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**A quantitative and qualitative exploration of changes in walking post-stroke and the impact of functional electrical stimulation for correction of dropped foot**

by

**Ingrid Anne Wilkinson Hart**

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## **Abstract**

The research presented in this thesis explores changes in walking following a stroke, empirically at a group level and from the perspective of the individual. Walking does not appear to have been previously been systematically explored from the perspective of the individual stroke survivor.

In the first phase of this research, quantitative methods were used to investigate existing gait rehabilitation interventions applied in a novel population. Problems with 'dropped foot' post-stroke are common and can result in trips, falls and restricted mobility. Electrical stimulation of the common peroneal nerve produces dorsiflexion and eversion to correct dropped foot and is associated with improved motor control and walking post-stroke, however most research studies have recruited people with chronic stroke to reduce sample variability. People who are less than six months post-stroke may gain added benefit from electrical stimulation as poor walking patterns may not yet have become habitual and the potential for motor recovery due to cortical reorganisation is greatest. A pilot parallel group partially single blinded randomised controlled clinical trial (n=20) identified statistically significant within group differences in mobility after the intervention period in both groups (maintained during follow-up). No statistically significant between group differences were observed apart from gait quality, which was slightly better in the intervention group. Participants in the intervention group also walked faster when stimulation was used than without it. The protocol was feasible and 144 participants per group would produce an adequately powered definitive study.

Participants in the pilot clinical trial spoke about valued personal aspects of walking but these were not fully captured by the outcome measures and are not reflected in the published literature. To systematically explore changes in walking post-stroke in depth interviews with a subgroup of the original participants were undertaken using an interpretative phenomenological approach (n=4). The participants gave examples of post-stroke walking related changes in their self-perception, roles and their embodied experience of walking that are rarely mentioned in the rehabilitation literature, apart from in personal accounts written by people living with chronic illness. They spoke about walking within the context of activities that they identified as personally important. These participants valued being able to walk distances at a reasonable speed, being independent, safe and confident. They said that they missed their pre-stroke spontaneity, freedom, agility and their lost automatic body movement, which are not usually assessed in stroke rehabilitation research or reflected in published research. Areas for further work have been identified.





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# Publications

## Journal publications

- Journal publication: A randomised controlled trial of integrated electrical stimulation and physiotherapy to improve mobility for people less than six months post-stroke. Wilkinson I, Burridge J, Strike P, Taylor P. Disability & Rehabilitation: Assistive Technology. Online May 14, 2014.

## Conferences

- Poster presentation: 'Talking about Walking' – a qualitative exploration of changes in walking post-stroke from the perspective of stroke survivors. Wilkinson I, Burridge J, Taylor P, Wintrup J. Stroke Forum 2014, Harrogate, UK.
- Poster presentation: Work in Progress Research - Exploring walking from stroke survivors' experiences. Wilkinson I, Burridge J, Taylor P, Wintrup J. Society for Research in Rehabilitation, Summer Meeting 2013, Nottingham, UK.
- Poster presentation: Work in Progress -Talking about Walking - A qualitative study exploring the experience of walking after a stroke. Wilkinson I, Taylor P, Wintrup J, Burridge J. Stroke Forum 2012, Harrogate, UK.
- Oral presentation: Feasibility of combining physiotherapy and electrical stimulation to improve gait in patients less than 6 months post-stroke. Wilkinson I, Strike P, Burridge, Taylor P. Stroke Forum 2011, Glasgow UK.
- Poster presentation: Important everyday activities selected by people with mobility limitations following stroke – what are the implications for outcome measurement? Wilkinson I, Esnouf J, Burridge J, Taylor P. Stroke Forum 2011, Glasgow UK.
- Oral presentation: Feasibility of combining physiotherapy and electrical stimulation to improve gait in patients less than 6 months post-stroke. Wilkinson I, Strike P, Burridge J, Taylor P. Society for Research in Rehabilitation, Summer Meeting 2011, Keele, UK. *Winner of Verna Wright prize for best oral presentation, 2011.*
- Poster presentation: Case report demonstrating feasibility of combining physiotherapy and functional electrical stimulation (FES) to improve mobility in patients who have recently left hospital after their first stroke. Wilkinson I, Taylor P, Burridge J. Stroke Forum 2009, Glasgow, UK



# DECLARATION OF AUTHORSHIP

I, .....

declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

## **A quantitative and qualitative exploration of changes in walking post-stroke and the impact of functional electrical stimulation for correction of dropped foot**

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. 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;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. 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;
5. I have acknowledged all main sources of help;
6. 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;
7. Parts of this work have been published, please see publications page for details

Signed: .....

Date:.....



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“The art of writing is the art of applying the seat of the pants to the seat of the chair.”  
Mary Heaton Vorse

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## Definitions and abbreviations

10mWT	10m walking test
6MWT	Six minute walking test
ABC	Activities Specific Balance Confidence Scale
ACA	Anterior cerebral artery
AFO	Ankle-foot orthosis
Agonist	In an antagonistic muscle pair, as one muscle contracts (the agonist) the other relaxes (the antagonist)
Antagonist	In an antagonistic muscle pair, as one muscle contracts (the agonist) the other relaxes (the antagonist)
APECS	Adapted Patient Evaluation Conference System
CASP	Critical Appraisal Skills Programme
CM	Chedoke-McMaster Stroke Assessment
CONSORT	Consolidated Standards of Reporting Trials
COPM	Canadian Occupational Performance Measure
COSIM	COnsensus-based Standards for the selection of health Measurement Instruments
CPN	Common peroneal nerve
EPSP	Excitatory postsynaptic potentials
FAC	Functional Ambulation Category
FIM	Functional Independence Measure
FES	Functional electrical stimulation of the common peroneal nerve for correction of dropped foot (unless another muscle group is specified)
GAS	Goal Attainment Scaling
HADS	Hospital Anxiety and Depression Scale
HAP	Human Activity Profile

ICF	International Classification of Functioning, Disability and Health
IPSP	Inhibitory postsynaptic potentials
LACI	Lacunar infarct
LTD	Long term depression
LTP	Long term potentiation
MCA	Middle cerebral artery
mEFAP	Modified Emory Functional Ambulation Profile
NHP	Nottingham Health Profile
NICE	National Institute of Clinical Excellence
ODFS	Odstock Dropped Foot Stimulator
PACI	Partial anterior circulation infarcts
PCA	Posterior cerebral artery
PCI	Physiological Cost Index
PIADS	Psychosocial Impact of Assistive Devices.
POCI	Posterior circulation infarcts
RCT	Randomised controlled trial
RMI	Rivermead Mobility Index
RMI	Rivermead Mobility Index
SF36	36 Item Short Form Health survey
SIS	Stroke Impact Scale
TACI	Total anterior circulation infarcts
TAW	‘Talking about walking’. This is the identifying name given to the qualitative phase of this research.
UK	United Kingdom
WHO	World Health Organisation

# **Chapter 1: Introduction**

## **1.1 Introduction to walking problems post-stroke**

Stroke is a major cause of mortality and morbidity in the UK and worldwide and has high human and financial costs [1, 2]. There is an emphasis on providing evidence based rehabilitation however there are issues translating advances in neurological science into clinical research and practice.

This thesis focuses on the common problem of reduced mobility post-stroke. Approximately 1.1 million stroke survivors live in the UK and it is estimated that 80% have reduced motor control and more than 30% are not able to walk unsupervised in their community [3, 4]. Walking is often difficult or impossible for people after a stroke because of difficulties with muscular activation and movement control. Independent mobility is a frequent goal in rehabilitation post-stroke and it is prioritized by stroke survivors [5]. Loss of independent ambulation is perceived as one of the most disabling consequences of stroke affecting many aspects of life [3, 6, 7].

## **1.2 Research aims**

1. To investigate the effects of electrical stimulation on mobility, when delivered as an integrated part of outpatient physiotherapy for people less than six months post-stroke.
2. To investigate changes in walking post-stroke from the perspective of individual stroke survivors.
3. To explore what aspects of walking are valued by participants and feelings about walking and the use of assistive devices, including electrical stimulation.
4. To draw conclusions from this research process (aims 1-3) that could inform the design of future gait rehabilitation studies.

## **1.3 Research structure**

This thesis investigates changes in walking following a stroke and comprises two phases of interlinked research. Firstly, a protocol to examine the effects of electrical stimulation on mobility post-stroke was piloted in a small randomised controlled trial (RCT). Completion of this trial prompted the second research study using qualitative

## Chapter 1: Introduction

methods to explore walking post-stroke in more depth from the perspective of the individual stroke survivor. These two sequential research phases are reflected in the structure of this thesis.

	<b>Phase 1</b>	<b>Phase 2</b>
Summary	Quantitative – Pilot RCT	Qualitative – Interview data collection
Participants	People less than six months post-stroke (n=20) were recruited between August 2007 and June 2010	Subset of Phase 1 participants (n=4) were interviewed in 2011.
Research questions	Phase 1 <ul style="list-style-type: none"> <li>• Is it feasible to integrate electrical stimulation into early outpatient physiotherapy treatment, determined by protocol adherence and user views?</li> <li>• What is the most appropriate primary outcome measure?</li> <li>• What sample size would be required in an adequately powered RCT to investigate the immediate and longer-term effects of electrical stimulation on mobility, when delivered as an integrated part of outpatient physiotherapy for people less than six months post-stroke?</li> </ul>	Phase 2 <ul style="list-style-type: none"> <li>• How do people who have had a stroke affecting walking and have taken part in gait rehabilitation, describe their own walking and how it has changed over time since the stroke?</li> <li>• What aspects of walking do they value and how have these changed since the stroke?</li> <li>• How do they describe their experiences of using assistive devices?</li> <li>• Can the conclusions be used to inform the design of future gait rehabilitation studies?</li> </ul>

*Table 1-1: Summary of the two phases of this research*

A literature review was undertaken (Chapter 2) and this informed the design of the Phase 1 trial. The biological processes of recovery and adaptation that follow a stroke underpin stroke rehabilitation and therefore they are considered in some detail in Section 2.1. The research presented in this thesis focusses on gait; relevant aspects of normal walking and common post-stroke gait abnormalities are described in Section 2.2. Many of these gait abnormalities are caused by disordered motor control post-stroke and guidelines recommend that people with these problems should be assessed by therapists with specialist knowledge and experience in neurological rehabilitation [4]. Section 2.2.2 summarises a range of rehabilitation strategies that are available to therapists to improve gait, and these include electrical stimulation. The evidence base for these gait rehabilitation interventions was examined and this highlighted that there is a lack of research evaluating the efficacy of electrical stimulation to improve mobility in people less than six months post-stroke. This thesis explores the use of electrical stimulation to improve mobility, integrated into physiotherapy, to improve mobility in this patient group. The physiotherapy interventions provided in the clinical trial needed to be clearly described. There has been a tendency to state in research papers that the physiotherapy provided was 'standard' or based on a named approach, such as Bobath. This literature review concludes that this 'shorthand' is no longer valid and therefore a list of evidence based physiotherapy gait rehabilitation interventions was developed to adequately describe the physiotherapy provided in the Phase 1 trial.

The third part of the literature review, Section 2.3, reviews relevant quantitative research methodology to develop a suitable experimental design in order to answer the Phase 1 research questions developed from the literature review. Careful selection of outcome measures is vital when planning a clinical trial of rehabilitation interventions to ensure that the research hypothesis can be rigorously tested and changes can be measured. So that suitable outcomes were selected for inclusion in the Phase 1 trial outcome measures that assessed gait were evaluated in the context of the World Health Organisation's classification of health and disease. Measures were included if they had robust measurement properties, also referred to as psychometric properties, and if they assessed change in walking, with particular attention paid to outcomes that may be most relevant to people who have had a stroke affecting their mobility.

The Phase 1 trial method, results, discussion and conclusion can be found in Chapter 4. The Phase 1 quantitative research prompted the second qualitative phase of the research and the reasons are explained fully in Chapter 5. Undertaking this qualitative research required the literature review to be extended (Section 2.4) to include a review

## Chapter 1: Introduction

of relevant aspects of qualitative research methods. This informed the design of the Phase 2 study and the findings of this study, a discussion in the context of the published literature and the Phase 2 conclusions are presented in Chapter 6.

The two phases of research consider the same aspect of human function, walking, from different perspectives and these were brought together in combined discussion, conclusion and further work sections that comprise Chapters 7, 8 and 9 respectively.



## Chapter 2: Literature review

### 2.1 Review of stroke and post-stroke recovery, adaption and learning

This section presents an overview of stroke and stroke related factors that affect outcome. Outcome post-stroke is affected by several factors such as time since stroke and age, which need to be considered in the design of gait rehabilitation research. Gait rehabilitation post-stroke exploits the physiological processes of recovery, adaptation and learning and therefore these concepts are also reviewed. This understanding of post-stroke motor (re)learning informed the gait rehabilitation strategies used in the Phase 1 quantitative study. Motor (re)learning and adaptation are also the processes underpinning the practice related improvements in walking post-stroke that were spoken about by stroke survivors in the second qualitative phase of the research.

#### 2.1.1 Stroke

A stroke may be a small detail in a person's life journey or a defining feature reshaping their future. A blood clot or haemorrhage in the cerebral arteries disturbs blood flow to brain tissue causing a stroke. The location and extent of damage to the brain determines the initial problems ensuing from the stroke.

The World Health Organisation uses a longstanding definition of a stroke as "a 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" [8, 9]. Prevention of strokes and optimisation of function post-stroke has become a major part of health policy as stroke is common (approx. 111,000 first strokes in the UK each year) and is a major cause of mortality and morbidity in the UK; 7% of deaths in men and 11% of deaths in women are attributed to stroke [10]. The EU population of older people (>65 years old) relative to the working age population is predicted to double by 2060 [11]. Therefore the incidence of stroke is likely to rise because risk of stroke increases with older age and prevalence is also likely to rise as more people survive strokes [12, 13].

Wide variation in outcome post-stroke is reported, even across European countries. Markus, 2007, showed that the United Kingdom (UK) had worse outcome following a stroke when compared to other European countries across several research studies.

He suggests this cannot be attributed wholly to investment inequalities thus indicating organisational and structural problems in the delivery of stroke services in the UK [14] [15]. A 2005 National Audit Office survey found many patients do not feel they get sufficient rehabilitation in the first six months post-stroke and that many healthcare providers agreed that patients do not receive rehabilitation services that meet their needs [16]. In subsequent years there has been a focus on improving stroke outcomes through the National Stroke Strategy [17] alongside substantial investment in hospital and community stroke services. There have been improvements in the organisation and provision of acute services, use of anticoagulant medication to reduce the effects of some strokes and access to specialist services however there remains substantial variability in service provision [18]. In the same time period there has been a focus on improving the evidence base for stroke rehabilitation with several evidence based reviews and an increase in published research into stroke rehabilitation [4, 19, 20].

In the design of research studies evaluating stroke rehabilitation, the characteristics of the patient or their stroke that influence outcome must be identified and controlled or evenly distributed between experimental groups to minimise bias. These factors are identified and discussed below.

### 2.1.2 Factors affecting outcome after stroke

Brain scans can identify the area(s) damaged after a stroke. Damage may occur through cerebral artery blockage (leading to infarcts) or disruption of blood vessel structure leading to bleeds (termed cerebral haemorrhage). Several factors are known to affect outcome post-stroke. One factor that may affect outcome is the site of the brain damage because it is related to subsequent clinical problems and is linked to different patterns of recovery [21, 22]. Factors associated with poor functional outcome and higher risk of death post-stroke are a cardiac source of embolism (an arterial blockage) leading to a stroke, very severe strokes, pre-existing disability and increased age [22-24]. Van de Port et al., 2006, linked mobility decline at three years post-stroke with the presence of physical inactivity, cognitive problems, depression and fatigue at one year post-stroke (n=205) [25]. Generally, depression and cognitive problems are linked to disability and worse outcome post-stroke although whether the associations are causal is not established [26-28]. It has been asserted that time since stroke is a more important determinant in predicting outcome post-stroke than lesion location [29]. In clinical gait rehabilitation practice, patients are usually treated with individualised

problem/goal orientated treatment protocols which are not dictated by stroke type or location but are instead based on clinical assessment.

In the context of clinical research, whether type or location of stroke or these other factors affecting outcome are included in the eligibility criteria will depend upon the research question. They need to be considered in the design of clinical trials comparing rehabilitation interventions however, in larger trials with robust randomisation their effects may be evenly distributed between groups. For the design of the Phase 1 pilot RCT a pragmatic mixed sample was most appropriate to reflect 'real life clinical settings' and because the intervention is based on clinical assessment of the presence of mobility difficulties.

As well as the factors discussed above, which are inherent to the stroke itself and the individual, time post-stroke also affects outcome. It is suggested that recovery post-stroke may be most rapid during the first weeks and months following stroke and may plateau later [1, 29-31]. Clinicians usually reduce their input and eventually withdraw formal gait rehabilitation despite ongoing mobility problems when it is felt the patient has reached a plateau and recovery has stopped or slowed. This is challenged by other researchers who suggest that the perceived plateau may be associated with a reduction in 'dose' or intensity of rehabilitation since reduced levels of rehabilitation may be insufficient to prompt further motor learning and adaptation [19, 32-35].

The selection of robust outcome measures is important in order to record and understand more about the factors affecting recovery following stroke however researchers have not always selected optimal outcome measurements. For example, the Copenhagen Stroke Study, [23, 36] examined outcome in the first six months post-stroke in more than a 1000 patients. They presented their walking related data and concluded that improvements in functional recovery of walking 'mainly occurred in the first 11 weeks after stroke' and 'should not be expected' later, apart from in a small minority of people' [23, 36]. This conclusion relied on analysis of the 'walking' question from the simple ten question Barthel Index which assesses aspects of functional independence in activities of daily living (ADL). The single question on indoor mobility categorises responses into 'unable to walk', 'wheelchair independent' 'requires assistance' and 'independent with or without an aid'. Achieving the independent classification in the Barthel Index would mask all further improvements in walking for example improved gait quality, speed, safety, confidence, efficiency or beginning to walk outdoors. This seems an unacceptable 'ceiling effect' for an outcome measure used to assess walking recovery post-stroke. The Copenhagen Stroke Study was

published in 1995; over the last 20 years there has been a focus on improving outcome measurement so that recovery post-stroke and the factors that affect it can be better understood.

### **Summary – Stroke**

This section has defined stroke and outlined the impact of variables such as lesion location, age and time since stroke on functional improvements. When designing quantitative research trials, researchers need an awareness of the possible (negative) impact of site of lesion, time since infarct, depression, cognitive problems, advanced age and pre-stroke disability on functional outcome post-stroke.

#### **2.1.3 Post-stroke recovery, adaptation and learning**

‘Learning is our best hope for remodelling the damaged brain’ Kleim & Jones, 2008 [37].

There is no cure for stroke and, as our population ages, incidence of stroke is likely to increase. The use of pharmacological ‘clot busting’ agents, termed thrombolysis, has reduced the impact of stroke for some and cut mortality but this leaves increasing numbers of people living with the effects of a stroke [13]. Therefore, scientists argue for the need to capitalize upon the way the brain normally creates functionally appropriate neural connections, which is through neural plasticity [37, 38]. This section gives an overview of the anatomy and physiology that underpins these processes. They enable recovery, adaptation and learning, which are the foundation of gait rehabilitation post-stroke.

##### **2.1.3.1 The neurone**

Neurones are specialised cells capable of adaptation in response to stimuli. They are the ‘building blocks’ of the nervous system. Cells in the human body consist of three main parts the cell nucleus, cytoplasm (cellular contents) and the surrounding outer surface, termed the plasma membrane. The membrane is a selective barrier regulating the flow of molecules in and out of the cell. The distribution of positively and negatively charged ions is different in the cytoplasm and the extracellular fluid and this imbalance is maintained by active and passive mechanisms occurring in the cell membrane. The imbalance in ionic concentration produces an electrical potential difference across the membrane termed the ‘resting membrane potential’, which is measured at about -70mV in neurones [39]. Sodium channels open if the membrane potential is lowered by

20mV, termed threshold. The resulting flood of positively charged sodium ions across the cell membrane makes the inside positively charged by approximately 40mV. This depolarization is followed by the opening of voltage-gated channels in the membrane which allows potassium ions to flow out returning the neurone to its resting membrane potential. Nerve depolarization is always the same amplitude and is termed an action potential which is analogous to pushing over the first domino standing on end in a line, once a threshold is reached it will topple [39]. This will then cause the next in line to fall over and so on, which is like conduction of a nerve impulse along a neurone. The nerve recovers quickly after an impulse during what is termed the refractory period, when no additional depolarisation is possible. The part of the nerve just depolarised is in a refractory state therefore nerve impulses only move along a nerve in one direction. An exception to this is action potentials initiated by electrical stimulation. Depolarisation occurs in the electric field under the electrodes and as no adjacent area is in a refractory state the impulse is propagated along the nerve in both directions which is termed orthodromic when in the normal direction and antidromic when the impulse travels in the opposite to normal direction.

Communication between neurones and at neuromuscular junctions occurs at electrical or chemical synapses. Electrical synapses allow fast-synchronised communication as there is direct flow of ions from one cell to the next; this occurs in nerves supplying visceral and heart muscles. Within chemical synapses, it is the release of a chemical neurotransmitter from the pre-synaptic neurone and the uptake of this neurotransmitter at the post-synaptic membrane, which allows communication across the synapse. The neurotransmitter may cause excitatory post-synaptic potentials (EPSPs) or inhibitory post-synaptic potentials (IPSPs) at below threshold levels. If total excitatory effects from many synaptic connections are greater than inhibitory when they are integrated at the axon hillock and they reach threshold, an action potential is triggered in the post-synaptic neurone. If a single pre-synaptic neurone repeatedly produces EPSPs in quick enough succession, they may summate causing post-synaptic depolarisation if threshold is reached (temporal summation). Several different pre-synaptic neurones may fire at the same time and cause summation, termed spatial summation [39]. Within the branching network of axons and dendrites (Figure 2-1), neuronal connections are constantly made (synaptogenesis) and remodelled in response to experience. The plasticity of the central nervous system is based on many structural and chemical processes. Experience dependent neuroplasticity is the foundation of motor learning and re-learning post-stroke [40].

### 2.1.3.2 The motor unit

The axon of a lower motor neurone extends from the spinal cord via a motor neurone bundle to a specific muscle. The axon typically branches multiple times attaching to different fibres within the skeletal muscle at neuromuscular junctions (Figure 2-1). Acetylcholine release at the neuromuscular junction activates the contractile elements of the muscle fibre. The number of muscle fibres contracting determines the strength of the contraction. The number of muscle fibres activated by a motor neurone is adapted to function – precise movements may require fewer muscle fibres to be activated at once.

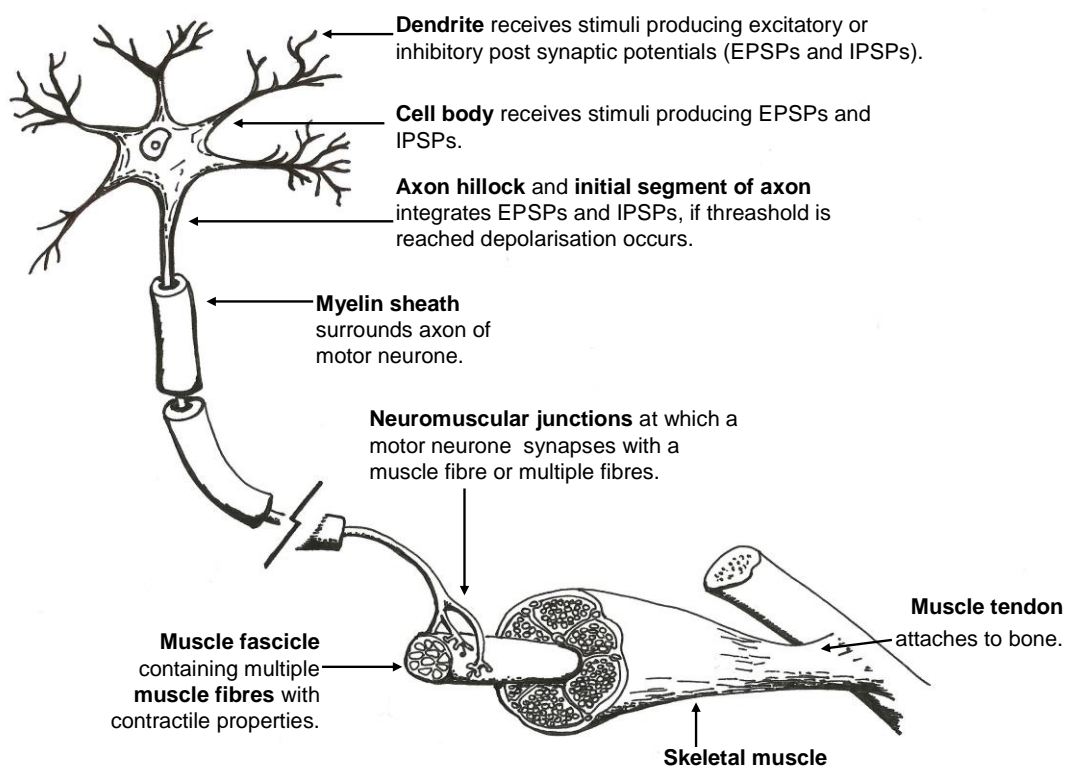


Figure 2-1: Component parts and function of a motor neurone.

Author's own diagram (not to scale), labelling drawn from several sources [39, 41].

Muscle fatigue is delayed by asynchronous firing of motor units. Muscle fibres are specialised with some more resistant to fatigue. Slow oxidative muscles have smaller diameter motor neurones that do not allow fast recruitment of motor units, they are more fatigue resistant, specialised for controlling anti-gravity muscles. Other muscles are adapted for short bursts of activity with large diameter faster conducting motor neurones. These are usually recruited last in normal activity and fatigue quickly [42].

The neuromuscular structures alter with training and contribute to motor learning post-stroke. Endurance training results in muscular and vascular adaptations that improve the ability to sustain motor performance whereas resistance training leads to gains in strength by hypertrophy and increased muscle bulk [39]. With increasing age and after stroke these general principles remain the same and both types of training have been shown to improve function and health [43-45].

### **2.1.3.3 The spinal cord**

The central nervous system (CNS) comprises of the brain and spinal cord and contains white and grey matter. White matter is made of groups of axons from motor and sensory neurones (descending and ascending respectively in the spinal cord). These bundles are termed tracts and the white myelination that occurs on many gives them the name 'white matter'. The grey matter in the CNS consists of cell bodies, unmyelinated axons, dendrites and this is where EPSPs and IPSPs are integrated. The spinal cord contains neural circuits that can respond rapidly to the environment. For example standing on a sharp object causes withdrawal of the limb from the object before conscious awareness of pain. The spinal cord reflexes allow fast, automatic, efficient responses to certain stimuli with little cortical involvement.

Clinicians involved in stroke rehabilitation often have to consider the role of spinal cord reflexes such as

- the stretch reflex – contraction in response to activation of stretch receptors
- reciprocal inhibition – relaxation of the antagonist during contraction of the agonist muscle
- flexor withdrawal – withdrawal of the limb from a painful stimulus [39]

Some reflexes may be functionally useful in gait rehabilitation, such as flexor withdrawal in electrical stimulation during walking, which is discussed later in Chapter 2.2.2.6. Other reflexes, especially when combined with deconditioning, can become problematic after stroke. One example is over active stretch reflexes thought to contribute to spasticity, defined as 'disordered sensori-motor control, resulting from an upper motor neurone lesion, presenting as intermittent or sustained involuntary activation of muscles' [46].

Connections at the spinal cord level alter with training and experience. Operant conditioning can allow faster and more efficient responses to repeated stimuli via reductions or increases in the spinal reflexes (by increasing threshold or reducing

inhibition respectively) [47]. Neural plasticity is seen at the spinal cord level in the form of synaptogenesis in response to endurance and strength training whereas skill training induces mainly cortical changes [47]. Adkins et al., 2006, suggest that training terms such as 'strength', 'endurance' or 'skill' fail to give a complete picture as they argue that it is the behavioural demands of the task that dictate the site and type of learning and there are often elements of all three involved [47]. For example starting to run longer distances for a regular runner may largely involve endurance training. People who rarely run will require much higher levels of skill training and strength training of relevant muscles when beginning to run as the movement is novel.

### **2.1.3.4 The brain**

The brain contains about 100 billion neurones and about  $10^{15}$  synapses. This incredible complexity allows integration of sensory and stored information allowing the planning and execution of actions and learning new activities [39]. The complexity of the human brain, containing centres for intellect, emotions and memory, allows a wide range of individual talents to be developed.

A summary of some of the main areas of the brain, in relation to sensorimotor control and learning, is presented in Figure 2-2. The primary motor cortex has been described as having specific areas that supply different body parts, with a larger representation for areas requiring greatest control; this is termed a somatotopic map. More recent transcranial magnetic stimulation studies have shown the classical somatotopic maps to be over simplified because areas controlling the hand for example are divided over multiple areas [48]. Skill training induces neuroplastic changes via synaptogenesis and reorganisation within the motor cortex and endurance training changes the cortical cerebrovasculature (via angiogenesis) allowing increased blood flow, possibly to meet greater metabolic demands [47].



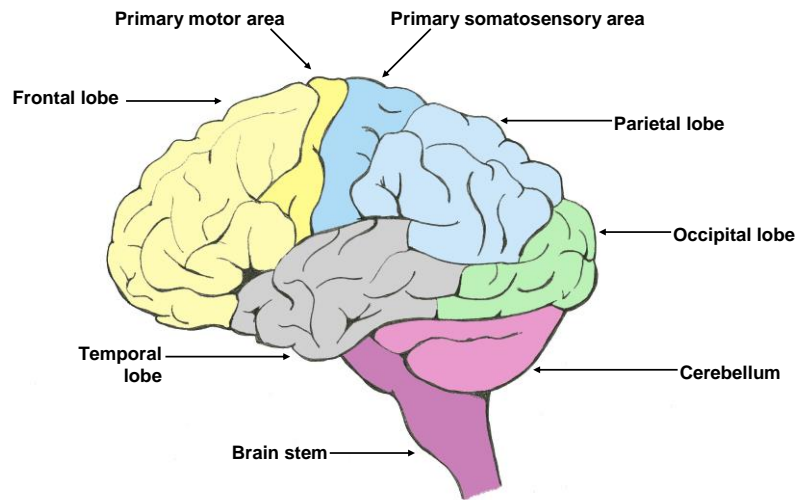


Figure 2-2: Major areas of the brain

Author's own diagram, labelling from Tortora & Grabowski, 2003 [39].

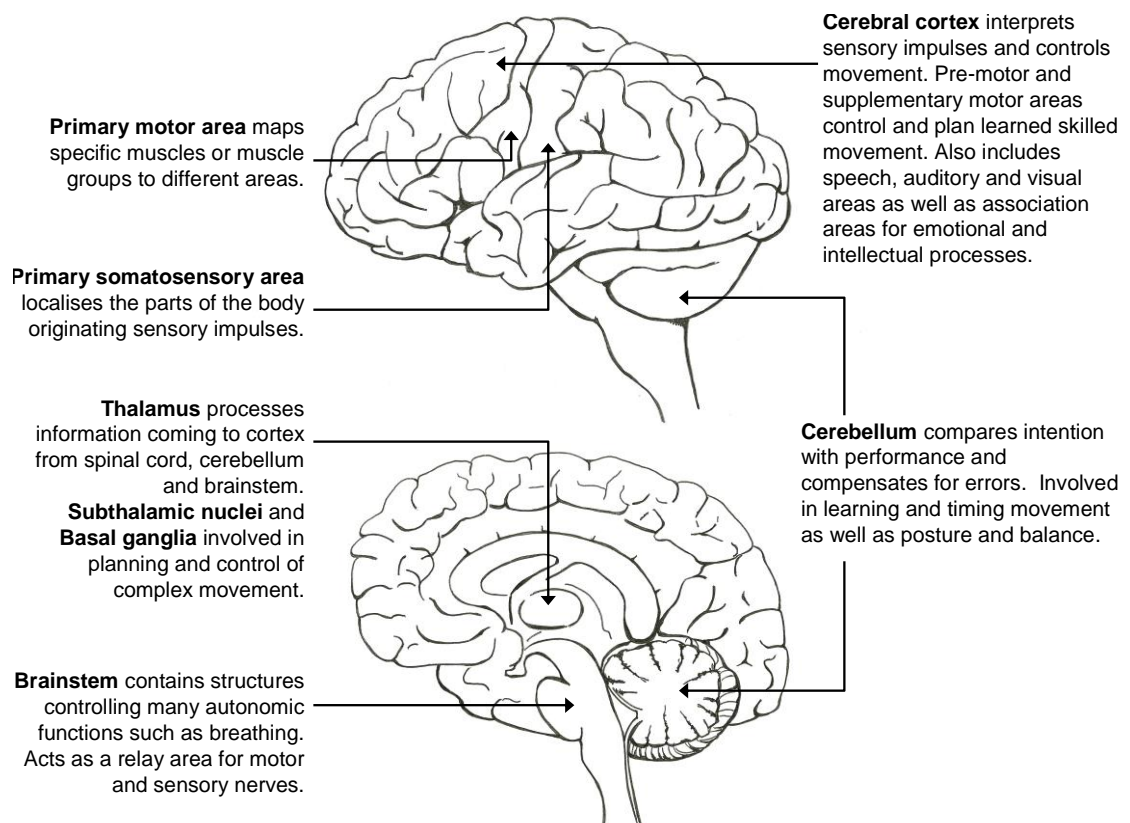


Figure 2-3: Summary of major areas of the brain, location and function

Author's own diagram, labelling drawn from several sources [39, 41].

Several processes occur when there is interruption of blood flow to the brain, such as during a stroke. Some of these start very quickly in the ischemic neural tissue leading to cell death. Although collateral blood flow may preserve brain structures adjacent to the primary ischemic centre, damage can also occur here. In this surrounding area various cell death mechanisms and inflammatory processes can cause reduced function, these are all described in detail in a review by Doyle et al., 2008. This paper also describes ways in which these processes of cell damage may be interrupted by neuroprotective therapies including thrombolysis, hypothermia and some drugs to reduce the impact of a stroke [49]. In the next section considers forms of learning post-stroke in more detail.

### **2.1.3.5 Concepts of recovery, adaptation and learning post-stroke**

Definitions of recovery post-stroke have evolved as technology has allowed greater understanding of the processes involved. Distinctions have been made between spontaneous recovery (positive changes in the tissue at the lesion site), motor relearning and learning [50]. Timmermans et al., 2009 associate spontaneous recovery with changes in function seen in the first weeks after a stroke and motor (re)learning occurring later, this general concept is widely accepted [29, 30, 50]. When movement is attempted after a stroke there can be an increase in the areas of the brain activated to achieve a task compared to controls, including areas in the contralesional hemisphere. In the best recovered patients, more normal activation patterns are seen [51, 52]. Learning post-stroke may result in achieving a goal utilising the same structures as before the stroke or relearning i.e. compensating for the neuronal loss by using different structures to achieve the goal. Levin et al., 2009 [53], highlighted that clinical research does not usually distinguish between these and uses the term 'recovery' to include restoration of movement in the same manner as before, as well as adaptations to achieve the goal. Post-stroke rehabilitation occurs in the context of self-taught, sometimes automatic, adaptive behaviours such as hip hitching to improve floor clearance in swing or reducing weight bearing in stance if the ankle is unstable or uncomfortable. These behaviours can be functionally useful but can also become maladaptive if they interfere with regaining normal patterns of use in the affected body parts.

Knowledge of motor (re)learning and adaptation from animal and human studies has gradually been translated into clinical rehabilitation strategies. Constraint induced movement upper limb therapy is one example that may have some relevance for gait rehabilitation. It is based on avoiding over compensating with the less affected limb

and overcoming learned non-use of the hemiplegic upper limb by massed task specific practice and use of a constraint on the less affected arm [54, 55]. Researchers have begun to consider intense walking practice as analogous to upper limb constraint induced movement therapy paradigms since it contains some of the main elements that are associated with motor learning i.e. massed task specific practice and forced use of the hemiplegic limb [56, 57].

Different terms and constructs are used to describe aspects of learning, pertinent terms are outlined below, with additional information widely available [41]. Memory underpins the processes of learning and is considered in this section firstly at a cognitive level and then at the synaptic level. Declarative or explicit memory refers to information that can be consciously recalled and can refer to the execution of a motor task. An example of this may be the need to actually mentally or verbally repeat 'lift foot, bring leg forward, heel down, weight across' while relearning to walk post-stroke. The expectation is that practice will encourage formation of automatic or procedural learning. Declarative motor learning often involves an internal focus which may be reinforced by physiotherapists during gait rehabilitation [58]. Motor skills may also be acquired using non-declarative learning using an external focus, such as a goal like walking across a room. Improvement of a movement through repetition and 'trial and error' involves the cerebellar 'error checking mechanisms' [41]. Repeating a skill in different environmental conditions leads to learning the 'rules' for a movement and enables performance in complex real word situations. The tasks are repeated until they can be performed automatically, without attention [41]. Automatic non-declarative training with an external focus has been associated with improved motor performance in healthy populations but its application in gait rehabilitation is under researched [58]. Some gait rehabilitation interventions may support an external focus and utilise non-declarative learning. For example, electrical stimulation for the correction of dropped foot may enable an external focus of attention during walking as it prevents the toes from catching during swing, which would otherwise draw cognitive attention.

Non-declarative learning also includes learned responses to stimuli. Associative learning recognises the relationships between one stimulus and another (classical conditioning) or the relationship between a behaviour and a consequence (operant conditioning) [41]. A conditioned stimulus may provoke an emotional response such as fear. This type of conditioning may result in desirable avoidance of risk or undesirable avoidance of activity, for example a person with poor balance may have a fear of falling and may consequently avoid walking; this fear could be further reinforced if a fall is

actually sustained. Operant conditioning is demonstrated in the context of motor learning. The relationship between the behaviour and the consequence is reinforced if a particular movement, for example dorsiflexion, is rewarded by successful accomplishment of a task desired by the learner e.g. managing to take a step. Many aspects of gait rehabilitation rely on associative learning.

At a synaptic level, habituation and sensitisation are other types of non-declarative learning. They are reasonably simple responses to a repeated stimulus. Repetition of a non-noxious stimulus can lead to habituation [41]. Here, excitation of a sensory nerve becomes associated with learned suppression of the response in sensory, motor or inter-neurons. There is a short-term decrease in excitatory post-synaptic potentials (EPSPs). An example is the initial responses to electrical stimulation that may be felt strongly. As the system accommodates to the altered sensory input, the sensation is decreased. If this change in synaptic efficiency is maintained and the stimulus persists it eventually results in habituation, structural changes at the synapse or 'learning' which involves a reduction in the numbers of connections.

Sensitisation occurs when a strong stimulus, especially one that is noxious or potentially threatening, induces increased sensitivity to subsequent stimuli. The first stimulus increases EPSPs making subsequent depolarisation to threshold more likely. Repeated sensitization over time can lead to learning by increasing numbers of synaptic connections [41, 59].

Similarities can be drawn between the mechanisms underpinning sensitisation/habituation and long term potentiation (LTP) which has been proposed as the neural correlate of memory [60]. LTP results from co-incident activity of pre and post-synaptic elements, bringing about a facilitation of chemical transmission at synapses, which persists over time. Multiple weak inputs may converge on a single post-synaptic neurone inducing LTP. Alternatively simultaneous weak and strong excitatory inputs may occur inducing LTP and increase response to the same weak stimulus in the future [61]. Hebbian learning describes simultaneous activation of pre and post-synaptic neurones leading to increased synaptic strength. It is suggested that this type of learning explains improvements seen in gait (without stimulation) after regular use of electrical stimulation for dropped foot [62]. The converse of the LTP process is termed long term depression (LTD) and weakens synaptic transmission. LTP/LTD can persist over time as structures are modified in response to stimuli. These neuroplastic changes are the underlying mechanisms for long term retention of memory and therefore (re)learning post-stroke [63].

In the past there appears to have been a gap in understanding of neuroplasticity between basic biological scientists, clinicians and clinical researchers; there has now been a call to foster greater cooperation [64]. In order to assist with this task Kleim and Jones, 2008, presented evidence for and explained their ten principles of experience dependent neural plasticity which are stated in Table 2-1.

<b>Principle</b>	<b>Description</b>
<b>1. Use it or lose it</b>	Failure to drive specific brain functions can lead to functional degradation.
<b>2. Use it and improve it</b>	Training that drives a specific brain function can lead to an enhancement of that function.
<b>3. Specificity</b>	The nature of the training experience dictates the nature of the plasticity.
<b>4. Repetition matters</b>	Induction of plasticity requires sufficient repetition.
<b>5. Intensity matters</b>	Induction of plasticity requires sufficient training intensity.
<b>6. Time matters</b>	Different forms of plasticity occur at different times during training.
<b>7. Salience matters</b>	The training experience must be sufficiently salient/relevant to produce plasticity.
<b>8. Age matters</b>	Training-induced plasticity occurs more readily in younger brains.
<b>9. Transference</b>	Plasticity in response to one training experience can enhance the acquisition of similar behaviours.
<b>10. Interference</b>	Plasticity in response to one experience can interfere with the acquisition of other behaviours.

*Table 2-1: Principles of experience dependent neural plasticity*

*From Kleim and Jones, 2008 [37]*

## Chapter 2: Literature Review

Neural circuits not actively engaged in task performance for an extended period of time can begin to degrade (principle 1) and performance of these tasks can become impaired. Throughout this section of the literature review, learning post-stroke has been shown to be associated with repetition of specific types of activity/stimuli at sufficient intensity to drive neuroplastic changes (principles 2, 3, 4 and 5). Utilising the brain's learning process and understanding how they can be promoted through rehabilitation is a focus of current clinical research [40].

### **Summary - Post-stroke recovery, adaptation and learning**

Interventions used in stroke rehabilitation need to capitalize upon the way the brain normally creates functionally appropriate neural connections, which is through learning and neural plasticity. This section has given an overview of the mechanisms involved and the typical responses in different parts of the nervous system. This literature review will now consider gait and then gait rehabilitation post-stroke in the context of this understanding of post-stroke recovery, adaptation and learning.

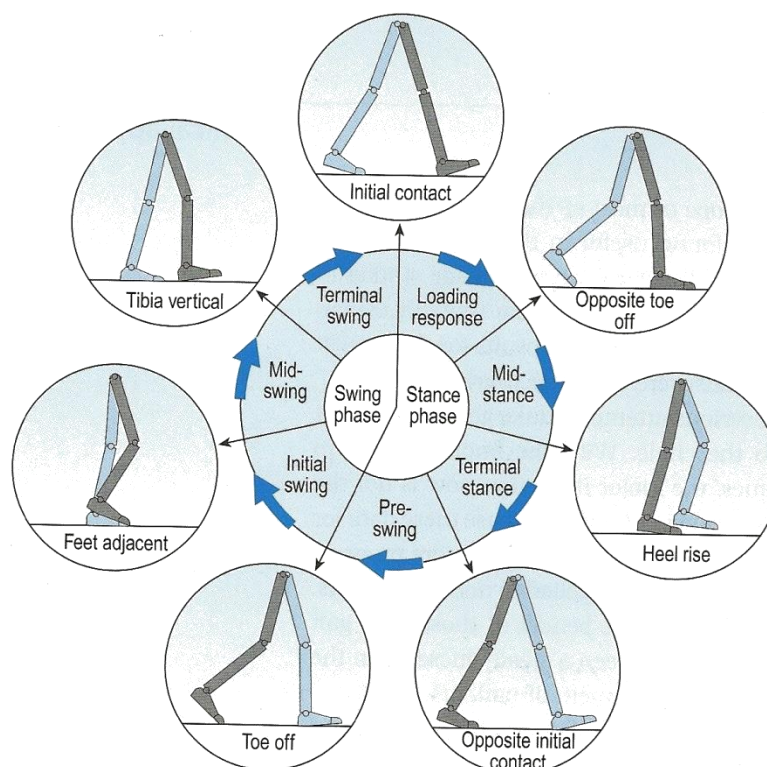
## **2.2 Review of gait and gait rehabilitation post-stroke**

This section presents an overview of normal gait and typical gait abnormalities that may be observed post-stroke. It outlines the effects of stroke related ankle and foot impairments and introduces the term dropped foot. This chapter reviews the evidence base for physiotherapy, orthotics and electrical stimulation in gait rehabilitation. The main purpose of this part of the literature review was the development of a clinically relevant and evidence based gait rehabilitation strategy to be delivered in the quantitative Phase 1 trial. This research trial investigates the efficacy of electrical stimulation delivered as part of normal physiotherapy to improve mobility in people less than six months post-stroke.

### **2.2.1 Gait**

Healthy people appear to require little conscious cognitive effort to walk on a flat surface and regularly multi-task while walking. For example walking and holding a conversation, carrying items, using a mobile phone and/or looking around. Difficulty multi-tasking has been found following stroke and may be associated with falls [65].

Normal gait is symmetrical and has rhythmic transitions between component phases. Many texts identify and describe in detail these components [66]. The synchronised flexion of hip, knee and ankle during normal stepping (swing phase) is followed by extension at the hip and knee to allow secure weight bearing during stance phase and progression of centre of mass forward. Figure 2-4 provides an overview of the timing of gait components and the 'markers' such as heel strike and heel rise which signal the transition between phases of gait. Understanding these is important in assessing and planning interventions to improve gait. Although the lower limbs perform the majority of the movement, the entire body is involved, from the eyes checking for obstacles, to trunk rotation and arm swing.



*Figure 2-4: The component phases of gait.*

*From [66] page 52 – with permission*

Alteration in the activation of muscles, the timing of contractions or range of movement about one or more joints causes changes in gait. People who have had a stroke often find that walking becomes more effortful physically and requires greater cognitive attention. Gait changes and compensatory strategies can be seen from stroke onset, however muscle over activity, spasticity and secondary problems arising from gait abnormalities may become more apparent over time [67].

Stroke usually leads to a less symmetrical gait pattern with characteristic problems and compensations. It often disrupts the normal activation of the muscles around the ankle particularly the agonist-antagonist pair of tibialis anterior that produces dorsiflexion (important in swing and early stance) and gastrocnemius that produces plantarflexion (required for push off). Dropped foot refers to walking changes that include the toes or foot being lifted inadequately in swing and/or reduced heel strike. This may be due to dorsiflexor inactivity allowing the foot to drop and/or plantarflexor over activity pulling the foot down. Post-stroke muscle over activity (spasticity) is common and may affect one third of people who have had a stroke [68]. Plantarflexor spasticity can also alter alignment and stability in weight bearing and cause the ankle to be inverted as well as plantarflexed [67]. Normally contraction is smoothly controlled and timed to avoid



excessive co-contraction, however this can occur when the effort of walking and lifting the foot increases plantarflexor spasticity. Table 2-2 describes some of the common changes in gait that are observed post-stroke. People with stroke often have several of these gait deviations apparent in their walking, some may be more pronounced than others. Abnormal walking patterns may become habitual with repetition. Prolonged gait asymmetry and use of compensation strategies can lead to secondary musculoskeletal problems such as loss of range of movement and joint pain [41]. Addressing issues at an earlier stage may improve outcome and this is the driver for the first phase of the research, using stimulation to correct dropped foot with people less than six months post-stroke.

<b>Observed gait deviation</b>	<b>Likely impairment</b>	<b>Implication for patient</b>	<b>Commonly seen compensation</b>
Reduced degree of dorsiflexion and eversion in swing phase	Dropped foot, weakness of the dorsiflexors and evertors	Risk of toes catching on ground during swing, especially if it is uneven. Increased risk of falls. Less energy efficient.	Hip hitching or vaulting (push up) on the supporting leg to increase floor clearance. Also circumduction of the leg. Possibly increased hip and/or knee flexion.
Excessive inversion with or without plantarflexion occurring during initial contact usually with diminished heel strike	Dropped foot, weakness of the dorsiflexors and evertors with or without plantarflexor spasticity	Abnormal weight bearing and alignment may cause musculoskeletal changes, joint instability, pain, difficulty maintaining balance, decreased confidence walking and increased risk of trips and falls.	Decreased weight bearing on affected side, often rely on walking aid(s) to help balance. Possible use of orthotics to improve stability.
Initial contact is made with forefoot and the heel never makes contact with ground in stance	Plantar flexor shortening and/or spasticity	As above.	As above.
Reduced push off	Weakness of plantarflexors	Unable to walk at faster speeds.	Reduced step length

<b>Observed gait deviation</b>	<b>Likely impairment</b>	<b>Implication for patient</b>	<b>Commonly seen compensation</b>
Prolonged heel contact and knee hyperextension in stance	Possible shortening of plantarflexors stopping passive dorsiflexion in stance. Poor knee control. Reduced hip extension allowing centre of gravity to fall behind heel	Abnormal alignment and weight bearing on affected leg. Risk of musculoskeletal problems.	Knee hyperextension in stance
Walking with a 'stiff knee' in swing phase	Weak hamstrings or quadriceps spasticity causing insufficient knee flexion	Problems with floor clearance during swing and may be a greater risk of falls. Less energy efficient.	Patients may hip hitch or vault (push up) on the supporting leg to allow more space for the limb to move forward or they may circumduct the leg.
Reduced hip extension in stance	Weak Gluteus Maximus muscles	Knee may hyperextend and there will be abnormal alignment and weight bearing on affected leg. Risk of musculoskeletal pain.	Reduced weight bearing on affected leg reduced single leg stance time, reliance on walking aids.
Reduced lateral stability at hip in stance	Weak Gluteus Medius, positive Trendelenburg sign	May lead to musculoskeletal pain.	Reduced weight bearing on affected side.
Reduced weight bearing on affected side	Due to problems above	Decreased confidence mobilising and less energy efficient gait.	Decreased single leg support time.
Generally flexed posture often combined with use of walking aids	Weak trunk extensors, insufficient core stability and decreased confidence mobilising	Difficulty looking ahead, musculoskeletal pain and reduced balance.	Decreased step length
Arm on hemiplegic side hangs flaccidly or is pulled into flexed position	Upper limb weakness with or without spasticity	Problems balancing, difficulty carrying objects or using a walking aid in affected hand and often reduced confidence.	Gait asymmetry and poor balance.

*Table 2-2: Common gait deviations post-stroke*

*Adapted from [66, 69]*

The gait changes described in Table 2-2 may be most evident when a person is challenged, for example as they tire, if anxious or in pain or when walking on uneven surfaces. Stroke survivors with foot and ankle impairment have said that it makes walking outside problematic, reduces balance, increases fear of falling and that altered walking patterns and use of supportive footwear/orthotics can make them feel self-conscious [70].

Related to the gait changes outlined above other post-stroke problems can occur such as difficulty turning or multi-tasking leading to increased risk of falls [71, 72] and reduced confidence mobilising especially in busy, crowded places or on uneven ground [5, 73]. Due to post-stroke mobility problems, including dropped foot, people may need to rely on walking aids/assistance, be more prone to falls, more frightened of falling and they may limit participation in activities in their home and community [74-77].

Gait pattern is altered by the task and environment but generally has the same or similar phases. Rehabilitation interventions often aim to improve mobility in the environments that are most relevant to the individual patient and their goals and this may include different walking related tasks such as walking outside, on slopes and on uneven ground.

This section has described the components of normal gait and common mobility problems seen post-stroke. Many post-stroke gait rehabilitation interventions aim to reduce one or more of these problems. Understanding the components of normal gait and typical stroke related problems is important for stroke rehabilitation, assessing change post-stroke and understanding the experience of living with the effects of a stroke.

### **2.2.2 Gait rehabilitation post-stroke**

The literature supports multidisciplinary rehabilitation delivered immediately after a stroke in stroke units, by a stroke specialist team, with a joint approach to goal and discharge planning. Specialist, multidisciplinary rehabilitation of patients post-stroke reduces mortality and increases the number of independent non-institutionalised individuals [78, 79]. Inpatient and then outpatient neurophysiotherapy is an integral part of this rehabilitation package [80].

### **2.2.2.1 Neurophysiotherapy**

Commonly used neurophysiotherapy approaches are reviewed in this section in order to develop and describe a clinically relevant and evidence based gait rehabilitation strategy for the Phase 1 trial. Neurological rehabilitation, including neurophysiotherapy, is a relatively young science with an underdeveloped research base [81, 82]. There is a need for more high quality studies to evaluate specific interventions and rehabilitation ‘packages’ of interventions however this is challenging as stroke rehabilitation is complex [83].

Randomised controlled trials may investigate a particular gait rehabilitation intervention given in addition to physiotherapy. It has been the norm to summarise the physiotherapy provided to both groups as ‘standard’ or as ‘physiotherapy based on a specified approach’, see Yan et al., 2005, for an example of the latter. This review will establish whether such summary terms give sufficient physiotherapy detail to allow replication of the trial methodology. Is it valid and meaningful to continue to use named approaches as ‘shorthand’ to describe the physiotherapy offered to stroke patients in clinical trials? If not, are there published lists of evidence based gait rehabilitation on which to base physiotherapy interventions so that the treatment can be standardised in the context of a trial?

### **2.2.2.2 Neurophysiotherapy context and content – from named approaches to evidence based practice**

Surveys have shown that sessions of normal clinical physiotherapy usually consist of several individual interventions, often based on a named approach [84]. Whether this is appropriate in the context of a trial of rehabilitation interventions will now be assessed.

A great deal of professional effort has been channelled into defining and evaluating named neurophysiotherapy approaches because these are relevant to many clinicians. Many UK physiotherapists say that they use the Bobath Concept as their main approach to treating people with stroke, however research shows that the Bobath Concept is not clearly defined and there is variation in its practice [85-92]. In general this treatment approach is based on promotion of normal movement patterns with an emphasis on ‘hands on therapy’, preparation for movement and reduction of abnormal tone. Within the Bobath Concept muscle weakness is viewed as a secondary problem and strengthening is not prioritised [89, 93]. Task specific practice is also not

prioritised; this approach assumes improvements in normal movement patterns gained in treatment sessions translate automatically into function and activities of daily living (ADL). In the USA Bobath based 'neurodevelopmental' approaches to therapy are popular while in other countries such as the Netherlands there has been a shift away from Bobath in the last ten years [94]. This shift is based on perceptions that therapist led 'hands on' facilitated movement has limited functional relevance and is at odds with current research into (re)learning post-stroke [37, 95]. Figure 2-5 shows a 2010 article from a professional physiotherapy magazine that illustrates the continued debate in this area.



Figure 2-5: Bobath in the press.

Recent article in the UK physiotherapy professional magazine from the Chartered Society of Physiotherapy, 'Frontline' illustrating the continuing debate about the relevance of the Bobath concept [85] – with permission.

In the 1990s Carr and Shepherd challenged many of the original Bobath Concept treatment assumptions and developed therapy interventions by presenting their evidence based theory of motor learning. Their 'Motor Learning' approach was task and context specific, individualised to the patient and their environment with therapists guiding and/or assisting efficient movement practice. Equipment and adjuncts to therapy were used if they were appropriate and evidence based. The therapist was

seen as a coach providing feedback and encouraging learning through some degree of 'trial and error' but discouraging ineffective behavioural adaptations. Motor Learning emphasised repetition and independent practice with strength training if required [96].

There is limited robust evidence for superiority or efficacy of any of the named approaches [97] and research investigating the effectiveness of individual techniques and treatment packages 'regardless of historical or philosophical origins' is required [98, 99]. In the Phase 1 RCT it would be inappropriate to simply state that the physiotherapy provided to both groups was based on a named approach, such as Bobath, since it would not allow replication of the trial and would not reflect the evidence for best practice.

### **2.2.2.3 Neurophysiotherapy – evidence based interventions**

The literature was searched to highlight evidence based treatment schedules that could be used to standardise the gait rehabilitation provided in a clinical trial. Schedules of physiotherapy interventions in common use have been published [84, 100]. These intervention recording tools are largely practice rather than evidence driven and therefore cannot be used to provide a comprehensive evidence based set of physiotherapy interventions for the Phase 1 trial.

Evidence based reviews of neurophysiotherapy and rehabilitation have been published that recommend specific interventions however there is widespread criticism of the lack of adequately sized and controlled trials upon which to base decisions [4, 95, 101-105]. Table 2-3 draws together evidence from rehabilitation guidelines, reviews and research to give an outline of evidence based interventions to improve mobility post-stroke. From research and clinical experience interventions less commonly used in the UK have been starred although it is difficult quantify this as service provision is variable and the frequency of use is not well researched.

<b>Evidence based gait rehabilitation interventions post-stroke</b>
Repetitive task specific and goal orientated practice
Practice of functional skills in real life contexts
Walking training for motor control, endurance and speed (including provision of suitable walking aids such as a stick)
Cardiovascular training, encourage regular physical activity and distance walking practice
Strength training incl. weights, progressive resisted exercise for post-stroke weakness
Balance training
Spasticity management (incl. oral or local antispasticity agents)
Orthotics, ankle-foot orthosis (AFO)
* Electrical stimulation to improve walking and reduce spasticity
* Treadmill training with or without body weight support
* Intensive therapy and practice

*Table 2-3: Evidence based interventions for gait rehabilitation post-stroke*

*Drawn from various sources with a starred interventions less commonly used in clinical gait rehabilitation in the UK [4, 20, 95, 104, 106].*

Intensity of activity within a therapy sessions, self-directed practice and amount of activity as an overall percentage of a patient's day have been identified as factors affecting rehabilitation outcome [34, 107, 108]. Two messages are generally supported from the literature that once the patient is medically stable 'any physiotherapy seems to be better than none' and 'the more the better' [98]. The National Institute for Health and Clinical Excellence 'Stroke quality standard' (2010) recommends that 'patients with stroke are offered a minimum of 45 minutes of each active therapy that is required, for a minimum of five days a week, at a level that enables the patient to meet their rehabilitation goals for as long as they are continuing to benefit from the therapy and

are able to tolerate it' [106]. This recommendation has been incorporated into the 2012 'National clinical guideline for stroke' alongside advice on how to stop treatment once all achievable goals have been reached and no new attainable goals can be set [4]. In the UK, once patients have left hospital service provision of outpatient or domiciliary physiotherapy is variable and may not reach or sustain these guideline therapy levels.

This review of the literature surrounding gait rehabilitation interventions concludes that clinicians/researchers should select neurophysiotherapy interventions from recent evidence based therapy guidelines and document interventions carefully for reproducibility while ensuring consistent intensity of practice across groups in research. Two of the interventions, orthotics and electrical stimulation, will now be discussed in more detail as they were used in the Phase 1 trial.

### **2.2.2.4 Orthotics to improve mobility**

Orthoses are external devices which are designed to apply or remove forces from the body in a controlled manner to improve movement and/or function [67]. There are many types of orthosis supplied to patients post-stroke to improve mobility. Moulded insoles can be made to help control foot position, particularly during weight bearing. Some orthotics may be designed to overcome dropped foot, to control the ankle or reduce knee flexion or hyperextension. For correction of knee hyperextension a 'Swedish knee cage' is also sometimes used. Simple ankle-foot orthoses (AFOs) are commonly prescribed post-stroke to avoid the toe catching. Other lighter weight ankle supports such as elasticated Foot Ups, can be used to overcome flaccid dropped foot.



*Figure 2-6: Example of standard ankle foot orthoses for correction of dropped foot*

AFOs have been shown to significantly improve gait kinematics, velocity and functional mobility with users reporting that the AFOs help them walk better [109-112]. AFO



users tolerate the devices well in the above studies but in clinical practice and qualitative studies some users criticise AFOs as uncomfortable, limiting footwear choice and causing them to buy slightly larger shoes to accommodate the device [113].

AFOs are evidence based, widely used for the correction of dropped foot and have become part of normal UK practice post-stroke [4]. AFOs can be modified to control the ankle position optimally in the presence of calf over activity and hinges can be incorporated to allow passive dorsiflexion in stance or in stair climbing in order to mimic more natural movement patterns [109]. However most AFOs hold the foot in a neutral position and active dorsiflexion in swing is not possible. One study reported significantly less activity in the tibialis anterior muscle when participants wore their AFO with shoes compared to walking barefoot, unfortunately no 'shoe only' condition was used for comparison [110]. Other studies have not shown this and further research is needed [112].

#### **2.2.2.5 Non-invasive electrical stimulation to improve mobility**

This review of electrical stimulation outlines its clinical use to improve mobility, the evidence base and its underlying motor and sensory effects. Electrical stimulation of a nerve can depolarise the cell membrane so that it reaches threshold, generates an action potential and causes a muscle contraction [114]. Most commercially available stimulators apply stimulation via self-adhesive surface electrodes but systems with intramuscular or implanted electrodes are also available [115].

The following muscles could be stimulated to improve mobility post-stroke;

- dorsiflexors/evertors to improve floor clearance in swing phase of gait and foot and ankle alignment in early stance.
- plantarflexors to improve push off pre-swing.
- hamstrings for greater knee flexion in swing or to avoid knee hyperextension in stance.
- quadriceps for improved knee extension in stance.
- gluteal muscles for improved hip extension or stability in stance.

This research is focussed on use of stimulation to produce dorsiflexion and eversion, which is a common clinical application of electrical stimulation in gait. Stimulation for correction of dropped foot uses a pressure switch or other trigger to synchronise stimulation of the dorsiflexors and evertors with each step. Functional Electrical Stimulation (FES) describes any application of electrical stimulation during a function

however, in practice it usually refers to dropped foot correction synchronised with gait as just described. Within this thesis the abbreviation FES refers to use of stimulation of dorsiflexors and evertors for correction of dropped foot that is synchronised with each step, unless a different muscle group is specified.

Stimulation can also be applied at rest i.e. outside of a functional movement. This is referred to as neuromuscular electrical stimulation or cyclical exercise stimulation and uses a stimulator that turns on and off in timed cycles. Figure 2-7 shows a stimulator connected to surface electrodes that have been placed for stimulation of the Common peroneal nerve (CPN) to produce dorsiflexion and eversion.



*Figure 2-7: Surface electrodes placed to produce dorsiflexion*

*Photograph showing ODFS Pace<sup>®</sup>, manufactured by Odstock Medical Ltd.*

*(Photograph by K. Hitchlock with permission)*

### **2.2.2.6 Stimulation parameters and treatment**

The output of an electrical stimulator is a series of electrical impulses. Three main pulse characteristics, pulse amplitude, pulse width and pulse frequency, can be adjusted to generate a comfortable and effective muscle contraction. Electrodes are usually placed over the motor point of a muscle or where the nerve is superficial and most easily stimulated. Increasing the pulse amplitude and width increases the size and depth of the electrical field underneath the electrodes. At lower stimulation intensity (pulse amplitude or width) the effects of stimulation are mainly sensory however when intensity is increased sufficiently it passes the motor threshold causing a

muscle contraction. As intensity is further increased, more motor units are recruited and greater muscular force is produced until a plateau is reached. This occurs when all muscle fibres supplied by a motor neurone bundle are activated so that further increases in intensity make no difference to muscle force, although tolerable sensation levels may have already been passed [114]. Most clinical protocols use electrical stimulation at a comfortable intensity that is sufficient to correct dropped foot in walking or produce the desired movement during cyclical exercise.

Higher stimulation frequencies produce a smoother muscle contraction but they do not alter the number of motor units recruited. Higher stimulation frequencies deplete muscle energy resources faster as the same motor units are repeatedly activated. Fatigue can become a problem unless adequate rest times are given between periods of stimulation [116]. In practice, the ability to manipulate 'on' and 'off' periods may be limited through stimulator design or because of the functional nature of the motor activity. For example during walking, stimulation is switched off in mid to late stance to mimic the normal firing patterns of the dorsiflexors and evertors as they are not particularly active at this point of the gait cycle.

The position of the electrodes is critical for CPN stimulation as it affects the relative amounts of dorsiflexion, eversion and knee flexion produced. Patients report that finding the optimum electrode positions for FES on a daily basis can be a challenge and clinical support, feedback and practice appear to help [113, 117]. Detailed descriptions of the walking and cyclical exercise stimulators used for CPN stimulation in the Phase 1 trial can be found in the manuals for these devices [118, 119]. These also include descriptions of the common electrode positions used in dropped foot stimulation and the clinical reasoning underlying the selection of each of these. Figure 2-8 shows representations of the electrode positions recommended in the manual for CPN stimulation that have been used in clinical research and published audits investigating FES [117, 120, 121].

