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A RANDOMISED CONTROLLED TRIAL EVALUATING FAMILY MEDIATED EXERCISE (FAME) THERAPY FOLLOWING STROKE

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B.Sc (Physio) Hons, Dip. Stat.

A Thesis submitted in fulfilment of the requirements for the degree of Doctor in Philosophy

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SUMMARY

The aim of this study was to examine the impact of additional family mediated exercise (FAME) therapy on outcome of the lower limb (LL) following acute stroke through the implementation of a randomised controlled trial (RCT). Outcome was assessed at the level of impairment, activity and participation. A secondary aim of the study was to evaluate the impact of the FAME programme on the person with stroke and the family member assisting in the delivery of the exercises to them through qualitative and quantitative data gathering techniques.

A systematic review and meta-analysis was completed to inform the development of the RCT. The aim of the review was to examine the impact of increased duration of exercise therapy on outcome following stroke. A meta-analysis was completed on studies that examined the impact of additional exercise therapy on outcome of the LL. While the results of the meta-analysis lacked significant findings, they were supportive of the hypothesis that additional exercise therapy has a positive impact on LL recovery. The systematic review raised issues that were considered in the development of the RCT. In addition, three user surveys were conducted to explore the views of the potential participants in the FAME programme. These included user surveys of people with stroke, 'family members/friends' of people with stroke and physiotherapists. A self-report questionnaire was administered to 100 'family members/friends' and 75 people with stroke. In addition, 10 semi-structured interviews were conducted with people with stroke to gain a more in-depth insight into their views on the involvement of their families in their physiotherapy programme after stroke. Finally, two focus groups were conducted with 10 physiotherapists working in the area of stroke rehabilitation. The results of the three user surveys indicated that family members of people with stroke were willing to participate in the delivery of unsupervised exercises in the hospital and the home setting, following suitable training by a physiotherapist. Furthermore, this method of exercise delivery was also acceptable to people with stroke as an adjunct to routine physiotherapy. The physiotherapists outlined a number of areas where family involvement can have an impact on recovery, such as treatment carry-over, assisting the family unit to cope on discharge and improving handling skills.

An eight week RCT was conducted in six acute hospitals in the greater Dublin area. Forty people with acute stroke participated in the study. The Orpington Prognostic Score (OPS) was used to ensure homogeneity in the two groups. Participants were randomly assigned to an intervention (FAME group) or a control group using pre-sealed, computer generated random numbers. All outcome measures were administered by the same blinded outcome assessor at baseline (T1), post-intervention (T2) and at a three month follow-up assessment (T3). The FAME group received routine therapy and additional LL exercise therapy in the form of family assisted exercises. The control group received routine therapy with no formal input from their family members. Statistically significant differences in favour of the FAME group were noted on all measures of impairment and activity following the additional FAME therapy ($p<0.05$). These improvements were still evident at T3. However, outcome on the Six Minute Walk Test and the Berg Balance Scale were only statistically significantly different to the control group at this time point. Participants in the FAME group also reported that they were significantly more integrated into their community, as measured by the Re-Integration to Normal Living Index and the Nottingham Extended Activities of Daily Living Index, than their counterparts in the control group at T3.

A semi-structured interview was conducted separately with each individual with stroke and their nominated family member in the FAME group following the additional exercise programme. This qualitative assessment examined the impact of the additional FAME programme from the perspective of the person with stroke and his/her nominated family member. Both individuals with stroke and their family members identified several benefits to themselves and each other as a result of their participation in the FAME programme. These included improvements in physical impairments, balance and mobility, confidence building, family involvement in exercise delivery and continued involvement and participation in exercise following stroke. Furthermore, family members of participants in the FAME group reported a significant decrease in their levels of carer strain from T2 to T3 when compared to family members in the control group.

To conclude, the FAME study represents an evidence based intervention that can be delivered in the hospital or the community setting and that is acceptable to people with stroke, their family members and physiotherapists.

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ABBREVIATIONS

ADL – Activity of daily living

BBS – Berg Balance Scale

BI – Barthel Index

CI – Confidence interval

CRA – Caregiver Reaction Assessment

CSI – Caregiver Strain Index

FAME – Family mediated exercises

FAST – Frenchay Aphasia Screening Test

FMA – Fugl-Meyer Assessment

ICC – Intraclass correlation oefficient

ICF – International Classification of Functioning, Disability and Health

IHF – Irish Heart Foundation

LL – Lower limb

LL-FMA – Lower limb section of the Fugl-Meyer Assessment

LL-LMA – Lower limb section of the Lindmark Motor Assessment

MAS – Motor Assessment Scale

MMSE – Mini Mental State Examination

N-EADL – Nottingham Extended Activities of Daily Living Index

SALT – Speech and Language Therapist

SCQ – Sense of Competence Questionnaire

SEM – Standard error of the measure

SES – Summary effect size

SMD – Standardised mean difference

SMWT – Six Minute Walk Test

T1 – Baseline assessment

T2 – Post-intervention assessment

T3 – Three month follow-up assessment

OPS – Orpington Prognostic Scale

PEDro Scale – Physiotherapy Evidence Database Scale

RCT – Randomised controlled trial

RMT – Robot mediated therapy

RNLI – Re-integration to Normal Living Index

UL – Upper limb

UL-FMA – Upper limb section of the Fugl-Meyer Assessment

WHO – World Health Organisation

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CHAPTER 1
RECOVERY FOLLOWING STROKE

1.1 Background

Stroke has been shown to be a major cause of death and acquired disability in all societies in which it has been studied. The first World Health Organisation (WHO) stroke register commenced in 1971 as a joint undertaking of the WHO and a number of collaborating centres in Africa, Asia and Europe (Hatano 1976). It was the first attempt to collect data on people with stroke in the community in a uniform manner from countries with different social, cultural and environmental backgrounds. In the first report published in 1976, the WHO provided a formal definition of stroke as a clinical syndrome consisting of 'rapidly developing clinical signs of focal (at times global) disturbance of cerebral function lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin' (Hatano 1976).

Stroke is both a preventable and treatable disease. However, as public health, medical and social advances continue to extend life expectancy, the prevalence of stroke is likely to increase in the future (Braun et al 2007). Approximately 10,000 people are admitted to hospital in the Republic of Ireland each year with stroke disease as a primary diagnosis and it is estimated that there are 30,000 people living with residual deficits following stroke in Ireland (Irish Heart Foundation 2008). The European Brain Council estimates that six million people have survived stroke in the European Union and that the total cost of stroke in Europe is €21.9 billion (Andlin-Sobocki et al 2005).

In 1989, the WHO established a Task Force on Stroke and Other Cerebrovascular Diseases (WHO 1989) aimed at identifying measures to prevent the occurrence of stroke and to provide information and advice on the efficacy and safety of different stroke therapies. Since the establishment of this Task Force, a growing body of high quality research has overturned the traditional perception that stroke is simply a consequence of ageing. There is an increasing understanding of the various aetiologies of stroke disease and increasingly effective ways to limit the degree of consequent brain damage. Evidence is accumulating for more effective primary and secondary prevention

strategies, increased recognition of individuals who are at a greater risk of stroke, and interventions that are effective soon after the onset of symptoms. Understanding of the particular care pathways that contribute to a better outcome has improved, and there is a growing body of evidence to support a variety of interventions and care processes in stroke rehabilitation.

The aim of this chapter is to outline the mechanisms of recovery of brain structures and function following stroke and to highlight the relationship between the physiological re-organisation of the brain and functional recovery. This is followed by an overview of different physiotherapy approaches aimed at promoting recovery after stroke, including the neurophysiological and motor re-learning methods. In addition, conventional and 'novel' interventions used by physiotherapists in the rehabilitation and research setting are evaluated. A synopsis of the WHO International Classification of Functioning, Disability and Health (ICF) framework (WHO 2001) is also provided, including an overview of how this model facilitates the description of stroke related impairments and outcomes in the clinical and research setting. Finally, a summary of the proposed research is provided and the content of the individual chapters is outlined.

1.2 Theories of recovery following stroke

Modern cortical mapping techniques in both human and non-human subjects indicate that the functional organisation of the brain is more complex than was traditionally described (Carr and Shepherd 2004). For many years the brain was considered to be a 'hard wired' organ that was incapable of recovery following insult or injury (Bach-y-Rita 2005). In addition, researchers believed that the functionality of the brain was compartmentalised into different areas and that these areas were rigid and unable to interconnect. However in the past number of years, an increase in the number of neuroscientific studies on mechanisms of cell and neural network injury, development and activity and a considerable body of research on brain plasticity and motor control has contributed to the wide acceptance that the brain is continuously remodelled throughout life. Research by Nudo et al (2001) found extensive overlap of muscle and joint representation within the primary motor cortex, extensive branching of corticospinal neurons into different motor pools and the inter-connection of these branches by other neurons. Furthermore, these representations can be multiplied by

the acquisition of new skills or the performance of tasks that are challenging and engaging (Ward 2005). Researchers now believe that this complex organisation may provide the foundation for functional plasticity in the motor cortex.

The potential of the brain to adapt and reorganise following a lesion such as a stroke has also been studied extensively. In recent years, advances in neuro-physiological and neuro-anatomical studies in animals, and neuro-imaging and other non-invasive mapping studies in humans have demonstrated that the animal and human brain are capable of significant recovery after stroke (Nudo et al 1996, Plautz et al 2000). Recent models have suggested that recovery involves at least three separate but interactive processes: preservation and resolution of diaschisis, behavioural compensation and neuroplasticity. Knowledge of these patterns of recovery after stroke is useful in determining when to expect recovery and in targeting appropriate treatment and timing of rehabilitation (Verheyden et al 2008).

1.2.1 Preservation and diaschisis

Neuronal damage after onset of stroke is progressive. Complex physiological, pathological and biochemical changes lead to brain cell death following stroke. However, there is a therapeutic window of opportunity in which stroke-specific therapy may minimise the effects of stroke or at least prevent further damage (Baer and Durward 2004). In the early phase following stroke, the initial improvement in function is thought to result from the resolution of oedema around the lesion, the absorption of necrotic tissue and the opening of collateral circulatory channels which allows the oxygen and blood supply to the impaired ischaemic (penumbral) tissue to return to normal (Lee and Van Doneklaar 1995, Held and Pay 1999). The 'ischaemic penumbra' is characterised by its severely impaired cerebral blood flow, abolished synaptic activity but preserved structural integrity. The outcome of this tissue is unpredictable and preservation is correlated with the degree and duration of ischemia (Furlan et al 1996).

Stroke also produces substantial changes in neuronal circuits adjacent to or connected to the infarct (Dobkin and Carmichael 2005). In addition to cell necrosis at the actual site of the lesion, there is a reduction of activity in remote non-damaged brain sites that are functionally connected to the area of lesion - a process known as diaschisis.

Robertson and Murre (1999) postulate that the weakening of synaptic connections between damaged and undamaged sites is due to the acute reduction in cell activity at the area of infarct. Therefore, cells in the two areas no longer fire synchronously and the loss of synaptic connectivity between them results in a disruption of function in the structurally undamaged but functionally connected remote site. It is also postulated that the effects of increased blood pressure combined with oedema and extracellular blood flow are responsible to some degree for this process and the temporary depression in activity in the remote sites (Hausen et al 1997). The complex nature of diaschisis makes it difficult for researchers to single out any one event that is responsible for its reversal. However, it is thought that the resolution of oedema, vascular changes, stabilisation of intracranial blood pressure, dispersion of toxic products and changes in transmitter levels all play a part in the reversal of diaschisis, further contributing to spontaneous recovery in the acute phase following stroke (Seitz et al 1999, Finger et al 2004).

1.2.2 Behavioural compensation

In addition to the resolution of diaschisis, motor recovery after cortical injury occurs in part through behavioural compensation, rather than via 'true recovery' or restoration of 'normal' motor strategies (Nudo et al 2001). Behavioural compensation is not well defined in the literature. However compensation aims to improve the 'mismatch' between an individual's impairments and the demands of the individual or the environment by using alternative strategies to complete a task (Dobkin and Carmichael 2005). Behavioural compensation may be linked to the ability of spared networks and assemblies of neurons to contribute to partial restoration of behaviours that were performed by other assemblies of neurons (Dobkin 2004a). In other words, one assembly of neurons may partially compensate for loss of another when an individual finds a strategy to activate spared neurons. However, the degree to which this reorganisation in spared tissues represents mechanisms related to true recovery, behavioural compensation, or both, is not entirely clear (Nudo et al 2001).

1.2.3 Neuroplasticity

The later ongoing improvement in neurological function occurs by a different set of mechanisms that allow structural and functional re-organisation to occur within the brain. Neuroplasticity (variously referred to as brain plasticity, cortical plasticity or cortical re-mapping) refers to changes that occur in the organisation of the brain following an insult or injury such as a stroke, and may continue for many months. Numerous non-invasive techniques have been used in humans to examine the effects of cortical injury on the function of intact cortical tissue. The majority of subjects examined in these studies presented with cortical lesions (either ischemic or hemorrhagic) or lacunar subcortical lesions involving the internal capsule (Nudo et al 2001) and techniques such as positron emission tomography (PET), functional magnetic resonance imaging (fMRI), transcranial magnetic stimulation (TMS), and magnetoencephalography (MEG) have been used to map the functional organisation of the damaged cortex. It is now believed that plastic changes can occur at the cortical level in a number of ways such as axonal regeneration, increases in axonal and dendritic collateral sprouting from uninjured neurons, changes in neuronal excitability and neurotransmitter regulation and synaptogenesis (Ward and Cohen 2004, Dobkin and Carmichael 2005). These processes occur in both local and diverging connections and produce novel projection patterns in the brain. This results in proliferation, migration and differentiation of new neurons into areas of damage bordering the area of infarct. Through this process, the adjacent area of brain is remodelled and an entirely new system of connections is created (Dobkin and Carmichael 2005).

In summary, the research to date demonstrates that the primary motor cortex forms a complex network in which muscles and movements are re-represented at multiple locations within a local region in the brain. In particular, the motor cortex is altered during the acquisition of new motor skills such that the muscles and movements required to complete the activity become represented over greater cortical territories (Nudo et al 1996). These changes in functional topography are accompanied by anatomical alterations, such as an increase in the number of synaptic connections and synaptogenesis (Nudo et al 2001, Dobkin 2004b). The basis for acquisition, retention and retrieval of information in the healthy brain is no different from that in people with stroke (Dobkin 2004b). Therefore, while the organisation of the motor cortex changes after a stroke, significant neuro-restoration can occur provided that the correct

treatment and stimuli are applied in adequate amounts at the right time (Teasell and Kalra 2004). Physiotherapists have traditionally been the primary mediators of exercise following stroke and well defined, evidence based interventions are essential for optimum management of rehabilitation-induced neural adaptations that produce functional gains. The following section describes a range of different physiotherapy interventions that are routinely used in the rehabilitation of individuals with stroke.

1.3 Rehabilitation following stroke

The specific impairments observed after stroke depend on the area of the brain affected and recovery is related to the site, extent and nature of the lesion, the integrity of the collateral circulation and the premorbid status of the individual (Baer and Durward 2004). The most common physical consequence after stroke is hemiplegia or hemiparesis, which results in weakness of the muscles of the arm, leg, trunk and sometimes face on one side of the body. Other sequelae of stroke include cognitive, sensory, communication and perceptual impairments.

Rehabilitation aims to enable people with such impairments and activity limitations to reach and maintain optimal functioning in the physical, intellectual, psychological and/or social domains (WHO 2001). Rehabilitation goals can shift from initial input which may be focused on minimising primary impairments to more complex interventions in the later stages of recovery that are designed to encourage active participation in daily and social activities. The ultimate goal of all rehabilitation strategies is to guide the individual towards a life situation in which they are participating in society as they wish. Thus, rehabilitation encompasses a diverse array of interventions, applied using distinct methodologies at various stages of the individual's recovery (Quinn et al 2009).

1.3.1 Physiotherapy approaches to rehabilitation following stroke

Physiotherapy covers all 'interventions that develop, maintain and restore maximum movement and functional ability throughout the lifespan' (World Confederation for Physical Therapy 2009). The physiotherapist plays a significant role in the rehabilitation of people with stroke, using skills acquired during education, clinical

practice and continuous professional development. Physiotherapists operate as part of a team of professionals including doctors, nurses, occupational therapists, speech and language therapists, clinical nutritionists, psychologists and social workers. Since the 1980s, the concept of evidence based practice has gained increased recognition in the field of medicine. Evidence based medicine involves 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients' (Sackett et al 1996). There is a requirement that neurological physiotherapy is based on methodical research in relevant areas such as medical science, neuroscience, exercise physiology and biomechanics. Furthermore, there is an increasing emphasis on the use of valid and reliable outcome measures to test various interventions in order to develop evidence-based physiotherapy. Bridging the gap between evidence and clinical practice is a considerable task for therapists, who must endeavour to keep up to date with scientific findings, as well as applying this information in a clinically meaningful way (Carr and Shepherd 2004). However, anecdotal evidence and the results of questionnaire-based studies suggest that traditionally, many physiotherapists continue to base their clinical practice around a specific treatment approach (Coote and Stokes 2003, Pollock et al 2007).

1.3.2 Neurological treatment approaches

Historically, physiotherapists have used a number of different approaches to facilitate the promotion of recovery after stroke. Prior to the 1940s, there was little evidence to support the view that the central nervous system could recover from damage following stroke and compensatory strategies were employed to enable the individual to become as independent as possible. There was an emphasis on orthopaedic interventions with various types of splints, strengthening exercises and surgical interventions frequently employed to train the individual to use their unaffected limbs to compensate for affected limbs (Mayston 2002, Lennon 2004). However from the 1940s onwards, several other ideas emerged based on available neurophysiological knowledge, including the methods of Bobath (Bobath 1990), Brunnström (Brunnström 1970), Rood (Goff 1969) and the proprioceptive neuromuscular facilitation approach (Knott and Voss 1968, Voss 1985). Approaches based on 'neurophysiological principles' primarily involve the physiotherapist moving the individual with stroke through different patterns of movement, with the therapist acting as the problem solver and decision

maker and the individual with stroke acting as a relatively passive recipient (Pollock et al 2007). In the early 1980s the potential significance of neuropsychology and motor learning was explored and the motor learning (or relearning) approach was proposed (Carr and Shepherd 1982). From the literature on motor learning, it is evident that the action or activity to be acquired by the individual with stroke should be practiced in its entirety (task-specific practice) with appropriate feedback to promote learning and motor recovery (Carr and Shepherd 1998). Currently the Bobath concept is the most widely used approach in the rehabilitation of people with stroke in Europe, and it is also well known and frequently used in many other countries, including the United States, Canada, Japan, Australia and Israel (Paci 2003). In direct contrast to the Bobath approach, motor relearning stresses the importance of active involvement by the individual (Carr and Shepherd 1998), while orthopaedic approaches emphasise muscle strengthening techniques and compensation with the unaffected side. Due to the difference in the practical application of these approaches and the pre-occupation with evidence based practice, physiotherapists often search for evidence relating to 'global' approaches to the treatment of people with stroke rather than evidence in support of individual interventions (Pollock et al 2007).

A Cochrane systematic review and meta-analysis by Pollock et al (2007) investigated if there was a difference in the recovery of postural control and lower limb (LL) function in people with stroke following physiotherapy input based on the 'neurophysiological approach', orthopaedic, or motor re-learning approach, or a mixture of these approaches. Outcomes of interest were those that focused on motor impairment, activity limitations or participation restrictions. The authors included 18 randomised controlled trials (RCTs), two quasi random controlled trials and one single subject design. Eight trials compared a neurophysiological approach with another approach, eight compared a motor learning approach with another approach and eight compared a mixed approach with another approach. Standardised mean differences (SMD) including 95% confidence intervals (CI) were calculated using a random effects model, to evaluate the impact of the different approaches on outcome in the intervention and the control groups. Results indicated that a mixed approach was significantly more effective in the recovery of functional independence (SMD 0.94, 95% CI 0.08-1.80) than no treatment or placebo control, as measured by the Functional Independence Scale. There was insufficient evidence to suggest that any one physiotherapy approach was

more effective in promoting recovery of LL function or postural control following stroke than any other approach. The authors concluded that physiotherapy, using a mix of different approaches, is significantly better than a single approach to treatment, or no treatment of posture and LL impairment following stroke. A more recent systematic review (Kollen et al 2009) including 16 RCTs also examined the efficacy of the Bobath concept in stroke rehabilitation. The methodological quality of the each trial was rated on the 10 point Physiotherapy Evidence Database (PEDro) scale. This scale is used to measure the internal and external validity of RCTs (Sherrington et al 2000). Methodological quality of the studies included in the review ranged from 4 to 8 points (median 7 points). Based on best evidence synthesis, there was no evidence to demonstrate that the Bobath approach to rehabilitation following stroke was superior to any other approach. Both reviews highlighted many methodological shortcomings in the studies reviewed and recommended the need for further high quality trials. Kollen et al (2009) also proposed that evidence-based guidelines, rather than therapist preference, should serve as a framework from which physiotherapists should develop the most effective treatment plan for individuals with stroke.

