores between baseline and week two

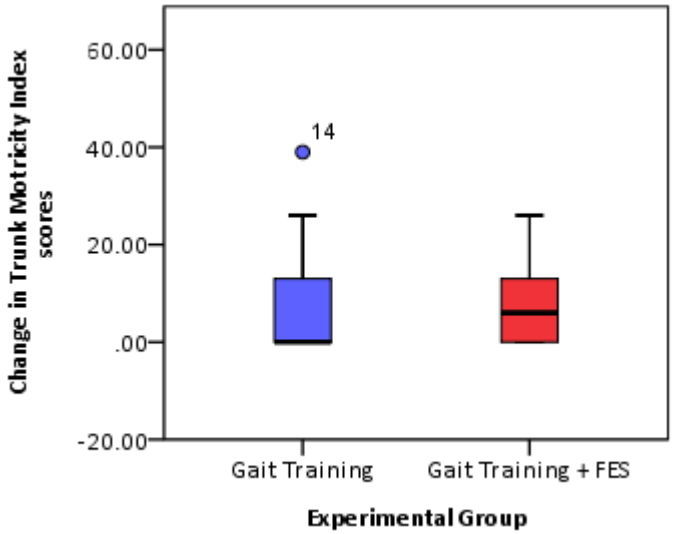


Figure 38: Box plot graph to show change in Trunk Motricity Index scores between week two and week six

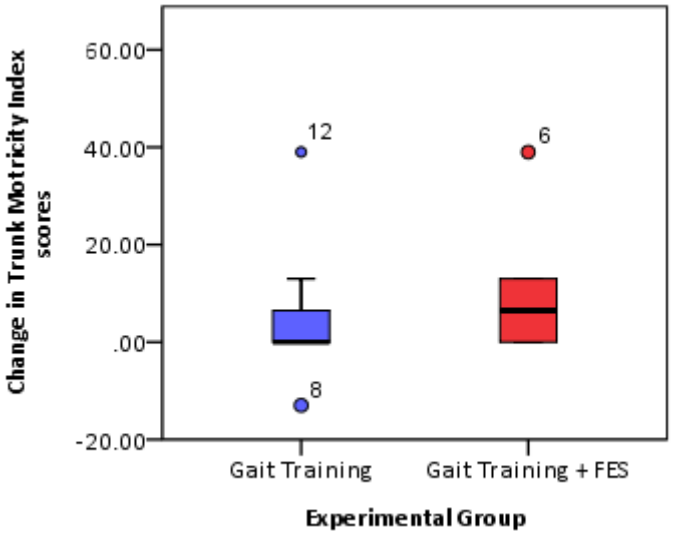
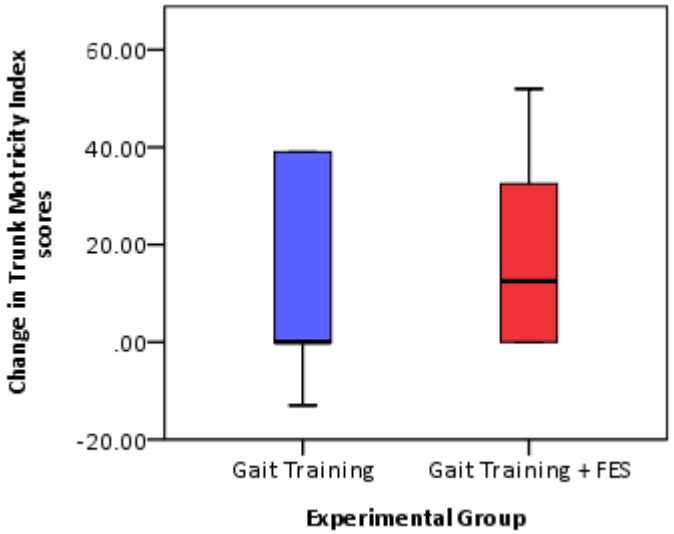


Figure 39: Box plot graph to show change in Trunk Motricity Index scores between baseline and week six



4.4.1.3 Rivermead Mobility Index

The Rivermead Mobility Index (RMI) was used to assess ability to complete activities associated with mobility ranging from turning over in bed to running. This questionnaire was completed by the assessor and included one direct observation of standing for 10 seconds. Scores range from 0 – 15, with lower scores indicating greater mobility deficits. Appendix 33 shows the results of RMI scores taken at baseline, week two and at week six follow-up.

The minimum RMI score at baseline was six, indicating that all participants were able to complete some activities related to mobility. This is in keeping with the inclusion criteria of the study, specifying that participants would need to be able to stand for 10 seconds unsupported to enable participation. Of the 15 participants, one showed a reduction in scores from baseline to week 2 (participant 15). All others remained the same (participants 1,3 and 6) or improved (participants 2,4,5,7,8,9,10,11,12,13 and 14). At six week follow-up, again one participant showed a reduction in scores from week two to week six (participant 10). All other participants remained the same (participants 4, 11 and 13) or improved (participants 1,2,3,5,6,7,8,9,12, 14 and 15). All participants made an improvement from baseline to week six.

To see whether there was a significant difference between RMI scores at baseline and week two, week two and six and baseline and week six, Wilcoxon Signed Ranks Tests were performed. This statistical test was selected as the data was ordinal and did not show normal distribution. Results showed that there was a significant difference between baseline and two weeks ($z = -2.878$, $p = 0.004$), between week two and week six ($z = -2.756$, $p = 0.006$) and baseline and week six ($z = -3.417$, $p = 0.001$). This indicates that participants improved their ability to complete mobility tasks following the two week intervention which was further improved at six week follow-up.

Figures 40, 41 and 42 compare change scores in RMI between groups. Mann-Whitney U tests showed that there was no significant difference in the change in RMI from baseline to week two, week two to week six and from baseline from week six between the Gait Training only group and the Gait Training and FES group (Table 19)

Table 19: Comparison of the change in Rivermead Mobility Index scores between the two groups

	Gait Training Only Group		**Gait Training and FES Group**		***U***	***Sig. (2 tailed)***
	Mean (SD) Change in RMI	***Median (IQR) Change in RMI***	***Mean (SD) Change in RMI***	***Median (IQR) Change in RMI***		
Change in RMI score during intervention phase (baseline and week two)	2.71 (2.69)	2 (3)	2.38 (2.72)	2 (5)	23.500	0.599
Change in RMI score during follow-up phase (week two to week six)	2.14 (1.21)	3 (1.5)	1.13 (1.73)	1.5 (2.25)	17.500	0.206
Change in RMI score from baseline to follow-up (baseline to week six)	4.86 (2.41)	4 (2.5)	3.50 (2.45)	3 (3.25)	19.000	0.292

Figure 40: Box plot graph to show change in RMI scores between baseline and week two

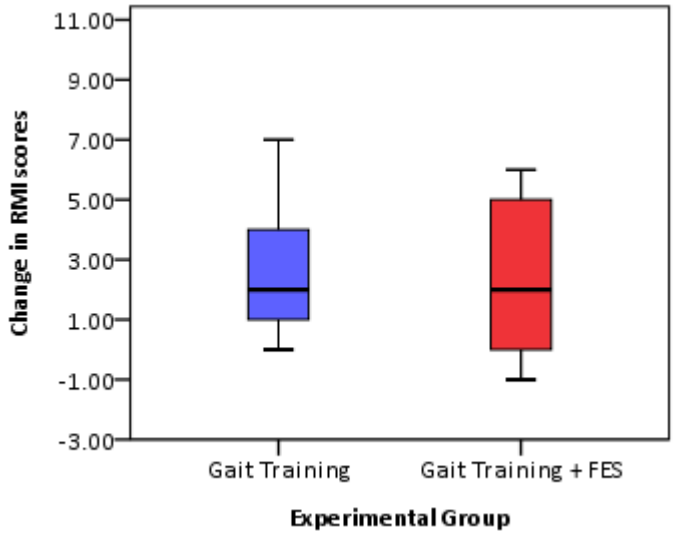


Figure 41: Box plot graph to show change in RMI scores between week two and week six

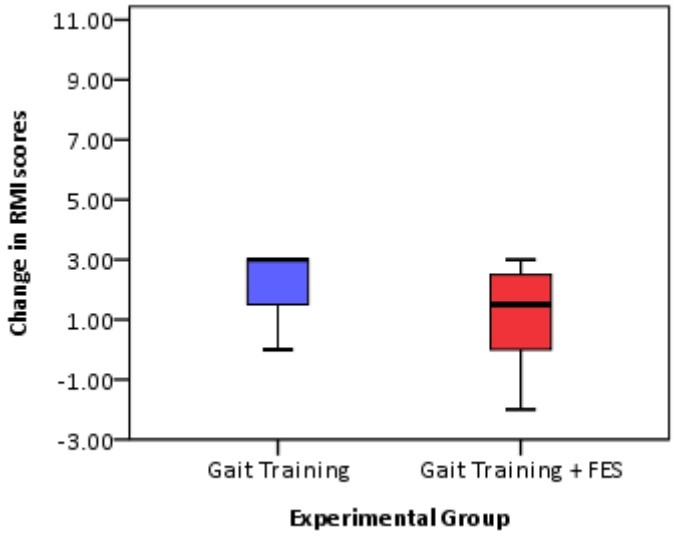
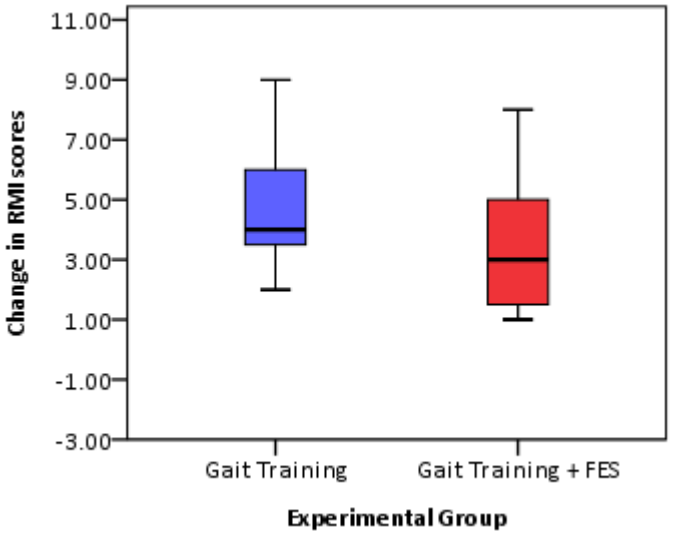


Figure 42: Box plot graph to show change in RMI scores between baseline and week six



4.4.1.4 Berg Balance

To complete the Berg Balance Test (BBT) the researcher observed the participants complete 14 observable tasks common to everyday life at baseline, week two following the intervention and at six week follow-up. They were each scored on a five point ordinal scale and the maximum score was 56, indicating better balance. Similar to baseline RMI scores, BBT scores at baseline showed that participants were able to complete at least some of the balance tasks (minimum score of 32). Again, this reflects the inclusion criteria of being able to stand for 10 seconds without support. All participants showed an improvement in BBT scores by week two, with the exception of Participant 1 who maintained the same score. However by week six, two participants maintained the same score as week two (participants 12 and 13) and four participants (participants 3,9,11 and 15) showed a reduction in BBT score. All participants showed an improvement in BBT from baseline to follow-up at six weeks (see Appendix 34).

To see whether there was a significant difference between BBT scores at baseline and week two, week two and week six and baseline and week six, Wilcoxon Signed Ranks Tests were performed. This statistical test was selected as the data was ordinal and did not show normal distribution. Results showed that there was a significant difference between baseline and two weeks ($z = -3.304$, $p = 0.001$), baseline and six weeks ($z = -3.413$, $p = 0.001$) but not between week two and week six ($z = -1.722$, $p = 0.085$).

Figures 43, 44 and 45 show the change in BBT scores in between baseline and week two, week two and week six and baseline and week six in the Gait Training only group and the Gait Training and FES group. Mann-Whitney U Tests revealed that there was no significant difference in the change in BBT scores at any of the assessment points (Table 20).

Table 20: Comparison of the change in Berg Balance Test (BBT) scores between the two groups

	Gait Training Only Group		**Gait Training and FES Group**		**U**	**Sig. (2 tailed)**
	Mean (SD) Change in BBT	**Median (IQR) Change in BBT**	**Mean (SD) Change in BBT**	**Median (IQR) Change in BBT**		
Change in BBT score during intervention phase (baseline and week two)	5.00 (4.97)	3.00 (5.50)	6.50 (3.12)	6.00 (3.50)	18.000	0.243
Change in BBT score during follow-up phase (week two to week six)	2.71 (4.03)	2.00 (3.50)	0.75 (2.82)	0.50 (4.25)	21.000	0.416
Change in BBT score from baseline to follow-up (baseline to week six)	8.14 (5.11)	8.00 (7.50)	7.25 (4.43)	8.00 (6.25)	24.000	0.641

Figure 43: Box plot graph to show change in BBT scores between baseline and week two

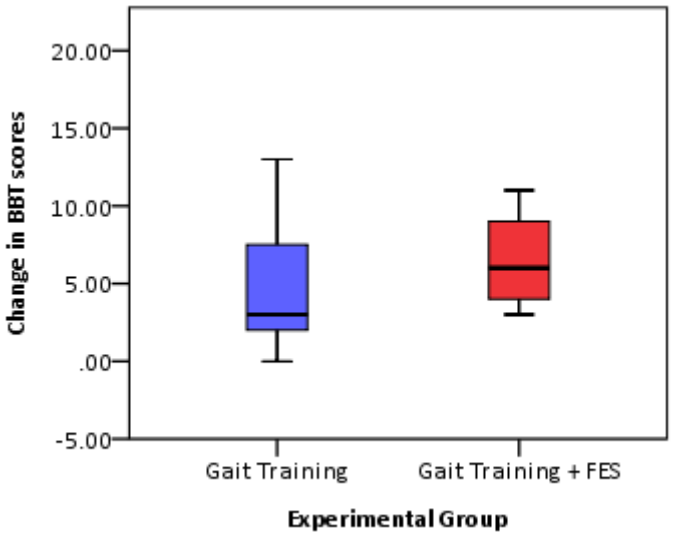


Figure 44: Box plot graph to show change in BBT scores between week two and week six

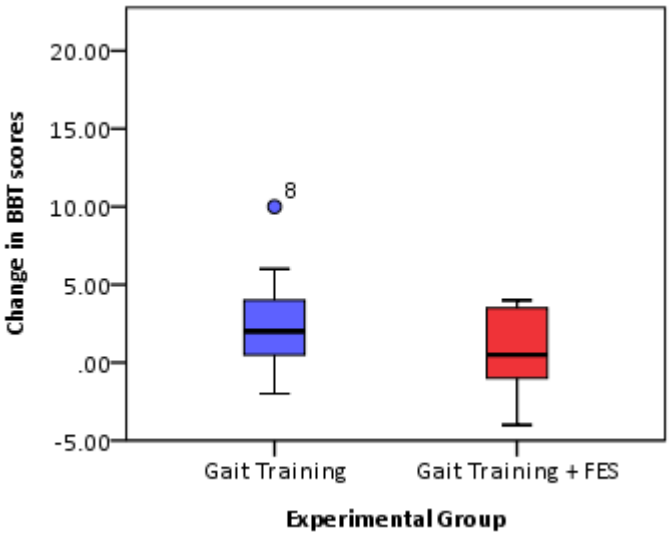
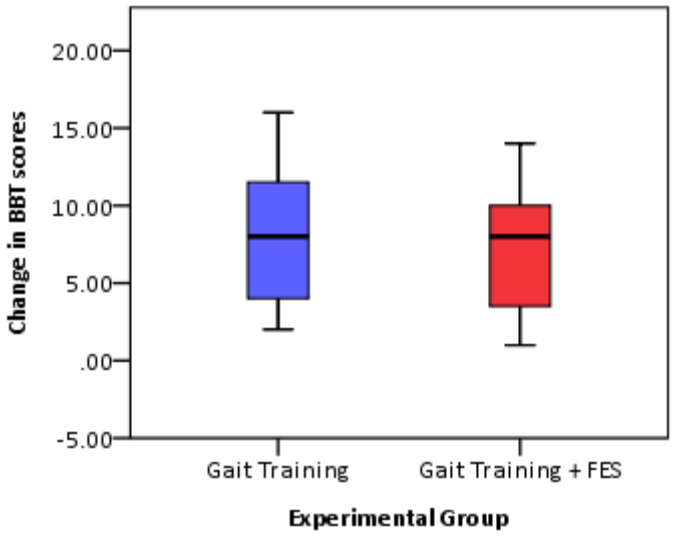


Figure 45: Box plot graph to show change in BBT scores between baseline and week six



4.4.1.5 Stroke Impact Scale

The Stroke Impact Scale is a questionnaire used to evaluate health related quality of life following stroke and was completed by the participants at baseline, week two and at six week follow-up (see Appendix 20). It is a multidimensional measure of self-reported stroke outcomes related to eight domains including: strength, hand function activities of daily living, mobility, communication, emotion, memory and thinking and participation. Each item is rated on a 5 point Likert Scale in terms of how difficult participants find each individual item. A score of one reflects an inability to complete the item whereas a score of five reflects no difficulty experienced at all. An additional question on stroke recovery asks participants to rate on a scale from 0 – 100 how much they feel they have recovered from their stroke. Appendix 35 summarises average scores for each of the eight domains and the ultimate recovery question at baseline, week two and at six week follow-up.

The largest amount of variation between participants at baseline, was found in the hand domain (SD 39.29 range 0-100), indicating that there were some participants who felt they were unable to use their hand whilst others had no difficulty in using their hand at all. There was a general trend towards improvement in all domains at week two and week six apart from hand function (remained the same at week two), communication (slightly reduced at week two compared with baseline) and participation (reduced at week two). The largest gains appear to be seen in the participants' perception of their strength, activities of daily living, mobility and recovery.

To test whether there was a significant difference in domains of the Stroke Impact Scale between baseline and week two, week two and week six, and baseline and week six the Wilcoxon signed ranks test was used on the data. It can be concluded at there was a significant improvement in Stroke Impact scores in the Physical ($z=-2.110$, $p=0.035$), Mobility ($z=-2.331$, $p=0.020$) and Recovery ($z=-3.025$, $p=0.002$) domains between baseline and immediately following the two week intervention. A significant improvement in Mobility ($z=-2.740$, $p=0.006$) was found between weeks two and at six week follow-up. Significant improvements were also seen in Physical ($z=-2.878$, $p=0.004$), Activities of Daily Living ($z=-2.417$, $p=0.016$), Mobility ($z=-3.299$, $p=0.001$), and Recovery ($z=-2.994$, $p=0.003$) between baseline assessment and at six week follow-up. All other changes in scores across the domains at any of the assessment points were not significant.

Table 21 shows the Stroke Impact scores compared between groups. Further statistical analysis to compare results between groups was carried out on Stroke Impact Scale domains. Mann Whitney U tests revealed that a significantly greater improvement was seen in the hand function domain of the Stroke Impact Scale in the Gait Training group from week two to week six compared with the Gait Training and FES group ($U=9.500$, $p=0.027$). There were no significant differences in change scores between groups for all other domains (see Appendix 36).

Table 21: Table to show the average scores (mean) for participants in the two groups in each of the nine domains of the scale

Domain of Stroke Impact Scale	Mean scores for Gait Training only group (SD)			Mean scores for Gait Training and FES group (SD)		
	Week 0	Week 2	Week 6	Week 0	Week 2	Week 6
Physical	55.36 (24.59)	62.51 (26.01)	68.76 (18.40)	57.81 (17.60)	65.63 (15.67)	70.31 (16.62)
Hand Function	57.86 (40.91)	55.71 (34.57)	68.57 (38.81)	54.38 (40.57)	56.25 (47.72)	61.88 (45.50)
ADL	76.25 (14.51)	79.94 (16.34)	86.13 (12.47)	72.14 (17.92)	80.99 (13.38)	79.42 (12.48)
Mobility	66.11 (14.16)	83.61 (7.98)	91.03 (9.53)	71.79 (18.30)	78.13 (14.81)	87.50 (9.82)
Memory and Thinking	86.49 (15.13)	91.52 (11.37)	91.45 (18.35)	89.45 (15.30)	89.84 (10.92)	91.80 (12.38)
Emotion	84.53 (15.19)	88.09 (7.98)	88.88 (9.07)	82.99 (12.73)	90.28 (12.15)	90.27 (11.97)
Communication	92.34 (14.35)	91.32 (12.01)	92.35 (16.03)	95.98 (6.73)	96.43 (5.73)	97.32 (5.31)
Social participation	80.20 (21.95)	75.59 (9.62)	78.42 (23.02)	74.99 (19.60)	77.77 (13.77)	84.72 (22.42)
Recovery	52.86 (16.29)	71.43 (18.64)	74.29 (14.84)	57.88 (20.50)	66.88 (21.20)	70.00 (17.93)

4.4.1.6 Summary of section 3: Results related to secondary outcomes

This section of the results chapter focused on determining whether participants responded to the intensive gait training programme as demonstrated by secondary outcome measures including the Modified Ashworth Scale (muscle tone), Motricity Index (motor impairment), Rivermead Mobility Index (mobility activity), Berg Balance Test (balance) and Stroke Impact Scale (health related quality of life).

Results of the Modified Ashworth scale have been presented. Only one participant demonstrated increase tone in their hip extensors (7%). Increased muscle tone in the biceps muscle of the affected side was present in six participants (40%) during at least one of the three assessments. Nine out of the fifteen participants (60%) demonstrated increased tone in the affected plantar flexors at one or more assessment points. Numerically, the groups were relatively comparable with changes in tone at each of the assessment points and there were no trends to demonstrate an increase or decrease in tone following either intervention.

A summary of the results related to other secondary outcome measures are presented in Table 22. The table compares significance values (two tailed) following Wilcoxon Signed Ranks Tests completed on each outcome measures between assessment points. A significant improvement ($p=<0.05$) was seen immediately following the intervention in lower limb Motricity index, trunk Motricity index, RMI, BBT and the Physical, Mobility and Recovery domains of the Stroke Impact Scale. Significant improvements were seen during the follow-up period (between weeks two and six) in RMI and the Mobility domain of the stroke impact scale. When comparing baseline with final follow-up (week six), significant improvements were seen in UL Motricity Index, LL Motricity Index, Trunk Motricity Index, RMI, BBT and Physical, ADL, Mobility and Recovery domains of the Stroke Impact Scale.

Further analysis was completed to investigate whether there were any statistically significant differences in outcome measures between groups. Results of Mann Whitney U tests revealed that there were no significant differences in any of the secondary outcomes, between the Gait Training and Gait Training and FES groups at any of the assessment points, with the exception of the hand function domain of the Stroke Impact Scale. Preliminary statistical analysis showed that there was a significant improvement in hand function during the follow-up period (week two to week six) in favour of the Gait Training group.

Table 22: Table to show p values (two tailed) of Wilcoxon Signed ranks Test related to secondary outcome measure comparison between assessment points

	p value for change between baseline and week 2	*p value for change between week 2 and week 6*	*p value between baseline and week 6*
UL Motricity Index	0.138	0.065	0.022
LL Motricity Index	0.005	0.098	0.003
Trunk Motricity Index	0.027	0.053	0.016
RMI	0.004	0.006	0.001
BBT	0.001	0.085	0.001
Stroke Impact Scale: Physical	0.035	0.236	0.004
Stroke Impact Scale: ADL	0.087	0.272	0.016
Stroke Impact Scale: Mobility	0.020	0.006	0.001
Stroke Impact Scale: Participation	0.570	0.211	0.347
Stroke Impact Scale: Recovery	0.002	0.169	0.003

4.5 Section 4: Sample size calculation

One of the objectives of the feasibility study was to explore whether this preliminary data could be used to inform a power calculation, to estimate the number of participants needed for a larger randomised controlled trial. A sample size calculation was therefore carried out in consultation with a statistician.

Gait speed was determined at the primary outcome measure on which to base a sample size calculation. It was felt that this gave the most objective outcome; gait speed has no floor or ceiling effect and shows sensitivity to change. In addition, there is published evidence of the meaningful clinically important difference (MCID) for gait speed in sub-acute stroke patients which is a required parameter for a sample size calculation (Borm et al., 2007). Tilson et al. found that in 283 participants less than 60 days post stroke, MCID was estimated as an improvement in comfortable walking speed of 0.16 m/s (Tilson et al., 2010). As the participants in the study were at a similar stage in their stroke recovery compared with the current study, this value was used to inform the sample size calculation (see Table 23).

In consultation with a statistician, it was decided to calculate the sample size required for the analysis of a covariance (ANCOVA) rather than a standard t-test. This would adjust for baseline speed differences between the groups. Borm et al. (2007) derived an approximate sample size formula for analysis of covariance in randomised controlled trials.

Data shown in Table 23 was used with the formula to calculate that a total of 138 participants would be needed for a follow on randomised controlled trial in order to detect the effect of interest; 46 in a control group; 46 in a gait training only group and 46 in a gait training with FES group.

Table 23: Table to show the parameters used for the sample size calculation

Parameter needed for sample size calculation	**Value**
Statistical power • *Based on commonly accepted levels (Jones et al., 2003, Eng, 2003)*	0.90
Maximum *p* value for which as difference would be considered statistically significant • *Based on commonly accepted levels (Jones et al., 2003, Eng, 2003)*	0.05
Minimum expected difference (effect size) • *Based on published data related to change in speed associated with change in disability (Borm et al., 2007)*	0.16 m/s
Highest standard deviation of speed • *Calculated from current results*	0.367m/s
Correlation of before and after speed scores • *Calculated from current results*	0.769

5. Chapter 5: Discussion

5.1 Introduction

The main finding of this study is that it is feasible to conduct a two week gait training programme combined with FES (targeted to glutei, ankle dorsiflexor and evertor muscles) for people with sub-acute stroke and reduced hip extensor and/or dorsiflexor activity. However, a number of modifications to the research methodology are required to ensure the success and scientific rigour of a subsequent larger scale RCT.

As in previous chapters, the feasibility of both the methodological approach and the scientific outcomes of the interventions will be considered in turn. Section 1 is structured to discuss the key findings in relation to the feasibility objectives and produce a series of recommendations of modifications for a future RCT. This includes reflecting on the recruitment and retention rates, suitability of outcome measures used and participants' and staff perceptions of the research assessments and interventions. The intensity and content of the gait training programme are evaluated, and recommendations are made as to ways in which to further improve the standardisation of gait training elements.

Section 2 reflects upon the preliminary analysis of the research in relation to the outcome measures. In particular, the discussion will focus on patterns of recovery seen within the sample size as a whole as well as make comparisons between the groups. Conclusions will be set within the content of earlier research. Section 3 provides a critique of the thesis, discussing in further depth the limitations for the study followed by Section 4, which will summarise the learning for a subsequent randomised controlled trial as well as suggesting areas for further research. Finally the thesis will be concluded, highlighting the original contributions made to the current evidence base in this field.

5.2 Section 1: Is the study feasible?

5.2.1 Introduction

The current study was designed to determine the feasibility of conducting a two week gait training programme combined with FES (targeted to glutei and/or ankle dorsiflexor and evertor muscles) in a sub-acute stroke population. More specifically, this study has provided information in relation to recruitment and retention, acceptability to patients and staff, variability in the interventions provided and estimates required for a sample size calculation. The results of the study in relation to the previously identified feasibility objectives will now be discussed in turn.

5.2.2 To determine the proportion of eligible patients

One of the objectives for this study was to determine the proportion of eligible patients admitted to the recruitment sites. The information gathered from the Stroke Data Analysts showed that in total 1041 new stroke patients were admitted to the three stroke unit sites during the 12 month period of recruitment. Only 26 of those were identified by the therapists as having met the study criteria and were referred to the researcher (2.5%), and from those, 15 participants were subsequently recruited (1.44%).

Even though the number recruited was only one less than the original recruitment target, recruitment rates were lower than expected. Few published studies investigating FES on the lower limb in a sub-acute stroke population have provided detailed recruitment information and it is therefore difficult to make comparisons. Those that have published their overall enrolment ratios (the percentage of participants recruited from the screened population) demonstrate larger recruitment percentages, including 4.2%, 10.06% and 14.95% (Kunkel et al., 2013, Salisbury et al., 2013, Tan et al., 2014). The following paragraphs will draw on comparisons with these studies to offer potential explanations for the differences seen in recruitment rates.

5.2.2.1 Stroke admission screening

Significant differences in recruitment methodology may help to explain the higher recruitment rates seen in other similar studies (Kunkel et al., 2013, Salisbury et al., 2013, Tan et al., 2014). All three studies involved a screening process for all stroke admissions and reported on the reasons for exclusion for each stroke admission. In the current study, with a single researcher

completing the consent process, assessments and the intervention, there was not enough resources for the research to also screen all stroke admissions across the three sites and comment on the reasons for exclusion. Instead, for pragmatic reasons, treating therapists were asked to screen all admissions as part of their routine assessments and identify appropriate patients to the researcher. They were not asked to record reasons for exclusion for each patient admitted as it was felt this would have involved additional work, potentially affecting their ability to deliver usual care.

With no formal recording of admission screening, it could be argued that a higher percentage of patients may have met the criteria but were not referred by the treating therapists. Previous research has documented that workload issues and managing competing proprieties in the clinical setting can lead to therapists forgetting to identify potential participants (Fitzgerald and Delitto, 2001), which may have been the case in this instance. With increased resources, a similar screening process used by previous authors could be implemented which may increase recruitment rates or at least offer a more robust understanding of the reasons for exclusion.