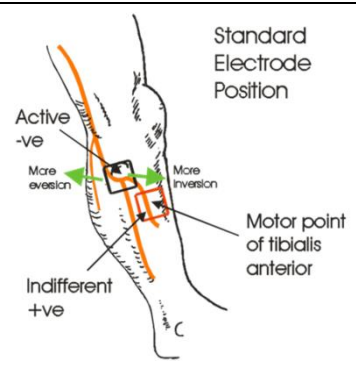
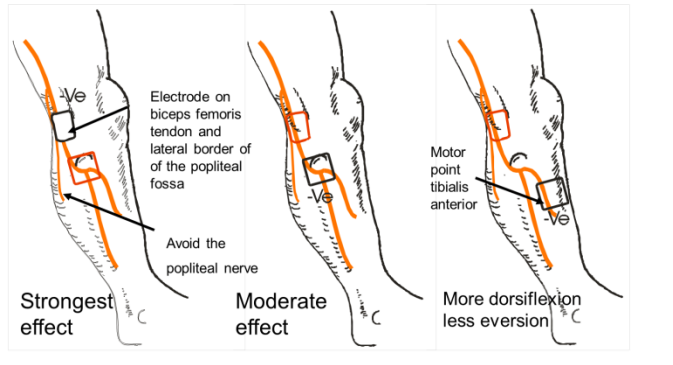
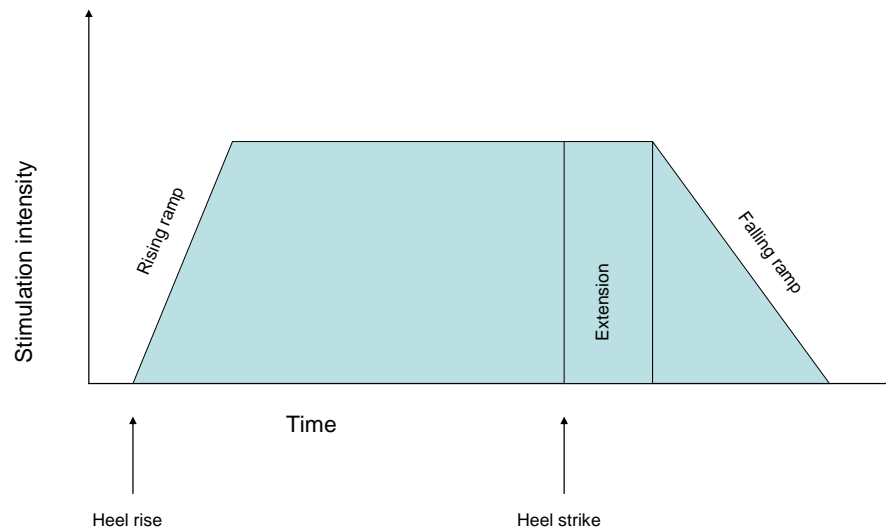
Electrode configuration and clinical reasoning	
 <p>Standard Electrode Position</p> <p>Active -ve</p> <p>Indifferent +ve</p> <p>Motor point of tibialis anterior</p>	<p>This is the standard position for the configuration of electrodes for CPN stimulation. It produces dorsiflexion with eversion and electrodes can be moved more laterally or medially to gain optimal movement. The polarity may be reversed to bias the movement to dorsiflexion if over eversion is a problem.</p>
 <p>Electrode on biceps femoris tendon and lateral border of the popliteal fossa</p> <p>Avoid the popliteal nerve</p> <p>Strongest effect</p> <p>Moderate effect</p> <p>Motor point tibialis anterior</p> <p>More dorsiflexion less eversion</p>	<p>These diagrams show the configuration of electrodes for CPN stimulation incorporating increased knee and hip flexion through flexor withdrawal.</p>

Figure 2-8: Electrode positions used for correction of dropped foot

(Electrode positions reproduced with permission from P. Taylor) [114, 118, 120]

Use of electrical stimulation can cause some discomfort due to awareness of the stimulation sensation and mechanical effects. Some users develop skin irritation under the electrodes [117] and advice on reducing the incidence of skin irritation and dealing with it if it occurs can be found in the device manuals. In order to overcome these problems more permanently, alternative methods of stimulation delivery using percutaneous or implanted epineural electrodes have been developed and are well tolerated by users [115, 122-124]. Kottink et al., 2004, suggests that implants may be most suitable for people with chronic hemiplegia and established foot drop when the benefits of long term correction may outweigh surgical risk [125]. This research is focussed on the use of surface stimulation because the Phase 1 trial population were less than six months post-stroke.

Electrical stimulation for the correction of dropped foot (FES) is synchronised with each step by a pressure sensitive switch usually placed under the heel on the affected side so that heel rise triggers stimulation and heel strike ends it. The stimulation may be turned 'on' (rising ramp) or 'off' (falling ramp) more quickly or slowly, which alters the clinical effects.



*Figure 2-9: Stimulation intensity profile of ODFS III<sup>®</sup> [118]*

Stimulation of the dorsiflexors and evertors (agonist) needs to turn on fast enough that the foot lifts and clears the ground without discomfort or eliciting a stretch reflex in the plantarflexors (antagonist). At the off trigger, stimulation may be stopped immediately but this can result in the foot slapping to the floor in an uncontrolled manner at initial weight bearing. This may be helped by extending the period of stimulation beyond heel strike (the 'off' trigger) by adding an 'extension' time period that maintains stimulation at the greatest stimulation output level or by adding a gradual ramp down in the output. Both are useful in CPN stimulation but need careful adjustment as excessive extension or falling ramps may lead to muscular fatigue due to inadequate off/rest time in stance. The combination of a stimulation extension period and adequate falling ramp is helpful because it mimics the eccentric firing of tibialis anterior and can improve tibial progression and therefore the position of the lower limb in stance. In patients with a strong tendency to invert, the activation of dorsiflexors and evertors improves clearance and alignment in swing phase of gait and keeping the stimulation on longer after heel strike can improve ankle position in stance and reduces ankle instability. In the presence of plantarflexor spasticity there may still be ankle instability in stance once stimulation finishes and additional supportive in-shoe or ankle orthotics may be required.

Correction of dropped foot by stimulation of the CPN in walking can be hampered by heightened calf stretch reflexes. Cyclical exercise stimulation with slow rising ramps may be used to desensitise the stretch reflex and may also increase range of movement and fatigue resistance. A period of regular exercise stimulation can also help the user learn where to place electrodes while remaining in a safe seated position.

prior to use of walking stimulation. If the stimulation sensation is difficult to tolerate use of cyclical exercise stimulation may help them get used to the sensation.

The knowledge presented in this section is based on published material and an accumulation of clinical experience using and developing electrical stimulators, accompanying manuals and training courses. Further information about clinical FES protocols can be found in the Rancho Los Amigos book, the device instruction manuals and in clinical research/reviews [114, 118, 120, 126].

### **2.2.2.7 Evidence for the use of electrical stimulation in gait rehabilitation post-stroke**

Cyclical exercise stimulation of the CPN and FES have both been used in gait rehabilitation and the evidence for their use in improving mobility post-stroke is discussed in this section. Cyclical exercise stimulation of the CPN in lying or sitting can increase muscle strength and may reduce spasticity and improve mobility in acute and chronic stroke [127, 128]. CPN stimulation can also be used in walking as an 'active orthosis' to improve dorsiflexion in swing, referred to as FES within this thesis. The National Institute of Clinical Excellence (NICE) and several other systematic reviews have concluded that FES can be used routinely to safely actively correct dropped foot of upper motor neurone origin and that this is associated with improvements in gait speed [129-132]. 10m walking speed (10mWT) has been shown to increase and effort decrease when stimulation is switched on compared to off (termed an orthotic effect) [115, 120, 121, 133]. Distance walked in six minutes can also increase with FES use [134]. FES can improve walking pattern post-stroke, which may explain the reduced effort of walking when stimulation is used. It has been shown that FES can increase knee and hip flexion in early swing, via the flexor withdrawal response [135], improve loading at initial stance [136, 137], reduce calf and quadriceps spasticity [138, 139] and improve gait speed on uneven surfaces [122, 140].

FES has been associated with improved function and mood. FES has been associated with a positive impact on scores in the Psychosocial Impact of Assistive Devices Scale (PIADS), Hospital Anxiety and Depression Scale (HADS) and the Canadian occupational Performance Measure (COPM) as well as reducing reliance on carers [117, 141-145]. Stroke survivors have explained that they use FES regularly because it reduced effort, risk of tripping and fear of falling and increased walking distance, speed and confidence [113, 117, 143, 146].

FES devices are more expensive than ‘off-the-shelf’ AFOs. Some studies have compared these two approaches to managing dropped foot. Experimental studies have demonstrated some benefits of FES over AFO in terms of greater tibialis anterior muscle activity, obstacle avoidance, walking distance over six minutes (6MWT), 10mWT and improvements in some aspects of quality of life [115, 140, 147]. However, another RCT showed that both interventions improved functional gait and quality of life in chronic stroke patients with no significant between group differences [112]. People with dropped foot problems following chronic stroke have reported a preference for FES use over AFO which they relate to a perception of being able to walk further, move the ankle more freely, walk more normally, safely, independently and with greater comfort when using FES rather than an AFO [113, 148, 149]. Studies have identified that both interventions have pros and cons from the perspective of device users [113].

Evidence from larger audits of chronic stroke patients using FES suggests that as well as the effects described above, FES may have a training effect i.e. an improvement in walking speeds with stimulation turned off over time [120, Taylor 1999, 133]. In the most recent audit of a group of 62 people, with an average time post-stroke of almost five years, the training effects continued over time but appeared to be most rapid in the first few months of use [120]. 52% of the stroke patients improved their functional walking category [120]. The underlying mechanism for this training effect is not well understood, however it has been hypothesised that synapses at the spinal cord level may be strengthened due to voluntary neural activity coinciding with antidromic impulses, initiated by electrical stimulation, when attempting to initiate a step i.e. Hebbian learning [150]. When used regularly, dropped foot stimulation provides an opportunity for augmented practice of more normal movement patterns within the desired task, walking, which could prompt motor (re)learning or refinement of motor strategies [37, 151]. Most FES users live at home and use FES around the house and garden and in their community for orthotic correction of dropped foot and to practice ‘better’ quality walking [152]. It has been suggested that dropped foot stimulation may have a training effect by ‘forcing’ massed practice of a repeated movement, combined with voluntary activation, in a goal orientated context with more opportunity for repetitive task specific practice [153, 154]. These conditions have been shown to be associated with motor learning [37, 155] (see Section 2.1.3).

People may be adapting and (re)learning movement at a faster rate in first weeks and months post-stroke [1]. Unfortunately, there is little published evidence upon which to base decisions about using electrical stimulation to achieve functional outcomes with

people less than six months post-stroke. This is because most of the studies referred to above attempted to reduce sample variability by recruiting people more than six months post-stroke i.e. chronic stroke. Some inpatient studies have been completed. Significant improvements in mobility, muscle strength and reductions in calf spasticity were found with cyclical electrical stimulation applied less than two months post-stroke in two RCTs [156, 157]. In another study, the feasibility of using FES in supervised walking in a sample of 16 inpatients less than four months post-stroke was investigated. The participants were more than two weeks post-stroke and medically stable [158]. They received routine gait rehabilitation for 20 minutes per day, five days per week, over 12 weeks and were randomly allocated to a control group (gait rehabilitation and AFO n=7) or the intervention group (gait rehabilitation and FES n=9). The participants used their AFO or FES (depending on group) within gait rehabilitation and also used it in the ward environment if they could mobilise without physical assistance. Outcome measures were collected at baseline and after six and 12 weeks and included gait speed (10mWT) and gait independence using the Functional Ambulation Categories (FAC). The authors noted that use of FES was more challenging with these inpatients in comparison to their experience treating chronic patients with FES because these more acute participants changed more rapidly and required more regular adjustment of their stimulation parameters. Two people in the intervention group stopped using FES over the trial period because of low mood and two stopped FES because they no longer had signs of dropped foot. One participant was excluded from this study because high tone prevented successful application of stimulation. The researchers suggested excluding people with high tone that made completion of passive movements difficult from future studies. Had their study had cyclical exercise stimulation available to reduce high plantarflexor tone, the excluded participant may have been able to use FES successfully and take part in the trial. The researchers in this study was unable to complete all of the outcome measures at each assessment point due to time constraints, participants being unable to walk, refusal or participant fatigue. Supported use of FES was possible in the inpatient ward environment although no wider conclusions could be made due to the small numbers, apart from suggesting that FAC should be used in a larger study as this had the highest completion rates. This small study demonstrated the feasibility of FES use with inpatients.

Inpatients after first stroke are often focused on 'just getting home' and moving about in any way possible, based on the researcher's clinical experience. Once home patients may be confronted by the changes in their ability to be active and participate as they



did before the stroke and are often keen to improve performance on functional tasks. At home, the individual may be highly motivated to participate in gait rehabilitation and practice outside of physiotherapy sessions in order to resume activities they previously valued [159]. Therefore, people who live at home and are less than six months post first stroke may gain added benefit from interventions to improve gait as motivation may be high, poor walking patterns may not yet have become habitual and the potential for motor recovery due to cortical reorganisation is greatest. They also have the opportunity to practice in their own real-life environments (rather than the ward) which may increase the salience and specificity of the task practice, which are associated with motor (re)learning [37].

Clinical protocols for use of FES often include cyclical exercise stimulation if needed, to desensitise the stretch reflex, increase range of movement or improve fatigue resistance [118-120]. No published RCTs using this pragmatic FES protocol (walking stimulation plus cyclical CPN stimulation if required) in chronic or acute stroke could be found. FES or cyclical stimulation have been used in research as stand-alone interventions or they have been used individually within conventional gait rehabilitation in research.

Motor (re)learning research post-stroke suggests that more repetition, particularly in a functional context, combined with voluntary activity, is likely to illicit motor (re)learning [37, 62, 108]. The amount of stimulation received and/or usage time was not monitored in most of the research studies referred to earlier in this section because most stimulators used did not contain a data logger. Due to problems with self-reported stimulator use it can be difficult to estimate usage without a built in data logger therefore optimum 'dose' and intensity of practice with electrical stimulation in walking or for cyclical exercise has not been established. When electrical stimulation is used in combination with conventional rehabilitation total therapy time should be balanced between groups in order to avoid introducing a between group confounding variable [34].

Research into electrical stimulation has increased since Liberson first published his work on clinical use of FES in 1961 [160]. Despite the increasing research interest in electrical stimulation and its increasing clinical popularity, particularly for dropped foot correction, there is little evidence on which to base clinical decisions for patients with dropped foot who are less than six months post-stroke.

#### **2.2.2.8 Neuromuscular effects of electrical stimulation**

This section reviews the effects of electrical stimulation that are relevant to the Phase 1 trial but not gait specific. Electrical stimulation has been associated with gains in muscular strength post-stroke (both acute and chronic) [157]. Newsam and Baker, 2004, completed a RCT to investigate the effects of a three week stimulation programme of quadriceps stimulation during weight bearing activities and walking, incorporated into gait rehabilitation, in a group of inpatients less than two months post-stroke (n=20). There was a significant increase in maximum voluntary isometric torque, perhaps indicating improved motor unit recruitment. They also found an increase in supramaximal contraction torque after treatment that was suggestive of hypertrophy [157]. The quadriceps stimulation intervention applied in this study could be considered as a form of task specific strength training at an enhanced intensity and these factors have been associated with improved motor control. Knee extensor strength has been associated with faster walking speed [161, 162] unfortunately Newsam and Baker's study did not include any functional outcomes which limits the translational relevance of their findings.

A peripheral nerve consists of a bundle of individual neurones of different axon diameters. In normal function smaller diameter neurones that supply predominantly slow fatiguing, low force muscle fibres are recruited before larger diameter neurones that supply faster fatiguing, higher force producing muscle fibres [116]. The normal physiological recruitment order, just described, minimises fatigue. Fatigue is also minimised in normal tetanic muscle contractions by the utilization of asynchronous firing of motor units, which maintains torque at low individual motor unit activation frequency with reduced associated fatigue. Electrical stimulation affects the recruitment order. It was hypothesised that electrical stimulation partially reverses the normal recruitment order as larger neurones are more easily depolarised and therefore it may recruit these preferentially [114, 163]. Gregory and Bickel, 2005, discredited this hypothesis after examining the published evidence. They concluded that 'electrical stimulation recruits motor units in a non-selective, spatially fixed and temporally synchronous pattern' [116]. Therefore fatigue may occur faster in muscles that are activated by electrical stimulation because motor units are activated non-selectively and at a relatively higher frequency [116]. This re-enforces the need for careful adjustment of stimulation parameters (see 2.2.2.6).

Another difference between electrical stimulation and normal nerve firing is that when electrical stimulation causes nerve depolarisation there is no adjacent area of the nerve

in a refractory state because there has not been prior conduction of the action potential along the axon. Therefore action potentials resulting from electrical stimulation can move in both directions along the axon, orthodromic impulses travel towards the periphery and antidromic towards the spinal cord [62]. When voluntary drive to activate a motor neurone repeatedly occurs with simultaneous activation of that motor neurone, the synapse is 'strengthened' through Hebbian Learning, as described in Chapter 2.1.3.5. It is proposed that some improvements in voluntary activation following long term stimulation use may occur when electrical stimulation induced antidromic activation of the anterior horn cell occurs repeatedly with simultaneous voluntary effort, causing synaptic modification [62].

Post-stroke ankle plantarflexor over activity (spasticity) is common and contributes to problems with drop foot in swing phase of gait and weight bearing in stance (see Table 2-2). Cyclical electrical stimulation has been shown to reduce co-contraction in the dorsiflexor/plantarflexor muscle pair [156] and can reduce spasticity [20]. Contraction of tibialis anterior by electrical stimulation reduces the soleus stretch reflex [164, 165]; a likely mechanism is reciprocal inhibition. Reductions in lower limb spasticity associated with CPN stimulation are not limited only to the antagonist muscle. Burridge et al. demonstrated this in 1997. They used triggered CPN stimulation to assist walking in a group of people with chronic stroke for twelve weeks (n=16) and found that quadriceps spasticity measured by the Wartenberg pendulum test reduced significantly compared to a control group (n=16) [138]. One possible explanation is that a more normal walking pattern was enabled by correction of dropped foot and this prompted more normal motor recruitment patterns in the whole lower limb. Flexor withdrawal may also have prompted quadriceps relaxation through reciprocal inhibition.

Electrical stimulation has sensory as well as motor effects because it causes afferent output from cutaneous receptors and mechanoreceptors, at the skin and within the muscles and joints affected by stimulation. Repetition of altered afferent input to the brain via electrical stimulation could affect somatosensory cortical mapping and potentially improve sensory awareness and function [41, 166]. No studies could be identified that investigate the effects of FES on lower limb sensation. Although up to 85% of stroke survivors report sensory changes, interventions to improve sensation post-stroke are generally under-researched [166, 167].

The electrical stimulation studies referred to thus far have applied stimulation at a level that elicits a motor response however it is also used at a lower intensity i.e. without a visible muscle contraction. Regular cyclical stimulation above motor threshold has

been associated with increased voluntary muscle activation in patients less than six months post-stroke but regular stimulation at only a sensory level does not appear to have the same effect [156, 168, 169]. In healthy subjects CPN stimulation that causes muscle twitch but not movement may alter cortical excitability and combining muscle twitch level stimulation and voluntary effort may enhance this effect [170, 171]. Increased corticospinal activity has been observed following regular use of FES (i.e. motor level stimulation used to correct dropped foot in walking) in a small group of people with chronic stroke [172]. The stimulation parameters most consistently associated with cortical plasticity are motor level stimulation and longer periods of repeated stimulation however more research is needed to establish the effects of these and other parameters in populations of people with neurological damage [168].

### **2.2.2.9 Summary - Gait rehabilitation post-stroke**

Common peroneal nerve stimulation produces dorsiflexion and eversion that can be synchronised with each step (FES). It is an evidence based intervention for correction of dropped foot post-stroke that has been shown to improve walking speed, with orthotic and training effects observed. Improvements in gait quality, functional ability, mood, walking confidence and fear of trips and falls have also been associated with FES use. Cyclical exercise stimulation of CPN in lying or sitting can increase muscle strength and may reduce spasticity and improve mobility in acute and chronic stroke. FES protocols, including cyclical exercise stimulation as required, have been used clinically and shown to be effective at improving 10mWT in audits of use in chronic stroke. Most research studies have recruited people with chronic stroke to reduce sample variability however people who are less than six months post first stroke may gain added benefit since the potential for motor recovery due to cortical reorganisation is greatest and altered walking patterns may not be habitual. Lack of research investigating the efficacy of FES in people with more recent strokes prompted the Phase 1 Trial to be undertaken.

A RCT investigating FES, with cyclical exercise stimulation as required, in combination with regular physiotherapy to improve gait in people less than six months post-stroke and living at home would address some of the outstanding uncertainties surrounding use of FES that have been highlighted. In order to ensure both groups received evidence based physiotherapy to improve gait, a review of the literature on gait rehabilitation was undertaken. This review established that it is no longer meaningful to describe physiotherapy delivered as part of a clinical trial by simple 'labels' of different named approaches. Neurophysiotherapy based on a single named approach

is not supported by the literature and a mixed treatment approach has been shown to be effective. In order to allow a trial to be reproduced and improve standardisation the use of treatment schedules or lists has been proposed. There is not a schedule based on current evidence based gait rehabilitation interventions available from the literature therefore a list of evidence based interventions has been created for use in the Phase 1 pilot RCT (Table 2-3). The next chapter focuses on the quantitative research methodology, including outcome measurement, that will enable the investigation of FES to improve gait in combination with physiotherapy interventions in people who are less than six months post-stroke and living at home.

## 2.3 Review of quantitative research methods

This section presents an overview of quantitative research methods that are relevant to designing a study investigating the efficacy of electrical stimulation delivered as part of normal physiotherapy to improve mobility in people less than six months post-stroke. This chapter reviews the literature surrounding pertinent areas of experimental trial design and highlights aspects of walking that the literature suggests should be measured in gait rehabilitation research. The chapter ends with a summary of this process and evidence based recommendations for the Phase 1 trial design.

### 2.3.1 Quantitative research methodology

Medicine relies heavily on scientific, quantitative methods, such as observation and measurement, to assess biological function and describe health and disease. It assumes facts can be known about bodies and individuals and that monitoring these will indicate change over time. A huge range of aspects of human life are measured, examples include temperature, blood pressure, daily footsteps by pedometer, exertion on a standardised scale and quality of life by validated questionnaires. Objective measurement techniques are a foundation of the scientific method.

*‘When you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind: it may be the beginning of knowledge, but you have scarcely, in your thoughts, advanced to the stage of science, whatever the matter may be.’* Lord Kelvin, lecture 1883 [173]

Medical research applies this objective approach to assessing aspects of a disease or individual responses to treatment. It is recognised that the research design or the researcher themselves may affect outcome so research designs have been developed to minimise bias. The randomised controlled trial (RCT) is seen as the gold standard in quantitative trial design in clinical research and is highly valued in evidence-based reviews. A controlled clinical trial compares the effects of standard treatment (control) to the treatment under investigation (intervention). The random allocation of participants to the control or intervention group attempts to balance known and unknown confounding variables that could affect response to treatment and ensures there is no allocation bias [174]. If it is possible for the researcher to know which treatment the patient is likely to receive before they are screened it could bias which participants they admit to a trial. The CONSORT Guidelines (Consolidated Standards

of Reporting Trials) aim to improve quality in clinical research methodology and subsequent reporting of outcomes from RCTs. They should inform the design of the Phase 1 trial, its analysis and subsequent publications [175-179].

### **2.3.1.1 Randomisation**

Participants can be randomly allocated to groups by chance alone (simple randomisation) or divided into groups from which a known proportion is allocated to each treatment group (block randomisation). Block randomisation ensures equal distribution of participants between groups, which is useful if fewer participants than expected are recruited. However in trials with small sample sizes, particularly if there are only two treatment groups, simple randomisation reduces the chances of recruitment or allocation bias as the researcher recruiting participants cannot predict the allocation of particular participants.

### **2.3.1.2 Blinding**

Blinding is when the assessor and/or participant is unaware of group allocation and it is used to reduce potential bias. Participants may try to 'please' their assessor by giving answers that are seen as acceptable or the assessor could attempt to manipulate the outcome in some way. Blinded assessments are usually carried out by a suitably trained individual, separate from the trial and unaware of the group allocation [174]. Trials are single blinded when one party is unaware of group allocation and double blinded when both participant and assessor are unaware of group allocation.

### **2.3.1.3 The purpose of pilot studies**

Cyclical exercise stimulation and stimulation to improve mobility have not been previously integrated together into current evidence based physiotherapy in a research trial with patients who are less than six months post-stroke. There was information from other studies to draw on in the design of such a study but no study which a similar protocol on which to check variability of selected outcome measures and make sample size calculations [121, 156]. Therefore, feasibility testing in this population was required. A pilot study was also indicated to test the novel protocol and assess outcome measure variability in order to subsequently calculate sample size for a suitably powered definitive study. Van Teijlingen and Hundley, 2001, describe the reasons why pilot studies might be undertaken, those relevant to this quantitative research are listed below:

## Chapter 2: Literature Review

- Develop and test adequacy of research instruments
- Assess feasibility of a full scale study
- Design a realistic and workable research protocol
- Assess success of proposed recruitment approaches
- Identify logistical problems which might occur using the proposed methods
- Estimate variability in outcomes to help determining sample size
- Determine what resources (finance, staff) are needed for a planned full study
- Assess the proposed data analysis techniques to uncover potential problems
- Gather evidence to convince funding bodies and stakeholders that the main study is feasible and worth supporting
- Training a researcher in as many elements of the research process as possible

Adapted from Van Teijlingen and Hundley, 2001 [180].

The Phase 1 pilot study with a randomised controlled design aimed to deliver the outcomes above. Outcome measures that could be selected to assess change in gait during the study period will now be discussed.

### 2.3.2 **‘Measuring’ gait**

When something can be measured accurately, one can monitor change over time and hopefully understand it better. In order to do this the measurement technique utilised needs to be reliable and valid. A reliable measurement technique measures consistently and it is valid if it measures what it is supposed to measure. Stability of a measurement between testing sessions is often called test retest reliability (or intra rater reliability when it is the same person performing the measurements). Inter rater reliability of outcome measures is also important if multiple researchers are likely to take measurements [181]. Measurement tools should be reliable, valid, feasible and practical [182]. In addition they should be sensitive to and able to detect clinically important changes, this is termed responsiveness [183]. Reliability, validity and sensitivity to change are often referred to as the psychometric properties of an outcome measure and practicality as clinical utility [184]. These measurement principles are used in this chapter to evaluate outcome measures that could be used in the Phase 1 trial.

As a group, human beings have common features of gait and individually can be characterised by their walking. We recognise people we know well at a distance by their appearance and pattern of walking and sometimes the sound of their footsteps



[185]. Although walking has a some predictable characteristics, it is highly adaptable to context and environment. For example a naturalist creeping up to film an endangered Amazonian frog would have clear differences in gait from a hurrying commuter walking in big city. Healthy people can develop altered gait patterns, for example a stone in one's shoe may alter weight bearing until the stone is removed. The wide variation in gait and large impact of task and environment on gait pattern presents classification and measurement challenges. To enable measurement, aspects of human walking function may be grouped together. The World Health Organisation (WHO) developed a conceptual framework for individual function in health (including walking) which is called the International Classification of Functioning, Disability and Health (ICF) (Table 2-4) [186].

<b>Functioning and Disability</b>		
<b>Body functions and structures</b>	<b>Activities</b>	<b>Participation</b>
Body functions are defined as the physiological functions of body systems and body structures as the anatomical parts of the body.  Deficits of body functions or structures are called impairments.	Activity is defined as the individual executing a task.  An individual can have activity limitations.	Participation is defined as the individual involved in an aspect of their life in the actual context in which they live. Therefore, this includes some elements of environment.  An individual can have participation restrictions.
<b>Contextual Factors</b>		
<b>Environmental factors</b>  External influences on functioning and disability	<b>Personal Factors</b>  Personal influences on functioning and disability.	

*Table 2-4: International classification of Functioning, Disability and Health*

*Adapted from the World Health Organisation publication [186]*

The ICF can be applied to walking problems post-stroke. An individual with a stroke could have dropped foot due to reduced dorsiflexor activity (impairment of body

function/structure) so they are unable to take a safe step and walk independently (activity limitation). One effect of this may be that they cannot walk their dog on the pavement outside their home independently (participation restriction). These aspects of function are influenced by contextual factors. Consideration of walking in a holistic manner may aid trial design and outcome selection. Impairment assessment can help clinicians and researchers understand the physiological mechanisms underlying change although it may be less meaningful to patients as it can be quite abstract. The most meaningful changes for patients may be at activity or participation levels. It would seem ideal to include activity and participation level measures in gait rehabilitation trials to increase relevance to participants. In the following subsections, various potential outcome measures have been considered and next to the title, the nearest ICF classifications have been shown although it is difficult to map to ICF terms precisely [184].

### 2.3.3 Ten metre walking test

#### *Impairment and activity ICF categories*

The 10m timed walk (10mWT) has been described as a near perfect outcome measure [182]. It is simple, practical and understandable, requiring very little equipment. This and other timed or distance walking tests reflect walking related body systems and walking as an activity therefore reflecting impairments and activity under the WHO classification system.

10mWT has good psychometric i.e. measurement properties. Same day and different day test retest reliability is good, as is inter rater reliability [184, 187-194]. Sensitivity to clinically important changes and concurrent validity has been established by multiple studies showing improvements in 10mWT and other outcome measures, including kinematic data gained from gait laboratories, lower limb muscle strength, the distance covered in six minutes, peak oxygen consumption and Berg Balance Test [5, 189, 195-197]. 10mWT also correlates with other well established physical measures such as 'timed up and go', the Fugel Myer impairment measure, Rivermead Mobility Index (RMI), the Barthel Index, the Functional Independence Measure (FIM), Functional Ambulation Category (FAC) and community walking ability (see Appendix A for examples).

The 10mWT does not capture detailed gait quality but does reflect and relate to temporal measures of gait (incl. hemiplegic limb stance period and double support time) [198]. Gait velocity was shown to be significantly different between those using

walking aids and those that do not [189]. 10mWT is generally recorded with patients using their normal walking aid and these should be recorded as they may affect speed.

10mWT reflects problems in the participation levels of the ICF. Schmid et al., 2007, found that results from a 10mWT could be used to divide people with mobility problems into 'household ambulators' (<0.4m/s), 'limited community ambulation' (0.4-0.8m/s) and 'full community ambulation' (>0.8m/s). These classifications correlated with Stroke Impact Scale (SIS) scores and the authors concluded that changes in velocity based community ambulation groups are related to meaningful improvements in function and quality of life [199]. Lord et al., 2004, concluded that 10mWT may be an appropriate primary outcome measure for trials aiming to improve community mobility but that it should be augmented by measures at participation level [5].

Watson, 2002, reviewed the history of short distance timed walking tests and reported of a range of test distances, from 4m to 10m. He concluded that 10m walking distances were chosen as it was a meaningful, functionally significant distance in the recovery of independent walking and practical to perform in most clinical environments. A variety of 10mWT protocols exist and Appendix A highlights the different test methodologies. From these tables it can be seen that the 10mWT is frequently carried out from a standing start or over a 14m course, where only the middle 10m section is timed. Generally the person timing with a stop watch walks alongside the patient and avoids standing 'waiting' at the finish line or walking just in front of the subject which can cause subjects to inadvertently try and 'keep up' [200]. Measurement with a stop watch, by an observer with a good view of the moment the leading foot crosses the start/finish line has been shown to be reliable. Handa et al., 2007, used a 16m track with a 10m measured central section. Ten healthy volunteers performed a 10mWT ten times and were simultaneously timed with stop watches and a three dimensional motion analyser. Strong correlations between the two methods were found and accuracy of the stop watch method was calculated at +/- 0.1s [201]. Stop watches are readily available and have been shown to be a reliable way of timing walking tests. They are used widely in studies exploring the psychometric properties of different walking tests and in experimental trials.

Instructions given to the subject also vary widely. Some 10mWTs are measures of fast walking and others of comfortable walking speed. It is apparent from this literature review and clinical experience that consistency in methodology including instructions is vital for reliability within a study [200]. A RCT of the ODFS III® in a chronic stroke population used the instructions to 'walk briskly but safely' over a 12m course,

measuring time taken to cover the middle 10m with a stop watch [121]. This study averaged three walks with stimulation and three without, in a set order and compared the means. This methodology was used until 2006 at the National Clinical FES Centre, Salisbury, with audits of data recorded during clinic appointments published [152, 202]. In 2006 a review of the 10mWT methodology used in clinic showed systematic variation in the time taken to walk; the first walk without stimulation was consistently significantly slower than the other walks when stimulation was not switched on. Van Herk and Green, 1998, also found this effect although Wade, 1987, did not [203, 204]. Amongst clinicians at the National Clinical FES Centre there was some concern that six walks may tire some patients and it would be ideal to do fewer repetitions to minimise fatigue as a confounding variable. It also excluded some patients from recording their walking times as they found 60m was too far to walk. The following has now been adopted as the 10mWT protocol at the National Clinical FES Centre. The first walk without FES assistance is recorded but not used in analysis. The second 10m walk, also without FES assistance, is used for comparison. The third walk is with stimulation and the last is without, to assess immediate carryover effects (not attempted if the patient is too fatigued). The 2nd and 3rd walks in the sequence are used for comparison to assess the orthotic effect of stimulation. This protocol has been used in published audits of FES [142, 205]. It is an acceptable methodology with respect to the other protocols used in the literature reviewed here.

The 10mWT has a floor effect i.e. some patients are not able to walk 10m independently with an aid, and it has a ceiling effect as normal walking speed is achieved. However, it is reliable, valid, sensitive to change and simple to administer. It is also meaningful as it correlates with a range of more complex measures of impairment, disability and participation and allows comparison of results with other trials.

Velocity as well as endurance is critical for community ambulation. Extrapolation of 10m walking speed to estimate distance covered in six minutes can overestimate capacity in people with stroke and therefore longer distance walks are often used in addition to 10mWT [206]. Studies aiming to improve participation in activities outside the home should include both short distance and longer distance/endurance walking tests since both are relevant to the stated aim and they measure different aspects of walking function.

### 2.3.4 Endurance walking tests

#### *Impairment and activity ICF categories*

Stroke survivors may find that their inability to walk a sufficient distance limits their participation in activities outside the home and increases reliance on carers [7]. Difficulty walking longer distances has been associated with worse health. The inability to walk 400m in under 362 seconds carried a higher risk of death, within six years, with slower performance also associated with cardiovascular disease and mobility disability in a population of community dwelling 70-79 year olds with follow-up of health status over six years [207]. This large group cohort study (n=3075) used a 400m 'long corridor walking test' although the distance covered in 2, 6 or 12 minutes is more commonly used. Studies of people with stroke have shown strong correlations between distance covered in six minutes and peak oxygen uptake, gait velocity over 10m, balance, Functional Independence Measure (FIM) and quadriceps strength (see Appendix B for examples). Patterson et al., 2007, found poor balance was a more important predictive factor for distance covered in a six minute walking test in slower walkers and cardiovascular fitness more important in faster walkers [208].

Subjects are usually asked to walk as far as possible in a given time (2, 6 or 12 minutes). There is evidence that the longer distances covered during 6 or 12 minutes yield more variation in results, possibly as participants tire, suggesting they may be better at discriminating better between subjects [209]. Testing over 12 minutes may be feasible in the healthy subjects tested by Butland et al., 1982, but could be daunting and very fatiguing for people who have had a stroke. Eng et al., 2002, studied the validity of the 6 and 12 minute walking tests in community dwelling people with stroke. They demonstrated a strong correlation between 6 and 12 minute walking tests. After the initial 2 minute segment of the tests the distance covered in all subsequent 2 minute segments in each of the 12 and 6 minute tests was similar. The stroke patients appeared to pace themselves similarly, irrespective of how long they knew that they had to walk for. The authors concluded that the six minute walking test (6MWT) could be used in place of longer tests [210]. The distance covered by the stroke patients in this test was 42-50%, less than that reported for healthy older people.

There was considerable variation in the administration, course, assistance given and instructions for the 6MWT across different published research papers [209, 211]. Guyatt et al., 1985, demonstrated that encouragement significantly increases the distance covered [212]. The evidence in Appendix B shows that it is common to ask subjects to walk up and down rather than in circles or a figure of eight. This may be

largely due to convenience as the test can then be administered in a corridor, of which there are many in most hospitals and research institutions. Participants are usually instructed to walk from end to end, covering as much ground as they can in the time. 'Stop' is called at the end of six minutes. They are allowed to stop and rest if they need to during the test, although they are made aware this is part of the timed six minutes.

Most test methodologies require participants to walk independently with walking aids if needed. Da Cunha et al., 2002, investigated walking speed with acute stroke patients using a range of walking aids including parallel bars and also assistance from another person [213]. They found it was possible to complete the 6MWT in this way. However, there are problems with this methodology as it is likely that the results would be biased by the assistant's support affecting the subject's confidence mobilising and thus influencing speed. Da Cunha et al., 2002, did not address the impact of such assistance on the reliability or validity of the 6MWT and no other reliability data addressing psychometric aspects of the 6MWT with physical assistance were found.

In order to make the test reliable and valid, the instructions, assistance and encouragement given during the test should be consistent to ensure changes in 6MWT reflect changes in participant ability and not confounding variables. After careful consideration of published 6MWT methodology, it is concluded that those participants unable to safely take a single step with a walking aid should not attempt the test, recording a score of zero. Most patients returning home and participating in gait rehabilitation are able to at least take one step independently with a walking aid and therefore will record a 6MWT distance greater than zero. This would mean that almost all those in the target population for the Phase 1 trial would be able to complete a 6MWT even if they could not complete a 10m walking test. In trials of acute patients the walking aids used over time could be expected to change more than in a stable chronic group of patients and therefore need to be recorded carefully at assessments.

The 6MWT is a simple practical measure with good reliability and validity and a minimal floor effect, with a ceiling effect as normal speed is approached. It is able to detect clinically significant change in acute and chronic stroke patients.

### 2.3.5 Physiological cost index

#### *Impairment and activity ICF categories*

The Physiological Cost Index (PCI) has been utilised as a proxy measure of energy cost during activity for many years [214]. A resting pre-exercise heart rate and heart

rate after exercise are recorded from a simple heart rate monitor on a chest strap. PCI is the change in heart rate divided by speed of walking in metres per minute to give beats/minute/metre (bt/min/m). This calculation assumes that there is a correlation between how hard a subject is working and their heart rate. This is usually true unless a cardiac pacemaker or certain medication (e.g. beta blockers) are used. Caffeine may also alter this relationship. It is thought that PCI may be most reliable over longer distance when a steady state exercise heart rate may be achieved [214-216]. PCI has been used as a outcome measure in previous trials and audits of FES in stroke populations [121, 142, 152, 202, 205]. Use of this measure in the Phase 1 trial will allow comparison with other trials.

### 2.3.6 Gait quality

#### *Impairment and activity ICF categories*

Visual analysis of movement is a core physiotherapy skill that underpins clinical assessment and treatment. 'Real time' clinical movement analysis is a skill that is common to many health professional groups, from manual handling considerations to provision of aids and orthotics to assist gait. In clinical environments physiotherapists usually rely on observational gait analysis in real time rather than on video and most do not use any scoring system [217]. Despite this lack of formal outcome measurement there is research showing the correlation between therapists and instrumented gait analysis [218].

Inclusion of a specific gait quality measurement was seen as desirable for the Phase 1 trial because the intervention aimed to improve walking and one aspect of this is gait quality. Instrumented gait analysis systems are regarded as the gold standard in gait assessment but are not widely available and are costly and very time consuming to run and are therefore impractical in large studies with multiple measurement points. Inclusion of instrumented gait analysis was discounted in the Phase 1 pilot trial as it would be impractical in a larger, sufficiently powered study in the future.

The use of standardised assessments of gait quality has been proposed as a practical alternative to instrumented gait analysis. When walking is videoed and a standardised gait quality measurement tool is used it has an added advantage that it can be analysed separately by a blinded assessor to reduce potential bias. This was seen as desirable for the Phase 1 trial. Several gait quality measures were considered for inclusion. The Rancho Los Amigos observational gait analysis system and the Wisconsin Gait Scale were discounted as there was limited evidence of test reliability

or validity or sensitivity to change [66, 219-221]. The Rivermead Visual Gait Analysis (RVGA) has better psychometric properties. It categorises deviations as normal, mild, moderate or severe at twenty body segments. The total RVGA score has reasonable inter and intra rater reliability and it is suggested that a change of 10.5 is considered significant [222]. Correlations were found between observed RVGA and 10mWT and other gait measures in a group of patients with mixed neurological problems. The RVGA is considered a valid and responsive measure, change in RVGA score and 10m walking time has been identified after rehabilitation [222]. Specific studies investigating reliability and validity for RVGA from video were not found although it has been used to assess gait quality in a variety of intervention studies with neurological patients [205, 223-226].

This review of the available evidence demonstrated that the RVGA had reasonable reliability and validity and therefore it should be included in the Phase 1 trial as a measure of gait quality. To examine the wider functional context of walking and particularly aspects of walking most relevant to patients, outcome measures including more ICF categories, particularly participation level items, should be considered.

### 2.3.7 **Standardised compound measures of mobility post-stroke**

#### ***Activity ICF categories***

The outcome measures reviewed so far have described steady walking on flat surfaces, perhaps including turning within the 6MWT. Moving position in normal life is much more varied and includes many walking related mobility tasks. To reflect this ICF mobility subcategory is divided into specific mobility related classifications that include moving by changing body position or location or by transferring from one place to another, by carrying, moving or manipulating objects, by walking and running.

There is a plethora of mobility outcome measures referred to in published gait research. Some have established psychometric properties but many have limited reliability or validity. In the context of this pilot study certain measurement properties were valued above others in a mobility outcome measure. Validity, reliability, responsiveness to change and utility in populations of people less than six months post-stroke were most important. A broad mobility measure would complement the outcome measures (10mWT, 6MWT, PCI and RVGA) that have so far been recommended from the literature for the Phase 1 trial. Ease of use is also important. As the measure was one amongst several outcome measures, it needed to be



reasonably quick to administer and not too physically demanding to avoid participant fatigue influencing the results

To limit the number of walking measures that needed to be reviewed in detail the literature was examined to identify measures with the greatest breadth of measurement. Mudge and Stott, 2007 systematically reviewed the outcome measures used to assess walking related mobility following stroke. They identified 61 outcome measures that assessed some aspect of walking and had been used in the stroke rehabilitation research literature [221]. Mudge and Stott designed a search strategy so that only outcome measures measuring walking with published psychometric testing were included in their review. Case studies and studies including other pathology were excluded. There may be some measures not included in their search, as these authors excluded studies if the research or measure were not available in English.

Mudge and Stott, 2007, compared the walking outcome measures that they had identified against the walking related mobility components of the ICF (listed below with their ICF codes) to see how many they assessed [186, 221].

- d4500 - walking short distances
- d4501 - walking long distances >1km
- d4502 - walking on different surfaces
- d4503 - walking around obstacles
- d4551 - climbing (stairs, steps, curbs)
- d5552 - running
- d4553 - jumping (hopping, skipping)
- d4600 - moving around within the home
- d4601 – moving around within other buildings
- d4602 – moving around outside home and other buildings
- d465 – moving around using equipment

Of the 61 walking measures that they analysed against the ICF categories, only 13 assessed four or more mobility subcategories. These are shown in Table 2-5.

<b>Outcome Measure</b>	<b>Number of ICF mobility components incorporated [221]</b>
Rivermead Mobility Index	6
Adapted Patient Evaluation Conference System	6
Rivermead Mobility Assessment	5
Chedoke-McMaster Stroke Assessment	5
Functional Walking Category	5
Activities-Specific Balance Confidence Scale	5
Human Activity Scale	5
36 Item Short form Health Survey	4
Nottingham Health profile	4
Modified Emory Functional Ambulation Profile	4
Rehabilitation Activities Profile	4
Clinical Outcome Variables Scale	4
Ewart's Self Efficacy Scale	4

*Table 2-5: Mobility outcome measures in relation to ICF*

*Adapted from Mudge and Stott, 2007 [221]*

This literature review aimed to identify a mobility measure that covered a broad range of mobility components, had good psychometric properties and was practical and suitable for use with people less than six months post-stroke. The thirteen mobility measures in Table 2-5 were reviewed against these criteria and this work is presented in Appendix C. The measures reviewed covered a wide breadth of mobility components. Some of the measures were shown to have good psychometric properties and practical utility in the context of a trial of people post-stroke. The Rivermead Mobility Index (RMI) stood out from the other measures as a simple measure that included many ICF mobility components with which a person less than six months post-stroke may have problems. It can be considered to primarily reflect mobility activity rather than impairment or participation. It has robust measurement properties and it has been widely used, which allows comparison with other trials. During completion of the RMI the patient demonstrates their ability to stand for 10

seconds unaided and reports whether they can perform the rest of the components on this fifteen point ordinal scale. Each item is scored yes, able to complete (1 point) or no, not able to complete (0 points). RMI is not too time consuming or tiring and it was recommended for inclusion in the Phase 1 trial because it best fitted the criteria of this mobility outcome measure literature search.

### **2.3.8 Reflecting the mobility concerns of people who have had a stroke - Canadian occupational performance measure**

#### ***Activity and participation ICF categories***

Clinicians/researchers have formulated the outcome measures explored and evaluated thus far, sometimes with assistance from patients. The measure is then refined, standardised and tested for reliability and validity. The risk within this process is that opportunities to capture problems from the patient's point of view are lost. One approach to trying to capture the individual's perception of their problems is Goal Attainment Scaling (GAS) which can be used to rate problems identified by the clinician or patient. GAS can also be clinician lead, with problems identified by the clinician and scored by the patient [227]. There is another standardised method whereby a patient rates their own self-selected individualised problematic everyday activities via a semi-structured interview with a clinician. This 'self-selection' of activities is a unique feature of the Canadian Occupational Performance Measure (COPM) and is the reason why its measurement properties will now be investigated in more depth.

COPM is rooted in patient or client-centred practice and it is based on the Canadian Model of Occupational Performance that identifies three main types of activity from the client's perspective [228, 229]. The first is self-care, examples are toileting, grooming, cooking and cleaning. The second is productivity, including all activities which make social or economic contributions and includes paid work. Leisure is the third component, including activities done for enjoyment and free from work or self-care activities. COPM uses a semi-structured interview to highlight activity limitations within the context of the person and their environment. Each problematic activity is then given an importance rating out of 10 by the client. Five of the most important tasks are chosen and rated using 10 point scales for performance from 1 (not at all able) to 10 (able to do extremely well) and satisfaction from 1(not at all satisfied) to 10 (extremely satisfied). These five tasks can be re-rated at a later time to identify change in satisfaction and performance. The interviewer needs to be experienced in using semi-structured interview techniques and no equipment other than the recording sheet and a

pen are required. The initial interview takes between 20-45 minutes with later rescoring taking much less time [230].

Convergent validity has been demonstrated as many of the self-selected COPM problems corresponded with items in the Sickness Impact Scale and The Disability and Impact Scale [230]. Dedding et al., 2004, found the COPM identified more problems than the other scales in a group of outpatients attending for occupational therapy (n=95, including people with stroke). Correlation with the standardised functional measures including Barthel Index and Functional Independence Measure was found to be low but this is likely to be because COPM measures different constructs [231, 232]. There is no gold standard scale for assessing self-perceived activity problems with which to compare COPM and therefore low correlations with other outcome measures are more acceptable.

Test retest reliability for performance and satisfaction scoring of the five chosen items with one week between tests in a group of 26 patients between two and six months post-stroke was found to be high [232]. It is suggested that large changes in total scores may be detected reliably i.e. more than two points [233, 234]. To improve reproducibility and reduce test retest variability clinicians using COPM are advised to be very specific about the problematic activity for example specifying 'tying shoe lace' instead of the more general 'dressing' [233].

The COPM has been used in many studies evaluating occupational therapy and has been used as an outcome measure in a few studies of other rehabilitation therapies including FES in a group of people with multiple sclerosis [235] and an exercise intervention for community dwelling chronic stroke patients [236, 237].

COPM focuses entirely on important activities that have been selected by the individual, which may not be the case with GAS. It supports the interviewee to reflect on self-selected activity and participation limitations and can therefore be used to guide therapy so that it is tailored to the individual's need. Therapists using COPM need to have a patient or client-centred approach, to be experienced in helping formulate specific patient goals, to have the skills to undertake semi-structured interviews and to understand the holistic Canadian Model of Occupational Performance. If this is the case this review concludes that researchers can reliably use this unique self-rating scale to evaluate change in performance and satisfaction in individual occupational performance activities that are rated as important by the patient.

### 2.3.9 **Psychosocial impact of assistive devices scale**

#### ***Satisfaction with assistive device, Group B only***

Simple measures like walking speed may not adequately reflect changes in quality of life associated with use of an assistive device. The reasons for continued use of orthotic devices are complex and individual. The Psychosocial Impact of Assistive Devices Scale (PIADS) was developed to quantify the effects of devices on aspects of quality of life. It has good reliability and validity [238-241] and has been used to evaluate FES [142]. Use of PIADS in the intervention group of this research enabled comparison with previous research.

### 2.3.10 **Hospital anxiety and depression scale**

The Hospital Anxiety and Depression Scale (HADS) is a simple mood measure, it is commonly used with good psychometric properties [242]. It has been used in previous studies of FES and in chronic stroke populations and its inclusion allowed comparison with previous trials [121].

### 2.3.11 **Phase 1 trial design – summary of recommendations from this literature review**

Early after a stroke, abnormal walking patterns may not have become habitual and the potential for motor recovery due to cortical reorganisation may be greatest. Electrical stimulation could improve gait post-stroke but the efficacy of cyclical exercise stimulation and walking stimulation integrated into physiotherapy for people less than six months post-stroke has not been previously rigorously tested. A two group randomised controlled trial is suggested as the methodology for testing this intervention. It should ideally be designed, analysed and reported according to the CONSORT Guidelines. Within the proposed experimental design a control treatment needed to be identified and described. Provision of physiotherapy, including walking aids and orthotics as required, is the standard treatment given to improve mobility post-stroke in the UK and will constitute the control intervention given to both groups in the Phase 1 trial. This literature review highlighted evidence based interventions that should inform the physiotherapy provided (Section 2.2.2.3). The literature review has identified blinding outcome measurement/group allocation and maintaining equal treatment 'doses' in the two groups as methods to reduce potential bias. From the literature, outcome measures that reflect the impairment, activity and participation categories of the ICF have been proposed and they are 10mWT, 6MWT, PCI, RVGA,

## Chapter 2: Literature Review

RMI and COPM. In addition, PIADS and HADS are suggested to enable comparison with other FES studies.

## **2.4 Review of qualitative research methods**

This section presents an overview of qualitative research methods that are relevant to designing a study exploring changes in walking post-stroke from the perspective of someone living with the effects of a stroke. This qualitative research component was prompted by completion of the Phase 1 pilot RCT, described in chapters 3 and 4. Once the necessity for an exploration of the experience of walking from the perspective of people with post-stroke mobility problems had been identified, suitable research methods needed to be investigated. The first part of this section introduces and critiques qualitative research methods and study designs and ends with a summary of recommendations for the design of the Phase 2 study.

### **2.4.1 Qualitative research methods**

Qualitative research can explore in depth the experiences of individuals. This contrasts with quantitative research where the purpose is frequently to identify objective, measureable 'group level' differences between and within the intervention and control groups. Mason, 2002, contrasts quantitative and qualitative research to give a pertinent description of qualitative methods as celebrating 'richness, depth, nuance, context, multi-dimensionality and complexity rather than being embarrassed or inconvenienced by them'. She suggests that quantitative research edits out many of these elements in search of 'the general picture or the average' whereas qualitative research factors them directly into its analyses and explanations [243]. Table 2-6 gives an overview of how different forms of knowledge can be explored using these two approaches.

	Qualitative	Quantitative
Ontology	Reality is a human construct and researchers can use qualitative research methodologies to investigate, interpret and describe this social reality	There is an objective reality and researchers can use quantitative methodology to investigate it
Epistemology	Explores the world as constructed, interpreted, and experienced by people from an interpretivist-constructivist epistemology	Scientific discourse derived from the epistemologies of positivism and realism
Aims	Inductive and exploratory aiming to describe or explain experience	Deductive, tests hypotheses scientifically
Method	Human science: interviews, participant observations, group work	Natural science: experiments, observation, surveys, physiological description
Researcher's role	Researcher is more subjective: relationship between the researcher and participants is acknowledged	Researcher is objective, neutral and detached
Findings	Uses words and/or creative arts	Uses numbers

*Table 2-6 Comparison of qualitative and quantitative research methods*

*Adapted from Finlay, 2011, Mason, 2002 and Carel, 2008 [243-245]*

Changes that occur due to illness have been researched using quantitative and qualitative approaches separately and in combination. Choice depends on the



research question and the researcher's ontological and epistemological positions. The interaction between health professionals and patients may mirror this quantitative/qualitative 'divide'. Illness is often described by medical professionals in terms of reported symptoms and objective physical or physiological changes. It has been argued that this contrasts with the patient's understanding of illness, which tends to focus on the impact on their daily life i.e. their lived experience of illness. Toombs, 1993, suggested that illness is 'fundamentally experienced as the disruption of lived body rather than as the dysfunction of biological body' [246]. She suggests that to get a more complete insight into illness the physician needs to have a 'medical gaze' that aims to understand the objective clinical picture with questions such as 'when did it start?' and also a 'human vision' focused on the subjective experience of the ill person that could include questions such as 'what is it like?'.

Parallels can be seen between these descriptions of quantitative versus qualitative research methods, assessment of biological dysfunction versus exploration of lived experience, the objective medical gaze versus subjective human vision. Jointly exploring a range of types of knowledge may enable the patient and clinician to work in partnership. It may also enable researchers to understand the wide-ranging effects of illness and disability better. Both quantitative and qualitative research methods are needed to gain an understanding of changes in walking post-stroke.

#### **2.4.2 Exploring walking post-stroke from the perspective of individuals who have had a stroke**

The gait rehabilitation literature is dominated by studies using quantitative methods. Outcomes such as speed of walking have been assessed alongside responses to questionnaires and scales exploring walking ability [4]. Less frequently, individualised outcome measures are included, such as COPM, which focuses on self-selected activities of daily living [141]. COPM has benefits that were outlined in section 2.3.8 however it is unable to yield an in depth account of the selected problems since each is reduced to a score out of ten for performance and satisfaction. Experience of using Functional Electrical Stimulation (FES) to help walking problems caused by stroke has also been explored using questionnaires [247], interviews [113, 143, 248] and focus groups [249]. These studies investigated the benefits and drawbacks of using an assistive device (FES) to improve gait, however walking, per se, was not the focus.

There are a limited number of qualitative research studies investigating how people who have had a stroke feel about their walking. Post-stroke changes in walking did not

appear to be the sole focus or starting point of any published qualitative studies however walking/mobility/community ambulation was referred to in many studies. For example, Pound and colleagues interviewed 40 people who were more than six months post-stroke to explore the consequences of their stroke [7]. These participants reported a number of ways in which the stroke had affected their daily lives, including difficulty leaving the house, doing the housework, pursuing former leisure activities and inability to walk in the way they wanted. The participants also reported problems with communicating, washing, bathing and dressing, and with confusion and deteriorating memory. They described a loss of social contact that accompanied these changes, and the loss of valued roles that had been embedded in the everyday functions they had previously performed. Dowswell et al., 2000, interviewed people with strokes who had been part of a RCT of a specialist nurse intervention. The one off interviews investigated the ways in which patients and caregivers explained what mattered to them and how they assessed or 'measured' progress and recovery over the year since the stroke. Despite the time that had elapsed, these authors did not report any difficulties concerning interviewees' recollection of events and feelings. Their main finding was that recovery was assessed by individuals with reference back to life before the stroke and that pre-stroke ability acted as the ultimate yardstick by which they measured progress. Clarke's 2009 review paper on 'understanding the experience of stroke' pulled together evidence from several studies and corroborates the conclusions of Dowswell et al., 2000 [250, 251]. The evidence from these studies suggests that individuals after stroke define their losses and progress in an individual manner according to what was important to them prior to the stroke. It also highlights the negative changes in a variety of aspects of life that can be associated with post-stroke mobility problems.

People interviewed by Dowswell et al., 2000, said that the stroke caused mainly negative changes in many aspects of life including physical, emotional and social areas. They gave an example where physical problems enforced changes in role and status from giver to receiver of help which was common to many of the people interviewed. Participants also spoke of mismatches between the positive external view of good recovery, from a physiotherapist etc., contrasting with their individual negative perception. They conclude that their quantitative RCT and subsequent qualitative study were both useful as they yielded different information. They also demonstrate how it is possible to conduct semi-structured interviews with participants from a completed RCT, although no details were given about how the interview subgroup of 30 were chosen from the original RCT group of 240 participants [251].

The semi-structured interview is a common method used to explore people's experiences and feelings surrounding health problems. It is often followed by transcription of the recorded interviews and detailed analysis to identify themes. For example, quality of life after vertebral fractures was studied through interviews. Analysis of these transcriptions produced the themes of threatened independence, strategies to maintain independence and the importance of maintaining independence [252]. Similar data generation methods and thematic analysis have been used to explore a variety of health related topics [113, 253-263].

Members of staff at three FES centres have been involved in separate qualitative research studies using interviews to understand more about the use of FES to assist walking. In 2002 Malone et al., published the results of their interviews with people with a stroke who use an FES and their partners. They found that the use of the FES had made participants more socially confident as they had less risk of trips and falls and could walk further and faster. Also, use of the FES reduced the mental effort of walking and increased opportunities for leisure and work. Additionally it enabled partners to feel more confident leaving the person who had a stroke alone at home at times. Some difficulties managing the equipment were noted which echoed the results other work gaining user's perspectives on use of FES via specially designed questionnaires [143, 247]. Bulley et al., 2011, interviewed people with stroke to explore preferences and choices relating to FES and splints to control foot drop. Their findings resonate with previous FES research studies and clinical experience of using FES. The people that they interviewed highlighted positive and negative experiences of both FES and splints but mostly stated a preference for FES due to improved ankle movement, comfort, safety, independence and more normal walking style [113]. Interviews were also used by Singleton et al., 2010, to investigate FES user's feelings about use of stimulation and explore what they perceived as generally positive benefits associated with the use of these devices [264]. There is a growing body of evidence using qualitative research methods to gain a greater depth of understanding regarding the response of individuals to dropped foot stimulation.

To conclude, the impact of physical problems on individuals post-stroke can be investigated in a systematic manner using qualitative research methods. However there is a paucity of published research specifically focussed upon people's experiences of changes in walking post-stroke and aspects of walking that they value. This was the justification for initiating the second qualitative phase of this research. In order to design the Phase 2 study, different approaches were considered that could

enable walking to be explored from the perspective of the individual living with post-stroke walking problems.

### 2.4.3 Phase 2 study theoretical framework

Observational methods can enable researchers to learn more about social behaviour but may be less well suited to the study of individual experience. The social reality under scrutiny in the proposed research is the subjective personal experience of walking after a stroke and this lends itself to qualitative methods based on interviews.

Use of an interview method assumes a connection between people's talk, their thinking and emotional state and this matches the epistemological position of this research. Use of a fully structured interview, basically a spoken questionnaire, leaves no opportunity for the interviewer to respond to what is said or probe interesting ideas to gain a greater depth of understanding [243]. Such fully structured interviews are less well suited to exploratory research contexts where little is known about the phenomenon under scrutiny i.e. circumstances when rich data are sought in order to increase understanding of the subject. Participants in the proposed research may not have previously considered all the topics discussed during the interview and their ideas may well be constructed or reconstructed while talking. This supports the use of a semi-structured interview over a fully structured interview for the Phase 2 exploratory study [243].

Holstein and Gubrium, 1995, suggested that there are two ways to view the nature of information which can be articulated by an interviewee. The first viewpoint assumes that the respondent is a 'vessel of answers' and will emit the unadulterated facts held within, if asked in the 'right' question in an unbiased way [265]. This position accepts that the truth can be obtained so long as it is not biased or contaminated by the interviewer or the setting. However this theory falls apart when it is considered that the interviewee may add to this truth or alter it in some way through the process of articulating it. They cannot 'contaminate' their own response and therefore should be considered as active within the context of the interview. Holstein and Gubrium, 1995, preferred to view the interviewee as a respondent with several 'vessels of answers' who is constructing the narrative of their reality in a manner which is dependent on the perspectives they adopt [265]. For example, a person who has had a stroke may explain its impact on walking in a variety of ways responding from the multiple perspectives of a grandmother, a recipient of formal care, a wife, a homeowner and a retired person.

Through the interview process, the interviewer can also become active, not merely coaxing responses but bringing in alternative considerations to facilitate the interviewee's interpretative capabilities [265]. This approach would seem particularly relevant to a situation where the interviewee is well known to the interviewer as richer information might be gained if it enables responses from different perspectives. However, in these circumstances particular care is required to avoid leading questions. The interviewee and interviewer are engaged in a dynamic interpretive process that is situation specific. Holstein and Gubrium, 1995, termed this 'active interviewing' and explained it as interactions between the interview participants (interviewee and interviewer) to collaborate in the production of meaning. This situation has been described as a 'double hermeneutic cycle' wherein the researcher is making sense of the participant who is making sense of their experience [266]. This approach could be described as the researcher 'trying to see what it is like' for the participant and also trying to analyse, illuminate and interpret the participant's experiential account.

Interviews have been used to collect data in qualitative studies that have been based on a variety of theoretical approaches. The choice of theoretical approach shapes the study design, interview style, data handling and 'directs the gaze' during the analysis [266]. It has been suggested that rigour in qualitative research is associated with the choice of a coherent research question, theoretical approach and method [243]. However, theoretical approaches can be difficult to define and understand, making planning a qualitative research project challenging [267-269]. Commonly used approaches are ethnography, grounded theory, action research, discourse analysis, thematic analysis and phenomenology. The aims of the Phase 2 qualitative study were to explore and illuminate the experience of walking, including any use of assistive devices to improve gait following a stroke. The explicit aims of this proposed research were not concerned with group action or membership (ethnography), theory generation (grounded theory research), practice or behaviour change (action research) nor were they focussed on language in the construction of the social world (discourse analysis) [266, 270]. The Phase 2 qualitative study could use thematic analysis or phenomenology to understand more about the experience of walking post-stroke via in depth semi-structured interviews. These will now be considered as potential approaches to use in this research.

Thematic analysis offers an approach to analysis and interpretation that could be used in the Phase 2 qualitative study. It involves immersion in the text and phases of initial coding, then refining codes to end up with themes that represent the interviews. One

type of thematic analysis, the Framework Approach for analysing interview transcripts has been used in many studies because of its 'interpretivism and reflexivity balanced with pragmatism and transparency' [268]. The Framework Approach provides clear guidelines for data management, synthesis of descriptive/explanatory accounts [259, 268] and has much in common with aspects of another systematic approach based on phenomenology.

The origins of phenomenology are in the Greek words 'phenomenon' that is translated as show or appear and 'logos' translated as reason and judgement [266]. Phenomenology has been associated with hermeneutics, or the theory of interpretation. Hermeneutic phenomenology is concerned with examining how a phenomenon appears and involves the analyst in facilitating and making sense of this appearance [245, 266]. One can observe overlap between this description and Holstein and Gubrium's 'active interview' described above [265].

Thematic analysis and hermeneutic or interpretive phenomenology can both provide frameworks for exploring lived experience and have a history of application in medicine. Therefore, either could be used in the Phase 2 qualitative study. Interpretative phenomenology is associated with an interest in embodied lived experience and has been used to explore how changes in body function can affect the way individuals experience their body, self and the world based upon the assumption that these are intertwined concepts [244, 245]. This aspect of phenomenology has been informed by the French philosopher Merleau-Ponty who considered the body as a central element in perception and experience and wrote widely about the embodied nature of our relationship to the world [266, 271, 272].

In both thematic analysis and phenomenology the researcher is part of the interpretation. Thematic analysis usually requires the researcher to put aside or bracket prior assumptions and can include member checking, triangulation and code verification by another analyst to ensure the comprehensiveness and credibility of the analysis. This is not usually part of interpretative phenomenology because the researcher is acknowledged as a co-creator of the research with the participant. Interpretative phenomenology requires the researcher to avoid habitual ways of thinking about the phenomena by identifying and suspending assumptions and by being curious and open to fresh ways of thinking about it [245]. This is referred to as the 'phenomenological attitude' and this process occurs alongside and within the double hermeneutic cycle described earlier. The depth of the analysis, the commitment to exploring embodied lived experience and previously taken for granted

aspects of human function all make a phenomenological approach the most suitable approach for use in the proposed Phase 2 study.