1.3.3 Conventional interventions

There are several different conventional physiotherapy interventions aimed at improving impairments, activity limitations and participation restrictions following stroke. In addition to the prescription of exercises, physiotherapists use a range of other techniques and assistive devices to optimise treatment. A systematic review and meta-analysis was conducted by Van Peppen et al (2004) to evaluate the efficacy of different interventions used by therapists in the rehabilitation of individuals following stroke. Interventions documented in the review included programmes for training sensorimotor function and muscle tone, cardiovascular fitness and aerobic programmes. Methods for training mobility and mobility related tasks including training of balance and postural control, treadmill training, use of external auditory cues, limb loading with weighted garments and wheelchair propulsion exercises were also considered in the review. In addition, exercises for the upper limb (UL) including constraint-induced movement therapy, bilateral arm training, mirror therapy and biofeedback therapy were included in the review. Furthermore, the effects of functional electrical stimulation on the LL, neuromuscular stimulation of the UL, application of orthotics,

assistive devices for the UL and LL and interventions aimed at reducing hemiplegic shoulder pain and hand oedema were examined also. The review included a total of 151 studies, 123 of which were RCTs and 28 controlled clinical trials. The methodological quality of each study was rated on the PEDro scale. Summary effect sizes (SES) were calculated to determine the efficacy of each intervention using a fixed effects model. However, if significant heterogeneity between studies existed, a random effects model was applied, resulting in larger 95% CIs than a fixed effects model would generate (Kwakkel et al 2007).

Methodological quality of all the RCTs ranged from 2 to 8 points (median 5 points). Large SESs were found in support of task-oriented exercise training to improve postural symmetry from sitting to standing (SES 0.92, 95% CI 0.54-1.29) and vice versa (SES 0.92, 95% CI 0.5-1.35), symmetry of weight distribution in standing (SES 0.5, 95% CI 0.14-0.87) and time needed to rise from a chair (SES 0.74, 95% CI 0.3-1.19). Large SESs were also reported in favour of treadmill training with body weight support to improve walking endurance (SES 0.70, 95% CI 0.29-1.10), treadmill training without body weight support to improve walking ability (SES 1.09, 95% CI 0.56-1.61) and external auditory rhythms to improve gait speed (SES 0.91, 95% CI 0.40-1.42). Strong evidence was also found in favour of constraint-induced movement therapy to improve dexterity of the UL (SES 0.46, 95% CI 0.07-0.91) and neuromuscular stimulation for glenohumeral subluxation (SES 1.41, 95% CI 0.76-2.06). Insufficient evidence was found for exercise therapy aimed at improving function of the UL or biofeedback therapy to improve impairment and function of the UL and LL. Finally, no evidence was found to support the use of functional and neuromuscular electrical stimulation to improve dexterity or gait performance, orthotics and assistive devices aimed at improving impairment and function of the UL and LL and various interventions aimed at reducing hemiplegic shoulder pain and hand oedema. There were methodological issues with some of the studies included in the review including lack of adequate randomisation or intention-to-treat analyses and the use of unblinded assessors. However, the authors concluded that task-oriented exercise training, in particular when applied intensively and early after stroke onset, had a positive impact on impairment and function (Van Peppen et al 2004).

1.3.4 Robot mediated therapy

Robotic devices have been used widely to assist in exercise delivery and quantify movements in stroke rehabilitation over the past 20 years (Brewer et al 2007). Both UL and LL units are commercially available but published research mainly focuses on the UL devices (O'Dell et al 2009). Potential advantages of robot mediated therapy (RMT) include the ability to accurately quantify the number of repetitions of tasks and activities, the potential to increase the intensity and complexity of tasks, improved participant engagement and compliance through the introduction of games and enhanced motor learning using visual stimuli. A recent systematic review and meta-analysis of UL robotics was conducted by Kwakkel et al (2007) and included 10 RCTs with a total of 218 participants. Robotic interventions varied from 4 to 12 weeks and focused on recovery of proximal and distal movements of the UL. The methodological quality of the studies ranged from 4 to 8 on the PEDro scale (median 6 points). Due to the heterogeneity in studies between distal and proximal arm robotics, the authors applied a random effects model when calculating the SESs. The impact of RMT on impairment of the UL was not significant (SES 0.65, 95% CI -0.02-1.33), when measured by the UL section of the Fugl-Meyer Assessment. The Functional Independence Measure was used to measure improvements in activities of daily living (ADLs) and a non-significant SES was also reported for RMT (SES 0.13, 95% CI -0.23-0.50). However, a subsequent sensitivity analysis (excluding one study) resulted in a positive trend in favour of RMT for the improvement of impairments in the proximal UL when compared with conventional interventions.

The most frequently studied LL robot driven device is the Lokomat (O'Dell et al 2009). The Lokomat combines partial body-weight-supported treadmill training with active robotic control at the hip and knee and passive control at the ankle. A recent RCT (Husemann et al 2007) involving 30 participants with acute stroke evaluated the impact of a 4 week Lokomat training programme when compared to conventional therapy. Following the intervention, the Lokomat training group increased the single leg stance time on their weaker leg during gait ($p=0.01$) but no improvement in speed or any other gait parameters were noted. A nine week crossover comparison trial that alternated 3 weeks of additional Lokomat training with conventional therapy was examined in 16 participants with acute stroke by Mayr et al (2007). Significant improvements were noted on a variety of outcome measures including the Rivermead

Motor Assessment Scale and the Six Minute Walk Test during the Lokomat training phase. These findings suggest that the use of robotic therapy, as an adjunct to routine therapy, has a positive outcome on recovery after stroke.

While optimal training strategies for people with stroke need to be explored further, particularly in the area of robotics, the field of stroke rehabilitation has been energised by the merging of literature from animal studies, neuro-imaging investigation of post stroke recovery and a considerable number of methodologically sound, large clinical rehabilitation trials. As scientists and clinical researchers converge, exciting new technologies and rigorous clinical methodologies provide increasing support for specific interventions to optimise outcome following stroke.

1.4 Assessment and measurement of recovery

Coupled with the development of evidence based interventions are the significant advances in the compilation and publication of the outcomes of such interventions. In recent years, physiotherapists are increasingly using different models or frameworks to assist them in the systematic assessment and management of individuals with stroke. The most widely used and internationally recognised framework is the International Classification of Functioning, Disability and Health (ICF) (WHO 2001). The ICF framework was developed by the WHO in 2001 to provide a standard language and template for the description of health and health related states. In the context of stroke, the ICF enables therapists to identify impairments in body structures and function, limitations in activities of daily living and restrictions in social participation in individuals who have had a stroke. A variety of stroke-specific, valid and reliable outcome measures exist to capture limitations at the level of impairment, activity and participation, thereby allowing physiotherapists to accurately assess individuals' needs, match interventions with their specific impairments, and assist with environmental assessments and outcome evaluation. As a research tool, the ICF provides a structure for interdisciplinary stroke research and allows for a more transparent comparison of stroke outcomes internationally thus creating a larger body of evidence in support, or otherwise of various interventions.

1.5 Recovery in the context of the proposed research

The previous sections have served to highlight that physiotherapy is an established component of stroke rehabilitation. However, in spite of advances in clinical and scientific research, it has been suggested that the duration of exercise therapy that is delivered post stroke is, at best, 'homeopathic' and uncertainties still remain about the most appropriate level of therapy input (Pomeroy and Tallis 2002). In the physiotherapy setting, staff limitations and/or established practices such as 'half an hour of treatment' and 'three times a week' schedules may prevent therapists from embracing treatment ideas to increase the duration of therapy (De Weerdt and Feys 2002). Research is now focusing on 'novel' ways of increasing the duration of exercise therapy that occurs following stroke with minimal use of resources (Pomeroy and Tallis 2002). One suggestion has been that 'physiotherapists need to develop strategies whereby patients and caregivers take full responsibility for the bulk of therapy - for instance, training of balance, strength and endurance, repetition of simple tasks, group therapy, fitness-related training and family involvement'(De Weerdt and Feys 2002). This sentiment has been re-iterated by several other authors (Morimoto et al 2001, Jullamate et al 2006, Jullamate et al 2007).

To date, no RCT has evaluated the delivery of exercises to individuals with stroke by people who are not healthcare workers. However, in a RCT by Lincoln et al (1999), both qualified physiotherapists and physiotherapy assistants delivered two different forms of additional exercise therapy to people with acute stroke and no differences were noted between the two groups following the 5 week additional intervention. Therefore, the primary aim of this research is to evaluate the impact of an evidence-based, user informed and centred RCT, on recovery of the LL following stroke. The experimental group will receive routine therapy and additional LL exercises in the form of family mediated exercise (FAME) therapy. The control group will receive routine therapy with no formal input from their family members. A secondary aim of the project is to evaluate the impact of the FAME programme on the person with stroke and the individual assisting in the delivery of the exercises through qualitative and quantitative data gathering techniques. The methodology is described in more detail in Chapter 4 and has been published elsewhere (Galvin et al 2008a). The publication is contained in Appendix I.

1.6 Chapter outline

Chapter 2 of this thesis examines the literature relating to the impact of increased duration of exercise therapy on outcome following stroke. Chapter 3 outlines the methodologies employed to explore the views of the potential participants in the FAME programme including the individual with stroke, 'family members/friends' of people with stroke and physiotherapists. Chapter 3 also contains the results of these 'user surveys'. Chapter 4 describes the qualitative and quantitative methodologies used to conduct the main RCT. Chapter 5 displays the quantitative results of the RCT and Chapter 6 contains the qualitative output of the semi-structured interviews undertaken with the individuals with stroke and their nominated family members who undertook the additional FAME intervention. Finally, a discussion of the results, recommendations for future research clinical practice and conclusions are detailed in Chapter 7.

1.7 Conclusion

In contrast with coronary heart disease and cancer, the burden of stroke lies with the long term disability as opposed to death. Therefore, any rehabilitation intervention that can speed recovery and reduce long-term disability will have a major impact on the individual and social burden of the illness. While the exact mechanisms of recovery following stroke may never be fully understood, the wealth of experimentation and advances in neurophysiological research support the dynamic characteristics of the brain to reorganise after injury. This evidence has enabled researchers and clinicians to design and test interventions that influence cerebral adaptations following stroke through the prevention of further neuronal degeneration and the activation of new neuronal pathways. This chapter provided an insight into the emerging evidence supporting a variety of interventions used by physiotherapists in the rehabilitation of people with stroke. These evidence based interventions serve to lessen impairments and functional limitations and optimise recovery.

CHAPTER 2

THE IMPACT OF INCREASED DURATION OF EXERCISE THERAPY ON OUTCOME FOLLOWING STROKE

The aim of this chapter is to explore the impact of increased duration of exercise therapy on outcome following stroke at the level of impairment, activity and participation. Chapter 1 focussed on some of the conventional and novel methods used by physiotherapists to promote recovery following stroke. The rationale behind many of these interventions stems from emerging evidence in the fields of medical science, neuroscience, exercise physiology and biomechanics. In recent years, many clinical trials have explored the effects of 'additional' or 'augmented' exercise therapy, delivered by a healthcare professional, on outcome after stroke. Indeed, evidence from two systematic reviews has suggested that a more intensive exercise therapy input is associated with enhanced improvement of the performance of functional activities after stroke, although the exact dose of practice required for significant functional improvements to take place is lacking (Langhorne et al 1996, Kwakkel et al 1997). A later meta-analysis (Kwakkel et al 2004) also demonstrated that additional exercise therapy has a positive outcome on gait speed and activities of daily living (ADLs). However, this meta-analysis included studies where no formal exercise therapy was documented in the control group (Wade et al 1992, Werner and Kessler 1996, Walker et al 1999, Parker et al 2001, Green et al 2002). Therefore, the purpose of this chapter is to examine in detail, the effects of 'additional' exercise therapy when compared to 'routine' exercise therapy on recovery following stroke. The author conducted a systematic review of the literature and completed a meta-analysis on studies that reported results of a common outcome measure. The results of this chapter have been published in Topics in Stroke Rehabilitation (Galvin et al 2008b) and the publication is contained in Appendix 2.

2.1 Methods

2.1.1 Definitions

Prior to conducting a review of the literature, a number of operational definitions were described using methods based on the Cochrane Handbook for Systematic Reviews of

Interventions 4.2.6 (Higgins and Green 2006). **Participants** in the studies to be included were people who presented with stroke as defined by the WHO (Hatano 1976). **Interventions** of interest were those where 'additional', 'augmented' or 'increased duration' of exercise therapy was compared to 'normal', 'routine' or 'traditional' levels of exercise therapy. '**Exercise therapy**' was defined as motion of the body or its parts to relieve symptoms or to improve function, leading to physical fitness, but not physical education and training (PubMed 2007) and included both occupational therapy and physiotherapy for the purposes of the review. There is a general lack of consensus on what constitutes '**traditional**' or '**routine**' exercise therapy and the exact definition can only be considered in relation to each individual study, where in many cases, this definition is not provided. '**Additional', 'augmented' or 'increased duration' of exercise therapy** referred to the amount, in minutes, of exercise therapy that people with stroke received that was in excess of their 'routine' exercise intervention. If no exercise therapy was delivered to the 'control' group, then such studies were not included in the analysis. '**Frequency**' referred to the number of days of exercise per week. **Outcome measures** included in the review were those that focused on impairments in function, limitations in ADLs and restrictions in community and social participation. Types of **study design** included were randomised controlled trials.

2.1.2 Literature search

A computerised literature search was conducted in March 2008 and included the following search engines: AMED, CINAHL, Science Direct, the Cochrane Library (all), MEDLINE, DARE, PEDro, EMBASE and Pub Med. This search was repeated in April 2009 and no new studies were identified for inclusion. The databases were searched using a combination of the following keywords: 'stroke', 'cerebrovascular accident', 'physical therapy', 'physiotherapy', 'occupational therapy', 'exercise therapy' 'dose of therapy', 'additional', 'augmented', 'intensity', 'frequency', 'arm', 'leg', 'upper limb' 'lower limb', 'rehabilitation', 'effectiveness', 'impact', 'randomised controlled trial' and 'functional outcome'. The search was supplemented by obtaining additional articles cited in articles in the original list.

2.1.3 Study identification and selection

The author read the titles of the identified references and eliminated irrelevant studies. Articles that did not meet the inclusion criteria, not published in English, not relevant to the nature of the topic or articles that included participants with diagnoses other than stroke were excluded from further analysis. This review focused purely on different physiotherapy treatment approaches that delivered 'additional' or 'augmented' time in exercise therapy as opposed to the use of specific interventions for recovery. Therefore, studies that considered a massed practice approach such as the effectiveness of constraint induced movement therapy or application of special equipment to augment therapy, such as balance platforms, robotic devices or bio-feedback equipment were excluded from analysis. The remaining articles were obtained and based on the inclusion criteria; the author marked them as relevant, irrelevant or unsure. A second reviewer[1] independently ranked these trials using the same method. Any disagreements were resolved through discussion between the reviewers.

2.1.4 Methodological quality

The two reviewers (RG, ES) independently documented the methodological quality of the studies and extracted the relevant data. Studies were evaluated using criteria to eliminate selection bias, performance bias, attrition bias, and detection bias (Higgins and Green 2006). Selection bias refers to the methods used to assemble the intervention and control groups. A person who is not involved in the recruitment procedure should ideally complete the process of assessing a potential participant's eligibility for the trial. The recruiters and the participants should remain unaware of randomisation until a decision has been made regarding eligibility. Approaches to allocation concealment should be considered as adequate, unclear, inadequate or no allocation concealment as criterion to assess validity. Performance bias refers to systematic differences in the care provided to the participants in the 'control' and 'intervention' group(s) in the study apart from the intervention under investigation. Contamination (provision of the intervention to the control group) and co-intervention (provision of additional care to either group) can affect study results. This section was previously rated as met, unmet or unclear, however this method is currently under review. If no 'control' group is used

[1] Dr. Emma Stokes, Senior Lecturer, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin.

or if baseline measurements are not recorded, a study is considered not to have met this criterion. Attrition bias refers to systematic differences between the groups involved in the study due to the loss of participants from the study. This section is rated as met, unmet or unclear. Detection bias refers to systematic differences between the comparison groups in terms of outcome assessment. Blinding the outcome assessor to the intervention allocation can reduce the likelihood of detection bias occurring in a particular study. This section is rated as met, unmet or unclear. A difference in baseline characteristics of the comparison groups in relation to time post stroke or levels of motor impairment are confounding factors to intervention, therefore studies are deemed not to have met this criterion if they do not compare the groups or if the outcome assessor is not blinded. If all of the criteria outlined above are met, the study is considered to have a low risk of bias. If one or more criteria are partly met, the study is deemed to have a moderate risk of bias and if one or more of the criteria are not met, then the study is considered to have a high risk of bias.

In addition, the Physiotherapy Evidence Database (PEDro) was also used to document the quality of the studies (Sherrington et al 2000). Each clinical trial on the PEDro database is rated on the basis of its methodological quality, including its internal and external validity, allowing access to the best available evidence of the effects of physiotherapy interventions. A copy of the PEDro rating scale is contained in Appendix 3. Any disagreements in the quality of the studies were resolved through discussion between the reviewers. Table 2.1 illustrates the results of the methodological quality of the studies included in the review.

Table 2.1: A review of the methodological quality of randomised controlled trials (RCTs) included in the systematic review

RCT	SELECTION BIAS	PERFORMANCE BIAS	ATTRITION BIAS	DETECTION BIAS	RISK OF BIAS	PEDRO SCORE
Sivenius et al 1985	Adequate	Unmet	Unmet	Met	High	5/10
Sunderland et al 1992	Adequate	Met	Unmet	Met	High	6/10
Richards et al 1993	Adequate	Met	Unmet	Met	High	6/10
Logan et al 1997	Adequate	Met	Met	Met	Low	7/10
Feys et al 1998	Unclear	Unmet	Met	Met	High	6/10
Kwakkel et al 1999	Adequate	Met	Met	Met	Low	7/10
Lincoln et al 1999	Adequate	Met	Met	Met	Low	6/10
Gilbertson et al 2000	Adequate	Met	Met	Met	Low	8/10
Partridge et al 2000	Adequate	Met	Unmet	Met	High	7/10
Anderson et al 2002	Adequate	Met	Met	Met	Low	8/10
Di Lauro et al 2003	Unclear	Met	Unmet	Met	High	6/10
Fang et al 2003	Adequate	Met	Unmet	Met	High	6/10
Martinsson et al 2003	Adequate	Unmet	Met	Met	High	7/10
Rodgers et al 2003	Adequate	Unmet	Unmet	Met	High	8/10
Blennerhassett and Dite 2004	Adequate	Met	Met	Met	Low	8/10
GAPS Group 2004	Adequate	Met	Met	Unmet	High	7/10
Winstein et al 2004	Adequate	Met	Met	Unmet	High	6/10
Platz et al 2005	Adequate	Met	Met	Met	Low	8/10
Yang et al 2005	Adequate	Met	Met	Unmet	High	6/10
Askim et al 2006	Adequate	Unmet	Met	Met	High	7/10

2.1.5 Data extraction

Data extraction was undertaken separately for each intervention. The following data was documented for each study: authors, size of intervention and control groups, study design, duration (in minutes) and frequency of intervention, results of the study and the battery of outcome measures used. For the purposes of the meta-analyses, scores (mean and standard deviation) on the relevant outcome measures were recorded at baseline, first assessment post-intervention, and again at a six month follow-up assessment point. Authors were contacted for clarification, or to provide missing data where necessary.

2.1.6 Quantitative analysis

The extracted data was inputted into Microsoft Office Excel 2003. In studies where the mean values were not available, the median was recorded instead. When the standard deviations were not available for the particular outcome measure, the interquartile ranges were recorded and if these were not available, the ranges were recorded when available. The median was used as a proxy for the mean. A multiple of 0.75 times the interquartile range or 0.25 times the range were used as proxies for the standard deviation values (Pudar-Hozo et al 2005). The meta-analyses were computed using the 'metacont' function in the meta-package version 0.8-2 (Schwarzer 2007) for the statistical package, R. The meta-analysis method outlined in Cooper and Hedges (1994) was implemented to complete each analysis. Standard mean difference (SMD) was used as the mode of analysis for each individual study. A summary effect size (SES) was then calculated to determine the effect of additional exercise therapy on each outcome measure. The impact of sample size was addressed by estimating a weighting factor for each study, and assigning larger effect-weights in studies with bigger samples. The fixed effect and random effect models were applied. If significant between study variation (statistical heterogeneity) existed, a random effects model was completed (DerSimonian and Laird 1986). Based on the classification of Cohen (1998), summary effect sizes below 0.2 were classified as small, from 0.2 to 0.5 as medium and above 0.5 as large.

2.2 Results

The search strategy resulted in a list of 4773 citations. Following the exclusion of irrelevant articles, forty-eight studies were deemed potentially relevant. Application of the inclusion criteria resulted in twenty-nine remaining articles. Two studies had a PEDro score less than 5 points and were also excluded from final analysis based on their methodological quality (Stern et al 1970, Smith et al 1981). A further study which included participants with traumatic brain injury was also excluded from the analysis (Slade et al 2002). Five studies compared routine treatment to no treatment and were thus excluded (Wade et al 1992, Werner and Kessler 1996, Walker et al 1999, Parker et al 2001, Green et al 2002). Two articles reported data on the same cohort of patients (Lincoln et al 1999, Parry et al 1999) - only one study was included in the meta- analysis (Lincoln et al 1999). Therefore twenty articles were included in the final analysis. Three of these studies followed up participants for one year or more (Sunderland et al 1994, Kwakkel et al 2002, Feys et al 2004).