5.2.2.2 Type of recruitment site

The nature of the recruitment site may also have had an impact on recruitment rates. Salisbury et al.(2013), Tan et al. (2014) and Kunkel et al. (2013) document recruiting from stroke rehabilitation units although it is unclear whether these facilities took acute admissions. The current study included an acute stroke unit (Royal Bournemouth Hospital), the stroke rehabilitation unit it referred into (Christchurch Hospital) as well as a combined acute and rehabilitation stroke unit (Salisbury District Hospital). Recruitment was particularly low from the acute stroke unit even though stroke admissions were high, with only one patient of the 697 admissions with stroke, being identified to the researcher. Again, without having a record of the reasons for exclusion it is not possible to establish definitive causes of reduced recruitment rates from this setting. Potential reasons may relate to the study criteria, including a higher incidence of medical instability in the acute phase or rapid recovery within the first few days following stroke reducing the need for gait training therapy. Equally, low recruitment rates may relate to reduced therapist capacity to identify potential participants due to the high patient turnover and workload pressures in this setting.

It is clear that in order to draw any firm conclusions related to recruitment rates, each stroke admission would need to be screened and the reasons for exclusion carefully recorded.

Furthermore, if a patient was excluded from the trial at admission to a ward, they would then need to be tracked on a regular basis to see whether their condition changed making them subsequently eligible.

5.2.3 To explore factors influencing eligibility and subsequent recruitment

5.2.3.1 Study selection criteria

It may have been that the study criteria considering walking ability were too stringent, both in terms of the minimum and maximum study entry requirements. A minimum level of walking ability was defined as being able to safely take part in a gait training programme with the assistance of one person and being able to stand for 10 seconds independently. This was based around the practicality and safety limits of a single researcher completing the intervention. Kunkel et al. (2013), recruiting 4% of the population screened, had similar criteria in terms of unsupported stand ability but set no boundaries around how many therapists were needed to deliver the intervention. Salisbury et al. (2013) set the minimum standard of walking ability to be five meters with moderate help of two people and achieved a recruitment rate of 10%. Tan et al. (2013) had the highest recruitment rate (15%) and set no criteria around walking or standing ability as their intervention was carried out in side lying. In view of the criteria of these publications it could be hypothesised that recruitment rate may be improved if the current criteria were broadened to include participants needing more than the support of one person to mobilise.

A maximum level of walking was defined as the ability to walk five meters in more than 5.75 seconds. If patients were able to walk faster than this they were deemed to have normal walking speed and did not demonstrate a need for walking training. Of the 11 patients excluded post identification by therapists, the majority of these were because they had reached normal walking speed by their initial assessment (n=6). It could be argued that as long as participants showed evidence of reduced dorsiflexion during swing phase and/or reduced hip extension during stance phase they could potentially benefit from gait training, irrespective of their walking speed. In summary, recruitment rates may be further improved by broadening the inclusion criteria to include more dependent patients and also those who have normal walking speed but show clinically observable gait deficits.

5.2.3.2 Patient willingness to take part

Two patients identified by therapists as meeting the inclusion criteria (8%) declined to take part in the study. Their reasons included that due to other commitments they would find it difficult to fit in the additional assessments and treatment sessions. Documented refusal rates of those patients that meet the inclusion criteria varies considerably in other similar studies including 40.5%, 0% and 10.4 % (Kunkel et al., 2013, Salisbury et al., 2013, Tan et al., 2014). With differences between studies in time post stroke, recruitment methods, study design and the intensity and nature of treatment approach, it is difficult to pinpoint reasons for the varied refusal rates. Subsequently, it is difficult to predict whether a similar low refusal rate would be seen in a subsequent follow on trial.

A concern would be that in the early stages of stroke, patients would feel that they would not be able to cope with an intervention in addition and separate to their routine therapy. This was the case found by Kunkel et al. (2013) who reported that 40.5% of patients who met the study criteria declined taking part. The authors explained that patients who declined to participate often reported that they did not feel 'up to it'. No further details are offered and it remains unclear whether the added intensity or the components of the experimental intervention itself were the main deterring factors.

It is also important to be mindful that the current study had no control group and participants would receive treatment in addition to usual care regardless of whether they were randomised to the gait training group or the gait training and FES group. This may have made entering the trial particularly attractive to patients. It is possible that adding the potential to be randomised to a control group that receives no additional therapy may negatively affect recruitment.

Having said that, there is now a growing body of evidence to support low refusal rates in high intensity therapy trials with control groups recruiting acute and sub-acute stroke patients. In their Phase II study, Bernhardt et al. (2008) randomised patients less than 24 hours post stroke to standard care (SC) or very early mobilisation (VEM) groups. Participants in the VEM group were assisted to be upright and out of bed (sitting or standing) at least twice per day, in addition to their usual care, 6 days per week. The goal was for the first mobilisation to occur less than 24 hours after symptom onset and for the intensive treatment to continue for 14 days or until discharge from the acute stroke unit, whichever came sooner. It was expected that this would be double the dose of therapy received by the control group. Of the 315

patients admitted to recruiting centres, 56 were recruited (18%) and all patients who met the inclusion criteria gave consent to take part in the study. It appears in this study, neither the risk of randomisation to a control group or the high intensity therapy offered in the experimental group, deterred participants from volunteering to take part. The follow-on, multicentre, phase III trial involving 56 stroke units in five countries, has recently been published ((The AVERT Trial Collaboration group, 2015)The AVERT Trial Collaboration group, 2015). Results showed that low refusal rates continued in the multi-centre trial with only 1.8% of participants refusing to take part.

A multicentre randomised controlled trial investigating intensive therapy targeted to the upper limb in the sub-acute phase of stroke reported refusal rates of 6.5% of the patients contacted (Blanton et al., 2006, Wolf et al., 2006). The Extremity Constraint Induced Therapy Evaluation (EXCITE) trial, involved participants being randomly allocated to receive either Constraint Induced Movement Therapy (CIMT) or usual care. CIMT consisted of participants wearing a restraining mitt on the less affected hand for 90% of their waking day while engaging in repetitive task practice and behavioural shaping with the hemiplegic hand for six hours per day over a two week period. Of the 3626 potential participants contacted, 235 were 'not interested' in participating (6.5%). However, this refusal rate should be interpreted with caution as this is a percentage of patients contacted, rather than a percentage of the participants who met the inclusion criteria. It is possible that patients who refused may have also been excluded from the trial for other reasons which would lower the refusal rate further.

In conclusion, there is conflicting information as to whether the low refusal rates seen in this feasibility study are comparable to other randomised controlled trials investigating augmented therapy in the acute and sub-acute phase of stroke. However, on balance, the weight of evidence from larger studies seems to be pointing towards a trend for low refusal rates. The reasons for patients volunteering to take part in research are multifactorial and complex (Newington and Metcalfe, 2014), making it difficult to predict recruitment accrual in a subsequent larger study. However, applying the lessons learned from recruitment approaches in larger randomised controlled trials may help to ensure successful participant accrual in a follow on larger study.

5.2.4 Summary of Recruitment Issues

Two of the objectives of this feasibility study were explicitly related to recruitment. One was to determine the proportion of eligible patients admitted to recruitment sites and another was to explore factors influencing eligibility and subsequent recruitment. It was found that 2.5% of stroke admissions were identified by the therapists working across three stroke wards over a 12 month period. This was fewer than expected and lower than enrolment rates seen in other similar studies.

As reasons for exclusion were not explicitly monitored for each stroke admission, it is difficult to identify to the extent to which factors such as recruitment methodology and study selection criteria affected recruitment. The lack of process of recording individual reasons for exclusion for each stroke admission may in itself have affected recruitment as potential participants may have 'slipped through the net'. Therapists may not have had the time, or may have forgotten to screen or refer patients. The study selection criteria may have been too stringent, particularly around the maximum and minimum level of walking ability required to participate in the study.

The relatively low refusal rates (patients declining to take part once referred by therapists) once deemed eligible, have been discussed and comparisons made with other studies. There is conflicting evidence with regards to acute/sub-acute stroke patients declining to participate in augmented therapy randomised controlled trials with documented refusal rates ranging from 40.5% to 0%. On balance, the weight of the evidence seems to be pointing towards lower numbers of patients declining to participate, and the argument that patients feel they cannot cope with additional therapy in the early stages of stroke remains unfounded.

5.2.5 Characteristics of sample

The following sections discuss the characteristics of the sample and whether they are representative of a larger stroke population. Participants were entered into the study depending on whether they belonged to a cohort of stroke patients with impaired walking ability, and therefore it was not expected that this would directly match the characteristics of a general stroke population. Comparisons are presented to highlight any major differences between the sample and the general stroke population.

5.2.5.1 Age and sex

The average age of the sample was 77.8 (range 66–87, SD = 6.11) years in women (n=8) and 66.4 (range 51-85, SD = 11.22) in men (n=7). The mean age across the sample was 72.4 (SD = 10.34). These figures are similar to those of the general stroke population in the UK documented to be a mean age of 77 years in women, 71 years in men (Lee et al., 2011) and 74.8 years across both sexes (RCP, 2011). The ratio of men to women was also similar to national benchmarks with relatively equal numbers of men (n =7) and women (n = 8) bearing in mind the uneven size of the groups (RCP, 2014).

5.2.5.2 Time since stroke

Time since stroke was an important factor in the current feasibility, as the aim was to recruit participants in the sub-acute phase of their recovery (new stroke within the last six months). The average time from stroke to baseline assessment was in fact an average of 41.8 days (range 10-106, SD = 26.75). Delays from initial identification by therapists to recruitment, occurred due to the researcher's limited capacity to take on multiple participants in the intervention phase, at any one time. The delay in this instance was a maximum of two weeks and all participants were recruited well within the six month since stroke time frame. Bearing this in mind, with an increase in research resource in a follow on study, it would be justifiable to expect a small reduction in average time from stroke to enrolment.

Research relating to the use of lower limb FES with patients less than six months post stroke report a variety of average time since stroke figures ranging from an average of 9.2 days +/- 4.1 (Yan et al., 2005) to 10.8 weeks (Wilkinson et al., 2014). Broadly speaking, randomised controlled trials including more dependent patients who are unable to walk, have reported an average time since stroke on enrolment, to be within the first four weeks after stroke (Macdonell et al., 1994, Ng et al., 2008, Tong et al., 2006b, Yan et al., 2005). In contrast studies

with a predefined minimal level of walking ability, report an average time post stroke, between two and six months (Granat et al., 1996, Salisbury et al., 2013, Wilkinson et al., 2014, Yavuzer et al., 2006).The current feasibility study did not outline a minimal level of walking ability, however one of the inclusion criteria related to them being safely able to take part in a gait training programme with the assistance of one person. This translated to participants being able to take one step or more with the assistance of one person or independently. It is therefore not surprising that the current feasibility study reports similar average time since stroke, to studies with similar inclusion criteria related to walking ability (Granat et al., 1996, Salisbury et al., 2013, Wilkinson et al., 2014, Yavuzer et al., 2006). Based on this evidence, it would be reasonable to expect a further reduction in time since stroke to recruitment if the inclusion criteria were broadened to include participants who were less able (for instance required the assistance of two people to take part in a gait training programme).

5.2.5.3 Stroke classification

The type of stroke was recorded according to the Oxford Stroke Classification (Bamford et al., 1991). All subjects had sustained an infarct rather than a haemorrhage, 6.7% of the sample had sustained a Total Anterior Circulation Infarct (TACI), 73.3% had a Partial Anterior Circulation Infarct (PACI), 20% had a Lacunar Infarct and 0% had suffered a Posterior Circulation Infarct (POCI). In comparison with the general stroke population (see Table 24) the sample contains a higher proportion of PACIs relative to the other subgroups. The lower incidence of TACIs is not unexpected due to the study's standing and mobility prerequisites. Patients suffering TACIs are less likely to walk in the early stages of stroke and at long term follow-up compared with the other infarct subgroups, and it has been hypothesised that this is likely due to the severity of motor, sensory, cognitive and visual symptoms associated with these larger strokes (Baer and Smith, 2001, Sánchez-Blanco et al., 1999).

The lack of participants recruited with POCIs was unexpected since these strokes can produce symptoms of motor weakness, clumsiness or paralysis (Merwick and Werring, 2014). Similarly, the lack of participants with haemorrhagic strokes was also surprising since they constitute 11% of all strokes (RCP, 2014). Haemorrhages can be severe and hold a higher risk of mortality within the first three months compared with infarcts (RCP, 2014). The low representation within the study sample may relate to this smaller percentage of stroke patients being less likely to survive. However, with a small sample size in the current study, it is possible that the lack of representation of these subgroups of strokes occurred through chance. A follow on study with a larger sample size should investigate the subgroups of stroke further in order to

draw conclusions as to where the results of the study are generalisable to the wider stroke population.

Table 24: Table to show Ischemic Stroke Classification

Classification of ischemic stroke subtype (Oxford Stroke Classification)	Percentage of participants in current study	National stroke population (Bamford et al., 1991)
Total Anterior Circulation Infarct (TACI)	6.7%	17%
Partial Anterior Circulation Infarct (PACI)	73.3%	34%
Posterior Circulation Infarct (POCI)	0%	24%
Lacunar Infarct (LACI)	20%	25%

5.2.5.4 Side of hemiplegia

In the present study there was a greater percentage of participants with a left sided hemiplegia (66.7%) compared with a right (33.3%). The question as to whether lesion lateralisation has an impact on functional recovery, remains unanswered. Poorer outcomes have been found in people with right hemisphere lesion and therefore left sided hemiplegia in some studies (Ween et al., 1996) but not others (Fink et al., 2008).

Laufer (2003) reported that stroke patients with a right hemi paresis demonstrated significantly greater gains in functional ability and balance control than those with left sided weakness. However, on subgroup analysis they found that there was no significant difference between left and right hemisphere lesions for patients who were able to stand for 30 seconds unsupported by one month following stroke. They concluded that the relationship between lesion side and recovery may depend on the level of initial impairment. It is worthy to note that they recruited participants from a rehabilitation facility and therefore may not have captured patients with mild or very severe strokes, who may have been discharged to the community (homes or care settings) directly from acute units. This selection bias limits the generalisability of the results to a wider stroke population.

Fink et al. (2008) eliminated this risk for bias obtaining data from three acute trials recruiting incident stroke patients admitted to acute facilities. They found that there was no difference

between hemispheres in 90 day modified Rankin Scale (mRS) or mortality. The mRS, used as a measure of independence following stroke, is a six point scale running from no symptoms to death. It could be argued that the mRS may have lacked the sensitivity to detect the more subtle changes in function and balance found by Laufer (2003).

As the evidence related to the relationship between lesion side and recovery is inconclusive, the risk of lesion side impacting the results cannot be ruled out. Therefore, analysis of outcomes in a follow on randomised controlled trial should monitor the effects of stroke lateralisation.

5.2.5.5 Length of Hospital Stay

The average length of hospital stay ranged from 12 to 91 days (mean 40.1, median 38). This is somewhat longer than the national average length of stay, which at the time of data collection was documented to be average of 19.5 and a median of 9 days (RCP, 2011). The longer length of stay seen in the study sample is not surprising given that walking and transfer ability are among the factors predicting length of inpatient stay (Ling, 2004), and the fact that the participants in the current study were recruited based on the presence of mobility deficits. The focus of their in-patient rehabilitation in preparation for discharge is therefore likely to have been around regaining a level of independence with their mobility to ensure a safe discharge home.

Changes in stroke service delivery since data collection are likely to reduce length of stay for a follow on trial. Stroke skilled Early Supported Discharge (ESD) services have been shown to reduce long term mortality and institutionalisation rates for up to 50% of patients admitted with stroke (Langhorne et al., 1999) and reduce length of stay (Fisher et al., 2015). Due to the weight of evidence supporting improved outcomes and cost effectiveness, the development of ESD teams across the country was advocated in the National Stroke Strategy (DOH, 2007). As a result, access to ESD has increased from 44% in 2010, to 66 % in 2012, to 74% in 2014 (RCP, 2014). At the time of data collection ESD services at recruitment sites were still under development, however they are now up and running which may have an impact on both recruitment and intensity of routine therapy.

5.2.5.6 Cognition

Baseline cognition was measured using the Mini Mental State Examination Test (MMSE). Scores of 25-30 are considered normal, 21-24 as mild and 10-20 as moderate cognitive

impairment (NICE, 2011). The average score of the study sample was 27.8 and ranged from 20 to 30. Only one participant scored less than 24 indicating a moderate cognitive impairment. A population based study investigating MMSE scores in acute stroke patients found that 42% of patients scored 23 or less (Pedersen et al., 1996). In another study, MMSE was carried out at 3 months post stroke, revealing that 39% of patients demonstrated a MMSE score of 23 or less (Patel et al., 2003). The sample of the current study recruited a smaller proportion of patients with moderate cognitive function than these previously documented figures. This may be because a lower proportion of patients suffered total anterior circulation infarcts which are associated with both physical and cognitive impairments (Bamford et al., 1991).

5.2.5.7 Summary of characteristics of the sample

This section has discussed characteristics of the sample including age, sex, time since stroke, stroke classification, side of hemiplegia, length of stay and cognition. The average age and sex of the study sample was characteristic of the general stroke population. Time since stroke was similar to that documented in other sub-acute stroke research trials with common study selection criteria. There was a higher percentage of Partial Anterior Circulation infarcts compared to statistics related to the general stroke population and a lower incidence of patients with total anterior circulation infarcts, posterior circulation infarcts and haemorrhages. This may be in part explained by the inclusion criteria around participants being able to engage in gait training with the assistance of one therapist, thereby excluding patients with more significant deficits resulting from larger strokes. It is also possible that the lack of representation of certain stroke subgroups occurred by chance, particularly in view of the small sample size.

There were more participants in the sample with a left sided hemiplegia, which has been associated by some authors with poorer outcomes, but not others. Whilst the comparative recovery of left sided versus right sided stroke remains inconclusive, it is the recommendation of the feasibility study that lateralisation of stroke be considered in a larger subsequent trial. Length of hospital stay was longer than the national average; however it is likely because patients with less severe stroke and subsequently relatively short lengths of stay, did not meet the inclusion criteria. Finally, the incidence of cognition impairment as measured by the MMSE was relatively low in the study sample with only one participant identified as having a cognitive impairment. It has been hypothesised that this may be in part related to the lower incidence of total anterior circulation infarcts.

5.2.6 To determine follow-up, retention and intervention completion rates

This section will review the third objective of the feasibility study, which was to determine follow-up and retention rates. The fourth objective was to determine where patient were able to complete the intervention schedule. It was found that 100% of participants completed all interventions sessions and assessments and none were lost to follow-up.

5.2.6.1 Intervention completion

Studies investigating the use of FES to improve walking ability in sub-acute stroke patients have reported mixed evidence of intervention completion ranging from 100% of patients attending the full quota of 12 one hour sessions over six weeks (Wilkinson et al., 2014) to participants attending less than 75% of the pre-set number of sessions over a two week period (Kunkel et al., 2013). Kunkel et al. (2013) reported that the shortfall in delivering the intervention was largely due to the difficulty of scheduling additional therapy around the busy ward routine. Other studies, limited to delivering the intervention in inpatient facilities, documented that missed training and assessment sessions were due to participants being discharged prior to study completion (Ng et al., 2008, Tong et al., 2006b, Yan et al., 2005).

Carrying out all eight treatment sessions in the current study was achievable as the researcher was able to continue interventions in the community once participants were discharged. In fact 80% of the interventions were delivered in the participants homes, highlighting the importance of a flexible approach to the location of intervention delivery. In addition, the researcher was also able to be flexible with intervention times including working at weekends and in the late afternoon. Whilst participants were still on the ward, the researcher negotiated timings of the intervention with the therapists, being careful to avoid set therapy times and ward activities such as meal times. For a follow on study this flexible approach would be useful in ensuring participants received the set frequency of intervention sessions.

5.2.6.2 Loss to follow-up

It has been reported that 81% of trials report some loss to follow-up, with higher loss to follow-up being associated with inadequate concealment of allocation, a longer length of follow-up and a non-medical, non-procedural intervention (Akl et al., 2012). Loss to follow-up has the potential to bias the results of the study for example if patients failed to return if their mobility had deteriorated and they could no longer manage the journey to the gym to have

their walking tests completed. It has been hypothesized that the reduction in risk of bias created through randomization could be lost if the distribution of such patients differed between study groups (Akl et al., 2012). The lack of loss to follow-up in the current study gives reassurance that bias through missing data in this instance did not occur. However, it cannot be assumed that a larger follow on study will demonstrate similar loss to follow-up rates, particularly if the follow-up time is extended.

Of the randomised controlled trials investigating FES to improve walking ability in a sub-acute stroke population, few have included a long term follow-up phase (Kunkel et al., 2013, Ng et al., 2008, Salisbury et al., 2013, Wilkinson et al., 2014, Yan et al., 2005). Of those follow-up time ranges from two weeks post randomisation (Kunkel et al., 2013) to six months (Ng et al., 2008). Loss to follow-up rates range from 0% (Wilkinson et al., 2014) to 18% (Tan et al., 2014) and common reasons for loss include death (Ng et al., 2008, Salisbury et al., 2013), medical instability (Kunkel et al., 2013), second stroke (Kunkel et al., 2013, Ng et al., 2008), out of area (Tan et al., 2014), lost contact (Ng et al., 2008, Tan et al., 2014) and refusal (Tan et al., 2014).

Multicentre sub-acute stroke trials investigating interventions in the upper limb have reported 76% retention rates at 12 month assessment and 59% at 24 months. Reasons for loss to follow-up were similar as described by previous studies including death, medical issues, second stroke, moving out of area and 'other'(Blanton et al., 2006, Wolf et al., 2006). Many of these factors are associated with the condition itself as the incidence of first time stroke is associated with death and a higher risk of a second stroke (Lai et al., 1995). Based on this evidence, whilst efforts can be made to enhance retention, it is likely that a proportion of participants will be lost to follow-up in a larger randomised controlled trial particularly if the time to follow-up from recruitment is lengthened. Therefore, in order to account for this, it is the recommendation of the current study that a subsequent trial be powered to allow for a loss to follow-up due to medical complications unrelated to the intervention itself.

5.2.6.3 Summary of retention and follow-up

The current study showed a 100% of participants completed the targeted eight intervention sessions. It is felt that this was because of the flexibility of the researcher to be able to plan the intervention sessions around routine care as well as the participant's location. This is important learning that should be carried forward to a follow-on study when planning the practicalities and resources around intervention delivery.

In this small study no participants were lost to follow-up. However in consideration of attrition rates in larger studies with longer follow-up periods, it seems likely that there would be a loss to follow-up in a subsequent larger randomised controlled trial. The follow-on study should therefore be powered to account for this.

5.2.7 To describe the variation in the intervention delivered

The fifth objective was to describe the variation in the intensity and content of the intervention delivered in order to determine the extent to which these elements can be standardised without the loss of an individualised, patient centred approach. For the purposes of the current feasibility trial the term 'intensity' has been broken down into a number of component parts. These include treatment duration, amount of time engaged in active exercise and total repetitions completed. These will be discussed in turn and set within the context of published research. Finally, the content of the training sessions will be discussed and compared with other gait training research. The extent to which elements of intensity and content of the gait training programme can be standardised will be discussed and recommendations for modifications to the study protocol for a larger scale trial will be outlined and justified.

5.2.7.1 Intended duration versus actual treatment delivery time

The intended training duration and frequency for both groups was set at eight, 45 – 60 minute sessions delivered over a period of two weeks. When an average of treatment times across the sample is taken it can be said that average actual treatment time (Mean =52.2, Median 50.88) reached 100% of the intended time. However, when average treatment times are looked at for individual participants, one participant received less than the intended amount (average 42 minutes per session).

Few randomised controlled trials investigating the effects of augmented therapy in stroke patients have reported on intended and actually applied therapy times (Cooke et al., 2010, G.A.P.S., 2004, Howe et al., 2005, Kunkel et al., 2013, Kwakkel et al., 1999). Reports include that the actual therapy time delivered ranged from 44% (Kunkel et al., 2013) to 100% (Howe et al., 2005) of the intended time. These figures relate to the average across the sample and details are not provided on an individual participant level.

The contrast in actual versus planned therapy dosage has been explained by factors such as lack of staffing, patients' schedules and fatigue (Veerbeek et al., 2011). In the current study, training sessions were carefully planned around the participants' diaries to ensure there was potential to deliver the full training time without interruption. The main limiting factor for training was therefore not related to external factors but rather the individual fatigue levels of the participants. Efforts were made to enable participants to take frequent rests during the

intervention which may explain why the majority were able to tolerate the targeted treatment time.

In current clinical practice when patients in the early stages of stroke are unable to tolerate longer treatment sessions, where resources allow, shorter, more frequent sessions are offered (for example two 30 minute sessions per day). It could be argued that this approach may help to ensure standardisation of treatment duration and perhaps even the amount of time physically engaged in exercise. However, to date no research has been published directly comparing the efficacy of longer treatment sessions compared with shorter more frequent sessions where the total treatment time has been matched under both conditions. It cannot be ruled out that introducing a split therapy strategy to a select group of participants who are unable to tolerate longer sessions, may introduce confounding variables that may affect the results. Applying this strategy to all participants may impair the feasibility of intervention delivery, making it harder from a practicality perspective to fit in additional sessions into a participant's routine, particularly considering the majority of sessions were carried out in the community. It has been well documented that further research is needed into the dose-response relationship to gait training and functional outcome, where 'dose' has been defined as the number of total minutes of therapy over a set amount of time (Veerbeek et al., 2011). However, evidence into the optimal number of sessions required to deliver a specified dose in different subgroups of stroke patients is equally lacking.

In conclusion, to reduce the risk of introducing bias through differences in treatment duration, a future trial should apply the learning from the current study and mitigate for external factors that may impact on treatment time. This may include ensuring sufficient resources to enable a flexible approach to intervention delivery that fits around the patient's schedule. Any internal factors affecting treatment delivery such as participant fatigue levels are to be expected and should be recorded. So too should be the total treatment length so that the impact of variability in treatment time on participant outcomes can be analysed and accounted for.

All participants received all eight treatment sessions without exception. The mean total treatment time was 417 minutes (median = 407 minutes) and ranged from 336 to 476 minutes. This equated to the average treatment session lasting 52 minutes (SD 5.2). The variation in treatment time may have related to the individual fatigue levels of the participants. In addition, as the time taken to set up stimulation was included in the overall treatment time, variation in setup time may have had an impact on overall treatment duration. The impact of

fatigue and stimulation setup time on total treatment time, will be discussed in further depth in the following paragraphs.

5.2.7.2 Variability in the amount of time engaged in exercise

It has been previously argued that treatment time may not directly reflect the amount of time spent practising movement. This was certainly the case in the current study where it was calculated that participants were physically active for on average 65.8% of the total treatment duration. The rest of the time was spent resting, setting up the stimulation or discussing treatment plans. This is comparable to other observational stroke studies that have reported an average of 60% of routine physiotherapy sessions spent actively exercising (Kaur et al., 2012, Tole et al., 2014).

There was a high degree of variability across the sample ranging from 41.2 to 90.8% (SD = 14.1%). This may reflect the variance in individual exercise tolerance levels within the sample which following stroke has been documented to relate to a vast range of factors including pre-existing conditions, sleep disorders and depression (Dobkin, 2005). With this in mind, it would not be possible to standardise the amount of time spent engaged in exercise across the sample. It may however be possible to ensure a standardised approach to optimising active treatment time. This may be particularly important in a larger trial where multiple therapists may be delivering the exercise intervention. Methods may include using participants' self-ratings of exertion and heart rate changes to inform the need for rest periods rather than relying on observed signs of fatigue (Host et al., 2014). In addition, research therapists could be trained in standardised approaches to encouraging high intensity, for example consistently providing positive reinforcement as to the benefits of intensity and providing regular and structured feedback on effort and progress (Hildebrand et al., 2012).

Stimulation setup time may also have had an impact on the amount of time patients were physically engaged in exercise. Results showed that whilst the total treatment time and total time spent in active exercise were not significantly different between the Gait Training only and the FES and Gait Training groups, there was a significant difference between the groups in terms of the proportion of the total treatment time spent actively exercising. The FES and Gait Training group spent less time in active training which is likely due to the amount of time taken during the session setting up the stimulation. This averaged at 18.1% of the total treatment time and ranged from 10.7 to 23.6%. It could be argued that had the FES and Gait Training group benefitted from the same active training time as the Gait Training group, their outcomes

may have been further improved. It is therefore the recommendation of the current feasibility trial that in a follow on study, stimulation setup time should be in addition to total treatment time. Based the maximum set up times from the current results, researchers should allocate 15 minutes to the setup of the electrical stimulation prior to the start of the treatment session.

5.2.7.3 Variability in the number of repetitions

The current study kept a tally of the number of repetitions of certain exercises performed by the participants including strengthening, sit to stand and stepping exercises. Results showed that there was a great deal of variability in total number of repetitions completed over all eight treatment sessions between participants; with strengthening exercises ranging from 0 – 600 repetitions, sit to stands ranging from 0 – 179 and steps ranging from 420 – 1580.

The number of repetitions completed both inside and outside of treatment sessions has recently become of more interest in the research arena, with authors giving more weight to repetitions completed as an indicator of training dose than overall treatment time (Holleran et al., 2014, Lang et al., 2009, Moore et al., 2010, Scrivener et al., 2012, Rand and Eng, 2012). This is in response to animal and human studies indicating that larger numbers of volitional motor training exercises are likely to have a greater influence on motor recovery (Nudo et al., 1996b, Wolf et al., 2006).

There is little evidence recommending definitive numbers of repetitions of gait orientated training to induce neuroplastic changes and optimise walking function. Animal studies have shown that transacted rats showed a greater improvement in the quality of stepping when they received 1000 steps per training session, compared with 100 steps (Cha et al., 2007). A human study involving 20 chronic stroke survivors (over six months post stroke) showed that participants engaged in intensive treadmill based gait training, achieving an average of 3896 steps per session improved daily stepping and gait efficiency to a greater extent than following routine physiotherapy sessions achieving an average of 886 steps per session (Moore et al., 2010). A more recent larger study involving 200 sub-acute stroke patients performed on average 288 repetitions of lower limb exercises per day and showed that higher exercise repetitions were associated with greater changes in walking speed (Scrivener et al., 2012).