Smith and his colleagues extended these ideas to develop a well-defined and clearly described theoretical and practical approach to investigating the lived experience, called 'Interpretative Phenomenological Analysis' (IPA). It has been informed by three areas of philosophy: phenomenology, hermeneutics (both described above) and idiography. The latter refers to the focus of IPA on the 'particular', in terms of detailed in depth analysis and a focus on grasping the meaning of something for a particular person, in a particular context rather than broad generalisations [266]. Smith et al., 2009, quote a pioneer in the field of statistics who stated that 'acquaintance with particulars is the beginning of all knowledge' (Galton, 1883, in Smith et al., 2009, page 31 [266]). Based on the assumption that at a deep level we all share a great deal in common with others, understanding of the individual may also aid understanding of the general [266]. IPA usually uses single case studies or small samples drawn from a relatively homogenous group in order to understand a particular perspective of the phenomenon under scrutiny. IPA data handling and analysis procedures involve transcription of recorded interviews, submersion in the text, thematic analysis and presentation of themes in the final reporting stages with use of excerpts from the original text to illustrate the themes [266]. The interpretative analysis attends closely to the verbatim account with consideration by the analyst of their own preconceptions/foreknowledge that may influence the process. Some writers in phenomenology suggest that the analyst needs to 'bracket' or 'put to one side' preconceptions in order to remain objective during the analysis and this is comparable to attempts to reduce bias in quantitative research. Smith et al., 2009, question whether it is possible or desirable to bracket previous knowledge in this way. They contest it may be impossible to be aware of all one's preconceptions prior to starting analysis and that, as a consequence, bracketing should be seen as a cycle of reflection that detects and challenges the influences of preconceptions on the data interpretation and analysis. This is termed reflexivity in some qualitative research [255]. The analyst's experientially-informed perspective could also positively add to the analysis and enable novel perspectives [266]. In summary IPA research is interpretative in several ways, by attempting to understand the participant's view i.e. 'to stand in their shoes' and to analyse and make sense of their experience from the perspective of 'standing alongside' them.

IPA was identified and selected as a suitable approach for use in the Phase 2 study because IPA is informed by a strong theoretical base that fits well with the aims of this research. IPA was selected because it is well suited to exploring otherwise 'taken for granted' everyday embodied experience, which is how walking could be considered. It has been utilised in a variety of health related studies including research on the experience of people who have had a stroke and their carers, living with ataxia, rehabilitation after hand surgery and use of FES for correction of dropped foot [113, 248, 254, 257, 273-275]. IPA was chosen to guide data generation and analysis in the qualitative phase of this research and suggestions to ensure quality in this qualitative research will now be discussed.

### 2.4.4 Quality in qualitative research

Qualitative research has been summarised as 'inductive-subjective-contextual' and has been contrasted with 'deductive-objective-generalising' quantitative research [243, 268, 270]. This perceived difference in research paradigms has been used as evidence for rejection of quality assessment based on quantitative research terms such as reliability and validity in qualitative research. However others have suggested that notions of validity and reliability can be applied to qualitative research by evaluating whether there are coherently linked research questions, data sources and methods with thorough, careful and accurate analysis to ensure data are not poorly represented [243, 276]. Other quality criteria have been applied to qualitative research, for example trustworthiness, credibility, transferability, sensitivity to context, rigour, coherence and resonance or impact [270, 277-280] however these are not accepted universally [281]. Discussions surrounding quality in qualitative research are likely to continue, making it difficult for qualitative researchers to be certain of the best ways to ensure quality from the literature.

Table 2-7 shows 10 questions that were developed as a qualitative research checklist by the Critical Appraisal Skills Programme (CASP) and have been used to review quality in qualitative research. Other similar checklists are available, all contain questions regarding the role of the researcher, suitability of the study design and suitability and quality of the analysis [279].



CASP checklist for qualitative research appraisal
<ol style="list-style-type: none"> <li>1. Was there a clear statement of the aims of the research?</li> <li>2. Is a qualitative methodology appropriate?</li> <li>3. Was the research design appropriate to address the aims of the research?</li> <li>4. Was the recruitment strategy appropriate to the aims of the research?</li> <li>5. Were data collected in a way that addressed the research issue?</li> <li>6. Has the relationship between researcher and participants been adequately considered?</li> <li>7. Have ethical issues been taken into consideration?</li> <li>8. Was data analysis sufficiently rigorous?</li> <li>9. Is there a clear statement of findings?</li> <li>10. How valuable is the research?</li> </ol>

*Table 2-7: CASP Checklist for appraisal of qualitative research*  
[279, 282]

These checklists aim to improve quality in qualitative research and reporting and they should inform the design of the Phase 2 study, the analysis and the subsequent publications.

To reduce subjectivity in qualitative data collection and analysis, forms of reliability testing have been suggested however, this is not straightforward in qualitative research based on interviews. As an interview could not be repeated and replicated later or by a different interviewer intra and inter rater reliability testing in data collection is not feasible. Suggestions to test reliability of data analysis include multiple coding of the data by different researchers and respondent validation [259, 281, 283]. These activities are problematical in some approaches, such as IPA, when interpretation is context specific and based on the double hermeneutic cycle [266, 284-286]. In these circumstances, the researcher/analyst is overtly part of the interpretation and therefore another researcher would be likely to interpret the transcripts differently.

Data generated by qualitative research can be analysed in a systematic and transparent manner, leaving an audit trail that another researcher could follow to assess the credibility or reliability of conclusions [283, 287]. Smith et al., 2009, recommend the creation of an evidence trail of documents that link the research questions, annotated transcripts, tables of themes and the reports to demonstrate that the account of the data is coherent and credible. IPA accepts that there may be a number of ways of credibly accounting for the data, however the inclusion of sufficient

data i.e. quotes in the final research report provides the reader with evidence that the interpretation offered can be adequately supported [243, 245, 266]. Smith et al., 2009, suggest that involvement of different people in discussing the data analysis can increase the variety and richness of the interpretations. They also urge analysts to pay adequate attention to divergent cases that do not fit with the themes as they emerge. In IPA it is suggested that the researcher cannot help but engage in the analysis in the 'light of their own experience' and therefore bracketing is only partially achievable. Rather than bracketing, IPA emphasises the importance of engaging with the participant and attending closely to their story.

### **2.4.5 Phase 2 study design – summary of recommendations from this literature review**

The conclusion of this review is that qualitative research is useful for investigating the social world and therefore the experiences of individuals who have had a stroke. Semi-structured interviews can be used to understand participant's experiences and can be considered as a joint interpretative venture between interviewee and interviewer. In order to address the research question a clear and appropriate theoretical approach to data generation and analysis was required. Quality can be maintained by considering all stages of the Phase 2 research in the light of the published quality checklists [282]. This includes paying attention to the role of the researcher in the research and ensuring the suitability of the study design and quality of the analysis. IPA as described by Smith et al, 2009, can satisfy these quality criteria and therefore underpinned the Phase 2 study design, data generation and analysis [266].

## **Chapter 3: Research questions**

### **3.1 Research aims**

To investigate the effect of electrical stimulation on mobility, when delivered as an integrated part of outpatient physiotherapy for people less than six months post-stroke. To explore changes in walking post-stroke from the perspective of individual stroke survivors and to identify aspects of walking that are valued by participants and feelings about walking and the use of assistive devices, including electrical stimulation. To draw conclusions that could inform the design of future gait rehabilitation studies.

### **3.2 Research questions**

The two phases of this research investigate walking using quantitative and qualitative research methods to address the following questions.

#### **Research questions - Phase 1 pilot study**

1. Is it feasible to integrate electrical stimulation into early outpatient physiotherapy treatment, determined by protocol adherence and user views?
2. What is the most appropriate primary outcome measure?
3. What sample size would be required in an adequately powered RCT to investigate the immediate and longer-term effects of electrical stimulation on mobility, when delivered as an integrated part of outpatient physiotherapy for people less than six months post-stroke?

#### **Research questions - Phase 2 qualitative study**

1. How do people who have had a stroke affecting walking and have taken part in gait rehabilitation, describe their own walking and how it has changed over time since the stroke?
2. What aspects of walking do they value and how have these changed since the stroke?
3. How do they describe their experiences of using assistive devices?
4. Can the conclusions be used to inform the design of future gait rehabilitation studies?



## Chapter 4: Phase 1 - Quantitative trial

### 4.1 Phase 1 - Research questions

1. Is it feasible to integrate electrical stimulation into early outpatient physiotherapy treatment, determined by protocol adherence and user views?
2. What is the most appropriate primary outcome measure?
3. What sample size would be required in an adequately powered RCT to investigate the immediate and longer-term effects of electrical stimulation on mobility, when delivered as an integrated part of outpatient physiotherapy for people less than six months post-stroke?

### 4.2 Phase 1 - Hypotheses

The Phase 1 trial comprised protocol development, feasibility testing, protocol piloting and sample size calculations for a fully powered study that could investigate the following hypotheses:

**Therapeutic effect** - Electrical stimulation delivered over six weeks (12 sessions), as an integrated part of outpatient physiotherapy gait rehabilitation for people less than six months post first stroke improves walking speed (without electrical stimulation) more than physiotherapy alone.

**Orthotic effect** – Participants using electrical stimulation walk faster with stimulation turned on at Week 8 and Week 20 assessments.

### 4.3 Phase 1 – Method

#### 4.3.1 Trial design

A parallel group partially single blinded randomised controlled trial that was conducted to test the feasibility of electrical stimulation to improve mobility in people less than six months post-stroke, pilot the protocol and estimate sample size for a fully powered trial.

### 4.3.2 Maintaining quality in the Phase 1 quantitative research design

The pilot study design, analysis and reporting was informed by guidelines that aim to improve quality in quantitative research [175-179]. The Phase 1 research protocol was developed after reviewing the literature on post-stroke rehabilitation and motor (re)learning, common stroke related changes in gait and quantitative research methods (Chapter 2). The Phase 1 trial design included random group allocation to reduce potential bias. Ideally RCTs should also include blinding of participant and assessor to group allocation to reduce potential bias. Participant blinding of treatment allocation was not feasible as participants allocated to a sham stimulator, that does not produce movement or sensation, would probably guess their allocation. Use of sensory level stimulation was considered to be an inadequate control as it alters afferent cortical input and may affect motor control and walking (see 2.2.2.8). To achieve blinding of assessor, a second researcher would need to be present at each assessment during mobility outcome measures, to deal with any issues surrounding use of FES/ensuring it was switched on or off appropriately with the blinded assessor actually recording the outcome measures. The participant would need to be reminded not to say anything to disrupt the blinding. The use of multiple blinded assessors would ensure that treatment stage was not known to the assessor. Such a system would reduce the potential for bias and was considered for this pilot study. However, practical, logistical and financial issues constrained the extent of assessor blinding. A separate blinded assessor assessed one outcome measure, RVGA, from video. Issues of assessor blinding to group allocation have been a limitation of other similar studies [158, 288].

Dose of therapy is known to affect outcome and the length and number of sessions was the same in both groups. The stimulators available for use in this study did not have a data logger. Treatment diaries to record home exercises and stimulator use were considered. However, they can be unreliable due to missing data and variations in recording. For example, home exercises may not be of a discrete nature, i.e. the participant may be shown how to improve the symmetry of sit to stand and asked to apply this to all sit to stand activities and that would be difficult to record. The problems of accurate reporting by participants and the burden placed upon them to complete such records did not seem appropriate in the light of their potentially limited value.

### 4.3.3 Research governance

The National Research Ethics Service (Wiltshire Ethics Committee see Appendix D) granted approval for this trial, it was registered with the International Clinical Trials

Registry in 2007 (ISRCTN 91639560). Salisbury Foundation NHS Trust acted as sponsor for this trial and funding for two years was secured from the Stroke Association (TSA 2006/07).

#### 4.3.4 **Sample size**

In order to estimate variability in the outcome measures and perform sample size calculations, sufficient data points were necessary, this was agreed with the hospital statistician. Recruiting 26 participants would give 78 data points for each outcome measure i.e. 26 participants times three assessment points equals 78 data points. The statistician suggested that at least 40 data points for each measure were required to estimate variability therefore the pilot sample size was set at 26. Aiming to recruit 26 participants allowed for dropouts and potential protocol change after the first four participants who tested the feasibility of the trial protocol. At a minimum, if no changes were needed after the first four participants, 14 participants were required (14 participants times three assessment points equals 42 data points).

#### 4.3.5 **Data management and statistical analysis**

All data were entered and separately verified. Anticipating a degree of skew in the study data distribution, non-parametric testing and estimation methods were used throughout. To determine the statistical significance of changes over time within groups a Wilcoxon's signed-rank test was performed and between group differences were subjected to an analysis of co-variance (ANCOVA) using Week 1 (baseline) values as a covariate. 10mWT was assessed with and without stimulation in Group B and any difference tested using Wilcoxon's signed-rank test. The level of statistical significance was set at  $P \leq 0.05$  and Minitab version 14 was used for statistical analysis. All analysis was performed on an intention to treat basis.

#### 4.3.6 **Screening tools used in the Phase 1 trial**

Homogeneity in the trial population was desirable for statistical analysis and this was achieved through careful choice and application of eligibility criteria. However, there was a need to balance the homogeneity desirable for statistical analysis with the need for the research to reflect 'real world' rehabilitation settings, since generalizability can be increased if entry criteria are not too narrow. The RMI and Mini Mental Short Examination (MMSE) were used as screening tools to ensure similar functional ability in the participants and sufficient cognitive ability to take part in the research. The RMI

has good reliability and validity [289, 290]. It was used in this screening process to identify potential participants who were able to stand, step and transfer but were likely to have mobility problems that required outpatient gait rehabilitation (scoring between 6 and 10 points on RMI). The MMSE also has good reliability and validity and has been used as a quick and simple cognitive screening tool in patients with neurological problems [291-294]. It was used in this study to ensure participants were likely to have the cognitive ability to complete the protocol (scoring over 25 on MMSE).

### 4.3.7 Eligibility criteria

These eligibility criteria were developed to highlight people with stroke related mobility problems and to ensure that they could safely and practically participate in the RCT.

#### **Inclusion Criteria**

- Over 18 years old
- Medically fit enough to undertake physiotherapy (confirmed by referral to physiotherapy)
- Less than six months post first stroke, confirmed by patient and from medical records
- Able to respond appropriately during screening procedures demonstrating their understanding of verbal instructions
- Interested in improving walking, confirmed by asking them directly
- Living at home
- Scored between 6 and 10 on Rivermead Mobility Index
- Living within 25 miles of the hospital with suitable transport available so that they could attend the hospital for twice weekly physiotherapy.

#### **Exclusion criteria**

- Unable to tolerate sensation of stimulation during a short test period of cyclical stimulation applied to the lower leg using a CPN electrode position.
- Had poor skin condition upon visual inspection making them unsuitable for stimulation
- Had previous neurological conditions likely to influence response to treatment , confirmed by patient and from medical records
- Had orthopaedic or other health problems limiting ability to complete the protocol or use stimulation/physiotherapy, confirmed by patient and from medical records



- Scored of 25 or under on Mini Mental Test
- Had a pacemaker and other active implant, confirmed by patient and from medical records
- Had poorly controlled epilepsy, confirmed by patient and from medical records
- Were pregnant, confirmed by patient/medical records

#### 4.3.8 Recruitment of study participants

Potential participants were identified by local inpatient and outpatient stroke specialist teams, between August 2007 and June 2010 and were given Participant Information Sheets (Appendix E) and if interested invited for eligibility screening. Initially participants were referred from one district general hospital but due to lower than expected recruitment rates, another two nearby rehabilitation centres also acted as participant identification sites (a substantial amendment was submitted to the Ethics Committee). For efficiency preliminary screening occurred before formal screening against the eligibility criteria. If eligible, informed consent to participate was gained and recorded.

#### 4.3.9 Trial organisation

Discussions with the Stroke Coordinator at Salisbury District Hospital suggested that recruiting 15 patients per year of the trial would be realistic. Stroke clinicians, including physiotherapists, occupational therapists, nursing and medical staff, were made aware of the study and the protocol. A trial name, logo and bright colour gave the trial an identity and allowed easy reference.



*Figure 4-1: Phase 1 'EPIC' trial logo*

A folder containing the patient information sheets and a cover letter, protocol, contact details for investigators and trial diagram was kept fully stocked in the therapists' offices in the recruiting centres. The aim of this folder was to make it straightforward for clinicians to introduce the trial to patients and distribute information sheets. A reply

slip could be detached from the patient cover letter (Appendix E) and returned to the researcher to signal interest in taking part. Broad criteria for the trial were printed on reminder cards to be placed in diaries and prominent places.

Initially participants were recruited from Salisbury District Hospital only however, due to slow recruitment, the recruitment period was extended and additional Participant Identification Centres were added via a substantial amendment to the Ethics Committee. These additional centres were geographically close and the same eligibility criteria were used.

### **Preliminary screening (completed by the researcher)**

When a reply slip was returned, the patient/clinician was telephoned to ascertain if the potential participant was less than six months post first stroke, could transfer independently, if they had mobility problems and if they were returning or had already returned home. If the response to all enquires was positive they were invited for formal screening. This saved inconveniencing obviously unsuitable possible participants and wasting trial resources.

### **Formal screening (completed by the researcher)**

The Phase 1 Screening Tool (Appendix G) was used to ensure potential participants met all of the eligibility criteria outlined above. If they met these criteria they were invited to attend a Week 1 assessment session, at which point they signed consent forms, completed the assessments and then were randomised to either Group A or B.

#### **4.3.10 Group randomisation**

The first four were allocated to A or B by block randomisation with subsequent participants assigned to Group A or B by computer generated, simple random allocation, all produced by an independent statistician. The concealed randomisation list that was produced by this independent statistician was kept in a separate locked office. Allocation of each participant was revealed to the researcher by the Head of Department once screening and Week 1 assessments had been completed. The Head of Department was separate to the trial and had no other role in this study. Participants were given their group allocation, A (physiotherapy control) or B (physiotherapy with electrical stimulation) after successful screening and completion of the Week 1 Outcome Measures. This timing reduced selection bias and potential bias in the recording of the baseline outcome measurements as participant and researcher were blind to group allocation until after all Week 1 assessments were completed.

### 4.3.11 Assessments and outcome measures

Outcome measures were completed at week 1, 8 and 20. These participants, people less than six months post-stroke, could be expected to improve over the trial period so no baseline period was indicated. There were twelve twice weekly physiotherapy sessions from Week 2 to Week 7 and the outcome assessments were repeated in Week 8, with another assessment at Week 20 after a follow-up period.

#### Study Schedule

<b>Initial Contact</b> Given Information Sheet	<b>Week 1</b> Informed consent recorded, Outcome Measures taken and participants randomly put in Group A or B	<b>Weeks 2-7</b> Treatment block, 2 appointments per week	<b>Week 8</b> Outcome Measures taken	<b>Weeks 9-19</b> No treatment, 12 week follow up period	<b>Week 20</b> Outcome Measures taken
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#### Patient Journey

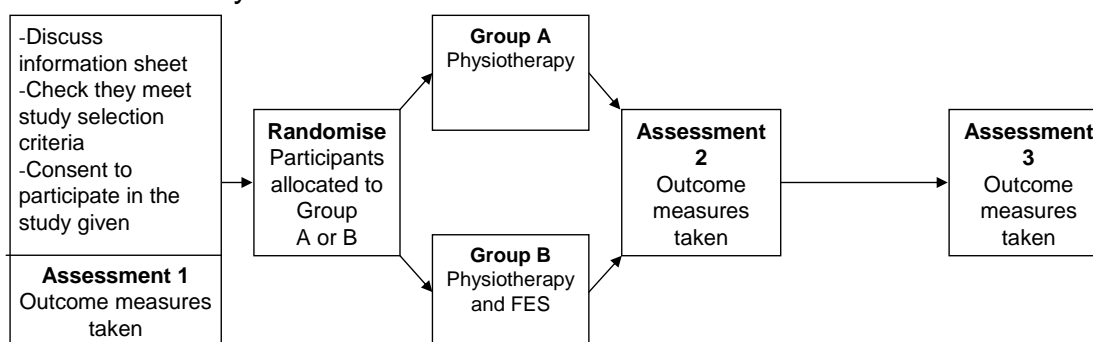


Figure 4-2: Diagram representing the Phase 1 trial

The outcome measures selected were based on those identified in the literature review as reliable, valid, sensitive to change in the target population, practical and representing impairment, activity and participation domains of the ICF. The outcome measures are listed in Table 4-1. The outcome measures were standardised based on published instructions and procedures (see Chapter 2.3). They are presented in Table 4-1 in test order (see Appendix F for details). The order was chosen to ensure that active walking outcome measures were interspersed with adequate rest periods, during which paper based outcome measures were completed.

Outcome measures were recorded pre and post-intervention phase (Week 1 and 8) and at follow-up (Week 20). They were 10mWT, 6MWT, RMI, RVGA, COPM and HADS, with PIADS at Week 20 only in Group B. 10mWT was recorded with and without dropped foot stimulation switched on at Week 8 and Week 20. Levels of ‘small meaningful change’ in 10mWT and 6MWT have been proposed by Perera et al, 2006,

as 0.05m/s and 20m respectively in people between one and five months post-stroke. They specified 'substantial meaningful change' as 0.1m/s (10mWT) and 50m (6MWT) [295]. The treating physiotherapist used standardised instructions/methods derived from the literature to conduct the outcome measures. Assessments took place in a clinic room at the Glanville Centre, Salisbury NHS Foundation Trust. A separate assessor who was blind to treatment allocation and assessment stage assessed RVGA from video. HADS [242] was completed at all three assessment points. At Week 20 participants still using FES also completed the PIADS [239]

**Activity level measures:** A stopwatch was used to record time taken to walk the middle 10m section of a 12m walkway, marked by lines on the floor [182, 191, 200, 201]. The instruction to walk 'briskly but safely' was given and participants walked with their usual aids (these were documented) and without encouragement. The time taken for the first walk was noted but was treated as a 'warm up'. Next the time taken for one 10m walk with FES switched off was recorded followed by another walk with FES switched on (Group B only at Week 8 and 20) [288]. Physical assistance was only given if it was required by the participant for safety [182]. Video (from the front and side) was taken during these 10m walks for later analysis by blinded assessor using RVGA [222]. 6MWT was timed using a stopwatch and conducted over a straight course that was the length of a room (14.2m) with turns at each end [184]. 6MWT was recorded with usual aids and at the patient's self-selected comfortable speed with FES switched off and with no physical assistance or encouragement. If walking was unsafe without physical assistance, a score of zero was recorded for 6MWT. The composite mobility measure RMI was completed [184].

**Participation level measures:** At Week 1 the participants identified their five most important 'occupational performance' activities via a semi-structured interview using the COPM [296]. These activities were scored out of ten by the participant for performance and satisfaction with that performance and they re-scored these at Week 8 and 20.

<b>Assessment schedule for outcome measures</b>	
Rivermead Mobility Index* (RMI)	Week 1, 8, 20
6 minute walk* (6MWT) including Physiological Cost Index* (PCI)	Week 1, 8, 20
Hospital Anxiety and Depression Scale* (HADS)	Week 1, 8, 20
Walking speed (over 10m)* (10mWT) including Physiological Cost Index over 10m* (PCI)  Group A repeated 10mWT twice without stimulation  Group B repeated 10mWT twice without stimulation then once with stimulation then once without	Week 1, 8, 20
Video taken to allow Rivermead Visual Gait Assessment* (RVGA) by a separate blinded assessor	Week 1, 8, 20
Canadian Occupational Performance Measure* (COPM)	Week 1, 8, 20
Falls diary	Throughout trial
Psychosocial impact of assistive devices scale* (PIADS)	Week 20  group B only

*Table 4-1 Assessment schedule for outcome measures*

*\*details of the standard instructions developed from the literature review or available in published literature can be found in Appendix F*

#### 4.3.12 Interventions

##### **Physiotherapy (Group A and B)**

All participants took part in physiotherapy that focussed on improving mobility and was individualised, goal orientated, task specific and contained opportunities for repetition and feedback (see Appendix H). These sessions aimed to improve walking and walking related mobility as described in the ICF mobility subcategory and discussed in Chapter 2.3.2 [186]. Sessions lasted one hour and the content was determined by the

participant's physical abilities, goals and responses, as well as the physiotherapist's on-going clinical assessment. Treatment sessions were based in a clinic room at the Glanville Centre, Salisbury NHS Foundation Trust. All participants had exercises and advice to practice/implement at home.

Upper limb problems were addressed by usual outpatient services and not specifically during the 12 study physiotherapy sessions. Normal access to other services i.e. occupational therapy and orthotics continued for both groups during the study. Whether these services were accessed was not recorded as part of the trial. During the follow-up period no physiotherapy or other intervention was offered as part of the RCT however participants may have accessed other therapy services and this was not monitored.

### **Electrical stimulation (Group B only)**

Group B used FES for dropped foot correction, integrated into their physiotherapy sessions and available for use at home during the intervention and follow-up periods. Two commercially available CE marked stimulators were used in this study, the Odstock Dropped Foot Stimulator (ODFS III<sup>®</sup>) for walking and the Microstim<sup>®</sup> (MSV2) for cyclical exercise (Figure 4-3). Both stimulators are manufactured by Odstock Medical Ltd, Salisbury, UK, and self-adhesive PALS Platinum Blue hypoallergenic 5cm square electrodes were used (Nidd Valley, Harrogate, UK).

The participants were taught how to use the devices according to the manufacturer's instructions, including the sections relating to avoiding skin irritation [118]. These instructions included the clinical indications for CPN cyclical exercise stimulation. Dropped foot correction in walking was the focus of the intervention however, use in walking can be problematic if there is plantarflexor spasticity, ankle swelling, poor muscle power/endurance, sensitivity to stimulation sensation or difficulty accurately locating electrodes. If these issues affect use of walking stimulation the addition of cyclical exercise stimulation is recommended [118, 119]. The cyclical exercise stimulation was used in addition to the walking stimulation if one of these issues indicated its use.



*Figure 4-3: The ODFS II<sup>®</sup> kit for dropped foot stimulation and Microstim<sup>®</sup>*

*ODFS II<sup>®</sup> kit on left and Microstim<sup>®</sup> pictured on right showing top and controls  
(Photograph by K. Hitchlock with permission)*

### **Treatment recording**

In line with good clinical practice guidelines, the treatment given in the 12 physiotherapy sessions was documented (including details of electrical stimulation in Group B) in accordance with professional guidelines [297]. No evidence based intervention recording tools could be found from the literature to support this record keeping. Therefore, parts of the TELER method were used as a tool to document the evidence based contents of the physiotherapy sessions within this study. TELER includes a simple recording sheet that made it straightforward to collate the treatment contents. The TELER method also incorporates adaptable indicators that show changes in specified goals and these were used to aid goal setting in the physiotherapy sessions. The evidence recommends goal focussed physiotherapy and this aspect of the TELER system was used to help maintain a focus on goals that the individual participants found important and these were often informed by the COPM semi-structured interview. The TELER indicators can be chosen by and adapted to the individual and consist of six levels. Use of TELER as an outcome measure depends on statistical analysis of these adaptable clinically driven indicators. The indicators are generally ordinal but should not be treated as interval data in statistical analysis. No statistical analysis of the indicators was undertaken in the Phase 1 trial because other outcome measures, with established psychometric properties that addressed the research questions, had already been selected.

## **4.4 Phase 1 - Results**

### **4.4.1 Feasibility of pilot study protocol**

The first four participants piloted the feasibility of the protocol and their data were included in the analysis because no post-pilot protocol changes were necessary. 20 participants were recruited and randomised. The protocol was feasible, there was 100% attendance at all assessments and appointments although some appointment rearrangement was required to achieve this. There were no drop-outs and no major deviations from the protocol therefore data from all 20 participants were available for analysis for most outcome measures (see CONSORT diagram Figure 4-4) Figure 4-4: CONSORT Diagram showing flow of participants through the Phase 1 trial. Group A – physiotherapy only, Group B – FES & physiotherapy.. 60 data points were available to estimate outcome measure variability for 10mWT, which were sufficient to perform sample size calculations for a fully powered study. There were no treatment related adverse events, although one participant in Group A (physiotherapy only group) had a first time epileptic seizure at the end of his Week 8 Assessment.

The content of the physiotherapy intervention can be found in Appendix H. All participants took part in the 12 planned physiotherapy sessions that focussed on improving mobility and were individualised, goal orientated, task specific and contained opportunities for repetition and feedback (see Appendix H). Dependent on clinical assessment the physiotherapy contained whole task practice and also practice of component parts. The physiotherapy sessions aimed to improve walking and walking related mobility. All participants had exercises and advice to practice/implement at home.

Sessions lasted one hour and the content was determined by the participant's physical abilities, goals and responses, as well as the physiotherapist's on-going clinical assessment. Once participants had been shown how to set up FES for correction of dropped foot they attended the physiotherapy sessions with their device set up and it did not appear to affect the time spent doing physical activities in these sessions even though it sometimes required adjustment, done while the participant rested.



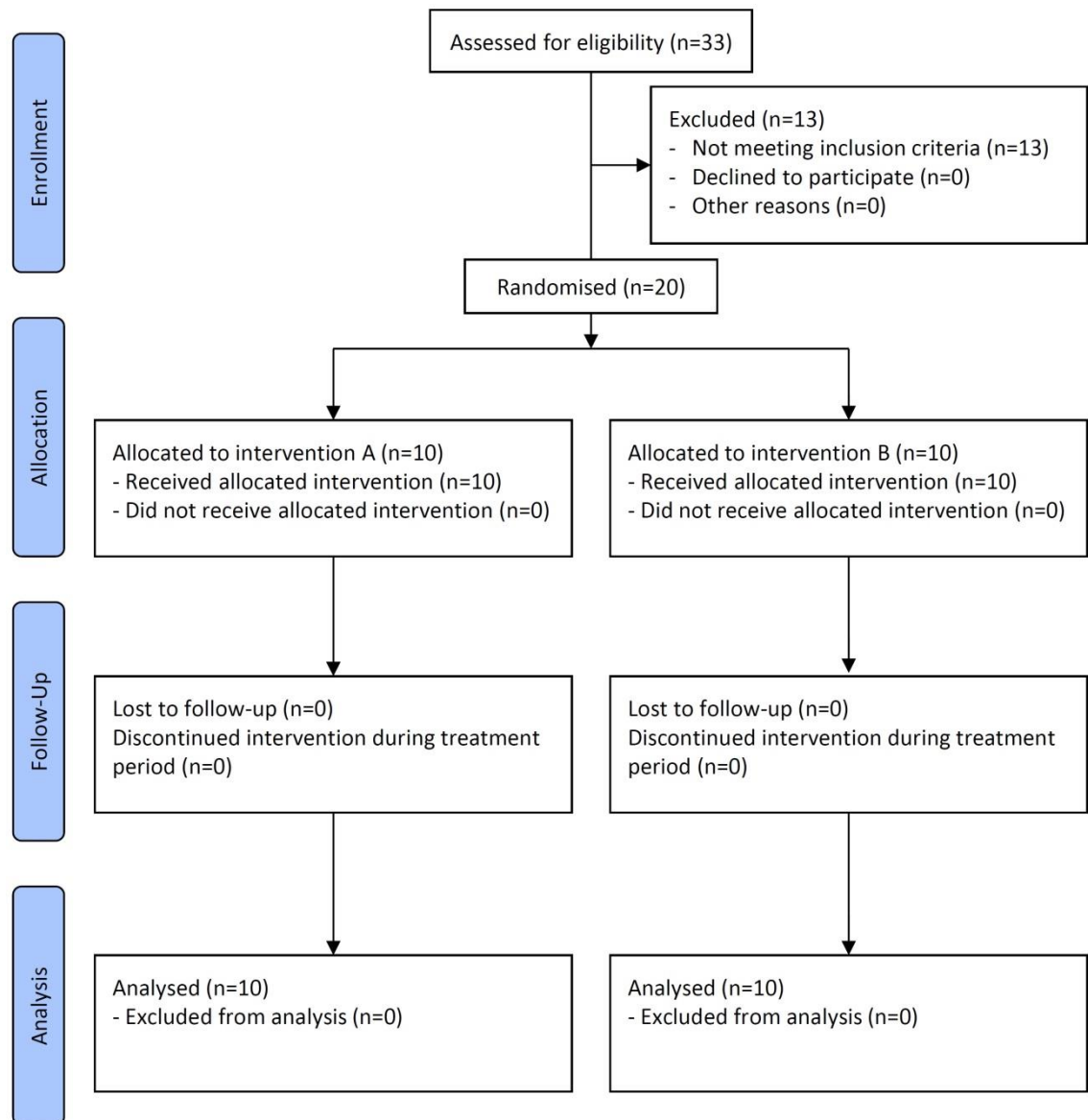


Figure 4-4: CONSORT Diagram showing flow of participants through the Phase 1 trial.  
Group A – physiotherapy only, Group B – FES & physiotherapy.

#### 4.4.2 Demographics

The two groups were similar, including key characteristics such as time since stroke and age (Table 4-2).

Characteristic	Group A	Group B
Number of participants	10	10
Sex, male/female	5/5	6/4
Age in years, mean (range)	64.5 (42-83)	65.4 (49-84)
Time post-stroke weeks, mean (range)	9.9 (3.6-20.1)	10.8 (5.1-17.7)
Type of stroke, infarct/haemorrhage	8/1 <sup>a</sup>	8/2
Hemisphere of stroke, left/right	4/6	4/6

Table 4-2: Participant characteristics at baseline (Week 1)

<sup>a</sup> one Group A participant had an inconclusive scan but had a clinical diagnosis of stroke

#### 4.4.3 Between group differences

There were no statistically significant between group differences in any of the outcome measures recorded at Week 1, 8 and 20 (ANCOVA with Week 1 as a covariate) except RVGA. Group B (physiotherapy and FES) had significantly higher RVGA scores at Week 8 compared to the control group and they were still significantly higher at Week 20.

#### 4.4.4 Interval measures (within group changes, stimulation switched off)

There were statistically significant within group changes that, these are displayed in Table 4-3 for interval outcome measures. There were too many missing data points for PCI data to be analysed reliably. This was caused by medication making PCI invalid for five participants taking beta blocking drugs and missing data due to researcher error (six occasions in 10mWT and eight in 6MWT) and problems recording (one occasion in 10mWT and one occasion in 6MWT).

Interval outcome measures	Group	Week 1, median (1 <sup>st</sup> quartile -3 <sup>rd</sup> quartile)	Week 8, median (1 <sup>st</sup> quartile -3 <sup>rd</sup> quartile)	Week 20, median (1 <sup>st</sup> quartile -3 <sup>rd</sup> quartile)	Treatment change - Within group estimated median of difference (95% CI) P value	Follow-up change - Within group estimated median of difference (95% CI) P value
10mWT (m/s)	A	0.42 (0.22-1.02)	0.75 (0.50-1.36)	0.85 (0.52-1.20)	0.28 (0.15 to 0.42) <b>P=0.006*</b>	-0.04 (-0.16 to 0.15) P=>0.3
	B	0.39 (0.17-0.73)	0.42 (0.29-1.04)	0.45 (0.27-1.32)	0.17 (0.05 to 0.31) <b>P=0.032*</b>	0.09 (-0.06 to 0.24) P=>0.3
6MWT (m)	A	91.6 (0.0-198.6)	162.7 (105.8-284.2)	196.7 (138.6-289.4)	86.7 (43.6 to 124.2) <b>P=0.013*</b>	10.2 (-19.2 to 75.8) P=>0.3
	B	79.8 (15.8-193.8)	120.8 (71.4-306.9)	121.5 (78.5-317.4)	69.8 (36.4 to 97.5) <b>P=0.009*</b>	8.5 (-37.6 to 37.1) P=>0.3

Table 4-3 Interval outcome measures. Within group changes in 10m walking speed (10mWT) and distance covered in six minutes (6MWT)

No stimulation was used in any of these tests. There were no missing data. Group A – physiotherapy only, Group B – FES & physiotherapy. CI: confidence interval. \*statistical significance at  $P \leq 0.05$  Wilcoxon's signed-rank test.

#### 4.4.5 Ordinal measures (within group changes, stimulation switched off)

There were statistically significant within group changes that are displayed in Table 4-4 for ordinal outcome measures. There were some missing ordinal outcome measure data. One participant had missing RVGA scores at Week 1 due to video technical problems (Group B) and another was unable to complete COPM at Week 1 due to time/transport (Group A). Three participants had missing HAD scores throughout (one Group A participant and two from Group B).

Ordinal outcome measures	Group	Week 1, median (1 <sup>st</sup> quartile - 3 <sup>rd</sup> quartile)	Week 8, median (1 <sup>st</sup> quartile - 3 <sup>rd</sup> quartile)	Week 20, median (1 <sup>st</sup> quartile - 3 <sup>rd</sup> quartile)	Treatment change - Within group estimated median of difference (95% CI) P value	Follow-up change - Within group estimated median of difference (95% CI) P value
<b>RMI (x/15)</b>	A	7.5 (6.0-9.3)	11.5 (8.8-14.0)	12.5 (9.5-14.0)	3.0 (2.0 to 4.5) <b>P=0.009*</b>	0.5 (-1.0 to 2.0) P=>0.3
	B	7.5 (6.0-10.0)	11.0 (8.0-14.0)	13.0 (9.0-14.0)	2.5 (1.5 to 4.0) <b>P=0.009*</b>	0.5 (0.0 to 2.5) P=0.100
<b>RVGA (x/59)</b>	A	13.0 (9.0-16.5)	9.5 (6.5-16.3)	8.5 (4.8-15.0)	-2.0 (-4.5 to 1.0) P=0.114	-1.0 (-4.5 to 1.5) P=0.286
	B	15 (5.5-22.5)	4.5 (2.5-18.8)	6.5 (3.8-15.0)	-5.0 (-7.5 to -1.0) <b>P=0.022*</b>	1.0 (-5.0 to 3) P=>0.3
<b>COPM perf (x/10)</b>	A	2.0 (1.7-2.5)	6.0 (4.3-7.3)	7.4 (4.4-8.2)	3.8 (2.2 to 5.8) <b>P=0.009*</b>	0.9 (-0.6 to 2.2) P=0.214
	B	3.0 (2.2-4.3)	6.2 (5.2-7.7)	7.4 (6.8-8.2)	3.1 (2.6 to 3.9) <b>P=0.006*</b>	1.1 (0.4 to 1.7) <b>P=0.013*</b>
<b>COPM sat (x/10)</b>	A	1.6 (1.3-2.5)	5.2 (4.8-7.7)	7.2 (4.5-7.9)	4.0 (2.4 to 5.5) <b>P=0.009*</b>	0.9 (-0.8 to 2.4) P=0.193
	B	2.7 (1.8-4.1)	6.2 (5.3-7.5)	6.9 (6.2-8.2)	3.6 (2.8 to 4.3) <b>P=0.006*</b>	0.7 (-0.3 to 1.6) P=0.139
<b>HADS Anxiety (x/21)</b>	A	6 (3.0-10.5)	7.0 (4.5-9.0)	6.0 (4.5-13.0)	0.5 (-3.0 to 3.5) P=>0.3	0.0 (-2.5 to 4.0) P=>0.3
	B	9.5 (5.5-12.8)	8.0 (2.3-11.3)	7.5 (3.3-9.5)	-2.0 (-6.0 to 4.0) P=>0.3	-0.5 (-3.5 to 1.0) P=>0.3
<b>HADS Depression (x/21)</b>	A	8.0 (4.0-11.0)	6.0 (5.0-9.5)	6.0 (3.5-10.0)	0.0 (-3.0 to 2.5) P=>0.3	-1.0 (-4.0 to 1.5) P=>0.3
	B	6.5 (3.8-9.5)	5.5 (4.3-6.8)	4.5 (1.8-7.3)	-1.0 (-3.5 to 1.5) P=>0.3	-1.0 (-2.5 to 0.5) P=0.205

Table 4-4: Ordinal outcome measures.

Within group changes in Rivermead Mobility Index (RMI), Rivermead Visual Gait Analysis (RVGA without stimulation switched on), Canadian Occupational Performance measure (COPM) and Hospital Anxiety and Depression Scale (HADS). Group A – physiotherapy only, Group B – FES & physiotherapy. CI: confidence interval \*statistical significance at  $P \leq 0.05$  Wilcoxon's signed-rank test.

#### 4.4.6 Falls Diary

Only four participants returned completed Falls Diaries at the end of the trial, therefore these data were not analysed.

#### 4.4.7 Group B results – 10mWT with and without FES switched on and PIADS

All participants in Group B had CPN stimulation using ODFSIII (n=10), some also used cyclical CPN stimulation if there was a clinical indication (n=7). There were no reports of skin irritation. In Group B there was an increase in 10mWT at Week 8 and 20 when FES was switched on. The median difference (1<sup>st</sup> quartile - 3<sup>rd</sup> quartile) at Week 8 was 0.05 m/s (0.0-0.08 m/s) which was statistically significant (P=0.025, df=9, Wilcoxon's signed-rank test) and crossed the threshold of small meaningful change in 10mWT. By Week 20 only five of the Group B participants still used FES and were tested with and without it over 10m. The median difference (1<sup>st</sup> quartile - 3<sup>rd</sup> quartile) at Week 20 was 0.07 m/s (0.02-0.12 m/s) which was close but not statistically significant (P=0.059, df=4, Wilcoxon's signed-rank test) but did cross the threshold of small meaningful change in 10mWT [295].

PIADS was recorded at Week 20 if participants said they used FES during the follow-up period (n=8). The median summed PIADS score was 3.55 (self-esteem sub score (median = 0.69), adaptability (median = 1.59) and competence (median = 1.25)).

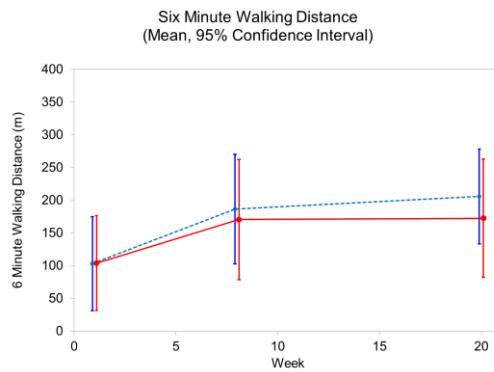
#### 4.4.8 Exploratory post hoc analysis

Two additional aspects of the Phase 1 trial data were analysed but this was not part of the pre-planned statistical comparisons.

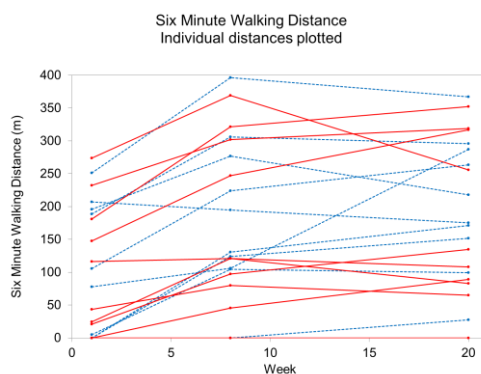
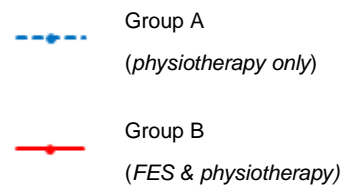
Firstly, the reasons why some of the Group B participants wanted to retain FES were explored. Four participants in Group B wished to continue using FES after the study, and were referred to a National Health Service (NHS) FES provider. These participants generally appeared to have worse walking and this idea was tested. Exploratory subgroup analysis of Group B data, using a test of common regression, was performed to compare the mean baseline characteristics of those who wanted to continue FES beyond the trial (n=4) and those that did not (n=6). The subgroup of participants wanting to continue using FES appeared to have greater walking difficulties than those wishing to stop, which were statistically significant for the 10mWT

#### Chapter 4: Phase 1 - Quantitative trial

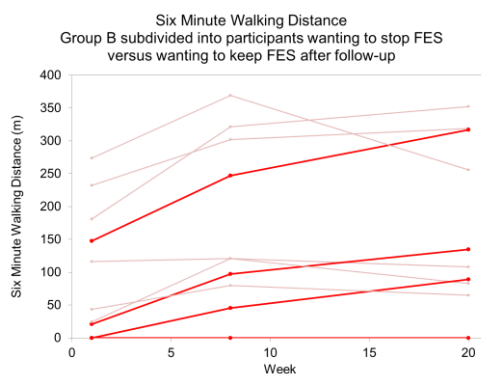
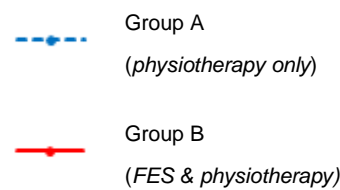
( $P = 0.008$ ) and 6MWT ( $P = 0.032$ ), and non-statistically significant for the RMI ( $P = 0.062$ ) and RVGA ( $P = 0.076$ ). This difference can be demonstrated graphically and the 6MWT data from group B are presented in Figure 4-5 as an example that is representative of this trend.



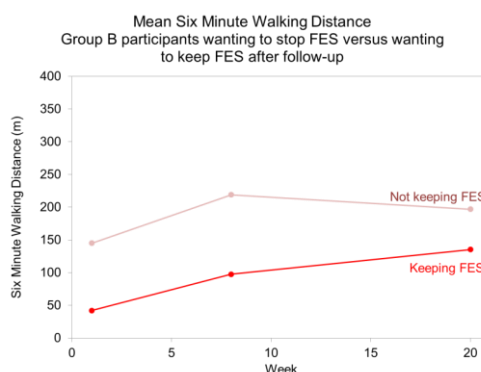
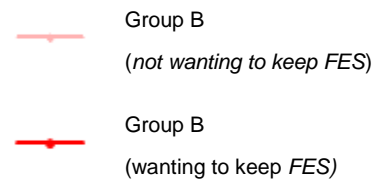
Mean six minute walking distance Group A and B shown



Individual six minute walking distances Group A and B shown



Individual six minute walking distances Group B only shown



Mean six minute walking distances Group B only shown

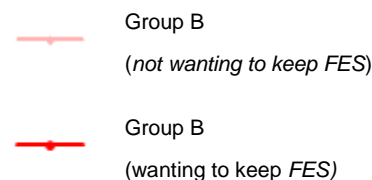


Figure 4-5: Graph series to demonstrate exploratory Group B analysis comparing participants wishing to keep FES after the trial and those that did not.

Post hoc analysis was also undertaken to allow comparison with a similar study with inpatients that used Functional Ambulation Categories (FAC) as a primary outcome [158]. This was published during the preparation of this analysis. FAC scores the assistance required to walk from one, which is defined as 'non-functional, requires assistance from two people', to six which was defined as 'independent'. It was possible to retrospectively assign FAC from the videos of walking taken at each assessment and the RMI responses. No significant between-group differences were found in FAC at any point; however, there were statistically significant within group increases in FAC during the intervention period that were maintained during follow-up.

### 4.4.9 Power calculation for definitive RCT based on this protocol

A sample size calculation was performed (80% power with a 0.05 statistical significance level) based on a target of substantial meaningful change [295] in walking speed (0.10m/s) and the standard deviation of the 10mWT changes reported in this study over 20 weeks (0.30m/s). Correlation between Week 1 and Week 20 10mWT is circa 0.7 (based on this study). Assuming use of ANCOVA (Week 1 as a covariate) to compare mean 10mWT between groups at Week 20 a sample size of 125 per group is required. Allowing 15% for attrition, 144 participants per group would produce an adequately powered study based on this protocol.

## 4.5 Phase 1 - Discussion

This study has established the feasibility of incorporating electrical stimulation into outpatient physiotherapy to improve mobility in people living at home, less than six months post-stroke. No significant between group differences were found at the end of the six-week treatment period or after a follow-up period of 12 weeks. 10m walking speed is feasible to use as a primary end point in this population as all participants could complete the test and it has robust psychometric properties.

During this 20 week study there were significant within group improvements in all mobility outcome measures and COPM (except RVGA Group A). A statistically significant improvement in these measures was observed during the intervention phase and, although maintained, did not continue to improve during the 12-week follow-up. There was a consistent pattern to these changes despite participants ranging from 3.6 to 20.1 weeks post-stroke at Week 1 (mean 9.8 weeks). These improvements can be attributed to either natural recovery or therapy. During the six-week intervention period



all participants received twice-weekly physiotherapy and home exercises but during the follow-up period they received whatever physiotherapy was available locally. It seems likely that the task specific gait training was at an intensity that was sufficient to prompt motor (re)learning during the intervention phase of this study but during follow-up practice was at an insufficient level to prompt additional significant increases. Further investigation is required to establish whether a longer treatment period would have yielded further improvements.

During the intervention period the physiotherapy sessions focussed on repeated task specific practice and utilised commonly available equipment, plinths, parallel bars, steps, balls (see Appendix H) and thus could be delivered in a larger study. Greater assistance was required in organising and providing transport than had been anticipated prior to the study. Group B participants required regular adjustment of the walking stimulation parameters as their walking abilities changed. These factors should also be considered in the planning of future similar studies and have been noted in other similar studies [158].

Participants reported positive effects associated with FES use via the PIADS, which reflects the results seen in its use with people with chronic stroke [142]. Previous studies have investigated either exercise stimulation or walking stimulation [128, 158] in people less than six months post-stroke but this is the first to combine these treatments in a protocol which mirrors clinical practice. Unfortunately, it was not possible to record 'dosage' of stimulation and future work should include devices with a usage logger.

Additional outcome measures should be included in order to further characterise the participants and reflect any training effects e.g. lower limb muscle power (Oxford Scale or repeated sit to stand), Modified Ashworth Scale and Stroke Impact Scale. A fully powered study should include subgroup analysis to explore any links between outcome measures and Group B participant's wish to continue FES use after the trial. Other studies have shown that participants with chronic stroke and lower levels of muscle power and functional ability (i.e. slower walking speeds) may respond 'better' to CPN stimulation [298]. This pilot RCT of more acute stroke has shown that people with greater walking problems tend to wish to continue stimulation at the end of the study. A larger fully powered study should include subgroup analysis comparing those that wish to keep FES and those that don't at the end of the trial. Subgroup analysis of participants with greater mobility problems should be planned into future studies, with appropriate stratification at randomisation.

A fully powered study could also assess cost effectiveness. This would be likely to require additional outcome measurement and data collection that could include completion of the Stroke Impact Scale or a standardised quality of life measure (e.g. EQ-5L-5D) and recording of any costs including consumables used, such as electrodes.

In a definitive RCT, the 10mWT would be a suitable primary outcome measure because it was feasible for most participants and is valid and reliable, with secondary measures to include 6MWT, RMI and COPM. Based on the present study PCI, HADS and RVGA could be omitted from a fully powered study for the following reasons:

- PCI. There were missing PCI data in this pilot study. Some participants were on medication that precluded reliable calculation of PCI and other data were missing due to assessor error. The single assessor design may have contributed to this. Were PCI retained in a fully powered study, the assessment protocol should contain more prompts to record heart rate. An alternative, Borg Rating of Perceived Effort Scale, is suggested for use in a fully powered study. Use of the Borg Rating of Perceived Effort Scale may be a suitable alternative to PCI since all the participants could complete it and as a copy of the 10 point scale can be carried by the assessor so it should not easily be forgotten.
- The HADS indicated the presence of anxiety and depression in this sample but did not appear to be affected by the treatment protocol. Since the improvement in mood is not the target of FES, this outcome measure could be omitted in a fully powered study.
- Most mobility outcomes demonstrated significant change during the treatment phase which was maintained in follow-up and RVGA showed a similar trend in both groups, reaching statistical significance in Group B only. The 59 item RVGA measure includes a wide variety of gait descriptors which did not seem as sensitive to change as the other outcome measures used in this study. There is no specific scale rating dropped foot during walking; were one available it may be a more sensitive outcome than RVGA in this type of study and could also be considered as a selection criteria. Assessment of RVGA from video was time consuming and the blinded assessor commented that use of different walking aids affected the scores and may have masked changes. RVGA should be replaced with a specific rating scale for dropped foot (if one is developed). FAC should also be used in a larger study as it is a much simpler descriptor of mobility than RVGA and includes the use of walking aids, which is likely to be sensitive to change in this population.

Use of a self-report paper-based falls diary did not seem feasible in this group. They were reminded to complete it when they attended for assessments but may need more prompting or a different way to capture the information such as reminders at each physiotherapy session and a weekly telephone call during follow-up.

In the Phase 1 pilot RCT there were no formal mechanisms to capture the comments from participants. A participant questionnaire could be completed at the Week 8 and 20 assessments to capture participant feedback. Additionally participants reported that seeing the video of their walking after the quantitative trial had ended motivated them. Participants who have completed the fully powered study intervention and assessments should be offered the opportunity to watch their previously videoed walking from the three assessments and any feedback could be recorded.

The current study is limited by its small size and the potential for bias arising from a lack of blinding to treatment allocation and the trial physiotherapist's dual roles of providing treatment and completing most outcome measures. There were problems recruiting to this pilot study, despite use of additional participant identification centres, therefore any future larger study would need a multicentre approach. Also gaining involvement from the whole team rather than concentrating on therapists and the stroke coordinator may increase recruitment rates.

Participant blinding of treatment allocation is not feasible as participants allocated to a sham stimulator that does not produce movement or sensation would probably guess their allocation and use of sensory level stimulation is an inadequate control as it may effect walking. The dual role of treating physiotherapist and assessor is another source of potential bias in this study. An independent assessor could have conducted these assessments and eliminated this possible source of bias. This would have isolated the treatment and assessment roles but would not have achieved blinding of group allocation. To blind the assessor to group allocation a second person (an 'assessment assistant') would be required (to turn on or off stimulation before the 10mWT/walking video and collect the Falls Efficacy Scale and PIADS). The assessment assistant would need to be present at each assessment during mobility outcome measures, to deal with any issues surrounding use of FES/ensuring it was switched on or off with the blinded assessor actually recording the outcome measures. The participant would need to be reminded not to say anything to disrupt the blinding. The use of multiple blinded assessors would ensure that treatment stage was not known to the assessor. Such a system would reduce the potential for bias but it presents practical difficulties and has been a limitation of other similar studies [158, 288].

#### Chapter 4: Phase 1 - Quantitative trial

The results of this study were published in 2014 and the abstract can be read in Appendix M.

In conclusion, this study has shown that incorporating electrical stimulation into outpatient physiotherapy is feasible for people less than six months post-stroke living at home and may increase walking speed and improve patient reported outcomes. A larger adequately powered multicentre single blinded RCT is indicated to establish whether there are training effects associated with use of stimulation in this group of people living with mobility problems following stroke.

## Chapter 5: Phase 2 - Qualitative study

This chapter begins with a description of how the research presented in this thesis developed from the Phase 1 quantitative study to a qualitative second phase. The Phase 1 trial addressed the research questions, however the participants spoke about aspects of walking that were important to them but were not fully captured by the outcome measures. Adoption of a RCT in gait rehabilitation assumes that mobility or walking can be 'measured' using a quantitative method given a well-chosen range of suitable, reliable and valid outcome measures and that this would describe the changes experienced by the participants. Completing this trial gave an insight into some aspects of post-stroke gait and also highlighted how this was an incomplete picture of participant's walking. The purely quantitative Phase 1 RCT raised questions about the experience of walking post-stroke that have not previously been explored in the published research.

The experience of conducting the pilot RCT offered me new insights and prompted me to alter my view of walking. I recognised as a researcher, what I had known as a physiotherapist, that walking meant different things to different people. From clinical experience, patients who have had a stroke often say that they did not really think about walking before their stroke and had not considered all the aspects of life that walking problems would affect. This was reflected in the informal talk of the RCT participants. I also realised that I take for granted my ability to walk independently and valued it only when it was reflected upon, threatened or reduced. My attitude shift has been a useful catalyst, I began to consider exactly what does walking mean to me? In my own life, walking is linked to my ability to work, exercise, take holidays, visit family and friends, 'nip out to the shops' and carry items. I can hold hands or link arms with others for pleasure rather than support and move confidently on different surfaces, in different circumstances and to perform varied tasks, such as cooking, household chores, rushing to the station or quietly creeping up to watch a kingfisher. It underpins my independence and spontaneity. This list of my initial responses to the question 'what does walking mean in my life?' suggests that walking may have a very individual personal meaning. Many of these aspects of walking, that I personally value, would not be measured on a standardised mobility scale.

Informal discussions with others, including supervisors, colleagues and friends recognised that they could, when prompted, also talk about the personal meaning they

associated with walking which varied from person to person. Upon reflection the personal meaning of walking seemed to be multi-factorial, including many elements such as individual history, experience, norms, ideas, practicalities, interests, hobbies, work, family, friends, pets (particularly having dogs), environment, motivation, goals, responsibilities, lifestyle, exercise, opportunity, effort and pain which could change over time. The Phase 2 qualitative research began with a literature review to investigate whether the aspects of walking outlined above had been explored previously (this has been presented as part of the main Literature Review, Section 2.4.2). This literature review concluded that there was a lack of published research specifically focussed upon people's experiences of changes in walking post-stroke and aspects of walking that they valued. This was the justification for initiating the second qualitative phase of this research, which is presented in this chapter.

### **5.1 Phase 2 - Research aims and questions**

The second phase of the research aimed to thoroughly explore walking changes over time from the perspective of individuals who have had a stroke and taken part in gait rehabilitation. It also aimed to explore valued aspects of walking and feelings about the use of assistive devices, including electrical stimulation. The following research questions were addressed by the Phase 2 study.

1. How do people who have had a stroke affecting walking and have taken part in gait rehabilitation, describe their own walking and how it has changed over time since the stroke?
2. What aspects of walking do they value and how have these changed since the stroke?
3. How do they describe their experiences of using assistive devices?

### **5.2 Phase 2 – Method**

#### **5.2.1 Study design**

An interpretative phenomenological study investigating changes in walking post-stroke from the perspective of people who have had a stroke affecting mobility.

Data generated in this qualitative research were analysed in a systematic and transparent manner using Interpretative Phenomenological Analysis (IPA). This approach was selected because it matched the research aims and questions, could be undertaken with small sample sizes (minimum one participant) and for its focus on understanding particular individual experience. It is especially suited to examining experiences that may be ordinary and otherwise 'taken for granted' [266]. Interpretative phenomenological analysis was utilised in Phase 2 to produce detailed description of the experience of walking from the perspective of the stroke survivor and enable multifaceted interpretation that could be discussed in relation to other theoretical positions.

### **5.2.2 Maintaining quality in the Phase 2 qualitative research design**

The literature review highlighted the different ways of maintaining quality and rigour in qualitative research and in IPA research specifically (section 2.4.4). To maintain quality in this research, the study design and reporting was based on the principles of IPA [266, 299] and checked against the CASP Qualitative Research Checklist (displayed in Table 2-7). Other applicable published quality criteria were also considered [280, 282, 300] as well as publications that concerned maintaining quality in qualitative research [301-304].

The concepts of quality and rigour are closely linked. Davies and Dodd's, 2002, paper described rigour as a term that can be used in both quantitative and qualitative research to describe good quality research that includes forms of reliability and validity. In addition, these authors suggest rigour in qualitative research encompasses ethics, attentiveness, empathy, carefulness, sensitivity, respect, honesty, reflection, engagement, awareness and openness [301]. Evidence for the application of these concepts during the interviews, analysis and discussion is given throughout this chapter on the Phase 2 research and in the excerpt from the data analysis, Appendix L.

There is no gold standard for maintaining quality in phenomenology based qualitative research however quality and credibility of the analysis are recurring themes in Smith et al's book describing IPA processes [266]. Authors suggest that the systematic nature of IPA can increase the rigour and robustness of findings [245, 299] and this reflects the careful and attentive research approaches that have been associated with rigour in qualitative research more generally [301]. Throughout the Phase 2 study, there was a commitment to engage with the participants and interview transcripts openly, attentively, empathetically and carefully. During the interviews, all of the

participants revealed personal aspects of their lives since the stroke that had been affected by their walking problems. This suggests that they were reasonably comfortable during the interview process and trusted the interviewer. Empathy and sensitivity were required to adapt the interviews to enable participants to talk about their experiences.

IPA demands that the researcher adopts a phenomenological attitude to enable them to disengage from habitual ways of seeing a phenomenon and attend to the participant's accounts of their experience. This attitude should be apparent throughout the analysis and reflexive accounts detailed later in this chapter and reflects the open and attentive approach valued by Davies and Dodd's [301]. The IPA approach does not include member checking or re-examination of the data by a second researcher to demonstrate the validity of the conclusions because of the active style of interview, co-created by the participant and researcher (See section Quality in qualitative research 2.4.4). Therefore, these were not undertaken in the Phase 2 study. Supervisors with experience in qualitative research methods and gait rehabilitation reviewed the study during all stages and helped to develop and challenge interpretations of the transcript data, as suggested by Smith et al., 2009 [266]. IPA does demand that there is a coherent evidence trail that is available for audit; how this was achieved in the Phase 2 research is discussed further and demonstrated section 5.2.8 (data analysis). Areas of agreement and divergence within the transcripts and between the participants are highlighted and explored later in this chapter. The role of the researcher within this research process is also explored in depth in this chapter. All of these stages contributed to the credibility of the findings and the rigour and quality of the qualitative research presented here.

The following paragraph outlines how the 10 points of the CASP quality checklist (Table 2-7) have been addressed in the Phase 2 study. The first three CASP checklist items relate to the need for a clear statement of the research aims and asks if a qualitative method/design was appropriate to meet the aims of the research. These three points have been addressed in sections 2.4.3 and 5.1 and are summarised above. The fourth and fifth CASP items address the coherency of the research questions and the recruitment strategy/data collection methods. Sections 5.2.6 and 5.2.7 demonstrate how the recruitment strategy and data collection were appropriate and consistent with the research question. The relationship between the researcher and participants (CASP item six) was considered before beginning and throughout data collection and analysis and is discussed in sections 5.2.9 and 5.4.6. Ethical aspects of



completing this research (CASP item seven) were considered during the Ethics and Research Governance process described in section 5.2.3 and throughout the planning and data collection/analysis stages. The last three CASP checklist items concern the rigour of the data analysis, if there is a clear statement of findings and the value of the research. The statement of findings can be viewed in section 5.3.3 and the value of the research is discussed in section 5.4. Appendix L and section 5.2.8 contain examples to demonstrate rigour during data analysis and the coherency of the chain of evidence from transcript to superordinate themes and reporting.

### **5.2.3 Research governance**

Completion of the University Ethics and Research Governance processes (ERGO) enabled the University of Southampton to act as sponsor for the Phase 2 study (Appendix I). No funding was received to complete the Phase 2 qualitative study.

The Participant Information Sheet (Appendix J) contained details of who to contact if the participant had concerns regarding any aspect of the research. There was potential that interviewees may become upset by talking about their stroke and the changes in walking they had to cope with. They may also disclose negative information about previous experiences of rehabilitation. The interview schedule discussed the more sensitive topics in the middle of the interview, beginning and ending on more general and less personal questions [305]. The interviews could be terminated at any point should the interviewee become unduly distressed.

The researcher could be emotionally affected by doing this research despite extensive clinical experience talking to people about their problems following a stroke. Support was available from a variety of informal and formal sources, such as supervisors, peers and the University Counselling Service.

### **5.2.4 Environmental and safety considerations**

Potential participants were approached after identification from a database held by the Faculty of Health Sciences, University of Southampton, and may be known or not known to the researcher depending on the search strategy employed. The University has several guidance documents and protocols relating to interviews done in participants' homes. These were followed, the accompanying paperwork was completed and the safety procedures implemented.

### 5.2.5 Eligibility criteria

IPA commonly uses case studies or small samples drawn from a relatively homogenous group in order to understand a particular perspective of the phenomenon under scrutiny. Purposive homogenous sampling enabled people with the shared characteristics of interest to be invited to participate. These characteristics were experience of post-stroke walking problems and gait rehabilitation. The eligibility criteria below identified these characteristics and also ensured that the practical aspects of a face-to-face interview were not too problematic.

#### Inclusion criteria

- Able to understand the information sheet and give informed consent
- Previously took part in the completed Phase 1 pilot RCT investigating FES and registered on the University of Southampton Faculty of Health Sciences Rehabilitation Research 'Participant Register' (first database filter).
- **Or** have been identified from the University database as having mobility problems following a stroke. This second back-up database filter was to be run if less than five people from the pilot RCT accepted the invitation to take part.