2.2.1 Effects of increased duration of arm exercise therapy on arm function

Eight RCTs were analysed to ascertain if increased exercise therapy had an impact on outcome of the affected arm following acute stroke (Sunderland et al 1992, Feys et al 1998, Kwakkel et al 1999, Lincoln et al 1999, Rodgers et al 2003, Blennerhassett and Dite 2004, Winstein et al 2004, Platz et al 2005). Two of these studies published one year follow-up studies (Sunderland et al 1994, Kwakkel et al 2002) and one study published a 5 year follow-up study (Feys et al 2004). Additional exercise therapy time (in minutes) prescribed to experimental groups ranged from 24 minutes (Rodgers et al 2003) to 60 minutes (Blennerhassett and Dite 2004, Winstein et al 2004). Six studies prescribed this additional therapy at a frequency of five times per week for a period of 4 to 6 weeks (Feys et al 1998, Lincoln et al 1999, Rodgers et al 2003, Blennerhassett and Dite 2004, Winstein et al 2004, Platz et al 2005). One study applied the additional therapy for a period of 20 weeks (Kwakkel et al 1999). An earlier study by Sunderland et al (1992) documented that participants in the experimental group received a median of 180 minutes additional arm exercise therapy per week for a median period of 18 weeks in comparison to a 10 week 'control' intervention. Methodological quality ranged from 5 to 8 points on the PEDro scale. Numbers of participants, characteristics of the interventions, measures of outcome and reported results are shown in Table 2.2.

Table 2.2: Impact of increased duration (in minutes) of arm exercise therapy on arm outcome following stroke

AUTHORS	INTERVENTION GROUP (IG)	CONTROL GROUP (CG)	STUDY DESIGN	INTERVENTION	RESULTS	OUTCOME MEASURES
Sunderland et al 1992	RT + conventional arm therapy (n=65)	RT (n=67)	Single centre RCT Median 8-10 days post CVA	Double therapy/18 weeks	Significant improvement in impairment at 6 months	Extended MI MCA FAT NHPT
Feys et al 1998	RT + sensorimotor stimulation (n=50)	RT(n=50)	Multi-centre RCT Mean 21-24 days post CVA	150 minutes per week/6weeks	Significant improvement in impairment at 6 and 12 months	FMA ARAT BI
Kwakkel et al 1999	RT + functional exercises (n=33)	RT + immobilisation of arm and leg (n=37)	Single centre RCT Mean 7-7.5 days post CVA	150 minutes per week/20 weeks	Significant difference in ARAT	ARAT BI
Lincoln et al 1999	IG 1 : RT + qualified PT (n=94) IG 2 : RT + assistant PT (n=93)	RT (n=95)	Single centre RCT Median 12 days post CVA	120 minutes per week/5 weeks	No significant changes in groups overall post-intervention or at 3 or 6 months	RMA ARAT BI THPT MCA
Rodgers et al 2003	RT + conventional arm therapy (n= 62)	RT (n= 61)	Single centre RCT Median 5 days post CVA	150 minutes per week /up to 6 weeks	No significant differences between the two groups at 3 and 6 months	ARAT MI FAT BI N-EADL

Table 2.2: Impact of increased duration (in minutes) of arm exercise therapy on arm outcome following stroke (continued)

AUTHORS	INTERVENTION GROUP (IG)	CONTROL GROUP (CG)	STUDY DESIGN	INTERVENTION	RESULTS	OUTCOME MEASURES
Blennerhassett and Dite 2004	RT + task related therapy (n=15)	RT + lower limb therapy (n=15)	Single centre RCT Mean 36-50.1 days post CVA	300 minutes per week/4 weeks	Significant changes in JTHFT and MAS at 4 weeks	JTHFT MAS
Winstein et al 2004	IG 1 : RT + functional task practice (n=22) IG 2 : RT + strength training (n=21)	RT (n=21)	Single centre RCT Mean 15-17 days post CVA	300 minutes per week/4-6 weeks	IG 1 and IG 2 improved significantly on FMA score and isometric torque post intervention	FMA Dynamometer FTHUE
Platz et al 2005	IG 1 : RT + conventional arm therapy (n=21) IG 2 : RT + arm impairment training (n=21)	RT (n=20)	Multi-centre RCT Mean 4.6-6.5 weeks post CVA	225 minutes per week/4 weeks	IG 2 improved significantly on FMA - UL score when compared to IG 1 and CG	UL-FMA ARAT Ashworth Scale

ARAT - Action Research Arm Test, **BI** - Barthel Index, **CVA** - Cerebrovascular Accident, **FAT** - Frenchay Arm Test, **FMA** - Fugl-Meyer Assessment, **UL-FMA** - upper limb section of Fugl-Meyer Assessment, **FTHUE** - Functional Test of Hemiplegic Upper Extremity, **JTHFT** - Jebsen Taylor Hand Function Test, **MAS** - Motor Assessment Scale, **MCA** - Motor Club Assessment, **MI** - Motricity Index, **N-EADL** - Nottingham Extended Activities of Daily Living Index, **NHPT/THPT** - Nine/Ten Hole Peg Test, **PT** - physiotherapy/physiotherapist, **RCT** - Randomised Controlled Trial, **RMA** - Rivermead Motor Assessment, **RT** - Routine therapy

2.2.2 Effects of increased duration of lower limb exercise therapy on lower limb function

Four RCTs that consider the effects of increased duration of exercise therapy on outcome of the affected leg are included in this analysis (Richards et al 1993, Kwakkel et al 1999, Blennerhassett and Dite 2004, Yang et al 2005). One study published a one-year follow-up of participants (Kwakkel et al 2002). Numbers of participants, characteristics of the interventions, measures of outcome and reported results are displayed in Table 2.3. Additional exercise therapy sessions ranged from 30 minutes (Kwakkel et al 1999, Yang et al 2005) to 120 minutes per day (Richards et al 1993) and were applied at a frequency of 3 to 5 times per week for a period of 3 to 20 weeks. Methodological quality ranged from 6 to 8 points on the PEDro scale.

2.2.3 Effects of increased duration of general additional exercise therapy on functional outcome

Six studies adopted a more general approach to the delivery of additional exercise therapy and merely increased the duration of conventional exercise therapy time provided to participants (Sivenius et al 1985, Partridge et al 2000, Di Lauro et al 2003, Fang et al 2003, Martinsson et al 2003, GAPS Group 2004). Participants received between 10 minutes (Sivenius et al 1985) and 75 minutes (Di Lauro et al 2003) of additional exercise therapy every weekday over a period of 1 to 24 weeks. Methodological quality ranged from 5 to 7 points on the PEDro scale. Numbers of participants, characteristics of the interventions, measures of outcome and reported results are shown in Table 2.4.

Table 2.3: Impact of increased duration (in minutes) of lower limb exercise therapy on lower limb outcome following stroke

AUTHORS	INTERVENTION GROUP (IG)	CONTROL GROUP (CG)	STUDY DESIGN	INTERVENTION	RESULTS	OUTCOME MEASURES
Richards et al 1993	IG 1 : RT + conventional therapy (n=8) IG 2 : RT + focused LL therapy (n=10)	RT (n=9)	Single centre RCT Mean 8.3-13 days post CVA	600 minutes per week/5weeks	Gait speed significantly higher in IG 2 at 6 weeks. No difference at 3 and 6 months.	BI Gait speed BBS FMA
Kwakkel et al 1999	RT + functional exercises + gait training (n=31)	RT + immobilisation of arm and leg (n=37)	Single centre RCT Mean 7-7.5 days post CVA	150 minutes per week/20 weeks	Significant improvement in ADL and walking ability	BI FAC
Blennerhassett and Dite 2004	RT + task related LL therapy (n=15)	RT + upper limb therapy (n=15)	Single centre RCT Mean 36-50.1 days post CVA	300 minutes per week/4 weeks	Significant improvement in TUG and SMWT	MAS TUG SMWT
Yang et al 2005	RT + gait training (n=13)	RT (n=12)	Single centre RCT Mean 5.45-7.33 months post CVA	90 minutes per week/3 weeks	Significant improvement in IG	Stride Analyser

BBS - Berg Balance Scale, **BI** - Barthel Index, **CVA** - Cerebrovascular Accident, **FAC** - Functional Ambulation Categories, **FMA** - Fugl-Meyer Assessment, **LL** - Lower limb, **MAS** - Motor Assessment Scale, **RCT** - Randomised Controlled Trial, **RT** - Routine Therapy, **SMWT** - Six Minute Walk Test, **TUG** - Timed Up and Go Test

Table 2.4: Impact of increased duration (in minutes) of general exercise therapy on outcome following stroke

AUTHORS	INTERVENTION GROUP (IG)	CONTROL GROUP (CG)	STUDY DESIGN	INTERVENTION	RESULTS	OUTCOME MEASURES
Sivenius et al 1985	RT + additional general therapy (n=50)	RT (n=45)	Single centre RCT < 1 week post CVA	54 minutes per week/12 weeks	No significant differences at 3, 6 or 12 month follow-up	ADL, strength and range of movement (4-point scale)
Partridge et al 2000	Double conventional PT (n=54)	RT (n=60)	Single centre RCT Participants post acute CVA	150 minutes per week/6 weeks	No significant differences at 6 or 26 weeks	Profiles of Recovery Scale Functional Reach 10MWT
Martinsson et al 2003	Intensive treatment (n=15)	RT (n=15)	Single centre RCT Median 2 days post CVA	65 minutes per day/5 days	No statistically significant differences in groups at 5 days or 3 or 6 months	LMAC NIH Stroke Scale Activity Index
Di Lauro et al 2003	Intensive therapy (n=29)	RT (n=31)	Single centre RCT < 24 hours post CVA	525 minutes per week/2 weeks	No significant differences in groups at 2 or 26 weeks	Modified NIH Stroke Scale BI
Fang et al 2003	RT + additional early physiotherapy (n=78)	RT (n=78)	Single centre RCT < one week post CVA	225 minutes per week/4 weeks	Significant difference in BI at 4 weeks. No difference at 6 months.	FMA Modified BI Clinical Neurological Deficit Scale
GAPS Group 2004	Double conventional therapy (n=35)	RT (n=35)	Multi-centre RCT Mean 22-25 days post CVA	125 minutes per week/-10 weeks	No significant differences in groups at 4, 12, 26 weeks	RMI Walking speed BI MI N-EADL

ADL - Activities of Daily Living, **BI** - Barthel Index, **CVA** - Cerebrovascular Accident, **FMA** - Fugl-Meyer Assessment, **LMAC** - Lindmark Motor Assessment Chart, **MI** - Motricity Index, **Modified NIH Stroke Scale** - Modified National Institute of Health Stroke Scale, **N-EADL** - Nottingham Extended Activities of Daily Living Index, **RCT** - Randomised Controlled Trial, **RMI** - Rivermead Mobility Index, **RT** - Routine Therapy, **10MWT** - Ten Metre Walk Test

2.2.4 Effects of increased duration of community-based exercise therapy on functional outcome

Four RCTs examined the effects of augmented community-based exercise therapy on functional outcome in people with stroke living in the community (Logan et al 1997, Gilbertson et al 2000, Anderson et al 2002, Askim et al 2006). Participants received between 167 minutes (Logan et al 1997) and 450 minutes (Gilbertson et al 2000) of additional exercise therapy over a period of 4 to 12 weeks. Methodological quality ranged from 7 to 8 points on the PEDro scale. Numbers of participants, characteristics of the interventions, measures of outcome and reported results are displayed in Table 2.5.

Table 2.5: Impact of increased duration (in minutes) of community exercise therapy

AUTHORS	INTERVENTION GROUP (IG)	CONTROL GROUP (CG)	STUDY DESIGN	INTERVENTION	RESULTS	OUTCOME MEASURES
Logan et al 1997	Enhanced service (n=53)	RT (n=58)	Multi-centre RTC Post discharge from hospital following CVA	167 minutes in total/6 weeks	Significant difference in N-EADL score at 3 months. Evident only in mobility section only at 6 months.	N-EADL BI General Health Questionnaire
Gilbertson et al 2000	Intensive service (n=67)	RT (n=71)	Single centre RCT Post discharge from hospital following CVA	300-450 minutes in total/6 weeks	Significant difference in N-EADL score at 8-weeks. No difference at 6 months.	N-EADL BI
Anderson et al 2002	Additional follow-up with PT (n=53)	CG 1 : Routine community care (n=48) CG 2 : Follow-up with physician (n=54)	Multi-centre RCT Post discharge from hospital following CVA	174 minutes in total/6-12 weeks	No significant differences in groups at 6 months	Functional Quality of Movement BI FAI ADL Index
Askim et al 2006	Intensive task specific therapy (n=31)	RT (n=31)	Multi-centre RTC Post discharge from hospital following CVA	Intensive therapy/4 weeks	No significant differences in groups at 1, 6, 26 and 52 weeks	BBS Gait speed Scandinavian Stroke Scale

ADL Index - Activities of Daily Living Index, **BI** - Barthel Index, **BBS** - Berg Balance Scale, **CVA** - Cerebrovascular Accident, **FAI** - Frenchay Activities Index, **N-EADL** - Nottingham Extended Activities of Daily Living Index, **PT** - Physiotherapist, **RCT** - Randomised Controlled Trial, **RT**- Routine Therapy

2.3 Meta-analysis

2.3.1 Upper limb outcome measures

Five studies (Feys et al 1998, Kwakkel et al 1999, Lincoln et al 1999, Rodgers et al 2003, Platz et al 2005) including a total of 669 participants (n=669) measured the effects of additional exercise therapy on the arm using the Action Research Arm Test (ARAT). No significant SES was demonstrated post treatment (SES -0.06; CI -0.21 – 0.09; Z=-0.80; p=0.43), or at 6 months (SES -0.07; CI -0.35 – 0.21; Z=-0.51; p=0.6561). Pooling post treatment effect sizes for the two studies (Rodgers et al 2003, GAPS Group 2004) (n=193) that used the Motricity Index (MI) yielded a non significant SES (SES 0.01; CI -0.27 – 0.29; Z=0.08; p=0.94). Furthermore the two studies (Winstein et al 2004, Platz et al 2005) (n=126) that used the upper limb section of the Fugl-Meyer Assessment (UL-FMA) also demonstrated a non significant SES post intervention (SES -0.2; CI -0.51 – 0.11; Z=-1.25; p=0.21). A summary of the findings is contained in Table 2.6.

2.3.2 Lower limb outcome measures

A meta-analysis was possible for the lower limb section of the Fugl-Meyer Assessment (LL-FMA) and gait speed. Pooling the five studies (Richards et al 1993, Kwakkel et al 1999, Partridge et al 2000, Yang et al 2005, Askim et al 2006) (n=296) that used gait speed as a common outcome measure showed no significant post intervention (SES 0.13; CI -0.1 – 0.36; Z=1.12; p=0.26) or 6 month effect (SES 0.24; CI -0.02 – 0.51; Z=1.81; p=0.07) supporting the use of additional exercise therapy. In addition, there was no evidence that additional exercise therapy demonstrated a favorable post intervention effect in the two studies (Richards et al 1993, Fang et al 2003) (n=183) that measured outcome using the LL-FMA (SES 0.23; CI -0.06 – 0.51; Z=1.56; p=0.12). Table 2.6 contains a summary of the results of the meta-analyses.

2.3.3 Measures of activities of daily living

A meta-analysis was possible for the Nottingham Extended Activities of Daily Living Index (N-EADL) and the Barthel Index (BI). Ten studies (Sunderland et al 1992, Feys et al 1998, Kwakkel et al 1999, Lincoln et al 1999, Anderson et al 2002, Rodgers et al 2003, Di Lauro et al 2003, Fang et al 2003, GAPS Group 2004, Askim et al 2006) (n=1349)

used the BI to measure recovery of activities of daily living following additional exercise therapy. Significant post treatment (SES 0.13; CI 0.01 - 0.25; Z=2.15; p=0.03) and 6 month outcomes (SES 0.15; CI 0.05 - 0.26; Z=2.8; p=0.00) favored the use of additional exercise therapy. Four studies (Lincoln et al 1999, Gilbertson et al 2000, Rodgers et al 2003, GAPS Group 2004) (n=613) used the N-EADL to measure performance following additional exercise therapy input. No significant six month outcome was demonstrated following augmented therapy (SES 0.13; CI -0.02 - 0.28; Z=1.72; p=0.85). These figures are also displayed in Table 2.6.

Table 2.6: Summary of findings of the meta-analysis

OUTCOME MEASURE	SUMMARY EFFECT SIZE (95% CI)	
	Baseline/post-intervention	Baseline/Six months
ARAT	-0.06 (-0.21 - 0.09)	-0.07 (-0.35 - 0.21)
Barthel Index	0.13 (0.01 - 0.25)*	0.15 (0.05 - 0.26)*
LL-FMA	0.23 (-0.06 - 0.51)	Not reported
UL-FMA	-0.2 (-0.51 - 0.11)	Not reported
Motricity Index	0.01 (-0.27 - 0.29)	Not reported
N-EADL	Not reported	0.13 (-0.02 - 0.20)
Gait Speed	0.13 (-0.1 - 0.36)	0.24 (-0.02 - 0.51)

* significant (p<0.05), ARAT - Action Research Arm Test, LL/UL FMA - lower/upper limb section of the Fugl-Meyer Assessment, N-EADL - Nottingham Extended Activities of Daily Living Index

2.4 Key findings from systematic review and meta-analysis

From the present meta-analysis it can be concluded that additional exercise therapy has a small but positive effect on ADLs as measured by the Barthel Index post intervention and that these improvements are maintained over a six month period. These findings are similar to those of a previous meta-analysis (Kwakkel et al 2004) that also reported that increased time spent in exercise training in the first six months after stroke resulted in small improvements in ADLs.

However, pooling reported differences in the various upper and lower limb outcome measures showed no significant SESs. In contrast, Kwakkel et al (2004) demonstrated a significant effect on gait speed but the analysis included studies that provided no formal exercise therapy to the control group (Wade et al 1992, Werner and Kessler 1996, Walker et al 1999, Parker et al 2001, Green et al 2002). The focus of this meta-

analysis was to compare studies that provided 'routine' therapy to the control group versus studies that provided 'routine' therapy as well as 'additional' exercise therapy to the intervention group. Although the LL meta-analyses lack significant findings, the results do not negate the hypothesis that more exercise therapy is indeed better. The post treatment and six month outcomes are nearing significance and the lack of significant findings may be as a result of the limited number of studies included in the analysis. The individual effect sizes of the studies included in the analysis also indicate that studies with a focused LL intervention demonstrate larger SMDs between the intervention and the control group than studies than studies that compare general augmented intervention to a control group. However, the number of minutes of additional exercise therapy that is required to demonstrate a significant effect is not clear from these studies. Additional exercise therapy delivered ranged from 270 minutes to 3000 minutes and requires further research. These results also highlight the need for more RCTs with large sample sizes to evaluate the impact of focused additional therapy on LL outcome following stroke.

In contrast, the benefits of additional exercise therapy on arm function are not evident from this meta-analysis. There are a number of possible reasons for the lack in significant findings. Two studies (Feys et al 1998, Platz et al 2005) with a combined total of 162 participants provided an additional 900 minutes of impairment orientated arm training and demonstrated significant post-treatment effects at the level of impairment as measured by the UL-FMA. Compliance was excellent and the quality of the studies ranged from 6 to 8 points on the PEDro scale respectively. Similarly, three studies (Kwakkel et al 1999, Blennerhassett and Dite 2004, Winstein et al 2004) delivered in excess of 1,200 minutes of focused additional intervention at the level of arm disability and also noted significant differences between the groups at the level of impairment and disability. In contrast to the more focused intervention, three studies (Lincoln et al 1999, Rodgers et al 2003, Platz et al 2005) that delivered an additional 600-900 minutes of 'traditional' or 'conventional' arm exercise therapy failed to demonstrate a significant effect following treatment. With the exception of one study (Feys et al 2004) with a focused UL exercise therapy intervention, none of the participants that had received the additional exercise therapy demonstrated long-term follow-up benefits.

The particular subgroup of patients that appear to benefit more from the additional exercise therapy is also of interest in these studies. Feys et al (1998) reported that participants who demonstrated more severe motor deficits initially had a more marked improvement following additional therapy. This finding is contrary to findings of a post hoc analysis (Parry et al 1999) of participants in the study by Lincoln et al (1999) and two other studies (Sunderland et al 1992, Winstein et al 2004) that report a more favourable improvement in impairment and function in the intervention group who presented with a milder initial impairment.

While none of the studies included in this review examined the psychosocial adaptation to the residual disability following stroke, there is evidence to suggest that positive coping strategies adopted by individuals following stroke contribute to success in rehabilitation (Meng et al 2006). Rehabilitation following stroke encompasses more than physical recovery alone as people often experience other psychological sequelae such as depression, anxiety and emotional difficulties, which can compromise the rehabilitation process and impact on the long term adjustment to stroke (Donnellan et al 2006). In a systematic review that examined the various methods and measures employed to quantify coping strategies after stroke (Donnellan et al 2006), the authors concluded that coping strategies adopted by individuals in the acute phase after stroke are unlikely to change in the longer term. Furthermore, the evidence to date indicates that higher levels of psychological distress and depression are experienced in those using less active, problem-oriented coping strategies and more avoidance strategies. Lack of family support has been cited in the literature as a contributory factor to depression after stroke in both individuals with stroke and their caregivers (King et al 2002, Epstein-Lubow et al 2009). Therefore, methods to improve coping strategies in individuals with stroke and their families, such as involvement of families in the rehabilitation process, goal setting and decision making from the outset, may serve to improve patient recovery.

Evidence from these studies suggests that further research work is required to establish what particular type of patient gains optimum benefit from additional exercise therapy post stroke. This review would also suggest that perhaps a more focused approach should be adopted when administering exercise therapy and that additional therapy needs to be delivered on a long term basis to demonstrate significant long term benefits.