In summary the evidence appears to be growing to support the notion that increased repetitions of lower limb exercises and steps during training sessions are associated with improved walking performance. It could be argued that the process of randomisation within the current trial should ensure that both groups are equally variable in terms of participants'

intrinsic ability to tolerate a high intensity of repetitions within the gait training sessions. However, the integration of FES could impact on repetitions performed, either by facilitating participants to work harder or conversely inducing fatigue leading to fewer repetitions. There is a current gap in the evidence to explore how introducing FES into a gait training programme effects numbers of repetitions completed. It is therefore recommended that a follow on trial collect and use data related to repetitions to investigate whether there is a link between the use of FES in a gait training programme and the number of repetitions completed. Subsequent insights would therefore be gained into the mechanisms by which FES may or may not have an effect on walking ability.

The number of steps completed within the current study fall a long way short of efficacious step repetitions reported by other trials, however comparisons should be made with caution. Repetitions of only three of the exercises within the gait training programme were recorded. In the absence of more advanced activity monitoring, the exercises chosen to be recorded could be counted easily by the researcher during the treatment session without interfering with treatment delivery. An additional 904.5 minutes across the eight treatment sessions was spent on walking which by definition would have involved additional unaccounted for steps. The potential implications of repetitions in motor recovery have been explained and the importance of this aspect of training intensity demonstrated. Therefore a follow-on trial should endeavour to gain a more complete record of total repetitions completed. Section 5.4.3. explores additional methods for accurately recording repetitions of each exercise.

5.2.7.4 Variability in the content of the gait training programme

The current study showed that the amount of time spent on various tasks within the gait training programme varied considerably between participants and from session to session. Overall, the most common components of gait training completed by all participants included stepping and walking practice. This is not surprising as the aim of the training programme was to be task specific in line with current guidelines and evidence supporting task orientated training (Jørgensen et al., 2010, Pohl et al., 2007, RCP, 2012, van de Port et al., 2007, Van Peppen et al., 2004). Other studies investigating the efficacy of high intensity task specific training in stroke also used stepping practice and over ground walking under various challenges as part of a gait training package (Holleran et al., 2014, Outermans et al., 2010). Results from these studies showed that the gait training strategy involving stepping and over ground walking led to improvements in gait speed and walking capacity in sub-acute stroke patients.

The current feasibility study adopted an open and flexible approach to the content of the gait training sessions in response to the individual needs of the participants and access to training equipment in patients homes' (for example stairs and a cycle). Whilst some gait training activities such as stepping and walking practice were common to all participants, other activities were restricted to a single participant or small subgroup of participants. This approach carries with it certain challenges for a full scale evaluation trial. Firstly, the degree of variability seen in the content of the gait training packages makes it difficult to replicate particularly if multiple researchers are delivering the intervention. Secondly, a lack of standardisation of the variants of the training package makes it difficult to maintain a clear separation between the two experimental conditions being tested. Therefore, methods of limiting variation of the gait training programme whilst still allowing for an individualised approach should be considered for a follow-on trial. A suggested standardised gait training package is described in Appendix 37.

5.2.7.5 Summary of variation of intervention intensity and content

Several subcategories of training intensity have been described to provide a comprehensive description of treatment dose. These include intervention duration, amount of time actively engaged in exercise and total repetitions completed. Participants on average received 100% of the intended treatment time. It has been hypothesised that this was due to an adequate amount of research resource being allocated to the trial as well as a flexible approach to fitting in training sessions around participants' schedules. The amount of time actively engaged in exercise was comparable to that found in other studies, although there was a great deal of variation between participants. This reflects the time taken to set up stimulation as well as individual endurance levels of participants. The current study therefore recommends that standardisation methods may include allowing 15 minutes for FES set up in addition to the training time, using participants' self-ratings of exertion and heart rate changes to inform the need for rest periods, and using common approaches to encouraging high intensity exercise.

The number of repetitions completed varied across participants and was considerably lower than numbers documented in other trials, although it is recognised that this should be interpreted with caution as numbers of steps taken during walking were not included in the current study. The potential impact of FES on repetition rate has also been highlighted and the relationship between repetition and motor recovery discussed. With this in mind, the results of

the feasibility study consolidate the need to accurately and comprehensively recorded repetitions in a follow on trial. In summary, monitoring intensity of training should be more comprehensive than just accounting for treatment session duration and session frequency. Total active time, time spent actively completing each component of the gait training programme and numbers of repetitions are all important factors in determining and demonstrating treatment intensity. It has been recommended that a future trial should explore standardised methods of encouraging higher intensity treatment and make efforts to comprehensively describe the dose delivered.

The content of the gait training programme varied and whilst stepping and walking practice was common to all participants, other aspects such as cycling and stair climbing were completed by a single participant or very small subgroup. Variability in the content of the training programme related to the individual needs of the participants but also the context of their environment and the facilities they had access to. It is highly likely that multiple researchers would be needed to deliver the training intervention in a larger scale follow on RCT. Therefore in order to maintain fidelity to a treatment protocol it is of paramount importance that efforts are made to improve the standardisation and provide a thorough description of training intensity and content. The current feasibility trial recommends that further standardisation of the training package should be considered in a subsequent trial, and an example of what this may look like is demonstrated in Appendix 37.

5.2.8 Intensity and content of routine care

The healthcare professionals involved in the participants' routine care were asked to document frequency, duration and content of their usual contact sessions during the two week intervention period. Information related to the content and intensity of routine care was considered important in this feasibility stage, to enable comparisons between usual care and the gait training interventions (Boutron et al., 2008).

Only records from three of the fifteen participants were returned which was fewer than expected. Analysis of the records showed that routine care was less intensive than the experimental gait training interventions in terms of frequency although sessions were equally varied in terms of content. However, with such limited information it is not possible to draw any definitive conclusions as to the extent to which the trial interventions (gait training or gait training and FES) differed from usual care both in terms of intensity and content. Future research should consider tracking routine care on a regular basis to ensure accurate and comprehensive information can be captured and comparisons can be made. Furthermore, it has been shown that therapists systematically overestimate treatment time (Bagley et al., 2009) and therefore more objective methods of capturing routine treatment intensity and content (for example observational analysis) may be beneficial.

Reasons for the low response rate are unclear owing to the absence of systematic and external methods of monitoring routine care within the current study. It may have been that participants did not receive routine therapy in addition to the intervention during the intervention period, or it may have been the case that they did, but the routine care charts were not completed and/or returned to the researcher. Treating therapists were aware that participants were gaining additional treatment as part of the trial and therefore may have intentionally or unintentionally reduced the routine level of therapy input to this group in favour of other patients who were not enrolled in the trial, and therefore not gaining the benefits of additional therapy. It is also possible that in some instances, the research intervention may have filled the gap in routine therapy during the transition from inpatient to community physiotherapy services.

It should be noted that the stroke pathway has changed since the data collection phase of the current study to include more stringent monitoring of therapy input. There is now a national target of patients being offered a minimum of 45 minutes of each therapy that is required for a minimum of 5 days a week (NICE, 2013). In addition, the recent increase in the provision of

Early Supported Discharge Services ensures continuity of care from an inpatient to a community setting with patients often being seen within 24 hours of discharge from hospital (Fearon and Langhorne, 2012). In view of these service level changes to the stroke pathway, a future trial should expect participants to be receiving regular routine care in addition to the study intervention.

5.2.9 To explore participant and staff perceptions related to acceptability

5.2.9.1 Participant perceptions

Participant perceptions' of how acceptable they found the intensity, application and use of the assessment and treatment methods was captured via questionnaires with an 80% response rate. Feedback was largely positive suggesting that participants found the assessments and interventions (gait training with and without FES) acceptable. Furthermore participants felt the intervention had a high impact on their walking ability.

There has been little research into the perceived acceptability of the shift towards higher intensity therapy making comparisons with previous literature difficult. Evidence captured via discrete choice experiments demonstrated that sub-acute stroke participants had an aversion to very high intensity programmes (six hours per day) and preferred lower intensity (three hours or 30 minutes per day) regimes (Laver et al., 2011). In addition, 88% of participants agreed or strongly agreed that rest was an important part of the rehabilitation programme. Whilst the study sample demographics were comparable to the current study's participants in terms of age and time since stroke, Laver et al. included only Australian participants and it should be considered that preferences between countries and healthcare systems may differ. Further UK based qualitative research is needed to explore patient preferences with regards to the intensity of therapy programmes, modes of delivery (for example individual or group based) and frequency, duration and nature of rest periods. Research should also consider the preferences of stroke severity subgroups of participants as this may help to tailor treatment dose to patient preference as well as rehabilitation need.

Feedback related to the stimulation itself was positive and indicated that the participants found the stimulation comfortable and setup time acceptable. Research related to participant perceptions of FES is largely focused on patient and carer's perceived impact of FES on walking ability and quality of life when used as an orthotic (Taylor et al., 1999a, Wilkie et al., 2012). There is limited research exploring participant perceptions of the acceptability of exercising whilst receiving stimulation as a treatment approach. However, there is some early evidence to support the current study's findings that participants find electrical stimulation combined with active exercise comfortable and even enjoyable (Hughes et al., 2011, Kunkel et al., 2013).

5.2.9.2 Staff perceptions

Healthcare professionals involved in routine treatment were provided with a questionnaire to gain an insight into their opinions about the intervention and assessment procedures used, and how they felt the study affected their daily routine. Only two healthcare professionals returned completed questionnaires making it difficult to draw any firm conclusions from the responses. Both professionals were consistent in their feedback that the study did not impact on routine care and that they would be willing to take part in a similar study again. One healthcare professional reported that there was competition for space in an in-patient setting when the ward therapists and researcher were using the same gym space.

As discussed in section 5.2.6 a future study should expect participants to be receiving routine therapy in parallel to the study intervention in line with more recent national guidelines and service developments. Therefore it is possible that sharing in-patient facilities and fitting in assessments and treatments around routine therapy sessions may be more problematic. The research team will need to take a flexible approach to delivering assessments and treatments to ensure that participants receive the targeted dose of gait training.

5.2.9.3 Summary of participant and staff perceptions

Questionnaires revealed that both participants and therapists found the assessments and interventions acceptable. The general consensus that the intensity offered was 'just about enough' is consistent with research showing participants have an aversion to highly intensive programmes (six hours per day) and appreciate rest periods. Participants also found the electrical stimulation tolerable, which again is consistent with early research investigating participant perceptions of FES combined with exercise programmes. The few responses from therapists indicated that the study did not impact on routine care, although further consideration should be given to flexible ways of working to reduce the competition for treatment facilities in an in-patient setting.

5.2.10 To determine suitability of the selected outcome measures

All measures were completed for all participants at each assessment point, on average taking one hour to complete. Therefore it can be concluded that in the main, the battery of outcome measures selected were feasible to complete and well tolerated in clinical/home settings. There were however some issues with the standardisation of the assessment procedures including variation in the assessment setting, additional assistance needed to measure gait speed and lack of clarity with some aspects of the Wisconsin Gait Scale.

Whilst all physical measures were completed in a clinical setting in one session, the Stroke Impact Scale on several instances was carried out in participants' homes one to two days following completion of other measures. This was because of participant preference, and on occasions where the time taken to complete the physical measurements exceeded one hour. Ideally assessment procedures should be standardised and completed in the same setting, in the same order and within the same timeframe at each assessment point. However, in the current study it would not have been possible to routinely carry out the Stroke Impact Scale in participants' homes as 40% were still in-patients at the time of baseline assessment. Equally, routinely carrying out the Stroke Impact Scale in the clinical setting either in one long assessment session or two successive sessions may have placed increased burden on the participants and may have led to missing data. The pragmatic approach enabled a complete data set but a potential reduction in reliability through lack of standardisation should be acknowledged. It has been suggested that a short version of the Stroke Impact Scale may reduce the burden placed on the patient without comprise to the content reliability (Jenkinson et al., 2013) and may allow all measures to be completed in one setting.

The two primary outcome measures were considered to be gait speed, measured over a pre-prepared walk way and gait quality assessed using the Wisconsin Gait Scale. Gait speed over five meters proved feasible to set up in two separate rehabilitation gym settings. Several participants required physical assistance or close supervision when walking. This could be a confounding factor owing to the difficulties in standardising the amount of physical assistance given by the researcher. In addition, when help was needed it was impossible for the single researcher to offer support and operate the stop watch, therefore therapists working in the gym at the time were asked to provide some assistance. A future multicentre trial should consider solutions to improve the reliability of measuring gait speed. This may include at least

two researchers being present to carry out walking assessments, or the use of portable technology to accurately measure gait speed.

The Wisconsin Gait scale was used by a blinded assessor to score the quality of walking using video footage of walking assessments. This method proved to have both advantages and disadvantages. It was relatively quick and easy to set up the camera with use of a tripod having prepared the area and established and optimal camera angles. The researcher was able to record the instructions given to the patient when completing the five meter walking test, ensuring that a standardised approach had been applied to all participants which could then be verified by the independent assessor. Finally, the researcher was able to mix up the video footage, giving it to the assessor in a random order of participants and assessment stages. This meant that the assessor was truly blinded and reduced the likelihood of bias towards a particular treatment group or time point.

However, feedback from the independent assessor included that certain aspects of the Wisconsin Gait Scale were difficult to score, particularly pelvic rotation. Often, this was because participants were wearing bulky clothing thereby masking pelvic movement. Certainly variations in clothing and footwear at assessment points were an issue particularly if baseline assessments were completed during in-patient spells. Furthermore, it was not possible to capture full view of the participants (from head to toe) when the camera was placed for a sagittal aspect due to the reduced width of the two gyms. The camera was therefore positioned to gain the best possible view of the participants' lower limbs which often did not include the hips and pelvis. These issues will have reduced the reliability of the measure, particularly in relation to subsections of the Wisconsin Gait Scale concerning the hips and pelvis. A follow on study should consider introducing further measures to standardise the gait analysis approach. This may include participants being instructed to wear the same clothing and footwear at each assessment. If possible and acceptable to participants, shorts or rolled up trousers should be worn to allow for improved visualisation of knee and ankle movement.

Since the original design of the current study a new observational gait assessment tool has been developed. The Gait Assessment and Intervention Tool (G.A.I.T) is a 31 item measure designed to assess the quality of gait in stroke patients using video footage (Daly et al., 2009). A systematic review of observational gait analysis tools used in stroke rehabilitation advocated the use of the G.A.I.T which scored above all other measures in terms of clinical utility, content

validity, inter-rater and intra-rater reliability and sensitivity to change (Ferrarello et al., 2013). In contrast, the Wisconsin Gait Scale was criticised for its lack of in depth kinematic analysis in stance phase omitting to score invariant features related to pelvis, knee and ankle behaviour. In addition the G.A.I.T offers further advantages, accounting for whether physical assistance was required and offering a detailed description of how to perform the test including camera angles and participant clothing. Although further research is indicated to establish its application to a sub-acute stroke population, the G.A.I.T. may provide a more comprehensive assessment of the quality of gait and should be considered as an alternative to the Wisconsin Gait Scale in a further trial.

Observational gait analysis offers a pragmatic solution to the lack of access to gait laboratory facilities, reducing the burden on participants to travel large distances for their assessments. However, there is no question that computerised three-dimensional gait analysis is the gold standard in the objective and sensitive assessment of gait. It could be argued that more subtle incremental changes achieved in response to gait training, particularly around the areas of electrical stimulation can be accurately captured using a more sensitive measurement tool. With this in mind, innovations in technology for example portable motion recording systems should be explored for a future trial.

5.2.10.1 Summary of suitability of outcome measures

All outcome measures were completed at each assessment point therefore, the outcomes are considered feasible and well tolerated in clinical/home settings. There were several standardisation issues with the measures which affects their suitability. The Stroke Impact Scale on several occasions was conducted in patients' homes due to participant preference and the amount of time taken to complete other measures. A shorter version of this assessment may aid standardisation of the assessment process by enabling completion of all outcomes in one sitting. Several patients required physical assistance to walk and therefore additional help was sought from therapists to help to measure and record gait speed. A future trial should consider additional resource to account for this, be it an additional researcher present for gait assessments or use or gait speed recording technology. Measuring the quality of walking using an independent assessor to score video footage proved difficult in some instances due to the lack of clarity of the footage to enable accurate scoring of certain sections. This was largely as a result of insufficient camera views and loose fitting clothing. The Wisconsin Gait Scale itself has been criticised for insufficient content and a new observational

measure of gait has been suggested. Furthermore the use of portable motion recording systems may offer further reliability in the assessment of the quality of gait, without the need for expensive and less accessible gait laboratory facilities and should be considered in a further trial.

5.2.11 To gain estimates required for a sample size calculation

Sufficient data was obtained to inform a sample size calculation. Based on standard deviations from gait speed data and the assumption that a third control group would be needed, a total of 138 participants would be required for a follow on randomised controlled trial in order to detect the effect of interest (46 participants in each group). To allow for a 25% attrition rate between randomisation and follow up, a total of 173 participants would be needed (58 in each group).

This calculation was based on gait speed as the primary outcome measure and used 0.16m/s as the meaningful clinically important difference (MCID) that would be perceived as beneficial (Tilson et al., 2010). In their study Tilson et al. anchored MCID in comfortable walking speed over ten meters on an improvement in of disability level (≥ 1) measured by the modified Rankin Scale (mRS). Participants approximately 20 days post stroke were documented to have an average walking speed of 0.18m/sec (SD: 0.16) which was slower than the average baseline speed in the current study (0.44m/sec SD: 0.22). This may be explained by the fact that participants in the current study were slightly further on in their recovery (mean of 42 days post stroke). The faster baseline walking speeds may also be indicative of a population of stroke patients with less significant gait deficits. The magnitude of change found by Tilson et al. is slightly larger than findings in other non-stroke populations with faster initial walking speeds (Perera et al., 2006). Authors hypothesised that a larger magnitude of meaningful change may be needed to benefit people with more severe deficits however, further research into patients with mild impairments secondary to stroke, is needed to confirm this. On balance and in the absence of further evidence to inform MCID in different stroke severity subgroups, the value of 0.16m/sec offers the best available estimate for a follow on study in a sub-acute stroke population.

5.2.12 Summary of Section 1: Is the study feasible?

This section of the Discussion Chapter has explored the results in reference to the research question; **Is it feasible to conduct a two week gait training programme combined with FES (targeted to glutei and/or ankle dorsiflexor and evertor muscles) for people with an acute/sub-acute stroke and reduced hip extensor and dorsiflexor activity?.**

The key finding here is that it is feasible, although the methodological process requires further development to ensure the success of a follow on randomised controlled study. Principle findings and recommendations related to the study objectives are summarised in Table 25.

Table 25: Key findings related to objectives of study and subsequent recommendations for a follow-on RCT

Objectives of the study	Findings and recommendations
a. To determine the proportion of eligible patients admitted to recruitment sites	• The admission/inpatient screening method was not sufficiently robust enough to reliably estimate the proportion of eligible patients. • Amend protocol so that researcher screens all new stroke admissions documenting reasons for exclusion. Patients that are deemed not suitable are subsequently tracked on a regular basis to see whether their condition changed making them subsequently eligible.
b. To explore factors influencing eligibility and subsequent recruitment	• Study criteria around walking ability potentially too stringent, both in terms of the minimum and maximum study entry requirements. • Broaden criteria to include participants that require assistance of two therapists to carry out gait training and those that show signs of clinically observable gait deficits regardless of walking speed.
c. To determine follow-up and retention rates	• 100% follow-up and retention rates in the current study is encouraging however it should not be assumed that retention will be equally high in a follow on trial, particularly if the follow-up period is extended. • Power follow-on trial to allow for a loss to follow-up due to medical complications unrelated to the intervention itself.
d. To determine whether patients were able to complete intervention schedule	• Carrying out all eight treatment sessions in the current study was achievable as the researcher was able to continue interventions in the community once participants were discharged. • Flexible approach to follow-up visits being completed at the person home, is key to ensuring retention and intervention schedule completion.
e. To describe the variation in the content and intensity of the intervention delivered	• Amount of time actively engaged in exercise was comparable to that found in other studies, although there was a great deal of variation between participants. Reflects the time taken to set up stimulation and individual participant endurance levels. • Number of repetitions completed varied across participants and was considerably lower than numbers documented in other trials, although it is recognised that this should be interpreted with caution as numbers of steps taken during walking were not included in the current study. • Content of the gait training programme varied and whilst stepping and walking practice was common to all participants other aspects such as cycling and stair climbing were completed by a single participant or very small subgroup. Variability in the content of the training programme related to the individual needs of the participants but also the context of their environment and the facilities they had access to. • Standardisation methods to include allowing 15 minutes for FES set up in addition to the training time, using participants' self-ratings of exertion and heart rate changes to inform the need for rest periods and using common approaches to encouraging high intensity exercise. • Further standardisation of the contents and repetitions of the training package should be considered in a subsequent trial (see Appendix 37 for suggestions).

Table 25 continued: Key findings and subsequent recommendations for a follow-on RCT

f. To explore participant and staff perceptions of the acceptability of the intervention (gait training and gait training and FES)	• Questionnaires revealed that both participants and therapists found the assessments and interventions acceptable. • General consensus that the intensity offered was 'just about enough' is consistent with research showing participants have an aversion to highly intensive programmes (six hours per day) and appreciate rest periods. • Few responses from therapists indicated that the study did not impact on routine care although further consideration should be given to flexible ways of working to reduce the competition for treatment facilities in an in-patient setting.
g. To determine whether the selected outcome measures are suitable and can be carried out in clinical/home settings	• All outcome measures completed at each assessment point therefore the outcomes are considered feasible and well tolerated in clinical/home settings. • Future trials should consider additional resource to assist gait speed recording, be it an additional researcher present for gait assessments or use or gait speed recording technology. • Measuring the quality of walking using an independent assessor to score video footage proved difficult in some instances. Use of alternative observation gait assessment tool or portable motion recording systems may offer further reliability in the assessment of the quality of gait. • Review any developments in the measurement of muscle tone including the use of the Modified Modified Ashworth Scale in a sub-acute stroke population (see section 5.3.4.1.) • Variation in setting of completion of Stroke Impact Scale due to participant preference and the amount of time taken to complete other measures. Shorter version of this assessment may enable completion of all outcomes in one sitting.
h. To gain estimates required for a sample size calculation	• Calculation was based on gait speed as the primary outcome. Standard deviation from current gait speed data was used. Value of 0.16m/sec offers the best available estimate to date for MCID for gait speed in a sub-acute stroke population. • Based on the standard deviations from gait speed data, and allowing for a 25% attrition rate, a total of 173 participants would be needed in a follow-on, three armed, randomised controlled trial.

5.3 Section 2: Preliminary analysis of results

5.3.1 Introduction

A similar pattern was seen across outcome measures; there was a statistically significant improvement in both groups following the intervention which was maintained at six week follow-up. The greatest positive changes in outcomes related to lower limb motor control, balance, gait and mobility were most often seen immediately following the two week intervention phase rather than during the four week follow-up phase. Analysis of the preliminary data showed no statistically significant improvement in the FES and Gait Training group compared with the Gait Training only group.

A note of caution is required here. The primary focus of the study was on feasibility rather that effectiveness and therefore the study was not powered to detect clinically significant differences. Statistical analysis was carried out only to make a preliminary examination of the data and not to address hypotheses about efficacy. An adequately powered randomised controlled trial is needed to conclusively answer questions about the efficacy of FES integrated with gait training.

As the current study had no control group receiving usual care only, the study is unable to differentiate spontaneous improvement from a specific benefit of the gait training intervention either with or without FES. As the greatest change often coincided with the intervention period it could be argued that the interventions showed a positive effect. However, a steeper recovery rate curve has been found in the first 12 weeks following stroke (Tilling et al., 2001). With this in mind greater improvements earlier on in the patient's recovery are to be expected and may not be related to a specific intervention. A control group receiving routine care only is needed to conclusively establish a relationship between the addition of a gait training intervention and recovery.

This section will discuss the preliminary results in turn including, gait related measures, Modified Ashworth, Motricity Index, Rivermead Mobility Index, Berg Balance and the Stroke Impact Scale. Findings will be compared with that of other studies both in terms of within group comparisons and between group comparisons.

5.3.2 Gait related measures; changes over time

Measures related to gait speed and quality showed similar trends in relation to changes between baseline and week two, week two and week six and baseline and week six. Both gait speed and quality significantly improved following the intervention (week two) and during the follow-up period (between weeks two and six). Results showed that the rate of improvement in both outcome measures was greatest following the two week intervention phase compared with the follow-up phase. The minimal clinically important difference in gait speed has been documented to be 0.16m/sec. Changes in speed superseded this value immediately following the gait training intervention (average change 0.22m/sec) but not during the follow-up phase (average change 0.12m/sec). A question is therefore raised as to the extent to which walking ability improved through processes of natural recovery, routine care or the gait training intervention with or without FES.

Animal studies have provided insights related to the biological processes of spontaneous recovery. It has been documented that in the days following stroke to the first few weeks the brain is primed to initiate repair and internal repair-related events at a molecular and cellular level reach their peak such as structural changes in axons, dendrites and synapses and increased activation and migration of neural stems (Cramer, 2008). From a systems level, brain mapping studies in humans have shown spontaneous recovery following stroke is supported by compensatory reorganisation of the central nervous system including, increased activation of secondary areas connected to injured zones of the brain and reduced lateralised activation. These changes are time dependent and have been shown to be increasingly seen in the early weeks following stroke and declining thereafter (Cramer, 2008, Ward et al., 2003). In summary, spontaneous recovery largely occurs in the acute and sub-acute phases of stroke and it is biologically plausible that the improvements seen in gait, particularly in the initial stages, were related to natural endogenous repair mechanisms within the central nervous system.

Indeed recovery rates specifically related to walking ability have been directly linked to time post stroke (Jørgensen et al., 1995, Kwakkel et al., 2006). A large population based study showed that for 80% of patients receiving routine rehabilitation, maximal functional walking ability measured by Barthel Index sub-scores was achieved within the first 35 days following stroke (Jørgensen et al., 1995). Making comparisons with the current study is difficult owing to the fact that Jorgensen et al. based functional walking ability on a crude assessment giving only

three options; unable to walk, requiring assistance and independent walking. This measure may not have been sensitive enough to detect more subtle but clinically important changes in walking ability achieved outside of the 35 day time frame. It is also unclear as to the intensity of therapy participants received as part of their routine rehabilitation.

It also cannot be ruled out that improvements seen in walking ability in the current study were attributable to routine rehabilitation. The data gained from the routine care charts was insufficient to enable a clear description of the content or intensity of standard therapy, or indeed whether participants received any other therapy in addition to the study intervention and it is therefore difficult to draw conclusions as to its potential impact. Randomised controlled studies have shown significant improvements in gait speed and quality in acute and sub-acute stroke populations with the addition of a more intensive task specific gait training programme compared with routine care alone (Kuys et al., 2011, Richards et al., 1993). However, small sample sizes and heterogeneous treatments limit the impact of the results and further research into the dose-response relationship focussing on task specific training to improve walking quality is needed. Nevertheless the evidence does fit with meta-analyses to show that walking ability and activities of daily living after stroke are improved with increased time spent on gait related activities (Kwakkel et al., 2004, Veerbeek et al., 2011). The current study involved only eight additional hours and whether this was enough to have a significant impact on gait related measures beyond that of routine care remains unclear.

In order to conclusively distinguish the relative impact of routine care and gait training interventions on walking ability in a sub-acute stroke population, a control group is needed. A follow-on study should therefore randomly allocate participants into three groups; routine care only, routine care with additional gait training and routine care with gait training integrated with FES. This will inform the justification of whether to invest additional resources to support more intensive gait training in addition to what is currently being provided as routine.

5.3.3 Gait related measures; differences between groups

There was a trend for gait speed to be marginally faster in the FES and gait training group with a mean difference in speed of 0.04m/sec between baseline and week 2, 0.03m/sec between weeks 2-6 and 0.07m/sec between baseline and week 6. However, preliminary statistical analysis showed that this difference between the groups both in terms of gait speed and quality did not reach significance. This was not surprising since the study was not adequately powered to detect significant differences. Indeed, other feasibility trials with small sample sizes have shown similar findings in their preliminary analyses (Kunkel et al., 2013, Salisbury et al., 2013, Wilkinson et al., 2014).

A recently published meta-analysis investigating whether FES was more effective in improving activity than training alone showed that FES had a small effect on walking speed, which was calculated to be a mean difference of 0.08m/sec (95% CI 0.02-0.15) in favour of FES (Howlett et al., 2015). Average differences within the current study fall within the 95% confidence intervals seen in the meta-analysis and the difference seen from baseline to week six is close to the documented pooled mean difference.

However, direct comparisons with the meta-analysis data should be made with caution. Firstly, data was pooled from eight clinical trials, only four of these related specifically to sub-acute patients (Bogataj et al., 1995, Kojovic et al., 2009, Lee et al., 2013, Ng et al., 2008), the rest were taken from chronic stroke studies (Burridge et al., 1997b, Cheng et al., 2010, Peurala et al., 2005, Sabut et al., 2010). Secondly, sample sizes in the majority of these studies was low with an average of 25 participants per trial. It is therefore possible that small trial bias may lead to an overestimate of the true effect. Thirdly, three of the nine trials were assessed to be low quality trials (PEDro score <6) failing to randomly allocate participants, conceal allocation or include methods for blinded assessment. Finally, there was a great deal of heterogeneity in terms of treatment methods with FES being integrated with a variety of training approaches ranging from over-ground gait training (Bogataj et al., 1995, Burridge et al., 1997b, Kojovic et al., 2009, Sabut et al., 2010) , rocker board training (Cheng et al., 2010), body weight support treadmill training (Lee et al., 2013, Peurala et al., 2005) and use of an electromechanical gait trainer (Ng et al., 2008).

Further research from high quality, adequately powered randomised controlled trials are needed to establish the efficacy of FES combined with gait training on walking speed and quality in a sub-acute stroke population. Future researchers would then be able to pool the

data from such trials and carry out further subgroup analysis to establish the effect of heterogeneity in treatment approach on outcomes.