#### Exclusion criteria

- Unable to communicate verbally at a level required to be an active participant in an interview (i.e. sufficient language and cognitive function) and give informed consent.
- Live more than 50 miles from Salisbury

### 5.2.6 Participant identification

People who had previously taken part in the first pilot RCT met all the eligibility criteria. Their relative homogeneity was an added advantage, they had all experienced walking difficulties following a stroke and many also had experience of using assistive devices including walking aids, orthotics and at least 10 had used FES. An additional advantage was that the rapport already established with the researcher in the Phase 1 trial might encourage participants to talk more freely about their experiences of walking and promote the two way 'active interview' process. The previous role of the interviewer as a researcher and clinician who was focussed on gait rehabilitation may also give the Phase 2 research questions greater legitimacy from the participant's perspective. The advantages and disadvantages of this dual clinician/researcher role are explored further in Section 5.4.6.

The people who had taken part in the Phase 1 RCT could not be asked directly if they wished to participate, as this was not part of the original RCT protocol and would not be ethical. The University of Southampton, Faculty of Health Sciences Rehabilitation Research maintains a 'Participant Register', which is a database of people who are interested in taking part in research. The most ethical way to recruit Phase 2 participants was via this database of people who identified themselves as interested in taking part in research. Participants involved in the original Phase 1 RCT may have been already registered on this database since it had been advertised locally. Awareness of this database in the target group was also raised via invitations to and attendance at a 'tea and cake' feedback and update session for the original RCT (in June 2012). The Phase 2 study was given a distinctive relatively self-explanatory name to aid understanding of its aims and recognition of it as separate to the first trial. The Phase 2 qualitative study was called 'Talking about walking'.

Identification of potential participants from the University Participant Register was done by the database manager using a filter to identify only people who participated in the Phase 1 pilot RCT (n=20 maximum). This approach had a risk that all 20 might be registered, which would have created a large IPA study. There was no straightforward way of distinguishing a subsample and therefore all those who responded positively to the invitation would have been interviewed. Larger IPA studies usually contain less depth of analysis for each individual case but they are possible and allow more comparison for divergent and convergent themes [266]. However, this was an unlikely scenario as it seemed improbable that all 20 original trial participants would be registered on the database and would accept the invitation to take part in these interviews. If the first database filter failed to identify sufficient participants willing to take part in the Phase 2 study, there was a back-up plan. An alternative second database filter could have been used to identify any individuals with a stroke affecting their lower limbs i.e. likely to affect mobility and these people would have been invited to participate.

### 5.2.7 Data generation

Interviews took place in the participant's home or somewhere quiet that they selected, they were digitally recorded and lasted between one and two hours. Interviews took place with the participants who were stroke survivors who had previously taken part in the Phase 1 RCT. Other people could be present at the participant's request but they were encouraged by the information sheet and interview introduction to avoid

interrupting too much as this study primarily sought the opinions of the person who has had a stroke. The interviews were based on IPA methodology and informed by 'Active Interview' theory [265, 266].

The interview schedule (Appendix K) was used as a basis for the semi-structured interviews however it acted as a guide not a script, allowing the interview to flow and enabling the interviewer to respond and probe interesting ideas with the interviewee. This required the interviewer to actively listen and review the planned questions and any prompts in the light of answers given during the interview to ensure the relevance to the interviewee/research aims and clarity of the questions. The schedule comprised of open questions and avoided leading questions. The interview schedule was designed to discuss more sensitive topics in the middle of the interview and it began and ended on more general and less personal questions [305]. The schedule was developed after reflection on the aspects of walking that were valued and spoken about but not fully captured in the Phase 1 trial and from the gaps identified in the published literature around understanding the experience of living with stroke related walking changes.

### 5.2.8 Data analysis

Interpretive Phenomenological Analysis (IPA) was undertaken based upon the method described by Smith et al., 2009 and Smith, 2008 [266, 305]. The aim of IPA is to understand more about the participant's world through analysis of what they said and how participants showed similarities and differences in their talk and experiences. After digitally recording the interview, an audio typist who had agreed to treat the interview contents as confidential, transcribed it for reasons of speed. I checked the resulting transcript word by word against the original interview audio recording before analysis was undertaken. Apart from the initial audio transcription I completed all stages of data collection and analysis and during this period I kept a reflective record. The Phase 2 analysis was completed in sequential stages using IPA and these are summarised below [266, 305]. This closely followed the methods explained by Smith et al., 2009, in their book on IPA with the main difference being use of a spreadsheet, rather than a word processing programme, for collating and comparing themes across cases. This spreadsheet also helped the synthesis of into superordinate themes.

During transcription and transcript checking, established conventions were followed with respect to noting long pauses and emotions, such as laughter. At this stage all real names were changed to pseudonyms and all identifiers removed and so that in all subsequent stages only these anonymised transcripts were analysed.

The analysis began with a period of 'immersion' in the first printed transcript, including multiple readings of the transcript and annotation of interesting or significant passages. The exploratory annotation included making descriptive, linguistic and conceptual comments. By convention, these are written to the right side of the interview text. Examples can be seen in Appendix L.

These initial notes and phrases were transformed into emergent themes that captured significant aspects of the text and were summarised to the left of the interview text. The whole transcript was treated as data. Each line of the spreadsheet captured a single quote (cut and pasted from the transcript) and the associated participant pseudonym, quote location, emergent theme labels and the initial notes linked with that section of the transcript (typed up from the original hand written transcript notes).

The emergent themes were reviewed and examined for connections, patterns and contradictions by 'clustering' similar themes into 'main themes' and checking for divergent cases. Themes were checked against the source material (i.e. whole transcript) for authenticity and to ensure they reflected the whole interview. Each interview was analysed sequentially and as independently as possible of the other transcripts. Analysis of the other interview recordings proceeded in the same manner, repeating the above stages.

Once all the transcripts had been analysed individually and copied into the spreadsheet, the emergent themes from all the participants were brought together for cross case analysis. Publications describing the process of IPA suggest making electronic or paper notes of the emergent themes from each participant with supportive data i.e. quotes, so that they can be grouped and regrouped [306]. This enables identification of consistency and inconsistency across cases and allows development of superordinate themes and sub-themes. Disadvantages of using paper based methods are space, portability and ability to organise and reorganise the data and themes. Instead, a large Excel spreadsheet was used in this analysis that had the advantage of being able to allow repeated reorganisation and grouping by various extra 'label columns'. This enabled testing of the grouping strategies. Various spreadsheet versions were saved to allow 'back-tracking' in the analysis if required. The transcripts and spreadsheet quotes were compared for evidence of convergence or divergence between and within the cases. After this analysis a list of main whole group themes, referred to as superordinate themes, was produced to account for all the data. This analysis and synthesis underpinned the written account of the findings presented in Section 5.3. At first there were many potential superordinate themes, suggestive of

incomplete IPA process [266]. Over time, these were refined so that four superordinate themes could account for all the data from the four participants.

The process of moving between initial coding, emergent themes and superordinate themes is described below, using examples from the first transcript that was analysed (Liz). The sections of Liz's transcript and spreadsheet coding for this example can be seen in Appendix L. These pages (3-5) of the annotated transcript contain some of Liz's most in depth descriptions of her physical impairment (including dropped foot and reduced sensation and motor control). She also describes problems with walking, confidence mobilising and difficulty with activities of daily living because of these impairments. She explains that she has lost 'trust' in her body to move as it did previously. On these pages, emergent themes from close reading of her transcript included control i.e. control of body, control of balance and her effort to regain control of her body and her situation. Other emergent themes were fear of falling and a sense of a new and strange body relationship where her body became the 'object' of her attention rather than 'taken for granted' as it had been previously.

Appendix L also contains spreadsheet entries for the quotes from pages 3-5 of Liz's transcript. In the table, the column labelled 'Initial theme' refers to the emergent themes from each annotated transcript. 'Strength' is my own reference for the contribution of the quote to the themes, five indicates the strongest quotes and lower scores of under three show that the quote contributed evidence for the theme but was not the strongest evidence for that theme. I devised this system and used it to help evidence the findings section of this qualitative research, to highlight the strongest quotes for each theme. The 'Superordinate theme' and 'Details' columns were compared and adapted across cases until superordinate themes and subthemes could be developed that accounted for all data, see section 5.3.3.

An excerpt from page 3 of the transcript in Appendix L that described Liz's dropped foot and use of a splint appears several times in the spreadsheet pages demonstrating how it contributed to multiple themes. It was classified under the emergent theme 'Control of body and balance' and this became a subtheme in the overall superordinate theme of 'Control' once all the transcripts had been analysed. The same description provided insights into Liz's adaptive strategies, using a brace (ankle foot orthosis) and moving her bed downstairs. These strategies were grouped together in the final analysis in a subtheme of 'Being active and taking part' called 'Coping with movement problems'.

This is a summary of the transcript analysis process and gives an indication of the steps that were undertaken to develop the final superordinate themes. Throughout this process consideration was given to my role in the analysis and the effects of my foreknowledge. Aspects that were known prior to the analysis are considered below and those that became apparent during the analysis process are described in section 5.4.6.

#### 5.2.9 **Consideration of the researcher/participant relationship and fore-knowledge**

Aspects of my role and influence within this qualitative study that were considered prior to undertaking the study are described below. The four people interviewed were well known to me because they had taken part in the original RCT that I conducted, which included gait rehabilitation and assessment over 20 weeks. There was potential for bias in both phases of the research due to this dual clinician/researcher role. Steps were taken to reduce bias in the Phase 1 pilot study and these were outlined in Chapter 2.3.1. My role in the Phase 2 study was only that of a researcher however the impact of my previous clinician/researcher role needs consideration. The existing relationship between me and any participants drawn from the original pilot RCT may have helped participants to be more relaxed during the interview. This may have encouraged participants to talk more freely about their experiences and promoted the two way 'active interview' process. Conversely, difficulties may have occurred stemming from a wish to 'please' me as the interviewer/ researcher/ physiotherapist. This might have been the case even if the participant was not known to me since the interviewer may be perceived as more powerful than the participant in many interview processes. Participants might have asked me questions about a problem related to their recovery since they were aware of my professional role as a physiotherapist. The protocol aimed to satisfy most enquiries by answering simple physiotherapy related questions and directing others to suitable sources of information i.e. GP or other local therapy services for advice or equipment. I took care to avoid presenting or dressing myself as a clinician and focussed the pre-interview introductory talk on my research studies. The participants did not ask me physiotherapy related questions, perhaps due to the time period that had elapsed since the first study, which was at least two years. My dual role as physiotherapist and researcher encompassed my interest in them as people with experience of post-stroke walking problems and gait rehabilitation. This may have given the Phase 2 interview study legitimacy since participants spoke in depth about their stroke related walking changes and their impact on their lives.

## Chapter 5: Phase 2 - Qualitative study

The ability to bracket is questioned in IPA with emphasis instead placed on understanding fore knowledge that may affect interpretation and this will now be considered. The researcher is an integral part of the double hermeneutic cycle that is a foundation of IPA i.e. the researcher is making sense of the participant who is making sense of their experience. As a clinician/researcher I found that it was necessary to make extra efforts to attempt adoption of the phenomenological attitude which requires the analyst to 'disengage' from the normal activity and 'attend to the taken for granted experience of it' [266]. I have a professional understanding of walking and gait rehabilitation research that affects research decisions and analysis. For example, in the planning of the Phase 1 RCT it was assumed that important aspects of mobility could be isolated and measured and that this would describe the changes experienced by the participants. In retrospect, after reflection on the aspects of walking that the participants spoke about but were not measured, this reliance on only quantitative outcome measures seems slightly naïve. However, as a researcher rooted in quantitative research methodology this common and possibly widespread assumption was not recognised at the outset. Discovering that individual stroke survivor's experiences of walking could be systematically examined and that this did not appear to have been done before motivated me to look with 'fresh eyes' on this previously taken for granted topic.



### 5.3 Phase 2 - Findings

The aim of 'Talking about walking' (TAW) was to explore walking changes over time with individuals who have had a stroke and taken part in gait rehabilitation. In addition, this phase of the research aimed to investigate feelings about the use of assistive devices, including electrical stimulation and if possible illuminate the personal meaning of walking for individuals. The interview schedule (Appendix K) reflected the research aims. The interviews were semi-structured so the interview schedule was broadly but not exactly followed. The schedule asked about aspects of walking that participants valued, framing questions around how walking had changed since the stroke, what aspects of walking they missed and what being able or less able to walk meant to participants and others in their lives.

The Interviews were recorded, transcribed, transferred to a spreadsheet and analysed as planned (see Chapter 5.2.8) and Appendix L for an example. The spreadsheet made development of the superordinate themes easier because it allowed searching and re-ordering by characteristic such as superordinate theme, subtheme, notes, key words, participant or emergent theme. During the interviews, participants shared their walking related challenges and achievements putting movement post-stroke into the context of their lives. From their talk, both prompted and unprompted by the schedule, it has been possible to explore the Phase 2 research questions (Chapter 5.1).

The quotes that are presented in this thesis have a standardised format. The quote is written in *italics* and presented within single speech marks, followed by the pseudonym (Jim, Jim-Bob, Liz or Rosa) of the quoted participant and the page number it can be located on in the annotated transcript. If someone other than the participant is speaking at the start of the quote it is specified. Within each quote '...' denotes a pause in the talking while [...] shows where text has been removed to aid readability and flow of the quote. Any supplementary information to improve understanding was added in square brackets.

The participants in this study were well known to me from the previous Phase 1 quantitative trial during which I treated them as their physiotherapist and collected outcome measures as a researcher. The advantages and disadvantages of this relationship for this qualitative research have been outlined in section 5.2.9 and the effects on the research findings are considered further in section 5.4.6.

### 5.3.1 Recruitment

Four participants who had taken part in the Phase 1 trial were registered on the University of Southampton, Faculty of Health Sciences rehabilitation research Participant Register. They were invited to take part in the Phase 2 'Talking about walking' interviews and all four agreed and were interviewed. This process happened over a five month period during which, nobody else registered who had taken part in the first Phase 1 Trial. Before applying the second filter, and recruiting a fifth interview participant from outside of the original RCT, recruitment was discussed within supervision. IPA is suited to small sample sizes. One of the main reasons for aiming for five participants was potential attrition; however, at the time of the supervision discussion four in-depth interviews had already been completed, without any dropouts or withdrawals. Recruiting a fifth person who had not taken part in the original study would have made the participants less homogeneous, which is at odds with IPA methodology. Therefore, recruitment to the Phase 2 study was stopped after four participants had been interviewed.

### 5.3.2 Participants and interview details

The participants were approximately three years post-stroke at the time of the interviews and all lived at home, their details are summarised in Table 5-1. All names used during transcription and analysis were pseudonyms, chosen by the participants, and all place names have been changed to preserve anonymity. Each participant's interview lasted between one and two hours and took place in their home, apart from Jim who chose to be interviewed at the hospital. He said that this was because his house was a mess. Jim's interview took place in a private and quiet consultation room where it would not be disturbed. Rosa and Liz were alone at home during the interviews. Jim-Bob was at home with his wife Crystal and he chose to ask her to remain in the room during the interview. He frequently invited his wife, by word or gesture, to answer or remember details to add to his talk. None of the interviewees became unduly upset during the interviews, one participant became a little tearful but quickly recovered, stating that she was happy to continue.

Characteristic		Liz	Rosa	Jim	Jim-Bob
Gender		Female	Female	Male	Male
Age at stroke		49	83	52	53
Infarct		Y	Y	Y	Y
Side of hemiplegia (R/L)		R	R	L	R
Hemiplegia affecting dominant hand? (Y/N)		Y	Y	N	N
RMI from quantitative trial (n/15)	Wk 1	6	6	12	9
	Wk 20	13	13	14	10
Synopsis		Liz is married and lives with her husband and two teenage sons in a small village. Pre-stroke she worked as a sports coach and a local radio DJ. Liz enjoyed active outdoor pursuits like riding her horses, tennis and walking.	Rosa was widowed more than 10 years before her stroke, she lives alone in a village but close to many members of her large family. She is a retired nurse and pre-stroke enjoyed gardening, volunteering at local clubs and walking. She also liked bowls and dancing.	Jim worked as a tiler, he is divorced with an adult daughter who does not live with him. He lives alone in a suburb of a town. Pre-stroke he enjoyed socialising in pubs and pub sports such as darts and pool. He enjoyed going fishing.	Jim-Bob is married and worked as a church minister in a church in which his wife also worked. He lives with his wife and daughter (a university student) in a city. Pre-stroke he enjoyed church activities and playing guitar.
Functional walking category at time of interview (observed)		6 (independent)	6 (independent)	6 (independent)	5 (independent on level surfaces, supervision or assistance required on inclines, stairs and/or non-level surfaces).

Table 5-1: Phase 2 - Participant characteristics

### 5.3.3 Summary of themes

Figure 5-1 shows the four superordinate themes and the subthemes associated with them that were identified in this analysis. In the following sections, these themes are explained individually. A full page version of this diagram can be seen in Appendix N.

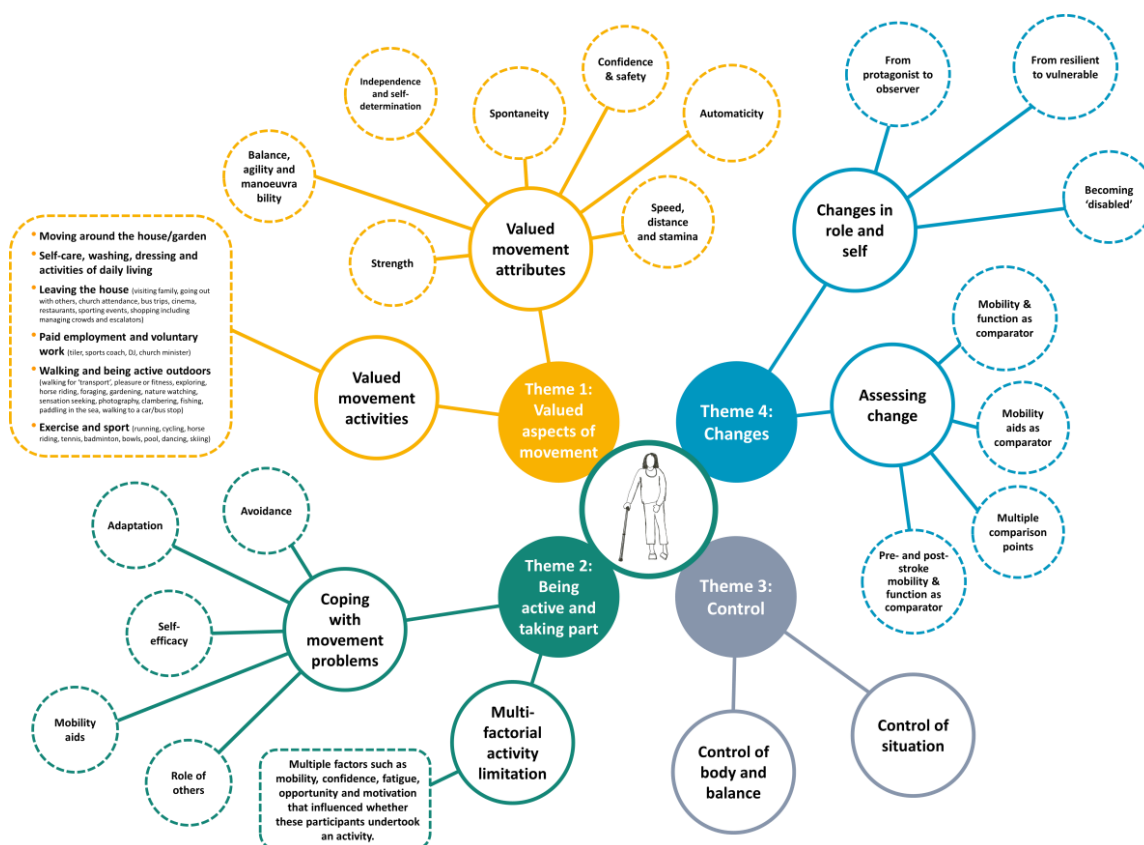


Figure 5-1: Diagram representing the superordinate themes and subthemes identified in the Phase 2 study

### 5.3.4 Theme 1 - Valued movement attributes and activities

The participants spoke about a diverse range of activities that were important to them in response to the interview schedule that referred only to walking. Therefore the first superordinate theme is titled 'valued aspects of movement' rather than valued aspects of walking or mobility, both of these latter terms would be too narrow to encapsulate the participant's wide ranging talk about walking. Two subthemes emerged 'valued movement attributes' and 'valued movement activities'; these are explored below. Most of the participants spoke about these movement attributes and activities in the context of 'loss', loss of the ability to complete them altogether or loss of the ability to

complete them as they would like. Participants implied via their loss based comments or explicitly stated that they valued these changed activities and both are included in the subthemes in order to explore research question 2. Liz summed up this process *'And it is only when something is almost taken away from you, of course it is, that we appreciate it more'* (Liz, page 24).

#### 5.3.4.1 Valued movement attributes

##### Independence and self-determination

Walking was valued by all of the participants in relation to avoiding dependence and being independent. In the quote below Liz emphasised her *'need'* to be able to mobilise independently.

*'... there is something very fundamental about the need – certainly, in me – to be able to stand and to be able to walk, to not to be reliant on other people.'* Liz, page 17

Avoiding reliance on others was a strong motivator for Liz, who is a married mother of two teenagers. Referring to her husband and sons she explained that *'... it was really, really important to me to be independent for their sake'* (Liz, page 49). At various times through her interview Liz repeated her wish to avoid people doing things for her and instead wishing to do them *'by myself'*. She focused her talk on her activity and function, on her goals with repetition of *'myself'*, *'me'* and *'my'* to emphasise this.

*'Yes, for me it was important to get back to leading ... a useful life. At home I wanted to get round the house safely, to get up and down stairs by myself, to get in and out of the shower by myself ... to be able to manage my own personal needs um ... particularly in the early days and to get myself up and mobile safely um ... was crucial to my independence and to my positive state of mind.'* Liz, page 40

Liz linked her independent mobility/function in ADLs to *'leading a useful life'* which implied that she made a value judgement, associating independence with positive self-worth. Later, as Liz's mobility improved, her focus appeared to shift from aiming for independence in ADL to independent community mobility. As an example, she talked about being able to take her sons to sports matches in neighbouring cities, a task that required her to drive, safely mobilise to her car and get in/out of it. She described accomplishing this as *'really important to me'* (Liz, page 50).

Rosa's interview also revealed her wish to avoid reliance on others *'... I miss my independence very much, dear. And to have carers come in ... was very difficult for me*

*to accept that to begin with'* (Rosa, page 47). Rosa and Liz returned to the subject of avoiding dependency several times during their interviews but this was not a focus of either Jim or Jim-Bob's interviews. Jim lived alone without close family support, both pre-stroke and post, therefore he was forced to be self-sufficient which may explain why he did not focus on talking about avoiding dependence. Jim-Bob, was assisted by his wife in many activities and his talk did not focus on avoiding reliance on others either. The fact that he chose to be interviewed alongside his wife could possibly have influenced how he spoke or avoided speaking about dependency.

Jim-Bob framed his talk about independent mobility in terms of personal *'freedom'* rather than self-sufficiency. When prompted he said that he was referring to the freedom to choose what you want to do and he explained this was similar to the freedom that Martin Luther King spoke about in his 'I have a dream' speech in 1963. All of the participants associated unrestricted mobility with personal freedom or self-determination and this can be seen in the following quotes.

*'I want to be able to walk whenever and however and as far as I want to ... [...] I do like my independence to just be able to take myself off when I want to.'* Liz, page 36

*'Yes, sort of, like, venturing out and ... I love walking down river banks and things like that, you know, sort of ... exploring the environment'* Jim, page 40

*'I miss being able to walk up there ... whenever I feel like it. That's what I miss most. I know that they can come and pick me up [...] but I miss going ... I miss seeing all the scenery and everything – I miss it so much ... being able to walk out and feel you are on your own being able to do something ... walking on your own ...'* Rosa, page 43

The participants were accepting of a degree of task adaptation if it allowed them greater activity choice. For example to avoid excessive fatigue and allow activity completion all of the participants accepted driving or being driven to manage journeys that they might have walked pre-stroke. This mitigated the impact of their mobility problems and maximised their ability to be active and participate.

Jim took buses for longer distances as he had little access to a car post-stroke because he said that he could not afford to run one without working. Jim-Bob could not drive due to his stroke and was driven or used a scooter for distances outside. He explained that *'... my legs won't do it. I don't trust myself to walk to the shops'*. In contrast the scooter gave him freedom and confidence, it was *'... gonna get me there. It's not gonna fail and ... uh ... I can run people down!'* (Jim-Bob, page 15). In these

phrases Jim-Bob used humour to demonstrate the sense of power and independence that the scooter provided him with, enabling him to access local places alone. This was not so easy over longer distances and Jim-Bob talked about an occasion when he had wanted to go into the city centre by bus and then on foot. He did not have confidence in his ability to do this alone and his wife Crystal acted as 'gate-keeper' by refusing to attempt this outing with him on the grounds that he '*wouldn't manage*' it (Jim-Bob, page 49). Jim-Bob then explained that this left him feeling frustrated and feeling '*imprisoned*' by his restricted mobility that limited his movement choices and therefore diminished his personal freedom.

The participants spoke about valuing independent movement for specific activities and for accessing, interacting with and exploring their environment. Reliance on others was spoken about in mostly negative terms and activities were sometimes curtailed or avoided to minimise dependency or because of other people's views. The personal freedom to achieve one's own choice of activity can be referred to as self-determination and all the participants associated self-determination with independent mobility and valued it highly.

#### Confidence and safety

All participants described having less trust in their own physical abilities post-stroke and explained how this changed over time as they adapted, experimented and changed. Rosa said that confidence was key to achieving her community mobility goals such as independently buying a new pair of shoes in her local town. Soon after her stroke, Rosa could not have attempted this activity due to her restricted mobility and risk of falls but this changed over time. She said that the difference was confidence.

*'... I had the confidence in me and ... I ... I went in with confidence and my mind made up I was going to do something ... and it just give me the will power to do it.'* Rosa, page 7

The other participants also spoke about lacking confidence in their body for example Jim-Bob said that he didn't '*trust*' himself (Jim-Bob, page 15) and Liz recognised her mobility limitations and wanted any help available to improve her physical ability and self-confidence.

*'I had no confidence in anything I could do or ... everything I thought I could do before ... well, everything I remembered being able to do before, I couldn't do any longer...'* Liz, page 22

Self-confidence in physical activities appeared to be related to certainty, trustworthiness and reliability in body control and affected by the demands of the task and environment. Liz talked about a visit to a sport stadium which made her feel *'trapped'* because the crowds of people combined with her walking problems led her to feel that *'... I couldn't help myself'* (Liz, page 29). None of the participants had significant mobility problems before their stroke and post-stroke all said they felt vulnerable and fearful when walking.

*'I was fearful of walking in the crowd [in town shopping] in case I would fall down if I was bumped ...'* Rosa, page 62

*'If I've got to walk up stairs I've got to sort of pull myself up by the hand rail, plus hold on, for feeling secure ... er ... feeling safe.'* Jim, page 28

*'I do fear falling now whereas I wouldn't have thought twice about it before – I was always very strong.'* Liz, page 15

All of the participants gave examples of their own falls and Liz and Jim reported sustaining injuries from falls. For example, Jim said he was hospitalised with fractured ribs due to a fall.

*'Quite often I keep on stumbling into the coffee table or something else ... falling down ... and seventeen ribs I've done over the last year or so.'* Jim, page 3

Falling and gaining additional injury appeared to be the biggest fear for Liz and Jim. All the participants lacked movement confidence and this was linked to fear of falling and the possible consequences of a fall on function, pain and independence. For example Rosa did not want to *'fall down and be a nuisance to people'* (Rosa, page 39). Each participant talked about how they developed strategies to cope with their lack of movement confidence e.g. being accompanied or avoiding risky situations. Performance was task and context dependent and participants valued movement confidence and safety, which promoted independence.

#### Automaticity

*'... my head is not connected to my left leg at all ... my brain wasn't talking to my left leg. It didn't even try to move, you know, just nothing happened.'* Liz, page 48



Liz lacked trust and confidence that her body would perform automatically as it did pre-stroke *'It was like me trying to move your leg and therefore I don't have any confidence...'* (Liz, page 48). She described challenging activities that demonstrated the value of automatic and independent movement such as being able to safely *'jump off an escalator'* or recover her balance when she tripped.

*'So when you catch your foot ... you automatically as an able-bodied person – whichever leg isn't caught will jump to rescue you and put you down in front. That doesn't happen with me, with the stroke – just nothing happened. My right leg caught in the bramble, my left leg just didn't move – nothing happened – and so I fell forward onto my knees ...'* Liz, page 47

Liz also said that *'my left leg won't react'* (Liz, page 47). Her use of the word 'react' implies unconscious fast automatic movement (referred to here as automaticity). Rosa also explained that she had problems with her stroke affected leg not reacting as expected.

*'I forget sometimes and I go to turn round and so ... I turned round and my leg hasn't come with me and the foot's still there ... and I over-balance then and fall down.'* Rosa, page 30

Rosa spoke about compensating for this reduction in automatic movement by increasing her cognitive focus on moving her leg and saying to herself *'bring your foot with you. Don't forget the foot'*. The problematic body part becomes the object of her attention and cognitive effort, this is discussed further in the 'control' super-ordinate theme (Chapter 5.3.6).

Jim did not specifically mention automaticity of movement but Jim-Bob did, describing his post-stroke movement difficulties as being as though the *'hard drive had been erased'* (Jim-Bob, page 22). These quotes encapsulate the problems associated with a lack of automatic or unconscious movement. All of the participants talked about the negative consequences of their new less reliable body and complained about their body's inability to move automatically or react appropriately in specific circumstances.

### Spontaneity

Throughout her interview Liz made reference to the 'sporty' leisure and employment activities that were her passion pre-stroke. In one section she said *'I do miss the active life I had before'* and then she listed activities that she missed including coaching and playing tennis, horse-riding, running and cycling (Liz, page 16). Her pre-stroke physical

ability allowed her to undertake a variety of active pursuits without planning *'I miss ... just the spontaneity of being able to run'*. She related physical spontaneity or unplanned actions to her sporty hobbies as well as more mundane movement like varying her speed when crossing a road.

*'... When I watched a girl running across the zebra crossing in front of me recently, dodging the traffic, I had a miserable head and I thought, no, you will never be able to run again [...]* Ingrid: *But you did used to dodge the traffic like that ...?* Liz: *Yes I did, you don't think about it – if you want to run, you run, don't you? And I do mind about that, but, tough.'* Liz, page 49

'Dodging the traffic' i.e. responding to fast changing environments such as crossing a road requires responsive movement which is largely automatic or unplanned. Spontaneity of movement is intrinsically linked to movement freedom and relies on a degree of automatic movement, therefore physical disability post-stroke imposed boundaries on these participant's available movement choices.

Rosa, Jim and Jim-Bob did not specifically mention 'spontaneity' in their interviews however Jim-Bob and his wife Crystal exemplified the opposite in their talk about movement related constraints and the need for extra planning in their lives post-stroke. Pre-stroke their life was far more spontaneous, they would *'just go – and do whatever'* but Jim-Bob's physical disability limited this, negatively impacting their quality of life. Crystal explained that her role in their relationship had always been to plan trips and pack suitcases but that this role had expanded greatly since Jim-Bob had his stroke.

*'Crystal: I think if you go away to an environment you haven't been to before, you know, you have to think of - is it flat? Or, if it's a hotel, you have to ask for a disabled room on the ground floor ... all those sort of activities you have to consider ... and the car you go in. [...]* Booking cinema seats – *we always book on a certain ... make sure it is on an aisle – this sort of thing. Yes. Ingrid: Stupid question, perhaps, would any of that have occurred to you before your stroke? Jim-Bob: No. Crystal: No, he used to just go ... Ingrid: Just go? Crystal: Yes, just go – and do whatever ... Jim-Bob: Uh-huh.'* Jim-Bob, page 36

Crystal compensated by additional planning although she admitted *'... sometimes it's easier not to do something than to plan it'* (Jim-Bob, page 39). There was tension associated with this role change, exemplified by statements from Crystal such as *'I'm thinking ahead even if he isn't thinking ahead.'* (Jim-Bob, page 38) and when she assumed a 'gate-keeper' role in activity selection. He described himself as *'imprisoned'*

by his lack of independent, confident and spontaneous movement and retained a determination to take some risks such as getting into a low car or visiting a new places.

The need for additional planning to compensate for physical limitations was also mentioned by Liz, however she took on this role of 'planner' herself in contrast to Jim-Bob.

*'I can't go anywhere in a hurry anymore because of my um ... walking difficulties ... nothing ... I have to sort of plan ahead to get from A to B ...'* Liz, page 25

#### Speed, distance and stamina

*'Well, I feel ... that if I can walk fast ... I'm in, say, going on a 'bus tour, like we do sometimes, if you can't keep up with the rest of them ... walking around the garden or walking round wherever it is, when you get off the bus ... if you can't keep up with them, you're no good ... you might as well stay behind in the coach.'* Rosa, page 59

Sufficient speed and stamina over appropriate distances was required for these outings, even with assistance. If she were unable to 'keep up' with the group Rosa was negative about taking part. This negativity which she related to walking slower may be her wish to avoid being a hindrance to others, or avoid being different to the rest of the group but it was also a (negative) value judgement of herself 'you're no good'. Rosa then said that her walking had got faster over time and described this as 'much better', suggesting an improved more positive value judgement (Rosa, page 59). All the participant's talk demonstrated the value they placed on having sufficient physical ability to maintain a reasonable speed over the required distance and terrain.

*'I couldn't walk any distance. I just couldn't do it ... I ... I felt so silly dragging the leg behind me ...'* Rosa, page 28

*'Well, not being able to walk so far ... is very frustrating. When you think that my son only lives at the top of the village... and I can't climb the hill now ... I can't go that far...'* Rosa, page 42

*'I like country walks on all terrain ... I used to like um ... if you like, going off-road, as it were, and walking hills and dales and um ... I would walk five or ten miles without thinking about it.'* Liz, page 9

Jim recounted walking his dog in the woods with other people post-stroke and being unable to maintain their pace. He spoke about other active hobbies that also required

stamina and distance walking in complex environments, such as fishing and, in the following extract, mushroom foraging.

*'Another one of my things I used to do, pre-stroke days, was ... um ... we used to go sort of wild mushroom hunting [...] that is through very uneven ground ... and you got to go through felled trees and branches and everything ... so that ain't too good ..Ingrid: And would you be able to do that now? Jim: Probably ... be able to go a little distance but not the distances we used to go along, you know ... I used to walk for miles ...'*  
Jim, page 45

Jim contrasted his limited post-stroke activity with the freedom of being able to 'walk for miles' pre-stroke. The unconscious freedom of comfortably walking distances that reasonable stamina and physical ability allows was reflected in all of the interviews. The boundaries or 'the limits' of one's body ability could be expected to change over a lifetime; for example with aging there may be expectations of a decline in stamina. Having a stroke that affected walking seemed to suddenly change the boundaries so that body limitations became more apparent to the individual stroke survivor.

Fatigue was an issue *'I get very tired quickly. If I do ever walk into town I've got to ... got to stop for a rest about four times ...'* (Jim, page 5). Liz complained that she felt 'worn out' and found *'I don't have anywhere like the stamina that I once had where I would be out all day and not even give it a second thought'* (Liz, page 10). Stamina and speed are interdependent aspects of walking and were valued by all the participants. Jim-Bob said that he valued being able to walk briskly indoors, specifically in relation to getting to the toilet urgently. He complained that sometimes his legs didn't respond fast enough to get him there in time. Mostly participants spoke about stamina, speed and distance in relation to outdoor leisure pursuits such as going for a walk or shopping although Jim also explained that not being able to comfortably walk distances outside in a reasonable time limited his alternative employment options.

The interviews gave an insight into the everyday experience of living with post-stroke walking difficulties and the value participants placed on having adequate stamina and being able to walk sufficient distances at reasonable speed without excessively limiting fatigue.

### Strength

Liz said she would value greater 'strength' and 'reliability' in the control of her knee that was affected by her stroke *'...it will 'snap' back um ... when I least expect it sometimes*

*and throw me off balance.*' (Liz, page 34). Jim also spoke about lacking strength in his lower limbs but Rosa's talk about strength was focussed on upper limb weakness. Both Liz and Jim said they would have liked strength and power to have been monitored more closely during their rehabilitation.

*'... I would have appreciated more advice on how to strengthen my knee, to measure that today ... you know, you have got this much control and in a week's time after these exercises you've got a bit more control and so on ...'* Liz, page 39

#### Balance, agility and manoeuvrability

*'They all stand up against the folding seat backs, don't they? and you've got a foot, probably, in order to squeeze past with what seems to me, again with my balancing, slightly wobbly, almost a sheer drop to my left.'* Liz, page 25

In this quote, Liz talked about the fear she experienced when trying to manoeuvre past people in tiered seating in a sports stadium. Moving in this situation was a complex physical task and a significant and frightening challenge, which Liz said she wished she could have avoided completely. She *'didn't drink all day'* to avoid needing to leave her seat and manoeuvre past people to get to the toilet (Liz, page 25). When considered in detail this can be seen as a complex mobility task, in a confined space, in a busy distracting environment, with potential for being self-conscious and at increased risk of falls.

Manoeuvrability and agility are interrelated concepts and it could be inferred from the transcripts that both were valued by these participants. Manoeuvrability has been defined as a movement or series of moves requiring skill and care and agility as being able to move quickly and easily [307] with synonyms including being nimble, light on one's feet, supple and dexterous; these are not words usually used in relation to hemiplegia. Good balance and body control appear to be pre-requisites for agility and manoeuvrability.

*'Ingrid: Were there other things that your leg got ... was a problem for? Rosa: Yes ... I ..I couldn't dress myself .. Ingrid: Why was that? Rosa: Because I couldn't ... I couldn't lift a leg ... I couldn't lift a leg to put my knickers on even. I ... I ... I over-balanced.'* Rosa, page 12

There were many other examples, Jim talked about negotiating uneven riverbanks in order to fish, Liz had problems walking on a rocky pebble beach and Rosa and Jim-

Bob both mentioned difficulties accessing the bath post-stroke due to their lack of body control.

*'You see, I couldn't lift the leg to get into the bath ... and when I got in the bath I couldn't get out.'* Rosa, page 46

Rosa, in particular, talked about a range of personal care tasks that she had problems managing independently post-stroke due to her walking related movement difficulties. Rosa was the only participant with paid carers, helping her with personal care on a daily basis; therefore these may have been issues that had become very important to her.

*'Ingrid: Is there anything else that you miss from before the stroke, that you would say ...the stroke ... the walking and the problems with walking really affected that? [...]  
Rosa: Well, the hygiene ... and the ... uh ... I used to ... make my ... cream my face ... and my body ... but they [carers] do cream my legs when I ask them to. They will cream ...  
Ingrid: It's not quite the same? ... Rosa: It's not the same as myself doing it.'*  
Rosa, page 48

In the extract above Rosa responded to a question about stroke and walking by explaining how she had always taken pride in looking after her skin by applying moisturiser. She appeared to associate this personal care task with the concept of walking post-stroke, perhaps relating it to lower limb function and implying that she considered walking in a wider movement context. The application of moisturiser to one's body requires coordinated dexterous movement of lower and upper limbs with a fair amount of flexibility without excessive fatigue i.e. agility. These examples show that the participants talked about valued movement activities that required balance, agility and manoeuvrability. However none of the participants actually named them or said they valued these movement attributes specifically.

#### **5.3.4.2 Valued movement activities**

The four participants were prompted to focus on walking by the project title 'Talking about Walking' and by the interview schedule but despite this participants spoke about a wide range of activities. Many were walking based and most required skilled lower limb movement often combined with upper limb tasks. The specific movement tasks that the participants spoke about will now be explored, starting with an unusual task.

*'I practised walking along the edge of my bath ... and I can't do that now ... I always used to go along, you know, handful of tiles in one hand and sort of popping them up ... these days, I can't even walk along the edge of a bath without, you know, sort of grabbing hold of something ... grabbing hold of the ceiling and that ... because I just haven't got the balance there any more ...'* Jim, page 13

In this quote Jim talked about the physical requirements of his pre-stroke occupation, specifically tiling a bathroom wall (balance, agility, ability to carry tiles and use arms to reach out). Physically he could not tile walls post-stroke and also could not tile floors because of *'... the effort of getting up off the floor as well so now, I can never do that'*. This kind of 'high-level' complex activity in a challenging environment is not the usual contents of post-stroke rehabilitation but Jim highlighted that it was an activity he valued, that he had attempted it and wished he could have done it safely post-stroke.

The participants all spoke about valued activities that they did outside their own homes. Jim-Bob focused on the importance of moving about independently in urban environments e.g. shopping and going to restaurants. Rosa, Liz and Jim all talked about the necessity and value of independent mobility in urban environments and, in addition, repeatedly spoke about how important it was for them to be outdoors in natural environments. They highlighted the following valued activities, walking (including dog walking) for pleasure and/or fitness, exploring, foraging, gardening, nature watching, photography, clambering, fishing and paddling in the sea. The different activity choices probably reflected participant's preferences for living in or spending leisure time in urban or more natural environments. Below is an exemplar quote.

*'It [fear of falling] would not put me off because of the pleasure I get when walking in the woods with the dogs and observing the wild life and getting fresh air is ... it far outweighs um ... issues I find about getting stuck in muddy puddles.'* Liz, page 14

Liz was the only participant to explicitly mention a link between mood and walking outside, although Rosa and Jim implied a link. Liz explained how she coped *'when life is really bad and when I am really feeling low and miserable about myself'* by walking outside with her dogs. She said she would *'... walk as far as I can ... in the woods or across the fields ... two or three hours out - even if I go and sit on a bank in the sun um ... is good for me. That clears my head and re-grounds me, if you like, and that's my space ...'* (Liz, page 37). The exercise itself and 'getting away from it all' may both be mood enhancing. Liz referred to the sensations of being outside and this was

important for other participants too. In the next passage, Rosa talks about her delight in walking and being active outdoors and the natural sensations this provided her with.

*'I miss seeing all the scenery and everything – I miss it so much ... being able to walk out and feel you are on your own being able to do something ... walking on your own ... looking at the trees and the birds and the wild life all around you ... that's an awful frustration ... just sitting here ... and I watch the trees over there ... I can see the birds and everything but it's not the same as getting out in it and walking in it ... it's so lovely to be able to walk out in the woods and just ... just feel the moss and the grass under your feet and everything. It's so lovely ... or all the fallen leaves ... Ingrid: Is that what you liked about your long walks? Rosa: Yes! I enjoyed that so much ... and then little streams ... and jump across little streams ...'* Rosa, page 43

Rosa emphasised through repetition how she was an active participant *in* the natural world pre-stroke and contrasted this to the 'observer' role that she has been forced to adopt post-stroke due to movement problems. Rosa gave a rich description of the natural sensations that she valued including touch, sound, movement and feel. She reminisced about using many of her senses to explore her environment and feel immersed in nature, with walking being the means by which she achieved this. She described simple pleasures such as feeling moss or leaves under her feet, bird watching or jumping over streams but post-stroke her enjoyment of these was hampered by walking problems. Finding pleasure in natural sensations is something that Liz mentioned in relation to paddling barefoot in the sea and Jim-Bob referred to, in the context of his time living in North America *'I miss the crunch of snow! When it's seventy below zero'* (Jim-Bob, page 52).

Walking outside for exercise to improve fitness post-stroke was talked about by Liz and Jim.

*'Definitely not – not as fit as what I used to be. Ingrid: And what do you put that down to? Jim: Well, my lack of mobility, I think, you know, me myself, you know, I'm not getting enough exercise really [...] ... Um ... basically what I mean by exercise is, you know, having to walk somewhere, you know and stuff like that.'* Jim, page 24

*'I walk every day with the dogs, maybe only quarter of a mile maximum, but I try to vary that ... I try to walk on uneven ground. I try to walk up hills as well as downhill. All the time trying to strengthen my left leg.'* Liz, page 8



These quotes show how Jim and Liz understood and used walking as a way of getting fitter and maintaining fitness pre- and post-stroke. Jim had been offered stroke specific gym based group sessions but was not very keen on this option and instead preferred *'... going out and doing natural things ...'* (Jim, page 57).

Apart from walking, participants said that they missed specific other outdoor activities. Rosa spoke about missing gardening, explaining that it was difficult because *'I couldn't use my ... my hands. And I ... I couldn't get my balance ... to do anything ... and I couldn't lift a spade ...'* (Rosa, page 28). At the time of the interview Rosa was accepting some help from her family so that she could continue gardening admitting *'when I went out on my own I tried to pull some weeds and I fell over.'* (Rosa, page 29).

Participants valued their pre-stroke ability to take part, with relatively few limitations, in various active pursuits such as walking, gardening, riding, fishing, tennis and running. All of these activities had an unspoken pre-requisite - movement.

*'So I can't run and I mind about that. I had a dream the other day that I was ... that I was running and doing something or other and then I woke up and it was so real and then it hit me that actually you can't do that anymore.'* Liz, page 12

The curtailment of these activities by her stroke has had a big effect on Liz, it has *'hit her'*, and she talked wistfully about her active pre-stroke life and coped by trying not to focus on things she could not do. Rosa explained that she played badminton, bowls and skittles and danced regularly right up until her stroke and then said that the stroke *'finished me altogether'* and her movement restrictions felt like *'the end of life'* (Rosa, page 17). Her word choice suggests the importance that she placed on the ending of these active hobbies that were important regular features of her pre-stroke life.

Rosa also explained how walking difficulties affected less 'active' areas of life, such as attending church services. Walking up to receive communion required many of the valued movement attributes described earlier i.e. speed, confidence and agility/manoeuvrability and she accepted help from a neighbour to manage this. Rosa described how the queue of people waiting for communion required her to vary her walking speed *'... sometimes it takes slow but sometimes there's a gap and you've got to be able to walk up smartly and to get in your place'*. Rosa said she felt self-conscious if she kept people in the queue waiting because then she would feel that *'everybody is looking at me'* (Rosa, page 58).

Post-stroke Jim-Bob found it difficult to return to work as a church minister due to his post-stroke walking problems, left sided hemiplegia and back problems which reduced his ability to stand for long periods. Liz was unable to work as a sports coach post-stroke and her other employment at a local radio station as a DJ was also limited by her stroke because of access issues. Rosa was retired pre-stroke and understandably did not speak about having to give up employment post-stroke. She did talk about how her voluntary activities had been affected, she explained that she had previously run and organised a group for older residents in her village and could not do this after her stroke.

Jim-Bob and Crystal described how he used to enjoy cooking but that his post-stroke problems moving, standing, lifting and carrying items affected his ability to cook efficiently. Another participant, Jim, also found difficulty standing, this made washing up less comfortable and also affected another of his hobbies - playing pool competitively in pubs. The quote below is lengthy but has been included to demonstrate how a lack of agility, balance, confidence, strength and coordination can have a significant effect on relatively 'less active' hobbies like pool playing. As a stroke survivor with mild left sided weakness and some sensory changes, mainly affecting the lower limb, Jim might have been expected to return to a hobby like pool that he had been passionate about and skilled at doing pre-stroke. However, Jim described how playing pool was less appealing when he cannot 'play like before' because of his physical disability. As a physiotherapist, I found that Jim's description made me rethink the degree of movement complexity I associated with this apparently sedentary hobby. It also made me consider the context of previously valued activity in more depth.

*'Ingrid: So you always quite liked kind of pub-based games? Jim: Yeah, yeah ...Ingrid: And do you still do those things? Jim: No ... no ... Ingrid: How come? Jim: I can't ... stand properly around a pool table and have control properly of my cue ... erm .. Ingrid: Your arms are working well enough though, or not? Jim: This one [left hemiplegic arm indicated], still, you know ... I still get tingly in it, yeah ... I still get some tingles in it and it's still not got ... the force ... the feelings back in it ... [...] Ingrid: So how come you couldn't play pool, did you say? Jim: 'Cause ... 'cause I can't stand still .... and ... control ... you know, reaching over and trying to control my cue. Especially ... when people ... you know, the level I used to play at used to be at quite a high level, you know .... people ... you know ... used to stitch you up and they put you in an awkward position ... [...] whereas before I could do it ... I could lean over and ... Ingrid: You could do all those compensations? Jim: Yes, yes. Ingrid: And so is that balance or*

*standing or ... what's the limit? Jim: I think it's balance ... and, you know, controlling my ... you know, as I say, I've got to keep my cue ... you've got to keep it rigid ... completely still ... Ingrid: You were kind of demonstrating ... and do you mean, like controlling like your legs and your arms and your middle all at the same time? Is that ...? Jim: Yeah, yeah [...] I just can't get the co-ordination and ... the stability ... Ingrid: And is that since your stroke? Jim: O yeah. Ingrid: Before your stroke, you were doing high level pool? [Jim concurs]. And have you tried much pool since? Jim: I've tried a couple of games and ... yes, I can still play pretty well but ... um ... it's not the same ... As long as they don't put you ... you know, leave you ... in that awkward position ... Ingrid: So if ... if you were absolutely as you were before your stroke physically, how would life be different now? What would you be doing that would be different ... would you be doing pool? Jim: Oh, yeah. I've had people ask me ... am I capable of playing pool yet and I say no, they say, if you are then let us know ... um ... Ingrid: Because you were good? Jim: Yes, 'cause ... cause I've got a good reputation ... I did have a good reputation around town.' Jim, page 32*

#### **5.3.4.3 Theme 1 - Valued aspects of movement – Findings summary**

Participants valued a variety of specific movement attributes and movement activities and there was generally consistency between participants although specific activities were valued by each participant depending on what was important to them.

<b>Superordinate theme 1 - Valued aspects of movement</b>	<b>Evidence from</b>
<b>1.1 Valued movement attributes</b>	All
• Independence and self-determination	All
• Confidence and safety	All
• Automaticity	All
• Spontaneity	Jim-Bob, Liz & Rosa
• Speed, distance and stamina	All
• Strength	Jim & Liz
• Balance, agility and manoeuvrability	All
<b>1.2 Valued movement activities (examples in brackets)</b>	All
• Moving around the home/garden (carrying items, standing, stairs and steps)	All
• Self-care, washing, dressing and ADLs (cooking, washing up)	All
• Leaving the house (visiting family, going out with others, church attendance, bus trips, cinema, restaurants, sporting events, shopping including managing crowds and escalators)	All
• Paid employment (tiler, sports coach, DJ, church minister) and voluntary work	All
• Walking and being active outdoors (walking for getting somewhere 'transport', pleasure or fitness, exploring, horse riding, foraging, gardening, nature watching, sensation seeking, photography, clambering, fishing, paddling in the sea, walking to a car/bus stop)	All
• Sport (running, cycling, horse riding, tennis, badminton, bowls, pool, dancing, skiing)	All

*Table 5-2: Evidence table for Theme 1 - Valued aspects of movement*

### 5.3.5 Theme 2 - Being active and taking part

This theme was developed from studying the participant's talk about being active and taking part in a range of activities that were affected by their post-stroke movement difficulties. Three subthemes were identified; how an activity was usually limited by

multiple factors, the coping strategies that the participants utilised and how participants spoke about mobility aids and their role in being active.

#### 5.3.5.1 Multi-factorial activity limitation

The participants talked about activity limitation and gave examples of how it was influenced by a mixture of factors such as physical ability, the task, environmental considerations and other people. Movement problems were central and common to all of the participant's 'being active and taking part' narratives.

Reduced physical ability, as discussed in Theme 1 'valued movement activity' and 'valued movement attributes', contributed to these participants having limitations in their activity and participation. Rosa said that she could not go shopping because she '*couldn't walk far enough*', was worried about falling over, especially in crowds, and couldn't get on the community bus to take her into town because she '*couldn't lift the leg high enough*' to get on board (Rosa, page 8). This is a simple example of the multi-factorial nature of her activity limitation and the restricting effects of her movement problems (limited walking distance, confidence and agility).

Jim summed up the multiple reasons for him stopping fishing as an '*accumulation of everything, really*' referring to his difficulty walking on uneven riverbanks, especially whilst carrying fishing equipment, and access to fishing areas since he sold his car (Jim, page 41). Participants spoke about various factors that limited their activity, including task and environmental characteristics.

*'... where I live it is virtually surrounded with blooming hills – you're either going up or going down – and ... um ... I'm not too bad at going down but it really tires me to go up now ...'* Jim, page 24

*'... I was unable to walk on those big pebbles because they were rocky [...] and I did find that my balance is still not good enough – my core strength is not good enough to keep me from falling in that situation.'* Liz, page 34

*'If I started walking there and I got past a certain point ... I ... am ... frightened that I would not be able to get back.'* Jim-Bob, page 15

*'I do try to go out as much as I can and enjoy this [sunny] weather but when it gets miserable I think 'Oh, well, another day in front of the telly then!''* Jim, page 24

These are reasonably simple examples however participants also identified more complex ‘webs’ of factors that were a barrier to completing an activity, an example of this was Jim’s dog ownership. Jim got his dog a few months after his stroke and found her good company *‘she was a real little live wire – a lovely little thing’* (Jim, page 17). He built up the distances he could walk her and was very positive about the fitness benefits of walking in the countryside stating his preference for *‘just going out and doing natural things’* over other forms of exercise such as attending a gym (Jim, page 57). He completed a sponsored three kilometre walk in aid of the stroke unit that he had been treated in and talked proudly about his walking ability during this post-stroke period.

*‘It’s like when I had my dog and used take her for great big long walks ...’* Jim, page 15

Jim used the sponsored walk and his dog walks as comparison points in his description to emphasise the recovery and subsequent decline in his walking abilities over time post-stroke, repeating *‘I don’t think I could’* or *‘would’*, doubting his own capability and being very aware of his reduced fitness *‘definitely not – not as fit as what I used to be’* (Jim, page 23). Jim reminisced about this positive post-stroke period when he had his dog, was fitter and had company from the dog and fellow dog walking friends. This was a subject that he returned to several times suggesting that this was an important, valued area of his concern.

In the three post-stroke years prior to the interview Jim had several falls in his home and outside, which he said contributed to his decline in walking ability. Jim said that his repeated falls resulted in fractured ribs, hospitalisation and recurring chest infections which negatively affected his exercise capacity and walking distance. He said that on some days he felt like he *‘never had the energy’* to take his dog for a walk and therefore eventually he had to *‘let her go because I just couldn’t really look after her anymore ... [it was] just tiring me out’* (Jim, page 18). Later Jim said he could have walked for exercise *‘on good days’* but without his dog he lacked the motivation, his *‘incentive’* had gone. He said *‘I just loved doing things with the dog but now by meself I get bored’* despite saying elsewhere that walking alone was a pre-stroke hobby (Jim, page 25). Jim’s talk about walking in general and dog walking/dog ownership contained many contradictions and demonstrated the complex interplay of factors that affected these activities.

Jim’s interview contained the two richest examples of the multi-factorial nature of activity limitation; his dog ownership and another example, his inability to return to

work. Both examples demonstrated the wide ranging effects of post-stroke mobility problems. Jim worked as a self-employed tiler pre-stroke and said he attempted to return to this but couldn't physically manage the work due to post-stroke movement problems including issues with agility, manoeuvrability and stamina (see Chapter 5.3.4.1). He attempted to organise his own phased return to work, by working for an old colleague who offered to *'get me back into it slowly ... but he has looked into it and the insurance company have said no'* (Jim, page 12). Jim spoke about how his attempts to find an alternative job were hampered by his poor literacy *'my English let me down'* (Jim, page 21). He was reliant on buses for travelling distances because without working he was no longer able to afford to run a car and this affected his ability to seek alternative employment. Taking buses was also challenging since bus stops could be *'a hell of a walk'* from potential employers (Jim, page 8).

No longer having a car restricted Jim's ability to find work, go fishing and also aspects of his social life, he admitted *'I don't seem to get out much these days'*. He reminisced about how he *'used to pick a load of friends up'* and go *'all round the country, visiting little tiny country pubs, [...] playing frisbee'* (Jim, page 45). Jim's lack of access to a car limited his ability to adapt to his post-stroke walking problems and this contrasted with the way Rosa, Liz and Jim-Bob adapted by relying on driving themselves or being driven to gain access to places to which they could not easily walk.

These two examples, Jim's talk about his dog ownership and difficulties returning to work post-stroke, demonstrated the wide ranging ramifications of his stroke, specifically how post-stroke movement problems contributed to a variety of activity and participation limitations. He explained that these negative changes in his lifestyle were *'not the fault of the stroke as such'* but his narrative demonstrated that these were stroke related and consequential limitations (Jim, page 4).

Liz spoke about her job as a local radio DJ. Her stroke did not affect her speech at all and one might have expected her to return to this sedentary employment post-stroke. However Liz showed how a mixture of stroke related issues such as movement problems, fatigue and reduced resilience contributed to her being unable to return to this job. She described the work as requiring concentration and being tiring because *'you've got to think on your feet, you've got to be very alert and aware of what you're doing'* (Liz, page 53). Post-stroke it was even more challenging because *'life is exhausting. Just doing the merest thing is exhausting'*. She worked at weekends and there was an access issue due to her post-stroke mobility problems, the studio *'was at the top of the building, you had to go up the back fire escape to get up and down at the*

*weekend as the main building was locked'* (Liz, page 53). Liz's description shows how, like Jim, her activity limitation was due to an accumulation of factors that eventually lead her to give up this job.

*'I'm just not one to give up but I just found myself not wanting to do it, you know, you have a sea change really in your head and you just think that's it, my heart's not really in this, I don't want to do it.'* Liz, page 53

Liz's description of the effect of a stroke as having *'a sea change in your head'* demonstrates the power of a stroke to alter motivation, ability and perspective. She did not mention it but the phrase 'sea change' originates from the Shakespeare's *'The Tempest'* [307] and refers to a transformation in which the form is retained but the substance is altered and this seems to reflect the changes that these stroke survivors talked about in their interviews.

This subtheme has evidenced the multi-factorial nature of these participant's activity and participation limitations and the central contribution of movement difficulties to these issues. Participants spoke about various strategies that they used to attempt to ameliorate problems and these coping strategies will now be discussed.

#### **5.3.5.2 Coping with movement problems**

These participants used activity avoidance, activity adaptation and mobility aids to cope with their movement problems post-stroke. Internal and external factors impacted on activity choices and the participant's approach to living with mobility problems post-stroke.

##### Coping with movement problems - Avoidance

All of the participants talked about managing risk, especially risk of falls and avoidance was a common strategy. Jim-Bob was keen to minimise the risk of falling over and therefore he avoided situations in which he perceived the risks were higher, admitting *'So I don't even try'* (Jim-Bob, page 16). He said that being in a situation where he could fall without anyone around to help was frightening and that it made him feel *'vulnerable'* (Jim-Bob, page 36). If accompanied Jim-Bob said he sometimes considered riskier manoeuvres such as getting into a friend's low car. Jim-Bob's willingness to take risks and apply physical effort to overcome obstacles was not consistent; the extract below shows how it was affected by his emotions.



*'Ingrid: What puts you off trying ... you know, pushing yourself? Jim-Bob: Um [Long pause 7 seconds]... um, I'm not sure ... Ingrid: The effort? [long pause] Or the consequences? [Long pause] Crystal: Or you think you are going to fail? Jim-Bob: Nope, I just think that ... sometimes I just think I feel sorry for myself and I, you know, all this crap has happened and uh ... it's not fair ... I don't want to have to think about this ...'* Jim-Bob, page 47

In this quote, Jim-Bob haltingly admitted that his avoidance of more difficult activities was linked to him not wanting to think about his problems. The pauses suggest that he had difficulty putting this into words and perhaps he had some reluctance about admitting these feelings, which may cause listeners or later readers to have a negative perception of him. In the extracts above, Jim-Bob demonstrated two avoidance based coping strategies that were also used by the other participants.

- Modified avoidance - avoidance of some physical elements of the task and task adaption i.e. minimising walking by using a scooter.
- Complete avoidance - avoiding challenging situations altogether i.e. avoidance of confronting physical limitations or difficult environments.

Walking in crowded places was challenging for these participants and they often appeared to avoid it. Rosa avoided going to more crowded places such as shopping in her local town until she had better walking ability and more confidence. Liz also mentioned avoiding crowds *'I just don't go, if I can possibly help it.'* (Liz, page 55). She returned to the subject of walking in crowds several times in her interview.

*'Ingrid: So the crowds wouldn't have affected you [pre-stroke]? Liz: No, but now I don't like crowds. I don't like being in an area where ... I don't like being indoors with lots of people at all. I can't go to a party, I can't go to the sales, I can't go to a packed supermarket – I just would rather not go there ...'* Liz, page 27

Avoidance of situations that made the participants feel vulnerable, especially to falling over, was a recurring theme in their interviews. Avoidance and adaptation were closely linked coping strategies and adaptation will now be explored in more detail.

#### Coping with movement problems - Adaptation

Having a stroke forced all of the participants into adapting their activity to allow for their changed physical abilities. They all spoke about changes that were required at home to make activities safer and easier. Accomplishment of ADLs was valued by

participants and required skilled movement and many of the valued movement attributes identified previously, such as agility, stamina and balance. Some tasks could be avoided but many required adaptation in terms of altering the task, location or equipment used. One example of altering the task and location was bringing the bed downstairs because *'... going upstairs to bed was impossible ... in the early stages of ... being at home. So we had to arrange for me to sleep downstairs'* (Liz, page 3). Other examples of changing task, location, equipment or accepting help within the home could be seen.

*'... when I get dressed I do everything on the bed, you know, sat on the bed to get myself ready.'* Jim, page 21

*'I couldn't wash myself properly [...] I couldn't lift my leg over and I couldn't do anything with the right hand. And so, I was stuck ... I couldn't do anything – so I had to put up with being washed all the time. It's terrible! When you are used to having a shower and then only having a wash. [...] I was so embarrassed! [...] It wasn't easy to accept ... them [the carers] at first, you know.'* Rosa, page 47

*'I couldn't dress myself [...] then all the carers came in ... it was so much easier when they came.'* Rosa, page 12

Participants appeared reluctant to ask for help, it was the 'last resort'. Rosa had been completely independent in ADLs pre-stroke but adapted the way she did these activities post-stroke due to movement problems. She accepted help from her family with household tasks and from paid carers for washing and dressing. Her interview reflected her mixed feelings about this help, she needed it but she found it hard to adjust to and would not accept it from everyone that tried to assist her *'I've got to bite my tongue and say that, 'I wish you wouldn't ... and say that 'I can manage, thank you very much, I'm all right'* (Rosa, page 58). Later, an occupational therapist organised her bath to be replaced with a wet room so that her paid carers assisted her to have a shower rather than a strip wash. Rosa described this simple structural adaptation as a *'relief'* that made *'all the difference in the world!'* (Rosa, page 46). Even structural adaptation was insufficient in some cases, Jim's discharge from hospital after his stroke was delayed because he needed to be re-housed *'they needed to find me a place to live because where I was then was up two flights of stairs which ... I find very difficult ...'* (Jim, page 2).

Jim adapted to his limited exercise capacity by pacing himself. He admitted that he found it difficult *'to keep up with housework'* and he talked about how he attempted to

adapt the household tasks by doing *'things in shifts'* and then resting *'I got to pace myself a hell of a lot'* (Jim, page 9). Jim did 'essential' tasks, such as washing up, but had difficulty with other cleaning tasks, which he said was due to problems standing and moving. He paused a lot when describing this perhaps due to discomfort admitting he was not really coping at home. He was not managing to complete the cleaning satisfactorily to the extent that his daughter did not want to visit *'she says it's too dusty for her boy'* (Jim, page 9). Jim was the only participant who did not want to be interviewed at home and hinted that this was because it was a 'mess'. Of these participants Jim was the most isolated, living alone without regular family contact and no paid care. He adapted to his movement problems by avoiding housework if possible and otherwise pacing himself.

Participants also spoke about how they adapted activities outside of the home by altering the task, location, equipment or by accepting help. Rosa held a friend's arm to enable her to walk in crowds or longer distances in church, on bus trips and when shopping *'I can go quite quickly... as long as I have her arm ...'* (Rosa, page 58). Rosa talked about how she had fallen over in the garden and had been persuaded by her family that she should not attempt gardening alone any longer and should wear a call bell. She also paced her activity to avoid fatigue. These various adaptations are exemplified in the quote below.