It also emerges from these studies that at least 900-1200 minutes of additional therapy delivered over a 4 to 6 week period following acute stroke is required to have a significant impact on level of impairment and/or function.

2.5 Implications for future research

Following the narrative review of the studies described above, the evidence is supportive of the hypothesis that 'additional', 'augmented' or 'increased duration' of exercise therapy results in better functional outcome as measured by the BI. The lack of evidence in the various upper and lower limb outcome measures may be as a result of a number of factors. The small number of studies included in the meta-analyses suggests that there is a need for further RCTs to examine the impact of additional exercise therapy, particularly on outcome of the LL. In addition, the systematic review raises a number of issues that may point the way for future research studies. Firstly, in the inpatient studies where no effect of additional exercise therapy is demonstrated, compliance within the experimental group has not been optimal (Lincoln et al 1999, Fang et al 2003). For this reason, a review of interventions that would be acceptable to people with stroke should be performed prior to the design of such an intervention. Secondly, there is contradictory evidence in the studies reviewed as to which sub-groups of people with stroke may benefit most from augmented intervention. The majority of the studies favor the suggestion that people with a milder initial impairment following stroke tend to benefit more from additional exercise therapy (Sunderland et al 1994, Parry et al 1999, Partridge et al 2000, Winstein et al 2004, Askim et al 2006). Hence, careful consideration should be given to the level of impairment of a person following stroke prior to the implementation of an additional exercise therapy programme. Thirdly, the nature of intervention that is delivered is of interest. Evidence from this review suggests that increasing the time spent on 'traditional' or 'conventional' therapy approaches is not beneficial (Richards et al 1993, Lincoln et al 1999, Partridge et al 2000, Anderson et al 2002, Di Lauro et al 2003, Martinsson et al 2003, Rodgers et al 2003, GAPS Group 2004, Platz et al 2005, Askim et al 2006) and that more focused exercise therapy interventions either at the level of impairment or function are more effective (Richards et al 1993, Feys et al 1998, Kwakkel et al 1999, Rodgers et al 2003, Blennerhassett and Dite 2004, Platz et al 2005, Yang et al 2005). There is a paucity of evidence examining the clinical and cost effectiveness of

novel technology as a method of delivering of additional exercises following stroke and further work building on the results of neuroscientific research should inform the design of such exercise interventions. Fourthly, in the majority of studies included in this review, therapists delivered the additional intervention. To date no RCT has evaluated the delivery of exercise to individuals with stroke by people who are not health care workers. However, in the RCT by Lincoln et al (1999) both qualified physiotherapists and physiotherapy assistants delivered two different forms of additional exercise therapy and no differences were noted between the groups. These findings would give credence to the suggestion in the Lancet by De Weerdt and Feys (2002) that, 'physiotherapists need to develop strategies whereby patients and caregivers take full responsibility for the bulk of therapy - for instance, training of balance, strength and endurance, repetition of simple tasks, group therapy, fitness-related training and family involvement'. Furthermore, the intensity of additional intervention is also a key factor that requires careful consideration - the inpatient groups that demonstrated successful augmented intervention delivered at least an additional 900 to 1200 minutes of exercise during a period of 4 to 6 weeks, although this varied between studies. Insufficient duration of the augmented intervention may have predisposed some studies to the inability to show statistically significant changes in outcome (Lincoln et al 1999, Anderson et al 2002). Finally, while the meta-analysis indicates that improvements in ADL are still evident at six months, two studies that published one year follow-up assessments (Sunderland et al 1992, Kwakkel et al 2002) reported no significant findings at this time-point. These findings suggest that the benefits of additional exercise therapy are not maintained if the additional therapy is not sustained.

2.6 European comparison of stroke rehabilitation

In Europe, great differences exist in stroke management and outcome (Putman and De Wit 2009). Comparing levels of therapy and outcomes across European countries may assist in the development of new intervention strategies to improve rehabilitation services and optimise outcome following stroke. The CERISE project (Collaborative Evaluation in Rehabilitation of Stroke across Europe) is a longitudinal pan European project that examined various clinical and organisational aspects of stroke rehabilitation in four European rehabilitation centres located in the United Kingdom,

Belgium, Switzerland and Germany. The amount of therapy (including physiotherapy and occupational therapy) that was delivered in the four centres was examined as part of the CERISE project. In each centre, 60 randomly selected individuals with stroke were observed at 10 minute intervals using behavioural mapping. Observations took place on 30 weekdays selected at random, on equal numbers of morning, afternoon and evening sessions. In terms of amount of therapy that was delivered to individuals with stroke in the inpatient setting, those individuals in the German, Belgian and Swiss centres received significantly more therapy than those in the British centre. In the UK, individuals with stroke spent, on average, 1 hour per day in therapy, whereas those in the Belgian centre received approximately 2 hours of therapy per day, those in the German centre received 2 hours and 30 minutes of therapy per day and those in the Swiss centre spent on average 2 hours and 45 minutes in therapy. Furthermore, gross motor and functional recovery as measured by the Rivermead Motor Assessment of Gross Function and the Barthel Index, were better at six months in the German and Swiss centres than in the British centre (De Wit et al 2007). In all centres, individuals with stroke spent almost 75% of their time between 7am and 5pm in non therapeutic activities such as sitting, lying, eating and sleeping (De Wit et al 2005).

The AVERT (A Very Early Rehabilitation Trial) trial is a randomised controlled trial that evaluates the impact of very early mobilisation (less than 24 hours) on outcome following stroke in centres in Australia, Canada, New Zealand and Europe. Recruitment for this RCT is ongoing and is due to be completed in 2014. As part of a series of studies to inform the development of the RCT, an observational study of patient activity was within the first fourteen days after stroke was conducted in Melbourne, Australia. Fifty eight individuals were observed at 10 minute intervals between 8am and 5pm each weekday over a two week period. Results indicated that not all individuals received therapy every day. Of those who received therapy, these individuals received on average 24 minutes of physiotherapy and 23 minutes of occupational therapy per day (Bernhardt et al 2007). A second element of the study compared physical activity patterns in the first fourteen days following stroke in individuals in centres in Melbourne Australia and Trondheim, Norway (Bernhardt et al 2008). Individuals in Norway spent approximately 23.2% of the day in activities involving standing and walking whereas those in Australia only spent 12.2%

performing such activities. The average number of minutes spent in therapy with a physiotherapist or an occupational therapist was comparable in both centres (approximately 21-27 minutes per session).

Stroke rehabilitation services are embedded in individual healthcare systems, creating contextual constraints that vary between countries, resulting in differences in the organisation of stroke rehabilitation. These large international trials have considered the various contextual elements such as limitations in staffing and facilities on individuals units and availability of services in the different centres. Such trials serve to increase our understanding of the components of inpatient rehabilitation and the optimal models for the delivery of stroke care.

2.7 Conclusion

The findings of this systematic review and meta-analysis and the potential impact of these findings on clinical practice and future research have been discussed. It is clear that there is a requirement for therapists to devise methods of delivering additional exercise therapy to people following stroke that are appropriate and suitable for each individual. It is also important that this programme can be delivered on a long term basis to optimise results. One such approach, which builds on the suggestion by De Weerdt and Feys (2002), is to allow people with stroke to take responsibility for delivery of their exercises through the active involvement of their family members in their rehabilitation programme from the outset. The involvement of family members in rehabilitation is not a new phenomenon. It is common practice in paedatrics and in the care of older people with dementia (Visser-Meily et al 2006). The concept of family mediated exercise (FAME) therapy and its potential efficacy in a stroke population is discussed in more detail in Chapter 3.

CHAPER 3

METHODOLOGY AND RESULTS OF USER SURVEYS

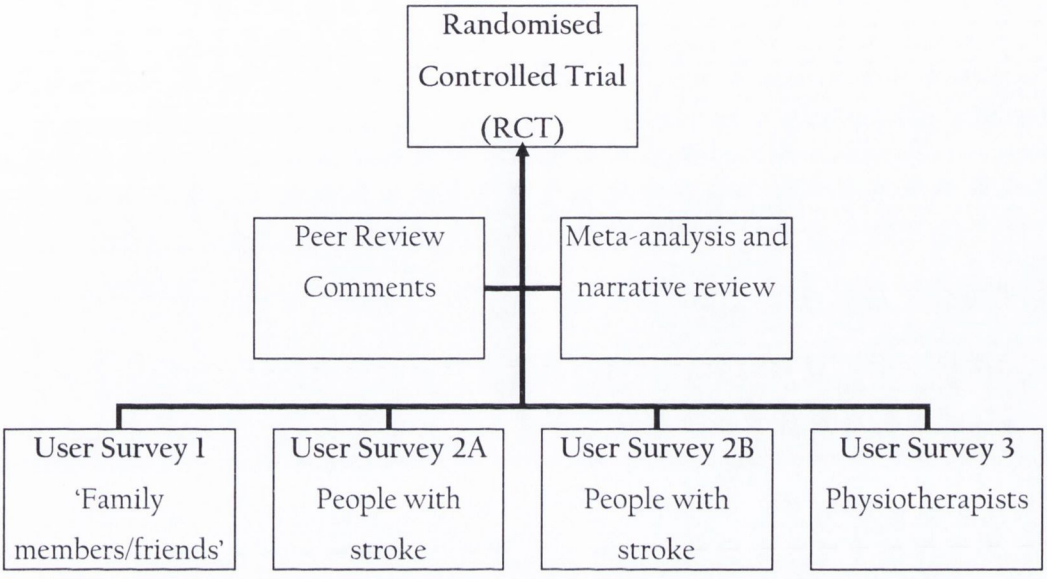
The aim of this chapter is to outline the methodology employed to ascertain the views of people with stroke, 'family members/friends' of people with stroke and physiotherapists on the involvement of family in physiotherapy and the delivery of exercises to people with stroke. In addition, the chapter discusses the results of these user surveys and the implications that the findings have on the development of the RCT. Chapter 2 focused on the impact of additional exercise therapy on recovery following stroke. The meta-analysis highlighted that additional focussed exercise therapy has a small but positive impact on activities of daily living (ADLs) as measured by the Barthel Index (BI). Furthermore, while the lower limb (LL) meta-analyses lacked significant findings, the post intervention and six month outcomes follow-up neared significance and the limited number of studies included in the analysis may have contributed to the non-significant findings. The narrative review of the literature reported that no RCT to date has examined the delivery of additional exercise therapy to individuals with stroke by a person who is not a healthcare worker. Therefore the aim of this chapter is to explore the views of people with stroke, 'family members/friends' and physiotherapists on the concept of family mediated exercise (FAME) therapy as an adjunct to routine physiotherapy following stroke. The results of these user surveys have been published (Galvin et al 2009a,b) and are contained in Appendices 4 and 5 respectively.

3.1 Methodology

The user surveys of the potential participants in the FAME project were conducted using quantitative and qualitative data gathering methods. The combined use of qualitative and quantitative techniques is increasingly used in clinical research to expand the scope of the research question and to improve the analytical power of studies (Sandelowski 2000, Borkan 2004, Anaf and Sheppard 2007). A mixed-method approach was utilised to deepen the authors insight into the involvement of 'family members/friends' in physiotherapy following stroke from the perspectives of people with stroke, 'family members/friends' of people with stroke and physiotherapists. The information obtained from these user surveys, as well as the information obtained from

the narrative review and meta-analysis contributed to the development of an evidence-based, user-informed and centred exercise intervention. See Figure 3.1.

Figure 3.1: Design of the randomised controlled trial



3.1.1 Operational definitions

Prior to conducting the user surveys, a number of operational definitions were clarified. 'Family members/friends' of people with stroke were defined as family, friends, carers, or significant others who interacted with the person with stroke on a daily basis. 'Exercise' was defined as any type of physical activity aimed at improving a particular skill or ability, delivered to the person with a stroke, in the inpatient, outpatient or home environment.

3.1.2 Quantitative methodology - self-report questionnaires

Two self-report questionnaires were developed, namely User Survey 1 and User Survey 2A (See Appendices 6 and 7 respectively). The questionnaires were designed by the author in liaison with her supervisor and reviewed by five senior physiotherapists working in neurology and age related healthcare. The surveys were also reviewed by a hospital based review board to ensure suitability for use with people with stroke and

their 'family members/friends'. Some changes to the content of the questionnaires were suggested and all of the recommendations made were implemented.

The aim of User Survey 1 was to investigate the views of 'family members/friends' of people with stroke on their perceived role in physiotherapy and exercise delivery following stroke. The self-report questionnaire contained four sections that documented the demographic details of the respondent, frequency of their involvement in their 'family member/friend's' physiotherapy following stroke, the views of respondents on the delivery of exercises by them with and without the supervision of a physiotherapist in the hospital and in the home environment, reasons that may limit or potentially enhance their participation in physiotherapy and opinions of respondents on different aspects of their 'family member/friends' physiotherapy.

The aim of User Survey 2A was to ascertain the views of people with stroke on the involvement of their 'family members/friends' in their physiotherapy and the delivery of exercises to them. The survey instrument consisted of 'mirror' questions that were recorded in User Survey 1. It was initially decided to use a quantitative methodology to explore the opinions of people with stroke and their 'family members/friends' as the questionnaires were brief and easy to administer, facilitating the recruitment of a large sample.

3.1.3 Qualitative methodology - semi-structured interviews

In addition to the administration of User Survey 2A to people with stroke, a series of semi-structured interviews (User Survey 2B) were also conducted with a sample of convenience of people with stroke. This methodology was used as an adjunct to the quantitative approach to give a richer insight into the views of people with stroke than was possible with the self-report questionnaires alone. The aim of the semi-structured interviews was to explore the views of people with stroke in relation to their physiotherapy intervention and the involvement of their family in their physiotherapy programme. Questions were prepared in advance by the author following a review of the literature and the responses emerging from User Survey 2A. Three areas were highlighted for exploration including the duration and content of the persons physiotherapy programme (at the time of participation in the interview), the role of

their family in their physiotherapy programme and their views on the concept of family assisted exercises as an adjunct to their routine physiotherapy. Details of the questions included in the interview are contained in Appendix 8.

3.1.4 Qualitative methodology - focus groups

Focus group research involves an organised discussion with a selected group of individuals, in this case senior physiotherapists, to gain information about their views and experiences of involving of family members in physiotherapy following stroke. This user survey was termed User Survey 3. The focus group methodology is particularly useful for examining people's knowledge and experiences and can be used to help people explore and clarify their views in ways that would be less easily accessible otherwise (Kitzinger 1995). This method was ulitised to explore the opinions of physiotherapists working in the area of stroke rehabilitation in relation to the involvement of 'family members' in the delivery of exercises to people with stroke. This methodology allowed the author to gain in-depth information in relation to each physiotherapist's previous experience of family involvement in physiotherapy.

A protocol was developed to facilitate the running of the focus group using information from the published literature (Britten at al 1995, Kitzinger 1995, Mays and Pope 1995, Powell and Single 1996) and guidelines produced by The Neurological Alliance Focus Group Research (2005). This protocol is contained in Appendix 9. Three topics were identified for discussion during the focus group. Questions were prepared in advance by the author and are contained in Table 3.1.

Table 3.1: Content of focus groups

THEME 1 **Frequency/duration/benefits of physiotherapy**
How many days per week do people with a stroke receive physiotherapy in your service? How long does a physiotherapy session last? PROBE: Do you think that patients could benefit from more physiotherapy? What particular patient subgroups, if any, would benefit from this additional therapy?
THEME 2 **Role of family members in physiotherapy**
Do you think that 'family members/friends' have a role in the delivery of exercise to people with stroke? PROBE: Do you think that their involvement in the delivery of exercises might be a cause of additional strain to the family member? Do you think that the family member would like to be involved in the delivery of exercises? Do you think that this is routine practice?
THEME 3 **Involvement of family members in physiotherapy**
Have you ever involved a 'family member/friend' of a patient in the delivery of an exercise programme in the inpatient, outpatient or home environment? PROBE: What were the characteristics of this person that you thought made them suitable to be involved in exercise delivery? Did you provide additional information in writing to the 'family member/friend' on how to perform the exercises while you were not available i.e. unsupervised? Did you provide an 'exercise log' that enabled 'family members/friends' of the person with the stroke to record whether or not the exercise programme had been completed?
CLOSE **Closing Question**
Finally, did you find that involving family members in your patients physiotherapy programme was a positive experience for the patient/you? PROBE: Can you tell me a little more about it?

3.2 Ethical approval

Ethical approval was granted from the Joint Research Ethics Committee of the Adelaide and Meath Hospital incorporating the National Children's Hospital and Saint James's Hospital (See Appendix 10), the Ethical and Medical Research Committee Saint Vincent's University Hospital (See Appendix 11) and the Physiotherapy Manager at the Royal Hospital Donnybrook (See Appendix 12).

3.3 Setting

3.3.1 Self-report questionnaires - User Survey 1 and User Survey 2A

The self-report questionnaires were distributed in four hospitals in the greater Dublin area. Samples of convenience were recruited for both questionnaires. Recruitment for User Survey 1 commenced in June 2005 and was completed in May 2006. 'Family members/friends' of people with stroke who were receiving inpatient physiotherapy following first unilateral stroke, and who were willing to give written informed consent were invited to participate in the study. Each potential participant was provided with a participant information brochure (Appendix 13) prior to obtaining written consent (Appendix 14). Only one response was permitted per family.

Recruitment for User Survey 2 commenced in September 2006 and was completed in August 2007. People with stroke receiving inpatient physiotherapy following first unilateral stroke and who were willing and able to give written informed consent were invited to participate in the study. Suitable participants were identified in liaison with the senior physiotherapists in the hospital. Each potential participant was provided with a participant information leaflet (Appendix 15) prior to obtaining written consent (Appendix 16). All questionnaires were administered by the author. There was no relationship between the individuals with stroke and the 'family members/friends' of people with stroke recruited in these two studies.

3.3.2 Semi-structured interviews - User Survey 2B

Recruitment for the semi-structured interviews commenced in May 2007 and was completed in August 2007. Individuals were eligible for interview if they presented with a diagnosis of first stroke, were attending physiotherapy at the time of recruitment and were willing to give informed consent to partake in the study. Individuals were not considered for interview if they presented with a diagnosis of another neurological condition (such as Parkinsons Disease or Multiple Sclerosis), had a cognitive impairment or a diagnosis of expressive or receptive dysphasia. Suitable participants were identified in each hospital in consultation with the senior neurological physiotherapist. Each potential participant was provided with a participant information leaflet (Appendix 17) prior to obtaining written consent

(Appendix 18). All interviews were conducted by the same researcher[2], experienced in qualitative methodologies, who was unknown to the individual with stroke, in a pre-booked meeting room in each hospital. All interviews were audio-recorded by means of a digital voice recorder for later transcription and analysis.

3.3.3 Focus groups - User Survey 3

Two focus groups were conducted in September 2006. The focus groups were conducted at the same venue and all participants provided written consent (Appendix 19) prior to the session. Group A and Group B were held two weeks apart. All participants were requested not to discuss the sessions with their colleagues in order to avoid contamination of the data. A moderator[2] facilitated the meeting and the author took notes during each session. Each focus group was audio-visually recorded by an independent person.

3.4 Data analysis

3.4.1 Quantitative data

The data generated from each questionnaire was inputted into Microsoft Office Excel 2003. Descriptive statistics were primarily used to represent the data. An independent researcher cross checked all entries. Appropriate statistical tests were carried out on the data where necessary using MINITAB Release 13.1.

3.4.2 Qualitative data

All recorded data from the semi-structured interviews and focus groups was transcribed verbatim by the author. The approach described by Miles and Huberman (1994) was adopted for analysis of the transcriptions. All participants were assigned a code to ensure anonymity in the transcript. The transcripts were explored by a process of reading and re-reading. On the first reading, transcripts were read in their entirety to acquire a sense of the whole. On the second reading, using line by line analysis, patterns and themes were identified and listed. A coding system was developed by the author in

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[2] Dr. Tara Cusack, Lecturer, School of Physiotherapy and Performance Science, University College Dublin.

order to facilitate the identification of recurrent patterns and themes. Prior to the third reading, the responses from all participants to each question were transferred to Microsoft Excel for further examination. The third reading involved checking the suitability of the coding system and pursuing patterns both consistent and inconsistent with the codes defined.

The author and two independent researchers were provided with the semi-structured interview transcripts and the focus group transcripts in an unencoded format and were requested to independently code the responses in succession using the predefined codes. Analysis of inter-rater reliability of the researchers coding the interviews of people with stroke revealed three areas of disagreement. The first disagreement related to the components of their physiotherapy programme that the people with stroke liked best. The second related to the acceptability of family involvement in their rehabilitation programme and the third disagreement arose when describing desirable attributes in a physiotherapist involved in the rehabilitation of people with stroke.

In relation to analysis of the data from the focus groups conducted with the physiotherapists involved in stroke rehabilitation, two disagreements arose. The first coding disagreement related to the characteristics of people with stroke who benefit most from physiotherapy and the second disagreement arose when coding the characteristics of family members who are involved in physiotherapy following stroke. All coding disagreements were resolved through discussion. The original coding systems were modified and further sub-divided to more clearly represent the emergent themes in the data. A fourth coder independently verified the coding systems following the conflict resolution meeting. This coder was in full agreement with the revised coding systems developed for the responses in question.