5.3.4 Secondary outcomes

5.3.4.1 Modified Ashworth Scale

There were no trends towards an increase or decrease in muscle tone following either intervention, as measured using the Modified Ashworth Scale. Numerically, the groups were relatively comparable. There are contradictory reports about the effect of electrical stimulation on spasticity with some authors arguing a positive effect (Bakhtiary and Fatemy, 2008, Malezic et al., 1994, Sabut et al., 2010, Yan et al., 2005), and others pointing towards no significant effect (Hines et al., 1993, Yamaguchi et al., 2012). Studies investigating electrical stimulation specifically to tibialis anterior in combination with physiotherapy intervention have shown a significant reduction of spasticity in the plantar flexors (Bakhtiary and Fatemy, 2008, Sabut et al., 2010, Yan et al., 2005) compared to physiotherapy without FES. This trend was not seen in the current study as both groups were equal in terms of numbers of participants showing a change in plantar flexor spasticity post treatment and at follow-up.

The lack of consistency in research findings related to the impact of FES on spasticity may in part relate to the difficulty in measuring spasticity. The Modified Ashworth is widely used in research although highly criticised. Inter-rater reliability has been documented as low to moderate (Ansari et al., 2006, Bhimani et al., 2011) and the construct validity has been questioned (Pandyan et al., 2003). More recently a Modified Modified Ashworth Scale has been developed to improve the reliability of the measure (Ansari et al., 2009). Early testing of this version has yielded promising results demonstrating improved inter-rater reliability in patients post stroke (Ansari et al., 2009) and intra-rater reliability as a measure of lower limb spasticity (Ghotbi et al., 2011) compared with the Modified Ashworth Scale. Further research is needed to establish its use in a sub-acute stroke population and its correlation with other lab based measures of spasticity. However, if given the choice between the use of the Modified Ashworth and the Modified Modified Ashworth, a follow on study should consider the Modified Modified Ashworth as a more reliable measure.

5.3.4.2 Motricity Index

A significant improvement was seen in lower limb and trunk Motricity Index scores immediately following the intervention compared with baseline in both groups, but not in the follow-up phase (weeks two to six). Furthermore, significant improvements were seen in upper limb, lower limb and trunk Motricity Index scores in both groups from base line assessment to week six. This trend for significant improvement is in keeping with gait speed and quality data and shows that the greatest recovery rates for lower limb and trunk motor function occurred within the initial two week intervention phase. As previously discussed, whether greater improvements during this phase were due to the intervention or due to natural non-linear logarithmic recovery patterns remains unclear (Kwakkel et al., 2006), once more highlighting the need for a control group receiving usual care only.

Results also showed that there were no statistically significant differences in Motricity Index between the groups. Tong et al. (2006b) also investigated the impact of intensive gait training with and without FES on changes in lower limb Motricity Index Scores. Their study, involving 50 sub-acute stroke patients compared three groups; intensive over-ground gait training, electromechanical gait training and electromechanical training with FES. Authors found statistically significant improvements in lower limb Motricity Index Scores in favour of the Electromechanical and FES gait training, compared with the conventional over-ground training at a matched intensity ($p = 0.011$). However, no significant differences were found between the two gait trainer groups or between the electromechanical training and over-ground training groups. Authors indicated that Electromechanical training with FES may have hastened the improvement of muscle strength more effectively than electromechanical training alone or conventional gait training. However, they concluded that a larger sample size may be needed to show a significant difference between the two treatment groups and the impact of the FES component. Furthermore, it should be noted that the control group was significantly older than the other groups and age may have been a confounding variable causing a Type I error.

Further research is needed by way of high quality adequately powered randomised controlled trials to firmly establish the impact of gait training integrated with FES, on motor control at an impairment level. Furthermore, future research should investigate the impact of gait training (with and without FES) on the relationship between changes in motor impairment, neurophysiological adaptions and functional improvement. This information may help inform current knowledge about the role such gait training interventions play in different mechanisms of recovery including restitution of normal motor control as well as applied compensation.

5.3.4.3 Rivermead Mobility Index

Results showed that there was a significant improvement in Rivermead Mobility Index immediately following the intervention phase that continued in the follow-up phase (between weeks two and six). This is in keeping with the pattern of recovery seen with gait speed and quality which is not surprising since the Rivermead Mobility Index has been shown to be significantly correlated with gait speed and walking dependency level scores (Collen et al., 1991).

Thresholds for minimal clinically important differences in Rivermead Mobility Scores are still unknown, however research has shown that a difference of greater than 2.2 indicates a real improvement accounting for measurement errors (Chen et al., 2007). A mean difference of 2.2 was exceeded during the intervention phase (mean difference between baseline and week two was 2.53) but not in the follow-up phase (mean difference between week two and week six was 1.6), despite the change reaching clinical significance. This highlights that the rate of recovery in terms of performance of mobility tasks may have been more meaningful during the two week intervention phase.

There was no significant difference in the change in Rivermead Mobility Index between the Gait Training only group and the Gait Training and FES group at any of the assessment points. Wilkinson et al. (2014) also used the Rivermead Mobility Index to measure mobility related activity pre and post gait training with FES in a sub-acute stroke population. Authors found similar results in terms of within group improvements immediately following gait training and gait training with FES but no significant differences in Rivermead Mobility scores between groups. However, the study had a small sample size (n=20) and was not adequately powered to detect significant differences. Based on the data and accounting for 15% attrition, authors calculated that a sample size of 144 per group would be required for a multicentre follow-on study.

5.3.4.4 Berg Balance Scale

A significant improvement was seen in the Berg Balance Score immediately following the gait training intervention but not in the follow-up phase. This finding is consistent with other studies that have shown significant improvements in Berg Balance scores are associated with rehabilitation following acute stroke (Garland et al., 2003). The minimum clinically meaningful change in Berg Balance Score has been documented to be six (Stevenson, 2001). The current study showed this level was very nearly achieved following the two week intervention (change of 5.9 from baseline to week two) and exceeded during the six week study phase (change of 7.67 from baseline to week six).

Results showed that there was no statistically significant difference in Berg Balance Scores between the two groups. Other studies involving multichannel FES used in combination with electromechanical gait training devices showed similar results although they too had relatively small sample sizes (Ng et al., 2008, Tong et al., 2006b). Conversely in a more recent study, Tan et al. (2014) found that Berg Balance scores were significantly improved following application of four channel FES in side lying to mimic normal gait patterns compared with placebo treatment. In the absence of documented power calculations it is unclear whether these studies were sufficiently powered to be able to detect significant differences. Other methodological flaws include high dropout rates and lack of assessor blinding to the treatment group thereby increasing the risk of bias. There is therefore still a lack of data from high quality randomised controlled trials as to whether FES integrated with gait training can positively influence Berg Balance scores and further research from larger studies are needed.

5.3.4.5 Stroke Impact Scale

Significant improvements were seen in multiple domains of the Stroke Impact Scale from baseline to week six follow-up including physical, activities of daily living, mobility and overall recovery. Significant differences in physical, mobility and recovery domains were seen immediately following the intervention phase however a significant difference during the follow-up phase was only found in the mobility subsection. This is in keeping with the pattern of change seen with other measures and highlights a potential correlation between the Mobility subsection of the Stroke Impact Scale and the Rivermead Mobility Score, which also showed a significant improvement during both the intervention phase and the follow-up phase.

A change of between 10 and 15 points has been shown to indicate a clinical meaningful difference (Duncan et al., 1999), which was achieved during the intervention phase in Mobility (change of 11.55) and Recovery (change of 13.46) subsections and from baseline to week six in Strength (change of 12.92), Mobility (change of 20.01) and Recovery (change of 16.47). It has been documented that the largest differences in Stroke Impact Scale scores are seen in the initial stages following stroke (one to three months) and that for milder strokes, recovery rated by the Stroke Impact Scale, tends to level off after 3 months (Duncan et al., 1999). Therefore, a greater rate of change during the earlier intervention phase may be attributable to routine care and natural recovery. Equally, the task specific nature of the gait training programme may also have been responsible for the improvements seen. The inclusion of a control group receiving routine care only in a future trial may help to identify the impact of a task specific training programme on participants self-rated perceptions of various aspects of their recovery. In addition, a future trial may gain some useful information from a qualitative element to establish participant perceptions of the impact of gait training with and without FES on their recovery.

Interestingly a slight reduction in the Participation subsection was seen at two weeks compared with baseline. Other authors have commented on the positive and negative changes seen in the Stroke Impact Scale ratings in the sub-acute stages of stroke and it has been documented that in up to 20% of participants ratings of Participation can get worse with time in the sub-acute phase post stroke (Guidetti et al., 2014). Indeed results related to the effects of rehabilitation interventions on participation measures have shown mixed results (Flansbjer et al., 2012, Pundik et al., 2012). A lack of consistency in changes in participation measures in

sub-acute rehabilitation has been documented to occur due to a number of reasons (Pundik et al., 2012). Firstly, it is likely that only very large motor-function gains are sufficient to produce changes in measures of life-role participation. The modest effect sizes seen in improved gait speeds and Wisconsin Gait Scores may not have been enough to have translated to life role participation measures. Secondly, at the beginning of the study, participants may have been more optimistic about their recovery, biasing subjective responses toward a high score. However, as time goes on, if functional recovery has not returned as expected, then perception of life-role participation may have been negatively affected leading to lower scores. Further qualitative research is needed to explore perceptions of life role participation in further depth, particularly in a sub-acute stroke population, in order to understand how interventions can help to maximise life role participation in the early stages of stroke.

There were no significant differences in Stroke Impact Scale scores between groups with the exception of hand function. A significantly greater improvement was seen in the hand function domain of the Stroke Impact Scale in the Gait Training group from week two to week six compared with the Gait Training and FES group. It is felt that this may be a false positive since neither gait training intervention focussed on improving hand function. The error may have occurred through multiple statistical testing. There are a number of statistical techniques that can correct multiple testing problems and a future trial should seek the support of statistician to consider the merits of additional analysis to account for potential errors. It is also possible, that in this small cohort, the Gait Training only group by chance demonstrated greater recovery of the upper limb. A larger sample size may account for this in a follow-on RCT.

5.3.4.6 Summary of section 2: preliminary analysis of the results

This section has discussed the preliminary analysis of results related to the outcome measures. Within group changes in outcome measures between assessment points have been explored. A similar pattern of improvement was seen across most measures showing greatest rates of recovery directly following the two week intervention phase (as seen with gait speed, Wisconsin Gait Scale, Motricity Index, Rivermead Mobility Index, Berg Balance and Physical, Mobility and Recovery aspects of the Stroke Impact scale). Improvements during this period exceeded (Gait Speed, Rivermead Mobility Index and Mobility and Recovery subsections of the Stroke Impact Scale) or were close to reaching (Berg Balance Scale) thresholds for meaningful change.

This study has proposed that an increase in within group improvements seen over this two week period may have been related to a number of factors. Firstly it has been shown that biological processes of spontaneous recovery are time dependent and that the increased rate of recovery seen in the earlier stages of stroke may be related to the natural endogenous repair mechanisms within the central nervous system. Secondly, the gait training programme (either with FES or without it) may have enhanced recovery. This is certainly consistent with literature showing that the more time that is spent on gait training, the greater the improvement. To conclusively distinguish the relative impact of routine care and additional gait training a control group receiving routine care only is required and is highly recommended for a follow-on larger scale trial.

In addition, further research is needed to explore the mechanisms of recovery. In particular, the impact of gait training on the relationship between changes in motor impairment, neurophysiological adaptations and functional improvement. This may help to inform current knowledge about the role interventions play in different mechanisms of recovery; in particular restitution of normal motor control at a body function level and applied compensation. Furthermore, this study has found that participation in life roles for many participants did not follow the same pattern of recovery as seen with other body function and activity based measures, a phenomenon seen by other studies. Further research is needed to explore perceptions of life role participation in further depth, particularly in a sub-acute stroke population, in order to understand how interventions can help to maximise life role participation in the early stages of stroke.

Comparisons between gait training and gait training and FES have also been discussed. No significant differences were found between groups, which is not surprising since the study was not adequately powered for efficacy hypothesis testing. This finding is consistent with other small sample size feasibility trials exploring the use of FES in a sub-acute stroke population. A significant difference was found in the hand function subsection of the Stroke Impact Scale in favour of the gait training group. Since hand function was not directly addressed by either gait training interventions it seems unlikely that the group allocation was attributable to the differences seen here.

5.4 Section 3: Critique of this thesis

5.4.1 Introduction

The current study was designed in line with the Medical Research Council guidelines for the evaluation of complex interventions (Craig et al., 2011) stating that a series of studies may be required to refine the research design before a full scale trial is carried out. The aims of the current study were therefore to evaluate the feasibility of the proposed methodology rather than to establish the efficacy of FES integrated with gait training. As such, the emphasis of ensuring the reduction of errors such as bias, confounding and chance was not as predominant as it would be for a follow-on randomised controlled trial. For example a follow-on trial would ensure concealed computerised randomisation and investigators assessing outcome would be fully blinded to intervention group. Furthermore, the trial would be adequately powered to identify any statistically significant differences between the groups. These measures were not necessary to meet the feasibility objectives of the current trial.

There were however several limitations of the current trial which impacted on the extent to which the feasibility objectives could be met. These included paucity in data related to the reasons for non-enrolment, potential inaccuracies in methods for recording the content and intensity of the intervention, and limited information about the content and intensity of routine care during the length of the trial. In addition, the chosen duration of the experimental and follow-up warrant further discussion.

5.4.2 Lack of information about reasons for exclusion

An objective of the feasibility study was to determine the proportion of eligible patients admitted to the three recruitment sites. As described earlier, the proportion of stroke patients recruited from the total number of stroke admissions was lower than expected. Treating therapists were asked to screen all admissions but were not asked to document reasons for exclusion. Therefore it is not possible to draw any conclusions as to why recruitment rates were so low, limiting the learning that could be carried forward for more successful recruitment in a follow on trial. As previously discussed, one explanation may relate to the use of clinical staff to identify patients; who are managing competing priorities and may not have the time and motivation to devote to recruitment processes (Bell et al., 2008, Fitzgerald and Delitto, 2001). A potential solution may be to invest dedicated researcher time to screening all new admissions while keeping some non-identifiable data related to the reasons for exclusion.

Other authors have documented recruitment success through a 'watchful waiting' approach (Tyson et al., 2015) whereby initially unsuitable patients are tracked to see if their condition changes making them eligible at a later date. This would be particularly appropriate for patients who are medically unstable, unable to stand or follow simple commands in the early stages but improve as time goes by.

5.4.3 Methods for recording content and intensity of gait training

Another objective was to describe the variation in the intensity and content of the intervention delivered in order to determine the extent to which these elements can be standardised without the loss of an individualised, patient centred approach. Content and intensity of gait training either with or without FES was completed by the researcher using a stop watch to monitor and record the content of the session, number of repetitions completed and the duration of each component of the session (see Appendix 9 and 10).

This method poses some limitations. Firstly, it may have potentially distracted the researcher for carrying out the intervention. The researcher used rest periods as an opportunity to write down data related to performance however it cannot be ruled out that rest periods were longer or more frequent because of this. There is also potential for errors in manual repetition counting. Furthermore, it was not feasible for the researcher to count repetitions for all gait training components (for example number of steps when walking). Monitoring intensity of the gait training programme is an important part of the trial and is considered a methodological strength of the current study. It allows for comparisons to be made between groups with regards to training dose and between intended versus actual training intensity.

A future trial should seek to gain this information using more reliable and consistent approaches. Other studies have used a direct observation of sessions by an independent researcher (Host et al., 2014), hand held counters (Scrivener et al., 2012), video –taping the sessions and analysing the sessions at a later date (Host et al., 2014, Kaur et al., 2012) or using portable activity recording systems (Moore et al., 2010). Indeed a combination of these methods may be most appropriate. With regards to counting repetitions, a standardised set of definitions is indicated. This may include for example each meter of walking may count as one repetition (Scrivener et al., 2012). Finally, further standardisation of the content of the gait training intervention and target intensities may allow for closer and more reliable monitoring (see Appendix 37).

5.4.4 Limited information about content and intensity of routine care

Routine care during the two week intervention phase was monitored by asking treating therapists to complete routine therapy paperwork (see Appendix 7). As discussed, responses from treating therapists related to the content and intensity of routine care were fewer than expected. Participant participation in routine care was not directly tracked and therefore is it not known whether participants were receiving therapy, and the therapists were not completing the relevant paperwork or whether participants in the trial were not receiving therapy during the intervention period. In order to meet the inclusion criteria participants needed to demonstrate a rehabilitation need for targeted gait training and therefore continued rehabilitation would have been indicated in this group. In a future trial there should be investment research resources to ensure that routine therapy is monitored by the research team, through closer working and more frequent contact with the treating therapists. It is also recommended that monitoring and recording of routine care extends to the follow-up phase. This will enable a more robust description of the content and intensity of routine therapy and its role as a potentially confounding variable at each assessment point accounted for.

5.4.5 Duration of experimental intervention and follow-up phase

The experimental intervention period lasted only two weeks. This time frame was chosen based on experience of what would be practical in current practice and in consideration of the time resource limitations of the single researcher. It could be argued that the intervention period should be prolonged to four weeks, in line with other sub-acute FES gait training trials (Kojovic et al., 2009, Lee et al., 2013, Ng et al., 2008, Tong et al., 2006b). In addition, treatment frequency limits should be set in line with the most recent guidelines for best practice which has now been documented to be a minimum of 45 minutes each day, five days of the week (RCP, 2012). This would then equate to participants receiving a total of 15 additional hours of gait training on top of their routine rehabilitation rather than eight received within the current study. This would be closer to the documented results of a meta-analysis which showed that augmented practice of at least 16 hours is needed to gain a mean improvement in activities of daily living of 5% in a sub-acute stroke population (Kwakkel et al., 2004).

However, the meta-analysis was based on heterogeneous trials in terms of the focus and content of rehabilitation interventions, making direct comparisons with the current study difficult. A more recently published meta-analysis specifically investigating the effects of augmented lower limb training to improve walking ability in the first six weeks after stroke, did

not show in a sensitivity analysis that a minimal treatment contrast of 16 hours is sufficient to achieve significant effects on walking ability (Veerbeek et al., 2011). Studies included in the analysis ranged from 4.5 – 50 hours of additional therapy time and a positive trend was found favouring higher treatment contrasts in terms of walking speed and ability speed. In the absence of definitive evidence to establish a minimal augmented contrast threshold, it appears that a compromise needs to be made between high intensity therapy and what is clinically practicable within current NHS resources. In preparation for a randomised controlled trial investigating the efficacy of FES integrated with gait training, a preliminary study comparing different doses of training (for example eight hours compared with 15) may provide useful information about optimal training intensity. It would also provide an opportunity to test how well a greater intensity of therapy is tolerated by participants reflected by their feedback and attrition rates.

The follow-up phase within the current study was limited to six weeks following enrolment (four weeks post completion of the gait training programme). This relatively short follow-up phase was chosen for pragmatic reasons due to the time constraints of the researcher. It is recommended that a follow-on study should include a longer follow-up phase (minimum of six months) to truly establish the longer term effects of the intervention.

5.4.6 Summary of Section 3: Critique of this thesis

Several limitations of the current study have been discussed. These have included inability to fully explore low recruitment rates due to paucity of information related to reasons for exclusion. Potential solutions have been discussed, including additional research resource allocated to new admission screening and watchful waiting. Although the consideration of the intensity of the gait training programme was considered to be a strength of the study, the methods used to gain this information may have posed some limitations. Learning has been drawn from other studies to account for potential errors including use of an independent observer, analysing video at a later date or the use of activity monitoring technology to monitor and time spent engaged in gait training components and repetitions completed. Limited information was gained about the content and intensity of routine care and a follow-on trial should invest resource in closer working with treating therapists to ensure these records are completed and returned for analysis. The duration of the treatment intervention and follow-up phase in the current trial was relatively short in comparison with other studies and suggestions for increasing the intervention duration, frequency and length of follow-up

have been made. Further investigation of optimal treatment dose off augmented gait training is required.

5.5 Section 4: Summary of learning for a subsequent randomised controlled trial and suggested areas for further research

Key findings of the current trial in relation to the study's feasibility objectives and associated recommendations to adapt the current methodology have been summarised in earlier sections (see Table 25). However, conducting this trial has resulted in additional learning related to procedural aspects of the study that were not specifically identified with the initial study's objectives. These have been discussed during the course of this chapter and have been summarised in Table 26.

Analysis and consideration of the results from the current study also identified gaps in the current knowledge base that need to be considered by further research projects. Future studies should investigate the impact of gait training (with and without FES) on the relationship between changes in motor impairment, neurophysiological adaptions and functional improvement. This information may help inform current knowledge about the role such gait training interventions play in different mechanisms of recovery, including restitution of normal motor control as well as applied compensation. In addition, qualitative research is needed to explore perceptions of life role participation in further depth, particularly in a sub-acute stroke population, in order to understand how interventions can help to maximise life role participation in the early stages of stroke.

Table 26: Additional learning points outside of feasibility objectives and associated recommendations for a follow-on RCT

	Additional findings of the study	Recommendations for a follow-on RCT
Stroke Type	• Study sample had fewer patients with POCI and Haemorrhagic Strokes; likely to have occurred due to the small sample size through chance • Study sample contained more left sided strokes than right; may have occurred through chance but unequal numbers between groups may impact on outcome measures	• Larger sample size as reflected by sample size calculation • Monitoring and analysis of stroke type to draw conclusions as to whether the results of the study are generalisable to the wider stroke population • Monitor the effects of stroke lateralisation by comparing stroke sides between groups
Intervention Intensity and Content	• Difficulty in gaining comprehensive data on number of repetitions completed for all task based activities • Manual methods of researcher leading intervention session as well as simultaneously recording content and repetitions was distracting and has potential for sources of error	• Gain more complete record of intervention content and intensity through one or a combination of the following methods: o direct observation of sessions by an independent researcher o hand held counters o video –taping the sessions and analysing the sessions at a later date o using portable activity recording systems. • With regards to counting repetitions, a standardised set of definitions is indicated. • Further standardisation of the content of the gait training may enable more accurate and efficient record keeping
Intervention duration	• Inconclusive evidence about optimal augmented therapy dose for improvement in walking ability and speed. Current study carried out eight sessions over a two week duration which may not have been enough to yield optimal effect sizes or lead to a significant difference in improvement between groups	• In preparation for a RCT investigating the efficacy of FES integrated with gait training, a preliminary study comparing different dose's of training may provide useful information about optimal training intensity. Also provide an opportunity to test how well a greater intensity of therapy is tolerated by participants.
Control, group	• No control group receiving routine care only; therefore unable to attribute improvements in outcome measures to gait training intervention (either with FES or without it)	• Follow on trial to include three groups; usual care (control), gait training and gait training and FES. Allow for conclusions to be drawn as to the relative effect of additional gait training.
Documentation of routine care	• Low number of responses related to routine care records. • In view of recent increase in investment in therapy resource a future trial should expect participants to be receiving regular routine care in addition to the study intervention	• Routine therapy monitored by the research team through closer working and more frequent contact with the treating therapists • Monitoring and recording of routine care extends to the follow-up phase, enabling a more robust description of the content and intensity of routine therapy and its role as a potentially confounding variable at each assessment point
Statistical analysis	• Potential for a false positive result found if carrying out comparative statistical tests on multiple outcome measures	• Consultation with statistician to consider statistical techniques that correct for multiple testing problems
Follow-up phase	• Follow-up phase within the current study was limited to six weeks following enrolment; chosen for pragmatic reasons due to the time constraints of the researcher	• Consider a longer follow-up phase (minimum of six months) to truly establish the longer term effects of the intervention

5.6 Section 5: Thesis conclusion

The aim of the current study, to establish whether it is feasible to conduct a two week gait training programme combined with FES (targeted to glutei and/or ankle dorsiflexor and evertor muscles) for people with a sub-acute stroke and reduced hip extensor and/or dorsiflexor activity, was achieved. The answer to the research question is yes it is feasible, although moderate adaptations to the research methodology are required to ensure the success of a follow-on RCT.

A systematic examination of the literature revealed that few authors have explored whether FES of the lower limb, incorporated into a clinically practicable gait training programme, leads to improvements in gait parameters in a sub-acute stroke population using a randomised controlled study design. Furthermore, evidence has shown that multiple channels are more effective than single channel stimulation yet, to our knowledge, no research has been published related to the use of a clinician operable, dual channel device, in task based over-ground gait training in sub-acute stroke. This study therefore offers a unique contribution to the current evidence base as to the feasibility of such an intervention in this group of patients with stroke.

This feasibility study has demonstrated that adaptations to recruitment strategies and inclusion criteria are warranted to ensure an appropriate sample size is achieved within a reasonable timeframe. Follow-up and retention rates were encouraging as was participant and staff feedback related to the acceptability of the assessment and intervention procedures. Further qualitative research may add additional information to participant perceptions of the value added by the intervention and in particular the extent to which it has affected their ability to participate in life roles.

Addressing the limitations of other trials, a major strength of the current study has been to consider and describe in depth the variation of content and intensity of the gait training programme between individuals and groups; including participant active time, numbers of repetitions and time spent on each component of the programme. Whilst it has been acknowledged that further standardisation of the programme and data collection methods around training intensity are warranted, this research highlights that training intensity is more complex than session duration and frequency alone. Recommendations have been made as to ways in which to standardise content and various elements of intensity whilst maintaining an individualised approach.

All outcomes were completed at each assessment point indicating that they were well tolerated within clinical/home settings. Having said this, several additional or replacement measures may further enhance ease of completion and reliability in a follow-on RCT. Finally, the data gained from the current study has informed a power calculation which will help to ensure a future trial is adequately powered to detect statistical differences.

In summary, subject to a number of methodological modifications, the research protocol adopted by the current trial, poses a feasible approach to efficacy testing of a novel and clinically practical gait training intervention. Based on the standard deviations from gait speed data, and allowing for a 25% attrition rate, a total of 173 participants would be needed in a follow-on, three armed, randomised controlled trial.

6. Appendices

Appendix 1: Search terms for literature review

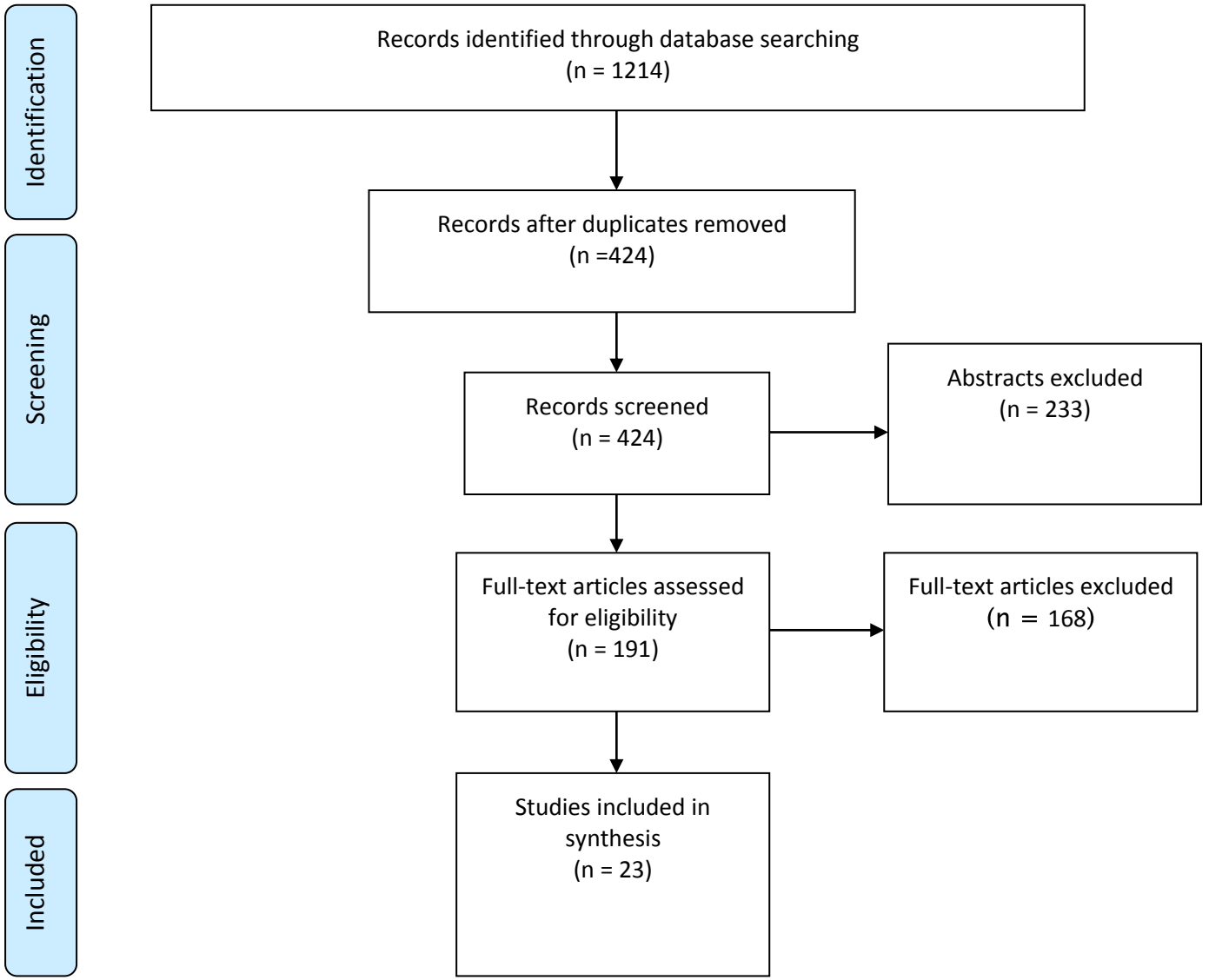
Item No.	Search Term
1	Stroke (cerebrovascular accident)
2	Hemiplegia
3	(hemipar* or hemipleg*)
4	2 or 3
5	1 or 4
6	Functional electrical stimulation
7	Electrostimulation
8	Electric stimulation
9	6 or 7 or 8
10	5 and 9
11	Gait
12	Walk*
13	Leg
14	Lower limb
15	11 or 12 or 13 or 14
16	15 and 10

**Used to perform a multiple character wildcard search for example hemipar* can be used to search for hemiparesis and hemiparetic*

Appendix 2: Literature review inclusion and exclusion criteria

Facet	Inclusion	Exclusion
Type of study	• Published and peer reviewed • Primary source rather than a review	• Theses, conference proceedings, reports, comments, letters, guidelines, single case studies, reviews.
Population	• Diagnosis of stroke (according to WHO definition) • Acute and sub-acute stroke population (less than 6 months post stroke onset)	• Non stroke conditions including spinal cord injury, Parkinson's disease, cerebral palsy, cardiac • Chronic stroke (over 6 months since onset of stroke)
Intervention	• Functional electrical stimulation • Surface stimulation • Peripheral stimulation • Electrical stimulation targeted to improve walking ability (see below)	• Electrical stimulation that does not directly produce a muscle contraction (TENS, Acupressure, Vibratory stimulation) • Implanted devices • Transcranial (TMS), direct current stimulation and brain computer interface • Direct spinal cord stimulation • Electrical stimulation targeted to solely improve upper limb function or for assessment purposes (used for analysis of H-Reflex) • Integrated with another treatment modality other than gait training (for example Botulinum Toxin Injections). Unable to extrapolate effects of FES from other interventions.
Outcomes	• Walking ability (including gait kinetic and kinematics, parameters including speed and distance, measures of independence with gait) • Walking ability measured without FES in situ (training/carryover effect)	• Measures of impairment, activity and participation related solely to the upper limbs • Walking ability only measured with FES in situ (orthotic effect only)
Other	• English language	• Not translated to English

Appendix 3: Flow diagram for systematic search of literature



Appendix 4: Participant information sheet

UNIVERSITY OF Southampton
School of Health Sciences

Participant Information Sheet

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

The use of Functional Electrical Stimulation combined with a gait training programme to improve quality of gait in sub-acute stroke patients.