*'... I just did some [gardening] today with my grandson when he is here ... I don't do it on my own. [...] I like to keep going. I don't like to sit too long. I just sit down and have a little rest and then go and do another little bit.'* Rosa, page 30

Jim also talked about pacing when walking distances outside *'I've always got to sort of pace myself and make sure I can sort of rest'*. He explained that if his hemiplegic leg gets *'too tired it starts stumbling'* and then won't *'pick up properly'*. He described this feeling as *'the weariness'* and how it made him need to adapt by resting, sitting down or leaning on a wall. Jim said that he planned to buy himself *'a shooting stick so I've always got a seat on me ...'* (Jim, page 14).

Crystal planned their trips out, carefully pacing activity to avoid risk of falls and make life as easy as possible for both Jim-Bob and herself. She used their *'disabled sticker so you get close to places'* when parking the car and requested easy access seating (Jim-Bob, page 18). They adapted the activity and environment as far as possible to simplify the movement task although much of this adaptation was lead and controlled by Crystal rather than Jim-Bob himself.

Some adaptation was task and context specific. Liz had problems descending steep slopes and steps and spoke about an occasion on a dog walk when she was alone and realised that she could not get back down a hill, at least '*not upright*'. So she came down on her bottom admitting that this was '*not elegant but it worked*' (Liz, 12). On another occasion, Liz was faced with descending steep steps. This was in the very different context of watching an Olympic event, sat in busy tiered stadium seating with her husband and sons. She considered her options for adapting the activity or avoiding it.

*'Yes. If I had to get out of here how do I do it? And I thought, well, you will have to go down on your bottom, won't you? And, for goodness sake, Richard's sitting ... my husband ... is sitting beside me and he would help me, of course he would. But, I still can't ask ... I still can't ask for help and I wouldn't. If I had needed to go to the loo in the middle of the competitions, the games, I would have not been able to ask him to come with me because I wouldn't have wanted him to miss anything so I would have ... how ridiculous is that? You know, I would have got out and gone down on my backside which he wouldn't have allowed so it would all have been very difficult so hence not drinking anything all day. But ... I just wanted to see blue sky and be outside ...'* Liz, page 30

Liz's feeling of helplessness in this situation lead her to feel trapped and '*suffocated*' due to her walking problems, the number of people around and the tiered seating and therefore she '*didn't drink all day*' to avoid the need to manoeuvre out of her seat (Liz, page 25). She coped by adapting the task and avoidance and she used internal coping strategies, including positive self-talk and '*mental escape*'.

Liz could have adapted the situation to make her visit to the Olympics easier by requesting accessible seating perhaps in a disabled area but did not do this, perhaps to normalise the visit for her family or to avoid acknowledging her physical disability. Liz's desire to avoid the crowded event conflicted with her wish to join in with her family and maintain a sense of normality for their sake. These extracts demonstrate that her mobility impairments post-stroke were core to her activity and participation challenges. The quote below demonstrates her internal struggle to overcome her instinct to avoid the situation.

*'...nothing awful was going to happen to me and so I just had to shut up and get on with it ... and for the sake of them, you know, if you love your children, you love your family – you want them to enjoy themselves. And they did, they had a ... thankfully,*

*had a fantastic time. Why wouldn't you? It's a once in a lifetime, as we know, experience – the Olympic Games coming to London – great, good for them. Ingrid: And you did it. Liz: I wouldn't have gone – I would never go ... I would not want to go to anything ... You know ... Ingrid: Would it put you off going again? Liz: Oh yes! God, I really wouldn't want to go! I absolutely would not want to go but I would do it because if they wanted it. Ingrid: But Liz in life before the stroke ... Liz: Would have been delighted to go!' Liz, 31*

#### Coping with movement problems -Role of others

How the participants selected and executed movement related tasks was affected by people around and close to them. Rosa spoke about accepting help from family and paid carers to adapt activities and avoiding more challenging or risky movement activity if alone. Rosa was also 'looked after' or protected by others in her community. She talked about first attempting to walk with a stick rather than her wheeled frame and said that the community bus driver asked *"Gracious. Where's your pusher? You can't go without your pusher!"* and she answered *"Yes, I can ... I'm determined I'm going to do it."* (Rosa, page 5). Rosa explained that her stroke affected her whole family, it had *'made them worry more'* (Rosa, page 52). Within her interview there was also evidence of her son taking on a protective role, perhaps over protective, and acting as an 'activity gatekeeper'. Rosa described a conversation with her son after she had a fall in her garden that exemplified this.

*'... and he said, 'Mother', he said, 'What the hell are you doing down there?' I said, 'Well, Gerry ...'. 'You keep off that garden!' he said, 'Sit in the chair! You don't have to get and do that garden. Just sit in the chair.' 'Oh, I can't sit in the chair and do nothing', I said, 'I've got to do a little bit.' 'You don't need to do what you're doing,' he said, 'There's gardening and gardening. You don't have to do that.' I said, 'Yes, I like to keep going'. I don't like to sit too long. I just sit down and have a little rest and go and do another little bit but I just over-balanced. [...] So he said, 'Well, sit still then.'* Rosa, page 30

Jim-Bob also acknowledged that his stroke had impacted on *'my family's life...'* (Jim-Bob, page 39). Crystal also acted as an 'activity gatekeeper' by limiting the activities they undertook, she spoke about avoiding activities as well as adapting them to minimise risk. In one section of his interview Jim-Bob talked about how he had enjoyed skiing but that he wouldn't consider it post-stroke as he would be scared of 'breaking

something' (Jim-Bob, page 20). Crystal explained how they coped with his post-stroke mobility problems and managed risk in wet or icy conditions.

*'Crystal: I wouldn't take him. I wouldn't allow him outside. Ingrid: Because? Crystal: Because I would be afraid he would fall – somebody would have to walk with him. Our pathway out there, the tiles when they are wet are slippery. We know that and for us it's quite normal, we can just walk on them but we usually have two people standing with him because ... you know, he could easily slip on them.'* Jim-Bob, page 20

Throughout the section above, Crystal talked about Jim-Bob and what movement she would 'allow' him to do or 'let' him do, this emphasised her control and his passivity. At the end of this conversation, he said *'But I have got ski boots up in the attic. You know, maybe I will book a ski trip in Canada'* (Jim-Bob, page 20), this may have been a joke but it could also have been his way of trying to regain some control. The people around Jim-Bob, particularly Crystal, openly restricted his movement choices which may have added to his sense of 'imprisonment' or limited freedom due to his walking problems. This has similarities with Rosa who also spoke about her family's concern and requests for her to avoid riskier activities such as heavy gardening. Their family members were trying to protect them; this could have been an entirely positive experience however these participants hinted at an underlying tension. This protection could be interpreted as 'wrapping in cotton wool' or 'containing' the individual who is trying to make sense of living with post-stroke movement difficulties. There is also a potential conflict between task avoidance and modern theories of movement skill acquisition that are based on movement repetition practice of challenging activities (see Section 2.2.2.3).

This protective and potentially restricting role of other people was not apparent in Liz or Jim's interviews but they did talk about the help they could receive from other people. Liz said that she would now accept help and understood that *'people have to do things for me'* despite always having been *'fiercely independent'* (Liz, page 12). Her words show evidence of adapting to accepting help, but this was at odds to the rest of her interview, especially the sections referring to her visit to the Olympics, in which most of her talk was about coping independently and going to some effort to avoid asking for help from others. Liz talked her ongoing *'fight'* for independence *'... going right back to the beginning, I still mind about having to ask people to help me and I mind very furiously about that.'* (Liz page 25). Both Liz and Rosa talked about situations when they hid their difficulties and the extent of their coping strategies from those around them. Jim did not really speak about help from others, except to wish he could have

some assistance especially when he was unwell with 'flu and needed '*a little bit of looking after*' (Jim, page 44).

*'Well, I would like to ... you know, have help for about an hour a day ... but they won't let me have one.[...] I don't get nothing for the care side of it ... and whereas ... I find it very difficult, you know, to sort of ... to keep up with sort of housework and stuff ...'* Jim, page 9

Jim seemed to perceive indifference from people around him regarding his mobility problems, he talked about people walking past him when he fell outside a pub or people not offering him the front seats on the bus that are '*for all the people with walking difficulties*'. He said he knew that he was '*not high up on the list*' i.e. that his mobility was quite good but said '*it just annoys me when I've got to walk to the back of the bus and that ...and I think, bloody ignorant people!*' (Jim, page 25). His account of societal indifference contrasted with Rosa's description of offers from help and expressions of concern from her extended community and strangers. Age, appearance, gender, social class, environment, social context and stereotypes such as Rosa being 'a sweet little old lady' and Jim being a 'middle aged man' may have influenced the support offered by those in contact with these participants.

The participants in this study occasionally referred to the assistance received from health professionals during and after the EPIC study. Physiotherapists and occupational therapists were referred to in the context of helping, motivating and guiding mobility related exercises, providing assistive devices and adapting the home environment. There were no negative references except when participants talked about healthcare workers as activity gatekeepers during their post-stroke inpatient admission and when some participants said they would have liked more rehabilitation input.

#### Coping with movement problems – Self-efficacy

Liz and Rosa talked about their regular self-guided walking practice. They set themselves walking goals and 'coached' themselves to gradually walk further, to negotiate more challenging environments and to reduce reliance on mobility aids or other assistance.

*'... the more I pushed myself ... the more I found that very slowly my muscles started to come back ... the control of my muscles started to come back and I managed to get some strength back into ... into my body.'* Liz, page 3

*'... so out I goes and I walked up the middle of the road and back again. Up and down and up and down [...] I didn't want anybody coming out and seeing me and interrupt me – or they would have kept me talking and I wouldn't have got my practice in ...'*

Rosa, page 41

These quotes show their determination to practice and improve. Liz and Rosa were unable to maintain a uniformly positive approach and both described times when they felt more negative however they both appeared to have strategies to overcome this. Some strategies relied on internal reinforcement, including positive self-talk.

*'I think to myself sometimes ... 'You can do it! You can do it quite easily, you know, if you want to try ... just try.'* Ingrid: *Keep concentrating ...* Rosa: *Keep concentrating on where you put your feet.'* Rosa, page 39

Both women identified goals and focussed on improving what they *'couldn't do'* (Liz, page 33). Rosa spoke about aiming to walk with a stick rather than the more stable four wheeled rollator *'I'm determined I'm going to do it'*. When she first tried she did manage to walk around town with the stick but said that she compromised on walking distance *'I got what I wanted from the shops and I made that do! But I was very pleased with myself'* (Rosa, page 5). As her mobility improved Rosa (and Liz) gained positive reinforcement from other people, including family, friends and health professionals *'I was amazed at myself but my sons were also amazed at me'* (Rosa, page 2). These two participants had resilient, generally positive approaches to achieving their movement goals and overcoming barriers to more independent mobility. Their interviews demonstrated that they believed that they could improve their performance of a movement task and influence their own movement ability through their own effort. This psychological construct is termed self-efficacy and sometimes referred to as a situation specific form of confidence. It was first defined by Bandura as people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives [308]. Thus Liz and Rosa's interviews suggest that they had reasonably high levels of walking related self-efficacy.

Jim's interview also demonstrated walking related self-efficacy, *'most of the time I try to leave my stick in there and try to walk along by myself'* (Jim, page 27) and *'I still try and walk down town, you know, at least ... well, once a week'* (Jim, page 26). However he could not maintain his efforts as consistently as Liz and Rosa and said he often took the easier option *'these days I get on the bus and I think 'you lazy git!''* (Jim, page 25).



Jim-Bob and Crystal did not talk at all about Jim-Bob pushing himself to achieve movement goals, his coping strategies appeared to be largely based upon avoidance or adaptation. He did talk several times about how he could not always be bothered to try *'I knew that I was being lazy'* (Jim-Bob, page 58). Therefore he appeared to have the lowest levels of walking related self-efficacy.

The coping strategies adopted by these four participants appeared to reflect their varying levels of self-efficacy. Therefore walking related self-efficacy appeared to affect their activity and participation; it had implications for task practice and progress and therefore may have affected their mobility outcomes post-stroke.

#### Coping with movement problems - Mobility aids

All of these participants drove or were driven (by car or bus) which enabled them to access places that were further away from their homes. Is a car or a bus a mobility aid? Such transport is not usually considered a mobility aid in rehabilitation however perhaps they are aids to mobility, if mobility is considered in the wider context of people's lives. Access to motorised transport maintained many opportunities for these participants to take part and be active even if the way they did activities was altered and they needed additional devices or help from another person to achieve them. For example, Liz associated her independence with access to driving her car and use of FES (she also relied on her stick although this was not specifically mentioned in the quote below).

*'My car is adapted so I can drive it, so if I want to take myself off shopping or go the hairdresser or go to the dentist or do anything I want to do, I can do it without having to rely on other people and that independence is absolutely essential to me and the FES device, as I have said before, allows me to do that. Although there are things I can't do there is a lot I can do.'* Liz, page 17

They all used specific devices designed to support them and help their ability to walk. Their descriptions of using walking aids have been grouped below by device, with quotes selected that give the richest insight into what it is like to use each device. Quotes reflecting positive and negative aspects of the assistive device have been included if available.

#### Walking stick

All of the participants used a stick for some or all walking activity at the time of the interviews and they were generally positive about using a stick. Most of their talk about

stick use centred on it helping them to feel more confident, to improve balance and avoid falls.

Jim was attempting to reduce his reliance on his stick but recognised its usefulness, especially if he lost his balance to *'Stop me from stumbling over when I do stumble ...'* and as something to lean on if he needed to rest (Jim, page 51).

*'I don't use my stick when I'm indoors. I try to leave that alone ... when I walk around the house.'* Jim, page 3

Use of a foldable stick that could easily be put away and carried, helped Jim practice walking independently. The environment also altered the degree of mobility challenge; he said he managed to walk on the flat but needed more support than a stick could offer on steeper slopes or stairs because *'I've got to sort of pull myself up by the hand rail, plus hold on, for feeling secure ... er ... feeling safe'* (Jim, page 28).

Jim-Bob relied more on his stick than Jim, he said that he felt *'fine'* about using a stick and explained *'I don't think I'd go anywhere without it because ... I wouldn't feel safe ...'* (Jim-Bob, page 53).

*'The drawback ... is that ... when I place it err... on the side of something it falls and the noise that it's going to make in a second really annoys Crystal! Crystal: There is that stick again! Ingrid: So that crash – it made her jump even though she could see that you were about to do it? Jim-Bob: Yeah. [...] Ingrid: Is that a negative or a positive? Jim-Bob: That's a positive! Ingrid: You can use your stick to annoy your wife? Jim-Bob: That's right, yes. And the other thing is to poke her! And I poke my daughter with it and she ... Crystal: Gets very annoyed. Very annoyed. Ingrid: I can believe it. Jim-Bob: Oh yes! Crystal: Teenagers! Jim-Bob: It's just like flint. [mimes striking flints] Ingrid: Igniting your spark? That's what you are on about? Crystal: And you find that amusing, don't you ... Jim-Bob: I do ...'* Jim-Bob, page 53

Use of his stick increased Jim-Bob's feeling of safety so he said that he used it all the time. He also described secondary benefits from using his stick that amused him. Sticks that are leant against things readily fall over and Jim-Bob used this to surprise and annoy his wife and he also used his stick to poke members of his family, to provoke a reaction.

Liz accepted that she needed a stick when she walked outside but ensured that it was one that she felt less self-conscious about and perhaps was more suited to her outdoor

and independent self-image. She was definite that she did not wish to use a standard issue NHS stick.

*'I use a stick if I'm out and about, yes, if I'm outside. [...] I have a stick I have cut from the woods. I don't want a proper, you know, NHS stick – I can't bear that.'* Liz, page 19

Rosa also found using a stick useful support and confirmed that she felt a sense of progress trying to walk with the stick, which indicated that she applied a kind of hierarchy to the walking aids on offer, valuing independent mobility with minimal assistance most highly.

*'I prefer to go with a stick because I must make myself do it. Ingrid: You feel that that's progress? Rosa: I feel that's progress when I ... I walk with my stick.'* Rosa, page 39

#### Wheelchairs and scooters

All of the participants had used a wheelchair at some point and some had used a scooter. Their interviews revealed mixed feelings about using these devices from very positive to very negative. The scooter enabled and empowered Jim-Bob to go out alone in his community but Jim associated scooters with being 'lazy' and feeling 'embarrassed'.

*'Mind you, I prefer to go out in my little ... Ingrid: Scooter? Jim-Bob: Scooter. Ingrid: And why is that? Jim-Bob: Well, because ... that's gonna get me there. It's not gonna fail and ... uh ... I can run people down! Ingrid: And when you say 'it can get me there' do you mean you don't trust yourself to get you there? Jim-Bob: I don't. Ingrid: Because? Jim-Bob: Because ... um ... my legs won't do it. I don't trust myself to walk to the shops [...] when I go to Waitrose ... um ... and I'm in the scooter the ... uh ... the shop assistants are quite good if they see me reaching for something they will come along and say, 'What would you like? I'll get it down for you,' and err ... which is great. Ingrid: How about when you are on your feet? Jim-Bob: I wouldn't be in Waitrose on my feet. It's too far to walk ...'* Jim-Bob, page 15

Jim-Bob described his scooter as reliable and compared favourably it to his own unreliable and untrustworthy body. Scooter use gave Jim-Bob control e.g. it enabled his self-sufficiency by allowing independent outdoor mobility and safe/timely toilet access. He also suggested that it had social benefits, for example shop assistants were more helpful. Perhaps the scooter was as an outward sign or 'badge of disability' and Jim-Bob used this to his advantage to achieve his goals when shopping. He

appeared to value the scooter as the mobility aid that enabled greatest independent mobility with minimal assistance. Compared to Jim, Jim-Bob was much more accepting of use of a scooter in his community. Jim-Bob expressed only two reservations about use of his scooter, firstly that he wished it could go faster *'soup it up a bit more'* and secondly that it could be dismantled more easily to get in the car. Needing a second person to dismantle and lift it into the car not a big issue for Jim-Bob as he could not drive post-stroke and would therefore always be driven.

Jim's talk about wheelchairs and scooters was generally negative, he did not feel he needed either but reluctantly conceded that a scooter could help him if his mobility deteriorated.

*'Ingrid: And is there anything else you have ever used? You never used a scooter or a wheelchair, or anything like that? Jim: No, no! Ingrid: Or anything like that? I can't think of anything else... Jim: No, my daughter keeps on saying to me she is going to save up and buy me ... a moped or scooter. I said, 'I won't use it'. I said 'I wouldn't want to be that embarrassed', you know, I... Ingrid: You could use it when you were outside away from town. Jim: Yes, yes, I suppose but it's getting the thing into town ... stuff like that ... you know, no, I would feel absolutely too lazy if I had to use one of them. Ingrid: You think it would stop you doing the exercise that you need to do? Jim: [Sighs] ... I think ... I think I would be totally embarrassed if it did actually come to that, you know, if I had to, I suppose, yes, I would have to ... um ... repent and sort of say, yes, I will use one then'* Jim, page 53

Rosa described how her upper limb difficulties stopped her using a scooter successfully *'I couldn't drive it because of the right arm ... I couldn't hold the wheel [...] and I had a job to steer it properly ... and I wasn't safe'* (Rosa, page 43). Her talk indicated that she would have liked to be able to use it for independent mobility because she could not easily walk everywhere she wanted in her village and could not drive herself, thus the scooter would have enabled maximal independent mobility with minimal assistance.

Liz was the only participant to speak about using a wheelchair (she did not use a scooter).

*'I have got a wheelchair but I try very hard not to use that. Ingrid: So why is that? Liz: Er ... Too vain! I can't bear the gadgets of disability. I refuse to admit that I can't do it. Ingrid: You don't mind the stick? Liz: No, I don't mind the stick. Ingrid: But the wheelchair pushes it too far? Liz: Yes.'* Liz, page 19

Liz explained that she was *'too vain'*, perhaps too self-conscious, to use a wheelchair and attempted to avoid these *'gadgets of disability'*. Perhaps she viewed wheelchairs as an outward symbol, akin to a badge, which may infer belonging to a group. Liz did not appear to wish to be identified as *'disabled'* by the mobility aids she used; even her stick was one of her choosing *'cut from the woods'*.

Liz described herself as being *'confined'* to a wheelchair early after her stroke (Liz, page 1). This implied that she associated wheelchair use with being trapped, perhaps also with being more dependent.

Liz did not talk about using a scooter but did explain how she depended on her car for distances and used the stick and FES when she got to her destination. This may be because a stick or FES are more discrete, are more in line with her self-image or they may be the minimum level of assistive device that would enable her to achieve her goals. This could indicate that Liz considered there to be a hierarchy of devices and valued independent mobility with minimal assistance most highly.

#### Rollator

Rosa was the only participant to use a rollator, a four-wheeled outdoor version with brakes, a basket and seat. She found it helpful for confidence and walking on uneven ground but did not regard it as something she wanted to use long term because she wanted to *'progress'* to using a stick.

*'The walking frame [...] makes me confident on the rough walking but ... I prefer to go with a stick because I must make myself do it. Ingrid: You feel that that's progress? Rosa: I feel that's progress when I ... I walk with my stick ...'* Rosa, page 39

Rosa said that she felt that the outdoor rollator, her *'pusher'*, and her stick were both *'great'*. The rollator had some advantages, a seat and a basket for carrying items (Rosa, page 4), and more stability on rougher ground but despite the convenience of these features Rosa still encouraged herself to *'progress'* to walking with a stick.

#### Ankle-Foot Orthosis for correction of dropped foot

Liz was the only participant to talk about having used a splint or brace. She used an ankle-foot orthosis (AFO) for correction of dropped foot and she said that it worked well to improve ankle stability but that it had some drawbacks. Liz had the most severe and persistent dropped foot problems of these participants, which may explain why the others did not use an AFO. Her foot twisted into plantarflexion and inversion due to

plantarflexor over activity and she used an AFO to control its position. She was issued with an AFO to control foot and ankle alignment as an inpatient and only stopped AFO use when she started using an alternative, the FES device, during and after the quantitative trial.

*'I had the dropped foot ... the common dropped foot problem, that if I tried to move my left leg I felt I would trip um ... and my left ankle inverted as well ... so I had a brace fitted to my ankle to ... which went inside my shoe ... to try to prevent this so that I could actually put my foot to the floor ... safely ... without my foot twisting under me.'* Liz, page 3

*'The drawbacks that I had with the splint, apart from the fitting of it, it was uncomfortable to wear but also it stretched my shoes so it almost had a ... a detrimental effect, despite it holding my ankle upright, it reduced the ... support that my shoes offered me, as well as it being cumbersome and so on.'* Liz, page 22

*'[the AFO] was discarded fairly early on and, again, I can't remember why now. Presumably because it ... oh, one broke, I remember, and then in terms of its replacement I think it was felt that we would try then without and with the FES and see how I got on with that. It's just progressed from there.'* Liz, page 21

The AFO helped Liz gain control of her ankle. She admitted that in the early days after her stroke she was so *'desperate to get upright and on my feet and walking again'* that she would have *'worn anything given to me just to get me going'* (Liz, page 22). She mentioned several issues with wearing an AFO in terms of comfort and footwear and then said the AFO was *'discarded'*. This word may suggest that Liz placed low value on the AFO and her phrase *'progressed from there'* indicated that she viewed FES as part of her mobility improvement/progression in a way that perhaps the AFO was not.

#### Functional Electrical Stimulation for correction of dropped foot

Rosa and Liz used Functional Electrical Stimulation (FES) for correction of dropped foot and talked about FES in largely positive terms. These included descriptions of improved foot and ankle alignment and increased confidence, independence and walking distance with FES. Liz was in the FES group during the Phase 1 trial and said she had used FES on an almost daily basis over the three years since starting the trial to control her problems with hypertonic dropped foot. She described some drawbacks to using the FES but was mostly very positive. Rosa was not in the FES arm of the trial but was referred for FES soon afterwards, funded by the NHS. She had flaccid

dropped foot and used FES for more than a year before deciding she no longer needed it.

Most of Liz and Rosa's talk was about the benefits of FES, although they did also describe some negative aspects of FES use, which were largely about practicality. The fact that the interviewer/researcher had introduced them to FES via the original trial or associated referrals may have contributed to their positive focus regarding FES. However their reported daily/regular use of the stimulator combined with their detailed descriptions and their degree of repetition of their positive FES experiences suggests that they were both accepting of this mobility aid and gained benefits from its use that outweighed negative aspects. These participants appeared at ease describing their experiences of living with post-stroke walking problems and using FES and provided rich and detailed descriptions of this; they may have been more forthcoming as they knew the researcher had an interest and clinical expertise in this area.

The FES device enabled Liz to have independence (it *'gives'* this to her) and she repeated this several times in her interview indicating the importance of this *'gift'*.

*'I have got my FES device and that to me is the best thing ever – that gives me my mobility'* Liz, page 17

*'... it [FES] gives me my independence, it's just fabulous.'* Liz, page 20

*'With the FES device I am able to walk ... to do most of what I would want to do ...'* Liz, page 12

The combination of the FES and access to a car (as well as her stick) allowed Liz to be independent or self-sufficient and enabled her to fulfil her roles *'I can do it without having to rely on other people'* (Liz, page 17). She said that she used FES *'all day, every day'* because without it, her foot would *'twist under'* and this would make it impossible to walk on uneven ground or walk *'any distance'* (Liz, page 18).

*'So, I manage it, it's not beautiful, it's not as, you know, it's not a normal movement but ... I'm ... I am fairly mobile now with my FES device, which is just the best thing ever!'* Liz, page 8

Liz relied on the FES to help her *'manage'* her mobility problems but recognised its limitations; her walking was not *'normal'*, not *'beautiful'*. Ankle control was not possible in all activities *'... my left ankle, even with my FES device, would not take me down the hill safely'* (Liz, page 12). This may be because hypertonia is often task dependent and

increased by anxiety or effort. Hypertonia may explain Liz's concerns about attempting challenging tasks such as getting off an escalator i.e. the FES may be insufficient to control tone in some more demanding circumstances *'I wouldn't be able to trust that my left leg was being talked to by the FES to get me off the escalator'* (Liz, page 48).

Liz did mention some drawbacks to FES use. She said she avoided shorter skirts, presumably because she did not want her FES device to be visible, but immediately added *'That's just how it is. It doesn't matter. It doesn't matter ... I just couldn't live without it [FES] – it's wonderful.'* (Liz, page 20). On holiday she *'missed not be able to paddle in the sea barefoot because, of course, I have got the FES device and the foot switch'* (Liz, page 15). She also said that finding the correct position for the electrodes was vital and needed her daily attention.

*'The only other minus if I have to be absolutely picky and believe me this is not an issue ... is you do need to get the pads placed accurately in order for it to work to the optimum benefit. There is a very small margin of error, if you like, before it won't be effective and um ... I'm aware instantly whether I feel safe with it or not [...] That's frankly, apart from the worry about it getting wet or it not working today, is the only issue with it that I have ... it gives me my independence'* Liz, page 20

In most instances that Liz raised any negative aspect of FES use she quickly balanced it with talk about how important daily use of FES was for her independence, perhaps indicating that she tended to overcome or adjust to any issues. It is likely that the advantages of FES use outweighed the disadvantages as Liz wore FES all day, every day and had done since being given it soon after her stroke.

Use of FES gave Rosa confidence and better gait quality i.e. *'walking properly'* (Rosa, page 13). Rosa described the conscious effort required to drag her leg along when walking and how this reduced with use of FES and over time.

*'FES gave me confidence ... it made me lift my foot off the floor. When I was walking, I was walking properly – putting one foot in front of the other ... automatically ... without me having to drag it along ... drag it along like I was doing ... I used to walk with the left foot and drag the right one behind me – but now I lift it. I can lift it and walk quite good altogether now.'* Rosa, page 13

*'It gave me complete confidence. I would walk up there ... and on the rough pavements with the stimulator ....'* Rosa, page 13



Rosa said that the FES gave her *'complete confidence'* allowing her to walk *'without worrying'* except on challenging uneven terrain when she still needed to *'be careful and don't fall over'* (Rosa, page 13). She repeatedly described the FES in strong positive terms e.g. *'tremendous'* and *'marvellous'* (Rosa, page 40). Rosa said that using FES marked a turning point in her recovery post-stroke by enabling her to have enough confidence to return to going shopping alone. She contrasted her new independence to a time before or without the FES when she said she *'couldn't do anything'* (Rosa, page 6). While apparently factually inaccurate since Rosa also talked about how she was active albeit with limitations before the FES, Rosa's exaggeration may highlight the lifting of some perceived mobility restrictions and the relative importance she placed on the activities she could undertake once she started using FES.

After regular FES use and walking practice, Rosa was comfortable and confident walking outside with FES and she said to herself *'now I wonder if I could try and go without it?'* (Rosa, page 41). Rosa's ultimate goal appeared to be self-sufficient independent walking and minimal reliance on others or assistive devices i.e. as close as possible to her unaided walking pre-stroke.

#### Reducing reliance on walking aids

Although these participants approached use of mobility aids in varied and individual ways, they had all identified a mobility aid or combination of assistive devices that enabled them to maximise their perceived independence. All of the participants, except Jim-Bob, talked about how they actively pushed themselves to improve their walking and reduce their reliance on walking aids. Rosa's description of trying walking outside without FES showed how she implemented encouraging self-talk, incremental goal setting and regular practice in the process of reducing her reliance on a mobility aid.

*"Now don't forget you are going to try without your stimulator. Just see how you get on' and I walked up the Close ... 'Yeah, you're not dragging your foot ... that's all right ... keep going, keep going, keep going.'" Rosa, page 13*

They generally wanted to use the least supportive walking aid or none at all; they aimed for maximal independent mobility with minimal assistance. Jim said that this was not completely straightforward for him *'most of the time I try to leave my stick in there and try to walk along by myself but ... if I got seen by certain people I could lose certain benefits'* (Jim, page 27).

### 5.3.5.3 Theme 2 – Being active and taking part – Findings summary

Participants described the multifactorial nature of their walking related activity limitation and how they coped with mobility problems post-stroke. They also described the role of walking aids in their activity and participation. There was generally consistency between participants.

<b>Superordinate theme 2 - Being active and taking part</b>	<b>Evidence from</b>
<b>2.1 Multi-factorial activity limitation</b>	All
<b>2.2 Coping with movement problems</b>	All
• Avoidance	All
• Adaptation	All
• Role of others	All
• Self-efficacy	All
• Mobility aids	All
○ Walking stick	All
○ Wheelchairs/scooters	All
○ Outdoor four wheeled rollator	Rosa
○ Ankle-Foot Orthosis (AFO) for correction f dropped foot	Liz
○ Functional Electrical Stimulation (FES) for correction of dropped foot	Liz and Rosa

*Table 5-3: Evidence table for Theme 2 - Being active and taking part*

### 5.3.6 Theme 3 - Control

The interview structure focussed on the experience of walking post-stroke and participants responded by talking about valued aspects of walking related movement (Theme 1) and the impact of walking problems on being able to be active and take part in self-selected activities (Theme 2). Participants also returned repeatedly to walking related examples of struggling to maintain control over their bodies and balance or their situation and this is the basis for this theme 'Control' which includes control of body, balance and situation.

### 5.3.6.1 Control of body and balance

Rich insights into how it feels to try to control limbs that have been affected by stroke were identified from the transcripts. The participants shared examples of problematic walking related activity, which suggested that they valued automatic movement, as discussed in Theme 1 (Chapter 5.3.4.1). In these first person accounts of diminished body control, the participants used descriptions that indicated that they thematised their body or body parts i.e. their body became the object of their attention due to its dysfunction.

*'It did illustrate to me how my head is not connected to my left [hemiplegic] leg at all ... my brain wasn't talking to my left leg. It didn't even try to move, you know, just nothing happened. It was like me trying to move your leg.'* Liz, page 48

Liz discovered a problematic discontinuity between her thoughts and her actual movement performance and this is often referred to as a self/body split. Her simile of this being *'like me trying to move your leg'* illustrates the extent of her perceived disconnection from her leg; it was as separate from herself as another person's limb. Self/body splits were apparent in all of the interviews.

*'I'm thinking, "Work – you stupid leg" and it doesn't do it.'* Jim-Bob, page 12

*'It's a lot do to with my leg, you know ... because if it gets sort of too tired, it starts stumbling and ...It ... just of sort of can't pick up properly and that, you know.'* Jim, page 14

*'I turned round and my leg hasn't come with me and the foot's still there ... and I over-balance then and fall down.'* Rosa, page 30

At times the participants all used the possessive adjective with respect to their leg or foot *'my leg/my foot'* which implies a relationship between self and the body part however they also sometimes referred their leg or foot as *'it'*. This use of *'it'* or *'the foot'* accentuated the leg or foot as the separate object of attention and was often used in sections of the interview when the participant was talking about struggling to control their hemiplegic body part.

Jim described how his knee could *'go'* underneath him and said his own unsteadiness was *'quite embarrassing sometimes'* (Jim, page 28) as well as leading to injuries that hospitalised him. At times all of the participants said they were fearful of falling due to their impaired body control. A *'disconnected'* leg resulted in these participants talking

about their increased cognitive effort when trying to move it, increased discomfort and greater risk of falls. Liz described all of these issues in the following quote, in which she spoke about attempting to walk soon after her stroke, before she had started using FES.

*'... without looking, visually, at where my foot ... how my foot was hitting on the ground ... I could not feel my foot touching the floor [...]. I did not trust my foot. I couldn't know that when I put my foot to the floor my foot would be on the floor [...] I would have to look down to check that my ankle hadn't twisted over and the initial touching the floor you don't feel but as soon as you try to put any weight on it the pain was so acute ... but by that time it could be too late, in that your balance was gone [...]. So it was a very frightening time because I didn't understand why my body was behaving in this way and I didn't trust it.'* Liz, page 4

This is a detailed first-hand explanation of the experience of trying to step on a leg that has been affected by post-stroke motor and sensory impairments, including high tone causing plantarflexion and inversion. She could not *'feel'* her foot on the ground and if she transferred her weight onto her *'twisted'* or inverted and plantarflexed foot she suffered intense pain and her *'balance was gone'*, resulting in a *'frightening'* experience that caused her to lose trust in her body. Liz compensated by remembering to check her foot position visually and increased mental effort. Her foot position in walking could no longer be *'taken for granted'*.

Increased cognitive effort directed at moving *'the foot'* was also spoken about by Rosa in the context of turning round. She scolded herself *"You silly thing", I say, 'bring your foot with you. Don't forget the foot.'* (Rosa, page 30). Jim-Bob and Jim experienced variable foot drop *'there are some times when I can pick up my left foot and other times I just drag it because I think [...] It doesn't want to do it properly'* (Jim-Bob, page 12). They associated worse foot-drop with tiredness and Jim-Bob also said stress, back pain and distraction made it worse. When asked what foot drop was like if someone talked to him while he was walking Jim-Bob implied that it would not be possible, he replied that he was *'Not even sure I can walk and chew gum at the same time'* (Jim-Bob, page 12). Jim-Bob found difficulty maintaining the cognitive effort required to lift his foot and sometimes gave up trying, which links to the self-efficacy subtheme in Theme 2.

*'I knew that I was being lazy and I wasn't picking up my left foot – I just thought, "Oh, blow it! I don't care" – and ... uh ... and so when Crystal reminded me ... it just sort of ... would even drag my foot even worse ...'. Jim- Bob, page 58*

In Jim-Bob's quote above, Crystal's reminder to lift his foot appeared to have a contradictory effect. Jim-Bob was the only participant to admit to reacting in this way to external comments. Walking or moving in front of other people sometimes made participants feel self-conscious *'I think everybody is looking at me'* (Rosa, page 58).

All of the participants also talked about 'other people' who had positive effects on their walking and were necessary to help them compensate for their impaired body control. These other people were sometimes staff on the ward, physiotherapists, occupational therapists or friends and family.

*'They said now hang onto the parallel bars and we are going to get you to stand up ... and I want you to walk to the other end of the parallel bars [...] when I first stood up I realised I didn't know how to walk. I was... I was frightened and frustrated and angry ... Ingrid: Because you didn't know how to walk? Jim-Bob: Yeah [...] Physically. I didn't understand what she meant. So she said, "I've got a video I can show you ... of a person walking ... and I can slow it down so that you can see exactly what the person does." And I said, "That would be great because I don't know what you are talking about". And so I saw it ... and I thought I don't know whether I can do that. So she grabbed my foot ... she said, "Don't you move it ... let me place your foot for you." And she placed my right foot and she got another physio and placed my left foot.'* Jim-Bob, page 5

*'She [a neighbour] comes and helps me up to the altar - she takes my hand for communion ... takes my arm and guides me up and I can go quite quickly up as long as I have her arm [...] and she's got a firm grip and I feel so confident I feel I could walk miles with her.'* Rosa, page 58

*'My walking was non-existent without considerable support. I couldn't stand properly ... Um ... I felt if ... I looked like a tree in the wind ... er ... waving about ... I felt that if I stood without ... well, I knew that if I stood without support I would have fallen over.'* Liz, page 1

In these quotes, the participants talked about occasions when they needed physical support or guidance from other people to stand or walk safely and confidently. Jim-Bob said that the stroke caused such a lack of body control that he felt as though *'my hard*

*drive had been erased*' (Jim-Bob, page 22). Liz's simile also suggested that she perceived herself as out of control and subject to external forces *'like a tree in the wind'* (Liz, page 1). Post-stroke these participants struggled for control of bodies that had become separate objects of their attention because they lacked skill, strength, dependability and predictability.

#### 5.3.6.2 Control of situation

Liz spoke about feeling out of control in specific situations that she related to body control during walking *'I am not safe on my feet'*. She attempted to avoid or adapt situations that caused her to feel this way because *'nothing is more frightening than falling and not being able to save your face, your head'*. She said that this *'dictates what situations I put myself into'* (Liz, page 12). She particularly feared crowds but forced herself to hide her anxiety on a trip to the London Olympics.

*'I was just frightened of the whole event [visiting the Olympics] – being out of my depth in that situation – not feeling comfortable, not being able to manage where I was or to feel safe, I suppose.'* Liz, page 26

In her interview Liz stated she felt *'trapped'* in two situations, at the Olympics and in hospital, and described both as *'like being buried alive'* (Liz, page 7, 29). She related her distress to her inability to move and feel in control. Rosa also worried about maintaining control of her balance in unpredictable, crowded environments such as shopping. She controlled the situation by using walking aids and adapting her walking *'when there are a lot of people ... people coming towards me – I just stand still and let them walk round me. And walk on after they've passed'* (Rosa, page 4). Jim-Bob avoided or minimised his exposure to such situations, as he could not depend on his body to get himself there or move safely to access public toilets *'my legs won't do it. I don't trust myself'* (Jim-Bob, page 15). Jim said that he had suffered several 'collapses' and falls that had hospitalised him and these could be considered as total loss of control of body and situation *'I come to in the back of an ambulance and I just didn't know what happened. I keep on ... having funny little turns like that...'* (Jim, page 29).

#### 5.3.6.3 Theme 3 – Control – Findings summary

All of the participants talked about situations where they lacked control of their body or the situation and sometimes both.

<b>Superordinate theme 3 - Control</b>	<b>Evidence from</b>
<b>3.1 Control of body and balance</b>	All
<b>3.2 Control of situation</b>	All

Table 5-4: Evidence table for Theme 3 - Control

### 5.3.7 Theme 4 - Changes

All of the participants talked about how having a stroke that affected their mobility disrupted their lives. As already explored in the other themes, during the interviews the participants spoke about problems controlling their bodies/situation and they talked about the effects of their walking problems on their lives and activities that they valued. In addition they explained how this affected their roles and perceptions of themselves and how these things had changed over time. When thinking about changes over time they used specific aspects of walking as their 'yardstick' or comparator, such as distance, speed or mobility aids.

#### 5.3.7.1 Changes in role and self

Three particular changes were evident from these conversations about the impact of walking problems post-stroke, all of the participants changed from more active 'protagonist' roles pre-stroke to less active or 'observer' roles post-stroke. These active roles were seen in retrospect to be based on independent movement and mobility and the stroke forced changes in these aspects of the participant's lives. They all described experiencing vulnerability post-stroke and two appeared to view themselves as disabled.

##### Changes in role and self - From protagonist to observer

The stroke transformed these participant's lives; it was described as '*a sea change in your head*' (Liz, page 53) and the '*the end of life*' (Rosa, page 18). For all of the participants having a stroke curtailed their more physical work and hobbies and forced them to change from an active 'protagonist' role to a less active role, as observer or occasionally mentor. The participants offered examples to show their pre-stroke strength, resilience or capability.

Jim was a self-employed tiler and post-stroke found that he was unable to manage the physical aspects of his job. He described his pre-stroke life-style '*I've always been the*

*worker ... um ... I used to work twelve days out of fourteen'* (Jim, page 5). His said his job kept him fit and if not working he enjoyed fishing or pub-based hobbies, socialising and playing darts or pool. Jim's description of being the '*worker*' with all its connotations of strength, productivity, resilience and stamina was a stark contrast with his post-stroke descriptions of his sedentary life.

*'... it only takes me sort of like a minute to come out of my bedroom to go to my sitting room and sit down on my seat ... basically, that's where I probably stay most of the day, watching telly ... I spend quite a bit of time on my laptop.'* Jim, page 21

Jim also talked about several aspects of his social role that changed post-stroke and these changes, from more active to less active, occurred directly or indirectly because of problems walking. He spoke wistfully about how his physical disability forced him to stop work and how he had inadvertently become a mentor to others in the tiling trade. He said that '*they pick me brains*' leaving him feeling that it was a '*shame*' that he couldn't do the job (Jim, page 22). He talked about his pre-stroke activity '*I used to enjoy walking through the countryside*' and self-critically compared it with his post-stroke life '*these days I get on the bus and I think, you lazy git!*' (Jim, page 25).

Jim's role changes from 'protagonist' to 'observer' and from 'active expert' to 'mentor' were echoed in Rosa's stories. Rosa described her active pre-stroke (retired) life, referring to herself as the '*heart and soul of the party*' and saying she had been called '*Super-Nan*' to emphasise her active lifestyle, lively persona and role in her family/village life. Despite being in her eighties Rosa ran a village club for older people. Her description of this, '*I used to have lovely parties for them*' (Rosa, page 22), suggests that she did not identify herself with the 'older people' who attended the events that she organised. Rosa was physically active right up until her stroke '*I was always in the skittle teams both summer and winter*' with little time for '*sitting down hobbies*' (Rosa, page 22). Rosa's enthusiastic descriptions of her pre-stroke life as the active participant and 'protagonist' in many activities starkly contrasted with the way she spoke about activities post-stroke, the stroke suddenly made her '*feel old*'.

*'I don't go to the [skittles] club at all now except when I'm taken out for a meal. Ingrid: But what put you off going back to the skittles? Was it just that you didn't fancy it? Rosa: I didn't fancy it. I thought I'm too old now, I'm too old now ... there are more youngsters ... Ingrid: Did you feel ... but ... before your stroke you didn't feel too old? Rosa: Oh no, no! Ingrid: So what was ...? The stroke made you feel old? Rosa: The stroke did make me feel old. I thought ... you silly old thing, you are, you think you can*



*cope with that ... with youngsters but you can't cope with the youngsters – they are all younger now ... and they are getting younger all the time and so ... I couldn't cope with them.'* Rosa, page 32

When talking about these role changes, as in the extract above, Rosa's tone became more passive and much less resilient, she was *'taken out'*. Much of her active persona appeared to have been built on independent walking and movement. Difficulty moving led to dependency on carers for personal care and reliance on family to support her in running her home and garden. Even the village club, she once ran, reinforced the new more passive role by making her *'honorary president'* (Rosa, page 23). She reluctantly became more sedentary, moving from her pre-stroke role of 'protagonist' to post-stroke becoming an 'observer'.

*'... that's an awful frustration ... just sitting here ... and I watch the trees over there ... I can see the birds and everything but it's not the same as getting out in it and walking in it ...'* Rosa, page 44

Liz also talked about her active and busy pre-stroke lifestyle and appeared take pride in her previous toughness e.g. *'out in all weathers'* and ability to use activity to help her mood *'I played a lot of tennis ... nothing beats thrashing the life out of a ball for a couple of hours'* (Liz, page 38). She combined her role as a mother and wife and work as a sports coach and local radio DJ with her outdoor hobbies (including owning and riding a horse) *'I do miss the active life I had before – I played a lot of sport...'* (Liz, page 16). Liz had post-stroke activity restrictions that were at odds with her sporty pre-stroke persona *'... even walking round town now I find, more than an hour, say, shopping and ... I'm worn out'* (Liz, page 10). She admitted that at low points she found herself *'useless'* and felt *'my body is rubbish'* and *'I just can't do anything – it's all hopeless'* (Liz, page 26). Walking problems forced her to always *'have a thought to my safety now whereas before it just did not dawn on me to curtail what I wanted to do'* (Liz, page 12).

Liz's walking problems also challenged her role as 'mum'. She was the only participant with children under 18 years old and was frustrated that she could not stand, balance or walk well enough to fulfil this role as she had done previously which included *'simple jobs'* such as *'Mum does the food, you know, go to the supermarket, cook meals for them'* (Liz, page 49). As she became better at walking (adapted by increased use of the car and use of a stick and FES) she resumed what she referred to as her *'pink jobs'*.

*'Richard has a long hours and stressful job – he works in London. The least I can do is cook a meal for him and the boys ... and because I have my car I can take them places and pick them up so their activities are not curtailed ...'* Liz, page 50

Liz's description of life pre-stroke suggested a previously *'taken for granted'* (Liz, page 10) sense of broadly unlimited possibility, this contrasted with her post-stroke activity limitations, activity adaptation and a change to more sedentary hobbies like photography and painting. Her stroke related walking and movement problems forced Liz from an 'active' to 'less active' lifestyle. She admitted to feelings of jealousy regarding people who moved freely *'... when I watched a girl running across the zebra crossing [...] I had a miserable head and I thought, no, you will never be able to run again ...'* (Liz, page 49). She spoke about frustration with people who did not make the most of their abilities. Liz sometimes described herself and her situation in very negative terms and referred to herself as *'an old crock'* (Liz, page 51) despite only being in her early fifties. Perhaps, like Rosa, she felt that the results of her stroke had made her feel older.

In common with the other participants, Jim-Bob also was forced to change from 'protagonist' to having less active roles due to the effects of the stroke, especially walking difficulties. Before his stroke, Jim-Bob and his wife were *'both working in the Church ... we went on holidays and we didn't think about what we were able to do'* (Jim- Bob, page 20). Jim-Bob described the effects of the stroke on his walking in terms of a loss of 'freedom'. His interview suggested that his role changed from being a church leader with sense of possibility and agency to a new more restricted version of himself. Post-stroke Jim-Bob said that he was unable to work and appeared to feel *'imprisoned'* by walking problems, back pain and the people around him who acted as his activity 'gate-keepers'.

#### Changes in role and self - From resilient to vulnerable

All of the participants gave examples of post-stroke walking related vulnerability which altered their self-perception. Jim summed up the transformative effects of the stroke as an *'eye-opener'*. Jim said that pre-stroke he *'felt immune to most things'* (Jim, page 4) and afterwards he couldn't *'get used to that feeling of vulnerability'* (Jim, page 2).

Jim-Bob also explained that he felt vulnerable in situations when he could fall and would minimise the chance of a fall by avoiding such situations or using his scooter.

*'Well, before the stroke I didn't have to think about it or consider ... any vulnerability ... But I now have to consider the fact that I am vulnerable and I don't like that – it makes me frustrated.'* Jim-Bob, page 19

Jim and Jim-Bob explicitly mentioned increased vulnerability post-stroke whereas Liz and Rosa implied this change. The gender split may be related to the small number of participants but could also indicate more general gender related differences. As able-bodied males Jim and Jim-Bob may not have perceived their vulnerability before their strokes and therefore it becomes a 'remarkable' change. Liz and Rosa focused on their pre-stroke capability in their talk, they could '*walk for miles*' pre-stroke and gave other examples of their stamina and activity, implying a sense of invulnerability. An example of her implied increase in vulnerability can be seen in Rosa's descriptions of increasing mobility related fear, particularly of falls.

**Pre-stroke:** *"Nan, can you give us a hand?" So I climbed up the bank as well and I was giving them a hand to make their den and the man walked underneath ... 'Rosa, what are doing up there? You'll break you neck!' 'No, my Nan's all right – she's our Super-Nan!'"* (Rosa, page 44)

**Post-stroke:** *'I tried to pull some weeds and I fell over'* (Rosa, page 29), *'... that's what I'm afraid off... if I fall down and be a nuisance to people'* (Rosa, page 39)

These exemplar quotes represent many sections of Rosa and Liz's transcripts where they describe the impact of post-stroke walking problems causing them to feel frightened or '*old*' due to reduced control of themselves and their situation.

*'I was always fit. Physically fit and strong and I didn't doubt myself in the terms of my ability to go where I wanted or do what I wanted to do.'* Liz, page 27

Post-stroke Rosa and Liz had a new 'doubt' or lack of confidence in their body function. If vulnerability is understood as susceptibility to negative events and defencelessness Liz and Rosa's changes in the way they talked about themselves, their mobility and feelings suggests increased vulnerability post-stroke.

#### Changes in role and self - Becoming 'disabled'

Jim-Bob referred to himself as disabled because of his post-stroke walking problems on several occasions in his interview and his wife, Crystal, referred to herself as becoming the '*carer*'.

*'I... I've realised that I was disabled and err ... that I didn't try to hide my disability but I didn't try to get false sympathy, either ... and .. uh ... so I just tried to live with it normally and hoped people would understand that ...'* Jim-Bob, page 33

He said that his daughter was not all that sympathetic at times *'... I have pretty well played the 'I'm a disabled person' card enough that she says, 'Get off your own ass and get it yourself!'*" (Jim-Bob, page 39). Jim did not refer to himself as disabled in such direct terms as Jim-Bob. Jim described his frustration at being ineligible for higher rate disability benefits and with people on the bus.

*'[I] wind meself up about the way people sit on a bus and that and think don't you realise that all the front seats are maybe for all the people with walking difficulties, you know ... I know I'm not high up on the list but it just annoys me when I've got to walk to the back of the bus and that ...and I think, bloody ignorant people!'* Jim, page 25

He said that he was *'not high up on the list'* suggesting that he acknowledged himself as disabled because of his walking problems but less disabled than others. Rosa and Liz did not refer to themselves as disabled nor did they infer that they felt that they belonged to the group of people in society referred to as disabled. In fact Liz rejected some walking aids because she said *'I can't bear the gadgets of disability'* (Liz, page 19).

#### **5.3.7.2 Assessing change**

The participants all compared their abilities post-stroke with what they could do before the stroke and also made comparisons with other time points. They were asked how walking had changed over time and they selected specific aspects of function and walking ability or their use of different mobility aids as their comparators. These acted as personal 'yardsticks' by which they judged their progress.

##### Assessing change – Mobility and function as a comparators

Mobility and walking related functional activity were commonly used by these participants to illustrate how much their lives had changed post-stroke. They often described their walking or an activity in combination with a judgement about their performance.

*'I used to walk with the left foot and drag the right one behind me – but now I lift it. I can lift it and walk quite good altogether now.'* Rosa, page 13

*'I knew that I was being lazy and I wasn't picking up my left foot'* Jim-Bob, page 58

*'I would have to hold on to a solid object to prevent me from falling ... my balance was non-existent ...'* Liz, page 2

*'When I get dressed I do everything on the bed, you know, sat on the bed to get myself ready. Yes, so I'm not too bad.'* Jim, page 21

*'But at one time when I had the dog I walked from my house all the way up to the Heath to go and see the doctor [...] an hour-and-a-half ...and we got there with ten minutes to spare so I was pretty chuffed with that ...'* Jim, page 58

Different aspects of activity appeared to act as personally nominated milestones or 'yardsticks', in the quotes above walking quality, distance, function and independence were the comparators. Jim talked about how long it took to walk distances and how many rests he needed as a comparator. Liz talked about tiredness as a comparator over time post-stroke.

*'It's much better now than it was. I would measure tiredness following the stroke in hours, in simple tasks, for example I would get up in the morning and get out of bed, get washed and dressed and come down the stairs – by which time I was absolutely exhausted and I'd have to lay on the sofa for an hour or two ... and go back to sleep. And that was the early days, the first months ... the first month or two ... Now, Monday I may be busy, Tuesday, Wednesday ... by Thursday, I will feel tired and so I measure it now in days, rather than in, just in simple tasks.'* Liz, page 11

Liz would 'measure tiredness' by the functional tasks that she could complete before she had to rest. Liz, Rosa and Jim also 'measured' their ability in personally relevant distances and activities. While still an inpatient post-stroke Rosa said she tried walking alongside her hospital bed *'I started to step ... a little step at a time ... along the edge and back again'* (Rosa, page 18). Liz also talked about her early days post-stroke when she had to *'practise standing up... and feeling safe about it'* before moving on to other *'simple tasks like getting up from a chair ... getting myself to the toilet'* (Liz, page 3).

The participants were able to discuss their walking abilities post-stroke in terms of personally meaningful mobility and functional activities and could use them to 'measure' change in their own context. The participants could compare these activities over time and judged their progress against them, which may reinforce the choice of some participant selected outcome measures such as COPM.

Assessing change - Mobility aids as a comparator

The participants used their mobility aids including physical support as another marker of change over time. Liz, Rosa and Jim-Bob acknowledged their progress in terms of independence from a time immediately post-stroke when they needed more physical support or assistance.

*'My walking was non-existent without considerable support. [...] I needed someone to hold onto me to stand ... I was unable to walk with a stick ... even ... even standing I would have to hold on to a solid object to prevent me from falling.'* Liz, page 1

Liz implied that being able to walk with a stick would have been better than this dependent situation. They described becoming more self-sufficient and using less supportive assistive devices as forms of 'progress'. Liz, Jim and Jim-Bob started using sticks quite soon after their strokes and still used them regularly at the time of the interviews. Rosa provided the clearest examples of using mobility aids as a comparator of changes over time because she used several different mobility aids and gradually stopped using each as she improved. She began with physical assistance or holding solid objects, followed by a rollator, then FES and gradually progressing to a stick and then stopping FES use.

*'Ingrid: How about things like walking around your house from room to room? Has that changed over time? Rosa: Oh, my goodness yes! Ingrid: In what way? Rosa: Well, sometimes I don't need a stick!'* Rosa, page 13

*'Oh, it's a lot easier now! And ... uh ... I can go without a stimulator and walk up around the Close without the stimulator and I found that ... amazing to myself.'* Rosa, page 13

*'...this last three times that I went to the town ... to do the shopping I just used my stick.'* Rosa, page 4

This sub-theme has demonstrated that some of these participants used mobility aids to compare mobility over time.

Assessing change - Comparison between pre- and post-stroke mobility and function

The participants all compared their limited mobility and function post-stroke to their ease of movement pre-stroke, when it had often been 'taken for granted'. They seemed frustrated when they were unable to complete tasks that they felt should be easy, based on their pre-stroke abilities. The participants explicitly and implicitly

compared their walking related function pre-stroke and post-stroke. The following quotes are examples of the explicit comparisons that these participants made.

*'I would be able to go a little distance but not the distances we used to go along, you know ... I used to walk for miles.'* Jim, 46

*'... we didn't think about what we were able to do.'* Jim-Bob, page 20

*'I do fear falling now whereas I wouldn't have thought twice about it before – I was always very strong.'* Liz, page 15

They also regularly implied comparison between pre-stroke 'normal' function and their post-stroke problematic ability to walk.

*'... **just** trying to walk ...'* Jim, page 5

*'... it was **just a little** [watering] can [...] but I over-balanced ...'* Rosa, page 31

*'... **even** standing I would have to hold on ...'* Liz, page 1

*'... **even** simple tasks like standing and walking safely.'* Liz, page 5

*'I just drag it [talking about dropped foot] [...] It doesn't want to do it **properly**'* Jim-Bob, page 12

*'I couldn't wash myself **properly**...'* Rosa, page 47

The use of the words 'just', 'even' and 'properly' (highlighted in bold) suggest the comparison with something that was easy or something that these participants felt should be easy. They all spoke about easily managing walking related activities pre-stroke and regularly compared pre and post-stroke function.

#### Assessing change - Multiple comparison points

The participants made frequent comparisons between a pre-stroke time period and how they functioned post-stroke, however other time points were also sometimes referenced. Occasionally they referred back to more distant time points. People may look back at their past with a degree of conscious or unconscious 'romanticism' i.e. 'through rose tinted glasses' and this perhaps applied to participants in the present study. Rosa, Jim-Bob and Jim all referred back to their younger days and compared their function then to the present time. For example, Jim-Bob reminisced about the 'walkathons' he completed at high school in order to illustrate his point that he had

physical freedom then compared to his current *'imprisoned'* state due to his mobility restrictions.

*'It was just the thing ... the actual thing about being able to do something like that and push your body ... to its limit'* (Jim-Bob, page 44).

They also made comparisons over the period of time post-stroke and used walking as the comparator. Jim and Jim-Bob described how walking had varied over this time, for both of them their walking had peaked during the first year after stroke and then worsened due to other health problems. Liz also had some mobility variability post-stroke, which she related to hospital admissions for other health problems.

*'Ingrid: What, don't you think you were as fit as you were when you first had your stroke? [Referring to the sponsored walk in his first year post-stroke] Jim: Definitely not – not as fit as what I used to be.'* Jim, page 23

*'Ingrid: So how did ... your walking was at a peak then – how have you found the walking since then? Has it been variable or quite consistent? Jim-Bob: I think it has been variable.'* Jim-Bob, page 12

*'So repeated hospitalisation and anaesthetic and so on ... has interfered with my ... stroke physio/rehab because each time I go back into hospital loads of things happen. I feel ... I get very low, very depressed, very miserable about it ... it's almost like being buried alive, being an outdoors and active sort of person ...'* Liz, page 7

The participants all also used their walking ability to highlight positive changes, by comparing their current ability with the problems they had at an earlier point post-stroke, often in the first few weeks after their stroke. The 'early days' were mostly referred to as a period when function was at its worst and this was followed by gradual recovery, Rosa summed this up as *'... everything went forward from there...'* (Rosa, page 2).

The participants were asked about whether they remembered any walking tests or questionnaires from their rehabilitation or from the Phase 1 trial, whether these matched what they were interested in and if they had any opinion about what should be measured. Jim said he would have been interested in measuring leg strength during the trial. Rosa remembered the tests and questionnaires as *'about right'* but did not add any more on the subject. Jim-Bob said he vaguely remembered the tests and answered my question about how health professionals should measure walking and how somebody is improving with the following admission.



*'I think that ... uh ... usually the patient themselves know a lot more than ... uh ... the doctors or the physios ... Ingrid: In what way? Jim-Bob: Well, umm ... I knew that ... uh ... after all those personal problems I ... I ... I knew that I was being lazy and I wasn't picking up my left foot – I just thought, 'Oh, blow it!' ... 'I don't care!'*" Jim-Bob, page 58

This was an unexpected answer that challenges the basis of objective outcome measures based on an assumption that the patient performance mirrors capability.

Liz said that she found feedback from health professionals about changes in walking speed or function as *'hugely motivating'* like *'a shot in the arm to think to myself 'It's working – you could do it''* (Liz, page 44). Feedback from other people enabled Liz to compare her mobility and function over time since she said she could not view herself objectively.

The participants mostly compared their current abilities against what they could do previously. Sometimes they also compared themselves against other people. Liz mentioned being jealous of a girl running however most comparisons were against people worse off than they were. These comparisons appeared to have the function of giving the participant greater perspective and reinforcing positive aspects of their function i.e. *'I've got a lot to be thankful for'* (Jim-Bob, page 41).

*'But far, far better off, as I keep saying, than so many other people. But ... I can't keep feeling sorry for myself.'* Liz, page 27

#### **5.3.7.3 Theme 4 – Changes – Findings summary**

Post-stroke mobility problems had a profound effect on the activities these participants could undertake and their view of themselves. The participant's activity choices were restricted by their stroke; this altered their role from protagonist to observer or less active participant. They all described that they were more anxious, fearful and vulnerable post-stroke and they linked this to their walking problems and fear of falling. In a variety of ways, they highlighted their former resilience and new vulnerability. The participants also described how they assessed their own changes in mobility.

<b>Superordinate theme 4 – Changes</b>	<b>Evidence from</b>
<b>4.1 Changes in role and self</b>	All
• From protagonist to observer	All
• From resilient to vulnerable	All
• Becoming 'disabled'	Jim-Bob and Jim
<b>4.2 Assessing change</b>	All
• Mobility and function as a comparator	All
• Mobility aids as a comparator	Liz, Rosa, Jim-Bob
• Comparison between pre- and post-stroke mobility and function	All
• Multiple comparison points	All

*Table 5-5: Evidence table for Theme 4 - Changes*

## 5.4 Phase 2 - Discussion

The Phase 2 interviews explored walking changes from the perspective of individuals who have had a stroke and taken part in gait rehabilitation. It has been possible to address the research questions and understand more about aspects of walking that the participants valued and their feelings about the use of assistive devices, including electrical stimulation. When writing this discussion, the main rehabilitation research databases (Medline, Cinahl and Amed) were searched again using the following broad search terms 'stroke AND (((walking) OR gait) OR mobility)) AND (((interview) OR phenomenology) OR qualitative)' (searched in October 2014). The results from each database search were checked by title and if necessary by accessing the abstract and no similar studies could be identified. There are many published studies that explore activity and participation post-stroke and refer to walking but none could be found that have the first person experience of post-stroke walking problems as the starting point and focus of the study. Therefore, this study appears to be the first time that walking has been explored using qualitative methods from the perspective of people who have had a stroke affecting their mobility.

The Phase 2 'Talking about walking' study and interview schedule focussed overtly on walking and post-stroke changes in walking (Appendix K). The participants responded

by talking about a range of walking related aspects of movement, activity and their lives. The participants did not appear to recognise walking as a distinct area of concern that was separate from other movements and activities that required standing, stepping, walking etc. These participants talked about various walking related activities that were similar to the ICF definition of mobility presented in Chapter 2.3.7 that includes moving by changing body position or location, by carrying, moving or manipulating objects, by walking or running [221]. Conversely, both stroke research and physiotherapy implicitly accept some separation into defined areas such as gait rehabilitation, upper limb rehabilitation and promotion of independence in ADLs. Gait was described as walking (lay language) in the Phase 2 interview schedule.

The walking focus of the Phase 2 protocol and interview schedule probably reflected my position at the outset, a research physiotherapist situated in stroke rehabilitation with an interest in gait and mobility. This standpoint was only recognised in retrospect because the participants generally spoke about walking in the context of their lives and in relation to a diverse range of movements, tasks and activities. Had the protocol or research questions for this study been developed with patient or public involvement, this assumption may have been recognised at an earlier stage. Due to the range of activities discussed mobility may be a more fitting term, as used in the ICF but it is not used in everyday language and therefore is perhaps less suitable for use in the interview schedule. Use of the term walking was positive, it achieved the study objectives and prompted the participants to explain the changes that they experience post-stroke and include descriptions at impairment, activity and participation levels.

Interpretative phenomenological analysis has a focus on individual experience and exploring aspects of life that may be otherwise taken for granted. As such, it was well suited to the Phase 2 research questions. The research aim was to explore valued aspects of walking, how walking changed over time and participant's feelings about the use of assistive devices. In addition, other relevant but unanticipated areas emerged as themes from the transcript analysis, in particular the embodied experience of mobility problems and the effect walking problems had on roles and the participant's sense of self. Each theme is discussed in relation to the published literature in the following discussion subsections, followed by the strengths and weaknesses of the Phase 2 study.

#### 5.4.1 Theme 1 - Valued aspects of movement

This theme addressed elements of the first two research questions: the participants were able to describe aspects of walking that they valued and how walking had changed over time post-stroke. Valued aspects of walking were inferred from the participant's descriptions of lost activities and post-stroke changes in walking. This can be justified by considering that people appear to take walking for granted and may be unable to describe valued aspects of walking unless they have been threatened or changed. When asked about whether she ever thought about walking pre-stroke Liz replied '*No. It just was something I took for granted, I'm ashamed to say. That is how it was*' (Liz, page 10). Pre-stroke walking related movement ability appeared to be taken for granted by all of these participants.