3.5 Results

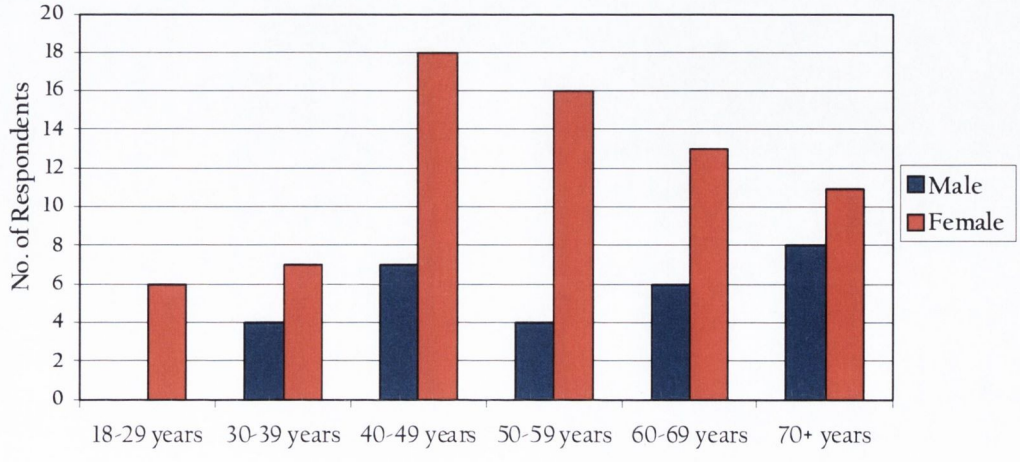
3.5.1 User Survey 1

The results of this user survey have been published in abstract (Galvin et al 2007a, Galvin et al 2006a,b) and paper format (Galvin et al 2009a) - See Appendix 4.

Section A

A convenience sample of 100 'family members/friends' of people with stroke were recruited during the study period. The first section of the questionnaire focused on respondents' demographic details. Twenty-nine respondents were male and seventy-one respondents were female. Ninety-seven of the respondents who were surveyed were related to the person with the stroke, for example, wife, husband, daughter or son. Three respondents described themselves as a 'friend' of the person with stroke and interacted with the person with the stroke on a daily basis in the home environment prior to their stroke. The majority of respondents surveyed (97%) reported that their 'family member/friend' was independent in ADLs prior to the occurrence of the stroke. Respondents were stratified according to their age categories - See Figure 3.2. A chi-squared distribution test was calculated to determine if there was a statistically significant difference in the proportion of male and female respondents across the different age categories. This difference did not reach statistical significance [χ^2 (5, n=100) = 5.19, p = 0.39].

Figure 3.2: Age categories of 'family members/friends'



Section B

Section B of the questionnaire primarily focussed on the respondents 'family member/friend' with stroke and their physiotherapy intervention. Table 3.2 details respondents' responses when asked how often they thought their 'family member/friend' with stroke received physiotherapy in the hospital. Sixty-nine percent of respondents (n=69) reported that their 'family member/friend' received physiotherapy five times a week.

Table 3.2: Frequency of physiotherapy as reported by 'family members/friends' of people with stroke

FREQUENCY OF PHYSIOTHERAPY	NUMBER OF RESPONDENTS
Once weekly	4
Two times a week	4
Three times a week	8
Four times a week	6
Five times a week	69
Don't know	9
TOTAL	100

Thirty-six respondents (36%) reported that they had been invited to attend physiotherapy sessions an average of two times (range 1-10 times) since their 'family member/friend' had commenced physiotherapy. Twenty-nine of these respondents were female. Thirty respondents (30%) took part in the physiotherapy sessions. Fourteen of these respondents had attended by a pre-arranged appointment and 16 had attended physiotherapy on a more casual 'drop-in' basis. The most common activities demonstrated by the physiotherapist to the respondent during these sessions were positioning of the affected arm/leg (n=21) and helping their 'family member/friend' to walk (n=21). Other activities demonstrated by the physiotherapist included assisting the person with stroke to get from sitting to standing (n=18), getting in and out of a bed (n=11) and transfers (n=8). Over 50% (n=17) of respondents who participated in the physiotherapy sessions were asked to deliver these exercises unsupervised and 11 respondents reported that they received information from the physiotherapist on how to perform these exercises unsupervised. Eight respondents received a one-to-one

educational treatment session with the physiotherapist and four respondents received written guidelines. Only one respondent received both types of information.

Section C

This section focused on the respondents' willingness to participate in the future delivery of exercises to their 'family member/friend' with stroke. The section also aimed to identify reasons that limited the respondents' participation in exercise delivery and methods that could potentially enhance their future participation. All respondents were asked if they would be available to help their 'family member/friend' with exercises if the physiotherapist invited them to attend sessions while their 'family member/friend' was an inpatient. Ninety-one (91%) respondents documented that they would be available to assist their 'family member/friend' with their exercises. Respondents were also asked if, following suitable training by a physiotherapist, they would be willing to assist in the delivery of different exercises to their 'family member/friend' following discharge from hospital. With the exception of one respondent, all were willing to help with the delivery of general bed exercises. However, only 85% were willing to help practice transfers and walking. This reluctance to help with more complex activities may be attributed to fear combined with lack of confidence in the respondents handling skills.

Respondents were then given a number of reasons that may limit or prevent them from participating in physiotherapy or helping with exercises and were requested to tick the most appropriate reasons. Twenty-four 'family members/friends' (24%) responded to this question. Commitment to work was documented as the primary reason that limited respondents' participation in exercise delivery (24%). However, twenty-two of these respondents documented that a pre-arranged time of attendance would facilitate their participation in physiotherapy. The various reasons that limited respondents' participation in physiotherapy are highlighted in Table 3.3.

Respondents were also given a number of suggestions that may facilitate their future participation in physiotherapy and involvement in the delivery of exercises to their 'family member/friend' with stroke. These suggestions included a pre-arranged time of attendance with the physiotherapist, 'hands on' training with the physiotherapist,

provision of educational material, supervised practice time following physiotherapy training and provision of an exercise diary. Seventy-two family members responded to this question. Their responses are also contained in Table 3.3.

Table 3.3: Reasons that limit/enhance 'family members/friends' participation in physiotherapy and exercise delivery

REASONS THAT MAY LIMIT PARTICIPATION IN PHYSIOTHERAPY*	REASONS THAT MAY ENHANCE PARTICIPATION IN PHYSIOTHERAPY**
'I have work commitments' (n=24)	Pre-arranged time of attendance (n=72)
'I have no confidence in delivering exercises' (n=20)	Hands on training with the physiotherapist (n=72)
'I am not physically able' (n=18)	Supervised practice time (n=62)
'The physiotherapy treatment times unsuitable' (n=13)	Provision of educational material (n=56)
'I have family commitments' (n=12)	Keeping an exercise diary (n=47)

* (n=24) - multiple responses were permitted

** (n=72) - multiple responses were permitted

Section D

In this section, respondents were asked to rate their satisfaction with different aspects of physiotherapy using a Likert type scale where the anchors were 'strongly agree' to 'strongly disagree'. The majority of respondents either 'agreed' or 'strongly agreed' that 'family members/friends' of people with stroke should be actively encouraged to participate in physiotherapy, would like to be more involved in their 'family members/friend's' physiotherapy intervention and would like the opportunity to discuss treatment goals and long term outcomes with the physiotherapist. Table 3.4 presents the results of these findings.

To conclude the questionnaire, respondents were asked to rank, in order of preference, what they thought was the most important part of their 'family member/friends' recovery. All respondents 'family member/friends' were in the acute stage following their stroke and had varying levels of physical impairment. Therefore responses to this particular question were individual and subjective. Thirty-four respondents (34%) reported that regaining the ability to walk was the most important part of their 'family

member/friend's' recovery. This was followed by 20% of respondents rating the ability to get into and out of bed without assistance as the most important part of their 'family member/friend's' recovery.

Table 3.4: 'Family members/friends' opinions on their role in physiotherapy

'FAMILY MEMBERS/ FRIENDS OF PEOPLE WITH STROKE ...'	STRONGLY AGREE (%)	AGREE (%)	NEITHER AGREE NOR DISAGREE (%)	DISAGREE (%)	STRONGLY DISAGREE (%)
should be actively encouraged to participate in physiotherapy	66	24	7	3	0
would like to be more involved in physiotherapy	60	26	12	2	0
wish to discuss treatment goals with physiotherapist	72	27	0	1	0
should get more information about the stroke	71	25	3	1	0
feel that physiotherapy is of benefit	86	13	0	0	1

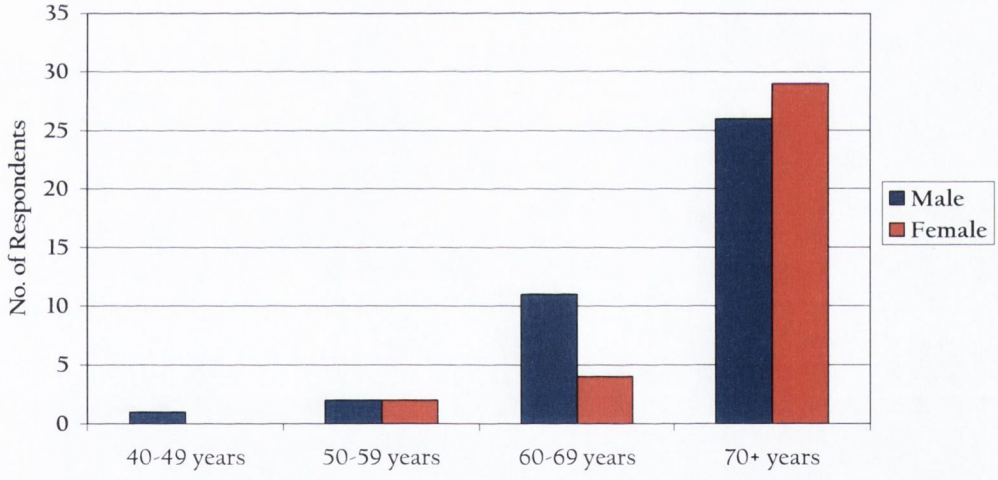
3.5.2 User Survey 2A

The results of this user survey have been published in abstract (Galvin et al 2007b) and paper format (Galvin et al 2009a).

Section A

A sample of convenience of 75 people with acute stroke was recruited during the study period. The first section of the questionnaire focused on respondents' demographic details. Forty respondents were male and thirty-five were female. Seventy four respondents (99%) reported that they were independent in ADLs prior to their stroke. Figure 3.3 displays the age category of respondents.

Figure 3.3: Age categories of people with stroke



Respondents were stratified according to age category and there was no significant difference in the proportion of male and female respondents across all age categories as measured by the chi-squared test [χ^2 (3, n = 75) = 4.12, p = 0.25].

Section B

Section B of the questionnaire primarily concentrated on the respondents' level of physiotherapy intervention (at the time the survey was administered). Table 3.5 displays respondents' responses when asked to document the frequency and duration of their physiotherapy intervention. Forty-seven respondents (63%) reported that they received physiotherapy five days per week. There was no relationship between frequency of physiotherapy and duration of treatment as measured by the Spearmann rank correlation coefficient (r=0.142). All respondents reported that physiotherapy was delivered to them on a one-to-one basis by a physiotherapist. Twelve respondents reported that they also received physiotherapy in the form of a group setting in the physiotherapy gym or on a one-to-one basis with a physiotherapy assistant (n=8). Sixty-six respondents (88%) reported that they could benefit from more physiotherapy.

Table 3.5: Frequency and duration of physiotherapy per week

FREQUENCY OF PHYSIOTHERAPY	NUMBER OF RESPONDENTS (n=75)	DURATION OF PHYSIOTHERAPY	NUMBER OF RESPONDENTS (n=75)
Once weekly	0	1-15 minutes	2
Two times/week	7	16-30 minutes	25
Three times/week	14	31-45 minutes	37
Four times/week	4	46-60 minutes	8
Five times/week	47	> 1 hour	3
Not at all	0	Don't know	0
Don't Know	3		

Section C

This section focused on the level of involvement of respondents 'family members/friends' in their physiotherapy. The majority of respondents (n=59) reported that their 'family members/friends' had not been invited to attend any of their physiotherapy sessions since they commenced physiotherapy following their stroke. In ten of the sixteen cases where 'family members/friends' of people with stroke were invited to attend physiotherapy, respondents reported that their 'family member/friend' approached the physiotherapist and volunteered to attend the session. The remaining six respondents reported that the physiotherapist nominated the particular 'family

member/friend' to attend their physiotherapy session. Fourteen 'family members/friends' agreed to participate in the physiotherapy sessions and they attended by pre-arranged appointment (n=10) and on a more casual 'drop-in basis' (n=4) a median of 4 times. Respondents reported that they and their 'family member/friend' were shown how to complete a variety of activities by the physiotherapist including positioning of the affected arm/leg (n=10), transferring on/off the toilet (n=8) and in/out of a car (n=7), standing up from a chair (n=5) and assistance with mobility (n=7). No participant reported that their 'family member/friend' had been asked by the physiotherapist to help them with their exercises unsupervised.

Section C of the user survey also explored the respondents' willingness to allow their 'family member/friend' to participate in future physiotherapy sessions. All respondents were asked if they would be willing in the future, to allow their 'family member/friend' to deliver a series of exercises to them in addition to their 'routine' physiotherapy. Sixty-five respondents (87%) reported that FAME therapy would be acceptable to them in the hospital and home environment following suitable training by a physiotherapist. In addition, respondents were asked if they would be happy to allow their 'family member/friend' to keep a record of exercises completed on a daily basis. Seventy-three respondents (97%) reported that they would be willing to allow their 'family member/friend' to keep a record of the exercises completed using an exercise 'diary'. The reasons documented by respondents who did not wish to have their 'family members/friends' involved in their physiotherapy are contained in Table 3.6.

Table 3.6: Reasons that limit 'family members/friends' participation in physiotherapy according to people with stroke

REASON FOR NOT INVOLVING FAMILY MEMBER/FRIEND IN PHYSIOTHERAPY	NUMBER OF RESPONDENTS*
'It is not the role of my family/friends'	7
'I would not feel confident'	5
'My family/friends would put too much pressure on me'	5
'I have no interest in allowing them to participate'	4
'I would not benefit from their additional therapy'	4

* (n=10) - Multiple responses permitted

Section D

In this section, respondents were asked to rate their satisfaction with different aspects of their 'family members/friends' involvement in their physiotherapy using a Likert type scale where the anchors were 'strongly agree' to 'strongly disagree'. The majority of respondents either 'agreed' or 'strongly agreed' that their 'family member/friend' had a role in their physiotherapy following stroke (90%) and should be more involved in the setting of short and long term goals (83%). Table 3.7 presents the results of these findings.

Finally, to complete the questionnaire, respondents were asked to rank, in order of preference, what they thought was the most important part of their physiotherapy intervention. All respondents were in the acute stage (< 3 months) following their stroke and had varying levels of physical impairment. Therefore responses to this particular question were individual and subjective. However, 76% (n=57) of respondents reported that regaining the ability to walk was the most important part of their recovery.

Table 3.7: The opinions of people with stroke (n=75) on 'family members/friends' involvement in physiotherapy

'FAMILY MEMBERS/ FRIENDS OF PEOPLE WITH STROKE ...'	STRONGLY AGREE (%)	AGREE (%)	NEITHER AGREE NOR DISAGREE (%)	DISAGREE (%)	STRONGLY DISAGREE (%)
should be actively encouraged to participate in PT	47	34	7	12	0
should be more involved in the delivery of exercises	45	32	3	16	4
should be more involved in short/long term goal setting	47	36	7	9	1
have a role in PT following stroke	41	49	3	7	0

PT - Physiotherapy

3.5.3 User Survey 2B - semi-structured interviews

The results of these semi-structured interviews have been published elsewhere (Galvin et al 2009b) - See Appendix 5. A sample of convenience of 10 people with stroke consented to participate in the semi-structured interview. These participants were not part of the cohort included in User Survey 2A. Four males and six females were interviewed by a person unknown to them. Participants were a mean of 58 days post stroke (range 31-89 days) and ranged in age from 56 to 88 years (mean 73 years). All participants were independent in ADLs prior to their stroke.

The majority of participants (n=8) reported that they received physiotherapy on a daily basis for 30-45 minutes. However, nine of the ten participants reported that they could benefit from additional physiotherapy, particularly walking (n=7) and LL exercises (n=5). Participants were asked if their families were invited to assist them with their physiotherapy programme. Seven participants reported that their family members were not invited to attend physiotherapy but would be happy to do so.

> *'They would like to know what help they could give me'* [TCD PT 02]

> *'...he would be interested in finding out what I do and doing it with me....'* [TCD PT 03]

Three participants reported that their families had attended a physiotherapy session and were *'very interested'* [TCD PT 01] in their physiotherapy programme. Another participant reported that her husband's involvement in her physiotherapy was a very positive experience.

> *'The first time he seen me walking and he... he... it was a major boost to him'* [TCD PT 06]

Participants were then asked if additional FAME therapy would be acceptable to them. Eight participants reported that that a FAME programme would be acceptable to them as an adjunct to routine physiotherapy for a variety of reasons. Participants identified potential benefits of this type of additional exercise therapy to their families (n=5) in terms of building confidence in relation to 'handling' the individual with stroke in the hospital and in the home environment. In addition, participants indicated that this

form of additional exercise therapy may be beneficial to them in terms of assisting them with walking and also contributing towards a more speedy physical recovery.

> *'They (family) would like it as well... ammm...well to make sure that I'm able to sit out of the chair now...step out of the chair now and stand without falling you know'*[TCD PT 01]

> *'Now anything my family would know about physiotherapy while I'm at home, even for these short periods, would be an advantage I would think.'* [TCD PT 05]

> *'My wife would feel more involved and any other member of the family would feel that they were making a very positive contribution to my recovery.'* [TCD PT 10]

Participants were asked if they perceived any drawbacks to this type of therapy. Six participants reported no drawbacks to this type of additional therapy. One participant reported that family assisted exercises would *'irritate'* him [TCD PT 01]. Two others reported that this type of therapy may add pressure to their families' daily lives.

> *'.... after all they have their lives to live as well...'* [TCD PT 08]

Participants were asked what component of their physiotherapy programme they liked the most. Walking was the most frequent response (n=6) followed by LL exercises (n=4). Finally participants were asked to identify what attributes they thought were important in a physiotherapist treating people with stroke. Characteristics identified included physiotherapists who were encouraging (n=6), caring (n=3) and honest (n=2).

3.5.4 User Survey 3 - focus groups

An invitation to participate in the focus group study was sent to twelve physiotherapists working in the area of stroke rehabilitation. Focus group A comprised of six physiotherapists and Focus group B comprised four physiotherapists. It was intended that Focus group B would also comprise six physiotherapists. However two were unable to attend on the scheduled day. Nine of the physiotherapists were female. Seven participants were senior physiotherapists working in the area of stroke rehabilitation with more than 5 years. One participant was a senior physiotherapist in stroke rehabilitation for 3 years. Two staff grade physiotherapists participated in the focus group discussion. Each had completed rotations in the area of stroke rehabilitation and at the time of the focus group discussion, more than half of their caseload consisted of people with a diagnosis of stroke. The output from these focus groups has been published (Galvin et al 2009a,b) - See Appendices 4 and 5 respectively.

All participants agreed that inpatients with stroke receive physiotherapy on a daily basis, five days per week and that outpatients receive physiotherapy 1-2 times per week. The average length of each physiotherapy session ranged from 30-60 minutes. The two groups identified particular subcategories of people with stroke who tended to benefit most from physiotherapy following stroke, such as individuals who were young and those who were motivated (n=4). In contrast, physiotherapists reported that physical and cognitive impairments as well as medical complications impeded recovery (n=7).

> *'The kind of patients who are well motivated and if they don't have any cognitive impairment and things like that, they're obviously going to improve.'* [TCD B1]

> *'Cognitive impairment would be a huge factor in the carry-over and instructions'* [TCD A4]

> *'Or, if they have a lot of other medical complications...'* [TCD A3]

> *'The younger patient groups.... as well as being more motivated'* [TCD B2]

One physiotherapist noted that fatigue was an issue for some of her patients in the acute setting and indicated that this was a factor that needed to be considered when developing a rehabilitation programme.

> *'I have some people that are able for one session during the day and I could try to bring them up for a second session but just they get so tired, and just they're completely wiped by the end of the first session that they're just not able for it'* [TCD B4]

The groups also agreed that people with stroke could benefit from more physiotherapy than is routinely provided following stroke (n=7). Four participants felt that additional therapy would be most beneficial following discharge from hospital.

> *'I think certainly on discharge, we find it, you know, they come from an acute setting into the sub-acute and then when we're planning discharge, we find that it is hard to get access to follow-up services..'* [TCD A3]

All therapists reported routinely involving family members in the rehabilitation process.

> *'Yeah we routinely would yeah.'* [TCD A3]

> *'Yeah you would try because I suppose just so much of our physio treatment is repetition'* [TCD A4]

Participants highlighted a number of different roles that the family member plays in the rehabilitation process especially in terms of treatment carry-over (n=8), and helping the family unit to cope, particularly on discharge (n=4).

> *'...just to maintain what you're doing, to carry over, to improve carry over and that.'* [TCD B4]

> *'If you have a family member who is involved from the start and it's just carrying over rather that giving out a prescriptive exercise sheet, I think that can make the transition [home] a lot easier'* [TCD A5]

'I think if you involve them earlier, you might have a better chance of lessening the shock when they go home' [TCD A5]

'I think it makes a huge difference because they're, they're not frightened' [TCD A1]

'If they're a bit more used of doing a little bit of hands on, the family members find it a lot easier.... A lot of the caring stuff that they'll have to do when they go home' [TCD A4]

'...if they were used to handling a bit earlier on, that it would be a lot easier to, to sort of cope with that as well.' [TCD A4]

Participants were also asked if they provided written information to family members on how to perform the particular exercises. The primary answer that emerged from the groups was that the physiotherapists provided individual written programmes to the families if they deemed that it was necessary to provide the same. One physiotherapist reported occasionally using an exercise log to document completion of exercises. However, all other participants reported that they followed up with the patient verbally.