Researcher: Anna Gould **Ethics number: 10/H0102/38**

What is the research about?
I am a senior physiotherapist interested in therapy approaches to improve walking ability early after stroke. The purpose of the study is to investigate the feasibility of using functional electrical stimulation in combination with an intensive walking training programme in patients who have recently had a stroke. If the study shows beneficial results, the information obtained will be used to plan further research.

Why have I been chosen?
You have been chosen as potentially suitable for this study because you have been identified by your therapist as having problems with your walking. If you fit the criteria for the trial you will be offered the opportunity to take part.

What is Functional Electrical Stimulation (FES)?
It is the use of small electrical impulses to activate paralysed muscles and so produce useful movement which is triggered to assist a function such as walking when applied to the leg. The electrical impulses work by exciting the nerves leading to the muscles. Self-adhesive patches (electrodes) are placed on the skin close to the nerve supplying the muscle. Leads connect the electrodes to a stimulator that produces the impulses. Electrical stimulation feels like pins and needles; most people quickly become used to the sensation.

What will happen to me if I take part?
You will first be assessed for suitability for the study by a research physiotherapist who will explain the study to you. If you are a suitable candidate for the research you will given five days to make a decision whether you wish to be involved with the project or not. If you require further information you will be

able to speak to the research physiotherapist at any time by telephone during this period.

If you do decide to take part you will be asked to sign a consent form. Your GP will be sent a letter to inform him/her that you are involved in the study. You will then be allocated into one of two groups; one group receives an intensive walking training programme and the other group receives an intensive walking training programme including the use of functional electrical stimulation. To try and make sure the groups are the same to start with, each participant is put into a group at random. If you consent to take part in the study you will be given an envelope to open before the baseline assessments are completed. The envelope will contain the details of the group you are in, which will have been randomly (by chance) allocated by an independent scientist. The researcher has no control over which group you are allocated to.

After your group has been allocated at the first session you will be asked to complete the following tests:

- Mini Mental State Test which is a short questionnaire which assesses memory and thinking.
- Star Cancellation Test which tests your visual awareness of both sides of your body.
- Rivermead Mobility Index which tests how mobile you are.
- Motricity Index which tests how well you can move your arms, legs and trunk.

The second session will follow within the next 5 days and you will be asked to complete the following assessments:

- Measurements will be taken to record the strength and stiffness (muscle tone) of the muscles in your arms and legs.
- Berg Balance test which measures your balance.
- Stroke Impact Scale which is a questionnaire to measure how you feel your stroke has impacted on your day to day life.
- Walking speed over 5 meters with assistance if required.
- Quality of walking pattern will be measured by taking video footage of you walking 5 meters. At a later date, the tape will then be shown to another therapist who will have no prior knowledge of your involvement in the study. This therapist will use a scoring system to measure the quality of your walking according to the video footage.

The first two sessions will take up to one and a half hours.

You will then be asked to take part in eight, one hour training sessions spread over the course of two weeks. These sessions will involve you taking part in a walking training programme helped by the research physiotherapist. Depending on which group you are in, this may also involve use of the functional electrical stimulation to produce useful movement in your leg. Training sessions will take place either in the hospital setting or in your own home depending on where you are at the time. The research physiotherapist will arrange sessions at a time convenient for yourself and your family.

At the end of the two week training period the assessments completed in the second session will be repeated. These assessments will be carried out within the hospital setting. You will then be followed up after a further four weeks and the assessments will be repeated again in the hospital setting. If you have been discharged home during this time, you will need to travel back into hospital for the assessments to be repeated. At the end of the trial you will also be given a questionnaire to evaluate your experiences of the gait training programme.

The table below summarises the total involvement in the study.

What is involved?	Where will it take place?	How long will it take?
1. Discussion with researcher and signing consent form	In Hospital	Up to an hour
2. First assessment session	In Hospital	Up to 45 minutes
3. Second assessment session	In Hospital	Up to 45 minutes
4. 2 week programme of intensive gait training (8 sessions over 2 weeks)	In hospital or in your own home (depending on where you are at the time)	Each session will last approximately 1 hour
5. Assessment session at the end of 2 week training period	In hospital	Up to an hour
6. Follow-up assessment session after a further 4 weeks	In hospital	Up to an hour
7. Completion of questionnaire	Can be carried out at your own leisure or at the follow-up assessment if you require help from the researcher.	15 to 30 minutes.

Will I have my travel expenses reimbursed?
You are entitled to claim travel expenses which will be reimbursed at 24 pence a mile up to a maximum of 100 miles for each return trip. Public transport fares may also be reimbursed. A claim form will be provided at the end of your treatment.

What are the possible disadvantages and risks of taking part?
There are no known side effects from using FES, but there are some minor risks.
The stimulation feels like pins and needles. Most people quickly become used to it, but it is possible that you may find the sensation too uncomfortable and you may decide not to use the stimulator. Similarly, turning the stimulation up too high may be uncomfortable, but not dangerous.

In some cases skin irritation can occur. The research therapist will monitor closely whether this is happening but if you notice a skin irritation following Electrical Stimulation please inform the research physiotherapist. Always remember to turn off the stimulator before you remove the electrodes to avoid the small possibility of minor discomfort.

Some people who have epilepsy can have an increase in symptoms in response to electrical stimulation. Electrical stimulation is also not recommended in pregnant women. It is unknown whether Functional Electrical Stimulation used during pregnancy will harm the unborn child. Pregnant women **must not** therefore take part in this project; neither should women who plan to become pregnant during the two week intervention period.

Women of childbearing age may be asked to take a pregnancy test before taking part, to exclude the possibility of pregnancy.

Are there any benefits in my taking part?
The training programme will be in addition to your routine therapy provided by the ward and or community therapists. Results of previous studies have shown that both task specific training and functional electrical stimulation may have positive effects on walking ability in the early phase of stroke.

What happens when the research project stops?
At the end of the two week intervention period use of the functional electrical stimulation devise will stop. In some cases, Functional Electrical Stimulation has been continued to be used on a more permanent basis to help improve walking ability on a day to day basis. This requires additional funding and an application will need to be made to your Primary Care Trust (PCT). This would be done by your GP on the recommendation of the researcher and/or treating physiotherapist. Your local PCT will then decide whether to approve further funding for functional electrical stimulation treatment. Currently this is done on a case by case basis and therefore is not always guaranteed. If the PCT do not approve further funding you would have the option of funding further treatment yourself.

Will my participation be confidential?
All information collected about you during the course of the research will be kept strictly confidential. Each participant involved in the research project will be given a unique code that does not contain any personal details. All data collected will be anonymised and confidentiality will be maintained at all times.

In the consent form, we will ask for your permission to allow restricted access to your medical records. This access will only be by the research physiotherapist who is a member of NHS staff within this department. We will also ask for your permission to inform your GP of your involvement in the study.

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. During the project, you are free to withdraw at any time and without giving a reason. A decision to withdraw at any

time, or a decision not to take part will not affect the standard of your ongoing care.

What happens if something goes wrong?
If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this project please contact the Research Governance Office at the University of Southampton.

Who has reviewed this study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the South West 4 Research Ethics Committee.

Where can I get more information?
If you need further information about the project, please contact:

- **Anna Gould,** Chartered Physiotherapist
Telephone: 07799581905 Email: anna.gould@nesc.nhs.uk

- **Professor Ann Ashburn**, Professor in Stroke Rehabilitation and Research Supervisor
Rehabilitation Research, Mailpoint 886, Southampton General Hospital, SO16 6YD. Telephone: 023 8079 6469 Email: a.m.ashburn@soton.ac.uk

- **Dr Martina Prude, Research Governance Office**
Research Governance Office, George Thomas Building 37, Room 4055, University of Southampton, Highfield, Southampton SO17 1BJ. Telephone: 023 8059 8848
Email: rgoinfo@soton.ac.uk

Thank you for reading this information sheet.

Anna Gould (MCSP SRP Chartered Physiotherapist)
Clinical Doctorate Research Student

Appendix 5: Consent form

UNIVERSITY OF Southampton
School of Health Sciences

The use of Functional Electrical Stimulation combined with a gait training programme to improve quality of gait in sub-acute stroke patients.

Please initial box

I confirm that I have read and understand the information sheet dated ..... for the above study and have had the opportunity to ask questions.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected	☐
I understand that at the end of the study data collected from me will be stored at The University Rehabilitation Research Unit, School of Health Science, Southampton General Hospital in line with the institutional guidelines for good clinical practice in research and with the policies for postgraduate research.	☐
I understand that relevant sections of my medical notes and data collected during the study, may be looked at by the Researcher, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give my permission for these individual to have access to my records.	☐
I give the research team permission to inform my GP of my participation in the study	☐
I am/am not taking part in another study at this time (delete as appropriate)	☐
I agree to being recorded on video during this study and to the video recording being used for teaching and presentations at scientific conferences.	☐
I agree to take part in the study	☐

When you have initialled all the boxes on the previous page, please complete below yourself, including the date

Name of Participant Date Signature

_____

If participant is signing form with non dominant, unaffected hand then a witness signature is required.

Witness Date Signature

_____

Researcher Date Signature

_____

Copies for participant & medical notes

Appendix 6: Pregnancy test consent form

UNIVERSITY OF Southampton
School of Health Sciences

Pregnancy Test Consent Form

The use of Functional Electrical Stimulation combined with a gait training programme to improve quality of gait in sub-acute stroke patients.

To date there is no research concerning the use of Functional Electrical Stimulation with pregnant women. It is therefore unknown whether Functional Electrical Stimulation used during pregnancy will harm the unborn child. Whilst there have been no reported cases of harm being caused during pregnancy, the possibility of negative effects on the unborn child caused by Functional Electrical Stimulation have not been ruled out.

Pregnant women **must not** therefore take part in this project; neither should women who plan to become pregnant during the two week intervention period.

As a potential participant of the study, you have been asked to take a pregnancy test before taking part, to exclude the possibility of pregnancy.

I understand that use of Functional Electrical Stimulation may pose unforeseen risks to an unborn baby, and therefore give my consent to take a pregnancy test. **Please initial box** ☐

When you have initialled the box above, please complete below yourself, including the date

Name of Participant Date Signature

If participant is signing form with non dominant, unaffected hand then a witness signature is required.

Witness Date Signature

Researcher Date Signature

Appendix 7: Record of usual care

Patient Name: ..... Date: ……..

Abbreviation	Full Title	Examples	Amount of time in minutes (to the nearest five minutes)
Passive	Positioning/passive movements	i.e. for normalizing position and range of movement.	
Bed Mob	Bed mobility	e.g. bridging and rolling.	
Sitting	Sitting balance	static and dynamic.	
Standing	Standing balance	static and dynamic	
Transfers	Sit to stand/transfers	i.e. practising skill.	
Walking	Walking	i.e. all aspects of skill acquisition.	
Stairs	Stairs	i.e. patient practise	
Pain	Control of pain	e.g. handling, ultrasound.	
Upper Limb	Movement patterns of upper limb	i.e. relearning movement	
Lower Limb	Movement patterns of lower limb	i.e. relearning movement	
Equipt	Aids and equipment	walking aids, wheelchair use	
Ed Pt	Education of patient	Information about stroke, care options, equipment, coping strategies, posture and positioning advice.	
Ed C	Education of carer	As above	
HV	Home visit	General home visit with patient and relatives present	
Other			

Appendix 8: Health professional opinion questionnaire

UNIVERSITY OF Southampton
School of Health Sciences

An investigation into the effect of a two week walking programme combined with Functional Electrical Stimulation on walking ability in sub-acute stroke patients

Health Professional Opinion Questionnaire

Thank you for your assistance with the above study. Now that the intervention phase of the study is completed, I am interested to know what you thought about the recruitment, intervention and assessment procedures used, and how this study has affected your daily routine. The information from these questionnaires will be used to inform the development of future studies.

This questionnaire is completely anonymous and I will have no way of knowing who sent them so please feel free to express your honest opinions.

If you decide to complete this questionnaire, please return it in the envelope attached.

Thank you again for helping us with the study and for considering this questionnaire.

Yours sincerely,

Anna Gould
Research Physiotherapist

An investigation into the effect of a two week walking programme combined with Functional Electrical Stimulation on walking ability in sub-acute stroke patients

Health Professional Opinion Questionnaire

1.How did you feel about delivering usual care?	**Yes**	**No**
Did you find it difficult to continue usual care with people who received the intervention?	☐	☐
Did the study make it more difficult for you to organise your day?	☐	☐
Did the study compete with space to deliver usual care?	☐	☐
Did you find it difficult to continue usual care with people Who did not receive the intervention?	☐	☐
Did you change your usual care in any way as a result of the study?	☐	☐

2. How did you feel about the demands of the study on the participants?	**Yes**	**No**
Do you think the study participants enjoyed being part of the study?	☐	☐
Did you find the demands of the study on the participants acceptable?	☐	☐

3a. Did you find that the intervention was helpful?	**Yes**	**No**
	☐	☐

3.b Can you explain why you think that?

……...

……

……

……

4. Did you feel that taking part in the study interfered with the ward/community team's routine? **Yes** ☐ **No** ☐

5. Would you be prepared to contribute to a similar study? **Yes** ☐ **No** ☐

Please feel free to write any additional comments about taking part in this study in the space below.

Thank you

……

……

……

……

……

……

……

Please return this questionnaire in the envelope provided to the following address:

Anna Gould
Care of Dr Walters Secretary
Salisbury NHS Foundation Trust
Salisbury
Wiltshire
SP2 8BJ

Appendix 9: Treatment log - Gait training only group

Participant ID …… Date…… Treatment session …… Location .....

Start time		Duration of session
Finish time		

Start time	Stop time	Exercise description	Support	No. Of Reps

Appendix 10: Treatment log - Gait training and FES group

Participant ID …… Date…… Treatment session …… Location .....

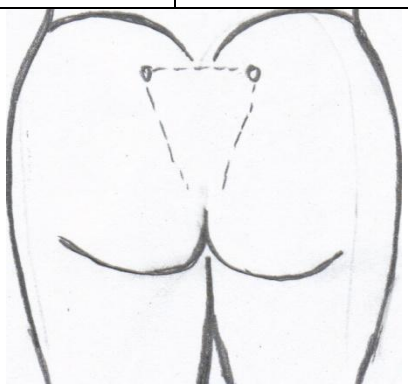
Start time		Duration of session
Finish time		

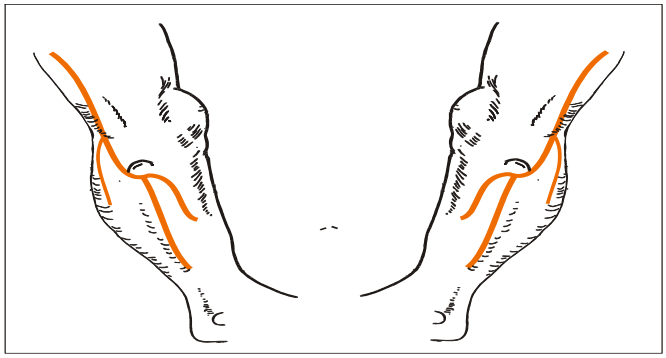
Preparation:

Activity	Description	Support	Number of reps	Time (mins)
FES electrode set up	Application, adjustment and removal			

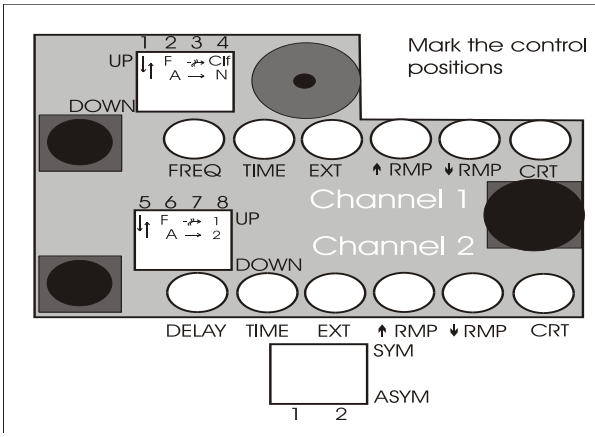
FES Settings: Skin checked ☐ Details: .....

Pulse Width	Channel 1		Channel 2	





Algorithm details and additional comments



Footswitch positioning and insertion	

Participant ID …… Date……. Treatment session…….

Start time	Stop time	Exercise description	Support	FES on/off	No. Of Reps

Appendix 11: Protocol for the 5meter walk test

Gait speed is to be evaluated by timing a 5-m walk with a stopwatch. Speed will be calculated in meters per second.

Cones and marked lines will be placed on the floor to mark out the start and end of a 5m course. Two additional meters will be marked with additional cones at the beginning and end of the marked lines to permit acceleration and deceleration (Salbach et al., 2001).

The subject is asked to stand at the start (first cone) and walk at a comfortable speed with any assistive device necessary towards the last cone (see instructions below). The evaluator will walk beside the participant and begin timing with a digital stop watch when the subject's first foot crosses the start line. Timing will stop when the first foot crosses the end line, though the patient will continue to walk the final 2 meters.

The walking speed is measured three times, and the average of 3 trials is recorded as definitive data to clarify the averaged measure of gait speed. If the patient cannot walk 12m continuously, his/her speed will be recorded as zero. A rest period after each of the 3 trials is provided (da Cunha et al., 2002).

INSTRUCTIONS FOR TESTS OF GAIT SPEED
Instructions for the 5- meter walk tests at a *comfortable* pace:
"I am going to measure your comfortable walking speed. When I say 'go,' walk in a straight line at a pace which is safe and comfortable for you, until you reach the very last cone.

Appendix 12: Independent assessment of the Wisconsin Gait Scale – scoring sheet

Name of Independent Assessor: .....

Date video footage assessed: .....

Code reference for video footage: .....

Was the protocol for the 5m walk test adhered to? YES / NO

Comments: .....

Measure	Sub measure	Finding	Points
Stance phase of the affected leg	Use of hand held gait aid	No gait aid	1
		Minimal gait aid use	2
		Minimal gait aid use and wide base	3
		Marked use	4
		Marked use wide base	5
	Stance time on impaired side	Equal (time spent on affected side same as time spent on unaffected side during single leg stance)	1
		Unequal	2
		Very brief	3
	Step length of unaffected side	Step through (heel of unaffected foot clearly advances beyond the toe of the affected foot)	1
		Foot does not clear	2
		Step to (unaffected foot placed behind or up to affected foot but not beyond)	3
	Weight shift to the affected side (with or without gait aid)	Full shift (head and trunk shift laterally over the affected foot during single stance)	1
		Decreased shift	2
		Very limited shift	3
	Stance width	Normal (up to 1 shoe width between feet)	1
		Moderate (up to 2 shoe widths)	2
		Wide (more than 2 shoe widths)	3

Toe off of the affected side	Guardedness	None (good forward movement with no hesitancy noted)	1
		Slight	2
		Marked hesitation	3
	Hip extension of affected side	Equal extension (hips equally extend during push off; maintains erect posture during toe off)	1
		Slight flexion	2
		Marked extension	3

Swing phase of the affected leg	External rotation during initial swing	Same as unimpaired leg	1
		Increased rotation	2
		Marked	3
	Circumduction at mid swing	None (affected foot adducts no more than unaffected foot during swing)	1
		Moderate	2
		Marked	3
	Hip hiking at mid swing	None (pelvis slightly dips during swing)	1
		Elevation	2
		Vaults	3
	Knee flexion from toe off to mid swing	Normal (affected knee flexes equally to unaffected)	1
		Some	2
		Minimal	3
		None	4
	Toe Clearance	Normal (toe clears floor throughout swing)	1
		Slight drag	2
		Marked	3
	Pelvic rotation at terminal swing	Forward (pelvis rotated forward to prepare for heel strike)	1
		Neutral	2
		Retracted	3

Initial Foot Contact	Initial foot contact	Heel strike (heel makes initial contact with the floor)	1
		Foot flat	2
		No contact of heel	3
Total Score			

Appendix 13: Advice for independent assessor in scoring using Wisconsin Gait Scale

The Wisconsin Gait Scale (WGS) can be used to evaluate the gait parameters experienced by a patient with hemiplegia following stroke. This can be used to monitor the effectiveness of rehabilitation training. The authors are from the University of Wisconsin.

- Choose one full gait cycle to analyse that is representative of the walking pattern across the full 5 meter distance in frontal, side and posterior views.
- Use slow motion, zoom and play back functions for analysis of specific joints and points in the gait cycle.
- Use the following table to guide points for observation in each view

Observations of the subject:

1. Walking towards the camera (frontal view)
2. Walking away from the camera (posterior view)
3. From the side (side view)

View	Period of gait cycle under observation	Specific Measure
Frontal view	Stance phase of the affected leg	Use of hand held gait
		Stance Time on impaired side
		Weight shift to the affected side
		Stance width (measure distance between feet prior to toe off of affected foot)
	Swing Phase of the affected leg	External rotation during swing
		Circumduction at mid swing
Posterior view	Swing phase of the affected leg	Hip hiking at mid swing
		Pelvis rotation
Side view	Stance phase of the affected leg	Step length on the unaffected side
	Toe off of the affected leg	Guardedness
		Hip extension of affected side
	Swing phase of the affected leg	Knee flexion for toe off to mid swing
		Toe clearance
	Heel Stroke of the affected leg	Heel strike

Appendix 14: Participant opinion questionnaire

UNIVERSITY OF Southampton
School of Health Sciences

An investigation into the effect of a two week walking programme combined with Functional Electrical Stimulation on walking ability in sub-acute stroke patients

Participant Opinion Questionnaire

Thank you for participating in the above study. Now that the main data collection phase is over, I am interested in finding out what you thought about the assessments and treatment programmes you were asked to complete. The information from these questionnaires will be used to inform the development of future studies.

This questionnaire is completely anonymous and I will have no way of knowing who sent them so please feel free to express your honest opinions.

If you decide to complete this questionnaire, please return it in the envelope attached.

Thank you again for helping us with the study and for considering this questionnaire.

Yours sincerely,

Anna Gould
Research Physiotherapist

An investigation into the effect of a two week walking programme combined with Functional Electrical Stimulation on walking ability in sub-acute Stroke patients

Participant Opinion Questionnaire

Everybody involved in the study can complete questions 1-5

1.How did you feel about taking part in the study?	**Yes**	**No**
Did you enjoy being involved in the study?	☐	☐
Was it in any way difficult to fit in additional assessments/ treatment sessions?	☐	☐
Did you find the study too tiring?	☐	☐

2. Did you think that taking part in the study interfered with your daily routine or other treatments you received?	**Yes** ☐	**No** ☐

3a. Did you ever think about leaving the study?	**Yes** ☐	**No** ☐

3b. What made you think about leaving the study?

……

……

……

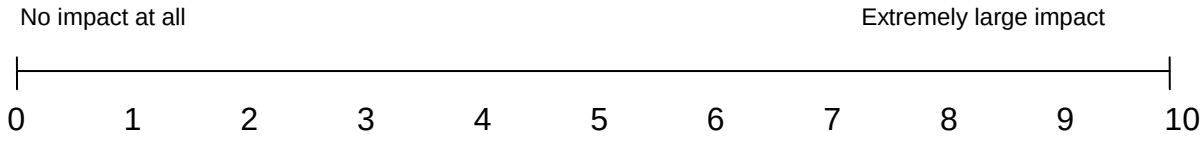
……

……

……

……

4a. On a scale of 1-10 how would you rate the impact the two week walking training programme had on your walking ability?



4b. Why did you think that?

……

……

……

……

……

5a. Overall, how did you feel about the quantity of the walking training you received as part of the study?

Too little exercise? ☐

Just about enough? ☐

Too much exercise? ☐

5b. Why did you think that?

……

……

……

……

……

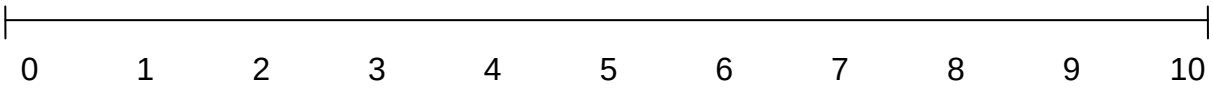
……

……

People who received the exercise and the electrical stimulation intervention will be able to answer Questions 6 – 9

6a. On a scale of 1-10 how would you rate the impact the two week intervention had on your walking ability?

No impact at all Extremely large impact



6b. Why did you think that?

……
……
……
……
……

7. How did you feel about the electrical stimulation intervention?

	Yes	No
Was the time required to apply the electrodes acceptable?	☐	☐
Did you feel comfortable whist exercising with the electrical stimulation on?	☐	☐
Did you find the electrical stimulation comfortable?	☐	☐

8a. Overall, how did you feel about the quantity of the walking training and electrical stimulation programme you received as part of the study?

Too little exercise? ☐

Just about enough? ☐

Too much exercise? ☐

8b. Why did you think that?

……

……

……

……

……

Please feel free to write any additional comments about taking part in this study in the space below.