Walking was valued by the participants in this study. It was talked about as a goal in itself, also as transportation and was referred to as '*fundamental*' (Liz, page 17). This is in line with other studies that suggest maximising community ambulation is valued and prioritized by people who have had a stroke [5, 7, 309]. Stroke survivors assess their recovery according to what was important to them pre-stroke [250, 251] and if walking was a valued leisure activity pre-stroke the literature suggests that people tend to want to resume it post-stroke [77]. Walking for pleasure or as an integral part of leisure activities was also spoken about as an important feature of all the participant's lives pre and post-stroke, except Jim-Bob. Walking for transport was part of his hobbies (such as visiting restaurants or the cinema) but walking for pleasure was not mentioned by Jim-Bob apart from occasional country 'walk and pub' outings.

This theme comprised two subthemes, which were valued movement attributes and valued movement activities. The participants valued particular walking related movement attributes - independence and self-determination, spontaneity, confidence, automaticity, speed, distance, stamina, strength, balance, agility and manoeuvrability. Perhaps this list of attributes represents 'obvious' things that people value about walking/movement however, they are not all well represented in the published rehabilitation literature. These attributes echo comments from countless patients and resonate with my own experience of movement but are not usually comprehensively 'measured' in quantitative rehabilitation research. Each attribute is presented below in the context of the published literature.

Independence in walking related movement was valued by these participants. It is often a rehabilitation goal and assessed in rehabilitation trials. However the

participants in this study did more than describe whether they were independent or if they needed help, they described *what it was like* to be dependent and they shared their battles for independence during their interviews. In her book 'When walking fails' Lisa Iezzoni wrote about the mobility experiences of adults with deteriorating chronic conditions, which she explored using interviews. She noted that some interviewees 'recalibrated' their perceptions of independence once they experienced walking problems. They accepted or requested some assistance while striving to maintain maximal self-sufficiency, which reflects Jim, Jim-Bob, Liz and Rosa's talk about their independence in relation to mobility [310].

Analysis of the Phase 2 transcripts has suggested that independence is a complex multi-faceted idea, indeed it has been described by Schwanen et al., 2012, as 'an unstable achievement' and a 'complex and fuzzy notion' that is difficult to describe in words [311]. Despite the challenges in describing independence, these authors who are social geographers, provided a useful understanding of independence based on the literature and their own interviews with 70 older people in a study into aging. They suggested that at one level independence is understood as 'not depending on others' especially for lifts or assistance with activities requiring them to leave the house. At the next level they describe independence in relation to the embodied experience of moving through space, which is facilitated by multiple factors including technology and devices (i.e. cars, mobile phones, walking aids), physical capability, environmental features (i.e. access to disabled parking spaces, level ground), infrastructure (i.e. public transport), social factors (i.e. income with respect to purchasing vehicles or fares). The idea of independence is further extended by these authors to include decisional and executional autonomy, which they define as the ability and freedom to make decisions and carry out personal activity choices without external coercion or restraint. This multi-layered description mirrors the multi-faceted interlinked descriptions of mobility related independence and self-determination found in the present study. This suggested that these Phase 2 participants (stroke survivors) and Schwanen et al.'s participants (an elderly population) appeared to have similar concerns regarding independence that warrant scrutiny in future research.

Participants in the Phase 2 study linked problems walking independently to their self-determination, personal choice and freedom. Elements of this finding are reflected in Schwanen et al.'s study and other qualitative studies exploring the lived experience of stroke and chronic illness [255, 311-314] however no studies that specifically considered post-stroke independent walking in relation to autonomy or personal

freedom could be identified. One of Iezzoni's interviewees said that being able to walk would give her 'more choices and experiences' [310] and this could also be seen in the Phase 2 'Talking about walking' interviews. Mobility appears to underpin much human freedom to act [311, 315, 316] and a lack of independent mobility narrows one's 'horizon of possibilities' [244]. This has been discussed in qualitative research and first-person accounts of illness but is not reflected in the published gait rehabilitation research. Havi Carel writes about illness as an academic philosopher and as a person living with a rare chronic and potentially fatal lung condition, which was diagnosed in her thirties. Her work discusses the experience of difficulties moving and walking easily. She has published several papers and books exploring the embodied experience of illness and in the quote below she compares it to rapidly aging.

'I slowed down. I imagine that this is what it must be like to grow old: to gradually realise that as your body loses capacity your world shrinks too. Except that old people have decades to prepare for this' [244].

The changes explained in this quote appeared to be similar to those described by the participants in the current study, stroke caused a rapid transformation in their actual and potential movement based activity choices. The 'modification of agency by bodily limitations' has been described as a central aspect of illness but it does not appear to be well researched in relation to walking changes post-stroke [244].

The four interview participants and Jim-Bob's wife spoke wistfully about their lost movement freedom and about spontaneity. Just like Jim-Bob's wife, a participant in Laliberte Rudman's 2006 study complained that 'there's just no spontaneity left' due to the effort involved in leaving the house and they described having 'restricted lives' post-stroke associated with reduced participation in meaningful activity [317]. Physical disability can create a new world, a 'world without spontaneity, a world of limitation and fear, a slow encumbered world' [244]. Spontaneity and movement freedom are not well-developed areas in the stroke rehabilitation literature but they have been mentioned as important to stroke survivors in other papers [317, 318].

Agility and manoeuvrability underpin movement automaticity and have been represented in the rehabilitation literature, in tests of physical function and intervention design. Agility and manoeuvrability require skilled movement, which is acquired through practice. Once a movement such as walking is mastered and practiced, it can become more automatic. Normal gait is usually a relatively unconscious action requiring higher cognitive input if the task demands are increased i.e. in a more

complex environments, under dual task conditions or if the person has a disability [319]. Physical tests requiring subjects to negotiate obstacles may partially reflect the issues that these participants highlighted. The participants in the current study valued manoeuvrability and agility in simple and complex tasks and environments, walking on riverbanks, tiling, sport, walking in crowds and confined spaces and this is an area of potential exploration for future research, particularly capturing changes in the lived experience of these issues.

Movement confidence was valued by the participants in this study and is closely linked to many of the other attributes already described. Illness can leave people vulnerable and with 'bodily doubt' rather than what can be understood as normal taken for granted 'bodily certainty' or reliability [244, 320]. Fear and specifically fear of falling act as barriers to activity and participation, particularly affected is confidence in community ambulation [321-323]. There are specific outcome measures that have been developed to assess fear of falling, such as the Falls Efficacy Scale, and could be incorporated more routinely into gait rehabilitation trials [324]. Barnsley et al., 2012, interviewed people with strokes about travelling outdoors and categorised them as either a 'hesitant' or 'confident' explorers, in relation to walking, catching public transport and driving [322]. Their confidence or hesitancy was affected by emotions, having a meaningful destination and the expectations of recovery and family members and health professionals who could act as enablers or as restricting 'gate-keepers'. The participants in the Phase 2 study talked about all of these aspects of movement confidence and demonstrated that it was task and context specific, which is in line with the published literature. There is a well-developed literature base demonstrating the value that people place upon movement confidence post-stroke and therefore it should be explicitly prioritized in clinical rehabilitation and more routinely assessed as an outcome.

The Phase 2 'Talking about walking' participants valued having sufficient stamina to walk personally defined distances outside and inside at a reasonable pace. Multiple factors such as gait speed, balance, fear of falling, motor function, endurance, environmental characteristics and assistive walking devices have been related to outdoor mobility post-stroke [3, 5, 309, 325]. Many of these, such as gait speed are well represented within outcome measures in gait rehabilitation whereas reduced stamina/endurance has been described as a 'hidden disability' that can effect everyday life, even after relatively mild strokes [326]. Environmental barriers and facilitators have been investigated in populations of older adults [327]. Shumway Cook and

colleagues developed a questionnaire that asked if potential environmental challenges such as distances, crossing roads, carrying items and uneven ground is encountered or avoided by the individual [327]. This questionnaire has been used with stroke survivors and it was found that they avoided all of the potential environmental challenges more than a control group [328]. If validity, reliability and sensitivity of this questionnaire in stroke populations is established it may become a useful outcome measure in this population as it combines many aspects of walking that have been highlighted as 'valued' by participants stroke rehabilitation studies, including this one.

A range of valued movement based activities were highlighted by participants in the current study which were grouped into moving around the home/garden, self-care and ADLs, leaving the house, employment, walking and being active outdoors and sport. Robison et al., 2009, asked people about returning to valued activities post-stroke and gained a very similar list [77]. It is uncertain whether current therapy provision, which has been criticised for being short term, would be able to support people to achieve some of the 'higher level goals' that were identified [4, 16]. More basic mobility, assessed outside of real life contexts is the focus of much rehabilitation and stroke research, which is at odds with stroke survivors' prioritization of returning to activity and social participation [321, 329, 330]. Participants in the current study mentioned the effects of specific impairments on walking i.e. foot drop, spasticity and muscle weakness but most of their talk centred on activity and participation. They did not often focus on walking as an abstract concept and usually spoke about it in the context of their own lives. The Phase 2 participants also talked about walking in specific environments, over personally important distances and to achieve particular goals.

### 5.4.2 Theme 2 - Being active and taking part

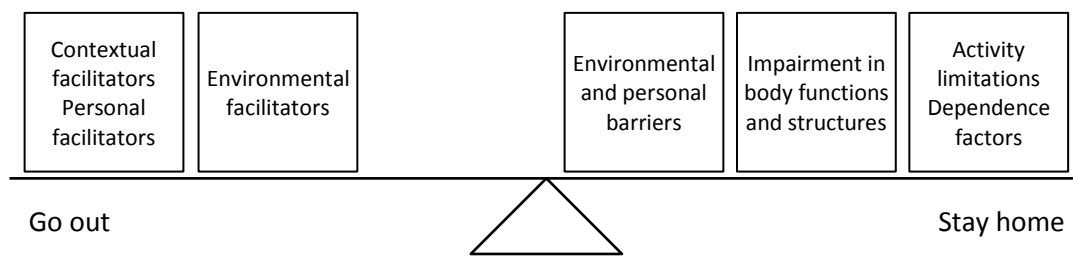
In response to the walking focussed interview schedule, these participants frequently spoke about being active and being able to participate. This became the second theme that included the multifactorial nature of activity limitation and the ways the participants coped with movement problems.

The Phase 2 'TAW' participants spent almost all of their interviews talking about elements of their activity and participation within and outside their homes that was largely walking or movement related and encompassed self-care, productivity and leisure domains of occupational performance. They each talked freely about this for about 90 minutes which suggested that 'activity and participation' was of importance to them. It has been suggested that, over time after a stroke, people move from an initial



focus on physical function, through activity, to focussing on community integration [331]. This could be seen in the descriptions of the participants in this study, they looked back to an early post-stroke time when they were learning to move again but their 'current' talk (at three years post-stroke) was mostly focussed on activity outside their homes and social participation. Had these interviews been conducted earlier post-stroke these participants may have spoken about the impact of their walking problems in a very different way.

The Phase 2 study questions focused on walking (an activity limitation) and the analysis illuminated aspects of the participant's experiences that can be seen to match the areas of the ICF model [186]. This was exemplified in Jim's talk about returning to work. His account suggested that he had impaired motor, sensory and cardio-respiratory systems that affected his walking activity and this restricted his ability to participate in work. Jim spoke about how environmental considerations such as the location and nature of any possible employment as well as the nearest public transport routes and the terrain affected his ability to return to work. Individual factors like his motivation, interests, state benefits and self-efficacy may also have affected uptake of potential employment opportunities. Employment is often limited by multiple factors [332], as are many other forms of social participation. Barker et al., put forward a 'balance' model for factors affecting community participation for post-stroke wheelchair users that is a development of the ICF model. This model suggests that community participation is most likely when factors enabling 'leaving the house', on the left of the fulcrum outweigh factors on the right side that act as a barrier to community participation [333]. The role of carers and significant others can be an enabler or barrier to social participation in this model. Participants in the current study described multiple factors that enabled or acted as barriers to activity and participation that suggests a similar underlying decision mechanism to the 'balance model' proposed by Barker et al. [333].



*Figure 5-2: Balance scale model of factors affecting community participation*

*Figure reproduced from Barker 2006 [333] –with permission.*

The individual factors that restrict activity and participation may be difficult for health professionals to identify, let alone anticipate. Jim's example of returning to playing pool in pubs demonstrated this point. He continued to frequent pubs, had good upper limb movement, reasonable walking abilities, he could stand and yet he did not wish to return to playing pool even though it was an activity that he had previously highly valued. His decision appeared to be influenced by social and personal factors such as being unwilling to play pool unless he could play as he did before his stroke. Perhaps he was motivated by a fear of failure in a public situation and the potential threats to his perceived internal or external social identity from his reduced body control. His coping strategy was complete avoidance of this previously valued activity and this response has been found in other research [273, 314, 334]. Lahberte-Rudman in 2002, pulled together the findings from three qualitative studies exploring identity and occupation [335]. She found that there was evidence in the studies that participants attempted to maintain their social identity and avoid stigma associated with being seen to be disabled by avoiding some situations or occupational tasks that could have highlighted their physical problems. Loss of valued walking related movement attributes and movement activities (highlighted in Theme 1) were central to these and the other examples of multi-factorial activity limitation that were identified in all four transcripts.

Activity and participation can be understood as a basis for our functioning in the world. Despite changes in health, functioning and social circumstances people seem to maintain consistency in many patterns of thinking and doing; the detail may vary but the pattern is retained, which echoes Liz's description of a '*sea change in your head*' (Liz, page 53) [333]. A recent meta-synthesis of qualitative research on social participation post-stroke suggested that a stroke could be seen as a disruption in the lives of stroke survivors that was associated with loss of autonomy and independence often secondary to mobility problems [313]. Some researchers question whether the stroke itself disrupts continuity or if it is the threat to independence in fundamental aspects of life, such as mobilising or attending to one's basic needs, that creates a disrupted sense of self [336]. Post-stroke, people adapted by continuously re-appraising their individual situation and making personal choices to resume or adapt an activity or focus on other activities, this was a process that involved similar factors to those described by Barker et al., 2006, in their balance model [313, 333]. The Phase 2 participants could be seen to have repeatedly enacted this appraisal process balancing mobility barriers and facilitators against potential activity loss, including its personal importance e.g. Liz weighing up factors affecting going to the Olympics or Rosa talking about going shopping. The present study and the published literature highlight the

importance that stroke survivors associated with being active and taking part in *self-selected meaningful* activity and how this is often limited by problems mobilising independently post-stroke. People may benefit from longer term support post-stroke to enable them to resume or adapt valued activities [77, 313, 337]. Quantitative rehabilitation research that assesses mobility post-stroke as a context free individual characteristic, such as gait speed or muscle power, will miss out on aspects of life that are prized by the stroke survivors themselves. The current study and other research in this area of activity and participation post-stroke poses a challenge to researchers; how can 'applied mobility' be better assessed?

Verbrugge and Jette, 1994 stated that 'disability occurs for a given activity when there is a gap between personal capability and the activity's demand' [338]. All of the participants in the Phase 2 study talked about activities that had become difficult i.e. where there was a demand-capability gap, and they described the various ways that they coped with this. People may avoid or reduce the frequency of some activities to overcome mobility problems, they may pace their activity by completing it more slowly or only partially and may modify the task by using helpers, assistive technology and/or environmental adjustment [318, 339-343]. All of these strategies were described by some or all of the participants in the present study. For example Jim said he paced most activities and Rosa avoided trips into town until she had sufficient confidence and then accepted help to get on the community bus and at first visited fewer shops per trip to control fatigue.

Sometimes the adaptive options open to 'disabled' people were not accessed by the Phase 2 participants e.g. Liz struggled to manoeuvre around tiered stadium seating at the London Olympics instead of requesting easy access seats in a disabled area. Perhaps she wanted to avoid labelling herself as disabled, or prioritised normalising the visit for her family or it could be that Liz did not view herself as disabled or at least not disabled enough to warrant special assistance. This latter idea was not explored further in the interview but large survey research has shown that people with mobility restrictions often prioritise independence or self-sufficiency over physical comfort [344] and even those who have to use wheelchairs, may not identify themselves as disabled [345].

The role of others in creating activity boundaries or acting as gatekeepers found in the present study is consistent with other research findings [317, 322, 346]. Spousal hypervigilance and increases in their protective role are regularly noted in the published research and have been shown to be counterproductive if prolonged or too intense

[326, 347]. People living with disability who avoid help from another person may accept increased tiredness, slowness and pain as the price for self-sufficiency [344].

Whether the participants had adequate situation specific confidence i.e. self-efficacy to overcome activity barriers was context dependent, varied between the participants and affected selection of coping strategies. Self-efficacy has been shown to affect movement performance in healthy people, for example athletes, and those affected by illnesses such as stroke [308, 348]. Successful practice of specific movement tasks may increase self-efficacy related to that task, for example researchers have found practice of balance and mobility tasks improves scores on a balance self-efficacy questionnaire [308, 349, 350]. A circular relationship seems to develop, self-efficacy increases with successful repetition of a task and having the confidence to practice challenging tasks requires some belief they can be accomplished i.e. some self-efficacy. The Phase 2 interviews showed a wide variation in participant's willingness to practice and this may have affected their mobility outcomes as practice is associated with improved movement performance [37]. This suggests that self-efficacy should be monitored as a baseline characteristic in intervention based rehabilitation research because it may increase an individual's inclination to practice and therefore predispose them to a better rehabilitation outcome. Designing interventions that maximise movement related self-efficacy may improve rehabilitation outcomes post-stroke [70, 308, 328, 346]. Suitable self-efficacy assessments may be the Stroke Self-efficacy Scale [351] or the Falls Efficacy Scale (International) [146, 324]. Behaviours known to increase self-efficacy are modelling similar successful people, setting small achievable activity increments, goal focussed activity and receiving external praise. Similarities can be seen between these behaviours and the self-efficacious approaches to their own rehabilitation that were employed by Liz and Rosa. At the end of the trial participants in the EPIC study often asked to see the video recordings that had been taken as baseline, 8 and 20 weeks. They appeared to derive pleasure and motivation from seeing their mobility improvements, *'this was how you were then and this is how you are now and there is a massive difference. All of that was so motivating'* (Liz, page 45). Use of such recording could be used systematically as objective feedback in clinical practice and research with the aim of improving self-efficacy, motivation and outcome.

This theme has also illuminated the role of walking aids in being active and taking part. This discussion will begin by considering the use of powered wheeled mobility aids that may enable access to a much wider world [333]. Jim-Bob appeared to be empowered

to access his community post-stroke because of his scooter and Rosa talked wistfully about wishing she could also use a scooter so that she could be self-sufficient around her village. Due to her hemiplegic upper limb, Rosa could not use a scooter and perhaps she would have benefitted from a powered wheelchair if she had lived in a more urban environment. Rosa and Jim-Bob did not seem to perceive any stigma associated with use of a mobility scooter. This contrasted with Jim who expressed his negative feelings towards use of a scooter. Similar mixed opinions of walking aids has been reported in the literature [352-354]. Resnik et al., 2009, asked focus groups of older adults to identify factors affecting uptake of mobility aids and found that many were open to using aids to maintain independence but associated them with aging and physical decline which stigmatised their use [353].

Driving or being driven by car has been seen as the primary 'compensation tool' for poor mobility [311, 346, 355] with scooters and public transport as an alternative, depending on accessibility and distance [310, 355, 356]. Apart from Liz who had returned to driving, participants in the current study talked about increased dependency related to loss of driving ability in the context of getting out and about in the community post-stroke and/or issues accessing public transport which reflects the published literature [5, 311]. Toombs described how using powered mobility was a tool that enabled her activity and participation and summed this up in the following quote 'functioning well at the personal level does not depend on whether I can walk, although it does relate to my ability to manage my illness (multiple sclerosis) in such a way that I can pursue those projects that are meaningful to me' [246]. Participants in the Phase 2 study were willing to use assistive devices to enable them to achieve their goals. Generally, they appeared to select the least supportive device, often equating this with progress. They also seemed to choose the most discreet options while always focusing on maintaining independent mobility or maximising self-sufficiency. They appeared to have a 'love-hate relationship' with these devices veering between reluctance, acceptance and positivity and always seeming to wish that they did not need them. This resonates with my clinical experience and the published research such as Pettersson et al., 2007 which found that post-stroke people 'need to have the devices but they do not really want to need them' [357].

In the structure of questionnaires and models such as the ICF there is general acceptance of the hierarchical ordering of mobility aids from least to most supportive i.e. from sticks or crutches, to walkers, then manual wheelchairs and lastly powered chairs or scooters [310]. No reference could be found to the way people with

disabilities perceive this hierarchy and there is limited research aimed at understanding how, when and why people choose to use different mobility aids post-stroke. Although this hierarchical order reflects comments from stroke survivors and participants in this study it appears to be clinically formulated and most commonly used in scales and questionnaires to 'describe' patient's mobility, for example in Functional Ambulation Categories. Participants in the present study had stark differences between their use and acceptance of aids or physical assistance, Jim-Bob appeared to accept reliance on his wife to walk to the car and used a scooter outside whereas the Jim, Rosa and Liz were gradually trying to reduce reliance on mobility aids and rarely or only if necessary had physical assistance. The current study and other published work suggest that people with stroke and other long term conditions perceive a hierarchy of walking aids. They seem to aim to use the least supportive devices that maximise self-sufficiency, autonomy, independence, confidence and safety and that appearance and perceived stigmatisation also appear to influence device choice [310, 353, 357].

Liz and Rosa explained that use of FES to control foot drop enabled them to be more independently active and increased their social participation by increasing walking safety and confidence. Increases in activity and participation related to using dropped foot stimulation have been found previously [143]. Liz explained her experiences of AFO and FES use and Bulley and colleagues identified very similar negative and positive factors associated with FES and AFO use [113].

This theme has investigated activity and participation and the strategies and devices used to enable it from the point of view of people with mobility problems post-stroke. Coping with post-stroke walking related activity restrictions is tiring, may require significant adjustment and self-efficacy. The participants in this study illustrated Verbrugge and Sevak's 2004, conclusion that 'adaptations for disability are hard to make, requiring a person's planning, inventiveness, and gumption' [344].

### 5.4.3 Theme 3 - Control

Stroke can lead people to experience a loss of control over 'their bodies and their individual circumstances' [330]. Phase 2 participants had to work hard to control their bodies and even three years after their strokes, they found this fatiguing. In this theme 'the body' emerged as an object of attention post-stroke, suggesting a 'self-body split' as highlighted in other health research [255, 318, 320, 358]. Stroke fundamentally changes the relationship with one's body so that as well as feeling separate it can seem precarious, perplexing and unreliable [320] or 'forcibly present' impeding function

[318]. Stroke survivors in Ellis-Hill and colleagues' study said that they needed to concentrate more on body control, especially in unfamiliar environments or in social situations when movement control and body appearance were paramount. This resonates with the current study in which all of the participants described similar challenges to their body control and talked in ways that often made their body the object of their concentration and mental effort. The Phase 2 participants also spoke about problematic body control causing a lack of control of their situation, such as Rosa fearing falling in crowds. The two subthemes, body control and control of the situation, can be seen as inter-linked and will be treated together in this discussion.

The 'taken-for-granted' background role of the body in normal healthy function appears to be the opposite of the problematic thematised body described by people when illness affects their physical function. People with stroke have described how they could feel comfortable during some activity such as sitting and reading and but less comfortable and experiencing heightened body awareness when physically active such as when walking [359]. They appeared to find this disconcerting and difficult to explain in words. Heightened body awareness has also been noted in occupational performance post-stroke [360]. The idea of a body that can recede in health and advance in illness has been discussed in some qualitative health-care research as well as socio-geographical and philosophical publications but is not prominent in clinical rehabilitation or the rehabilitation research literature, even though it is central to our functioning as humans.

'Our body is the silent, taken-for-granted base from which we act on and learn about the world' [361]

The body is the background to our healthy activity and we could not function if our brains consciously attended to every nerve signal. Therefore much of our body control is unconscious, automatic and out of sight. This has been explored by Drew Leder who used his medical and philosophical training to write extensively about the various ways that the healthy body may be 'absent' whether transparent or recessive within our everyday activity [362]. Leder develops his hypothesis from Merleau-Ponty's work that regards the body as a basis for interaction with the world. Leder gave the example of eating an apple (summarised below) to illustrate the unconscious, 'taken for granted' transparent and recessive aspects of normal body function [362].

- Transparent body. As I sit working at a desk and eat an apple I perceive the size, temperature, firmness, colour, texture and taste *through* my eyes, hand,

mouth and all of their sensori-motor organs but these body parts are not themselves perceived. They have become 'transparent' the 'unthematized substratum from which the world is acted upon' [362].

- Recessive body. While sitting at the desk and during the process of eating an apple my body has receded from my thoughts, it is not the object of attention. Various processes may bring the body 'surface' to conscious awareness i.e. realising the apple has left a sticky residue on my fingers. Once removed the body returns to the background of my awareness as I resume working. The body surface can be brought at will or when required to the foreground of attention in a way that the deeper biological systems, such as the digestive tract dealing with the apple, can never be despite its vital role in sustaining life [362].

Thus Leder suggests that 'certain modes of disappearance are essential to the body's functioning' and describes the 'lived body as necessarily self-effacing' [362]. According to this description of embodiment when the body seizes our awareness in dysfunction it disturbs the normal patterns of absence and can appear separate, 'other', alien and possibly opposed to self [362]. In illness 'certain possibilities of sensation and action, certain resources of energy are simply 'missing' and movement 'must be attended to and actively willed' to overcome the 'sick body' which 'stands in the way, an obstinate force interfering with our projects' [362]. The similarity with the accounts from participants in the present study is pronounced, all of the participants described decreased body control that made their body the problematic focus of their attention. They talked their bodies in ways that inferred its 'separateness', how it became an obstacle to achieving their goals and needed to be actively willed to move appropriately. Many different illnesses seem to heighten body awareness and disrupt normal body absence suggesting that this is not a condition specific response [362]. Heightened body awareness also occurs during skill acquisition. There appear to be some similarities between the experiential descriptions of motor performance that is problematic due to a lack of expertise or due to illness and the two quotes that follow illustrate this.

'One of the important steps on the road to becoming expert in a motor skill occurs when the individual can perform the movements in a seemingly effortless and automatic fashion.' Milton et al., 2004 [363]



'Walking difficulties break a trust forged in infancy: the unquestioning confidence that our legs will reliably, without conscious effort, carry us wherever we want to go.' Iezzoni, 2003 [310]

An awareness of normal body transparency and absence adds a new perspective to understanding the Phase 2 interviews. For example, pre-stroke Rosa enjoyed healthy body function that allowed her to live independently, to walk, dance and play bowls. She spoke about enjoying walking in the woods, watching the birds and feeling *'the moss and the grass under your feet'* (Rosa, page 43). Pre-stroke her ability to concentrate on her surroundings while walking on uneven ground suggests that her body would have had a background role, supporting her in achieving her goals while remaining transparent and relatively unproblematic. Post-stroke her hemiplegic foot became the problematic object of her attention due to impaired motor control *"You silly thing", I say, 'bring your foot with you. Don't forget the foot.'* (Rosa, page 30). Thus, her leg and foot function moved to the foreground of her attention. Use of walking aids including FES appeared to change this by enabling easier movement so that the foot and leg could recede from Rosa's attention and they could work 'automatically' again.

*'FES gave me confidence ... it made me lift my foot off the floor. When I was walking, I was walking properly – putting one foot in front of the other ... automatically ... without me having to drag it along ... drag it along like I was doing ... I used to walk with the left foot and drag the right one behind me – but now I lift it. I can lift it and walk quite good altogether now.'* Rosa, page 13

The process of needing to concentrate on lifting her foot may have Her recovery was been characterised by her previously thematised body becoming more transparent and receding to a more normal background position as her level of physical dysfunction reduced or an assistive devices was used. Leder presented his ideas on body transparency in his book and this has often been referred to in papers on embodiment although Leder offered no empirical evidence to underpin his hypothesis [362]. First hand descriptions from people living with physical disability, such as the descriptions from stroke survivors participating in the Phase 2 Study, may provide some evidence for Leder's model of body transparency that could be extended in future research. Some authors have made a connection between body transparency and wellbeing.

'Transparency of the body, of social ease, can be characterised more generally as transparency of well-being. Well-being is the invisible context enabling us to pursue possibilities and engage in projects.' Carel, 2008 [244]

Changes in normal body absence/transparency as a result of illness have not been thoroughly addressed in the rehabilitation literature. The effects of rehabilitation interventions such as FES or gait training on 'body absence/transparency' also do not appear to have been previously investigated. Both present interesting avenues for future research.

### 5.4.4 Theme 4 - Changes

The Phase 2 participants talked about many walking related changes that had occurred since their strokes. Within their talk about activities and participation were descriptions of changes in their self-perception and roles and how they 'measured' or compared their mobility and function over time. There are many studies investigating the 'lived experience' of stroke and other long term conditions and several of these have highlighted that illness, including mobility restriction, is linked to changes in self-perception [255, 364-366]. Some of the changes in self-perception and roles reported in the Phase 2 study appeared to be a direct result of walking problems i.e. initially Liz could not shop or cook for her family as she had done before her stroke due to mobility problems and this challenged her role as 'Mum'. The current study appears to be the first to make 'walking' the focus and starting point of a qualitative investigation that has identified walking related changes in roles and self. Although there were no explicit prompts asking participants in this study about changes in their self-perception, in retrospect it feels intuitive that changes in such a fundamental aspect of life as 'how we move around' could alter one's sense of self.

It is suggested that people may need to 'negotiate new identities that take account of their reduced physical capacities' in a process that may persist long after the stroke [273]. A recent study addressed the question 'How do persons with stroke view the impact of stroke on their roles and self?'. By examining 33 qualitative studies, with 465 participants from eight countries, this synthesis paper showed that many stroke survivors experienced discontinuity and uncertainty as they struggled to adapt and regain their lives [367]. Developing or adapting roles and a (new) sense of self over a long period is likely to be a challenging process however it may ultimately increase satisfaction and fulfilment [326, 365, 367, 368]. Dependent on the individual, adapting to life post-stroke may be a major disruption or treated as 'just another thing to cope with' in their biographical flow [369]. Although two of the participants identified themselves as disabled none of the four participants talked about joining a stroke club or seeking the company of other people with experience of a stroke. They did not refer

to themselves as 'stroke survivors' although they did talk about their battles for independence.

The Phase 2 participants spoke about becoming less active and adopting an 'observer' role due to mobility restrictions post-stroke. This is not a prominent feature of published post-stroke gait rehabilitation research but echoes my experience in clinical practice. It may be closely related to reduced confidence when mobilising and fear of falling [324, 370, 371]. It may be that other researchers have actually identified similar role changes but described them in different terms. They may have talked about activity restriction due to a 'perplexing'/'unreliable' body or 'body doubt' instead of the subtheme terms 'vulnerability' and 'protagonist to observer' that were used here [318, 359, 360]. Both increasing vulnerability and becoming marginalised are recurring themes in aging research. One can imagine that aging could be seen as a gradual accumulation of physical restrictions, somewhat depressingly the precariousness of our physical ability through life has been described as 'temporary ablebodiedness' [372]. Some of the Phase 2 participants described the effects of their strokes as 'aging' and this sense of restriction and loss of body confidence may be what they alluded to. It is interesting that it was the male participants who mentioned the term vulnerability specifically. One can speculate whether the sudden unaccustomed feeling of vulnerability brought on by the stroke was more pronounced for these male participants, perhaps they were less experienced in feeling vulnerable due to cultural stereotypes and expectations of men as stronger or as 'protector' rather than 'protected' or perhaps it was just linked to the small sample size. This may be an area worth investigating further, as increases in vulnerability have been highlighted in other research investigating the experiences of male stroke survivors and their wives [326].

Participants used their physical ability as a comparator over time. Dowdeswell et al. referred to such comparators as 'yardsticks' in their paper and researchers have suggested that pre-stroke physical ability and return to valued activity appeared to be the ultimate comparator and goal for many individuals [251, 326]. The Phase 2 study also highlighted that these particular participants used multiple comparison points allowing them to recognise variability in their post-stroke ability. This variability has been reflected in other qualitative research, Clarke, 2009, summed this up as 'the trajectory of life after a stroke is a dynamic process characterized by uncertainty and variability, where unexpected plateaus or reversals in the recovery process can foster a sense of frustration and despair' [250]. The Phase 2 participants often used physical disability immediately post-stroke as a comparator; a measure of 'how bad things were'

## Chapter 5: Phase 2 - Qualitative study

that they appeared to find motivating when they felt lower in mood. The participants in the present study also appeared to gain motivation from comparing themselves to others 'worse off' than themselves, which is a common source of comparison in everyday conversation and has been identified in other research [343, 373].

Existing measures of self-selected activity, such as COPM, may reflect changes in role and could be more widely adopted in quantitative gait rehabilitation research and clinical practice. To explore this, the self-selected 'important' COPM items were reviewed for the four Phase 2 participants. Some of the roles that appeared important in their interviews (approximately three years post-stroke) were apparent in the COPM items selected by these participants at a time point less than six months after their stroke. The five most important self-selected COPM activities from the Phase 1 trial are shown in Table 1-1. The COPM items that were related to 'role' have been highlighted in italics for these four participants.

<b>COPM items selected in the Phase 1 quantitative trial</b>					
<b>Jim</b>	<i>Unable to work as a tiler as unable to stand for long enough and due to reduced balance.</i>	Unable to drive due to recent stroke.	Unable to walk for pleasure around 'Town Path' due to fatigue.	Difficulty stepping down deeper steps holding a stick due to balance and mobility.	<i>Unable to work as a tiler due to reduced strength and dexterity in non-dominant left hand.</i>
<b>Jim-Bob</b>	Unable to get in/out of bath independently.	<i>Unable to stand at front of church due to stamina, leg strength and emotional control.</i>	<i>Unable to lead music playing guitar in church due to problems standing (balance and stamina).</i>	Unable to wipe bottom independently.	Unable to walk from room to room due to left leg being heavy and stumbling.
<b>Liz</b>	<i>Unable to cook a meal for family due to reduced balance and left hand function.</i>	Unable to walk independently from room to room due to left leg control including dropped foot.	Unable to manage stairs independently due to tiredness and reduced mobility.	Unable to get in/out of the shower safely independently due to reduced balance and leg control.	Unable to ride her horse due to reduced mobility and arm/leg control.
<b>Rosa</b>	Unable to stand at kitchen worktop to make a cup of tea due to limited balance and reduced right hand function, uses left to hold on.	Unable to lift and move a pan in the kitchen due to reduced mobility and balance.	Unable to use shower or wash independently due to reduced balance and right hand function.	<i>Unable to play games on floor with great-grandchildren due to inability to safely get up and down.</i>	Unable to carry items between rooms due to reduced mobility, balance and right hand function (stick used in left hand).

Table 5-6: Five most important self-selected COPM items from the Phase 1 quantitative trial

The finding that the participants echoed occupational activity priorities selected less than six months post-stroke in their interviews several years post-stroke mirrors other research. People appear to seek continuity following a stroke through resumption of roles and activities that were important to them, described by Ellis Hill and colleagues in their narrative 'life thread model' [374]. It has been suggested that these narrative threads have stability over time and that understanding the threads i.e. roles and activities that are important to a person may enhance rehabilitation [375]. Physical and cognitive post-stroke impairments may prevent survivors from engaging in self-defining activities that constitute important aspects of their identity [250]. One can see parallels between accounts of the contribution of physical ability to 'identity' outlined in the literature and the role changes related to walking difficulties that were described by Phase 2 participants. Mukherjee et al., 2006, described a stroke as 'a radical break in the flow of identity, often due to the loss of skills or activities that were profoundly intertwined with the individual's sense of self (e.g., athlete, breadwinner, traveller)' [365]. Murray and Harrison, 2004, suggest that alongside 'a radical change in embodiment' also comes 'a misalignment between self-identity and embodied capabilities' [273].

The central role of the body in our experience was highlighted in 'Theme 3 – Control' and this can be extended in relation to roles and a sense of self. Leder suggested that 'due to our embodied nature the body becomes the 'ground of personal identity and personal construct and social self-consciousness'' [362]. Carel, 2012, explains that it is precisely because we are embodied that a change in one's body affects our sense of self.

'Thus, restricting movement is inhibiting certain ways of being in the world. The implication for illness is clear: restriction of bodily movement or abilities is a restriction of one's being in the world.' Carel, 2012 [271]

The Phase 2 qualitative study presented in this thesis adds to the literature in this area by providing some evidence that restrictions in self-sufficient mobility challenge retention of a positive sense of self and/or role continuity. Here self-sufficient mobility is used in a broad context to encompass wheeled and non-wheeled mobility. Improvement in mobility and reduced reliance on mobility aids was linked by these participants to more positive self-regard and vice versa (this can be seen in the analysis examples below):

- Jim-Bob talked about being free to '*do whatever*' pre-stroke and post-stroke he said he felt '*imprisoned*' due to walking problems. Becoming self-sufficient in mobility by using a scooter appeared to enable him to feel less restricted.
- Liz spoke about her physical limitations in the 'early days' causing her to use up her energy on '*simple things*' i.e. activities of daily living and self-care. Years later, Liz could safely and independently walk with a stick and FES and she was able to drive a car. At this point a much wider range of opportunities for continuity in life roles was available, she could independently do the shopping, care for her family, attend social events and transport her children to sports matches. Thus her improved self-sufficient mobility (by walking and driving) enabled a resumption of valued aspects of her role in her family, albeit with some adaptation to manner in which activities were undertaken.

The impact of mobility changes on self and roles appears under investigated in the literature and could be developed as a potential outcome measure in rehabilitation and research, particularly physiotherapy based gait rehabilitation. This would help to extend understanding of the personal meaning of walking.

#### 5.4.5 **Mobility in context**

The mobility related activities that have been discussed mirror aspects of existing models of human walking related function such as the ICF and the recently published revised Community Ambulation Model after stroke [186, 309]. This latter model is based on mixed methods research includes walking on different surfaces and at different speeds, endurance, health perception, mood, the environment and personal goals [309]. However, these existing models do not fully reflect the Phase 2 findings. Participants in the Phase 2 study consistently responded to questions about walking by talking about a range of movement activities. Walking as an abstract concept was not their focus. Instead, their focus was on walking in the context of their lives or on the embodied experience of walking. Their descriptions of walking and mobility are more akin to those of the social philosophers or geographers in that they go beyond the existing rehabilitation models of walking function. Social geographers, such as Tim Cresswell, working in the emerging field of 'mobility studies', have defined mobility as 'movement imbued with meaning' and this idea is developed in Figure 5-3 [376-378]. For example two people cross the English Channel on a ferry, they move across the same distance but if one is a lorry driver and the other an illegal immigrant stowed

away in the cargo, they will have a very different embodied experience and meaning to their mobility.

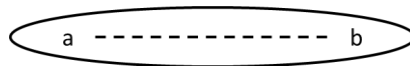
**Mobility** 'Understanding physical movement is one aspect of mobility. But this says next to nothing about what these mobilities are made to mean or how they are practised.' [376]

### Abstracted mobility

a ----- b

This is simple movement i.e. getting from A to B. It is observable and measurable in positivist analysis, such as gait speed in a randomised controlled trial.

### Mobility in context



There are three elements of 'mobility in context' movement, meaning and experience.

1. **Simple movement** or abstracted mobility i.e. getting from A to B.
2. **Meaning** The representations of movement or mobility that give it shared meanings, from conformity or public transport to liberation and the human right to free movement. The language used around mobility highlights its important meaning in our lives. People may be 'slow coaches', they could 'walk tall' or with a 'spring in their step'. Mobility is encoded socially and culturally, e.g. people who can afford to may pay extra for a speedy airport check-in.
3. **Experience** The embodied experience of movement reflects the individual and context e.g. we move differently if in pain or feeling joyful, driving may be nerve wracking or exciting. Mobility is practiced and experienced through the body.

*Figure 5-3: Definition of abstract mobility and mobility in context based on Cresswell 2006 & 2010 and Adey, 2006 [376-378]*



The participants in the current study spoke about movement that was imbued with meaning in the context of their lives. To demonstrate this, one example from the transcripts, Liz walking in the countryside, can be considered using the three layers presented as 'mobility in context' as presented in Figure 5-3. Liz's accounts of walking a distance outside, with a stick, over uneven terrain can be seen as pure movement. The walk in the countryside has meaning, she is a dog walker, an 'outdoors' active type of person, she uses a stick but it is a rough 'natural' stick that perhaps represents her rejection of stereotypes of disability. Liz mainly described the embodied experience of this activity in positive terms (enhanced mood and enjoying the sensations of the walk in the sunny countryside) although she also acknowledged frustrations regarding her lack of body control and increased risk of falls. This is 'mobility in context' as defined by Cresswell 2010 and it extends previous models of mobility by incorporating meaning and embodied experience. Rehabilitation researchers have a choice whether to continue their traditional narrow focus on abstracted mobility or widen their gaze to encompass more contextual factors including the lived meaning and experience of mobility that may be of most relevance to people post-stroke.

#### 5.4.6 **Strengths and limitations of Phase 2 study**

It felt possible to become immersed in the analysis of each participant's transcript because each had such a strong individual narrative and personal context. This analysis was done over more than one year of part time study, which helped each transcript to be considered separately. Despite the differences between the participants, there were strong similarities in the participant's talk about post-stroke movement problems, for example controlling their leg when walking. These could result from limited bracketing but could also be expected due to participant selection based on homogeneous characteristics i.e. a stroke affecting mobility.

Undertaking these interviews required a step away from my usual clinical communication style and the adoption of a new research persona. As a novice qualitative researcher I sought methodological training, via university lectures and courses and gained a valuable third supervisor who is experienced in qualitative research. As outlined in the Phase 2 method (Section 5.2) IPA appeared to suit my research question and epistemological position. Epistemology describes the nature of knowledge and in this case, the knowledge sought concerned how people describe their walking after a stroke and what aspects of walking they value. The selection of IPA methodology was underpinned by my belief that people can share their experience

## Chapter 5: Phase 2 - Qualitative study

of walking after being affected by a stroke by talking about it (as long as they do not have aphasia or cognitive problems). I also believe that the transcripts produced from such conversations can be analysed to allow the phenomenon of walking to be better understood. The IPA approach was well suited to the 'taken for granted' phenomenon of walking, the study size and the relatively homogenous participants. It has also been described clearly, making it accessible to less experienced qualitative researchers.

As a physiotherapist with clinical and scientific understanding of the phenomena (walking) and a deep interest in the experiences of stroke survivors, I had relevant knowledge to begin devising an interview schedule. However, I had little experience of qualitative methodologies, interview methods or qualitative analysis. I also did not have an academic background in psychology, philosophy or occupational therapy on which to draw during the formulation of this phase of my studies.

There was potential that I might gain more in depth accounts from these participants as they were well known to me via their participation in the first quantitative phase of this work. As their physiotherapist in the first phase, I had a quite different role from interviewer in Phase 2. The transition between these roles was enabled by the long time period that divided them and by deciding to interview the participants away from the normal clinical environment. The interview schedule and the information sheet also made the change from NHS research clinician (in the Phase 1 RCT) to University PhD student in Phase 2 explicit. The participants appeared to understand this role shift as none of them asked for any physiotherapy/clinical advice during the interviews. They were all able to talk at length and appeared at ease. They were forthcoming and shared positive and negative comments on physiotherapy, the Phase 1 trial and post-stroke clinical care generally.

I undertook interviewing skills training, qualitative methods training and a specialist IPA methodology course. These were particularly useful as was the qualitative literature search and reading 'Interpretative phenomenological analysis: Theory, method and research' by Smith et al. and 'The active interview' by Holstein and Gubrium [265, 266]. Gradually the language of qualitative research became a little more understandable after initially appearing to be a seemingly impenetrable obstacle that at first prevented me from undertaking this work. In order to aid readability for readers with varied quantitative and qualitative backgrounds I have avoided overuse of jargon in this thesis.

At the completion of the quantitative RCT I was struck by the aspects of walking that the participants spoke about but were not captured in the quantitative outcome measures. This prompted the second phase of this thesis, a qualitative exploration of the experience of walking after a stroke affecting mobility. This simple description of completion of the two sequential phases of this research belies a much deeper shift in attitude and theoretical underpinnings. As a physiotherapist trained in quantitative research methods I was well equipped to undertake Phase 1, in which participants were selected to ensure similarity and then outcome measures and interventions were administered according to the protocol to reduce potential bias and allow statistical analysis and conclusions to be drawn. In Phase 2, I wanted to ask questions about the experience of people who have had a stroke and this demanded an entirely different approach. Rather than the objective recorder of measurements, I became a partner in the creation of four interviews. At first, the notion of the researcher affecting the research positively seemed quite alien. However after hearing the participants interpreting their experience in the interviews and noting how we were both active in the interviews, I began to understand and value the process. The interview participants were not a passive 'vessel of answers' that when asked the right question would always give the same answer. In quantitative research this is often taken to be the case but it ignores our fundamental human individuality. Care was needed to avoid leading questions and as a novice interviewer I did not always manage to do this at all times. Where a prompting comment from me could be interpreted as 'leading', the responses from the participants were treated with more caution in the analysis.

In the process of this thesis I have gained a greater appreciation of both quantitative and qualitative research. I know that as clinicians we need to know something of the average response to interventions to improve outcome and aid decision making but also believe that the detailed description of particular individual experience can give depth to our understanding. Another more experienced qualitative researcher may well have conducted the interviews and analysis more expertly or efficiently or with greater appreciation of the psychological, occupational or philosophical background. These disadvantages may have been counter balanced by the privileged access to experiences of movement post-stroke that these participants shared with me as a researcher and for eight weeks as *their* physiotherapist. I was known to be interested in walking and movement and they talked at length and in detail about the changes that had occurred in the years after their strokes. Having read more widely in this area I am unable to find other studies that have focused only on exploring the experience of walking post-stroke although many explore change in role, activity or participation and

have identified that problematic body control and walking contributes to these changes. I would suggest that choosing to focus on walking may be a result of my professional experience that may not have occurred to other researchers from different backgrounds.

If a PhD is considered an apprenticeship in research, I feel that the two phases of this research have broadened my horizons of knowledge, interest and at a fundamental level altered my attitude to data and evidence. In Phase 1 my data were objective, it was numbers that required a particular quantitative approach to analysis and in Phase 2 the data were words in transcripts that required an equally systematic and rigorous approach. In the first, the researcher is apart and as far as possible attempts to avoid influencing the research and in the second, they become part of the research, the interpretation and the meaning making in a double hermeneutic cycle. Undertaking this qualitative research in a systematic manner has enabled me to overcome my initial distrust and discomfort in becoming part of the research and to begin seeing this as essential to the process rather than 'negative'. Due to the 'double hermeneutic cycle' inherent in IPA there is no comforting member checking or peer checking to triangulate and ensure that the 'right' themes and interpretations have been reached. Quality was maintained by the systematic nature of the interpretation, the transparent data management processes and in the feedback from supervisors and others. This process depended on initial noting and coding of emergent themes on each participant's paper transcript. The data (transcript quotes) and the initial notes were then transferred to Excel before an iterative process of coding and recoding themes occurred until the overall structure that is presented in this thesis was developed. During this process, I repeatedly labelled and re-labelled data trying different themes until the all data could be accounted for in the overall structure of the themes. No doubt, another researcher would have interpreted these transcripts differently but that is part of the nature of this type of research. As a novice qualitative researcher with a quantitative background, the Excel table enabled me to deal with the qualitative data in a transparent and rigorous manner and to record this process.

I have now had the opportunity to present the Phase 1 and 2 findings to diverse audiences and reflect on how I perceive the quantitative and qualitative components of this work. The identification of the diverse valued aspects of movement and normal body transparency has altered the way I assess and provide treatment to people who have had a stroke. In particular, I ask far more about their experience of walking problems and try to understand more about the activities they are most keen to

resume. My shift in understanding reflects the shift in experience that Carel, 2008, highlighted in the following quote '... being ill is not just an objective constraint imposed on a biological body part, but a systematic shift in the way the body experiences, reacts and performs tasks as a whole' [244].



## Chapter 6: Discussion phases 1 & 2

Outcome measurement in gait rehabilitation presents clinicians and researchers with many challenges. Even when standardised measures with established psychometric properties are used, comparison between individuals may be limited because the same score on a measure such as Rivermead Mobility Index or COPM may mean quite different levels of success to different people. There may also be improvement on some scales and not others e.g. low levels of social and leisure activities have been recorded in patient groups with 'good' physical recovery on standard scales [379]. Some authors have argued against the dominance of short term quantitative outcomes in stroke rehabilitation research. Dowswell et al., 2000, suggested that many standardised outcome measures may be most relevant to the concerns of researchers who may prioritise reliability and validity rather than 'the subjective, lived experience of stroke' which is likely to be of greatest importance to patients [251]. A standardised scale, like Rivermead Mobility Index, may highlight changes in walking function but only very partially reflect the complexity and diversity of walking in the context of people's lives. After using quantitative and qualitative approaches to investigate recovery following stroke Dowswell et al., 2000, concluded:

*'Lives encompass more than physical function: they are a complicated mesh of roles, relationships, activities and perceptions. Objectively and reliably measured improvements (as identified by accepted instruments such as those used in the accompanying quantitative study) may not be regarded as improvements of any significance by stroke patients themselves. Patients and caregivers held holistic views about health and well-being and evaluated their overall recovery in this context.'* [251].

The Phase 1 quantitative study design allowed systematic hypothesis testing but gave a relatively narrow assessment of the effects of walking problems on the participants' lives. Therefore, the second phase of research was undertaken in which people living with post-stroke walking problems were interviewed. They spoke at length about valued aspects of walking related movement in the context of their lives. The interview participants valued aspects of walking such as confidence, spontaneity and automaticity that appear to be under researched, perhaps because they are challenging to measure or have not been fully considered before. It is also possible that they are reflected in other qualitative research studies but this has not been transferred into clinical practice or research. Quantitative outcome measurement in

gait rehabilitation is often decontextualized in the process of producing reliable and valid measures that are sensitive to change. This may increase the chance of mismatches between what is measured in gait rehabilitation research and what is meaningful for individuals. The wide ranging impact of gait dysfunction on every day activity, participation and roles post-stroke was illuminated by the Phase 2 study.

Participants in the Phase 2 study described what it was like to live with reduced motor control and thematised their bodies i.e. their post-stroke impairments and activity limitations forced their bodies to the 'foreground' of their attention. As they improved and could engage in activities that were meaningful to them, their body seemed to recede to a more 'background' role. This phenomenon has been noted in qualitative studies and first person accounts of living with chronic illness affecting walking and has been considered in phenomenological writing about embodied experience. However, it is under researched in gait rehabilitation post-stroke and has not been fully considered in outcome measurement. The outcome measures that are available at present allow researchers and clinicians to understand more about individual and group changes in gait but do not appear to fully capture the embodied experience of living with post-stroke walking problems.

### **6.1 Rehabilitation research: adding to the case for quantitative and qualitative methods**

The outcomes of the two phases of this research have been discussed separately (sections 4.5 and 5.4) and together (above) and this has demonstrated how each contributed different types of knowledge about walking and how they complemented each other. Other researchers, such as Dowswell et al., 2000, have also made the case for mixed methods research in rehabilitation [251].

Section 5.4.5 introduced 'mobility in context' as a concept that contained the abstract 'measurable aspects' of moving from A to B as well as the meanings that movement can have and the embodied experience of movement. This moves the focus in gait rehabilitation research from a narrow naturalistic or scientific knowledge of gait that focuses on measurable aspects such as gait speed to one that also encompasses wider aspects of activity and participation and also the embodied experience and personal meaning of walking.

Gait has mostly been researched as a dysfunction of the biological body with the focus on a comparison with and a return to 'normal'. However it has been suggested that



patients describe it as a disruption of their lived body [244, 246] and this can be seen in the Phase 2 findings presented in this thesis. There is a need to adopt new perspectives in rehabilitation. This is not just an issue for researchers but also for health professionals who often approach illness from an objective, scientific perspective akin to quantitative research. Other researchers, especially authors writing with a first person experience of illness such as Havi Carel and Kay Toombs, have expressed the need to expand the conversations about illness so that the lived experience of patients is considered alongside the measurable aspects of their disease that have often been the focus of medicine and research [244, 246]. Kay Toombs suggests that physicians and patients inhabit different worlds because of the fundamental difference that exists 'between the lived experience' of the patient and the medical 'conceptualisation of illness as a disease state' [246].

Toombs' criticism of the divergent worlds of the physician and patient could be equally applicable to the divergent foci of most quantitative clinical research and published first person and qualitative research accounts of illness. The 'separateness' of the research methods and the imbalance of attributed value are evident in published rehabilitation research. This can be seen when comparing the editions of the National Clinical Guidelines for Stroke. Early editions did not include qualitative research at all and made the RCT the 'gold standard'. The third and fourth editions from 2008 and 2012 included qualitative research where it was appropriate for the research question or the only evidence available. In these later editions, selected qualitative studies were described as 'powerful and informative' [4]. However there is still a major imbalance between the majority of quantitative research and the small numbers of qualitative studies included in these guidelines.

Similar imbalances may be seen in other areas of rehabilitation. The ICF (Table 2-4) gives a well recognised and widely accepted view of human functioning. The ICF model does not include reference to the embodied experience of illness and disability which would largely be explored using qualitative methods. Perhaps this is similar to other publications such as the Stroke Guidelines referred to above and reflects the majority of published research that is quantitative rather than qualitative and the historical lack of value attributed to qualitative research in rehabilitation. Both forms of knowledge are important in forming more holistic rehabilitation clinical practice and research.

In summary, Phase 1 of this research found outcome measures based on activity and participation were feasible in this trial. It also made the case for inclusion of more

impairment based outcomes in future similar research in order to help describe the population more fully. Inclusion of outcome measures across the impairment, activity and participation domains appears important in this type of research in order to capture changes in function. Phase 1 concluded that further research was required to explore the experience of post-stroke walking problems and the personal, meaning of walking. Phase 2 of this research has explored the experience of walking post-stroke and drawn novel conclusions about the embodied experience of walking post-stroke. Both phases add to a more comprehensive understanding of walking problems post-stroke.

The research presented in this thesis supports the continuation and expansion of the exploration of lived experience of illness alongside objective scientific accounts of illness in order to inform a comprehensive view of illness, rehabilitation, impairment, activity and participation. This applies to individual medical encounters and the wider published research. Focussing on only one type of knowledge gives an incomplete understanding. There is a place and value for all these varied types of knowledge because paying attention to the lived experience of illness as well as objective aspects of body dysfunction is likely to improve care and reduce suffering due to illness.

## Chapter 7: Conclusions

This thesis has used both quantitative and qualitative methods to investigate walking problems post-stroke. As a result, this thesis contains analysis of average changes in walking in a group of people with post-stroke mobility problems and the particular experiences of a subgroup of these participants. The two phases of research addressed several research questions and conclusions for each question are presented in Sections 7.1 and 7.2.

The Phase 1 pilot RCT addressed the quantitative research questions but highlighted the need for a more in-depth and nuanced understanding of the experience of trying to walk following a stroke. The quantitative and qualitative phases of this research were sequential and separate. They represent a shift in understanding, yet can be thought of as exploring different perspectives of the same phenomenon. The two phases of this research have informed a new understanding of mobility in context post-stroke and highlighted a mismatch between commonly used outcome measures in gait rehabilitation and the priorities of people with stroke. The Phase 2 qualitative research appears to be unique in its 'bottom up' approach i.e. starting with the phenomenon itself, walking. Interpretive phenomenological research methods, rooted in individual experience, were used to begin investigating walking from this different perspective. This contributes depth and breadth to the published, relatively abstract, understanding of walking post-stroke that dominates quantitative gait rehabilitation research. The research presented in this thesis has extended understanding of gait post-stroke, identified gaps in the stroke literature and areas for future work. This may have wider relevance for people with other conditions that affect gait.

## 7.1 Conclusions - Phase 1 pilot study research questions

### 1. Is it feasible to integrate electrical stimulation into early outpatient physiotherapy treatment, determined by protocol adherence and user views?

The feasibility of the trial protocol was demonstrated by 100% attendance at assessments and physiotherapy sessions, with no dropouts. The eligibility criteria identified potential participants who could complete the protocol and were suitable for the interventions. Feedback after the trial from participants and carers was positive and no negative points or issues were raised. Most of the outcome measures were feasible in this participant group but the pilot RCT suggests that PCI, RVGA, HADS and the Falls Diary should be replaced or removed in a fully powered study, for the following reasons:

- There was missing PCI data in this pilot study. Some participants were on medication that precluded reliable calculation of PCI and other data were missing due to assessor error. The single assessor design may have contributed to this. Were PCI retained in a fully powered study, the assessment protocol should contain more prompts to record heart rate. An alternative, Borg Rating of Perceived Effort Scale, has been suggested for use in a fully powered study.
- RVGA from video by blinded assessor was feasible but was so time consuming that utility in a fully powered study may be questionable. It was also broad, including many aspects of gait that may not be affected by the intervention tested. Therefore, analysis of this pilot study suggests that alternatives should be developed that are more specific to dropped foot, prior to a fully powered study.
- The HADS showed no consistent trends, unlike previous studies with participants who were more than six months post-stroke. It may be that people with more recent strokes have more variable scores and this should be investigated prior to a fully powered study. Since mood was not the focus of the intervention HADS could be excluded from a larger trial.
- Completion of a self-report Falls Diary did not appear feasible, with the current protocol instructions and support, since the completion rate was low (20%).

The completion of the Phase 2 qualitative study raised the importance of confidence when walking and the linked concept of fear of falling. It is proposed that a fully powered study should include Falls Efficacy Scale (International) as a measure of

walking confidence that reflects fear of falling. It is simple to administer and in the intervention group can be scored twice, as though walking with and without FES. This may extend understanding of the effects of electrical stimulation. The qualitative study also raised the importance that stroke survivors placed on stamina, strength, walking speed and distance. This reinforces the case for continued inclusion of 10mWT and 6MWT and the addition of a measure reflecting effort of walking, such as Borg Rating of Perceived Effort Scale, in a future fully powered study. A suitable strength measure may be a functional lower limb muscle power test such as repeated timed sit to stand. Other walking attributes valued by the Phase 2 participants are not commonly assessed in quantitative trials were spontaneity, automaticity, self-determination and balance, agility and manoeuvrability. Inclusion of Falls Self Efficacy Scale in a larger study may partially reflect some of these attributes.

The Phase 2 analysis suggested that individuals valued a wide range of walking related activities and that these often impacted on their sense of self and roles. This reinforced the usefulness of COPM as an individualised outcome measure that can capture some of the participant's valued activities.

## **2. What is the most appropriate primary outcome measure?**

10mWT is the most appropriate primary outcome measure for a fully powered trial because it has robust psychometric properties and was feasible in this pilot RCT. Walking speed was identified by participants in the Phase 2 study as a valued aspect of walking and selection as the primary outcome is strengthened by other studies that recognize 10mWT as a meaningful outcome (see Section 2.3.3).

## **3. What sample size would be required in an adequately powered RCT to investigate the immediate and longer-term effects of electrical stimulation on mobility, when delivered as an integrated part of outpatient physiotherapy for people less than six months post-stroke?**

Allowing 15% for attrition, 144 participants per group would produce an adequately powered study based on this Phase 1 protocol and the variability of 10mWT measurements.

## **7.2 Conclusions - Phase 2 qualitative study research questions**

- 1. How do people who have had a stroke affecting walking and have taken part in gait rehabilitation, describe their own walking and how it has changed over time since the stroke?**

When asked about walking and how it had changed post-stroke these participants mostly spoke about walking in relation to activities that were important to them. They could talk about how walking had changed and compared their ability over time, often in comparison to their pre-stroke ability. These participants also used their mobility, function and walking aids as comparators over time.

- 2. What aspects of walking do they value and how have these changed since the stroke?**

These participants valued various walking related movement activities. These mirrored the Canadian Model of Occupational Performance, which is an existing model of human function that includes self-care, leisure and productivity domains. This strengthens the inclusion of COPM in future gait rehabilitation studies since it is based on this model.

These participants spoke about walking related activities that explicitly or implicitly suggested that they valued walking speed, distance, stamina, confidence, balance, agility, independence and strength. These participants linked independent mobility to freedom and self-determination and spontaneity, which are under researched areas of gait rehabilitation post-stroke. Also under researched is automaticity of walking movement. From their descriptions, this attribute seems closely linked to effort of movement and fatigue that were talked about by these participants as barriers to walking.

### **3. How do they describe their experiences of using assistive devices?**

Assistive devices and mobility aids were spoken about in the context of coping with post-stroke movement problems. They appeared to perceive a hierarchy of walking aids, with some seen more positively as 'progress'. Most participants selected the least supportive option they could safely walk with. This is an under researched area of gait rehabilitation. In line with other research, the Phase 2 participants who had used FES spoke positively about its use but highlighted some drawbacks.

### **4. Can the conclusions be used to inform the design of future gait rehabilitation studies?**

The themes that emerged from the qualitative interviews could inform the design of future gait rehabilitation studies and this is explored more fully in Chapter 9.

The valued walking attributes highlighted by these participants could be explored with other people who have had a stroke affecting mobility to assess whether a common set of valued walking related movement attributes can be developed. This may have relevance for other patient groups and therefore gait rehabilitation and research more widely. The valued movement attributes identified by the Phase 2 participants reinforce the inclusion of some outcome measures in future studies i.e. 10mWT, 6MWT, effort of walking, Falls Efficacy Scale and muscle strength. The participant's descriptions of activity and participation also suggest that COPM is a meaningful outcome measure.

Analysis of these transcripts indicated that these participants had varied self-efficacy, which may have affected willingness to practice challenging tasks and may have affected outcome. This qualitative research therefore concludes that self-efficacy should be explored in relation to walking outcome in gait rehabilitation studies. It also highlighted the need for further exploration of the effects of post-stroke walking problems on roles and the embodied experience of walking.





## **Chapter 8: Future work**

### **8.1 Recommendations for a fully powered trial based on the Phase 1 pilot RCT and Phase 2 interviews.**

This research recommends that a fully powered RCT should be undertaken to determine the effectiveness of electrical stimulation for gait rehabilitation in people who are less than six months post-stroke.

Power calculations based on the Phase 1 pilot RCT suggest that 144 participants per group would produce an adequately powered study based on this protocol and the variability of 10mWT measurements, allowing 15% for attrition. To recruit this many participants the fully powered study would need to be multicentre. Participants could be identified in a similar manner to the Phase 1 study i.e. by inpatient and outpatient stroke rehabilitation clinicians. However, due to lower than expected recruitment rates in the Phase 1 trial efforts should be made to increase the number of Participation Identification Sites and to offer 'identifying clinicians' additional support and encouragement. Also gaining involvement from the whole team rather than concentrating on therapists and the stroke coordinator may increase recruitment rates. The Phase 1 eligibility criteria identified potential participants who could complete the protocol and were suitable for the interventions therefore the same eligibility criteria can be retained in a fully powered study.

Both groups improved during the Phase 1 intervention period and maintained this through follow-up, one explanation is that the physiotherapy gait intervention given to both groups improved mobility. There were no problems delivering this intervention and no changes are suggested to the physiotherapy intervention for a fully powered study. It may be interesting to consider shorter or longer intervention or follow-up phases however, since the Phase 1 treatment protocol has been piloted and was feasible no changes are suggested to the study timeframe before use in a fully powered study.

In a fully powered a multicentre study, all the treating physiotherapists would need to be experienced in stroke rehabilitation and trained in use of FES and cyclical exercise stimulation. It is clear from the literature that the contents of gait rehabilitation vary. Therefore, in a fully powered study the physiotherapy treatment contents should be

## Chapter 8: Future work

informed by the evidence discussed in Section 2.2 of the literature review (presented in Table 2-3) and the activities that were carried out in the Phase 1 treatment sessions (Appendix H). A fully powered effectiveness study based on the Phase 1 protocol would investigate whether electrical stimulation improves mobility in standard NHS clinical practice and would be a pragmatic test of the intervention. With multiple clinicians with varied experience, the interventions provided may benefit from regular audit by a trial organisation team to ensure consistency with the protocol and adherence to electrical stimulation clinical practice guidelines as described and referred to in Section 2.2.2.6. Currently available stimulators can combine the functions of FES for correction of dropped foot and cyclical electrical stimulation and have a digital display that would enable audit of settings and usage logging. These devices were not available at the time of the Phase 1 pilot RCT but should be used in a fully powered study.

The Phase 1 pilot suggested that that PCI, RVGA, HADS and the Falls Diary should be replaced or removed in a fully powered study. The Phase 2 study indicated that confidence and fear of falling were important aspects of walking. The following assessment protocol was developed from the research presented in this thesis and could be used in fully powered study.