No physiotherapist perceived that involvement of family members in physiotherapy would be a cause of additional strain to the family and reported that families were often motivated and eager to participate in physiotherapy (n=8). Furthermore, a number of issues were identified that influenced participation in physiotherapy, such as level of interest and motivation of the family members (n=5), availability (n=3) and importance of adequate education and training prior to exercise delivery (n=2).

'Often that they will ask, "What input can I have while they [the patient] are not getting physio" and they would take that on board' [TCD B1]

'They're [families] enthusiastic about trying to be part [of physiotherapy] and trying to help' [TCD B2]

'They'd be keen to do whatever they can' [TCD B3]

'Like some families would approach, would approach me and ask what they can do' [TCD A4]

'Families are quite glad to be involved' [TCD A1]

'Like their families are asking what I can do in the evening time...' [TCD B4]

Finally, the groups were asked to discuss any negative incidents that they experienced when involving family members in physiotherapy sessions. The therapists highlighted incidences where some families were over enthusiastic (n=5), very emotional (n=1) or overly critical of the patient's performance (n=1) and therefore would always ask the patient for permission prior to asking the family member to be involved in physiotherapy.

'...the family member wants to do so much and they're so intense...' [TCD A1]

'Or it can be a bit emotional sometimes...' [TCD A2]

'...their spouse or son or daughter trying to say, "no you're not doing that properly" or "do that again", it can create frustration...' [TCD A3]

3.6 Discussion

These user surveys examined the role of 'family members/friends' in physiotherapy and the delivery of exercises to people with stroke from three different perspectives, that of the individual with stroke, 'family members/friends' of people with stroke and physiotherapists. Due to the multifaceted nature of the research question, a mixed methodology approach was chosen to provide a more robust consideration of the topic. The qualitative interviews with individuals with acute stroke and physiotherapists working in the area of stroke rehabilitation provided the author with an insight into their expectations and experiences of physiotherapy and family mediated exercise delivery following stroke. The output from the self-report questionnaires also provided useful quantitative data in relation to the duration and frequency of physiotherapy and the level of involvement of family members in exercise delivery. Furthermore, the questionnaires identified factors that limited participation of family members in

physiotherapy and also highlighted methods that may enhance the future involvement of family members in physiotherapy and exercise delivery following stroke.

3.6.1 Duration of physiotherapy

There are several concordant opinions and similarities between the perspectives of people with stroke, 'family members/friends' and physiotherapists in relation to the duration of physiotherapy and the provision of additional therapy following stroke. All groups agreed that people with stroke could benefit from more physiotherapy than they routinely received which, according to the majority of respondents in all groups, varied from 30-60 minutes a day five times per week. However, physiotherapists suggested that additional therapy would be most beneficial on discharge from hospital whereas in the semi-structured interviews, nine of the ten participants with stroke reported that they could benefit from additional physiotherapy during their inpatient stay. In a study of patients' expectations of recovery following acute stroke, Wiles et al (2002) reported that individuals with stroke (n=16) felt that more physiotherapy would be beneficial in the acute stage and raised concerns that they were not receiving the amount of physiotherapy that they needed to maximise their recovery. There is still considerable uncertainty in the physiotherapy profession about the process and timescale of recovery post stroke because of a lack of evidence; however most researchers agree that the bulk of recovery occurs in the first three months following stroke (Wiles et al 2002), typically when the individual with stroke is an inpatient. It has also been suggested that the amount of input professionals can give to inpatients is very little compared with normal daily activities. In the physiotherapy setting, staff limitations and/or established practises such as 'half an hour of treatment' and 'three times a week' regimes may prevent therapists from embracing different treatment ideas, such as the involvement of families, to increase exercise delivery (De Weerdt and Feys 2002). While one cannot deny that the involvement of family members in exercise delivery may be more time consuming initially than a 'one-to-one' treatment session with the individual with stroke, the involvement of family members from the outset may serve to enhance input on a longer term basis by increasing repetition of tasks and exercises through family mediated exercise delivery.

3.6.2 Involvement of 'family members/friends' in physiotherapy

In this study, 88% of people with stroke documented that they could benefit from more physiotherapy that was provided to them in the in-patient setting following stroke. Physiotherapists also identified the benefits of increased duration of physiotherapy following stroke, in keeping with the findings of two recent meta-analyses (Kwakkel et al 2004, Galvin et al 2008b) and the systematic review presented in Chapter 2. Furthermore, in both the qualitative and quantitative survey instruments, people with stroke reported that family mediated exercise intervention, as an adjunct to routine therapy, would be acceptable to them. Additionally, 91% of 'family members/friends' (n=91) reported that they would be available to assist with these exercises following suitable training by the physiotherapist. These results are similar to those reported by Bailey and Rennie (1997), where 86% of the cohort of carers (n=42) that they studied wished to assist in physiotherapy following stroke. The findings from the current study suggest that FAME therapy is acceptable to all groups and could be used to maximise the carry over outside of formal physiotherapy, giving patients the opportunity for informal practice with their 'family member/friend' (Carr and Shepherd 1987).

While some studies have found that caregivers of people with stroke often experience high levels of burden (Scholte op Reimer et al 1998, Blake et al 2003), Carr and Shepherd (1987) and Kalra et al (2004) suggest that carer involvement in the rehabilitation process may help to reduce fears that carers may have about their ability to cope at home. This theme also emerged clearly from the two focus groups and physiotherapists strongly agreed that family involvement from the outset can help families to cope and indeed *'lessen the shock'* [TCD A5] and *'fright'* [TCD B1] on discharge.

All physiotherapists reported that they 'routinely' involved families in their inpatient physiotherapy programmes. Contrary to this, in the semi-structured interviews, seven out of ten participants with stroke reported that their family members had not been invited to attend physiotherapy sessions even though this was acceptable to the person with stroke and the family were happy to do so. Furthermore, the results of the two self-report questionnaires indicated that family involvement in physiotherapy was not practised routinely following stroke. The level of involvement of 'family members/friends' in physiotherapy reported in the two groups of respondents ranged from 21% to 36%, the latter figure being reported by 'family members/friends' of the

person with stroke. The inconsistency in reported involvement of families in physiotherapy by the three groups may have arisen for a number of reasons, the most likely being the lack of availability of family members at the time of treatment. However, family involvement in physiotherapy following stroke should be facilitated where possible and pre-arranged times of attendance should be organised with families to maximise involvement. This sentiment was also highlighted by the family members in the self-report questionnaire.

There was a discrepancy between people with stroke and family members in reported participation in unsupervised exercises. This may have arisen due to retrospective self-report nature of the question, where the accuracy of the response was dependent on people's perspective, memory and interpretation of the particular question. In addition, this question may have prompted a response from families that was 'socially desirable' and acceptable rather than accurate. Furthermore, it emerged from the focus groups that the majority of physiotherapists reported that they did not request that patients and their families keep a written record of unsupervised exercises completed. Therefore it may prove useful in future to formally document the completion of exercises in an 'exercise diary' to avoid such inconsistencies.

It also needs to be acknowledged that a significant minority of people with stroke do not want their family members involved in their therapy. In the quantitative survey, 13% of respondents with stroke indicated that they did not want their family member to be involved in their physiotherapy rehabilitation. While some participants reported that they would not feel confident in their family members ability to assist in exercise delivery, seven respondents reported that it was not the role of their family member to be involved in exercise delivery while three others reported that their family members would put too much pressure on them to complete the series of exercises. This finding was re-iterated by one individual with stroke who took part in the semi-structured interviews, who reported that family assisted exercises would '*irritate*' him **[TCD PT 01]**. This finding highlights importance of involving individuals with stroke in planning the recovery process and also highlights that health professionals should consult with the individual with stroke prior to involving their family members in their physiotherapy and exercise delivery.

3.6.3 Role of 'family members/friends' in the rehabilitation process

People with stroke identified several potential benefits to themselves and their families, should their families become involved in their rehabilitation. Such benefits included improving the confidence and handling skills of their families in the hospital and home setting and increasing the individual's ability to exercise through provision of adequate assistance by their relative during exercises such as walking. The physiotherapists also highlighted a number of areas that family involvement can have an impact, such as treatment carry-over, assisting the family unit to cope and improving handling skills. Carr and Shepherd (1987) report that carer involvement in the rehabilitation of a person with stroke can serve to optimise the effects of rehabilitation by allowing the patient to practice activities with the carer outside of the routine treatment hours. Evans et al (1994) found that gains made in initial rehabilitation were more effectively maintained if the family were involved. They also suggest that family members can be helped by healthcare workers to adjust to stroke in several practical ways, including involvement in the rehabilitation process to maximise learning and to provide a means for generalising new behaviours at home. This theory is also supported by Forster and Young (1992), whose letter to the editor of the British Medical Journal emphasised that if carers were not aware of an individuals' progress, then the 'carry-over' from therapy may be limited. The physiotherapists involved in the focus group discussion in this study also highlighted the positive impact of family involvement in terms of treatment carry-over.

While the physiotherapists reported that they routinely involved family members in physiotherapy, they identified a number of issues that limited participation such as lack of interest, motivation and availability of family members. 'Family members/friends' of people with stroke in this study reported that commitment to work was the primary reason that limited their participation in physiotherapy. Visser-Meily et al (2006) suggest that the rehabilitation of people with stroke could be progressed by taking into account the position of the family during the different rehabilitation phases - this hypothesis was also re-iterated by the respondents in this study. Seventy-two percent (n=72) of 'family members/friends' reported that a pre-arranged time of attendance would facilitate their participation in physiotherapy. Almost 24% of 'family members/friends' were limited in their participation in physiotherapy by a daily commitment to work and unsuitable therapy treatment hours. This finding would

support the use of an 'out of hours' physiotherapy service to improve family involvement in the acute setting.

Physiotherapists reported that younger and more motivated patients benefit most from physiotherapy following stroke. This finding is consistent with previous findings where physiotherapists view patient motivation as central to outcome in stroke rehabilitation (Maclean and Pound 2000). However, in order to develop patient motivation, physiotherapists need to encourage patients and their families to believe that physiotherapy is effective and families can assist in motivating the patient to participate fully in their rehabilitation programme. However, it must be noted that those individuals who may be perceived as being 'less motivated' by their treating physiotherapist may have stroke related impairments such as dysexecutive syndrome or other mood disorders such as depression that may impede recovery. Indeed, the physiotherapists who participated in the focus groups reported that cognitive impairment can impede recovery due to limited carryover by the patient. These additional impairments need to be considered carefully in the context of stroke rehabilitation and the timely evaluation of physiological and emotional barriers to post stroke physical activity requires an evaluation of primary factors of stroke severity, other comorbidities, and clinical deficits, as well as secondary factors such as depression, post stroke fatigue, social integration, and cultural issues (Gordon et al 2004). Timely professional assessment and interventions are important to help prevent a cycle of diminished motivation, loss of engagement in activity and deconditioning in stroke survivors. Furthermore, the combination of comorbidities and neurological deficits that are unique to each stroke survivor requires an individual approach to ensure that the patient can safely and effectively engage in a physical activity programme. These findings need to be considered carefully in the development of exercise programmes for people with stroke because findings from studies included in the review in Chapter 2 also indicated that people with a more severe initial impairment following stroke, including cognitive impairment, did not tend to benefit from additional exercise therapy. However, other studies have reported that involvement of the family in the rehabilitation process improves carry-over by allowing the patient to practice activities with the carer outside of the routine treatment hours (Carr and Shepherd 1987, Forster and Young 1992, Evans et al 1994).

Finally, it is clear from Table 3.4 that 'family members/friends' of people with stroke would like to receive more information about stroke. Lack of information about the nature, causes and consequences of stroke and available services is frequently reported (Rodgers et al 2003, Wiles et al 2004). Garrett and Cowdell (2005) conducted a study to explore the perceived need for information following stroke among individuals with stroke and carers (n=16). The study found that there was a marked desire from both groups to revisit information in order to build on it or to make sense of it at different time points in their stroke journey. This finding correlates with the results of the current study and with those of Bailey and Rennie (1997), where respondents reported that they would like the opportunity to discuss treatment goals with the physiotherapist. Similarly, physiotherapists also reported that adequate education was an important factor in the involvement of families in rehabilitation.

3.6.4 Characteristics of physiotherapists

People with stroke identified encouragement and honesty as two important characteristics in a physiotherapist involved in the rehabilitation of a person with stroke. While physiotherapists need to encourage patients to participate in physiotherapy, they also need to be pragmatic and discourage over-optimistic expectations that may develop through the process. However, there is considerable evidence that patients and their carers want to have a clear and honest appraisal of their condition and information about likely recovery as well as information on a range of other issues in relation to stroke (Wiles et al 1998, Wiles et al 2002).

It is clear from the findings presented in this chapter that 'family members/friends', people with stroke and physiotherapists agree that that families are eager and motivated to participate in the physiotherapy and that their involvement can be advantageous both physically and emotionally. This is in keeping with previous findings where people with stroke and their carers view physiotherapy positively and that participating in physiotherapy provides them with a sense of well-being, self-worth and control (Pound et al 1994, Wiles et al 2002) thereby allowing them to regain a sense of control over their condition, which is imperative for the rehabilitation process of a person with stroke (Rochette et al 2006).

3.7 Conclusion

The concept of family mediated care is not a new phenomenon. It is common practice in other areas of rehabilitation such as pediatrics and in the care of older people with dementia (Visser-Meily et al 2006). However, 'family members/friends' are not routinely involved in a systematic way to enhance stroke rehabilitation. While the sudden and profound effects of stroke on family roles and functioning create stress for the stroke survivor and their families, the available evidence suggests that carers and families desire more information about stroke and are happy to participate in physiotherapy and exercise delivery. Indeed the primary theme emerging from the two focus groups was that the involvement of the family in physiotherapy may serve to reduce fears that family members may have about their ability to cope at home.

Obtaining the perspective of individuals with stroke, and indeed their families and carers, is an important and valuable way of evaluating healthcare services and assessing progress and implementation of standards set out in each department's framework. This part of my PhD enabled an insight to be gained into the expectations and experiences of people with stroke, 'family members/friends' and physiotherapists on the involvement of families in physiotherapy and exercise delivery. All participants identified areas where the quality of physiotherapy care could be improved such as the need for additional physiotherapy in the inpatient and outpatient setting and increased involvement of families in physiotherapy. Physiotherapists need to be cognisant of the elements of rehabilitation that are important to people with stroke. The challenge to physiotherapists is to find ways of encouraging realistic goals and expectations of physiotherapy without affecting the process of active rehabilitation and skill acquisition. Many of the people who survive a stroke will suffer long term effects and will require continuing care and support from their family. Therefore it is essential that families play a key role in their rehabilitation programme from the outset.

The output from this mixed methods approach has provided the author with vital qualitative and quantitative data on the impact and limitations of a family mediated exercise programme from the perspectives of potential participants in such a programme. Chapter 4 describes how this information, combined with the information

presented in Chapter 2 informed the development of an evidence-based, user informed and centred family mediated exercise intervention.

3.8 Limitations

Like other studies of this nature, there are methodological limitations that need to be considered. Samples of convenience were used which may have introduced a systematic bias in the data. In addition, different qualitative methodologies were employed for people with stroke and physiotherapists. However, focus groups were considered to be difficult for individuals with acute stroke as confidentiality and anonymity could not be assured for the participants in the different settings. Furthermore, given the nature of the topic under discussion, it was thought that a focus group discussion among inpatients with stroke may have prompted responses that were acceptable rather than accurate. The focus group methodology was chosen for physiotherapists to enhance discussion and development of ideas. It also must be noted that, due to their qualitative nature, the findings from the focus groups and the semi-structured interviews are specific to the participants who took part in this research. Nonetheless, transferability of the findings was enhanced by using extensive quotes from which conclusions were drawn. Finally, due to the complex nature of the topic under evaluation, a mixed methodology approach was chosen to provide a more thorough consideration of the research question. However, the use of three different data gathering methods to collect data from physiotherapists and people with stroke as well as their family members may have limited the study's ability to make the data from the three groups of persons comparable in all aspects.

CHAPTER 4

METHODOLOGY FOR FAME RANDOMISED CONTROLLED TRIAL (RCT)

The aim of this chapter is to describe the methodology utilised to evaluate the impact of additional family mediated exercise (FAME) therapy on outcome following stroke. The design of the intervention was informed by the output of the user surveys detailed in Chapter 3, the systematic review and meta-analysis of the relevant literature presented in Chapter 2 and by feedback from peer-reviewers contained in Appendix 20. The protocol for this RCT has been published in BMC (BioMed Central) Neurology (Galvin et al 2008a). The components of the trial are described in the following sections.

4.1 Study design

A single blind multi-centre RCT was designed to evaluate the impact of additional FAME therapy on outcome in people with acute stroke. Forty participants were randomly assigned into a control group or an experimental group. The control group received routine therapy with no additional formal input from their family members for the duration of the eight week trial. The experimental group received routine therapy and additional lower limb physiotherapy in the form of family mediated exercises for the duration of the trial. Each participant was assessed at baseline (T1), at eight weeks (T2) and again at three months following completion of the intervention (T3) using a series of standardised outcome measures. In addition, a qualitative interview was completed with each participant with stroke and their family member in the experimental group following completion of the intervention. This mixed methodology allowed the author to gain a more comprehensive understanding of the impact of the FAME programme on levels of recovery and activities of daily living from the perspective of the individual with stroke and his/her family member.

4.2 Rationale

The rationale for this study stems from the findings of the systematic review and meta-analysis of the relevant literature (Galvin et al 2008b), the results of the user surveys (Galvin et al 2009a,b), comments and feedback from peer-reviewers (Appendix 20) and by a gap identified in the research literature around the area of family mediated exercise therapy in people with stroke. The findings from the systematic review and meta-analysis highlighted that additional exercise therapy after stroke had a small but significant impact of function. While the results of the LL meta-analysis did not indicate that additional exercise therapy had a significant impact on LL outcome, only four RCTs were included in the analysis. These results were nearing significance, favouring the hypothesis that additional focused exercise therapy has a positive impact on LL recovery. Furthermore, the narrative review also highlighted that no RCT to date has evaluated the delivery of exercise by people who are not health care workers. However, in a RCT by Lincoln et al (1999), both qualified physiotherapists and physiotherapy assistants delivered two different forms of additional exercise therapy and no differences were noted between the groups. In the study by Lincoln et al (1999), the physiotherapy assistants delivered the exercise intervention following training and supervised practice by the physiotherapist. Finally, in an editorial in the Lancet, De Weerdt and Feys (2002) suggested that 'physiotherapists need to develop strategies whereby patients and caregivers take full responsibility for the bulk of therapy - for instance, training of balance, strength and endurance, repetition of simple tasks, group therapy, fitness-related training and family involvement'. Therefore, the aim of this evidence-based, user informed and centred RCT is to evaluate the impact of increased duration of FAME therapy on outcome in people with acute stroke.

4.3 Sample size calculations

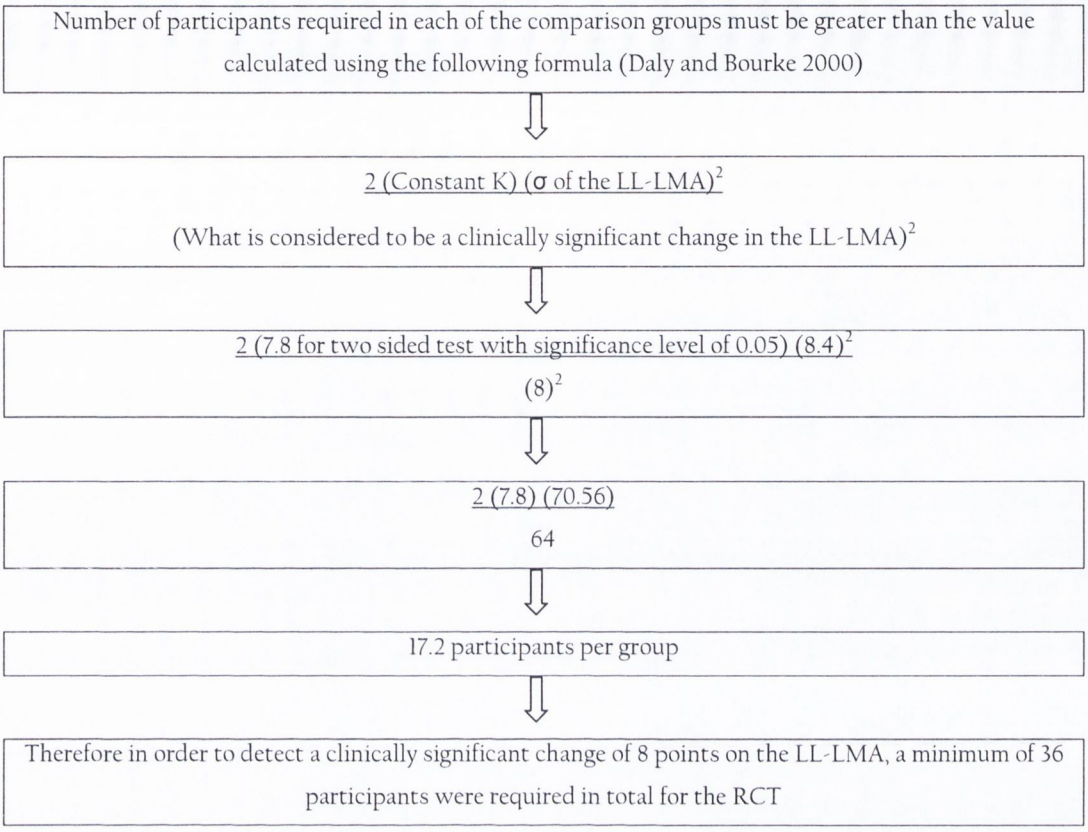
A sample size calculation was performed based on the primary outcome measure, which was the LL section of the Fugl-Meyer Assessment, modified by Lindmark and Hamrin (1988a). This scale is commonly known as the modified Fugl-Meyer Assessment Scale, the Lindmark Adaptation of the Fugl-Meyer Assessment or the Lindmark Motor Assessment (LMA). This measure was chosen as it is a widely used measure of LL impairment in the clinical and research setting and its psychometric properties have been previously established (Lindmark 1988a, Lindmark and Hamrin

1988b, Kierkegaard and Tollbäck 2005). The number of participants required to produce a statistically meaningful change in impairment of the LL was calculated using the power calculation for the comparison of means in two independent samples (Daly and Bourke 2000). The formula used to determine the number of participants required in the RCT involved the prediction of the standard deviation (σ) for the LL-LMA and an anticipated significant clinical change (Δ).