Thank you

……

……

……

……

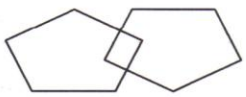
……

Appendix 15: Mini Mental State Examination (MMSE)

Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

Instructions: ***Ask the questions in the order listed. Score one point for each correct response within each question or activity.***

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

1

ource: www.medicine.uiowa.edu/igec/tools/cognitive/MMSE.pdf Provided by NHCQF. 0106-410

Appendix 16: Modified Ashworth Scale

Grade	Description
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release, or by minimal resistance toward the end of the movement when the affected part (s) is (are) moved
1+	Slight increase in muscle tone, manifested by a catch and release followed by a minimal resistance throughout the remainder (less than half) of the range of movement (ROM)
2	More marked increase in muscle tone through most of the ROM, buf affected part (s) easily moved
3	Considerable increase in muscle tone, passive movement difficult
4	Affected part (s) rigid

The following muscle groups were tested:

Hip Flexors
Hip Extensors
Hip internal rotators
Hip external rotators
Hip adductors
Hip adductors
Knee extensors
Knee flexors
Dorsi-flexors
Plantar-flexors
Invertors
Evertors
Biceps

Appendix 17: Motricity Index

Tests (in sitting position) The patient should be sitting in a chair or on the edge of the bed, but can be tested lying if necessary		
Arm Score	**Score**	**Scoring Instructions**
1. Pinch grip; 2,5 cm cube between thumb and forefinger Ask patient to grip a 2.5 cm object (cube) between his thumb and forefinger. Object should be on a flat surface (for example, a book). Monitor any forearm or small hand muscles. ***19*** *= drops object when lifted (examiner may need to lift wrist)* ***22*** *= can hold in air, but easily dislodged*		0: No movement 11: Beginnings of prehesion (any movement of finger or thumb) 19: Grips cube, but unable to hold against gravity 22: Grips cube, held against gravity, but not against weak pull 26: Grips cube against pull, weaker than other side 33: Normal pinch grip
2. Elbow flexion; from 90 degrees, voluntary contraction/Movement Elbow flexed to 90 degrees, forearm horizontal and upper arm vertical. Patient asked to bend elbow so that touches the shoulder. Examiner resists with hand on wrist. Monitor biceps. ***14*** *= if no movement seen, may hold elbow out so that arm is horizontal.*		0: No movement 9: Palpable contraction in muscle, but no movement 14: Movement seen, but not full range/not against gravity 19: Movement; full range against gravity, not against resistance 25: Movement against resistance, but weaker than other side 33: Normal power
3. Shoulder abduction; from against chest. With elbow fully flexed and against chest, patient asked to abduct arm. Monitor contraction of deltoid; movement of shoulder girdle does not count - there must be movement of humerus in relation to scapula. *19 = abducted more than 90 degrees beyond horizontal.*		
(1)+(2)+(3)+1 (to make 100)		

Leg Score	Score	Scoring Instructions
4. Ankle dorsiflexion; from plantar flexed position **Sitting** Foot relaxed in plantar flexed position. Patient asked to dorsiflex foot (´As if standing on your heels`). Monitor tibialis anterior. ***14*** *= less than full range of dorsiflexion*		0: No movement 9: Palpable contraction in muscle, but no movement 14: Movement seen, but not full range/not

5. Knee extension; from 90 degrees, voluntary contraction/Movement Foot unsupported, knee at 90 degrees. Patient asked to extend (straighten) knee to touch examiner´s hand level with the knee. Monitor contraction of the quadriceps. ***14*** *= less than 50 per cent of full extension (i.e. 45 degrees only)* ***19*** *= knee fully extended, but easily pushed down.*		against gravity 19: Movement; full range against gravity, not against resistance 25: Movement against resistance, but weaker than other side 33: Normal power
6. Hip flexion; usually from 90 degrees Sitting with hip bent at 90 degrees. Patient asked to lift knee toward chin. Check for associated (trick) movement of leaning back, by placing hand behind back and asking patient not to lean back. Monitor contraction of ilio-psoas (hip flexors). ***14*** *= less than full range of possible flexion (check passive movement)* ***19*** *= fully flexed, but easily pushed down*		
(4)+(5)+(6)+1 (to make 100)		
Side score = (ARM + LEG) / 2		

Trunk Tests (on bed) Four movements / functions are tested, with the patient lying on the bed.	**Score**	
1. Rolling to weak side From lying on back, rolling over on to weak side. May push / pull on bed with good arm.		0 : Unable to do on own 12: Able to do, but only with non- muscular help - for example, pulling on bed clothes, using arms to steady self when sitting, pulling up on rope or monkey pole 25: Able to complete normally
2. Rolling to strong side From lying on back, bringing weak limbs over **12** = if uses good limbs to help		
3. Sitting up from lying down From lying on back - may use arm(s) to push or pull **12** = if pulls on pole, rope, sheets, etc.		
4. Balance in sitting position (on side of bed) Sitting on edge of bed, feet off ground – balance for 30 sec. **12** = if needs to touch anything with hands to stay upright **0** = if unable to stay up (any way) for 30 sec.		
Trunk score = score (1)+(2)+(3)+(4)		

Appendix 18: Rivermead Mobility Index

Score: **0 = No** **1 = Yes**	
Item	***Score***
1. Do you turn over from your back to your side without help?	
2. From lying in bed, are you able to sit up on the edge of the bed on your own?	
3. Could you sit on the edge of the bed without holding on for 10 seconds?	
4. Can you (using your hands as an aid if necessary) stand up from a chair in less than 15 seconds, and stand there for 15 seconds?	
5. Observe patient standing for 10 seconds without an aid.	
6. Are you able to move from bed to chair and back without any help?	
7. Can you walk 10 meters with an aid if necessary but with no stand by help?	
8. Can you manage a flight of steps alone, without help?	
9. Do you walk around outside alone, on pavements?	
10. Can you walk 10 meters inside with no calliper, splint or aid and no stand by help?	
11. If you drop something on the floor, can you manage to walk 5 meters to pick it up and walk back?	
12. Can you walk over uneven ground (grass, gravel, dirt, snow or ice) without help?	
13. Can you get in and out of a shower or bath unsupervised, and wash yourself?	
14. Are you able to climb up and down four steps with no rail but using an aid if necessary?	
15. Could you run 10 meters in 4 seconds without limping? (A fast walk is acceptable.)	
TOTAL SCORE	

Appendix 19: Berg Balance Score

SITTING TO STANDING
Instructions: Please stand up. Try not to use your hand for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
Instructions: Please stand for two minutes without holding on.
( ) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unsupported
If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
Instructions: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
Instructions:: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assist to sit

TRANSFERS
Instructions: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
Instructions: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely
( ) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
Instructions: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
Instructions: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
Instructions: Pick up the shoe/slipper, which is place in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
Instructions: Turn to look directly behind you over toward the left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
Instructions: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
Instructions: Place each foot alternately on the step/stool. Continue until each foot has touch the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT
Instructions: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)
( ) 4 able to place foot stride length ahead independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG
Instructions: Stand on one leg as long as you can without holding on.
( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

TOTAL SCORE (Maximum = 56)

Appendix 20: Stroke Impact Scale

The purpose of this questionnaire is to evaluate how stroke has affected the health and life of _____ (patient name). We want to know from YOUR POINT OF VIEW how stroke has affected him/her. We will ask you questions about impairments and disabilities caused by his/her stroke, as well as how stroke has affected his/her quality of life. Finally, we will ask you to rate how much you think he/she has recovered from the stroke.

These questions are about the physical problems which may have occurred as a result of the stroke

1. In the past week, how would you rate the strength of his/her...	**A lot of strength**	**Quite a bit of strength**	**Some strength**	**A little strength**	**No strength at all**
a. Arm that was most affected by the stroke?	5	4	3	2	1
b. Grip of the hand that was most affected by the stroke?	5	4	3	2	1
c. Leg that was most affected by the stroke?	5	4	3	2	1
d. Foot/ankle that was most affected by the stroke?	5	4	3	2	1

These questions are about his/her memory and thinking capacities

2. In the past week, how difficult was it for him/her to...	**Not difficult at all**	**A little difficult**	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
a. Remember things that people had just told him/her?	5	4	3	2	1
b. Remember things that happened the day before?	5	4	3	2	1
c. Remember to do things (e.g. keep scheduled appointments or take medication)?	5	4	3	2	1
d. Remember the day of the week?	5	4	3	2	1
e. Add and subtract numbers?	5	4	3	2	1
f. Concentrate?	5	4	3	2	1
g. Think quickly?	5	4	3	2	1
h. Solve everyday problems?	5	4	3	2	1

These questions are about feelings, about changes in his/her mood and about his/her ability to control emotions since the stroke

3. In the past week, how often did he/she...	**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**
a. Feel sad?	5	4	3	2	1
b. Feel that there was nobody he/she was close to?	5	4	3	2	1
c. Feel that he/she was a burden to others?	5	4	3	2	1
d. Feel that he/she had nothing to look forward to?	5	4	3	2	1
e. Blame her/himself for mistakes or mishappenings?	5	4	3	2	1
f. Enjoy things as much as ever?	5	4	3	2	1
g. Feel nervous?	5	4	3	2	1
h. Feel that life would be worth living?	5	4	3	2	1
i. Smile and laugh at least once a day?	5	4	3	2	1

The following questions are about his/her ability to communicate with other people, as well ashis/her ability to understand what he/she reads and hears in a conversation

4. In the past week, how difficult was it for him/her to...	**Not difficult at all**	**A little difficult**	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
a. Say the name of someone who was in front of him/her?	5	4	3	2	1
b. Understand what was being said to him/her in a conversation?	5	4	3	2	1
c. Reply to questions?	5	4	3	2	1
d. Correctly name objects?	5	4	3	2	1
e. Participate in a conversation with a group of people?	5	4	3	2	1
f. Have a conversation on the telephone?	5	4	3	2	1
g. Call another person on the telephone, including selecting the correct phone number and dialing?	5	4	3	2	1

The following items ask about activities he/she might do during a typical day

5. In the past 2 weeks, how difficult was it for him/her to...	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Cannot do at all
a. Cut food with a knife and fork?	5	4	3	2	1
b. Dress the top part (from the waist up) of his/her body?	5	4	3	2	1
c. Wash him/herself (bath, shower…)?	5	4	3	2	1
d. Clip his/her toenails?	5	4	3	2	1
e. Get to the toilet quickly?	5	4	3	2	1
f. Control his/her bladder (not have an accident)?	5	4	3	2	1
g. Control his/her bowels (not have an accident)?	5	4	3	2	1
h. Do light household tasks/chores?	5	4	3	2	1
i. Go shopping?	5	4	3	2	1
j. Handle money (e.g. count out money)?	5	4	3	2	1
k. Manage finances (e.g. pay monthly bills, manage a bank account)?	5	4	3	2	1
l. Do heavy household tasks/chores?	5	4	3	2	1

The following questions are about his/her ability to be mobile, at home and in the community

6. In the past 2 weeks, how difficult was it for him/her to...	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Cannot do at all
a. Stay sitting without losing his/her balance?	5	4	3	2	1
b. Stay standing without losing his/her balance?	5	4	3	2	1
c. Walk without losing his/her balance?	5	4	3	2	1
d. Move from a bed to a chair?	5	4	3	2	1
e. Get out of a chair without using his/her hands for support?	5	4	3	2	1
f. Walk one hundred yards?	5	4	3	2	1
g. Walk fast?	5	4	3	2	1
h. Climb one flight of stairs?	5	4	3	2	1
i. Climb several flights of stairs?	5	4	3	2	1
j. Get in and out of a car?	5	4	3	2	1

The following questions are about his/her ability to use the hand that was MOST AFFECTED by the stroke

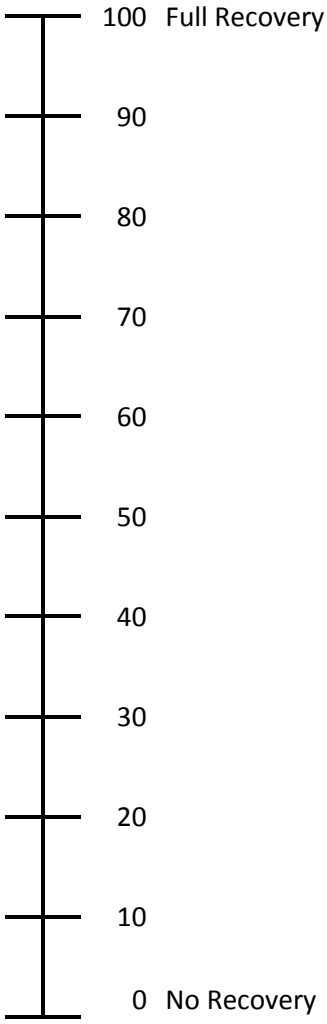
7. In the past 2 weeks, how difficult was it for him/her to use the hand that was most affected by the stroke to...	**Not difficult at all**	**A little difficult**	**Somewhat difficult**	**Very difficult**	**Cannot do at all**
a. Carry heavy objects?	5	4	3	2	1
b. Turn a doorknob?	5	4	3	2	1
c. Open a can or jar?	5	4	3	2	1
d. Tie a shoe lace?	5	4	3	2	1
e. Pick up a small coin?	5	4	3	2	1

The following questions are about how stroke has affected _____ (name) ability to participate in the activities that he/she would usually do, things that are meaningful to him/her and help him/her to find purpose in life.

8. During the past 4 weeks, how much of the time has he/she been limited in...	**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**
a. His/her work (paid, voluntary or other)?	5	4	3	2	1
b. His/her social activities?	5	4	3	2	1
c. Quiet recreation ?	5	4	3	2	1
d. Active recreation?	5	4	3	2	1
e. His/her role as a family member and/or friend?	5	4	3	2	1
f. His/her participation in spiritual or religious activities?	5	4	3	2	1
g. His/her ability to show his/her feelings to those close to him/her?	5	4	3	2	1
h. His/her ability to control his/her life as he/she wishes?	5	4	3	2	1
i. His/her ability to help others?	5	4	3	2	1

9. Stroke Recovery

On a scale of 0 to 100, with 100 representing full recovery and 0 representing no recovery, how much do you feel _____ (name) has recovered from stroke?



Appendix 21: Oxford Stroke Classification

(Bamford et al., 1991)

TAC — Total Anterior Circulation Stroke

LAC — Lacunar Stroke

PAC — Partial Anterior Circulation Stroke

POC — Posterior Circulation Stroke

Code last letter as follows:

(S) — Syndrome: Indeterminate pathogenesis, prior to imaging (e.g., TACS)

(I) — Infarct (e.g., TACI)

(H) — Haemorrhage (e.g., TACH)

Appendix 22: Location of intervention sessions

Participant ID	Gait training only Group							Gait training and FES Group							
	1	4	5	8	9	12	14	2	3	6	7	10	11	13	15
Session 1	H	C	C	C	H	H	H	H	H	C	C	C	H	H	H
Session 2	H	C	C	C	H	H	H	H	H	C	C	C	H	H	H
Session 3	H	C	H	C	H	H	H	H	H	C	C	C	H	H	H
Session 4	H	C	H	C	H	H	H	H	H	C	H	C	H	H	H
Session 5	H	C	H	H	H	H	H	H	H	C	H	C	H	H	H
Session 6	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H
Session 7	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H
Session 8	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H

Session undertaken in clinical settings are highlighted in red. H= Patient's home setting, C=Clinical setting

Appendix 23: Intervention duration

Participant No.	Total Treatment time for 8 sessions (mins)	Average Treatment Time for individual sessions
1	464	58.00
2	474	59.25
3	414	51.75
4	401	50.13
5	397	49.63
6	476	59.50
7	467	58.38
8	377	47.13
9	393	49.13
10	446	55.75
11	377	47.13
12	424	53.00
13	407	50.88
14	336	42.00
15	397	49.63
Mean	416.7	52.08
SD	41.3	5.16
Median	407	50.88
Min	336.0	42.00
Max	476.0	59.50

SD: Standard deviation

Appendix 24 : Time taken to set up electrical stimulation

Participant No.	Total time to set up stimulation across 8 sessions	Average time to set up stimulation per session (mins)	Average percentage of session time spent setting up stimulation (%)
2	56.7	07.1	10.7
3	80.0	10.0	19.3
6	112.5	14.1	23.6
7	85.3	10.7	18.2
10	77.3	09.7	17.4
11	76.0	09.5	20.2
13	58.8	07.4	14.5
15	82.0	10.3	20.7
Mean	78.6	09.8	18.1
SD	17.3	02.2	04.0
Median	78.65	9.85	18.75
Min	56.7	07.1	10.7
Max	112.5	14.1	23.6

SD: Standard deviation

Appendix 25: Amount of time physically engaged in exercise

Participant No.	Total Treatment time for 8 sessions (mins)	Total time physically engaged in exercise over 8 sessions (min)	% of total treatment time spent physically engaged in exercise
1	464	300.37	64.73
2	474	242.12	51.08
3	414	170.55	41.18
4	401	252.18	62.89
5	397	240.70	60.63
6	476	204.48	42.96
7	467	326.67	69.96
8	377	273.99	72.68
9	393	326.23	83.00
10	446	256.98	57.62
11	377	234.17	62.12
12	424	384.99	90.80
13	407	291.83	71.57
14	336	272.91	81.22
15	397	297.51	74.94
Mean	416.67	271.67	65.83
SD	41.26	52.98	14.15
Median	407.00	272.91	64.73
Min	336.00	170.54	41.18
Max	476.00	384.99	90.80

SD: Standard deviation

Appendix 26: Amount of time spent on gait training components

Participant No.	Amount of time spent on gait training programme components across all 8 treatment sessions (min)							
	Lower Limb muscle and soft tissue stretching	Core and lower limb strengthening	Sit to stand and stand to sit practice	Standing towards walking	Stepping practice	Walking practice	Climbing stairs	Cycling
1	43.0	48.7	0.3	28.8	135.0	44.7	0.0	0.0
2	0.0	35.3	0.0	35.3	119.2	52.3	0.0	0.0
3	14.6	5.0	0.0	23.0	87.1	40.8	0.0	0.0
4	25.3	19.5	3.0	23.0	121.5	59.8	0.0	0.0
5	0.0	29.9	7.2	32.2	117.0	52.4	2.0	0.0
6	28.6	0.0	37.3	18.5	78.3	41.0	1.2	0.0
7	32.7	31.3	24.3	10.2	181.7	46.5	0.0	0.0
8	6.5	82.2	15.8	11.5	126.2	31.8	0.0	0.0
9	0.0	95.2	8.0	25.5	121.8	75.7	0.0	0.0
10	24.5	7.5	17.2	5.0	100.7	97.2	5.0	0.0
11	7.2	4.7	0.0	7.7	123.0	60.0	1.0	30.7
12	24.7	92.5	9.0	20.8	148.3	81.7	8.0	0.0
13	10.2	76.5	0.0	7.0	141.2	57.0	0.0	0.0
14	0.0	111.0	6.5	0.0	68.3	87.1	0.0	0.0
15	0.0	105.3	0.0	0.0	115.7	76.5	0.0	0.0
Total	217.3	744.6	128.6	248.5	1785.0	904.5	17.2	30.7
Mean	14.5	49.6	8.6	16.6	119.0	60.3	1.1	2.0
SD	14.3	40.2	10.9	11.5	28.3	19.2	2.3	7.9
Median	10.2	35.3	6.5	18.5	121.5	57	0	0
IQR	25	73.85	12.4	16.9	22.4	30.5	1.1	0
Min	0.0	0.0	0.0	0.0	68.3	31.8	0.0	0.0
Max	43.0	111.0	37.3	35.3	181.7	97.2	8.0	30.7

IQR = Interquartile Range

SD: Standard deviation

Appendix 27: Number of repetitions

Participant No.	Total Strengthening Exercises Repetitions	Sit to Stand Repetitions	Total Stepping Repetitions
1	161	1	710
2	178	0	658
3	43	0	1143
4	136	30	1170
5	237	32	1384
6	0	179	718
7	108	89	826
8	375	80	975
9	391	20	1001
10	70	60	836
11	50	0	920
12	215	10	730
13	282	0	1580
14	600	30	420
15	452	0	865
Total	3298	531	13936
Mean	219.9	35.4	929.1
SD	171.5	49.6	296.4
Median	178	20	865
IQR	239.5	46	348
Min	0	0	420
Max	600	179	1580

IQR = Interquartile Range

SD: Standard deviation

Appendix 28: Gait Speed at baseline, week two and week six

Participant ID	Baseline assessment gait speed (meters/sec)	Week 2 gait speed (meters/sec)	6 Week follow-up gait speed (meters/sec)
1	0.39	0.60	0.66
2	0.54	0.88	1.17
3	0.61	0.63	0.72
4	0.61	0.79	1.05
5	0.56	0.64	0.75
6	0.10	0.75	0.80
7	0.09	0.26	0.42
8	0.36	0.39	0.47
9	0.69	1.17	1.41
10	0.44	0.61	0.75
11	0.49	0.91	0.93
12	0.30	0.29	0.39
13	0.89	1.04	1.33
14	0.17	0.59	0.50
15	0.34	0.36	0.43
Mean	0.44	0.66	0.79
SD	0.22	0.27	0.33
Min	0.09	0.26	0.39
Max	0.89	1.17	1.41

Appendix 29: Wisconsin Gait Scores at baseline, week two and week six

Participant ID	Baseline assessment Wisconsin Gait Score	Week 2 gait speed Wisconsin Gait Score	6 Week follow-up gait Wisconsin Gait Score
1	26.9	16.95	19.7
2	23.65	16.7	16.1
3	20.3	20.7	17.1
4	25.3	23.1	19.1
5	19.35	20.1	13.35
6	23.5	17.3	15.55
7	31.5	27.3	18.55
8	34.25	30.65	24.7
9	19.35	14.55	13.35
10	16.3	13.95	14.95
11	17.3	13.35	15.35
12	24.9	24.9	20.7
13	20.7	13.35	14.35
14	26.5	18.75	13.35
15	19.95	17.7	18.7
Mean	23.32	19.29	16.99
SD	5.07	5.23	3.24
Min	16.30	13.35	13.35
Max	34.25	30.65	24.70

Appendix 30: Upper Limb Motricity Scores at baseline, week two and week six

Participant ID	Upper Limb Motricity Index at Baseline	Upper Limb Motricity Index at Week 2	Upper Limb Motricity Index at Week 6
1	61	61	77
2	40	40	40
3	100	100	100
4	91	84	100
5	100	100	100
6	81	92	84
7	51	51	65
8	51	55	60
9	93	100	100
10	100	100	100
11	55	65	84
12	30	29	19
13	84	92	100
14	39	92	100
15	100	92	100
Mean	71.73	76.87	81.92
SD	25.82	24.35	25.54
Min	30	29	19
Max	100	100	100

Appendix 31: Lower Limb Motricity Scores at baseline, week two and week six

Participant ID	Lower Limb Motricity Index at Baseline	Lower Limb Motricity Index at Week 2	Lower Limb Motricity Index at Week 6
1	53	58	59
2	76	76	76
3	65	84	100
4	76	76	92
5	76	84	100
6	59	84	76
7	53	65	67
8	29	49	60
9	76	100	92
10	92	100	92
11	65	65	81
12	64	64	61
13	84	84	84
14	39	76	76
15	65	75	84
Mean	64.8	76	80
SD	16.63	14.26	13.81
Min	29	49	59
Max	92	100	100

Appendix 32: Trunk Motricity Scores at baseline, week two and week six

Participant ID	Lower Limb Motricity Index at Baseline	Lower Limb Motricity Index at Week 2	Lower Limb Motricity Index at Week 6
1	61	87	100
2	61	74	87
3	100	100	100
4	100	100	100
5	100	100	100
6	48	61	100
7	49	61	74
8	61	61	48
9	100	100	100
10	100	100	100
11	100	100	100
12	61	61	100
13	100	100	100
14	61	100	100
15	61	87	100
Mean	77.53	86.13	93.93
SD	21.14	17.35	14.63
Median	61	100	100
Min	48	61	48
Max	100	100	100

Appendix 33: Rivermead Mobility Index (RMI) at baseline, week two and week six

Participant ID	RMI at Baseline	RMI at Week 2	RMI at Week 6
1	8	8	11
2	6	11	14
3	12	12	13
4	6	13	13
5	10	11	12
6	8	8	10
7	6	9	11
8	6	7	10
9	6	12	15
10	8	14	12
11	8	13	13
12	7	9	12
13	13	14	14
14	7	9	11
15	10	9	12
Mean	8.07	10.6	12.2
SD	2.25	2.32	1.47
Median	8	11	12
Min	6	7	10
Max	13	14	15

Appendix 34: Berg Balance Test (BBT) at baseline, week two and week six

Participant ID	BBT at Baseline	BBT at Week 2	BBT at Week 6
1	48	48	50
2	42	48	52
3	37	48	47
4	40	51	52
5	44	46	48
6	32	43	46
7	41	47	51
8	43	46	56
9	42	55	53
10	46	49	50
11	49	56	55
12	46	50	50
13	50	53	53
14	42	44	50
15	45	50	46
Mean	43.13	48.93	50.80
SD	4.67	3.71	3.47
Median	43	48	50
Min	32	43	46
Max	50	56	59

Appendix 35: Stroke Impact Scores at baseline, week two and week six

Domain of Stroke Impact Scale	Baseline Mean (SD)	Week 2 Mean (SD)	Week 6 Mean (SD)
Strength	56.67 (20.39)	64.17 (20.38)	69.59 (16.85)
Hand Function	56 (39.29)	56 (40.63)	65 (41.10)
ADL	74.06 (15.98)	80.5 (14.29)	82.55 (12.51)
Mobility	69.14 (16.18)	80.69 (12.04)	89.15 (9.51)
Memory and thinking	88.07 (14.75)	90.63 (10.76)	91.64 (14.87)
Emotion	83.71 (13.44)	89.26 (10.12)	89.63 (10.36)
Communication	94.29 (10.70)	94.05 (9.23)	95.00 (11.44)
Participation	77.42 (20.14)	76.75 (11.65)	81.78 (22.11)
Recovery	55.53 (18.19)	69.00 (19.48)	72.00 (16.12)

Appendix 36: Comparison of Stroke Impact scores (SIS) between assessment points for each intervention group

		Gait Training Only Group		Gait Training + FES Group		*U*	*Sig. (2 tailed)*
		Mean (SD) Change in SIS	***Median (IQR) Change in SIS***	***Mean (SD) Change in SIS***	***Median (IQR) Change in SIS***		
Physical	**Change in score during intervention phase (baseline and week 2)**	7.15 (15.50)	12.50 (25.03)	7.82 (8.68)	6.25 (9.38)	26.500	0.861
	Change in score during follow-up phase (week 2 to week 6)	6.25 (20.09)	6.25 (31.25)	4.69 (15.58)	0.00 (17.19)	26.500	0.861
	Change in score during trial duration (baseline and week 6)	13.40 (14.64)	6.25 (9.38)	12.50 (12.94)	15.63 (25.00)	27.000	0.907
Hand Function	**Change in score during intervention phase (baseline and week 2)**	-2.14 (11.85)	-5.00 (12.50)	1.88 (12.80)	0.00 (16.25)	23.500	0.598
	Change in score during follow-up phase (week 2 to week 6)	12.86 (9.06)	10.00 (12.50)	5.63 (26.92)	0.00 (1.25)	9.500	0.027
	Change in score during trial duration (baseline and week 6)	10.71 (12.72)	5.00 (20.00)	7.50 (24.93)	2.50 (16.25)	20.000	0.349
ADL	**Change in score during intervention phase (baseline and week 2)**	3.69 (11.81)	0.00 (13.12)	8.85 (11.57)	5.21 (9.38)	17.000	0.201
	Change in score during follow-up phase (week 2 to week 6)	6.19 (17.11)	6.25 (8.34)	-1.57 (7.93)	0.00 (8.32)	13.500	0.091
	Change in score during trial duration (baseline and week 6)	9.88 (12.05)	4.17 (14.48)	7.28 (13.91)	3.13 (9.96)	23.500	0.602

Appendix 36 continued: Comparison of Stroke Impact scores (SIS) between assessment points for each intervention group

		Gait Training Only Group		Gait Training + FES Group		*U*	*Sig. (2 tailed)*
		Mean (SD) Change in SIS	***Median (IQR) Change in SIS***	***Mean (SD) Change in SIS***	***Median (IQR) Change in SIS***		
Mobility	**Change in score during intervention phase (baseline and week 2)**	17.50 (16.89)	25.00 (20.00)	6.34 (12.38)	6.61 (11.25)	17.000	0.202
	Change in score during follow-up phase (week 2 to week 6)	7.41 (8.76)	7.50 (8.75)	9.38 (10.67)	6.25 (14.38)	27.000	0.907
	Change in score during trial duration (baseline and week 6)	24.91 (14.73)	30.00 (13.75)	15.71 (13.15)	12.50 (21.16)	16.500	0.182
Memory and thinking	**Change in score during intervention phase (baseline and week 2)**	5.03 (5.11)	6.25 (8.24)	0.39 (11.14)	-1.57 (11.73)	17.000	0.199
	Change in score during follow-up phase (week 2 to week 6)	-0.07 (13.49)	0.00 (1.56)	1.96 (4.71)	3.14 (7.03)	21.000	0.408
	Change in score during trial duration (baseline and week 6)	4.96 (12.47)	3.12 (7.82)	2.35 (8.95)	0.01 (9.37)	23.500	0.601
Emotion	**Change in score during intervention phase (baseline and week 2)**	3.56 (8.58)	2.77 (5.56)	7.29 (13.28)	2.78 (20.84)	26.000	0.816
	Change in score during follow-up phase (week 2 to week 6)	0.79 (13.58)	0.00 (12.50)	0.00 (6.80)	0.00 (0.69)	27.000	0.905
	Change in score during trial duration (baseline and week 6)	4.36 (19.62)	0.00 (9.73)	7.29 (10.39)	8.32 (15.28)	20.500	0.381

Appendix 36 continued: Comparison of Stroke Impact scores (SIS) between assessment points for each intervention group

		Gait Training Only Group		**Gait Training + FES Group**		***U***	***Sig. (2 tailed)***
		Mean (SD) Change in SIS	***Median (IQR) Change in SIS***	***Mean (SD) Change in SIS***	***Median (IQR) Change in SIS***		
Communication	**Change in score during intervention phase (baseline and week 2)**	-1.02 (8.92)	0.00 (8.93)	0.45 (1.26)	0.00 (0.00)	26.500	0.836
	Change in score during follow-up phase (week 2 to week 6)	1.03 (12.16)	0.00 (5.36)	0.89 (3.17)	0.00 (0.89)	26.000	0.794
	Change in score during trial duration (baseline and week 6)	0.00 (18.90)	0.00 (3.57)	1.34 (4.25)	0.00 (0.89)	27.000	0.896
Participation	**Change in score during intervention phase (baseline and week 2)**	-4.61 (18.71)	-8.33 (9.20)	2.78 (12.87)	-4.20 (18.76)	13.500	0.092
	Change in score during follow-up phase (week 2 to week 6)	2.82 (24.17)	5.55 (30.72)	6.95 (19.90)	5.56 (11.80)	25.500	0.771
	Change in score during trial duration (baseline and week 6)	-1.79 (22.97)	0.00 (14.59)	9.73 (26.49)	11.12 (27.09)	18.500	0.269
Recovery	**Change in score during intervention phase (baseline and week 2)**	18.57	15.00	9.00	10.00	13.500	0.082
	Change in score during follow-up phase (week 2 to week 6)	2.86	5.00	3.13	7.50	24.000	0.628
	Change in score during trial duration (baseline and week 6)	21.43	20.00	12.13	16.00	17.000	0.200

Appendix 37: Suggested development of task orientated gait training programme

<table>
<tr><th colspan="3">1. Sit to Stand Training: Level chosen based on individual participant's needs and progressed in response to performance (Chou et al., 2003, Cooke et al., 2010, Mares et al., 2014, Wilkinson et al., 2014)</th></tr>
<tr><th>Description of progression</th><th>Target Intensity</th><th>FES Guidance</th></tr>
<tr><td>Level 1
Sit to stand and stand to sit from dining room chair or equivalent</td><td rowspan="2">Target Repetitions: 15
Target Sets: 3
(Gordon et al., 2004)</td><td rowspan="4">Channel 1: on tibialis anterior during forward progression phase of sit to stand (at low intensity)
Channel 2: used on during extension phase of sit to stand.