<b>Assessment schedule for outcome measures in a fully powered study</b>	
Rivermead Mobility Index (RMI)	Week 1, 8, 20
6 minute walk (6MWT) including recording Borg Rating of Perceived Effort Scale at the end	Week 1, 8, 20
Walking speed (over 10m) (10mWT) including recording Borg Rating of Perceived Effort Scale at the end of each walk  Group A repeated 10mWT twice without stimulation  Group B repeated 10mWT twice without stimulation then once with stimulation then once without	Week 1, 8, 20
Functional Ambulation Category (FAC)	Week 1, 8, 20
Video taken to allow Rivermead Visual Gait Assessment (RVGA) or an alternative specific dropped foot assessment scale by a separate blinded assessor.	Week 1, 8, 20
Canadian Occupational Performance Measure (COPM)	Week 1, 8, 20
Falls Efficacy Scale (International)  Group A recorded once at each assessment  Group B recorded twice, scored as though without stimulation then with stimulation	Week 1, 8, 20
Psychosocial impact of assistive devices scale* (PIADS)  Group B only	Week 20

*Table 8-1: Assessment schedule for outcome measures in a fully powered study*

A separate assessor could conduct these assessments. This would separate the treatment and assessment roles but would not achieve blinding of group allocation. To blind to group allocation a second person (an 'assessment assistant') would be required (to turn on or off stimulation before the 10mWT/walking video and collect the Falls Efficacy Scale and PIADS).

A fully powered study should include subgroup analysis to explore any links between outcome measures and Group B participant's wish to continue FES use after the trial. A fully powered study could also assess cost effectiveness. This would be likely to require additional outcome measurement and data collection that could include completion of the Stroke Impact Scale or a standardised quality of life measure (e.g. EQ-5L-5D) and recording of any costs including consumables used, such as electrodes.

In the Phase 1 pilot RCT there were no formal mechanisms to capture the comments from participants. A participant questionnaire could be completed at the Week 8 and 20 assessments to capture participant feedback. Additionally participants reported that seeing the video of their walking after the quantitative trial had ended motivated them. Participants who have completed the fully powered study intervention and assessments should be offered the opportunity to watch their previously videoed walking from the three assessments and any feedback could be recorded.

### **8.2 Development of a dropped foot assessment scale**

Participants in the Phase 2 study spoke about the problems that they experienced due to disordered motor control of their affected foot and ankle. Analysis of their interviews suggests that measurement of dropped foot may be meaningful to people who have had a stroke affecting their walking. The absence of a specific 'dropped foot scale' presents measurement challenges to researchers and clinicians in gait rehabilitation as there are no ideal alternatives. For example, RVGA from video by blinded assessor has been piloted in the Phase 1 trial but it was time consuming and it may be too broad to fully and reliably capture changes in dropped foot. The two phases of this thesis suggest that developing a dropped foot assessment scale could have clinical and research relevance. It would have been useful to have such a scale available for screening and assessment in the Phase 1 trial. Such a scale needs to be practical, with no specialist equipment required and preferably possible to assess in real time and from video. Important guidelines have been published to improve the quality of

outcome measures and these should be considered during the development of any new outcome measure. These guidelines are called 'COnsensus-based Standards for the selection of health Measurement Instruments' [380]).

Completion of the research presented in this thesis has highlighted the potential for a mismatch between what is measured in clinical trials and issues that are relevant to people with stroke. Therefore it is suggested that a dropped foot assessment scale should be co-produced with people who have experienced the problem. This could be achieved through the following multi stage process:

1. Expert consensus regarding the pertinent aspects of stance and swing that could be recorded, such as 'absent heel strike', 'weight bearing on lateral border of foot' and 'poor floor clearance' or 'scuffing'. This consensus group could include clinicians and people with stroke who have experienced dropped foot.
2. Video and gait laboratory analysis of individuals with dropped foot, including mild, moderate and severe cases and people walking with different walking aids and with hyper/hypo tonicity. RMI and 10mWT and FAC (with normal walking aids) should be assessed. Some or all of these participants should use FES or AFOs and videos should be taken with and without the devices correcting dropped foot. Participants should also be asked to describe how their walking problems affect their lives and what it feels like to walk with dropped foot problems. They should be asked to rate their walking and their foot and ankle control on each videoed test. Visual analogue scales could be used to do this.
3. Matching gait laboratory assessment and video to develop a dropped foot assessment from the terms identified in step 1. Testing of the new scale for redundancy and assessing measurement properties would be required during development.
4. Once refined this assessment tool could be given to separate clinicians to score from the videos taken in step 2 to establish intra and inter tester reliability. Scores could be compared to RMI, 10mWT and participant scores/descriptions to assess validity. Sensitivity to change could be assessed by comparison of videoed walking with and without electrical stimulation/AFO.
5. Intra and inter rater reliability and validity would also need to be established in real time dropped foot assessment using the new tool. Sensitivity to change could be assessed by comparison of walking with and without stimulation/AFO in real time.

A dropped foot assessment scale could be used in eligibility screening and outcome measurement and would be a valuable addition to the outcome measures available to clinicians. It may also have relevance to people with dropped foot from a cause other than stroke.

### 8.3 Development of a core set of valued aspects of walking related movement

The Phase 2 participants spoke about walking related activities that explicitly or implicitly suggested that they valued walking speed, distance, stamina, confidence, balance, agility, independence and strength. These participants also linked independent mobility to freedom and self-determination and spontaneity, which are not usually 'measured' in stroke rehabilitation research or reflected in published research. A new outcome measure could be developed and potential questions could be based on a visual analogue scale and ask participants to rate the item between two extremes of response. Please see Table 8-2 for an example of how such questions could be framed. They would need to be developed following best practice guidelines [380].

Valued movement attributes	Please consider how you have felt when you have walked about in the last week.  (The possible question to be assessed on a visual analogue scale is written in italics, with possible descriptors for minimum/maximum on a visual analogue scale in brackets)
<ul style="list-style-type: none"> <li><b>Dependence, independence and self-determination</b></li> </ul>	<p><i>'Do you feel that your physical ability has restricted your activity choices in the last week?'</i></p> <p>(My physical ability does not usually restrict my movement choices/My physical ability usually restricts my movement choices)</p>
<ul style="list-style-type: none"> <li><b>Confidence</b></li> </ul>	<p><i>'How concerned are you about falling or losing your balance when you walk inside with your normal walking aids?'</i></p> <p>(I am not usually concerned about falling or losing my balance/I am usually concerned about falling or losing my</p>

	<p>balance)</p> <p><i>'How concerned are you about falling or losing your balance when you walk outside with your normal walking aids?'</i></p> <p>(I am not usually concerned about falling or losing my balance/I am usually concerned about falling or losing my balance)</p>
<ul style="list-style-type: none"> <li>• <b>Automaticity</b></li> </ul>	<p><i>'How much do you need to concentrate on your body movements when you walk?'</i></p> <p>(I do not usually need to concentrate on my body movements/I usually need to concentrate on my body movements)</p>
<ul style="list-style-type: none"> <li>• <b>Spontaneity</b></li> </ul>	<p><i>'Do you feel that you can walk around without planning?'</i></p> <p>(I do not usually consciously plan how I walk around/I usually need to consciously plan how I walk around)</p>
<ul style="list-style-type: none"> <li>• <b>Speed, distance and stamina</b></li> </ul>	<p><i>'Does fatigue restrict how far you can walk?'</i></p> <p>(My walking distance is not usually limited by fatigue/My walking distance is usually limited by fatigue)</p>
<ul style="list-style-type: none"> <li>• <b>Strength</b></li> </ul>	<p><i>'When you walk does your body feel powerful?'</i></p> <p>(My body usually feels powerful when I am walking/My body does not usually feel powerful when I am walking)</p>
<ul style="list-style-type: none"> <li>• <b>Agility and manoeuvrability</b></li> </ul>	<p><i>'When you walk does your body feel agile?'</i></p> <p>(My body usually feels agile when I am walking/My body does not usually feel agile when I am walking)</p>

*Table 8-2: Styles of question that could be used in an outcome measure to explore changes in the aspects of walking that were valued by the Phase 2 participants.*

The valued movement attributes were common to many if not all four of the participants and have been reflected in other studies. An extended literature review is required to identify all the literature in this area including studies relating to people with other health conditions affecting walking. Further work could establish a core set of valued walking related movement attributes that may be relevant to people with stroke but may

also have wider relevance to people with other conditions. These could be generated via interviews or focus groups. If similar movement attributes were valued by the larger more varied group, an outcome measure might contain questions in the style of those in Table 8-2. The sets of valued attributes could be formulated into questions and tested for generalizability using survey methods of large groups of people living with different conditions affecting gait. Were a core set of valued walking related movement attributes identified, it could be used to direct research and in the development of interventions and outcome measures so that they reflect the concerns of people with mobility problems. They could also contribute to other work identifying minimum core sets of outcomes that should be assessed in effectiveness trials [381].

### **8.4 Walking in relation to activity and participation**

Studies have highlighted the effects of a stroke on activity and participation and have emphasised the contribution of mobility difficulties to this process, see Section 5.4.2. The Phase 2 study had a 'bottom up' approach that began by asking about walking and gained information about activity and participation. There is scope to explore the role of walking in activity and participation further. The role of walking in the resumption of previously valued activity should also be explored further. Both of these inter linked areas of research could improve understanding of living with post-stroke mobility problems and could inform outcome measurement selection and development. Walking related self-efficacy and walking task avoidance could also be considered as they have implications for gait rehabilitation and activity/participation. Phase 2 interviewees indicated that walking activities changed over time and were associated with physical ability. Activity and participation have been considered in published qualitative interviews but no studies focussed on the role of walking in activity and participation could be found. Walking in relation to individual activity/participation and changes over time could be explored during a series of interviews with the same participant at different time points post-stroke. Alongside the interviews outcome measures such as FAC, Falls Efficacy Scale (International) and RMI could be recorded and repeated at each time point to allow the participant's walking to be considered from multiple perspectives.

### **8.5 Motor control in relation to embodied experience**

The individual's embodied experience may also be an interesting avenue for further research. Consideration could be given to 'body foreground/background' (foreground



in dysfunction and receding in health) in relation to outcome measurement and rehabilitation more generally. This is an established model in philosophy and has been discussed in some published research. This model resonates with my clinical experience but has not been widely adopted in stroke rehabilitation or healthcare generally.

There is scope to investigate the foreground/background role of the body in specific activities in far more detail. An important activity that could be explored is walking. An extended literature review would be necessary to identify all the published work in this area, including health research as well as humanities publications. Further enquiry could focus on the experience of body 'integration' after stroke and other illnesses affecting walking. The Phase 2 study and published research highlights the objectification or thematisation of body parts in dysfunction and during skill acquisition that warrant further investigation. This may describe aspects of the embodied experience of motor re(learning). Use of FES and other walking aids appeared to enable the previously thematised foot/ankle to recede to a more normal background role and this could be explored further.

In order to explore the foreground/background role of the body in walking post-stroke a series of interviews with the same participant could be conducted at different time points post-stroke. This would allow greater understanding of how body integration changes and is experienced in relation to walking post-stroke. It has the potential to inform post-stroke rehabilitation and have a wider relevance, particularly for use in outcome measurement.

## **8.6 Further exploration of walking as a phenomenon.**

The research presented in this thesis has brought together evidence from people with stroke and the published literature to show that quantitative measures of mobility miss important aspects of the experience of walking and walking dysfunction post-stroke. Quantitative measures do not reflect the richness and liveliness of walking as a basic human function that is orientated towards individually specific goals and plans. Wider dissemination of the Phase 2 research findings could also stimulate discussion about this area of lived experience. This is an issue post-stroke that may have implications for people with other causes of limited mobility. Walking as a lived, socially situated phenomenon appears to be an under researched area and it could be considered from a variety of perspectives for example from the perspective of:

## Chapter 8: Future work

- people who have experienced gait problems and their paid or unpaid carers and family
- health care clinicians including gait specialists and non-specialists
- people outside health care e.g. healthy people
- researchers from non-healthcare disciplines (such as the humanities e.g. philosophy, geography) to reflect culture and society.

An extended literature review and information gathering activity outside traditional gait rehabilitation may inform the understanding of walking as a phenomenon and highlight if other work in this area has been undertaken. If it continues to appear under researched, awareness raising conversations with people from diverse backgrounds may begin the process of exploring walking from the multiple perspectives outlined above. There is a recent precedent for bringing together a diverse range of expertise to aid understanding of a previously taken for granted basic human function. The Wellcome Trust recently funded a five year project called 'Life of Breath' to understand breathing from multiple perspectives. The investigators have backgrounds in the humanities and medicine and the following is reproduced from the project web page:

'Breathing is a basic physiological process, but also has deep cultural and personal meaning. It is intimately associated with our state of mind and can be controlled. Breathing's pathological derivative, breathlessness, is a major symptom in cardiac disease, respiratory disease and anxiety disorders and respiratory disease. Whilst its physiology is well recognised, the subjective experience of breathing and of breathlessness is poorly understood. We set out to address this problem with a novel interdisciplinary study of a somatic sensation, breathlessness, and its non-pathological counterpart, breathing' [382].

The aims of the Life of Breath project are to understand an under researched area of basic human function from multiple perspectives, bringing together information from different academic and clinical disciplines to better understand the experience of breathing and breathlessness. There are parallels with the further work proposed here to increase understanding of the embodied experience of walking and walking as a basic human function with personal meaning.

## **8.7 Concluding remarks**

The quantitative and qualitative phases of this research explored different perspectives of the same phenomenon, walking. The two phases of this research have informed a broader understanding of contexted and embodied mobility post-stroke and highlighted a mismatch between commonly used outcome measures in gait rehabilitation and aspects of walking valued by people with stroke. The research presented in this thesis has extended understanding of gait post-stroke, identified gaps in the stroke literature and areas for future work. This research is likely to be of relevance to people with mobility problems post-stroke but may resonate with people with other conditions that affect gait and with the clinicians who try to support them.





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## Appendix A 10 metre walking test characteristics




Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Holden et al. [188]	1984	Stroke and multiple sclerosis (n=61)	Reliability study same session with a rest between tests.	Showed a correlation between velocity and FAC	High inter and intra-rater reliability, patients could use walking aids and/or physical assistance		9.2m course 
Wade et al. [204]	1987	Acute Stroke (n=60)	Longitudinal study with matched healthy controls (n=64)	Showed a wide range of gait speed in this group and that 10mWT correlates with gait quality and use of aids.	Concludes 10mWT is reliable.		No details
Bohannon [161]	1990	Stroke (acute and chronic) (n=26)	Validity study	10mWT correlated with paretic knee extensor muscle force.			8m course 


Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Colleen et al. [383]	1990	Chronic stroke (n=25)	Test-retest inter-rater reliability study		High inter and intra-rater reliability (3 assessments over 5 weeks. 3 assessors).		10m course with a turn
Wade et al. [384]	1992	Chronic stroke (n=94)	Randomised crossover trial of physiotherapy intervention			10mWT detected improvements. Categorical measures did not.	10m course with a turn
Perry et al. [196]	1995	Sub acute stroke (n=147)	Validation of new classification of gait	Correlates community walking with faster gait velocity, proprioception and greater lower limb muscle strength.		10mWT most useful for distinguishing between household or community ambulation.	10m walk but only middle 6m measured.





Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Liston et al. [192]	1996	Chronic stroke (n=20)	Reliability study		High test-retest reliability. Tested 3 times at weekly intervals		Normal pace. 
Burridge et al. [121]	1997	Chronic stroke (n=32)	RCT, use of ODFS compared to control physiotherapy group).			Considered a 10% increase in speed to be functionally relevant.	'Briskly but safely', using a stop watch 
Roth et al. [198]	1997	Stroke (n=25)	Validity study	Gait velocity (15m) correlates with many temporal measures of gait incl. cadence, hemiplegic stance duration.			15m section of longer walk was timed.


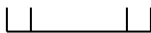

Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Bernhardt et al. [195]	1998	Acute stroke (n=29)	Longitudinal study.	10mWT correlated with Motor Assessment Scale.		Improvements in all measures over time. Some unable to walk 10m scored 0.	Comfortable speed 
Van Herk et al. [203]	1998	Stroke (n=43)	Reliability study 10mWT with a turn compared to without	10mWT with and without turn correlate although the former normally takes longer.	First and second 10mWT (no turn) correlate but the first is significantly longer.		Usual walking speed. 

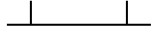
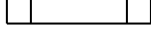
Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Taylor et al. [133]	1999	Chronic stroke (n=111)	Retrospective study of patients using the ODFS over 4.5 months.			Detected change in patients using ODFS	'Briskly but safely', using a stop watch 
Maeda et al. [385]	2000	Stroke (n=40)	Validity and reliability study	10mWT correlated with quadriceps activity, timed up and go and reaching.	Good test retest reliability within session and between sessions 1 year apart		Usual walking speed. 
Salbach et al. [386]	2001	Acute stroke (n=50)	Cohort study	Improvements in 10mWT correlated with subjective participant reported improvement.		Slower walking speeds initially were associated with longer rehab	

Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Rosier et al. [189]	2001	Mixed stable neurological (n=46)  Stroke (n=21)	Reliability and validity study	10mWT correlates with RMI, 2MWT	High test retest reliability (tests one week apart).	10mWT slower if using an aid or if there is sensory loss.	No course details.
Dean et al. [206]	2001	Stroke (n=14) compared to healthy volunteers.	Descriptive study	Stroke group walked slower. In stroke group 10mWT over estimates 6MWT.			Comfortable speed, 

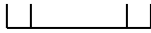

Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Green et al. [191]	2002	Chronic stroke (n=22)	Reliability study, sessions 1 week apart		Within session reliability high and between session less reliable. First walk consistently slower than 2 <sup>nd</sup> and 3 <sup>rd</sup> .		10m with a turn. Time to turn not included.
Steffen et al. [194]	2002	Community dwelling elderly (n=96)	Reliability study	Fast 10mWT correlates with comfortable 10mWT.	Within session test retest reliability high. 1 <sup>st</sup> walk not significantly slower.		Speed over central 6m of 10m walk recorded.
Watson [200]	2002	Healthy adults (n=28) people with head injuries (n=17)	Reliability study.		High test retest reliability. Concludes that it is valid to average 3 trials or just complete one.		


Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Kelly et al. [387]	2003	Acute stroke (n=17)	Single assessment , compared to age matched group.	10m WT correlates with 6MWT and peak VO <sub>2</sub> 10mWT approx. 50% of that recorded in healthy subjects.			Best of 2 10mWTs analysed. 
Lord et al. [5]	2004	Sub acute stroke living at home (n=115)	Single assessment	10mWT correlates with RMI and with ability to walk outside which is considered very important by 74.6% of group			No details given
Lord and Rochester. [73]	2005	Stroke	Review of community ambulation outcome measures	Suggests 10mWT used alone is insufficient to describe community ambulation			N/A


Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Flansbjer et al. [190]	2005	Chronic stroke (n=50)	Test retest reliability study		Test-retest high reliability. Fast walk test had best reliability.	Suggests smallest clinically significant difference for 10mWT	Comfortable and fast speeds. 
Flansbjer et al. [162]	2006	Chronic stroke (n=50)	Single assessment	10mWT correlated with paretic quadriceps strength and participation (SIS)			Comfortable and fast speeds 
Kollen et al. [388]	2006	Acute stroke (n=81)	1 year prospective cohort study.	Strong correlation between comfortable and maximum speed over 10m.			Mean of 3 Stop watch 

Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Kollen et al. [197]	2006	Acute stroke (n=73)	1 year prospective cohort study.	Strong correlation between 10mWT and FAC			Mean of 3 Stop watch 
Taylor et al. [389]	2006	Chronic stroke (n=28)	10mWT taken in clinic compared to community walking speed over 10m & 300m	10mWT speeds >0.8m/s in clinic correlates with community walking. In subjects with slower 10mWT community gait velocity was over estimated by 10mWT.			Mean of 3 Usual speed 



Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Handa et al. [201]	2007	Healthy adults	Reliability study comparing stop watch to instrumented system	Strong correlation between 10mWT calculated from instrumented gait lab and stop watch.	Stop watch is a reliable method for measuring 10m walk speed with high inter tester and test re-test reliability.		Comfortable speed 
Kottink et al. [115]	2007	Chronic stroke (n=29)	RCT implanted CPN stimulation against control			10mWT increased in stimulation group but not the control group using an AFO	Comfortable speed 4 walks mean of 2 <sup>nd</sup> , 3 <sup>rd</sup> and 4 <sup>th</sup> 


Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Schmid et al. [199]	2007	Sub acute stroke (n=64)	Comparison between 10mWT and Stroke Impact Scale (SIS).	10mWT correlates with function (SIS), suggests 10mWT can divide mobility into 3 categories.			Comfortable speed  Mean of 3 
Donovan et al. [390]	2008	Chronic stroke (n=30)	10mWT assessed in clinic compared to 6MWT in clinic and community	Limited correlation between clinic 10mWT and clinic 6MWT	Impact of environment found to be small.	Slower <0.58m/s subjects 10mWT over estimated 6MWT  Faster > 0.58m/s subjects 10mWT under estimated 6MWT	Comfortable speed lacks details of course.

Author	Year	Population	Design	Validity	Reliability	Sensitivity	Course
Graham et al. [391]	2008	Stroke	Literature review of test methodology		Lack of detail in reporting, variation in methodology and distance (5m, 10m) may affect reliability of 10mWT and generalisability of results.		N/A
Barrett et al. [392]	2009	Multiple sclerosis	Intervention study, RCT of ODFS			Significant increase in 10mWT i.e. orthotic effect from ODFS	'Briskly but safely', using a stop watch 

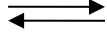



## Appendix B Six minute walking test characteristics

Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
Butland [209]	1982	Stable chronic respiratory disease (n=30)	Test-retest Comparison of 2, 6 and 12 minute walk tests	All three tests are highly correlated; concludes they are similar measures of exercise tolerance.	Not assessed.	Longer tests showed more spread. 6 and 12MWT may discriminate more	Not described.
Guyatt et al. [212]	1985	Community dwelling patients with chronic heart or lung disease	6x 6MWT over 12 weeks. Compared to cycle ergometer testing and cardiac function status tests.	6MWT correlated with conventional measures of functional status and exercise capacity. Not strongly correlated with cycle exercise testing suggesting that they measure different constructs.	Guyatt et al., suggest that distance walked is stable (95% of the time they were within 12% of mean 6MWT distance). There is a learning effect during first 2 walks.  Subjects walked	In cardiac patients authors suggest test re-test is stable enough to detect small change.	↕

Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
					significantly further if encouraged		
Harada et al. [393]	1999	Community dwelling older people at home or living in retirement homes (n=86)	Test retest 6MWT compared with performance based clinical and self report measures. Single 6MWT done on each occasion.	Correlated with other measures. Study reports 69% of variance in the 6MWT explained by self reported physical functioning, lower body strength, balance and gait speed.  Known group validity – more active participants covered significantly greater distances than less active.	One week test retest reliability shown to be $r=0.96$ for 6MWT.	Not assessed.	




Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
Gibbons et al. [394]	2001	Healthy volunteers aged 20-80 (n=79)	Test-retest Four 6MWT performed on same day	Direct correlation between height and 6MWT distance and inversely related to age.	Learning effect in healthy volunteers over 4 trials. First walk was not furthest in 86% and last walk was the furthest in 48%.	Not assessed.	↔
Solway et al. [211]	2001	Cardiac and/or respiratory patients	Qualitative Systematic review of 2, 6 & 12 minute self paced walking tests, and shuttle walk test.	Improvement in 6MWT related to decreased breathlessness, improvement in quality of life and VO <sub>2</sub> max. Recommends 6MWT over others.	Consistent on third walk in a series over time.  Time of day had no effect but encouragement did. Mood can be a confounding variable.	In COPD a change of 54m is clinically significant translating into change in functional status.	↔

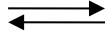
Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
Cunha et al. [395]	2002	Inpatients <6 weeks post first stroke (n=20)	Single assessment. Comparison of 5MWT to 5m walking test, energy expenditure, oxygen uptake and Functional ambulation category (FAC).	5MWT gave better discrimination between patients than qualitative measures. Good correlation amongst gait tests these correlate to FAC	Sources of potential bias surrounding use in parallel bars not fully explored.  General method not reproducible.	Not assessed	*5MWT    5MWT adapted for use in parallel bars if required but few details.
Eng et al. [210]	2002	Community dwelling chronic stroke cohort	Self paced 12MWT and 6MWT compared to 8m walking	6MWT and 12MWT correlate and subjects cover similar distances in each 2 minute segment.	Not assessed.	Not assessed.	


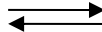



Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
		(n=25).	test.	Suggest 6MWT can be used instead of 12MWT			
Kelly et al. [387]	2003	<7weeks post first stroke (n=17)	Comparison of peak oxygen uptake from semi recumbent cycle with 10m and 6MWT.	Cardiovascular fitness was impaired post-stroke. Strong correlation between all 3 measures.	Not assessed	Not assessed	↔
Enright et al. [396]	2003	Community dwelling elderly cohort (n=3333).	One off 6MWT in a longitudinal study 68% could complete the	No adverse events recorded in this large cohort. 6MWT correlates with age, waist size, moderate-severe left ventricular	Not assessed.	Not assessed.	↔

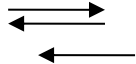
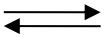

Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
			6MWT others were excluded on health grounds.	wall abnormalities, use of some cardiac drugs, MMSE, depression symptom score, grip strength. Gives reference distances.			
Oulette et al. [397]	2004	6 months to 6 years post single stroke (n=42)	Intervention study. Randomised trial of lower limb resistance training v control.	Not assessed.	Not assessed.	No significant differences in 6MWT or 10mWT between groups. Muscle power increased with intervention	Not described

Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
Eng et al. [398]	2004	Chronic stroke (n=12).	Test-retest VO <sub>2</sub> max, 6MWT, sub maximal treadmill and cycle ergometer compared.	VO <sub>2</sub> max not correlated to 6MWT	High test retest reliability (ICC>0.90)	Not assessed.	
Flansbjer et al. [190]	2005	Chronic stroke (n=50)	Test-retest	Fast 10mWT and 6MWT correlated	High intra rater reliability.	Suggests smallest clinically significant difference in 6MWT.	
Flansbjer et al. [162]	2006	Chronic stroke (n=50)	Descriptive analysis of convenience	Strong correlation between 6MWT and paretic	Not assessed	Not assessed	

Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
			sample	quadriceps/hamstring strength and participation (SIS)			
Newman et al. [207]	2006	Community dwelling 70-79 year olds (n=3075)	Cohort study Single long-distance corridor walk test of 400m taken at start; follow-up of health status over six years.	Inability to complete 400m and slower performance were prognostic factors for total mortality, cardiovascular disease, mobility limitation and mobility disability. Long-distance corridor walking correlates with health outcomes.	Long-distance corridor walk test NOT 6MWT Included in table as the test covers similar distance	Not assessed.	Long-distance corridor walk test NOT 6MWT    400m course
Kottink et	2007	Chronic	RCT			6MWT	

Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
al. [115]		stroke (n=29)	implanted CPN stimulation against control			increased in stimulation group but not the control group using an AFO.	
Patterson et al. [208]	2007	Chronic stroke with residual hemiplegia (n=74)	Single measurements incl. treadmill walking, stress test, Berg Balance Test, quads strength and 6MWT.	6MWT strongly related to Peak VO <sub>2</sub> in people with milder deficits. 6MWT correlated with balance and quads strength. Poor balance more important predictive factor for 6MWT in slower walkers and cardiovascular fitness	Not assessed.	Not assessed	

Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
				more predictive in faster walkers.			
Donovan et al. [390]	2008	Chronic stroke (n=30)	10mWT assessed in clinic compared to 6MWT in clinic and community	Acceptable limits of agreement found between clinic 6MWT and community 6MWT.	Impact of environment found to be small.	Not assessed	Not described
Fulk et al. [399]	2008	Acute stroke inpatients undergoing stroke rehab (n=37)	Test-retest. 6MWT, 5m walking speed and Functional Independence Measure (FIM).	Found 6MWT related to FIM and correlated with 5m walk speed.	Overall sig increase from first 6MWT to the second (144.2m and 160.9m) but not when individuals requiring physical assistance were	Change >54.1 m at 90% confidence suggested as level of clinical difference.	

Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
			Discounted if FIM changed between trials.		excluded (191.5m and 210.4m).		
Muren et al. [400]	2008	Chronic stroke (n=30)	Single measurements 6MWT and quality of life	6MWT correlated with quality of life	Not assessed	Not assessed	
<b>Key</b>	<div>  <p>walk repeatedly between two points with a turn at each end e.g. up and down a corridor</p> </div> <div>  <p>walk repeatedly round an oval track</p> </div>						

Author	Year	Population	Design	Validity	Reliability	Sensitivity	6MWT course
		<div></div>	walk repeatedly around a rectangular track				



## **Appendix C Review of mobility assessments considered for inclusion in the Phase 1 trial**

These mobility assessments were selected for review because it has been suggested that they cover a wide range of aspects of mobility and such a mobility measure needed to be identified for the Phase 1 trial [221]. Mudge and Stott, 2007 systematically reviewed the outcome measures used to assess walking ability following stroke. They identified 61 outcome measures that assessed some aspect of walking and had been used in the stroke rehabilitation research literature, the thirteen measures that measured the broadest range of mobility subcategories according to the ICF are reviewed here [221]. They were reviewed to identify a mobility measure that covers a broad range of mobility components, has good psychometric properties and is practical and suitable for use with people less than six months post-stroke.

### **Rivermead Mobility Index (Activity level)**

Collen et al., 1991 developed the Rivermead Mobility Index (RMI) from the gross function subscale of the Motor Assessment Scale [401]. They aimed to make a simple, reliable, and valid measure of 'mobility disability'. Disability was a definition in the ICF that became activity and participation in its later development [186]. The intended focus of the instrument was the patient's ability to move their own body and it does not measure the effective use of a wheelchair or mobility increases gained by help from another person. It is simple consisting of 14 questions and one observation. No equipment is required other than the questionnaire paper and a pen. It can therefore be administered in any comfortable location including clinical and non-clinical settings. The authors state it is reliable in different locations and when used by health professionals with varied backgrounds, i.e. experienced and training physiotherapists and doctors. Collen et al., 1991, conclude by stating that 'While the RMI may not be perfect, we are unaware of any better test' [401]. This is supported by more recent reviews [184].

There is evidence that the individual items have acceptable reliability and that the RMI strongly correlates with other measures including, Barthel Index, 10mWT, 6MWT, Berg Balance Scale and falls [100, 189, 290, 401]. The RMI has good test retest reliability and inter rater reliability showing agreement within 2.2 points [289, 402, 403]. It has

been shown to be sensitive to change in patients during the first year after stroke [290, 404]. The RMI items largely move from easier to more difficult tasks but summated scores only should be reported as it is not a hierarchically ranked scale [405]. Each item is scored equally but some researchers have criticised this, suggesting that people with a stroke may not value the ability to stand up unaided equally with the ability to run. The RMI is a widely used, quick, simple, sensitive, largely self-report measure of 15 meaningful mobility items and it has known measurement properties in samples of acute and chronic stroke patients.

### **Adapted Patient Evaluation Conference System (Activity level)**

The Patient Evaluation Conference System (PECS) was developed in 1979 by Harvey and Jellinek. Their 1981 publication gave details of the development of PECS and the independence/assistance required for specified activities on an eight point rating system [406]. They used the PECS as a focus for multidisciplinary goal setting in a rehabilitation unit. Inter rater reliability was described as 'consistent' with no further details given. They stated that 'content validity appears to be present' although no supporting evidence for this statement is presented. Harvey and Jellinek published a later paper showing how results can be displayed on a computer [407]. Another article investigated using the subjective cues used by physicians to set goals for the patient with respect to PECS items [408]. There is no evidence for patients being involved at all in the design of the outcome measure or in setting goals for their rehabilitation. This would now be seen as a limitation as there is a move away from paternalistic medical models of healthcare.

The PECS mobility subsection was used as a stand-alone outcome measure of function in 204 stroke patients [409]. This PECS subsection includes sitting balance, rolling, moving from lying to sitting, ambulation, stairs, motor loss and abnormal muscle tone with an adapted scoring system. It is termed the Adapted Patient Evaluation Conference System (APECS) by Korner-Bitensky et al., 1989. There is no reference to the validity or reliability of using this subsection as a functional outcome measure. Subsequent research uses the APECS as a measure of functional status post-stroke citing the work by Korner-Bitensky et al.[410-412]. Mudge and Stott, 2007 cite this subsequent research in their review as evidence of psychometric properties but no published data for the reliability or validity of APECS were found. It therefore does not fit the criteria of this search.

### **Rivermead Motor Assessment (Activity Level)**

The Rivermead Motor Assessment (RMA) is based on clinician observation of the patient completing a series of tasks which can be time consuming and tiring to complete [383, 402]. Therefore this mobility measure does not fit the criteria of this search.

### **Chedoke-McMaster Stroke Assessment (Activity Level)**

The Chedoke-McMaster Stroke Assessment (CM) is a two part measure, including a physical impairment inventory and a disability inventory. The impairment inventory is based on the recovery stages post-stroke identified by Brunnstrom [413]. These stages were adapted for the CM impairment inventory and assess motor recovery on a range from zero (flaccid) to seven (normal) over six body areas (shoulder, arm, hand, leg, foot and postural control). Gowland et al., 1993, demonstrated high inter rater and test retest reliability for this section of the CM. They propose that this subsection can be used to classify patients based on recovery. Low scores in this section have been correlated with low Berg Balance Test scores, low Functional Independence Measure (FIM) scores and falls in a group of inpatient stroke patients [414].

The second section of the CM, scores fourteen items, including several walking activities, using the same independence/assistance ratings used in FIM. The FIM is a commonly used outcome measure in the USA and rates performance in six domains (personal care, sphincter control, mobility (transfers), locomotion (walking and stairs), communication and social cognition) [182]. Within these domains different activities are specified and the degree of independence or dependence on another person is scored on a seven point scale. The fifteenth CM item is walking distance over 2 minutes for which points are given if distance is similar to that expected for age matched healthy people. Gowland et al., 1993, describe the CM as valid and reliable. It is however time consuming to score and only a limited number of the CM items in either part one or part two score walking activities. Salter et al., 2005, describe this test as mainly assessing motor impairment rather than activity limitation as many items are non-functional [402]. This test does not meet the criteria of being easy to administer and mainly measuring mobility limitations.

### **Functional Walking Category (Activity Level)**

Perry developed categories to characterise people's walking ability post-stroke [196]. The categories were linked to walking speed and ability to negotiate obstacles. The six

functional walking categories were physiological walking, limited and unlimited household walker, limited, least limited and unlimited community walker. Categories are assigned by a clinician based on the clinician matching the patient to the category which best describes them. The categories have been used as outcome measures in intervention studies in order to evaluate change in 'mobility' [415, 416]. These studies reported increases in mobility as subjects moved from one category to the next. There is some face validity to this approach as clinician and patient are likely to have a clear idea if they walk in the home or community but allocation to the exact category appears subjective. No evidence of reliability, validity or sensitivity to change could be found despite use of the categories in stroke research as an outcome measure [196, 415, 416]; therefore this test does not match the criteria.

### **Activities Specific Balance Confidence Scale (Activity & Participation Level)**

This scale is based on Bandura's concept of self-efficacy. The belief that a task is unachievable may lead to avoidance. This outcome measure reflects self-perceived confidence in performing a range of sixteen tasks without falling [417]. Good reliability, validity and responsiveness have been demonstrated for the Activities Specific Balance Confidence Scale (ABC) in older adults [418]. Measurement properties were evaluated in a stroke population and moderate correlations were found with Berg Balance Test and gait speed over 8m (n=77) [419]. Test retest reliability was high with a four week gap between tests in a subgroup of 24 participants (ICC of 0.85). Formal testing of validity and reliability in samples of people less than six months post-stroke was not apparent although one study could be found which used ABC Scale as an outcome measure with this group [350]. They question its use in an acute population with cognitive difficulties due to the difficulty of the concept and this could also be true of language problems. Insight is required to rate self-perceived confidence in performing tasks like standing on a chair to reach an item. Reliability of estimation in a group with recent onset of problems and rapid change in abilities may be less than in samples of patients with chronic stable conditions. Patients with stroke who have just returned home after their first stroke and begun attempting or resuming normal activities of daily living may have particular problems perceiving ability to perform the more unusual tasks in this scale and therefore reliability in the target population may be reduced.

### **Human Activity Profile (Activity & Participation Level)**

The Human Activity Profile (HAP) has been used to assess levels of activity in a variety of clinical settings. This questionnaire is made up of 94 self-report items of daily living

ordered according to metabolic demand. Activities range from independently getting out of bed (number 1) to jogging 3 miles in less than 30 minutes (number 94). Respondents record if they are still doing the activity, have stopped doing it or never did it. The highest numbered task that the respondent is still doing is recorded as the maximum activities score. An adjusted score is calculated by subtracting the number of activities they have stopped doing from the maximum score [420]. Davidson and de Morton, 2007, systematically reviewed the HAP and suggested the minimum detectable change is 7.8. They reported good test retest reliability and high correlation with other measures of activity across a diverse range of health problems. Reliability of the measure in stroke was established by Teixeira-Salmela et al., 2007 [421]. Participants were recruited from local stroke clubs and by advertisement; there is no mention of time since stroke (n=24). Proxy scores were compared to the observed score. Proxy scores from a person who knows the subject well correlated with observed scores but were often underestimates of the subject's actual abilities. There was strong correlation between self-reported and observed ability (ICC 0.86). The authors conclude that HAP has good concurrent validity as they found strong associations with 10mWT. They demonstrate reliability of the self-report and the possibility of using proxy reports. No studies examining reliability of people with acute or sub-acute stroke to self-report activity levels could be found. Teixeira-Salmela et al., 2007 mention that 'recent relearning of skills' could create discrepancy in self-reported and observed performance. It could be suggested that this group is in a period of adjustment and potentially quickly changing abilities thus creating potential variability in response and measurement error. For example a family caring for someone with a recent stroke may be unlikely to encourage them to scrub floors, walls or cars in the first weeks out of hospital. Therefore the person may respond that they have stopped scrubbing these items (number 47) and it would be unclear if they could not physically do the task or if it was no longer part of their role. No mention of insight problems affecting HAP score was mentioned although this could also affect reliability of the scores. Experience suggests that some people with a stroke can have good mini mental examination scores and very poor insight into their abilities. In more acute stroke populations observed, self-report and proxy answers may vary considerably and there appears to be scope extending the work of Teixeira-Salmela et al., to examine the psychometric properties of HAP with respect to people with more acute strokes. As reliability in this patient group has not been established this measure does not fit the criteria.

### **36 Item Short Form Health survey (Activity Level)**

The 36 Item Short Form Health survey (SF36) does not fit the criteria as it includes many items which are not mobility focused although it does have good psychometric properties [402].

### **Nottingham Health Profile (Activity & Participation Level)**

The physical, emotional and social status of an individual influences response to ill health and Hunt et al., designed the Nottingham Health Profile (NHP) to reflect this [422]. It is a simple written assessment which is easily understood by healthy people and people with health conditions including stroke [423, 424]. The NHP items can be grouped into six areas which are sleep, physical ability, energy, pain emotional reactions and social isolation. The scores for each area are usually summed [422]. A second part investigating social activities such as work and hobbies is not used widely and has less testing to establish psychometric qualities.

The NHP is a reliable and valid outcome measure of perceived health status and particularly perceived distress as it has strong correlations with mood [424]. It is not focussed on mobility so does not meet the criteria.

### **Modified Emory Functional Ambulation Profile (Activity Level)**

The Emory Functional Ambulation Profile records the time taken to complete five standardised tasks. It was modified to incorporate a weighting for different walking aids, assistive devices and manual assistance [425]. The tasks included in the modified Emory Functional Ambulation Profile (mEFAP) are timed by two researchers, one of whom is able to give manual assistance as required. The tasks are firstly a 5m walk on hard floor then a 5m walk on carpet. This is followed by a timed 'up and go' during which the subject rises from a chair walks 3m. The fourth task is to walk around an obstacle course where two bricks are spaced over a 5m walk on hard surface and the subject must step over both before turning round a large dustbin and returning to the start stepping over both bricks again. The fifth task is to walk up and down five steps with a handrail [426].

The mEFAP has demonstrated test retest and inter rater reliability and good validity, correlating with other measures of mobility (10mWT and RMI) [426]. It has been evaluated with inpatient and sub-acute stroke patients attending outpatient rehabilitation. Some equipment is required although these items are available in most rehabilitation centres. It requires two researchers to administer the test in a

standardised manner. A timed measure of this sort has a ceiling effect for high functioning subjects taking a similar amount of time to healthy age matched individuals. A floor effect will also be apparent, as some participants would not be able to complete the tasks at all. The mEFAP is a physical test that could potentially tire participants and is time consuming to administer so therefore does not meet the criteria.

#### **Rehabilitation Activities Profile (Activity Level)**

This outcome measure is designed to improve interdisciplinary care through interviews and observation and is not mobility focussed [427, 428]. It therefore does not meet the criteria.

#### **Clinical Outcome Variables Scale (Activity Level)**

This mobility measure includes assessment by observation of 13 items on a 7 point scale by a therapist [429, 430]. Reliability has not been demonstrated and no information regarding sensitivity to change and validity in patients less than six months post-stroke could be found. Therefore this test does not meet the criteria of this search.

#### **Ewart's Self Efficacy Scale (Activity Level)**

This measure assesses self-perceived ability to perform a number of different activities of daily living. It has been used in one study of post-stroke muscle power related to behavioural factors [431]. This measure does not meet the criteria as it has not been validated for use with people post-stroke and reliability has not been established.





## Appendix D Phase 1 - Ethics and sponsorship letter



### National Research Ethics Service Wiltshire Research Ethics Committee

Room 11  
John Apley Building  
Royal United Hospital  
Combe Park  
Bath  
BA1 3NG

Telephone: 01225 821031  
Facsimile: 01225 825725

26 April 2007

Doctor Paul Taylor  
Consultant Clinical Engineer  
National Clinical FES Centre  
Salisbury NHS Foundation Trust  
Salisbury District Hospital  
Salisbury  
Wiltshire  
SP2 8BJ

Dear Doctor Taylor

**Full title of study:** Pilot study to investigate the effectiveness of combining physiotherapy and electrical stimulation to improve mobility in recently discharged stroke patients.  
**REC reference number:** 07/Q2004/19

The Research Ethics Committee reviewed the above application at the meeting held on 05 April 2007.

#### Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation. The committee would ask you to ensure that the following matters are addressed:

- (1) Please ensure that the appropriate headed notepaper is used.
- (2) On the Patient Information Sheet reference to Wiltshire Research Ethics Committee having given the study a 'favourable opinion' must be amended to 'have reviewed the study'.
- (3) Please clarify on the Consent Form exactly who will have access to data.
- (4) Please ensure that the title is consistent throughout.

#### Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form.

#### Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

This Research Ethics Committee is an advisory committee to South West Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committee

**Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Application	5.3	15 March 2007
Investigator CV	Paul Taylor	
Protocol	1	01 March 2007
Summary/Synopsis	1	01 March 2007
Letter from Sponsor		06 March 2007
Compensation Arrangements		01 June 2006
Questionnaire: PIADS		
Questionnaire: HAD Scale		
Letter of invitation to participant	1	01 March 2007
GP/Consultant Information Sheets	1	01 March 2007
Participant Information Sheet	1	01 March 2007
Participant Consent Form	1	01 March 2007
Overview	Dr Jane Burridge	
Letter from funder		27 June 2006

**R&D approval**

The study should not commence at any NHS site until the local Principal Investigator has obtained final approval from the R&D office for the relevant NHS care organisation.

**Membership of the Committee**

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**REC reference number 07/Q2004/19 please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

pp Mrs Katrina Brockbank  
Dr Elizabeth Price  
Co Chair

Encs:

List of names and professions of members who were present at the meeting and those who submitted written comments  
Standard approval conditions  
Site approval form (SF1)

cc:

Salisbury NHS Foundation Trust



Salisbury NHS Foundation Trust

Wiltshire Primary Care Trust

R&D Management Committee  
South Wiltshire R&D Consortium  
Room 9, Level 4  
Salisbury District Hospital  
Salisbury  
Wiltshire  
SP2 8BJ

Telephone: (01722) 425027  
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email: stef.scott@salisbury.nhs.uk

06 March 2007

Dr Paul Taylor  
Medical Physics  
SDH

Dear Paul

**RDMC23/06/07: Pilot study to investigate the effectiveness of combining physiotherapy and electrical stimulation to improve mobility in recently discharged stroke patients**

Thank you for submitting the above project to the South Wiltshire Consortium R&D Management Committee (Consortium RDMC). The Consortium RDMC reviewed your submission at their meeting on 27 February 2007. The documents reviewed were as follows:

1. NHS REC application form parts A, B and C
2. Research Protocol (undated)
3. Grant application to the stroke association
4. Certificate of insurance for OML
5. Funding letter from the stroke association
6. Patient information sheet
7. Consent form
8. Invitation to take part in a research study letter
9. GP letter
10. Sponsor request form dated 19/02/2007
11. Risk assessment
12. Monitoring and reporting schedule

The committee have provisionally agreed to sponsor the above project, subject to you providing a copy of:

1. the research ethics approval letter;
2. the ISRCTN registration

Once the committee have received the above information a full approval letter will be sent.



INVESTOR IN PEOPLE

## Appendix D

If you do not intend to proceed with this project then please let the Consortium RDMC know so that we can amend our records.

If you have any questions about this letter, then please do not hesitate to contact Stef Scott on 01722 425027.

Yours sincerely

Mr Alistair Flowerdew  
Chair of the Consortium R&D Management Committee.

21 December 200

## Appendix E Phase 1 - Cover letter and Participant information sheet



National Clinical FES Centre  
Department of Medical Physics and  
Biomedical Engineering  
Salisbury District Hospital  
Salisbury  
Wiltshire  
SP2 8BJ

Tel 01722 429065  
Fax 01722 425263

June 2007

Dear Sir or Madam,

We would like to invite you to take part in a research study. Your clinicians in Hospital think you may be suitable. Before you decide you need to understand why the research is being done and what it would involve for you. There is an information sheet about the research attached. Please ask us if there is anything that is not clear or if you would like more information.

We will only know if you are interested if you contact us. There are several ways to get in touch with Paul Taylor or me. They are

- telephone
- email
- post – by returning the slip below

If you are still in hospital and think you may be suitable you can still get in touch and staff will return the slip in the internal mail. Thank you for your time.

Yours sincerely,

Ingrid Wilkinson  
Specialist Research and Clinical Physiotherapist.

I **am interested** in taking part in the FES in stroke research trial.

Signed..... Printed .....

Date..... Your telephone number.....

Please return to **Miss Ingrid Wilkinson,**  
**Specialist Research Physiotherapist,**  
**National Clinical FES Centre,**  
**Department of Medical Physics,**  
**Salisbury District Hospital,**  
**Salisbury, Wilts. SP2 8BJ.**  
E mail 'ingrid@salisburyfes.com'

Tel. 01722 336262 x 4060

Version 2  
June 2007



## Patient Information Sheet - Part 1

### **Study to investigate the effectiveness of combining physiotherapy and electrical stimulation to improve mobility in patients who have recently left hospital after their first stroke.**

*We would like to invite you to take part in a research study.*

*Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Section 1 tells you the purpose of this study and what will happen to you if you take part. Section 2 gives you more detailed information about the conduct of the study.*

*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.*

#### **What is the purpose of the study?**

We are trying to understand more about the best ways to help people after they have had a stroke.

Physiotherapy is often part of rehabilitation. After stroke some muscles may not work properly and Physiotherapists use exercises to help. Dropped foot is when the muscles which lift the foot don't work well and is a common problem following stroke. It can make the foot drag and can cause someone to feel unsteady or trip. Physiotherapy exercises may help this problem. Electrical stimulation to lift the foot can also help. We want to find out if combining these treatments is a good idea in early stroke rehabilitation.

#### **Why have I been invited?**

You have been invited to take part in this research because you had a stroke less than six months ago and have recently gone home from hospital or are just about to go home. While a patient on the stroke ward the physiotherapists, the Stroke Coordinator or the Consultant thought you may be suitable to take part in this research. If you take part, you will be one of 30 people in the study.

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**Do I have to take part?**

No, it is up to you to decide. We will describe the study and go through this information sheet with you, which you can then have to keep. We will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw from this study at any time and without giving a reason. Doing so will not affect the standard of care you receive.

**What is electrical stimulation?**

Impulses of electricity can be delivered through self adhesive electrodes placed on the skin surface. The electrodes can be positioned so that they activate certain muscles and this is comfortable for most people. Electrical stimulation devices have been developed at Salisbury District Hospital, where over 1600 patients, with neurological problems, have received treatment to improve walking. The majority of these patients use an Odstock Dropped Foot Stimulator (ODFS) which delivers electrical impulses to the common peroneal nerve supplying the muscles which lift and slightly pull the foot out sideways. Stimulation is delivered through self adhesive electrodes placed on the skin of the lower leg. A pressure switch worn in the shoe controls the system. Stimulation begins when weight is taken off the switch and stops when weight returns.

When people who have had a stroke a long time ago use the ODFS, their walking speed increases and the effort of walking is reduced. Other research has shown that some people who have used the stimulation for a few months, had a 'learning effect' so that their walking improved, even when they did not have the stimulation turned on. We are now interested to find out whether this 'learning effect' is increased if people use the ODFS soon after they have had a stroke.

Other paralysed muscles can be stimulated to improve strength. This study will integrate the functional application of ODFS in walking, with exercise stimulation for strengthening leg muscles and physiotherapy as there is evidence each element individually can improve walking.

**What are our research questions?**

We want to find out if using electrical stimulation as part of physiotherapy is better than physiotherapy on its own in people who have had a stroke recently. We also want to find out if people who have recently had a stroke receive a similar benefit to patients whose stroke was a long time ago. We want to investigate if any benefit lasts.

**What will happen to me if I take part?**

Once you are sure you want to take part and have filled in some forms we will start the study.

As you would expect when you start outpatient physiotherapy, after your stay in hospital, you will be reassessed by the new physiotherapist and together you will set some goals for the treatment. The new physiotherapist will have been told a bit about you by the staff on the ward to ensure you are suitable for the trial and so they can give good follow up physiotherapy.

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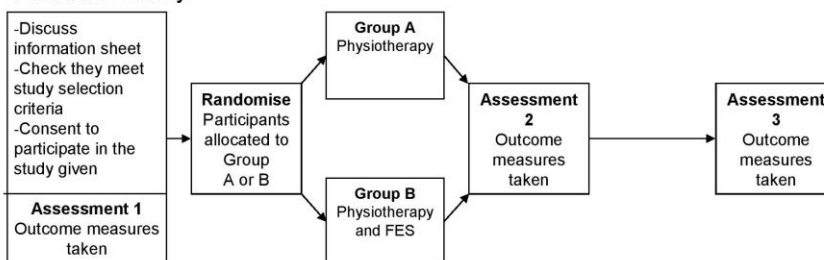
This is a Randomised Trial comparing physiotherapy including electrical stimulation to physiotherapy alone. Sometimes we don't know which way of treating patients is best. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). There are 2 groups so you have a 50/50 chance of being in each group. Then twice weekly physio sessions will be organised for you. The type of physiotherapy will depend on which group you are put in at the first appointment, see below. After six weeks of physio you will be reassessed and the main part of the trial will be over.

After the 6 weeks of treatment you may need more physiotherapy or wish to continue to have electrical stimulation. We will request this, although what is available may depend on your area and is outside our control. 20 weeks after you started on the trial you will be asked to come back for another reassessment to find out about the long term effects of the treatment.

#### Study Schedule

Initial Contact	Week 1	Weeks 2-7	Week 8	Weeks 9-19	Week 20
Given Information Sheet	Informed consent recorded, Outcome Measures taken and participants randomly put in Group A or B	Treatment block, 2 appointments per week	Outcome Measures taken	No treatment, 12 week follow up period	Outcome Measures taken

#### Patient Journey



All of the treatment and the assessments will be carried out at Salisbury District Hospital by an experienced Chartered Physiotherapist who has specialised in treating patients with neurological problems such as stroke. Each appointment should last about 1 hour.

It will take about 18 months for all 30 patients to be seen and 2 years to complete the research.

The physiotherapy will be what you would normally expect but the assessment appointments may take a bit longer and will be a bit different because it is a research project. No treatment which would normally be available will be withheld. Electrical



stimulation is not used as a standard part of outpatient physiotherapy in most UK hospitals. The focus of this study will be improving walking. The physiotherapy, exercises and stimulation you may take part in will be targeted towards improving walking.

At the assessments at the beginning and end of the six weeks of physio and 20 weeks later we will do the following tests with you:

- We will ask you to walk 10 metres with your stick or normal support, 4 times, and measure your speed and heart rate while you do this.
- We will ask you to walk as far as you can in 6 minutes, with rests and use of your stick or normal support.
- A video will be made of you walking. Later, the quality of your walking will be scored, from the video, by a clinician who is not involved in your treatment and will not know which group you are in.
- You will also be asked to complete several questionnaires about your life after the stroke, about the stimulation and about your ability to do day to day tasks.
- Throughout the project you will be asked keep a 'falls diary'. In this diary you will record each occasion on which you trip and fall.

Facilities will be available to ensure privacy when changing, placing electrodes or measurement equipment. As necessary, chaperones will also be provided. The walking tests will include use of a chest strap to measure heart rate. This strap needs to be placed next to the skin around your ribs, we can help with this.

#### Expenses

You will be able to claim for travelling costs to and from the hospital for all trial appointments.

#### What will I have to do?

If you are involved in any other trials please discuss them with us.

If you wish to volunteer for this trial you will need to:

- get in touch with us to organise an assessment appointment

If suitable for this trial you would need to:

- fill in treatment and falls diaries
- attend appointments.
- be an active participant in the sessions and do the home exercises and use stimulation (if required) according to the plan agreed by us during physio sessions.

#### What are the alternatives for treatment?

A splint can be used to stop the foot from dragging and avoid trips.

**What are the possible disadvantages of taking part?**

Taking part will mean you spend a little longer attending appointments.

If you are in the FES group.

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 may decide to stop using the stimulator. Similarly, if you do use the stimulator, then turning the stimulation up too high may be uncomfortable, but not dangerous. Some patients develop a skin reaction under the electrodes. If this happens, you are asked to contact us. We will provide advice on how to solve this problem.

**What are the possible benefits of taking part?**

Both groups should find the carefully targeted physiotherapy and home exercises beneficial. Electrical stimulation has been shown to help people who have had a stroke. While it is known that this combination of therapy is safe to use, it has not yet been scientifically investigated to see if it is more effective for people who are recovering from a recent stroke. Whatever we find in this study we will be able to improve treatment for other people in the future by only using treatments which have evidence to show they work.

**What happens when the research study stops?**

After the main 6 weeks of treatment you may need more physiotherapy or wish to be referred to have electrical stimulation. We will request this, although what is available may depend on funding and services in your area and is outside our control. 20 weeks after you start on the trial you will be asked to come back for another reassessment to find out about the long term effects of the treatment.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed and there is more detailed information about this in Part 2.

**Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

***If this information has interested you and you are considering taking part please read the additional information in Part 2.***

***Thank you***

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## Further information and contact details

The main researchers on this project are

**Ingrid Wilkinson** BSc (Hons) Phys MCSP  
**Senior Clinical and Research Physiotherapist**  
 Tel: 01722 429 065 or 01722 429 060  
 Email: [ingrid@salisburyfes.com](mailto:ingrid@salisburyfes.com)

**Dr Paul Taylor** PhD MSc BSc C. Eng  
**Consultant Clinical Engineer, FES Coordinator**  
 Tel: 01722 429 119  
 Email: [p.taylor@salisburyfes.com](mailto:p.taylor@salisburyfes.com)

**Address for Ingrid and Paul**  
 National Clinical FES Centre  
 Salisbury NHS Foundation Trust  
 Salisbury District Hospital, Salisbury  
 Wiltshire, SP2 8BJ

**For general information about research the Medical Research Council website below has a Frequently Asked Questions section for potential trial participants**  
 MRC Clinical Trials Unit – please note main focus is drug trials  
[www.ctu.mrc.ac.uk/TrialInfo.asp](http://www.ctu.mrc.ac.uk/TrialInfo.asp)

**This research is organised with the Salisbury Research and Development Unit**  
 Salisbury RDSU Room 9, Level 4  
 Salisbury NHS Foundation Trust  
 Salisbury District Hospital  
 Salisbury Wiltshire  
 SP2 8BJ  
 Tel: 01722 425026

**If you are unhappy with this study please approach the researchers or your doctor. The Patient Advice and Liaison Service PALS are also there to help.**  
 Telephone our free phone help desk on 0800 374 208  
 Website: [www.salisbury.nhs.uk/patient/pals/home.asp](http://www.salisbury.nhs.uk/patient/pals/home.asp)  
 Email: [pals.service@salisbury.nhs.uk](mailto:pals.service@salisbury.nhs.uk)

## **Patient Information Sheet - Part 2**

### **Study to investigate the effectiveness of combining physiotherapy and electrical stimulation to improve mobility in patients who have recently left hospital after their first stroke.**

#### **What if new information becomes available during the course of the study?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, we will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

With your permission, we will contact your doctor and your medical consultant before you start on the trial. If you do start the trial and there is any new information from your doctor, consultant or one of the researchers that could affect you continuing on the project, we may ask you to withdraw from the project. In reaching any decision we will discuss it fully with you and consider your best interests at all times.

If the study is stopped for any other reason, we will tell you and arrange your continuing care.

#### **What will happen if I don't want to carry on with the study?**

You can withdraw from treatment at any time, without giving a reason but keep in contact with us to let us know your progress. We will need to use the data collected up to your withdrawal to give a complete view of what has happened in the trial.

#### **What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers, who will do their best to answer your questions (see below for contact numbers). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Patient Advice and Liaison Service known as PALS. They can be contacted on 0800 374 208 and act on the patient's behalf.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Salisbury District Hospital but you may have to pay your legal

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costs. The normal National Health Service complaints mechanisms will still be available to you.

**Will my taking part in this study be kept confidential?**

Yes, as described in Part 1, in addition to normal clinical notes some extra written information will be collected such as questionnaires and walking speeds. Each trial participant will be given a unique trial number which identifies this information and your name or other identifiable data will not be on these files. The researchers only will have access to the names linked to these trial numbers but they will be kept securely and kept confidential. In the same way all video taken will be identified with your trial number not your name. The video needs to show your head and body as well as legs in order to allow us to analyse your walking quality.

**Will my General Practitioner (GP)/Family Doctor be informed?**

Your GP will be notified that you are on this trial and may be approached at the end of it to refer you to have more physiotherapy or electrical stimulation.

**What will happen to the results of the research study?**

The results of this trial will be written up and sent to the Stroke Association as a report which they may wish to publish, on their website etc. Scientific reports would also be submitted to professional journals and conferences. In this way we can tell other clinicians what we have found. If a further larger trial is needed to show effects of these treatments we will apply for funding to do it using the results from this trial as justification. This trial will also be used by Ingrid Wilkinson as part of her postgraduate degree.

You may wish to see the scientific reports. We will write and tell you how to access this information at the end of the trial. We plan to hold a feedback session for trial participants, so that you can meet other people who have taken part and find out about the results.

**Who is organising and funding the research?**

The Stroke Association ([www.stroke.org.uk](http://www.stroke.org.uk)) has given a grant to us to cover the costs of doing this research. The main organisation is being done by the researchers in Salisbury District Hospital. All research needs a sponsor to take responsibility for the research and in this case it is Salisbury NHS Foundation Trust.

**Who has reviewed this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. Wiltshire Research Ethics Committee have reviewed this study.

### **Further information and contact details**

**The main researchers on this project are**

**Ingrid Wilkinson** BSc (Hons) Phys MCSP  
**Senior Clinical and Research Physiotherapist**  
Tel: 01722 429 065 or 01722 429 060  
Email: [ingrid@salisburyfes.com](mailto:ingrid@salisburyfes.com)

**Dr Paul Taylor** PhD MSc BSc C. Eng  
**Consultant Clinical Engineer, FES Coordinator**  
Tel: 01722 429 119  
Email: [p.taylor@salisburyfes.com](mailto:p.taylor@salisburyfes.com)

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Email: [pals.service@salisbury.nhs.uk](mailto:pals.service@salisbury.nhs.uk)



## Appendix F Phase 1 - Instructions for outcome measures

### **Rivermead Mobility Index**

#### **Verbal Instructions pre-test**

*'This is a standard questionnaire investigating what you are able to do'.*

#### **Researcher Instructions**

Read out items and observe item five as per printed test instructions. Score one point for the items that the participant can do and zero for items they cannot do.

#### **Scoring**

Sum the test scores. Score out of possible 15

### **Six Minute Walk**

#### **Verbal Instructions pre-test**

*'For the next test I want you to walk up and down between the points I show you, for six minutes. Please walk in your normal way. During that time you may stop if you need to and we will give you a chair if you want to sit down. Rest periods are counted in the six minutes. I will ask you if you are OK to continue at one minute intervals.'*

*At the end I will record your distance and the reading from the heart rate 'watch'.*

*The aim of the test is to see how far you are able to walk in six minutes'.*

#### **Researcher Instructions**

Place chairs at both ends of the Gait Lab and one in the middle. Ensure participant has usual walking aid(s) and is able to safely take a step prior to test. If unable to step without physical assistance to ensure significant risk of falls is avoided, record distance as zero (amended after first four pilot participants).

If able to walk +/- a walking aid, ask patient to stand as close as possible to Gait Lab wall and start the stop watch when they begin walking. After each minute ask 'you have done x minutes you can stop and rest if you want to'. If the participant wants to rest, offer to fetch a chair if they want one. During rests do not talk apart from saying 'you can continue when or if you wish to'.

At every metre there is a mark on the skirting, made by applying tape. At the end of the six minutes record the distance covered to the nearest metre marking and heart rate from the heart rate monitor display watch.

## **Hospital Anxiety and Depression Scale**

### **Verbal Instructions pre-test**

Read out the test instructions from the published test although explain that they should replace 'doctor' with researcher.

### **Researcher Instructions**

Read out the statement and possible responses, ask participant to tell you which to tick. If they ask questions refer back to the standardised instructions printed at the top of the test.

### **Scoring**

Score using the overlay to give a score for anxiety and another score for depression.

## **10m Walking Test with Physiological Cost Index (PCI)**

### **Verbal Instructions pre-test**

*'Please walk from this nearest line to the furthest line (point at the line), briskly but safely. I will time you and when we get to the end I will record the reading from your heart rate 'watch'.*

### **Researcher Instructions - Group A and B**

Use usual walking aid/s and record type. The ten metre test is marked on the floor with tape; this test takes up the length of the Gait Lab. There is a 10m section marked with additional lines 1m from each end demarcating the beginning and end of the acceleration/deceleration zones.

From one end of the room, start at the first line on the floor. Start the stopwatch as their first foot crosses the next line 1m from the first. Stop the stopwatch as the first foot crosses the line 10m away, they will continue to walk to the furthest line 1m further on. Check the heart rate display watch as soon as they stop. Repeat the test twice.

### **Researcher Instructions - Group B**

Complete 10m test twice without stimulation, then once using a walking stimulator and then once more without it on to assess immediate carryover.

### **Adaptation for participants with very poor mobility/exercise tolerance**



Should the participant require physical assistance to walk 10m safely this should be provided, being careful to avoid intentional verbal and physical encouragement. Record walking aids and assistance given. Record 'unable to complete test' if a participant is unable to safely walk 10m, even with physical assistance. If a participant would clearly be unable to walk 10m more than twice without significant fatigue record time and heart rate from two walks without stimulation (Group 1 participants) and one 10m walk without stimulation followed by one walk with stimulation (Group B participants).

### **Calculations**

Record time taken to cover 10m to nearest 0.1 second and use the following equations to calculate 10m speed and PCI

Speed (m/s) = distance/time

PCI = heart rate difference (bpm) (working-resting)/speed (m/minute)

## **Video recording for Rivermead Visual Gait Analysis**

### **Verbal Instructions pre-test**

*'Please walk in your normal way to this point, turn round and walk back so that the cameras can record the way you walk for later analysis'.*

### **Researcher Instructions**

Use usual walking aid/s and record type of aid including physical assistance if required. Place a piece of comfortable Tubigrip bandage over the fibula head and upper part of the lower leg. Tuck a 1.2m footswitch into their waistband or pocket and thread under the Tubigrip and place end into the side of their sock unless the participant is using FES and has this set up already. Start video recording when they begin walking and continue while they walk, turn and until they return. Use a two video cameras one capturing from the side and one from the front. Save under participant number and Week 1, 8 or 20 and with/without FES.