The value for the σ was obtained by completing a CINAHL search for studies that used the LL-LMA as an outcome measure in people with acute stroke. While several studies used the LMA, only two studies reported the baseline LL-LMA scores (Widén Holmqvist et al 1998, Sommerfeld et al 2004). The authors reported the baseline interquartile ranges of the LL-LMA in the study groups. A multiple of 0.75 times the interquartile range was used as a proxy for the σ (Pudar-Hozo et al 2005) and a σ of 8.4 points was obtained. This figure was used to represent the σ of the LL-LMA in the FAME trial. For the motor scores in the LMA, a change of greater than 20% is regarded as clinically meaningful (Martinsson et al 2003), which represents a change of greater than eight points on the LL-LMA. The value of the constant 'K', 7.8, was dictated by the significance level chosen for the study, in this case a two-sided significance level of 5% with an 80% chance of detecting a treatment effect.

Based on a two group comparison (Daly and Bourke 2000), power calculations indicated that a minimum of 36 participants were required to detect an increase of 8 points on the LL-LMA at a two-sided significance level of 5% and a power of 80%, assuming a σ of 8.4 points. Using this output, it was decided that a sample size of 40 participants would be recruited to the FAME RCT to allow for attrition. The sample size calculation is detailed in Figure 4.1.

Figure 4.1: Calculation of the sample size required for the RCT



4.4 Ethical approval

Ethical approval was originally sought and granted in Saint Vincent's University Hospital (Dublin) in September 2007 (See Appendix 21). Thereafter the author applied for ethical approval in a number of other clinical sites in an effort to increase participant numbers. Permission was granted to conduct the RCT in Saint Colmcilles Hospital Loughlinstown (Dublin) based on the ethical approval received from Saint Vincent's University Hospital, the Mater Misercordiae Hospital (Dublin), Beaumont Hospital (Dublin), Our Lady's Hospital Navan (Meath) and Saint James's Hospital (Dublin). A copy of ethical approval for each site is contained in Appendices 22 - 25 respectively.

4.5 Participants

4.5.1 Recruitment

Participants for the study were recruited from the six acute hospitals in the greater Dublin area. Each week a person independent of the research project (usually the senior physiotherapist in neurology in each centre) compiled a register of all people admitted to the hospital with a suspected stroke. The author contacted the senior physiotherapist in neurology in each of the clinical sites on a particular day of the week (nominated by the senior physiotherapist) to discuss the list of admissions.

4.5.2 Level of recovery following stroke

It was clear from the findings of the systematic review described in Chapter 3 that severity of initial impairment has an impact on level of recovery following stroke. Kwakkel (2006) also reported that the impact of additional deliberate practice after stroke is not only defined by the efficacy of the particular programme but also by the identification of those individuals who will benefit most from intensive practice. Therefore those patients who were survivors at two weeks following the confirmed onset of primary stroke were stratified using the Orpington Prognostic Scale (OPS).

The OPS was developed by Kalra and Crome (1993) in order to stratify individuals according to severity of stroke. The OPS is a clinically derived score that incorporates measures of cognitive impairment, motor deficit, balance and proprioception. The score ranges from 1.6 (best prognosis/lowest level of disability) to 6.8 (worst prognosis/highest level of disability) - see Table 4.1. The OPS is widely used as an inclusion criterion by those conducting research as a means of describing stroke severity to ensure that study groups are balanced on prognosis (Rieck and Moreland 2005). In this study, the OPS was chosen to achieve homogeneity between the two study groups. Furthermore, it was administered at two weeks as it has its highest predictive power of levels of dependence when assessed at two weeks following the onset of stroke (Kalra and Crome 1993, Kalra 1994a, Pittock et al 2003). In addition, the scale has been validated for both an older and an Irish stroke population (Kalra and Crome 1993, Horgan et al 2005). The test-retest and inter-rater reliability of the OPS has also been established (Rieck and Moreland 2005).

Table 4.1: Definition of scores on Orpington Prognostic Scale

DEFICIT	PROGNOSIS	OPS SCORE
Mild - moderate deficit	'Best' prognosis	Score < 3.2
Moderate - severe deficit	'Intermediate' prognosis	Score 3.2 - 5.2
Severe - very severe deficit	'Poor' prognosis	Score > 5.2

The author was responsible for assessing all potential participants at two weeks following stroke and determining their suitability for entry to the study, using the documented criteria for inclusion and exclusion. While many of the RCTs included in the systematic review in Chapter 2 failed to state who considered potential participants for inclusion to the RCT (Richards et al 1993, Lincoln et al 1999, Parry et al 1999, Partridge et al 2000, Rodgers et al 2003, Yang et al 2005), other studies used the primary researcher to determine eligibility (Sunderland et al 1992, Feys et al 1998, Blennerhassett and Dite 2004, GAPS group 2004, Ada et al 2005, Platz et al 2005). People with stroke who achieved a score between 3.2 - 5.2 on the OPS at two weeks following stroke were recruited to the FAME study. This cohort of individuals consisted of people presenting with a 'moderate/severe' deficit following stroke.

4.5.3 Inclusion criteria

Person with stroke

Individuals who fulfilled the following inclusion criteria were admitted into the study:

- A formal diagnosis of first unilateral stroke

  '*Formal diagnosis*' was defined as diagnosis using results from magnetic resonance imaging (MRI) or computed axial tomography (CAT) scans

  '*Stroke*' was defined as a 'rapidly developing clinical signs of focal (at times global) disturbance of cerebral function lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin' (Hatano 1976)
- Admission to the participating hospitals following onset of stroke and an inpatient two weeks post onset of stroke
- Score between 3.2 - 5.2 on the OPS at two weeks following stroke
- Over 18 years of age
- Participation in a physiotherapy programme at two weeks following stroke

- Willing to give informed written consent
- Individuals with a nominated 'family members/friend' willing to participate in their assigned physiotherapy intervention programme

'Family member/friend'

'Family member/friends' of the person with stroke who fulfilled the following inclusion criteria were admitted into the study:

- 'Family member/friend' with a 'formal diagnosis' of primary stroke, satisfying the inclusion criteria and willing to participate in the RCT
- The individual with stroke must have nominated this person as the 'family member/friend' that he/she would most like to assist him/her in the performance of the prescribed exercises
- There was a requirement that the person was medically stable and physically able to assist in the delivery of exercises to his/her 'family member/friend' with stroke. Suitability was determined in liaison with the family and physiotherapist in charge on the patients' routine care.
- Informed written consent was required prior to inclusion in the study

4.5.4 Exclusion Criteria

Person with stroke

- Hemiplegia of a non-vascular origin (e.g. aneurysm, trauma)
- Discharge from hospital less than two weeks following stroke
- Less than 18 years of age
- 'Formal diagnosis' of a previous stroke
- OPS score of less than 3.2 or greater than 5.2 at two weeks following stroke
- Pre-existing neurological disorder such as Parkinson's Disease or Multiple Sclerosis, resulting in a motor deficit in addition to that resulting from the stroke
- Presence of any LL orthopaedic condition such as recent fractured femur or amputation that may limit exercise capacity and assessment of mobility
- Individuals with aphasia - the author liaised with the treating Speech and Language Therapist (SALT) and in the event of a query on presence of

aphasia, the Frenchay Aphasia Screening Test (FAST) was administered by the SALT.

- Individuals with a cognitive impairment - this was determined by a score of less than 24/30 on the Mini Mental State Examination (MMSE)
- Individuals not receiving physiotherapy after their stroke
- Individuals not willing to give written consent
- Individuals whose nominated 'family members/friend' was not willing to participate in the research study

'Family members/friend'

- Individuals who were not medically stable or physically able to assist in the delivery of exercises to the person with the stroke
- Individuals who were not willing to give informed written consent

4.6 Consent

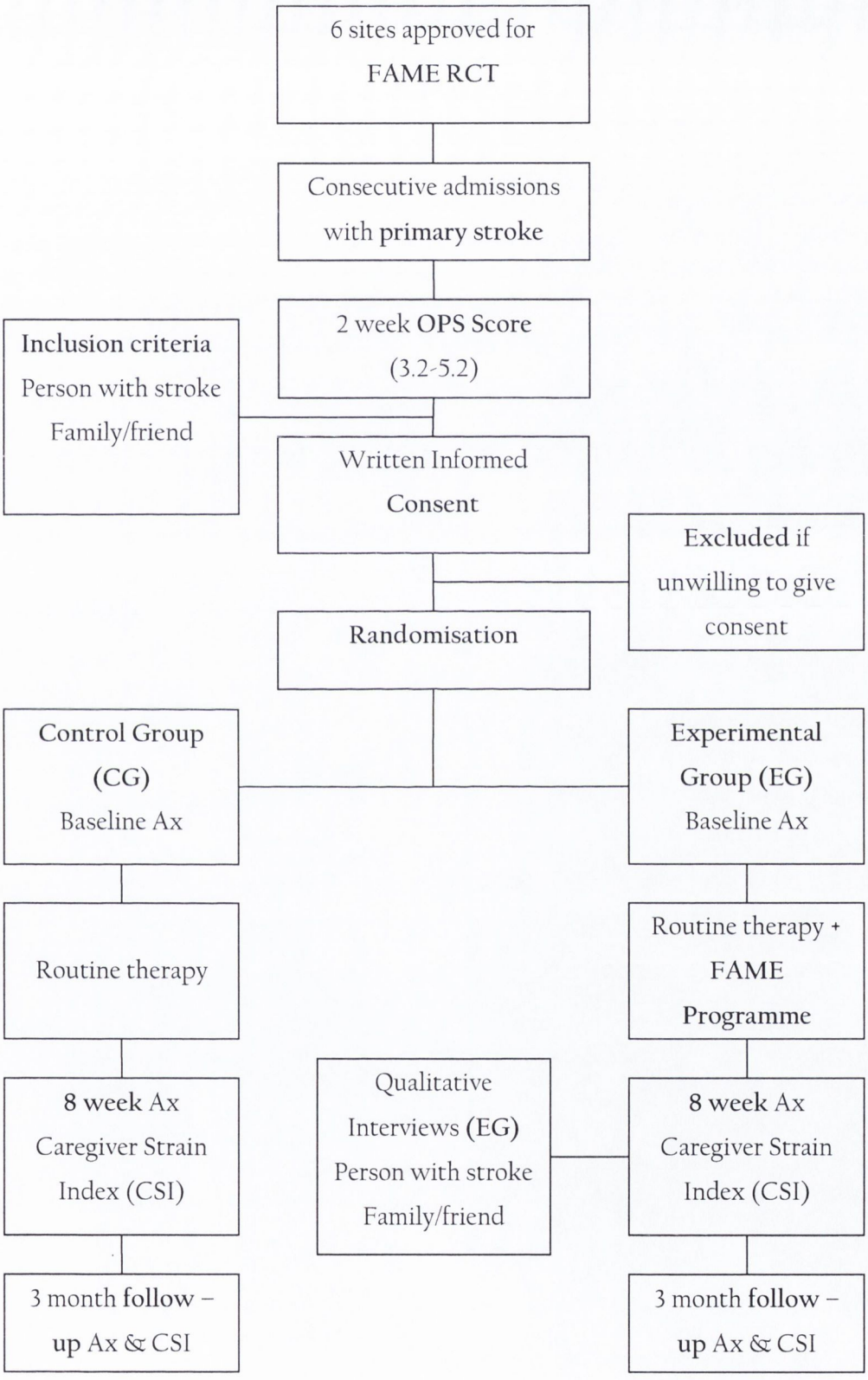
Following identification of suitable participants (individual with stroke and their nominated 'family member/friend'), a face-to-face meeting was arranged with the author where the aims of the project, including the role of the individual with stroke and his/her 'family member/friend' in the FAME project, were outlined. Both individuals received a separate information brochure (See Appendices 26 and 27 respectively). Participants were given up to seven days between receipt of the information brochure and being requested to give written permission.

A second meeting was then arranged between the author and the participants. During this meeting the author answered/clarified any further questions that arose and at the end of the meeting the person with stroke and his/her 'family member/friend' were requested to sign a consent form in the presence of each other (See Appendix 28). They were then allocated to the experimental/FAME group or the control group by random group allocation. If either person was unwilling to give written consent, they were excluded from the study.

4.7 Randomisation

To minimise the possibility of recruitment bias, a person independent of the recruitment process completed random group allocation. With random assignment, the aim is to give all participants an equal chance of being assigned to either the experimental group or the control group. By assigning participants at random, it is possible to infer that any observed group differences are attributable to the independent variable. Computer generated random numbers were created and placed in sealed envelopes by this independent person. These numbers were stored in the pre-sealed envelopes in a locked drawer in the Discipline of Physiotherapy at Trinity College. Allocation was revealed after recruitment by a telephone call from the author to the independent person, who opened the next envelope in the sequence and gave the randomisation information to the author. Each envelope was opened on enrollment of an eligible participant. After allocation was revealed, the appropriate intervention was organised by the author. The process from screening to enrollment is outlined in Figure 4.2.

Figure 4.2: Outline of FAME study design



4.8 Description of interventions

4.8.1 Control group

Members of the control group received 'conventional', 'routine' or 'traditional' levels of physiotherapy for the duration of the trial, which was delivered by the physiotherapy staff at the individual sites. Participants did not receive any additional structured physiotherapy intervention in the form of family mediated exercises. A placebo group, or a group that would receive 'sham' exercises such as additional upper limb exercises, was considered during the development of the RCT. However the logistics of demonstrating upper limb exercises to 20 family members in such a placebo group, in terms of time required to teach the exercises, correct positioning technique and the provision of support was not feasible but should be considered in future trials.

Routine therapy

'Routine' inpatient physiotherapy following acute stroke in hospitals and rehabilitation units in Ireland varies between and within centres. However, a previous piece of research (Galvin et al 2009b) conducted with people with acute stroke in the Dublin area and senior physiotherapists indicated that 'routine' physiotherapy following acute stroke generally consisted of physiotherapy every weekday for a period of 30-60 minutes. In the outpatient setting, the senior physiotherapists reported that 'routine' physiotherapy generally consisted of physiotherapy once a week for a period of 45-60 minutes.

The frequency and duration of 'routine' physiotherapy received by each individual in the control and experimental group was not documented in this study as this was beyond the scope of the project. The logistics of arranging the treating physiotherapist and/or occupational therapist to document the frequency and duration of each session in each centre was not possible due to the number of centres involved, changing staff grade rotations and annual leave. Furthermore, some participants were transferred to different areas of the hospital and were treated by different physiotherapists during the course of the RCT. While the author accepts that the 'routine' physiotherapy varied between the participants due to the multi-centre nature of the trial and the discharge outcome of some participants, this is 'routine' physiotherapy practice in all of these centres. Furthermore, in previous multi-centre studies that have examined the impact

of additional exercise therapy on people with acute stroke, the frequency and duration of 'routine' physiotherapy was not documented by the authors (See Chapter 2, Table 2.2 - 2.5).

Multi-centre trial

While there was a requirement to recruit individuals with stroke from different centres in order to achieve an adequate sample size, the levels of routine therapy in each of the centres were not recorded. Despite the evidence supporting the benefits of stroke unit care, and the recommendations of the Irish Heart Foundation Stroke Report (2001), the Republic of Ireland is at present very underdeveloped with regard to the provision of specialised stroke units in the acute hospital setting and only one of the centres included in the FAME trial had a dedicated stroke unit. However, the majority of participants (n=34) included in the trial were assessed by a physiotherapist within 72 hours of admission. The remaining participants were assessed within 96 hours following admission. Participants' access to other multi-disciplinary services such as occupational therapy and speech and language therapy was not recorded as part of the trial. In the centres with no dedicated stroke unit, participants were treated on a general medical ward for the duration of their inpatient stay. There was no significant difference in the proportion of individuals allocated to either the control or the FAME group in any of the centres ($p<0.001$).

4.8.2 Experimental/FAME group

Similar to the control group, participants in the experimental group received 'conventional', 'routine' or 'traditional' levels of physiotherapy for the duration of the trial, which was delivered by the physiotherapy staff in the hospital. The frequency and duration of 'routine' therapy was not recorded. In addition to their 'routine' physiotherapy, members of the experimental group were given special individualised FAME programmes. Each programme consisted of training a nominated 'family member/friend' with the necessary skills to carry out the exercise-training programme with the person with stroke at the person's bedside/on the ward. This individualised intervention was designed and delivered by the author.

Duration of intervention

The output of the systematic review and meta-analysis contained in Chapter 2 (Galvin et al 2008b) suggested that in studies where a significant impact of additional exercise therapy was demonstrated, at least an additional 900-1200 minutes of additional exercise was delivered during a period of 4 to 6 weeks, although this varied between studies. Similar findings were noted in a previous review of additional therapy (Kwakkel et al 2004) where the researchers concluded that although the required exact dose of practice for functional effects to take place varied, a minimal duration of at least 960 minutes was necessary. The mode duration of all the trials included in the review presented in Chapter 2 was seven weeks.

Based on the output from the two reviews (Kwakkel et al 1999, Galvin et al 2008b), it was decided that the trial would continue for a period of eight weeks with an expectation that at least 1200 additional minutes of FAME therapy would be delivered over this time period. Each FAME session was expected to last 35 minutes. Furthermore, there was a requirement that the nominated 'family member/friend' of the person with the stroke would deliver these exercises on a daily basis, including weekends, for the duration of the trial. One hundred percent compliance with the programme would result in the person with stroke receiving 1960 minutes additional exercise therapy over an eight-week period.

Content of FAME programme

The emphasis of the LL exercise programme was to strengthen the LL through functional exercises, achieve optimal stability and balance in sitting and standing and to improve gait velocity. Exercises were designed appropriate to the participants' ability. Exercises completed by participants in the experimental group included repetitive sit to stand exercises with an emphasis on improving symmetry, weight bearing exercises during standing, bridging, straight leg raises, quadriceps strengthening exercises, active/active assisted range of movement exercises for the LL, balance activities in sitting and standing and walking activities. These exercises were based on patterns derived from findings reported in a review of 151 intervention studies on stroke rehabilitation (Van Peppen et al 2004). The findings from this review were discussed in Chapter 1 (Section 1.3.3).

Progression of FAME programme

On the first day of the FAME programme, the person with the stroke and his/her 'family member/friend' were required to meet with the author at the bedside of the person with stroke (at a time convenient for both the person with stroke and the nominated 'family member/friend').This initial meeting with the family members usually comprised of a one hour consultation, where the author demonstrated basic manual handling techniques to the family members. The purpose of this session was to provide the 'family member/friend' with the knowledge and skills necessary to complete a series of lower limb exercises with the person with stroke. This session and subsequent sessions were individual and specific to the needs of the family and the individual with stroke. The initial session consisted of training the family members on safe methods to assist the individual with stroke from supine to to side-lying and to sitting over the edge of the bed. Safe transfers were also taught and correct handing of the weaker upper limb during exercise delivery (where required) was demonstrated. In the event of the persin with stroke requiring assistance of more than one person to transfer, the family member was instructed to ask one of the nursing staff to assist with the transfer. All nursing staff on the ward were informed of group allocation of each participant. Family members were provided with the opportunity to practice the handling techniques during all sessions under the supervision of the research physiotherapist. In addition, the nominated family member was advised to contact the research physiotherapist in the event of any problems arising with the exercise delivery. Families were provided with written instructions on how to perform these manaul handling and exercise activities each week.

A series of five repetitive exercises were designed by the author, in consultation with the physiotherapist treating the individual, prior to this meeting. Following a demonstration of the exercises by the author, the nominated 'family member/friend' was given supervised practice time to complete these exercises. The nominated 'family member/friend' was then requested to fill out an exercise log/diary (similar to that outlined in Appendix 29) everyday, following completion of the documented exercises. The exercise diary contained details of the daily exercise programme and the 'family member/friend' was required to tick as appropriate whether the exercises were completed.

Each week (for eight weeks), the author met with the nominated 'family member/friend' and the individual with the stroke to review the exercise programme. The series of exercises were progressed and new exercises were demonstrated each week, depending on the individuals' ability. Throughout the programme, the nominated 'family member/friend' was encouraged to contact the author by telephone if there was an issue with exercise delivery and the necessary support was arranged and documented by the author. At the end of the programme, the author encouraged all participants and their family members who undertook the additional programme to continue with their family mediated exercise therapy. All participants in the control group were advised to continue on with their prescribed care package that may or may not have included physiotherapy input.