Trigger method: Hand held switch (by researcher) – delay between channel 1 & 2</td></tr>
<tr><td>Level 2
Once can achieve 15 reps and three sets progressed to reduced height of chair and not using upper limbs</td></tr>
<tr><td>Level 3
Wearing weighted vest or holding weight in arms</td><td rowspan="2">Weight options may include: 0.5kg, 1kg, 1.5kg, 2kg, 2.5kg, 3kg, 3.5kg, 4kg, 4.5kg, 5kg</td></tr>
<tr><td>Level 4
Reduced height of chair and weights with non hemiparetic foot placed in front of more affected leg (marked with tapped line on floor)</td></tr>
</table>

Appendix 37 continued: Suggested development of task orientated gait training programme

<table>
<tr><th colspan="3">2. Specific component of gait: Performed over duration of 10 minutes. Level chosen based on individual participant's needs and progressed in response to performance and Borg Scale ratings (Holleran et al., 2014, Mayo et al., 2013).</th></tr>
<tr><td colspan="3">a. Stance practice: Target Duration 5 minutes</td></tr>
<tr><td>Description of progression</td><td>Target Intensity</td><td>FES Guidance</td></tr>
<tr><td>Level 1:

Upper limb support (hand rails/kitchen work surface/ table, walking aid, therapist). Stepping non hemiparetic leg forwards and backwards to a line marked with tape on the floor (ground level)</td><td rowspan="4">Continuous stepping for entire target time. Repetitions counted. Rests when asked for by participant or when reports Borg Scale of 15 and above

Progress height of step (for example use of four section adjustable bath step, each section is 25mm thick).

Weighted vest weighing 4.5kg (able to increase up to 9kg in 250gram increments).

Ankle weights comfort straps weighing 2lb, 3lb and 5lb</td><td rowspan="4">Channel 2: on weight transfer to hemi-paretic leg.

Trigger method: Heel switch (activity started with hemiparetic leg heel strike)</td></tr>
<tr><td>Level 2

Upper limb support (hand rails/kitchen work surface/ table, walking aid, therapist). Stepping non hemiparetic leg forwards and backwards onto a step</td></tr>
<tr><td>Level 3

No upper limb support. Stepping non hemiparetic leg forwards and backwards onto a step</td></tr>
<tr><td>Level 4

No upper limb support. Stepping non hemiparetic leg forwards and backwards onto a step wearing ankle weights or weighted vest.</td></tr>
</table>

Appendix 37 continued: Suggested development of task orientated gait training programme

b. Swing practice: **Target Duration 5 minutes**		
Description of progression :	**Target Intensity**	**FES Guidance**
Level 1 Upper limb support (hand rails/kitchen work surface/ table, walking aid, therapist). Stepping hemiparetic leg forwards and backwards to a line marked with tape on the floor (ground level)	Continuous stepping for entire target time. Repetitions counted. Rests when asked for by participant or when reports Borg Scale of 15 or above. Progress height of step (for example use of four section adjustable bath step, each section is 25mm thick). Resistance band options including very light, light, medium, heavy and very heavy. Ankle weight comfort straps weighing 2lb, 3lb and 5lb	Channel 1&2: Channel 1 activated on stepping with hemi paretic leg and channel 2 activated during stepping with non hemiplegic leg. Trigger method: Heel switch
Level 2 Upper limb support (hand rails/kitchen work surface/ table, walking aid, therapist). Stepping hemiparetic leg forwards and backwards onto a step		
Level 3 No upper limb support. Stepping hemiparetic leg forwards and backwards onto a step		
Level 4 Upper limb or no upper limb support (depending on patient's ability). Stepping hemiparetic leg forwards and backwards to a line marked with tape on the floor (ground level) with elastic band applied to hemiparetic limb to challenge swing and propulsion		
Level 5 No upper limb support. Stepping hemiparetic leg forwards and backwards onto a step wearing ankle weights and/or elastic band to challenge swing and propulsion		

Appendix 37 continued: Suggested development of task orientated gait training programme

3. Obstacle Course: Level chosen based on individual participant's needs and progressed in response to performance (Blennerhassett and Dite, 2004, Clark and Patten, 2013, Holleran et al., 2014, Mares et al., 2014, Outermans et al., 2010) **Target time 10 minutes.**		
Description of progression	**Target Intensity**	**FES Guidance**
Level 1 Walking around cones on even surface with/without support from therapist/walking aid turning at end and changing direction	Continuous for entire target time. Repetitions counted (steps and laps). Rests when asked for by participant or when reports Borg Scale of 15 or above.	Channel 1&2: Channel 1 activated on stepping with hemi paretic leg and channel 2 activated during stepping with non hemiplegic leg. Trigger method: Heel switch
Level 2 Walking around cones and stepping over hurdles with/without support from therapist/walking aid turning at end and changing direction		
Level 3 Walking around cones, stepping over hurdles, stepping on and off foam cushion (compliant surface), on and off inclined/declined wedge turning at end and changing direction with speed element		
Level 4 Community ambulation including in/out of front door, up and down curbs, uneven surfaces (for example grass and concrete).		

Appendix 37 continued: Suggested development of task orientated gait training programme

4. Walking with auditory cues delivered via pre-prepared music or metronome with beats related to cadence (Nascimento et al., 2015, Thaut et al., 2007) **Target time 12 minutes. Level chosen based on individual participant's needs and progressed in response to performance**		
Description of progression	**Target Intensity**	**FES Guidance**
Level 1 Walking forwards, backwards and sideways with therapist support/walking aid and auditory cues	Continuous for entire target time. Repetitions counted (steps and laps). Rests when asked for by participant or when reports Borg Scale of 15 or above. First 3 minutes walking forwards with cueing frequencies matched to initial cadence, following 3 minutes frequencies increased in 5% increments as kinematically indicated. Following 3 minutes spent walking sideways and backwards with cues and final 3 minutes spent phasing cues out intermittently to encourage carryover (Thaut et al., 2007).	Channel 1&2: Channel 1 activated on stepping with hemi paretic leg and channel 2 activated during stepping with non hemiplegic leg. Trigger method: Heel switch
Level 2 Walking forwards, backwards and sideways without any assistance and auditory cues		

Appendix 37 continued: Suggested development of task orientated gait training programme

4. Walking with dual task element (Hyndman et al., 2006, Plummer et al., 2014, Plummer-D'Amato et al., 2008, Plummer-D'Amato et al., 2012, Yang et al., 2007) **Target Time: 8 minutes**			
	Description of progression	Target Intensity	FES Guidance
Motor Dual Task	Level 1 Walk and turn head as directed by therapist	Continuous for entire target time. Repetitions counted (steps and laps). Rests when asked for by participant or when reports Borg Scale of 15 or above.	Channel 1&2: Channel 1 activated on stepping with hemi paretic leg and channel 2 activated during stepping with non hemiplegic leg. Trigger method: Heel switch
	Level 2 Walking whilst dribbling ball, throwing and catching ball or carrying a glass of water or a tray of glasses		
Cognitive Dual task	Walking whilst performing mathematical subtraction, spelling words backwards and counting backwards	Continuous for entire target time. Repetitions counted (steps and laps). Rests when asked for by participant or when reports Borg Scale of 15 or above.	Channel 1&2: Channel 1 activated on stepping with hemi paretic leg and channel 2 activated during stepping with non hemiplegic leg. Trigger method: Heel switch

7. List of References

AKL, E. A., BRIEL, M., YOU, J. J., SUN, X., JOHNSTON, B. C., BUSSE, J. W., MULLA, S., LAMONTAGNE, F., BASSLER, D., VERA, C., ALSHURAFA, M., KATSIOS, C. M., ZHOU, Q., CUKIERMAN-YAFFE, T., GANGJI, A., MILLS, E. J., WALTER, S. D., COOK, D. J., SCHÜNEMANN, H. J., ALTMAN, D. G. & GUYATT, G. H. 2012. Potential impact on estimated treatment effects of information lost to follow-up in randomised controlled trials (LOST-IT): systematic review. *The British Medical Journal,* 344**,** e2809.

ALON, G. & RING, H. 2003. Gait and hand function enhancement following training with a multi-segment hybrid-orthosis stimulation system in stroke patients. *Journal of Stroke & Cerebrovascular Diseases,* 12**,** 209-216.

ANSARI, N. N., NAGHDI, S., HASSON, S., MOUSAKHANI, A., NOURIYAN, A. & OMIDVAR, Z. 2009. Inter-rater reliability of the Modified Modified Ashworth Scale as a clinical tool in measurements of post-stroke elbow flexor spasticity. *NeuroRehabilitation,* 24**,** 225-9.

ANSARI, N. N., NAGHDI, S., MOAMMERI, H. & JALAIE, S. 2006. Ashworth Scales are unreliable for the assessment of muscle spasticity. *Physiotherapy Theory Practice,* 22**,** 119-25.

ARAIN, M., CAMPBELL, M., COOPER, C. & LANCASTER, G. 2010. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Medical Research Methodology,* 10**,** 67.

ASANUMA, H. & KELLER, A. 1991. Neuronal mechanisms of motor learning in mammals. *NeuroReport,* 2**,** 217-224.

BAER, G. & SMITH, M. 2001. The recovery of walking ability and subclassification of stroke. *Physiotherapy Research International,* 6**,** 135-144.

BAGLEY, P., HUDSON, M., GREEN, J., FORSTER, A. & YOUNG, J. 2009. Do physiotherapy staff record treatment time accurately? An observational study. *Clinical Rehabilitation,* 23**,** 841-845.

BAKHTIARY, A. & FATEMY, E. 2008. Does electrical stimulation reduce spasticity after stroke? A randomized controlled study. *Clinical Rehabilitation,* 22**,** 418-25.

BAMFORD, J., SANDERCOCK, P., DENNIS, M., WARLOW, C. & BURN, J. 1991. Classification and natural history of clinically identifiable subtypes of cerebral infarction. *The Lancet,* 337**,** 1521-1526.

BELL, K. R., HAMMOND, F., HART, T., BICKETT, A. K., TEMKIN, N. R. & DIKMEN, S. 2008. Participant recruitment and retention in rehabilitation research. *American Journal of Physical Medicine & Rehabilitation,* 87**,** 330-338.

BERG, K. 1989. Measuring balance in the elderly: preliminary development of an instrument. *Physiotherapy Canada,* 41**,** 304-311.

BERNHARDT, J., DEWEY, H., THRIFT, A., COLLIER, J. & DONNAN, G. 2008. A Very Early Rehabilitation Trial for Stroke (AVERT): Phase II Safety and Feasibility. *Stroke,* 39**,** 390-396.

BHIMANI, R. H., ANDERSON, L. C., HENLY, S. J. & STODDARD, S. A. 2011. Clinical Measurement of Limb Spasticity in Adults: State of the Science. *Journal of Neuroscience Nursing,* 43**,** 104-115.

BLANTON, S., MORRIS, D. M., PRETTYMAN, M. G., MCCULLOCH, K., REDMOND, S., LIGHT, K. E. & WOLF, S. L. 2006. Lessons Learned in Participant Recruitment and Retention: The EXCITE Trial. *Physical Therapy,* 86**,** 1520-1533.

BLENNERHASSETT, J. & DITE, W. 2004. Additional task-related practice improves mobility and upper limb function early after stroke: a randomised controlled trial. *Australian Journal of Physiotherapy,* 50**,** 219-24.
BOGATAJ, U., GROS, N., KLJAJIC, M., ACIMOVIC, R. & MALEZIC, M. 1995. The rehabilitation of gait in patients with hemiplegia: a comparison between conventional therapy and multichannel functional electrical stimulation therapy. *Physical Therapy,* 75**,** 490-502.
BOHANNON, R. W., ANDREWS, A. W. & SMITH, M. B. 1988. Rehabilitation goals of patients with hemiplegia. *International Journal of Rehabilitation Research,* 11**,** 181-184.
BOHANNON, R. W. & SMITH, M. B. 1987. Interrater Reliability of a Modified Ashworth Scale of Muscle Spasticity. *Physical Therapy,* 67**,** 206-207.
BORM, G. F., FRANSEN, J. & LEMMENS, W. A. 2007. A simple sample size formula for analysis of covariance in randomized clinical trials. *Journal of Clinical Epidemiology,* 60**,** 1234-8. Epub 2007 Jun 6.
BOUTRON, I., MOHER, D., ALTMAN, D. G., SCHULZ, K. F. & RAVAUD, P. 2008. Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration. *Annals of Internal Medicine,* 148**,** 295-309.
BROSSEAU, L., POTVIN, L., PHILIPPE, P. & BOULANGER, Y.-L. 1996. Post-Stroke Inpatient Rehabilitation: II. Predicting Discharge Disposition. *American Journal of Physical Medicine & Rehabilitation,* 75**,** 431-436.
BURRIDGE, J. & MCLELLAN, D. 2000. Relation between abnormal patterns of muscle activation and response to common peroneal nerve stimulation in hemiplegia. *Journal of Neurology, Neurosurgery and Psychiatry,* 69**,** 353-61.
BURRIDGE, J., SWAIN, I. & TAYLOR, P. 1998. Functional electrical stimulation: a review of the literature published on common peroneal nerve stimulation for the correction of dropped foot. *Reviews in Clinical Gerontology,* 8**,** 155-161.
BURRIDGE, J., TAYLOR, P., HAGAN, S., WOOD, D. & SWAIN, I. 1997a. The Effect of Common Peroneal Nerve Stimulation on Quadriceps Spasticity in Hemiplegia. *Physiotherapy,* 83**,** 82-89.
BURRIDGE, J., TAYLOR, P., HAGAN, S., WOOD, D. & SWAIN, I. 1997b. The effects of common peroneal stimulation on the effort and speed of walking: a randomized controlled trial with chronic hemiplegic patients. *Clinical Rehabilitation,* 11**,** 201-10.
BURRIDGE, J. H., ELESSI, K., PICKERING, R. M. & TAYLOR, P. N. 2007. Walking on an Uneven Surface: The Effect of Common Peroneal Stimulation on Gait Parameters and Relationship Between Perceived and Measured Benefits in a Sample of Participants With a Drop-Foot. *Neuromodulation: Technology at the Neural Interface,* 10**,** 59-67.
CAROD-ARTAL, F. J., GONZÁLEZ-GUTIÉRREZ, J. L., HERRERO, J. A. E., HORAN, T. & SEIJAS, E. V. D. 2002. Functional recovery and instrumental activities of daily living: follow-up 1-year after treatment in a stroke unit. *Brain Injury,* 16**,** 207-216.
CHA, J., HENG, C., REINKENSMEYER, D. J., ROY, R. R., EDGERTON, V. R. & DE LEON, R. D. 2007. Locomotor ability in spinal rats is dependent on the amount of activity imposed on the hindlimbs during treadmill training. *Journal of Neurotrauma,* 24**,** 1000-12.
CHEN, H.-M., HSIEH, C.-L., LO, S. K., LIAW, L.-J., CHEN, S.-M. & LIN, J.-H. 2007. The Test-Retest Reliability of 2 Mobility Performance Tests in Patients With Chronic Stroke. *Neurorehabilitation and Neural Repair*.

CHENG, J., YANG, Y., CHENG, S., LIN, P. & WANG, R. 2010. Effects of combining electric stimulation with active ankle dorsiflexion while standing on a rocker board: A pilot study for subjects with spastic foot after stroke. *Archives of Physical Medicine and Rehabilitation,* 91**,** 505-12.
CHENG, P.-T., WANG, C.-M., CHUNG, C.-Y. & CHEN, C.-L. 2004. Effects of visual feedback rhythmic weight-shift training on hemiplegic stroke patients. *Clinical Rehabilitation,* 18**,** 747-753.
CHOU, S. W., WONG, A. M. K., HONG, W. S., TANG, F. T., LIN, T. H. & LEONG, C. P. 2003. Postural control during sit-to stand and gait in stroke patients. *American Journal of Physical Medicine and Rehabilitation,* 82**,** 42-47.
CLARK, D. J. & PATTEN, C. 2013. Eccentric versus concentric resistance training to enhance neuromuscular activation and walking speed following stroke. *Neurorehabilitation and Neural Repair,* 27**,** 335-344.
COLLEN, F. M., WADE, D. T., ROBB, G. F. & BRADSHAW, C. M. 1991. The Rivermead Mobility Index: A further development of the Rivermead Motor Assessment. *Disability And Rehabilitation,* 13**,** 50-54.
COOKE, E. V., TALLIS, R. C., CLARK, A. & POMEROY, V. M. 2010. Efficacy of functional strength training on restoration of lower-limb motor function early after stroke: Phase 1 randomized controlled trial. *Neurorehabilitation and Neural Repair,* 24**,** 88-96.
CRAIG, P., DIEPPE, P., MACINTYRE, S., MICHIE, S., NAZARETH, I. & PETTICREW, M. 2011. Developing and evaluating complex interventions: new guidance. *International Journal of Stroke,* 6**,** 321-327.
CRAMER, S. C. 2008. Repairing the human brain after stroke: I. Mechanisms of spontaneous recovery. *Annals of Neurology,* 63**,** 272-287.
DA CUNHA, I., LIM, P., QURESHY, H., HENSON, H., MONGA, T. & PROTAS, E. 2002. Gait outcomes after acute stroke rehabilitation with supported treadmill ambulation training: a randomized controlled pilot study. *Archives of Physical Medicine and Rehabilitation,* 83**,** 1258-65.
DALY, J., NETHERY, J., MCCABE, J., BRENNER, I., ROGERS, J., GANSEN, J., BUTLER, K., BURDSALL, R., ROENIGK, K. & HOLCOMB, J. 2009. Development and testing of the Gait Assessment and Intervention Tool (G.A.I.T.): a measure of coordinated gait components. *Journal Of Neuroscience Methods,* 178**,** 334-9.
DALY, J. J., HOGAN, N., PEREPEZKO, E. M., KREBS, H. I., ROGERS, J. M., GOYAL, K. S., DOHRING, M. E., FREDRICKSON, E., NETHERY, J. & RUFF, R. L. 2005. Response to upper-limb robotics and functional neuromuscular stimulation following stroke. *Journal Of Rehabilitation Research And Development,* 42**,** 723.
DEAN, C. M., ADA, L., BAMPTON, J., MORRIS, M. E., KATRAK, P. H. & POTTS, S. 2010. Treadmill walking with body weight support in subacute non-ambulatory stroke improves walking capacity more than overground walking: a randomised trial. *Journal Of Physiotherapy,* 56**,** 97-103.
DEMEURISSE, G., DEMOL, O. & ROBAYE, E. 1980. Motor Evaluation in Vascular Hemiplegia. *European Neurology,* 19**,** 382-389.
DI CARLO, A. 2009. Human and economic burden of stroke. *Age Ageing,* 38**,** 4-5.
DOBKIN, B. H. 2005. Rehabilitation after Stroke. *New England Journal of Medicine,* 352**,** 1677-1684.
DOH 2007. National Stroke Strategy. London: Department of Health.
DOH 2010. National Audit Office: Progress in improving stroke care. London: The Stationary Office.

DUNCAN, P. W., WALLACE, D., LAI, S. M., JOHNSON, D., EMBRETSON, S. & LASTER, L. J. 1999. The Stroke Impact Scale Version 2.0 : Evaluation of Reliability, Validity, and Sensitivity to Change. *Stroke,* 30**,** 2131-2140.
DUNNING, K., BLACK, K., HARRISON, A., MCBRIDE, K. & ISRAEL, S. 2009. Neuroprosthesis peroneal functional electrical stimulation in the acute inpatient rehabilitation setting: a case series. *Physical Therapy,* 89**,** 499-506.
ENG, J. 2003. Sample Size Estimation: How Many Individuals Should Be Studied? . *Radiology,* 227**,** 309-313.
EVERAERT, D. G., THOMPSON, A. K., CHONG, S. L. & STEIN, R. B. 2010. Does functional electrical stimulation for foot drop strengthen corticospinal connections? *Neurorehabilitation and Neural Repair,* 24**,** 168-77.
FAGHRI, P. D., VOTTO, J. J. & HOVORKA, C. F. 1998. Venous hemodynamics of the lower extremities in response to electrical stimulation. *Archives of Physical Medicine and Rehabilitation,* 79**,** 842-848.
FEARON, P. & LANGHORNE, P. 2012. Services for reducing duration of hospital care for acute stroke patients. *Cochrane Database of Systematic Reviews* [Online], 9. [Accessed 1/10/2014].
FERRARELLO, F., BIANCHI, V. A. M., BACCINI, M., RUBBIERI, G., MOSSELLO, E., CAVALLINI, M. C., MARCHIONNI, N. & DI BARI, M. 2013. Tools for Observational Gait Analysis in Patients With Stroke: A Systematic Review. *Physical Therapy,* 93**,** 1673-1685.
FINK, J. N., FRAMPTON, C. M., LYDEN, P., LEES, K. R. & INVESTIGATORS, O. B. O. T. V. 2008. Does Hemispheric Lateralization Influence Functional and Cardiovascular Outcomes After Stroke?: An Analysis of Placebo-Treated Patients From Prospective Acute Stroke Trials. *Stroke,* 39**,** 3335-3340.
FISHER, R. J., COBLEY, C. S., POTGIETER, I., MOODY, A., NOURI, F., GAYNOR, C., BYRNE, A. & WALKER, M. F. 2015. Is Stroke Early Supported Discharge still effective in practice? A prospective comparative study. *Clinical Rehabilitation* [Online]. Available: http://cre.sagepub.com/content/early/2015/03/27/0269215515578697.abstract [Accessed 1/10/2015].
FITZGERALD, G. K. & DELITTO, A. 2001. Considerations for Planning and Conducting Clinic-Based Research in Physical Therapy. *Physical Therapy,* 81**,** 1446-1454.
FLANSBJER, U. B., LEXELL, J. & BROGARDH, C. 2012. Long-term benefits of progressive resistance training in chronic stroke: a 4-year follow-up. *Journal of Rehabilitation Medicine,* 44**,** 218-21.
FRIEDMAN, P., RICHMOND, D. & BASKETT, J. 1988. A prospective trial of serial gait speed as a measure of rehabilitation in the elderly. *Age and Ageing,* 17**,** 227-235.
G.A.P.S. 2004. Can augmented physiotherapy input enhance recovery of mobility after stroke? A randomized controlled trial. *Clinical Rehabilitation,* 18**,** 529-537.
GARLAND, S. J., WILLEMS, D. A., IVANOVA, T. D. & MILLER, K. J. 2003. Recovery of standing balance and functional mobility after stroke1. *Archives of Physical Medicine and Rehabilitation,* 84**,** 1753-1759.
GHOTBI, N., ANSARI, N. N., NAGHDI, S. & HASSON, S. 2011. Measurement of lower-limb muscle spasticity: Intrarater reliability of Modified Modified Ashworth Scale. *Journal of Rehabilitation Research & Development,* 48**,** 83-88.
GLANZ, M., KLAWANSKY, S., STASON, W., BERKEY, C. & CHALMERS, T. 1996. Functional electrostimulation in poststroke rehabilitation: a meta-

analysis of the randomized controlled trials. *Archives of Physical Medicine and Rehabilitation,* 77**,** 549-53.
GOLDIE, P. A., MATYAS, T. A. & EVANS, O. M. 1996. Deficit and change in gait velocity during rehabilitation after stroke. *Archives of Physical Medicine and Rehabilitation,* 77**,** 1074-1082.
GORDON, N. F., GULANICK, M., COSTA, F., FLETCHER, G., FRANKLIN, B. A., ROTH, E. J. & SHEPHARD, T. 2004. Physical Activity and Exercise Recommendations for Stroke Survivors: An American Heart Association Scientific Statement From the Council on Clinical Cardiology, Subcommittee on Exercise, Cardiac Rehabilitation, and Prevention; the Council on Cardiovascular Nursing; the Council on Nutrition, Physical Activity, and Metabolism; and the Stroke Council. *Stroke,* 35**,** 1230-1240.
GRANAT, M., MAXWELL, D., FERGUSON, A., LEES, K. & BARBENEL, J. 1996. Peroneal stimulator: evaluation for the correction of spastic foot in hemiplegia. *Archives of Physical Medicine and Rehabilitation,* 77**,** 19-24.
GUIDETTI, S., YTTERBERG, C., EKSTAM, L., JOHANSSON, U. & ERIKSSON, G. 2014. Changes in the impact of stroke between 3 and 12 months post-stroke, assessed with the Stroke Impact Scale. *Journal of Rehabilitation Medicine,* 46**,** 963-8.
HEBB, D. O. 2005. *The organization of behavior: a neuropsychological theory*, Psychology Press.
HILDEBRAND, M. W., HOST, H. H., BINDER, E. F., CARPENTER, B., FREEDLAND, K. E., MORROW-HOWELL, N., BAUM, C. M., DORE, P. & LENZE, E. J. 2012. Measuring Treatment Fidelity in a Rehabilitation Intervention Study. *American Journal of Physical Medicine & Rehabilitation,* 91**,** 715-724.
HINES, A. E., CRAGO, P. E. & BILLIAN, C. 1993. Functional electrical stimulation for the reduction of spasticity in the hemiplegic hand. *Biomedical Science Instruments,* 29**,** 259-66.
HOLLERAN, C. L., STRAUBE, D. D., KINNAIRD, C. R., LEDDY, A. L. & HORNBY, T. G. 2014. Feasibility and potential efficacy of high-intensity stepping training in variable contexts in subacute and chronic stroke. *Neurorehabilitation and Neural Repair,* 28**,** 643-651.
HOST, H. H., LANG, C. E., HILDEBRAND, M. W., ZOU, D., BINDER, E. F., BAUM, C. M., FREEDLAND, K. E., MORROW-HOWELL, N. & LENZE, E. J. 2014. Patient active time during therapy sessions in postacute rehabilitation: Development and validation of a new measure. *Physical and Occupational Therapy in Geriatrics,* 32**,** 169-178.
HOWE, T. E., TAYLOR, I., FINN, P. & JONES, H. 2005. Lateral weight transference exercises following acute stroke: a preliminary study of clinical effectiveness. *Clinical Rehabilitation,* 19**,** 45-53.
HOWLETT, O. A., LANNIN, N. A., ADA, L. & MCKINSTRY, C. 2015. Functional Electrical Stimulation Improves Activity After Stroke: A Systematic Review With Meta-Analysis. *Archives of Physical Medicine and Rehabilitation,* 96**,** 934-943.
HSU, A.-L., TANG, P.-F. & JAN, M.-H. 2003. Analysis of impairments influencing gait velocity and asymmetry of hemiplegic patients after mild to moderate stroke. *Archives of Physical Medicine and Rehabilitation,* 84**,** 1185-1193.
HUGHES, A.-M., BURRIDGE, J., FREEMAN, C. T., DONNOVAN-HALL, M., CHAPPELL, P. H., LEWIN, P. L., ROGERS, E. & DIBB, B. 2011. Stroke participants' perceptions of robotic and electrical stimulation therapy: a new approach. *Disability and Rehabilitation: Assistive Technology,* 6**,** 130-138.