Use video editing software to remove unnecessary 'waiting periods' re-save with the anonymous codes (participant number and symbol as filenames) as shown in the following table. These anonymised files can then be given to the blinded assessor.

## Appendix F

Participant Number	Label-Week 1	Label-Week 8	Label-Week 8 FES on	Label-Week 20	Label-Week 20 FES on
1	⊗	Δ	Ω	□	#
2	Δ	#	□	⊗	Ω
3	Ω	#	⊗	Δ	□
4	⊗	□	Ω	#	Δ
5	⊗	Δ	#	Ω	□
6	#	Δ	Ω	□	⊗
7	Δ	□	⊗	#	Ω
8	□	Δ	#	Ω	⊗
9	□	#	⊗	Δ	Ω
10	#	Δ	Ω	□	⊗
11	⊗	Ω	□	#	Δ
12	Δ	#	□	⊗	Ω
13	□	Δ	Ω	⊗	#
14	Δ	⊗	#	□	Ω
15	Ω	□	Δ	⊗	#
16	Ω	Δ	⊗	□	#
17	⊗	Δ	#	□	Ω
18	#	⊗	Ω	Δ	□
19	Δ	□	Ω	⊗	#
20	Ω	#	□	⊗	Δ
21	□	⊗	#	Δ	Ω
22	#	□	Ω	Δ	⊗
23	Ω	⊗	Δ	□	#
24	⊗	Δ	#	□	Ω
25	#	□	Δ	⊗	Ω
26	Ω	Δ	□	⊗	#
27	□	Ω	⊗	Δ	#
28	#	Δ	Ω	⊗	□
29	Δ	□	#	⊗	Ω
30	⊗	□	Ω	Δ	#

## **Canadian Occupational Performance measure**

### **Verbal Instructions pre-test**

Explain the interview process at Week 1 using the instructions printed on recording sheet. Record any activities that cannot be completed as the participant needs, wishes or is expected to. Rate each activity out of 10, using the standard 'Importance' score cards. Confirm the five most important activities the participant wishes to score further, state that the trial investigates mobility if they ask for guidance in selection i.e. if there are many activities with high 'importance' scores. Less than five can be selected if less than five activities are identified.

At Week 1, 8 and 20 score the activities out of 10 for 'Performance' and 'Satisfaction' using the standard score cards. Say to the participant 'Please rate performance as 0, not possible at all or 10, able to do extremely well or somewhere in between'. Use same form of instructions for 'Satisfaction'.

### **Researcher Instructions**

Ensure the activities are described in sufficient detail to remember the activity limitations when rescored later. At Week 1, 8 and 20 score the activities out of 10 for 'Performance' and 'Satisfaction' using the standard score cards.

### **Scoring**

Total Performance and Satisfaction scores can be gained from totalling the performance/satisfaction scores and dividing by the number of activities.

## **Falls Diary**

### **Verbal Instructions pre-test**

Give the record form to the participant at the Week 1 assessment and read out instructions on front. Ask the participant to record any falls and ask for guidance or help if necessary.

### **Researcher Instructions**

At Week 8 check that the participant is recording any falls on the form and collect it at the Week 20 assessment. Should a participant mention a fall during the treatment phase the researcher should prompt them to record it on the form.

## **Psychosocial Impact of Assistive Devices (PIADS)**

### **Verbal Instructions pre-test – Group B only**

Read out the instructions on the published recording sheet. Read out each of the 26 items and say the explanation from the glossary if the participant asks for clarification of any terms. Record a tick on score sheet in appropriate column.

### **Scoring**

Use the PIADS score sheet to analyse responses and give average for competence, adaptability and self-esteem.



## Appendix G Phase 1 - Assessment forms including screening

### Screening and Enrolment

#### Assessor 1

Name: .....

Profession/Title .....

E-mail address .....

Tel Number: .....

Fax Number: .....

Signature: .....

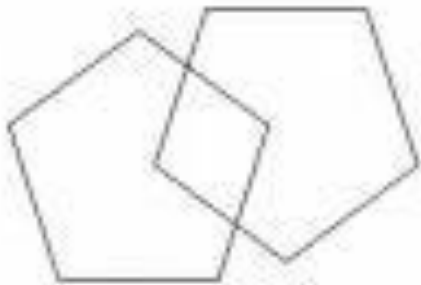
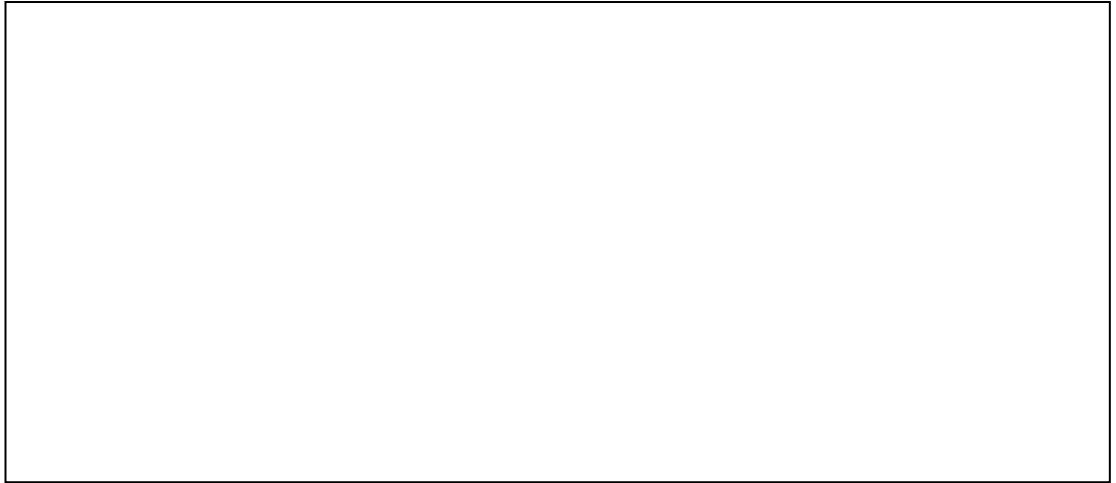
Initials

Enrolled    Yes ☐  
                  No ☐

## Mini mental status examination

Orientation	Score
What is the year, season, date, day and month (1 point for each).	/5
Where are we: town, county, country, which hospital, surgery or house, and which floor (1 point for each).	/5
<b>Registration</b>	
Name 3 objects (e.g., <b>apple, table, penny</b> ) taking 1 second to say each one. Then ask the individual to repeat the names of all 3 objects. Give 1 point for each correct answer. Repeat the object names until all 3 are learned (up to 6 trials). Record number of trials needed.	/3
<b>Attention and Calculation</b>	
Spell "world" backwards. Give 1 point for each letter that is in the right place (e.g., DLROW = 5, DLORW = 3).  Alternatively, do serial 7s. Ask the person to count backwards from 100 in blocks of 7 (i.e., 93, 86, 79, 72, 65). Stop after 5 subtractions. Give one point for each correct answer. If one answer is incorrect (e.g. 92) but the following answer is 7 less than the previous answer (i.e., 85), count the second answer as being correct. 1 point for each subtraction.	/5
<b>Recall</b>	
Ask for the 3 objects repeated above (e.g., <b>apple, table, penny</b> ). Give 1 point for each correct object.	/3
<b>Language</b>	
Point to a pencil and ask the person to name this object (1 point). Do the same thing with a wrist-watch (1 point).	/2
Ask the person to repeat the following: " <b>No ifs, ands or buts</b> " (1 point). Allow only one trial.	/1
Give the person a piece of blank white paper and ask them to follow a 3-stage command: " <b>Take a paper in your right hand, fold it in half and put it on the floor</b> " (1 point for each part that is correctly followed).	/3
Write "CLOSE YOUR EYES" in large letters and show it to the patient. Ask him or her to read the message and do what it says (give 1 point if they actually close their eyes).	/1
Ask the individual to write a sentence of their choice on a blank piece of paper. The sentence must contain a subject and a verb, and must make sense. Spelling, punctuation and grammar are not important (1 point).	/1
Show the person a drawing of 2 pentagons which intersect to form a quadrangle. Each side should be about 1.5 cm. Ask them to copy the design exactly as it is (1 point). All 10 angles need to be present and the two shapes must intersect to score 1 point. Tremor and rotation are ignored.	/1
TOTAL	/30

# Close your eyes



## RIVERMEAD MOBILITY INDEX

1. Do you turn over from your back to your side without help?	
2. From lying in bed, are you able to get up to sit 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 hands and 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 any aid.	
6. Are you able to move from bed to chair and back without any help?	
7. Can you walk 10 metres with an aid if necessary but with no standby 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 metres inside with no calliper, splint or aid and no standby help?	
11. If you drop something on the floor, can you manage to walk 5 metres 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 metres in 4 seconds without limping? (A fast walk is acceptable.)	
<b>TOTAL</b>	

**Score 0 = No 1 = Yes**

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<b>Inclusion criteria</b>	<b>Yes</b>	<b>No</b>
<b>Over 18, returning home</b>		
<b>Medically fit</b>		
<b>First stroke</b>		
<b>Demonstrated ability to be an active participant in therapy</b>		
<b>Able to understand spoken instructions</b>		
<b>Patient wants to improve gait</b>		
<b>Rivermead Mobility Index between 6-10</b>		
<b>Able to attend for twice weekly physio</b>		
<b>Tolerates stimulation sensation</b>		
<b>Skin intact</b>		
<b>No previous neurological conditions</b>		
<b>Mini mental Status Test above 25</b>		
<b>Pregnancy</b>	<b>NOT pregnant</b>	<b>Pregnant</b>
<b>Pacemaker</b>	<b>Does NOT have a pacemaker</b>	<b>Does have a pacemaker</b>
<b>Epilepsy</b>	<b>Controlled epilepsy or not epileptic</b>	<b>Uncontrolled epilepsy</b>
	<b>IF ALL ANSWERS ARE IN THIS COLUMN SUBJECT IS SUITABLE FOR TRIAL</b>	<b>ANY ANSWERS IN THIS COLUMN, SUBJECT NOT SUITABLE FOR TRIAL</b>
	<b>PROCEED</b>	

## CONSENT FORM

**Study to investigate the effectiveness of combining physiotherapy and electrical stimulation to improve mobility in patients who have recently left hospital after their first stroke.**

Please initial box

- ☐ I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- ☐ 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 relevant sections of my medical notes and data collected during the study may be looked at by the researchers. Also staff/supervisor at Southampton University, where it is relevant to my taking part in this research, may look at anonymous trial data. I give permission for these individuals to have access to my (trial) data.
- ☐ I agree to be have video/photographs taken as part of this trial
- ☐ I agree to my GP being informed of my participation in the study
- ☐ I agree to take part in the above study.
- ☐ I agree to my data, including video, being used in reports and presentations in order to demonstrate this treatment approach and the results of the trial.

.....  
Name of Patient

Date

Signature

.....  
Name of Person  
(consent)

Date

Signature (person taking  
consent)

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

**Study to investigate the effectiveness of combining physiotherapy and electrical stimulation to improve mobility in patients who have recently left hospital after their first stroke.**

Schedule for .....

During the course of this research study, you will need to attend the hospital or clinic for appointments to assess your progress and for treatment.

The dates and times for these appointments are given. In your patient information sheet you will find details of what happens at each appointment

Please don't hesitate to contact Ingrid Wilkinson (01722 429065) or Paul Taylor (01722 429065) at any time during the course of your participation in the study.

Week	Date	Time		Date	Time
1 assessment					
2			And		
3			And		
4			And		
5			And		
6			And		
7			and		
8 assessment					
20 assessment					

# Case record form Week 1

<b>Pre Trial Participant Information Transfer Form</b>			
<b>DEMOGRAPHIC DATA</b>			
Date of Birth:			
<div style="display: flex; justify-content: space-between;"> <div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> </div> <div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> </div> <div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-bottom: 2px;"></div> </div> </div> <div style="display: flex; justify-content: space-between; font-size: 0.8em; margin-top: 2px;"> <span>D D</span> <span>M M</span> <span>Y Y</span> <span>Y Y</span> </div>	Gender: <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> 1 Male <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> 2 Female		
Living Arrangements: <input type="checkbox"/> Alone <input type="checkbox"/> With a spouse, other relative or friend			
<div style="text-align: center;"> <input type="checkbox"/> In sheltered housing    <input type="checkbox"/> Other _____         </div>			
Is subject left handed or right handed?: <input type="checkbox"/> Left <input type="checkbox"/> Right			

[illegible]

Description of main impairments and disabilities:

<b>Name</b> <b>Date of Birth</b> <b>Address</b>  <b>Telephone Number</b> <b>Hospital number:</b>	<b>GP:</b> <b>GP Address:</b>  <b>GP Telephone Number:</b>  <b>Consultant</b> <b>Consultant address</b>
Subjective Assessment	
Present complaint	
History of present complaint	

Appendix G

<b>Other</b>	
<b>Past medical History</b> Heart Lungs Epilepsy Diabetes Blood Pressure	General Health Serious illnesses Operations Psychological well being
<b>Drug History</b>	
<b>Treatment transfer summary</b>	

## 6 Minute Walk

	6 minute walk			Resting Heart Rate RHR (Bt/min)		
		Distance X (m)	Heart rate HR (Bt/min)	Change in HR (Bt/min) =HR-RHR	Speed WS (m/s) = X / 180*	PCI (Bt/m) = $\frac{(HR-RHR)}{(WS \times 60)}$
1	No FES					

## 10 m Walk

Assessment number				Resting Heart Rate RHR (Bt/min)		
		Time (s)	Heart rate HR (Bt/min)	Change in HR (Bt/min) =HR-RHR	Speed m/s WS = 10 / Time	PCI (Bt/m) = $\frac{(HR-RHR)}{(WS \times 60)}$
1	No FES					
2	No FES					
Use of aids						

**HAD**

**COPM**

## Rivermead Visual Gait Analysis Score

Symbol code

\_\_\_\_\_ /59

## RIVERMEAD MOBILITY INDEX

1. Do you turn over from your back to your side without help?	
2. From lying in bed, are you able to get up to sit 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 hands and 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 any aid.	
6. Are you able to move from bed to chair and back without any help?	
7. Can you walk 10 metres with an aid if necessary but with no standby 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 metres inside with no calliper, splint or aid and no standby help?	
11. If you drop something on the floor, can you manage to walk 5 metres 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 metres in 4 seconds without limping? (A fast walk is acceptable.)	
<b>TOTAL</b>	

**Score 0 = No 1 = Yes**

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# HAD Scale

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more.

This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

*Tick only one box in each section*

## I feel tense or 'wound up':

Most of the time .....  
A lot of the time .....  
Time to time, Occasionally .....  
Not at all .....


## I feel as if I am slowed down:

Nearly all the time .....  
Very often .....  
Sometimes .....  
Not at all .....


## I still enjoy the things I used to enjoy:

Definitely as much .....  
Not quite so much .....  
Only a little .....  
Hardly at all .....


## I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all .....  
Occasionally .....  
Quite often .....  
Very often .....


## I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly .....  
Yes, but not too badly .....  
A little, but it doesn't worry me .....  
Not at all .....


## I have lost interest in my appearance:

Definitely .....  
I don't take so much care as I should.....  
I may not take quite as much care .....  
I take just as much care as ever .....


## I can laugh and see the funny side of things:

As much as I always could .....  
Not quite so much now .....  
Definitely not so much now .....  
Not at all .....


## I feel restless as if I have to be on the move:

Very much indeed .....  
Quite a lot .....  
Not very much .....  
Not at all .....


## Worrying thoughts go through my mind:

A great deal of the time .....  
A lot of the time .....  
From time to time but not too often .....  
Only occasionally .....


## I look forward with enjoyment to things:

As much as ever I did .....  
Rather less than I used to .....  
Definitely less than I used to .....  
Hardly at all .....


## I feel cheerful:

Not at all .....  
Not often .....  
Sometimes .....  
Most of the time .....


## I get sudden feelings of panic:

Very often indeed .....  
Quite often .....  
Not very often .....  
Not at all .....


## I can sit at ease and feel relaxed:

Definitely .....  
Usually .....  
Not often .....  
Not at all .....


## I can enjoy a good book or radio or TV programme:

Often .....  
Sometimes .....  
Not often .....  
Very seldom .....


*Do not write below this line*

Printed as a service to medicine by [unintelligible]

# CANADIAN OCCUPATIONAL PERFORMANCE MEASURE

**Authors:**

**Mary Law, Sue Baptiste, Anne Carswell,  
Mary Ann McColl, Helene Polatajko, Nancy Pollock**

The Canadian Occupational Performance Measure (COPM) is an individualized measure designed for use by occupational therapists to detect self-perceived change in occupational performance problems over time.

Published by CAOT Publications ACE

© M. Law, S. Baptiste, A. Carswell, M.A. McColl, H. Polatajko, N. Pollock, 2000

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Client Name:		
Age:	Gender:	ID#:
Respondent (if not client):		
Date of Assessment:	Planned Date of Reassessment:	Date of Reassessment:
Therapist:		
Facility/Agency:		
Program:		

**STEP 1:  
IDENTIFICATION OF OCCUPATIONAL PERFORMANCE ISSUES**

To identify occupational performance problems, concerns and issues, interview the client, asking about daily activities in self-care, productivity and leisure. Ask clients to identify daily activities which they want to do, need to do or are expected to do by encouraging them to think about a typical day. Then ask the client to identify which of these activities are difficult for them to do now to their satisfaction. Record these activity problems in Steps 1A, 1B, or 1C.

**STEP 2:  
RATING  
IMPORTANCE**

Using the scoring card provided, ask the client to rate, on a scale of 1 to 10, the importance of each activity. Place the ratings in the corresponding boxes in Steps 1A, 1B, or 1C.

**STEP 1A: Self-care**

**Personal Care**  
(e.g., dressing, bathing,  
feeding, hygiene)

---

---

---

**Functional Mobility**  
(e.g., transfers,  
indoor, outdoor)

---

---

---

**Community Management**  
(e.g., transportation,  
shopping, finances)

---

---

---

**IMPORTANCE**









**STEP 1B: Productivity**

**Paid/Unpaid Work**  
(e.g., finding/keeping  
a job, volunteering)

---

---

---

**Household Management**  
(e.g., cleaning,  
laundry, cooking)

---

---

---

**Play/School**  
(e.g., play skills,  
homework)

---

---

---

**STEP 1C: Leisure**

**Quiet Recreation**  
(e.g., hobbies,  
crafts, reading)

**Active Recreation**  
(e.g., sports,  
outings, travel)

**Socialization**  
(e.g., visiting,  
phone calls, parties,  
correspondence)

**IMPORTANCE**


**STEPS 3 & 4: SCORING - INITIAL ASSESSMENT and REASSESSMENT**

Confirm with the client the 5 most important problems and record them below. Using the scoring cards, ask the client to rate each problem on performance and satisfaction, then calculate the total scores. Total scores are calculated by adding together the performance or satisfaction scores for all problems and dividing by the number of problems. At reassessment, the client scores each problem again for performance and satisfaction. Calculate the new scores and the change score.

**Initial Assessment:****OCCUPATIONAL PERFORMANCE PROBLEMS:**

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_

**PERFORMANCE 1****SATISFACTION 1**



**Reassessment:****PERFORMANCE 2****SATISFACTION 2**



**SCORING:**

Total score =  $\frac{\text{Total performance or satisfaction scores}}{\text{\# of problems}}$

**PERFORMANCE SCORE 1****SATISFACTION SCORE 1****PERFORMANCE SCORE 2****SATISFACTION SCORE 2**

$\frac{\quad}{\quad}$   
=  

$\frac{\quad}{\quad}$   
=  

$\frac{\quad}{\quad}$   
=  

$\frac{\quad}{\quad}$   
=  

CHANGE IN PERFORMANCE = Performance Score 2   - Performance Score 1   =  

CHANGE IN SATISFACTION = Satisfaction Score 2   - Satisfaction Score 1   =

PERFORMANCE									
1	2	3	4	5	6	7	8	9	10
not able to do it								able to do it extremely well	

IMPORTANCE									
1	2	3	4	5	6	7	8	9	10
not important at all								extremely important	

SATISFACTION									
1	2	3	4	5	6	7	8	9	10
not satisfied at all								extremely satisfied	

COPM score cards

## Week 8

### 6 Minute Walk

	6 minute walk	Resting Heart Rate RHR (Bt/min)				
		Distance X (m)	Heart rate HR (Bt/min)	Change in HR (Bt/min) = HR-RHR	Speed WS (m/s) = $X / 180^*$	PCI (Bt/m) = $\frac{(HR-RHR)}{(WS \times 60)}$
1	No FES					
% change <sup>2</sup> No FES week1: No FES now						

### 10 m Walk

Assessment number			Resting Heart Rate RHR (Bt/min)			
		Time (s)	Heart rate HR (Bt/min)	Change in HR (Bt/min)	Speed m/s WS = $10 / \text{Time}$	PCI (Bt/m) = $\frac{(HR-RHR)}{(WS \times 60)}$
1	No FES					
2	No FES					
3	FES					
4	No FES					
% change <sup>1</sup> No FES (2) : FES						
% change <sup>2</sup> No FES week1: No FES (2) now						
% change <sup>3</sup> No FES week1: FES now						
% change <sup>4</sup> No FES(walk2) : No FES(walk4)						
Use of aids						



## Rivermead Visual Gait Analysis Score

Symbol code

\_\_\_\_\_ /59

## RIVERMEAD MOBILITY INDEX

1. Do you turn over from your back to your side without help?	
2. From lying in bed, are you able to get up to sit 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 hands and 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 any aid.	
6. Are you able to move from bed to chair and back without any help?	
7. Can you walk 10 metres with an aid if necessary but with no standby 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 metres inside with no calliper, splint or aid and no standby help?	
11. If you drop something on the floor, can you manage to walk 5 metres 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 metres in 4 seconds without limping? (A fast walk is acceptable.)	
<b>TOTAL</b>	

**Score 0 = No 1 = Yes**

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**HADS**

**COPM**

## Week 20

### 6 Minute Walk

	6 minute walk	Resting Heart Rate RHR (Bt/min)				
		Distance X (m)	Heart rate HR (Bt/min)	Change in HR (Bt/min) = HR-RHR	Speed WS (m/s) = $X / 180^*$	PCI (Bt/m) = $\frac{(HR-RHR)}{(WS \times 60)}$
1	No FES					
% change <sup>2</sup> No FES week1: No FES now						

### 10 m Walk

Assessment number			Resting Heart Rate RHR (Bt/min)			
		Time (s)	Heart rate HR (Bt/min)	Change in HR (Bt/min)	Speed m/s WS = $10 / \text{Time}$	PCI (Bt/m) = $\frac{(HR-RHR)}{(WS \times 60)}$
1	No FES					
2	No FES					
3	FES					
4	No FES					
% change <sup>1</sup> No FES (2) : FES						
% change <sup>2</sup> No FES week1: No FES (2) now						
% change <sup>3</sup> No FES week1: FES now						
% change <sup>4</sup> No FES(walk2) : No FES(walk4)						
Use of aids						



## Rivermead Visual Gait Analysis Score

Symbol code

\_\_\_\_\_ /59

## RIVERMEAD MOBILITY INDEX

1. Do you turn over from your back to your side without help?	
2. From lying in bed, are you able to get up to sit 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 hands and an aid if necessary) stand up from a chair in less than 15 seconds, and stand there for 15 seconds?	
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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 metres inside with no calliper, splint or aid and no standby help?	
11. If you drop something on the floor, can you manage to walk 5 metres 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 metres in 4 seconds without limping? (A fast walk is acceptable.)	
<b>TOTAL</b>	

**Score 0 = No 1 = Yes**

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**HADS**

**COPM**

## Appendix G

June 2007 V.0.1		PIADS SCORING SHEET		FES DEVICE (S)	
ITEM		Competence	Adaptability	Self-esteem	
• Competence		1.			
• Happiness				2.	
3. Independence		3.			
4. Adequacy		4.			
5. <u>Confusion</u> *		5.			
6. Efficiency		6.			
7. Self-esteem				7.	
8. Productivity		8.			
9. Security				9.	
10. <u>Frustration</u> *				10.	
11. Usefulness		11.			
12. Self-confidence				12.	
13. Expertise		13.			
14. Skilfulness		14.			
15. Well-being			15.		
16. Capability		16.			
17. Quality of Life		17.			
18. Performance		18.			
19. Sense of power				19.	
20. Sense of Control				20.	
21. <u>Embarrassment</u> *				21.	
22. Willingness to take Chances			22.		
23. Ability to participate			23.		
24. Eagerness to try new things			24.		
25. Ability to adapt to the activities of daily living			25.		
26. Ability to take advantage of opportunities			26.		
<b>(A) Sum of subscale column</b>					
<b>(B) Number of items in subscale</b>					
<b>SUBSCALE SCORE A ÷ B</b>					
<p><i>*A high <u>positive</u> score on these items (5,10 and 21) would indicate <u>negative</u> impact on QOL. To capture the meaning of these items the score must be reversed. E.g. A score of -2 for frustration would indicate a positive impact on QOL and should therefore be reversed to +2 on the scoring sheet.</i></p>					

Table 3: PIADS Questionnaire Version 3.0

**Psychosocial Impact of Assistive Devices Scale (PIADS)**Today's Date: \_\_\_\_\_  
month/day/yearClient Name: \_\_\_\_\_  
(last name, then first name)☐ male ☐ female

Diagnosis: \_\_\_\_\_

Date of Birth: \_\_\_\_\_  
month/day/yearThe form is being filled out at (choose one) 1. ☐ home 2. ☐ a clinic 3. ☐ other (describe): \_\_\_\_\_The form is being filled out by (choose one) 1. ☐ the client, without any help 2. ☐ the client, with help from the caregiver (e.g., client showed or told caregiver what answers to give) 3. ☐ the caregiver on behalf of the client, without any direction from the client 4. ☐ other (describe): \_\_\_\_\_

Each word or phrase below describes how using an assistive device may affect a user. Some might seem unusual but it is important that you answer every one of the 26 items. So, for each word or phrase, put an "X" in the appropriate box to show how you are affected by using the \_\_\_\_\_ (device name).

	Decreases	-3	-2	-1	0	1	2	3	Increases
1) competence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2) happiness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3) independence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4) adequacy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5) confusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6) efficiency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7) self-esteem	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8) productivity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9) security	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10) frustration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11) usefulness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12) self-confidence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13) expertise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14) skillfulness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15) well-being	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16) capability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17) quality of life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18) performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19) sense of power	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20) sense of control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21) embarrassment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22) willingness to take chances	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23) ability to participate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
24) eagerness to try new things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
25) ability to adapt to the activities of daily living	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
26) ability to take advantage of opportunities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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**Glossary of PIADS Items**


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**Ability to Adapt to the Activities of Daily Living** (item 25) Ability to cope with change; ability to make basic tasks more manageable

**Ability to Participate** (item 23) Ability to join in activities with other people

**Ability to take advantage of opportunities** (item 26) Ability to act quickly and confidently when there is a chance to improve something in your life

**Adequacy** (item 4) Capable of handling life situations, and handling little crises

**Capability** (item 16) Feeling more capable; able to cope

**Competence** (item 1) Ability to do well the important things you need to do in life

**Confusion** (item 5) Unable to think clearly, act decisively

**Eagerness to Try New Things** (item 24) Feeling adventuresome and open to new experiences

**Efficiency** (item 6) Effective management of day to day tasks

**Embarrassment** (item 21) Feeling awkward or ashamed

**Expertise** (item 13) Knowledge in a particular area or occupation

**Frustration** (item 10) Being upset about lack of progress in achieving your desires; feeling disappointed

**Happiness** (item 2) Gladness, pleasure; satisfaction with life

**Independence** (item 3) Not dependent on, or not always needing help from, someone or something

**Performance** (item 18) Able to demonstrate your skills

**Productivity** (item 8) Able to get more things done in a day

**Quality of Life** (item 17) How good your life is

**Security** (item 9) Feeling safe rather than feeling vulnerable or insecure

**Self-Confidence** (item 12) Self-reliance; trust in yourself and your abilities

**Self-Esteem** (item 7) How you feel about yourself, and like yourself as a person

**Sense of Control** (item 20) Sense of being able to do what you want in your environment

**Sense of Power** (item 19) Sense of inner strength; feeling that you have significant influence over your life

**Skillfulness** (item 14) Able to show your expertise; perform tasks well

**Usefulness** (item 11) Helpful to yourself and others; can get things done

**Well-being** (item 15) Feeling well; optimistic about your life and future

**Willingness to Take Chances** (item 22) Willing to take some risks; willing to take on new challenges

## Falls Diary Guidance

### Instructions for filling out your falls diary

We have given you a falls diary so that we can record whether the treatment we give you during the trial affects how often you trip or fall.

Please record on the table how many times you fall each day. Do this with a line (/) for each fall. Put the mark in the appropriate box according to whether you were walking with no aid, with the ODFS switched on, or with a splint (AFO).

***A fall is when you lose your balance and come to rest on a surface lower than where you started! If you save yourself from falling by grabbing a nearby person or object but would have fallen if you had not done this, it also counts as a fall. If you trip but manage to keep walking without grabbing anything to save yourself, this does not count as a fall.***

**Please bring this form to all your appointments. Thank you.**

### Falls Diary



## Appendix H Phase 1 - Physiotherapy treatment content

Physiotherapy for both groups consisted of the activities listed below. Equipment, assistance, feedback (verbal, tactile and visual, using a mirror), encouragement was provided and altered as required to ensure safety and variety of practice. Activity and environment were modified to maintain difficulty/challenge and salience to the individual.

<b>Sitting</b>	<ul style="list-style-type: none"> <li>• transfer practice</li> <li>• hip hitching alternating sides to move forward/backward on seat</li> <li>• repeated sit/stand practice</li> <li>• repeated slow or partial sit/stand practice</li> <li>• repeated sit/stand practice less affected leg on a mat/low step to maximise weight on affected leg</li> <li>• dorsiflexion/plantarflexion</li> <li>• ankle circling</li> <li>• knee flexion/extension on a roll or ball in sitting</li> <li>• encouragement of midline symmetrical sitting posture between activities</li> </ul>
<b>Standing</b>	<ul style="list-style-type: none"> <li>• calf stretches</li> <li>• squats</li> <li>• side stepping, cross stepping (aiming for alternating)</li> <li>• kicking a ball indoors</li> <li>• active plantarflexion standing toe rises (unilateral/bilateral)</li> <li>• encouragement of midline symmetrical standing posture between activities</li> <li>• weight transfer in standing</li> <li>• knee flexion/extension control in activity (standing/walking/reaching/stairs)</li> <li>• step/mat/balance disc under one foot to increase weight on other during activity</li> <li>• combining reaching &amp; bending to move objects between different heights</li> <li>• reaching/bending out of base of support</li> <li>• reaching/bending while standing on a slope</li> <li>• marching on spot</li> <li>• placing one foot on/off a step in front</li> <li>• standing on one leg</li> <li>• stair practice</li> <li>• repeated stepping down for eccentric quads control</li> <li>• prompting active release of flexor tone in affected U/L during activity</li> <li>• placing foot to different targets in standing</li> <li>• proprioception - eyes closed/looking away placing foot to target</li> <li>• throwing/catching/rolling a ball indoors</li> <li>• kicking a ball outside on grass</li> <li>• throwing and catching a ball outside on grass</li> </ul>
<b>Walking</b>	<ul style="list-style-type: none"> <li>• walking practice indoors +/- facilitation, assistance, walking aids</li> <li>• walking forward/backwards</li> </ul>

## Appendix H

	<ul style="list-style-type: none"> <li>walking indoors carrying items in one/two hands</li> <li>walking indoors/outdoors varying speed and distance</li> <li>walking indoors/outdoors around/over obstacles</li> <li>walking indoors/outdoors dual tasking (maths or speech task or holding an object or bouncing a ball)</li> <li>walking outside on pavements, uneven ground (grass/gravel/camber/slopes)</li> <li>walking outside up/down steps</li> <li>walking in crowded/busy areas</li> <li>jogging</li> </ul>
<b>On plinth or floor</b>	<ul style="list-style-type: none"> <li>Transversus Abdominis contraction lying or during activity</li> <li>single leg heel slides, drop outs and foot lifts in crook lying</li> <li>single leg/arm lifts or triceps dips in four point kneeling</li> <li>practice on/off floor from lying to standing (components or whole activity) for safety or repeated for exercise</li> <li>'walking' in high kneeling (forward/backwards/sideways)</li> <li>high kneeling reaching outside base of support</li> </ul>
<b>Group B</b>	<ul style="list-style-type: none"> <li>teaching or practicing use of Microstim in sitting (CPN)</li> <li>teaching or practicing use of ODFSIII in walking/activity (CPN)</li> </ul>

*Physiotherapy content (Groups A and B unless specified)*



## Appendix I Phase 2 - Sponsorship letter

UNIVERSITY OF  
Southampton

Miss Ingrid Wilkinson  
School of Health Sciences  
University of Southampton  
University Road  
Highfield  
Southampton  
SO17 1BJ

RCO Ref: 8574

08 May 2012

Dear Miss Wilkinson

**Project Title Talking about Walking – A Qualitative Study Exploring the Experience of Walking after a Stroke**

This is to confirm the University of Southampton is prepared to act as Research Sponsor for this study, and the work detailed in the protocol/study outline will be covered by the University of Southampton insurance programme.

As the sponsor's representative for the University this office is tasked with:

1. Ensuring the researcher has obtained the necessary approvals for the study
2. Monitoring the conduct of the study
3. Registering and resolving any complaints arising from the study

As the researcher you are responsible for the conduct of the study and you are expected to:

1. Ensure the study is conducted as described in the protocol/study outline approved by this office
2. Advise this office of any change to the protocol, methodology, study documents, research team, participant numbers or start/end date of the study
3. Report to this office as soon as possible any concern, complaint or adverse event arising from the study

Failure to do any of the above may invalidate the insurance agreement and/or affect sponsorship of your study i.e. suspension or even withdrawal.

On receipt of this letter you may commence your research but please be aware other approvals may be required by the host organisation if your research takes place outside the University. It is your responsibility to check with the host organisation and obtain the appropriate approvals before recruitment is underway in that location.

May I take this opportunity to wish you every success for your research.

Yours sincerely

Dr Martina Prude  
Head of Research Governance

Tel: 023 8059 5058  
email: rgoinfo@soton.ac.uk

Corporate Services, University of Southampton, Highfield Campus, Southampton SO17 1BJ United Kingdom  
Tel: +44 (0) 23 8059 4684 Fax: +44 (0) 23 8059 5781 www.southampton.ac.uk



## Appendix J Phase 2 - Cover letter and Participant information sheet

Health  
Sciences

UNIVERSITY OF  
Southampton

August 2012

Dear Sir or Madam,

I would like to invite you to take part in a research study called 'Talking about Walking - A qualitative study exploring the experience of walking after a stroke'. This will involve being interviewed once about how your walking has changed since having a stroke. Before you decide you need to understand why this research is being done and what it would involve for you. There is an information sheet about the research attached. Please ask if there is anything that is not clear or if you would like more information.

We will only know if you are interested if you contact us. If we do not hear from you within a month from the date of this letter we will assume you are not interested in taking part.

There are several ways to get in touch if you do wish to take part and they are

- telephone
- email
- post – by returning the slip below

Thank you for your time.

Yours sincerely,

Ingrid Wilkinson

PhD student and Specialist Clinical and Research Physiotherapist.

I **am interested** in taking part in an interview about walking following stroke.

Signed..... Printed .....

Date..... Your telephone number.....

Please fill in then return this reply slip in the envelope provided to **Ms Ingrid Wilkinson**,  
Care of Dr. Martin Warner  
University of Southampton  
Faculty of Health Sciences  
FREEPOST NAT7537  
Building 67, Highfield  
University Road  
Southampton, SO17 1UA

Tel. 01722 429065 or 07968377363  
Email [iaw1a06@soton.ac.uk](mailto:iaw1a06@soton.ac.uk)

Version 1.1 March 2012

Faculty of Health Sciences, University of Southampton, Building 45, Highfield Campus, Southampton SO17 1BJ United Kingdom  
Tel: +44 (0)23 8059 7979 Fax: +44 (0)23 8059 7900 [www.southampton.ac.uk/healthsciences](http://www.southampton.ac.uk/healthsciences)

## **Participant Information Sheet**

### **Talking about Walking – A qualitative study exploring the experience of walking after a stroke**

**We would like to invite you to take part in this research study run by Ingrid Wilkinson, towards her PhD studies at the University of Southampton.**

**Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully, it tells you the purpose of this study and what will happen to you if you take part. Talk to others about this if you wish.**

**Please ask us if there is anything that is not clear or if you would like more information.**

#### **What is the purpose of the study?**

We are trying to understand more about the best ways to help people walk better after a stroke. To do this we need to find out more about aspects of walking which are most important to people who have had a stroke. Someone's feelings about walking may change after a stroke has occurred and in the months and years following. This study uses an interview to explore the idea that people attach individual meaning and value to different aspects of walking.

The information generated by this work will hopefully help us gain a better understanding of the importance of different aspects of walking and how these change after a stroke. This information may help future clinical trials of walking rehabilitation to measure aspects of walking which are most relevant to the people with stroke taking part.

#### **Why have I been invited?**

You have been invited to take part in this research because you had a stroke and registered your interest in helping with research with The University of Southampton. Although your stroke may have happened quite a while ago this 'Talking about Walking' interview will try to explore and make use of your experience to improve future research. It is hoped that you will be able to tell us about how your feelings about walking have changed over time. Therefore you can take part if you have had a stroke which caused walking problems even if these have got better now.

**Do I have to take part?**

No, it is up to you to decide. We can describe the one off interview and go through this information sheet with you. If you want to take part we will ask you to sign a consent form to show you have agreed to be interviewed. You are free to change your mind at any time, without giving a reason and this will not affect any care you receive.

**What are your research questions?**

We want to find out how people who have had a stroke describe their walking problems and the impact of them on their lives. We also want to explore how these issues change over time and what aspects of pre-stroke walking people miss most. If aspects of walking which are most important to people who have had a stroke can be identified these will be compared to those commonly measured in research trials and in clinical practice. This information will be used to give an indication of whether trials are measuring the 'right things', in other words things that are important to people who have had a stroke.

**What will happen if I take part?**

Once you think that you might want to take part, please return the reply slip or contact the research team, we will telephone you to arrange a time to interview you. This will be at a convenient time for you and will probably be at your home. It will be a one off informal interview which will be recorded so that later on the researchers can analyse what you have said and can compare it to other people's interviews. The 'Talking about Walking' interview should feel like a conversation with a purpose.

The researcher, Ingrid Wilkinson, will ensure that any questions you have are answered prior to the interview. A consent form will be signed to show that you agree to take part and to have the interview recorded and later typed out and analysed by the researchers. The analysis will include looking for themes in what you have said. Your real name will not be used in the written account. These themes will be used to compare what you have said about walking and which aspects are most important to you with what other participants in the have said. The themes identified by the group of people interviewed will be compared to what is being measured already in clinical trials. If you, or people who know you well, read the final documents which discuss the themes and outcomes of the 'Talking about Walking' study you may be able to recognise what you said. Other people, who don't know you, will not be able to identify you from the report.

**How long will the interviews take?**

Interviews are likely to take between 1 and 1 ½ hours but may be a little longer or shorter. You may be tired after talking like this and you may like to keep 2 hours free for the interview to include a rest afterwards and/or allow for any delays.

**Where will the interview take place?**

In order for the voice recorder to work a quiet environment is required with as few interruptions as possible. This will also help concentration. Most people are likely to choose to do the interviews at home, in a quiet room where they feel comfortable. This can be discussed with the researcher and another location may be possible.

**Who will be present?**

At this stage it is the opinions of the person who has had a stroke which are trying to be understood and therefore it may be just you (the research participant) and the researcher, Ingrid Wilkinson, present. A family member or friend can also be in the room but it is not expected that they will be particularly active in the interview.

**Expenses**

It is not anticipated this study will incur you any costs.

**What are the possible disadvantages of taking part?**

The interview will take some time and you may be tired after the interview.

**What are the possible benefits of taking part?**

You will be able to explain what aspects of walking are most important to you and contribute towards a better understanding of walking after a stroke. This has not really been investigated before. Therefore the results may be very helpful in the design of future research trials.

**What will happen to the results of the research study?**

The results of this study will be written up as a report and will be submitted to professional journals and conferences to let other researchers and clinicians know about the study and results. In this way we can tell other clinicians what we have found. You may wish to see the reports and we can send this to you at the end of the study. The results will contribute to Ingrid Wilkinson's PhD studies.

**What if there is a problem?**

You can withdraw from the study at any time, without giving a reason.

If you have a question about any aspect of this study, you should ask to speak to the researchers, who will do their best to answer your questions (see below for contact details).

If you have a concern or a complaint about this study you should contact Dr Martina Prude, Head of the Governance Office, at the Research Governance Office (Address: University of Southampton, Building 37, Highfield, Southampton, SO17 1BJ ; Tel: +44 (0)23 8059 5058; Email: [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk) . If you remain unhappy and wish to complain formally Martina can provide you with details of the University of Southampton Complaints Procedure.

**Will my taking part in this study be kept confidential?**

Yes. What was said will be typed out by Ingrid Wilkinson from the voice recording made at the interview; your real name will not be used in this written account. Your real name will only be on your consent form and this will be kept for 10 years in a secure storage area at the University of Southampton before being securely destroyed.

The themes identified in the analysis will be used to compare what you have said about your feelings about walking and which aspects are most important to you with what other participants in the research have said. The themes identified by the group of people interviewed will be compared to what is being measured already in trials. If you, or people who know you well, read the final documents which will include quotes and will discuss the themes and outcomes of the 'Talking about Walking' study you may be able to recognise what you said. Other people who don't know you will not be able to identify you from the report.

**Who has reviewed this research and funded/organised it?**

All research in the University is reviewed by a group of people, called a Research Ethics Committee and also has to meet University criteria set by the Research Governance Office in order to protect your safety, rights, wellbeing and dignity. No funding has been received to organise this study. It is being organised by Ingrid Wilkinson, with support from her PhD Supervisors.

**If this information has interested you and you are considering taking part please contact Ingrid Wilkinson, details below. If we do not hear from you within a month we will assume that you are not interested.**

***Thank you***

**Further information and contact details**

The main researcher on this project is Ingrid Wilkinson

She is a PhD university student and Specialist Clinical and Research Physiotherapist

Tel: **01722 429 065** or **07968 377363**

Email: [iaw1a06@soton.ac](mailto:iaw1a06@soton.ac)

Postal address

Ingrid Wilkinson,  
Care of Ms Margaret Bush  
Faculty of Health Sciences  
University of Southampton, Building 67  
University Road, Highfield  
Southampton SO17 1UA

Version 1.1 March 2012

Page 4 of 5



**Academic supervisors are**

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## **Appendix K Phase 2 - Interview schedule**

- **‘Talking about Walking’ Study**

### **Introduction and purpose**

As part of my University of Southampton PhD studies, I am conducting this interview project called ‘Talking about Walking’. It has approval from the University Ethics Committee.

I am very interested in recording your experience of stroke as I think it will help clinicians and researchers to understand walking from the perspective of someone who has had a stroke.

### **Have you had a chance to read the Participant Information Sheet v1.2?**

Do you have any questions?

Check the sections of the PIS with the participant and sign Consent Form.

We will start the recording equipment now for a test run, it should pick up your speech at your normal volume (record, stop, listen).

I have a list of questions here and may need to make occasional notes to remind me of something important to come back to. Are you happy if we begin recording now?  
(record)

- **Interview Schedule**

<b>Could you please tell me about your stroke focussing on your walking problems?</b>	
<ul style="list-style-type: none"> <li>• <b>Can you tell me about your walking now ...</b></li> </ul>	
<ul style="list-style-type: none"> <li>• <b>And before the stroke?</b></li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Can you tell me about how it has changed over time since the stroke?</b></li> </ul>	
<p><b>What does being able or less able to walk mean to you and others in your life?</b></p> <p>Prompt: hobbies, leisure, interests, fitness, and things you do at work, home, around the house, to look after yourself or for other people</p>	
<b>Can you tell me about the impact of your walking problems on your life?</b>	
<b>How has that changed over time since the stroke?</b>	
<p><b>Which aspects of walking are most important to you?</b></p> <ul style="list-style-type: none"> <li>• <b>Which aspects of walking from before the stroke do you miss most?</b></li> <li>• <b>Has that changed since you had the stroke?</b></li> <li>• <b>What would you tell someone who has not had a stroke to value?</b></li> </ul>	

<p><b>Can you tell me about any assistive devices that you have used to help walking?</b></p> <ul style="list-style-type: none"> <li>• <b>What effect did it have on walking?</b></li> </ul> <p>Prompt: devices may be walking aids, scooters, wheelchairs, electrical stimulation or splints etc. Effect on important aspects you have just talked about, + and – aspects?</p>	
<p><b>As part of your rehabilitation or as part of a trial do you remember doing walking tests or filling in questionnaires? Can you tell me about them?</b></p> <ul style="list-style-type: none"> <li>• Did any the mobility/walking measurements taken match what you were interested in?</li> </ul> <p>Prompt: speed, distance, quality, different activities and impact on activities of daily life.</p> <ul style="list-style-type: none"> <li>• Do you have an opinion about what should be measured to monitor the benefit of gait rehabilitation in practice or future gait rehabilitation trials?</li> </ul>	

- **Thank you**

**...that is all my questions, do you want to tell me or ask me anything else?**

**End, stop recording**



## Appendix L Excerpts of Phase 2 analysis stages

Scanned excerpts from Liz's annotated transcript showing initial noting on right and emergent themes on left.

<p><u>looking for control</u></p> <p><u>balance</u></p> <p><u>fear of falling</u></p> <p><u>lack of control</u> (over legs / arms)</p> <p><u>Nina's Trust would be broken</u></p> <p><u>standing</u></p> <p><u>body strengthening</u></p> <p><u>body back strengthening</u></p> <p><u>Cooperation</u></p> <p><u>regain "control"</u></p> <p><u>"I want to feel safe &amp; secure"</u></p> <p><u>Control of self &amp; environment</u></p>	<p>basic strengthening exercises and upper body exercises to try to get some sort of sense of balance back.</p> <p>Ingrid:</p> <p>So how did your walking change then? Because that was November ... so how ...? ... it changed kind of whilst you were on the study - I remember that much. So how did it change?</p> <p>Liz:</p> <p>Yes er ... I had the dropped foot ... the common dropped foot problem, that if I tried to move my left leg I felt I would trip/um ... and my left ankle inverted as well ... so I had a brace fitted to my ankle too... which went inside my shoe ... to try to prevent this so that I could actually put my foot to the floor ... safely ... without my foot twisting under me. Um ... Initially just standing was difficult. The drugs I had to control my blood pressure had the opposite effect and lowered my blood pressure so when I stood up I felt very light-headed often ... as well as being very weak and wobbly. So I had to ... if you like ... practise standing up ... and feeling safe about it. Also, simple tasks like getting up from a chair ... getting myself to the toilet ... all of that was very difficult. Even getting in and out of bed was very hard to start with ... going upstairs to bed was impossible at the ... in the early stages of ... being at home. So we had to arrange for me to sleep downstairs ... bring a mattress down and I had to sleep downstairs initially. Um ... but I was very determined to get upstairs and sleep in my own bed ... that was important. So ... hard though it was the more I pushed myself ... the more I found that very slowly my muscles started to come back ... the control of my some strength back into ... into my body.</p> <p>Ingrid:</p>	<p>to our own body then like a wind?</p> <p>basic strengthening — compared to make not complex physio? Aiming to get 'balance' back <u>balance last</u></p> <p>dropped foot in version — adaptation of medical term. if I tried to move I would trip — fear of falling? fear of consequences? pain?</p> <p>aim for safety — safety putting cast to floor with help of brace to prevent inversion inversion — associated with difficulty putting cast to floor twisting under me</p> <p>emphasises actually put cast to floor — is this an acknowledgement that this should be simple/easy? again just standing acknowledgement this should be easy light headed 2nd hospital or well as 'weak + wobbly' presumably go to stroke.</p> <p>I had to practice standing up + feeling safe about it Simple tasks like x y z — before stroke these are simple but after there were v difficult</p> <p>this this like I took them far granted! Again simple tasks like even getting in/out bed impossibility of going up stairs at beginning.</p> <p>Process was hard, slow own loss of control. pushed myself. Liz pushing hard, determined, control came back through. gaining control over our body gradually. but it is a fight? to overcome feeling out of control like tree in wind?</p>
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<p>person with pain in lower back &amp; feet</p> <p>body self spirit of the whole to lower body &amp; feet</p> <p>to put in body</p> <p>to put in body</p>	<p>Can I ask you one question? You said that your foot twisted underneath you to start with and that that was a problem. How does that feel?</p> <p>Liz: Now?</p> <p>Ingrid: No, how did it feel then? ... When you tried to put weight on it when it was twisting?</p> <p>Liz: Initially ... the pain you feel. Um ... in the stroke-affected side ... is very <u>acute</u>. It is not a normal pain - it is very sharp, very vicious. Um ... very difficult to describe um ... it .. it .. when you turn over on your ankle ... you know, most of us have twisted an ankle at some point or another ... it can be jolly painful - you know, you twist - you pull a tendon - or pull a muscle - or whatever ... it was that but <u>magnified</u> ... <u>very sharp</u>, very intense, very agonising pain - quite a <u>frightening</u> pain ... it was because too I couldn't feel that ... the haptic sensation had gone in my body so without looking, visually, at where my foot ... how my foot was hitting on the ground ... I could not feel my foot touching the floor so on anything that wasn't a completely flat surface any sort of even slightly uneven ground I did not trust my foot. I couldn't know that when I put my foot to the floor my foot would be on the floor, as you would have expected ... you know, a flat sole to the floor to be able to walk I would have to look down to check that my ankle hadn't twisted over and the initial touching the floor you don't feel but as soon as you try to put any weight on it the pain was so acute ... but by that time it could be too late, in that your balance was gone because your ... you were putting your weight onto your left side and the risk of falling and obviously serious injury from pulling a</p>	<p>inversion. I have never seen a written account of what drop foot, high tone inversion feel like.</p> <p>what does inversion feel like. hesitant - difficult to describe "put into words" Different to normal twisting "jolly painful" Pain associated with stroke affected foot and weight bearing when twisted "acute, sharp, vicious, the frightening pain" not twisting foot to be where it should be without looking. if not checked early have foot - mass on - injury rather than to put in foot 2° to sensation and pain to put in body "back of control" "The stroke affected side" - I did not trust my foot putting weight on the side need to check first as don't trust it off foot leg</p>
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5



Excerpts from Excel analysis sheet corresponding to Liz's annotated transcript pages.

Super-ordinate themes	Super-ordinate subtheme detail	Strength	Initial theme	Idea and notes	Inter-viewee	Page	Evidence - Quotes
Yardstick	Walking as yardstick	2	Pre-stroke yardstick	use of easy or simple for tasks pre-stroke Practice simple tasks. Even getting in/out of bed was difficult.	Liz	3	So I had to ... if you like ... practise standing up... and feeling safe about it. Also, simple tasks like getting up from a chair ... getting myself to the toilet ... all of that was very difficult. Even getting in and out of bed was very hard to start with ... going upstairs to bed was impossible ...
Control	Self as coach	2	Control of body/balance	self-efficacy self as coach Pushed myself, I managed... Liz starts to regain control of limbs. Fights to gain control?	Liz	3	... the more I pushed myself ... the more I found that very slowly my muscles started to come back ... the control of my muscles started to come back and I managed to get some strength back into ... into my body.
Control	FoF - confidence	2	Control - fear of falling	self-efficacy self as coach, multifactorial loss of balance	Liz	3	Um ... Initially just standing was difficult. The drugs I had to control my blood pressure had the opposite effect and lowered my blood pressure so when I stood up I felt very light-headed often ... as well as being very weak and wobbly. So I had to ... if you like ... practise standing up... and feeling safe about it.
Control	Body foreground instead of background	2	Control of body/balance	self/head/body split Loss of control over limbs	Liz	3	Yes er ... I had the dropped foot ... the common dropped foot problem, that if I tried to move my left leg I felt I would trip um ... and my left ankle inverted as well ... so I had a brace fitted to my ankle to ... which went inside my shoe ... to try to prevent this so that I could actually put my foot to the floor ... safely ... without my foot twisting under



Super-ordinate themes	Super-ordinate subtheme detail	Strength	Initial theme	Idea and notes	Inter-viewee	Page	Evidence - Quotes
							me. Um ... Initially just standing was difficult. ... So ... hard though it was the more I pushed myself ... the more I found that very slowly my muscles started to come back ... the control of my muscles started to come back and I managed to get some strength back into ... into my body.
Activity and participation	Adapting	2	Coping	Adapting	Liz	3	... going upstairs to bed was impossible at the ... in the early stages of ... being at home. So we had to arrange for me to sleep downstairs ... bring a mattress down and I had to sleep downstairs initially.
Activity and participation	Positive	1	Mobility aids	Brace helped stabilise ankle before FES  Brace helped her put her foot to floor safely	Liz	3	Yes er ... I had the dropped foot ... the common dropped foot problem, that if I tried to move my left leg I felt I would trip um ... and my left ankle inverted as well ... so I had a brace fitted to my ankle to ... which went inside my shoe ... to try to prevent this so that I could actually put my foot to the floor ... safely ... without my foot twisting under me.
Control	FoF - injury	4	Control of body/balance	Dropped foot  Lack of control, leg untrustworthy risk of pain and falls	Liz	4	... it was because too I couldn't feel that ... the haptic sensation had gone in my body so without looking, visually, at where my foot ... how my foot was hitting on the ground ... I could not feel my foot touching the floor so on anything that wasn't a completely flat surface any sort of even slightly uneven ground I did not trust my foot. I couldn't know that when I put my foot to the floor my foot would be on the floor, as you would have expected ... you know, a flat sole to the floor to be able to walk I would have to look down to check that my ankle hadn't twisted over and the initial touching the floor you don't feel but as soon as you try to put any weight on it the pain was so acute ... but by that time it could be too late, in that your balance was

Super-ordinate themes	Super-ordinate subtheme detail	Strength	Initial theme	Idea and notes	Inter-viewee	Page	Evidence - Quotes
Control	Body foreground instead of background	4	Control of body/balance	distrustful frightening body, self body split  Uncertain body, not read a description of this before. Reduced trust in own leg due to reduced sensation and pain when ankle twists	Liz	4	gone because your ... you were putting your weight onto your left side and the risk of falling and obviously serious injury from pulling a muscle um ... is very great.  ... the haptic sensation had gone in my body so without looking, visually, at where my foot ... how my foot was hitting on the ground ... I could not feel my foot touching the floor so on anything that wasn't a completely flat surface any sort of even slightly uneven ground I did not trust my foot.. I couldn't know that when I put my foot to the floor my foot would be on the floor, as you would have expected ... you know, a flat sole to the floor to be able to walk I would have to look down to check that my ankle hadn't twisted over and the initial touching the floor you don't feel but as soon as you try to put any weight on it the pain was so acute ... but by that time it could be too late, in that your balance was gone because your ... you were putting your weight onto your left side and the risk of falling and obviously serious injury from pulling a muscle um ... is very great. So it was a very frightening time because I didn't understand why my body was behaving in this way and I didn't trust it.
Control	Body foreground instead of background	3	Control of body/balance	dropped foot  Adoption of medical terms.	Liz	4	Yes er ... I had the dropped foot ... the common dropped foot problem, that if I tried to move my left leg I felt I would trip um ... and my left ankle inverted as well ... so I had a brace fitted to my ankle to ... which went inside my shoe ... to try to prevent this so that I could actually put my foot to the floor ... safely ... without my foot twisting under me.
Self and	New self	1	New self	pain	Liz	4	Ingrid: You said that your foot twisted underneath you to

Super-ordinate themes	Super-ordinate subtheme detail	Strength	Initial theme	Idea and notes	Inter-viewee	Page	Evidence - Quotes
Identity	post stroke			strange painful sensations from left leg. I have not read a description of pain assoc with inversion before			start with and that that was a problem. How does that feel? Liz: Now? Ingrid: No, how did it feel then? ... When you tried to put weight on it when it was twisting? Liz: Initially ... the pain you feel. Um ... in the stroke-affected side ... is very acute. It is not a normal pain - it is very sharp, very vicious. Um ... very difficult to describe um ... it ... when you turn over on your ankle ... you know, most of us have twisted an ankle at some point or another ... it can be jolly painful – you know, you twist – you pull a tendon – or pull a muscle – or whatever ... it was that but magnified .. a very sharp, very intense, very agonising pain – quite a frightening pain ...
Control	Body foreground instead of background	4	Perplexing body	information seeking  A need to understand problems, thirsty for information... information needs not always met?	Liz	5	Observing what my body was doing. When you first have a stroke you don't understand what you can't do ... when you have had a stroke and your body doesn't perform in the way you understand and the way that you are familiar with, you need to re-learn what it is doing and what I found really helpful ... <u>I was so thirsty for information about why my body was behaving in this way. I really wanted to try to understand what was happening to me. why my body behaved the way it did it did in order to manage the situation and when you understand the background to all of it - I personally found it much more helpful to ... much easier, rather ... to understand how I could ... perform what I wanted to perform, even simple tasks like standing and walking safely.</u>
Control	Body foreground instead of	4	Pre-stroke taken for granted	not thinking about body	Liz	5	<u>... your memory is only of living a normal able-bodied life and treating your body with almost disregard, you understand that when you put your foot to the floor that</u>

Super-ordinate themes	Super-ordinate subtheme detail	Strength	Initial theme	Idea and notes	Inter-viewee	Page	Evidence - Quotes
	background						you will be able to walk in this way and so on. You don't even think about it, of course you don't, but when you have had a stroke and your body doesn't perform in the way you understand and the way that you are familiar with, you need to re-learn what it is doing ...
Yardstick	Walking as yardstick	3	Pre-stroke yardstick	use of easy or simple for tasks pre-stroke	Liz	5	... even simple tasks like standing and walking safely.
Control	Body foreground instead of background	3	Control of body/balance	self-efficacy self as coach - regaining control	Liz	5	So I needed to manage how I put my foot to the floor.

# Appendix M Disability & Rehabilitation Assistive Technology Publication

Disability  
and  
Rehabilitation  
**Assistive Technology**

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**informa**  
healthcare

## RESEARCH PAPER

### A randomised controlled trial of integrated electrical stimulation and physiotherapy to improve mobility for people less than 6 months post stroke

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#### Abstract

**Purpose:** To investigate the feasibility of combining physiotherapy and functional electrical stimulation to improve gait post stroke. **Methods:** A parallel group partially single-blinded randomised clinical trial. Adults living at home, less than 6 months post stroke, were randomised to Group A (physiotherapy,  $n=10$ ) or Group B (physiotherapy and common peroneal nerve stimulation,  $n=10$ ). Assessments were conducted before randomisation (Week 1), after intervention (Week 8) and after 12 weeks follow-up (Week 20). **Results:** No between group differences were observed. There were statistically significant within group differences after the intervention period in both groups for walking speed and distance walked (without stimulation), Rivermead Mobility Index and Canadian Occupational Performance Measure, maintained at Week 20. There was statistically significant improvement in 10-m walking speed (Group B) when the stimulator was used at Week 8 ( $p=0.03$ , median 0.04 m/s (8%)). Only Group B had statistically significant within group change in Rivermead Visual Gait Analysis (Week 8), maintained at Week 20. **Conclusions:** Integrating electrical stimulation and physiotherapy was feasible and improved walking speed. There was no evidence of a training effect compared with physiotherapy alone. One-hundred forty-four participants per group would produce an adequately powered study based on this protocol.

#### Keywords

CVA, drop foot, electrical stimulation, gait, physical therapy modalities, physiotherapy

#### History

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#### ► Implications for Rehabilitation

- At the end of the intervention period participants using electrical stimulation to correct dropped foot walked faster.
- It was feasible for electrical stimulation to be combined with physiotherapy for people less than 6 months post stroke.
- A larger adequately powered study is required to establish whether there are training effects associated with use of stimulation in this population.



# Appendix N Poster: 'Talking about Walking'

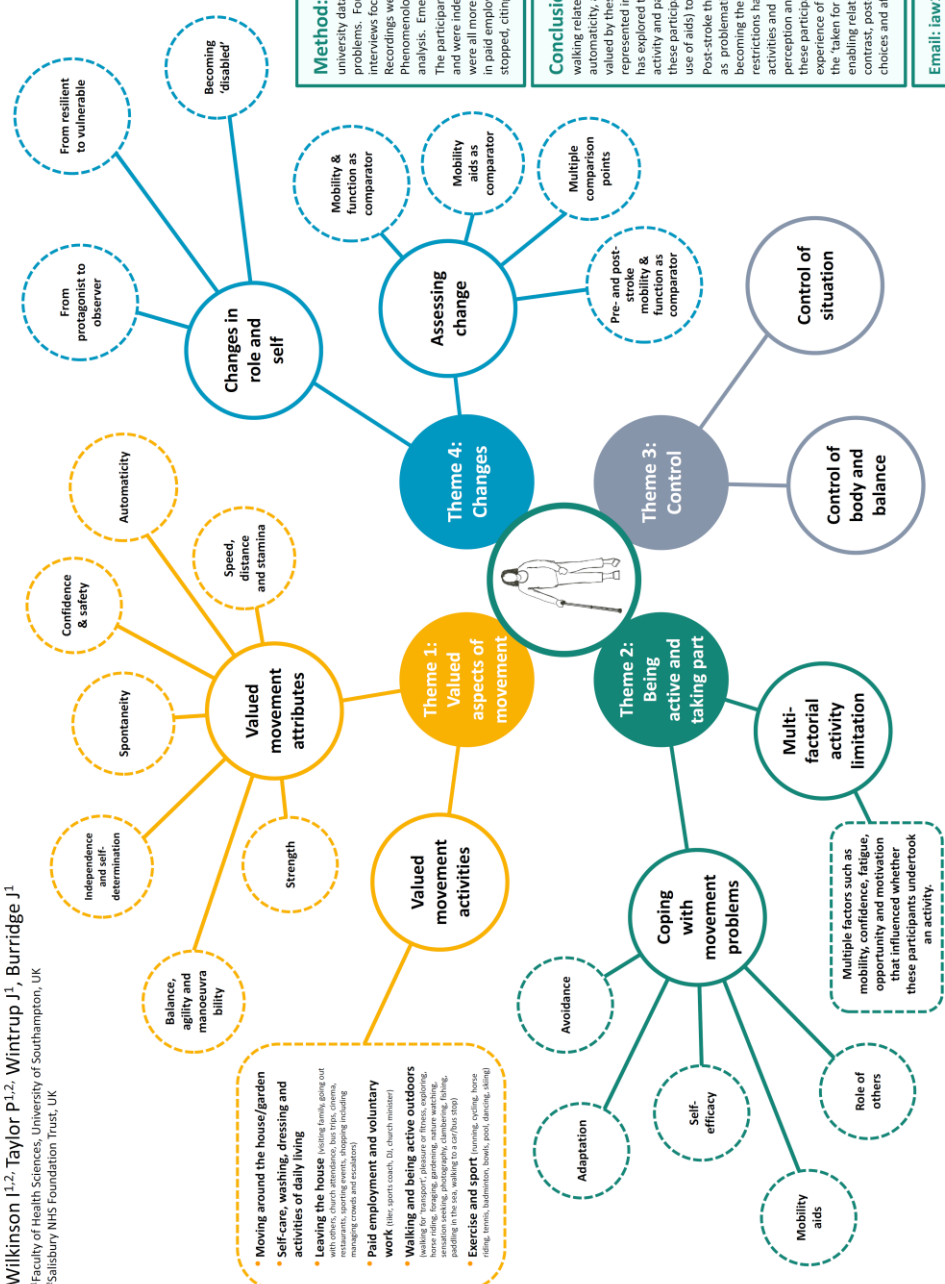
UNIVERSITY OF  
Southampton

## 'Talking about Walking' – a qualitative exploration of changes in walking post-stroke from the perspective of stroke survivors

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'Talking about Walking' – a qualitative exploration of changes in walking post-stroke from the perspective of stroke survivors. Wilkinson J, Burrridge J, Taylor P, Wintrup J. Stroke Forum 2014, Harrogate, UK.





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