HYNDMAN, D., ASHBURN, A., YARDLEY, L. & STACK, E. 2006. Interference between balance, gait and cognitive task performance among people with stroke living in the community. *Disability And Rehabilitation,* 28**,** 849-856.
JENKINSON, C., FITZPATRICK, R., CROCKER, H. & PETERS, M. 2013. The Stroke Impact Scale: Validation in a UK Setting and Development of a SIS Short Form and SIS Index. *Stroke,* 44**,** 2532-2535.
JONES, S. R., CARLEY, S. & HARRISON, M. 2003. An introduction to power and sample size estimation. *Emergency Medicine Journal,* 20**,** 453-458.
JØRGENSEN, H. S., NAKAYAMA, H., RAASCHOU, H. O. & OLSEN, T. S. 1995. Recovery of walking function in stroke patients: The copenhagen stroke study. *Archives of Physical Medicine and Rehabilitation,* 76**,** 27-32.
JØRGENSEN, J. R., BECH-PEDERSEN, D. T., ZEEMAN, P., SØRENSEN, J., ANDERSEN, L. L. & SCHÖNBERGER, M. 2010. Effect of Intensive Outpatient Physical Training on Gait Performance and Cardiovascular Health in People With Hemiparesis After Stroke. *Physical Therapy,* 90**,** 527-537.
KARPMAN, C., LEBRASSEUR, N. K., DEPEW, Z. S., NOVOTNY, P. J. & BENZO, R. P. 2014. Measuring gait speed in the out-patient clinic: methodology and feasibility. *Respiratory Care,* 59**,** 531-7.
KAUR, G., ENGLISH, C. & HILLIER, S. 2012. How physically active are people with stroke in physiotherapy sessions aimed at improving motor function? A systematic review. *Stroke Research and Treatment* [Online]. Available: http://dx.doi.org/10.1155/2012/820673 [Accessed 1/10/2015].
KIM, J.-H., CHUNG, Y., KIM, Y. & HWANG, S. 2012. Functional electrical stimulation applied to gluteus medius and tibialis anterior corresponding gait cycle for stroke. *Gait & posture,* 36**,** 65-67.
KIM, J.-H., LEE, L.-K., LEE, J.-U., KIM, M.-Y., YANG, S.-M., JEON, H.-J., LEE, W.-D., NOH, J.-W., KIM, J.-H., KIM, J.-H., LEE, T.-H. & KIM, J. 2013. A Pilot Study on the Effect of Functional Electrical Stimulation of Stroke Patients in a Sitting Position on Balance and Activities of Daily Living. *Journal of Physical Therapy Science,* 25**,** 1097-1101.
KIMBERLEY, T., LEWIS, S., AUERBACH, E., DORSEY, L., LOJOVICH, J. & CAREY, J. 2004. Electrical stimulation driving functional improvements and cortical changes in subjects with stroke. *Experimental Brain Research,* 154**,** 450-460.
KOJOVIC, J., DJURIC-JOVICIC, M., DOSEN, S., POPOVIC, M. B. & POPOVIC, D. B. 2009. Sensor-driven four-channel stimulation of paretic leg: Functional electrical walking therapy. *Journal of Neuroscience Methods,* 181 (1)**,** 100-105.
KOJOVIC, J., MILJKOVIC, N., JANKOVIC, M. M. & POPOVIC, D. B. 2011. Recovery of motor function after stroke: A polymyography-based analysis. *Journal of Neuroscience Methods,* 194 (2)**,** 321-328.
KOTTINK, A. I. R., OOSTENDORP, L. J. M., BUURKE, J. H., NENE, A. V., HERMENS, H. J. & IJZERMAN, M. J. 2004. The orthotic effect of functional electrical stimulation on the improvement of walking in stroke patients with a dropped foot: a systematic review. *Artificial Organs,* 28**,** 577-586.
KUNKEL, D., PICKERING, R. M., BURNETT, M., LITTLEWOOD, J., BURRIDGE, J. H. & ASHBURN, A. 2013. Functional electrical stimulation with exercises for standing balance and weight transfer in acute stroke patients: a feasibility randomized controlled trial. *Neuromodulation: Journal Of The International Neuromodulation Society,* 16**,** 168-177.
KUYS, S. S., BRAUER, S. G. & ADA, L. 2011. Higher-intensity treadmill walking during rehabilitation after stroke in feasible and not detrimental to

walking pattern or quality: a pilot randomized trial. *Clinical Rehabilitation,* 25**,** 316-326.
KWAKKEL, G., KOLLEN, B. & TWISK, J. 2006. Impact of Time on Improvement of Outcome After Stroke. *Stroke,* 37**,** 2348-2353.
KWAKKEL, G., KOLLEN, B. J. & WAGENAAR, R. C. 1999. Therapy Impact on Functional Recovery in Stroke Rehabilitation: A critical review of the literature. *Physiotherapy,* 85**,** 377-391.
KWAKKEL, G., VAN PEPPEN, R., WAGENAAR, R. C., WOOD DAUPHINEE, S., RICHARDS, C., ASHBURN, A., MILLER, K., LINCOLN, N., PARTRIDGE, C., WELLWOOD, I. & LANGHORNE, P. 2004. Effects of augmented exercise therapy time after stroke: a meta-analysis. *Stroke; A Journal Of Cerebral Circulation,* 35**,** 2529-2539.
LAI, S. M., ALTER, M., FRIDAY, G. & SOBEL, E. 1995. Prognosis for Survival After an Initial Stroke. *Stroke,* 26**,** 2011-2015.
LANCASTER, G., DODD, S. & WILLIAMSON, P. 2004. Design and analysis of pilot studies: recommendations for good practice. *Journal of Evaluation Clinical Practice,* 10**,** 307 - 312.
LANG, C. E., MACDONALD, J. R., REISMAN, D. S., BOYD, L., JACOBSON KIMBERLEY, T., SCHINDLER-IVENS, S. M., HORNBY, T. G., ROSS, S. A. & SCHEETS, P. L. 2009. Observation of Amounts of Movement Practice Provided During Stroke Rehabilitation. *Archives of Physical Medicine and Rehabilitation,* 90**,** 1692-1698.
LANGHORNE, P., DENNIS, M., KALRA, L., SHEPPERD, S., WADE, D. & WOLFE CHARLES, D. A. 1999. Services for helping acute stroke patients avoid hospital admission. *Cochrane Database of Systematic Reviews* [Online]. Available: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD000444/frame.html [Accessed 1/10/2015].
LAUFER, Y., SIVAN, D., SCHWARZMANN, R. & SPRECHER, E. 2003. Standing Balance and Functional Recovery of Patients with Right and Left Hemiparesis in the Early Stages of Rehabilitation. *Neurorehabilitation and Neural Repair,* 17**,** 207-213.
LAVER, K., RATCLIFFE, J., GEORGE, S., LESTER, L., WALKER, R., BURGESS, L. & CROTTY, M. 2011. Early rehabilitation management after stroke: What do stroke patients prefer? *Journal of Rehabilitation Medicine,* 43**,** 354-358.
LEE, H.-J., CHO, K.-H. & LEE, W.-H. 2013. The effects of body weight support treadmill training with power-assisted functional electrical stimulation on functional movement and gait in stroke patients. *American Journal Of Physical Medicine & Rehabilitation / Association Of Academic Physiatrists,* 92**,** 1051-1059.
LEE, S., SHAFE, A. C. E. & COWIE, M. R. 2011. UK stroke incidence, mortality and cardiovascular risk management 1999-2008: time-trend analysis from the General Practice Research Database. *BMJ Open* [Online], 1. Available: http://bmjopen.bmj.com/content/1/2/e000269 [Accessed January 1, 2011].
LIBERSON, W. T., HOLMQUEST, H. J., SCOT, D. & DOW, M. 1961. Functional electrotherapy: stimulation of the peroneal nerve synchronized with the swing phase of the gait of hemiplegic patients. *Archives of Physical Medicine and Rehabilitation,* 42**,** 101-105.
LING, F. M. 2004. Stroke Rehabilitation: Predicting Inpatient Length of Stay and Discharge Placement. *Hong Kong Journal of Occupational Therapy,* 14**,** 3-11.

MACDONELL, R. A. L., TRIGGS, W. J., LEIKAUSKAS, J., BOURQUE, M., ROBB, K., DAY, B. J. & SHAHANI, B. T. 1994. Functional electrical stimulation to the affected lower limb and recovery after cerebral infarction. *Journal of Stroke and Cerebrovascular Diseases,* 4**,** 155-160.
MAGUIRE, C., SIEBEN, J. M., FRANK, M. & ROMKES, J. 2010. Hip abductor control in walking following stroke — the immediate effect of canes, taping and TheraTogs on gait. *Clinical Rehabilitation,* 24**,** 37-45.
MALEZIC, M., BOGATAJ, U. & GROS, N. 1987a. Evaluation of gait with multichannel electrical stimulation. *Orthopedics,* 10 (5)**,** 769-772.
MALEZIC, M., HESSE, S., SCHEWE, H. & MAURITZ, K. 1994. Restoration of standing, weight-shift and gait by multichannel electrical stimulation in hemiparetic patients. *International Journal of Rehabilitation Research,* 17**,** 169-79.
MALEZIC, M., KLJAJIC, M., ACIMOVIC-JANEZIC, R., GROS, N., KRAJNIK, J. & STANIC, U. 1987b. Therapeutic effects of multisite electric stimulation of gait in motor-disabled patients. *Archives of Physical Medicine and Rehabilitation,* 68**,** 553-560.
MARES, K., CROSS, J., CLARK, A., VAUGHAN, S., BARTON, G. R., POLAND, F., MCGLASHAN, K., WATSON, M., MYINT, P. K., O'DRISCOLL, M. L. & POMEROY, V. M. 2014. Feasibility of a randomized controlled trial of functional strength training for people between six months and five years after stroke: FeSTivaLS trial. *Trials* [Online], 15. Available: http://trialsjournal.com/content/15/1/322 [Accessed 1/10/15].
MAYO, N. E., MACKAY-LYONS, M. J., SCOTT, S. C., MORIELLO, C. & BROPHY, J. 2013. A randomized trial of two home-based exercise programmes to improve functional walking post-stroke. *Clinical Rehabilitation,* 27**,** 659-671.
MCCAIN, K. J., POLLO, F. E., BAUM, B. S., COLEMAN, S. C., BAKER, S. & SMITH, P. S. 2008. Locomotor treadmill training with partial body-weight support before overground gait in adults with acute stroke: a pilot study. *Archives of Physical Medicine and Rehabilitation,* 89**,** 684-691.
MERWICK, Á. & WERRING, D. 2014. Posterior circulation ischaemic stroke. *BMJ* [Online], 348. Available: http://www.bmj.com/bmj/348/bmj.g3175.full.pdf [Accessed 1/10/2015].
MEYER, S., VERHEYDEN, G., BRINKMANN, N., DEJAEGER, E., DE WEERDT, W., FEYS, H., GANTENBEIN, A. R., JENNI, W., LAENEN, A., LINCOLN, N., PUTMAN, K., SCHUBACK, B., SCHUPP, W., THIJS, V. & DE WIT, L. 2015. Functional and Motor Outcome 5 Years After Stroke Is Equivalent to Outcome at 2 Months: Follow-Up of the Collaborative Evaluation of Rehabilitation in Stroke Across Europe. *Stroke* [Online], 46. Available: http://stroke.ahajournals.org/content/early/2015/05/07/STROKEAHA.115.009421 [Accessed 1/10/2015].
MOORE, J. L., ROTH, E. J., KILLIAN, C. & HORNBY, T. G. 2010. Locomotor Training Improves Daily Stepping Activity and Gait Efficiency in Individuals Poststroke Who Have Reached a "Plateau" in Recovery. *Stroke,* 41**,** 129-135.
MOSELEY, A. M., STARK, A., CAMERON, I. D. & POLLOCK, A. 2005. Treadmill training and body weight support for walking after stroke. *Cochrane Database of Systematic Reviews* [Online]. [Accessed 1/10/2015].
NASCIMENTO, L. R., DE OLIVEIRA, C. Q., ADA, L., MICHAELSEN, S. M. & TEIXEIRA-SALMELA, L. F. 2015. Walking training with cueing of cadence improves walking speed and stride length after stroke more than

walking training alone: a systematic review. *Journal of Physiotherapy,* 61**,** 10-15.
NEWINGTON, L. & METCALFE, A. 2014. Factors influencing recruitment to research: qualitative study of the experiences and perceptions of research teams. *BMC Medical Resaerch Methodology,* 14**,** 1471-2288.
NEWSAM, C. & BAKER, L. 2004. Effect of an electric stimulation facilitation program on quadriceps motor unit recruitment after stroke. *Archives of Physical Medicine and Rehabilitation,* 85**,** 2040-5.
NG, M., TONG, R. & LI, L. 2008. A Pilot Study of Randomized Clinical Controlled Trial of Gait Training in Subacute Stroke Patients With Partial Body-Weight Support Electromechanical Gait Trainer and Functional Electrical Stimulation: Six-Month Follow-Up. *Stroke,* 39**,** 154-160.
NICE 2009. Functional electrical stimulation for drop foot of central neurological origin. *Stroke: Interventional Procedure (IPG278).* London: National Institute for Health and Clinical Excellence.
NICE 2011. Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease. London: National Institute for Health and Clinical Excellence.
NICE 2013. Stroke rehabilitation: Long-term rehabilitation after stroke. *(CG162).* London: National Institute for Health and Clinical Excellence.
NUDO, R. J. 2006. Plasticity. *Neurorx: The Journal Of The American Society For Experimental Neurotherapeutics,* 3**,** 420-427.
NUDO, R. J., MILLIKEN, G. W., JENKINS, W. M. & MERZENICH, M. M. 1996a. Use-dependent alterations of movement representations in primary motor cortex of adult squirrel monkeys. *The Journal Of Neuroscience: The Official Journal Of The Society For Neuroscience,* 16**,** 785-807.
NUDO, R. J., WISE, B. M., SIFUENTES, F. & MILLIKEN, G. W. 1996b. Neural Substrates for the Effects of Rehabilitative Training on Motor Recovery After Ischemic Infarct. *Science,* 272**,** 1791-1794.
OLNEY, S. J. & RICHARDS, C. 1996. Hemiparetic gait following stroke. Part I: Characteristics. *Gait & posture,* 4**,** 136-148.
OUTERMANS, J. C., VAN PEPPEN, R. P., WITTINK, H., TAKKEN, T. & KWAKKEL, G. 2010. Effects of a high-intensity task-oriented training on gait performance early after stroke: A pilot study. *Clinical Rehabilitation,* 24**,** 979.
PANDYAN, A., GRANAT, M. & STOTT, D. 1997. Effects of electrical stimulation on flexion contractures in the hemiplegic wrist. *Clinical Rehabilitation,* 11**,** 123-130.
PANDYAN, A. D., PRICE, C. I., BARNES, M. P. & JOHNSON, G. R. 2003. A biomechanical investigation into the validity of the modified Ashworth Scale as a measure of elbow spasticity. *Clinical Rehabilitation,* 17**,** 290-3.
PAOLUCCI, S., ANTONUCCI, G., GRASSO, M. G., MORELLI, D., TROISI, E., COIRO, P. & BRAGONI, M. 2000. Early versus delayed inpatient stroke rehabilitation: A matched comparison conducted in Italy. *Archives of Physical Medicine and Rehabilitation,* 81**,** 695-700.
PATEL, M., COSHALL, C., RUDD, A. G. & WOLFE, C. D. 2003. Natural history of cognitive impairment after stroke and factors associated with its recovery. *Clinical Rehabilitation,* 17**,** 158-166.
PEDERSEN, P. M., JØRGENSEN, H. S., NAKAYAMA, H., RAASCHOU, H. O. & OLSEN, T. S. 1996. General Cognitive Function in Acute Stroke: The Copenhagen Stroke Study. *Neurorehabilitation and Neural Repair,* 10**,** 153-158.

PEREIRA, S., MEHTA, S., MCINTYRE, A., LOBO, L. & TEASELL, R. W. 2012. Functional electrical stimulation for improving gait in persons with chronic stroke. *Topics in Stroke Rehabilitation,* 19**,** 491-498.
PERERA, S., MODY, S. H., WOODMAN, R. C. & STUDENSKI, S. A. 2006. Meaningful change and responsiveness in common physical performance measures in older adults. *Journal of American Geriatrics Society,* 54**,** 743-9.
PETERS, D. M., FRITZ, S. L. & KROTISH, D. E. 2013. Assessing the Reliability and Validity of a Shorter Walk Test Compared With the 10-Meter Walk Test for Measurements of Gait Speed in Healthy, Older Adults. *Journal of Geriatric Physical Therapy,* 36**,** 24-30.
PEURALA, S., AIRAKSINEN, O., JAKALA, P., TARKKA, I. & SIVENIUS, J. 2007. Effects of intensive gait-oriented physiotherapy during early acute phase of stroke. *Journal of Rehabilitation Research and Development,* 44**,** 637-48.
PEURALA, S. H., TARKKA, I. M., PITKANEN, K. & SIVENIUS, J. 2005. The effectiveness of body weight-supported gait training and floor walking in patients with chronic stroke. *Archives of Physical Medicine & Rehabilitation,* 86**,** 1557-1564.
PLAUTZ, E. J., MILLIKEN, G. W. & NUDO, R. J. 2000. Effects of repetitive motor training on movement representations in adult squirrel monkeys: role of use versus learning. *Neurobiology Of Learning And Memory,* 74**,** 27-55.
PLUMMER-D'AMATO, P., KYVELIDOU, A., STERNAD, D., NAJAFI, B., VILLALOBOS, R. M. & ZURAKOWSKI, D. 2012. Training dual-task walking in community-dwelling adults within 1 year of stroke: a protocol for a single-blind randomized controlled trial. *BMC Neurology,* 12**,** 129-129.
PLUMMER-D'AMATO, P., ALTMANN, L. J., SARACINO, D., FOX, E., BEHRMAN, A. L. & MARSISKE, M. 2008. Interactions between cognitive tasks and gait after stroke: a dual task study. *Gait & posture,* 27**,** 683-688.
PLUMMER, P., VILLALOBOS, R. M., VAYDA, M. S., MOSER, M. & JOHNSON, E. 2014. Feasibility of dual-task gait training for community-dwelling adults after stroke: a case series. *Stroke Research and Treatment,* 2014**,** 538602-538602.
POHL, M., WERNER, C., HOLZGRAEFE, M., KROCZEK, G., MEHRHOLZ, J., WINGENDORF, I., HOLIG, G., KOCH, R. & HESSE, S. 2007. Repetitive locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial (DEutsche GAngtrainerStudie, DEGAS). *Clinical Rehabilitation,* 21**,** 17-27.
POMEROY, V. M., COOKE, E., HAMILTON, S., WHITTET, A. & TALLIS, R. C. 2005. Development of a Schedule of Current Physiotherapy Treatment Used to Improve Movement Control and Functional Use of the Lower Limb after Stroke: A Precursor to a Clinical Trial. *Neurorehabilitation and Neural Repair,* 19**,** 350-359.
PUNDIK, S., HOLCOMB, J., MCCABE, J. & DALY, J. J. 2012. Enhanced life-role participation in response to comprehensive gait training in chronic stroke survivors. *Disability and Rehabilitation,* 34**,** 2264.
RAND, D. & ENG, J. J. 2012. Disparity between functional recovery and daily use of the upper and lower extremities during subacute stroke rehabilitation. *Neurorehabilitation and Neural Repair,* 26**,** 76-84.
RCP 2011. The National Sentinel Stroke Audit 2010: Round 7, Public report for England, Wales and Northern Ireland. London: RCP.
RCP 2012. National clinical guideline for stroke; 4th Edition. Intercollegiate Stroke Working Party: London.

RCP. 2014. *How good is stroke care? First SSNAP Annual Report* [Online]. Available: https://www.strokeaudit.org/Documents/Newspress/SSNAP-Annual-Report-(April-2013-March-2014).pdf [Accessed 08/04 2015].
RICHARDS, C. L., MALOUIN, F., WOOD-DAUPHINEE, S., WILLIAMS, J. I., BOUCHARD, J. P. & BRUNET, D. 1993. Task-specific physical therapy for optimization of gait recovery in acute stroke patients. *Archives of Physical Medicine and Rehabilitation,* 74**,** 612-620.
ROBBINS, S., HOUGHTON, P., WOODBURY, M. & BROWN, J. 2006. The therapeutic effect of functional and transcutaneous electric stimulation on improving gait speed in stroke patients: a meta-analysis. *Archives of Physical Medicine and Rehabilitation,* 87**,** 853-9.
ROCHE, A., LAIGHIN, G. & COOTE, S. 2009. Surface-applied functional electrical stimulation for orthotic and therapeutic treatment of drop-foot after stroke -- a systematic review. *Physical Therapy Reviews,* 14**,** 63-80.
RODRIQUEZ, A. A., BLACK, P. O., KILE, K. A., SHERMAN, J., STELLBERG, B., MCCORMICK, J., ROSZKOWSKI, J. & SWIGGUM, E. 1996. Gait training efficacy using a home-based practice model in chronic hemiplegia. *Archives of Physical Medicine and Rehabilitation,* 77**,** 801-805.
RUSHTON, D. N. 2003. Functional Electrical Stimulation and rehabilitation--an hypothesis. *Medical engineering & physics,* 25**,** 75-78.
SABUT, S. K., SIKDAR, C., MONDAL, R., KUMAR, R. & MAHADEVAPPA, M. 2010. Restoration of gait and motor recovery by functional electrical stimulation therapy in persons with stroke. *Disability & Rehabilitation,* 32**,** 1594-1603.
SALBACH, N. M., MAYO, N. E., HIGGINS, J., AHMED, S., FINCH, L. E. & RICHARDS, C. L. 2001. Responsiveness and predictability of gait speed and other disability measures in acute stroke. *Archives of Physical Medicine and Rehabilitation,* 82**,** 1204-1212.
SALISBURY, L., SHIELS, J., TODD, I. & DENNIS, M. 2013. A feasibility study to investigate the clinical application of functional electrical stimulation (FES), for dropped foot, during the sub-acute phase of stroke: A randomized controlled trial. *Physiotherapy Theory and Practice,* 29**,** 31-40.
SÁNCHEZ-BLANCO, I., OCHOA-SANGRADOR, C., LÓPEZ-MUNAÍN, L., IZQUIERDO-SÁNCHEZ, M. & FERMOSO-GARCÍA, J. 1999. Predictive model of functional independence in stroke patients admitted to a rehabilitation programme. *Clinical Rehabilitation,* 13**,** 464-475.
SCRIVENER, K., SHERRINGTON, C. & SCHURR, K. 2012. Exercise dose and mobility outcome in a comprehensive stroke unit : Description and prediction from a prospective cohort study. *Journal of Rehabilitation Medicine,* 44**,** 824-829.
SHEFFLER, L. R. & CHAE, J. 2007. Neuromuscular electrical stimulation in neurorehabilitation. *Muscle & Nerve,* 35**,** 562-590.
SPAICH, E. G., SVANEBORG, N., JØRGENSEN, H. R. M. & ANDERSEN, O. K. 2014. Rehabilitation of the hemiparetic gait by nociceptive withdrawal reflex-based functional electrical therapy: a randomized, single-blinded study. *Journal Of Neuroengineering And Rehabilitation,* 11**,** 81-81.
STANIC, U., ACIMOVIC-JANEZIC, R., GROS, N., KLJAJIC, M., MALEZIC, M., BOGATAJ, U. & ROZMAN, J. 1991. Functional Electrical Stimulation in Lower Extremity Orthoses in Hemiplegia. *Neurorehabilitation and Neural Repair,* 5**,** 23-36.
STEVENSON, T. J. 2001. Detecting change in patients with stroke using the Berg Balance Scale. *Australian Journal of Physiotherapy,* 47**,** 29-38.

TAN, Z., LIU, H., YAN, T., JIN, D., HE, X., ZHENG, X., XU, S. & TAN, C. 2014. The effectiveness of functional electrical stimulation based on a normal gait pattern on subjects with early stroke: a randomized controlled trial. *BioMed Research International,* 2014**,** 545408-545408.
TAYLOR, P. N., BURRIDGE, J. H., DUNKERLEY, A. L., LAMB, A., WOOD, D. E., NORTON, J. A. & SWAIN, I. D. 1999a. Patients' perceptions of the Odstock Dropped Foot Stimulator (ODFS). *Clinical Rehabilitation,* 13**,** 439-446.
TAYLOR, P. N., BURRIDGE, J. H., DUNKERLEY, A. L., WOOD, D. E., NORTON, J. A., SINGLETON, C. & SWAIN, I. D. 1999b. Clinical use of the Odstock dropped foot stimulator: its effect on the speed and effort of walking. *Archives of Physical Medicine & Rehabilitation,* 80**,** 1577-1583.
THABANE, L., MA, J., CHU, R., CHENG, J., ISMAILA, A., RIOS, L., ROBSON, R., THABANE, M., GIANGREGORIO, L. & GOLDSMITH, C. 2010. A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology,* 10**,** 1.
THAUT, M. H., LEINS, A. K., RICE, R. R., ARGSTATTER, H., KENYON, G. P., MCINTOSH, G. C., BOLAY, H. V. & FETTER, M. 2007. Rhythmic Auditory Stimulation Improves Gait More Than NDT/Bobath Training in Near-Ambulatory Patients Early Poststroke: A Single-Blind, Randomized Trial. *Neurorehabilitation and Neural Repair,* 21**,** 455-459.
THE AVERT TRIAL COLLABORATION GROUP. 2015. Efficacy and safety of very early mobilisation within 24 h of stroke onset (AVERT): a randomised controlled trial. *The Lancet* [Online], 386. Available: http://dx.doi.org/10.1016/S0140-6736(15)60690-0 [Accessed 01/10/2015].
THOMPSON, A. K., ESTABROOKS, K. L., CHONG, S. & STEIN, R. B. 2009. Spinal reflexes in ankle flexor and extensor muscles after chronic central nervous system lesions and functional electrical stimulation. *Neurorehabilitation and Neural Repair,* 23**,** 133-142.
TILLING, K., STERNE, J. A. C., RUDD, A. G., GLASS, T. A., WITYK, R. J. & WOLFE, C. D. A. 2001. A New Method for Predicting Recovery After Stroke. *Stroke,* 32**,** 2867-2873.
TILSON, J. K., SULLIVAN, K. J., CEN, S. Y., ROSE, D. K., KORADIA, C. H., AZEN, S. P. & P.W, D. 2010. Meaningful gait speed improvement during the first 60 days poststroke: minimal clinically important difference. *Physical Therapy,* 90**,** 196-208.
TOLE, G., WILLIAMS, G., CLARK, R. & HOLLAND, A. E. 2014. An observational study on usual physiotherapy care in a stroke rehabilitation unit for patients with mobility deficits. *International Journal of Therapy and Rehabilitation,* 21**,** 585-588.
TONG, R., NG, M., LI, L. & SO, E. 2006a. Gait training of patients after stroke using an electromechanical gait trainer combined with simultaneous functional electrical stimulation. *Physical Therapy,* 86**,** 1282-94.
TONG, R. K., NG, M. F. & LI, L. S. 2006b. Effectiveness of gait training using an electromechanical gait trainer, with and without functional electric stimulation, in subacute stroke: a randomized controlled trial. *Archives of Physical Medicine & Rehabilitation,* 87**,** 1298-1304.
TURANI, N., KEMIKSIZOĞLU, A., KARATAŞ, M. & ÖZKER, R. 2004. Assessment of hemiplegic gait using the Wisconsin Gait Scale. *Scandinavian Journal of Caring Sciences,* 18**,** 103-108.
TYSON, S., THOMAS, N., VAIL, A. & TYRRELL, P. 2015. Recruiting to inpatient-based rehabilitation trials: lessons learned. *Trials* [Online], 16. Available: http://www.trialsjournal.com/content/16/1/75 [Accessed 1/10/2015].

VAN DE PORT, G. L., WOOD-DAUPHINEE, S., LINDEMAN, E. & KWAKKEL, G. 2007. Effects of Exercise Training Programs on Walking Competency After Stroke A Systematic Review. *American Journal of Physical Medicine & Rehabilitation,* 86**,** 935-951.

VAN PEPPEN, R., KWAKKEL, G., WOOD-DAUPHINEE, S., HENDRIKS, H., VAN, D. W. P. & DEKKER, J. 2004. The impact of physical therapy on functional outcomes after stroke: what's the evidence? *Clinical Rehabilitation,* 18**,** 833-62.

VEERBEEK, J. M., KOOLSTRA, M., KET, J. C., VAN WEGEN, E. E. & KWAKKEL, G. 2011. Effects of augmented exercise therapy on outcome of gait and gait- related activities in the first 6 months after stroke: A meta-analysis. *Stroke,* 42**,** 3311-3315.

WADE, D. T. & HEWER, R. L. 1987. Functional abilities after stroke: measurement, natural history and prognosis. *Journal of Neurology, Neurosurgery & Psychiatry,* 50**,** 177-182.

WADE, D. T., WOOD, V. A., HELLER, A., MAGGS, J. & LANGTON HEWER, R. 1987. Walking after stroke. Measurement and recovery over the first 3 months. *Scandinavian Journal of Rehabilitation Medicine,* 19**,** 25-30.

WANG, Y. C., MCPHERSON, K., MARSH, T., GORTMAKER, S. L. & BROWN, M. 2012. Health and economic burden of the projected obesity trends in the USA and the UK. *The Lancet,* 378**,** 815-825.

WARD, N. S., BROWN, M. M., THOMPSON, A. J. & FRACKOWIAK, R. S. J. 2003. Neural correlates of motor recovery after stroke: a longitudinal fMRI study. *Brain : a journal of neurology,* 126**,** 2476-2496.

WEEN, J. E., ALEXANDER, M. P., D'ESPOSITO, M. & ROBERTS, M. 1996. Factors predictive of stroke outcome in a rehabilitation setting. *Neurology,* 47**,** 388-392.

WEINGARDEN, H. P., ZEILIG, G., HERUTI, R., SHEMESH, Y., OHRY, A., DAR, A., KATZ, D., NATHAN, R. & SMITH, A. 1998. Hybrid functional electrical stimulation orthosis system for the upper limb: Effects on Spasticity in Chronic Stable Hemiplegia1. *American Journal of Physical Medicine & Rehabilitation,* 77**,** 276-281.

WELLMON, R., CAMPBELL, S. L., RUBERTONE, J. A., ELLISON, J., KING, R., MEDURI, R. & SPATAFORE, A. 2003. The interrater and intrarater reliability of the Wisconsin Gait Scale when administered by physical therapists to individuals post-stroke. *Proceedings of the American Physical Therapy Association Combined Sections Meetings.* Tampa, Florida.

WHO 2006. WHO STEPS Stroke Manual: The WHO STEPwise approach to stroke surveillance. Geneva: World Health Organisation.

WILKIE, K. M., SHIELS, J. E., BULLEY, C. & SALISBURY, L. G. 2012. "Functional electrical stimulation (FES) impacted on important aspects of my life"—A qualitative exploration of chronic stroke patients' and carers' perceptions of FES in the management of dropped foot. *Physiotherapy Theory and Practice,* 28**,** 1-9.

WILKINSON, I. A., BURRIDGE, J., STRIKE, P. & TAYLOR, P. 2014. A randomised controlled trial of integrated electrical stimulation and physiotherapy to improve mobility for people less than 6 months post stroke. *Disability And Rehabilitation. Assistive Technology***,** 1-7.

WINSTEIN, C. J., GARDNER, E. R., MCNEAL, D. R., BARTO, P. S. & NICHOLSON, D. E. 1989. Standing balance training: effect on balance and locomotion in hemiparetic adults. *Archives of Physical Medicine and Rehabilitation,* 70**,** 755-762.

WOLF, S. L., WINSTEIN, C. J., MILLER, J. & ET AL. 2006. Effect of constraint-induced movement therapy on upper extremity function 3 to 9 months after stroke: The excite randomized clinical trial. *JAMA,* 296**,** 2095-2104.

YAMAGUCHI, T., TANABE, S., MURAOKA, Y., MASAKADO, Y., KIMURA, A., TSUJI, T. & LIU, M. 2012. Immediate effects of electrical stimulation combined with passive locomotion-like movement on gait velocity and spasticity in persons with hemiparetic stroke: a randomized controlled study. *Clinical Rehabilitation,* 26**,** 619-628.

YAN, T., HUI-CHAN, C. & LI, L. 2005. Functional electrical stimulation improves motor recovery of the lower extremity and walking ability of subjects with first acute stroke: a randomized placebo-controlled trial. *Stroke,* 36**,** 80-5.

YANG, Y.-R., CHEN, Y.-C., LEE, C.-S., CHENG, S.-J. & WANG, R.-Y. 2007. Dual-task-related gait changes in individuals with stroke. *Gait and posture,* 25**,** 185-190.

YAVUZER, G., GELER-KULCU, D., SONEL-TUR, B., KUTLAY, S., ERGIN, S. & STAM, H. 2006. Neuromuscular electric stimulation effect on lower-extremity motor recovery and gait kinematics of patients with stroke: a randomized controlled trial. *Archives of Physical Medicine and Rehabilitation,* 87**,** 536-40.