4.9 Outcome measurement

Recent years have seen continued technical advances in the methods used to develop and assess health measurement instruments (McDowell 2006). Methods of expressing validity, reliability and sensitivity to change and the correct interpretation of the results of these methods are important when assessing the properties of the various outcome measures. The measures used in this study were chosen to reflect recovery of the LL at the level of impairment, activity and participation and also because the psychometric properties of the measures have been previously examined. Measurement properties are discussed in the following sections and the properties of the various outcome measures are outlined.

4.9.1 Measurement properties

Reliability

Reliability or consistency is concerned with error in measurement. It refers to the consistency or stability of the measurement process across time, patients or raters (McDowell 2006). There are three distinct subsections of reliability. Test-retest reliability refers to the assessment of individuals on different occasions using the same assessment format, when the status of the individual is not expected to have changed (Finch et al 2002). Inter-rater reliability refers to the assessment of an individual by different raters at the same time. Internal consistency refers to the ability of the

measure to generate similar results when the components of a test are applied in a different order. This subsection of reliability is primarily concerned with multidimensional scales and questionnaires.

Reliability can be expressed as either relative reliability or absolute reliability. Relative reliability refers to the ability of a measure to distinguish among different patient groups and is generally expressed as an intraclass correlation coefficient (ICC). ICCs refer to a family of analysis of variance that express reliability as the ratio of variance between individuals to total variance in scores. A graphical approach described by Bland and Altman is also used (McDowell 2006). Previous researchers have used linear correlations in the form of Pearson or Spearman correlations as a relative reliability index. However, there are two inherent flaws with the linear method of correlation. Firstly, this method only considers the relationship between two measurements and secondly, due to the linear nature of correlation, it is not sensitive to systematic differences between measurements. For example, if one rater consistently documents higher values than the second rater, the Pearson or Spearman linear correlation (r) model will report a 'false' high reliability of measurement.

The second method of expressing the reliability of a measure is to express the measurement error in the same units as the original measure. This is termed absolute reliability and is expressed using the standard error of the measure (SEM) which can be calculated in a number of ways (McDowell 2006). Only one assessor was responsible for all quantitative assessments, therefore test-retest reliability and the SEM are only included in the discussion of the psychometric properties of each individual measure.

Validity

The core concept of validity concerns the meaning, or interpretation of the scores on a measure. Validity has previously been described as the extent to which a measure assesses what it is intended to measure (McDowell 2006, Finch et al 2002). However, there has been a shift from this definition of validity as many measures may have other uses than those originally intended for them. A more general definition holds that validity describes the range of interpretations that can be appropriately placed on a measurement score. This shift in definition is significant in that validity is no longer a

property of the measurement, but rather of the interpretation placed on the results (McDowell 2006). Validity can be expressed as face, content, construct or criterion validity (Finch et al 2002). Face validity considers whether a measure appears to be assessing what it is actually intended to measure. For example, if a measure is designed to evaluate LL impairment, one would expect to see items examining range of movement, strength and other impairments of the LL. Content validity refers to extent to which the measure examines all aspects of the domain of interest. For example if the goal is to examine balance, one would expect to see items that examine static and dynamic balance in sitting and standing. Criterion validity considers whether scores on the instrument agree with a definitive 'gold standard' measurement of the same theme. Criterion validity can be concurrent or predictive in nature. Concurrent validity compares the output of the measure under investigation to the output of the 'gold standard' measure that is obtained at approximately the same point in time. Predictive validity refers to the ability of the measure to predict some subsequent criterion event. For example, a score generated by a measure of balance may be used to predict future risk of falling. Construct validity refers to the validation of an instrument through the examination of its components and the way in which they relate to other constructs. This can be further sub-divided into convergent validity, where the measure is compared to another measure (not the 'gold standard') that assesses the same attribute, known group validity, where two or more distinct groups are assessed to examine the ability of the measure to represent different levels of the attribute of interest, or discriminant validity, where the measure is correlated with measures of attributes that are different from the attributes that the measures is designed to assess (Finch et al 2002). The construct (convergent) validity of each measure is reported in the following sections. Correlation coefficients are often used to quantify the convergent validity of a measure (Finch et al 2002).

Sensitivity to change

The term sensitivity to change refers to a measures ability to capture change that actually occurs (McDowell 2006). While the terms sensitivity to change and responsiveness have been used interchangeably in the past (Finch et al 2002), Liang (2000) suggests that the term responsiveness refers to 'the ability of an instrument to measure a meaningful or clinically important change in a clinical state' whereas the

term sensitivity refers to 'the ability of an instrument to measure change in a state regardless of whether it is relevant or meaningful to the decision maker'. The ability of a measure to detect change, without making a reference to whether the change is clinically meaningful or not, is also referred to as longitudinal validity and can be measured by calculating an effect size (change in mean score/standard deviation at baseline) or the standardized response mean (change in mean score/standard deviation of change scores). Other approaches include the application of specific t-tests and responsiveness statistics (McDowell 2006). The term sensitivity will be used in this section to reflect the ability of the particular measures to capture small amounts of change that are not necessarily clinically meaningful.

4.10 Quantitative measures

The demographic details of each participant including age, gender, side of stroke, date of onset of stroke, CT/MRI scan result, name of nominated family member and date of initial 'routine' physiotherapy intervention were recorded at baseline. A record of length of hospital stay and discharge location was also documented for each participant.

All participants were assessed on admission to the study (T1) using a battery of outcome measures at the level of impairment, activity and participation. This assessment was completed by an independent assessor blinded to group allocation and familiar with the battery of outcome measures used in the research. This independent assessor is a qualified physiotherapist[3], who is currently completing a research MSc. in the area of stroke rehabilitation in the Discipline of Physiotherapy at Trinity College. The outcome measures were repeated at the end of the eight week trial (T2) and at three month follow-up assessment point (T3) by the same assessor. Quantitative outcome measures were initially recorded in paper format. The battery of outcome measures used in the RCT is contained in Appendix 30. The results of these measures were then stored securely in individual patient files together with the consent forms (Appendix 28). The measurements were later transferred to computer files in order to facilitate statistical analysis.

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4.10.1 Primary standardised outcome measure

Lindmark Motor Assessment

The primary outcome measure used in this trial was the Lindmark adaptation (Lindmark and Hamrin 1988a) of the Fugl Meyer Assessment (LL-FMA) (Fugl-Meyer et al 1975). The Lindmark Motor Assessment (LMA) was designed as a modification of the original Fugl-Meyer assessment method (Lyden and Lau 1991, Kierkegaard and Tollbäck 2005). The LL section (Part A) of the LMA differs from the LL section (Parts E and F) of the original FMA in three ways. Firstly, both the paretic and non-paretic sides are evaluated in the LL-LMA while the paretic side is only evaluated in the original scale. Secondly, while both scales contain an ordinal scale for the grading of items, the original FMA scores each item on a three point scale from 0-2 points whereas the LMA scores each item on a four point scale from 0-3 points. In both scales, a score of 0 indicates that the person is unable to perform the movement and a score of 2 on the FMA or a score of 3 on the LMA indicates that the person can perform the movement normally. Gladstone et al (2002) suggest that expanding the grading system of the original scale contributes to the ability of the scale to detect change. Thirdly, the assessment of LL reflex activity has been excluded from the LMA and the evaluation of coordination is contained in a separate section (Part B). The total score for the LL-FMA is 34 points and the total score for the paretic side of LL-LMA scale is 36 points. The LL-LMA, contained in Appendix 30, consists of 12 items that reflect the individual's ability to perform selective active movements in supine, sitting and supported standing.

Test-retest reliability and SEM

Kierkegaard and Tollbäck (2005) examined the test-retest reliability of the LMA in 21 individuals with acute stroke. The participants were rated by three physiotherapists with 2 to 16 years experience in neurological rehabilitation. Kappa statistics were used to calculate the test-retest reliability. With regard to the LL-LMA, the kappa coefficients ranged from 0.79 to 0.87, indicating a high level of reliability. The percentage agreement between raters was not reported. Lindmark (1988a) also examined the test-retest reliability in 28 people more than six months following stroke onset and reported a correlation coefficient of 0.98 for the entire scale. While the statistical methods used in this study were not optimal, the results would suggest that the scale is reliable in the measurement of post-stroke impairment. Test-retest

reliability of the original FMA was examined by Beckerman et al (1996). Forty nine people with chronic stroke were examined on two occasions, three weeks apart by a physiotherapist and the ICC reported for the LL-FMA was 0.84, indicating a high level of correlation. Test retest reliability of the FMA was also examined in 19 people with chronic stroke by Duncan et al (1983). A Pearson correlation of 0.96 was reported for the LL-FMA.

The SEM of the LL-LMA has not been reported to date. However Martinsson et al (2003) suggest that an increase of 50 points on the motor score (maximum 210 points) represents a clinically meaningful change. This equates to a change of 8 points on the LL-LMA. Beckerman et al (1996) examined the stability of the LL-FMA in 49 people with chronic stroke and reported a SEM of 1.76 points. The error threshold (a criterion to differentiate real changes from changes due to chance variation or measurement error) was also calculated and yielded a score of 5 points, indicating that a change of 5 points or more is necessary on the LL-FMA to determine that the changes are real rather than due to a measurement error.

Construct validity

Lindmark and Hamrin (1988b) compared the LMA to the FMA in 107 people with acute stroke and reported a Spearman correlation of 0.95 in the motor scores. A further 124 individuals with acute stroke were also assessed using the FMA and the LMA and a Spearman correlation of 0.98 was reported for the motor scores (Lindmark and Hamrin 1988b). These results indicate a high level of concurrent validity of the LMA.

Sensitivity to change

The sensitivity of the LL-LMA has not been examined to date. The sensitivity of the FMA to capture change in 118 individuals with acute stroke following five weeks of rehabilitation was examined by Wood-Dauphinee et al (1990) and the authors reported an effect size of 0.19. Malouin et al (1994) compared the distribution of scores on the MAS to the original FMA in 32 people with acute stroke on two consecutive days. A cumulative frequency distribution analysis indicated that a larger proportion of individuals were found in the lower class interval scores of the MAS in comparison to the FMA, suggesting that the FMA is more sensitive to level of motor recovery in people with a greater level of impairment in the early stages after stroke.

4.10.2 Secondary standardised outcome measures

A series of secondary outcome measures were also used to document participants' recovery including the Motor Assessment Scale (MAS), the Berg Balance Scale (BBS), the Six Minute Walk Test (SMWT) and the Barthel Index (BI). These outcome measures were administered on entry into the study, post intervention and finally at the three month follow-up by the same blinded assessor. The Re-integration to Normal Living Index (RNLI) and the Nottingham Extended Activities of Daily Living Index (N-EADL) were used to record participants' level of participation and were administered post-intervention and at the three month follow up assessment. The series of secondary outcome measures were chosen to reflect recovery at the level of activity and participation and also because the properties of the measures had been previously examined.

Motor Assessment Scale

The MAS was developed by Janet Carr and Roberta Shepherd (Carr et al 1985) to assess individuals with stroke using relevant and functional motor activities. It is a performance-based measure and consists of eight items intended to measure motor function and one item related to muscle tone on the affected side. Each item is scored on a seven point scale from 0 - 6. The motor functions tested are supine to side lying, supine to sitting over the side of the bed, balanced sitting, sitting to standing, walking, upper arm function, hand movements and advanced hand activities. For each section of the MAS, a score of six indicates the optimal motor behaviour. The maximum score for the MAS is 48. The category of general tonus was initially included to gain an impression about the presence of excessive or depressed motor activity. However this category was later excluded the section in a later version of the scale due to the subjective nature of muscle testing (Loewen and Anderson 1988).

Test-retest reliability and SEM

In the first assessment of test-retest reliability of the MAS, the developers (Carr et al 1985) reported results on 14 people with chronic stroke when assessed by one therapist on two occasions separated by a four week interval. A Pearson correlation was used to determine reliability and an average correlation of 0.98 was reported, indicating high levels of reliability. Loewen and Anderson (1988) also investigated the test-retest reliability of the MAS (excluding section on tone). Seven inpatients with stroke were

video-recorded completing the MAS. Fourteen therapists were asked to rate the performance of the individuals and this procedure was repeated one month later. A Spearman correlation of 0.81 was recorded for one therapist and 1.0 was recorded for three therapists, with 85% of kappa values indicating excellent levels of agreement (k › 0.75). While the methods used to examine reliability may not have been optimal, the results indicate a high level of test-retest reliability of the MAS. The SEM of the MAS has not been established to date.

Construct validity

Poole and Whitney (1988) compared the MAS to the FMA in 30 people with stroke (acute and chronic) and reported a Spearman correlation of 0.88 in total scores. Selected items on the MAS were then compared to corresponding items on the FMA and correlations ranged from 0.64 to 0.92, except for sitting balance 0.28. The authors suggest that this may due to a difference in the construct of the tests (the MAS examines sitting balance during a dynamic task rather than in response to an external disturbance). Malouin et al (1994) also assessed the validity of the MAS when compared to the FMA in 32 people with acute stroke and reported a Spearman correlation of 0.96 for the total scores in both measures. Similar to the results of the previous study, the correlations for selected items on the MAS and corresponding items on the FMA range from 0.65 to 0.92, except for sitting balance (r =-0.10).

Sensitivity to change

The sensitivity of the MAS to capture change was examined by English et al (2006). Sixty one participants with stroke were assessed within one week of admission and one week of discharge from a rehabilitation facility. Effect sizes ranged from 0.36 (for upper arm function) to 1.03 (rolling). The UL items demonstrated the smallest effect sizes whereas the LL activities yielded effect sizes from 0.61 to 1.03. Malouin et al (1994) also compared the distribution of scores on the MAS to the FMA in 32 people with acute stroke and findings indicated that the FMA was more sensitive in discriminating recovery levels in people with a higher level of impairment early after stroke. This finding may be due to the difference in the construct of the scales - the MAS is an activity based measure whereas the FMA is an impairment based measure.

Berg Balance Scale

The BBS was developed by Berg et al (1989) and is a 14-item performance based measure intended for individuals with some degree of balance impairment. Each item is scored on a 5 point scale (0-4). Higher scores are awarded for independent performance of activities that meet specific time and distance requirements. The maximum score is 56 points. The BBS measures both static and dynamic aspects of balance in sitting and standing.

Test-retest reliability and SEM

Berg et al (1995) examined the test-retest reliability of the BBS in 6 individuals with acute stroke. Seven raters assessed the individuals on two occasions, one week apart. An excellent level of test-retest reliability was reported (ICC=0.99). The test-retest reliability of the BBS was examined by Liston and Brouwer (1996) in 20 people with chronic stroke. Data was collected on three occasions, one week apart and an ICC of 0.98 was reported. These results suggest that the BBS is a reliable measure for use in people with stroke.

Stevenson (2001) examined the stability of the BBS in 48 people with acute stroke and reported a SEM of 2.49 points. The minimal detectable change was also calculated in all subjects and yielded a score of 6.9 points, indicating that a change of 7 points or more are necessary in the BBS to determine that the changes are real rather than due to a measurement error. Individuals in this study were also subdivided (according to scores on the Functional Ambulation Classification) into those who were independent (n=15), those who required standby assistance (n=17) and those who required physical assistance (n=16). SEMs were also reported for these sub-groups and were 2.26, 2.15 and 2.93 respectively.

Construct validity

Berg et al (1992) periodically rated 70 people with acute stroke over a period of three months for functional independence (BI), motor performance (FMA) and balance (BBS). The authors reported correlations in excess of 0.80 between total BBS scores and total and sub-scale BI scores. Additionally, correlations in excess of 0.70 between total BBS scores and total FMA scores and in excess of 0.84 with scores on the balance subscale of the FMA were reported. Liston and Brouwer (1996) compared the BBS to

the 10-metre timed gait test and reported a Pearson correlation of 0.81 between total BBS scores and gait speed in the 20 participants with chronic stroke.

Sensitivity to change

The sensitivity of the BBS to capture change in people with stroke was examined by English et al (2006). Sixty one individuals with stroke were assessed within one week of admission and one week of discharge from a rehabilitation facility. The effect size reported for the BBS was 1.01 indicating a high level of sensitivity. Salbach et al (2001) also examined the responsiveness of the measure in 50 people with acute stroke. Participants were following admission and at one month after stroke. The authors reported a standardised response mean of 1.04 suggesting that the BBS is sensitive to change in people with acute stroke.

Six Minute Walk Test

The SMWT (Butland et al 1982) was originally designed as a sub-maximal measure of exercise tolerance among individuals with respiratory disease. The SMWT is a performance based test. Distance walked (including number and duration of rests) in six minutes is measured and reported in metres or feet.

Test-retest reliability and SEM

The reliability of the SMWT in measuring gait performance in people with stroke has been examined by Flansbjer et al (2005). Fifty people at various levels of recovery following stroke were tested on two occasions, one week apart and an ICC of 0.99 was reported. Kosak and Smith (2005) also examined the test-retest reliability of the SMWT in 18 people with acute stroke and reported an ICC of 0.74.

Perera et al (2006) investigated the stability of the SMWT in 100 people with sub-acute stroke and reported a SEM of 22 metres. Flansbjer et al (2005) also examined the stability of the SMWT in 50 people with stroke and reported a SEM of 18.6 metres. The smallest real difference (another criterion to differentiate real change from change due to chance variation or measurement error) was also calculated and expressed as a percentage value. The finding indicated that the size of the relative change in performance on the SMWT should exceed 13% to detect real change.

Construct validity

Kosak and Smith (2005) compared the SMWT to two other gait tests, the 2 and 12 minute walk tests in 18 individuals with acute stroke. All assessments were administered by the same assessor on the same day. Pearson correlations for the 2 and 6 minute walk tests yielded coefficient of 0.997 and a coefficient of 0.994 for the 6 and 12 minute walk tests. Flansbjer et al (2005) compared the SMWT to the Timed Up and Go test on two different occasions and reported inverse Pearson correlations of -0.89 to -0.92. The findings from these studies indicate a high level of construct validity in people with stroke.

Sensitivity to change

Kosak and Smith (2005) examined the sensitivity of the SMWT in 18 people with acute stroke over a 4 week period. The authors reported a standardised response mean of 1.52 suggesting that the SWMT is sensitive to capturing change when used to measure distance walked in this population.

Barthel Index

The BI (Mahoney and Barthel 1965) was developed to measure functional independence in personal care and mobility. The BI is 10-item performance based instrument that evaluates activities of daily living. Scores range between 0 and 100, with a score of 100 indicating the highest level of independence. Each item is assigned a score of 5, 10 or 15 - items are weighted differently reflecting the relative importance of each type of disability in terms of the assistance required. The items assessed are feeding, transfers, personal hygiene, dressing, toileting, bathing, mobility (including wheelchair) and ability to ascend/descend stairs.

Test-retest reliability and SEM

The test-retest reliability of the BI was examined by Wolfe et al (1991) in 14 people with sub-acute stroke. Assessments were recorded by the same assessor on two occasions two weeks apart. A weighted kappa coefficient was calculated and yielded a score of 0.98. The test-retest reliability among three different assessors was also calculated on a total of 50 individuals with stroke and a weighted kappa score of 0.96 was recorded. The SEM of the 100 point BI has not been established to date.

Construct validity

The BI was compared to the Motricity Index by Wade and Hewer (1987) in 572 people with acute stroke. A Pearson correlation of 0.77 was reported for total scores on both scales. The BI also achieved a significant correlation with the Kenny Self-Care Evaluation (r=0.73) and the Katz Index of Activities of Daily Living (K=0.77) in 148 people with stroke (Gresham et al 1980).

Sensitivity to change and SEM

Salbach et al (2001) examined the responsiveness of the BI in 50 people with acute stroke. Participants were assessed following admission and at one month after stroke. The authors reported a standardised response mean of 0.99 suggesting that the BI is sensitive to change in people with acute stroke. Van der Putten et al (1999) also examined the sensitivity of the BI in 82 people with acute stroke at admission and discharge and reported an effect size of 0.95 indicating a high level of sensitivity of the BI.

Re-integration to Normal Living Index

The Re-integration to Normal Living Index (RNLI) (Wood-Dauphinee and Williams 1987) is an outcome measure designed to assess how well individuals return to normal living patterns following illness or injury. The 11-item instrument is designed to assess personal satisfaction with performance of everyday activities. Concepts measured by the RNLI include indoor, community and distance mobility, self care, daily, recreational and social activity, general coping skills, family roles, personal relationships and self-perception in the company of others. Each domain is accompanied by a 4-point categorical scale where the anchors are 'does not describe my situation' (1 point) to 'fully describes my situation' (4 points). The response to each domain is calculated and a maximum score of 44 can be obtained. Higher scores denote better integration. The RNLI can be interview administered face to face or by telephone, self-completed or completed by proxy (Finch et al 2002).

Test-retest reliability and SEM

The test-retest reliability of the postal version of the questionnaire was examined by Daneski et al (2003) on 26 people with sub-acute stroke. The kappa statistic was used to assess levels of agreement between the responses on the two occasions (two weeks

apart) for each of the 11 individual questions. The coefficients ranged from 0.38 (level of comfort in the company of others) to 0.92 (outdoor mobility). The SEM of the RNLI has not been reported to date.

Construct validity

The RNLI was compared to the Activities-specific Balance Confidence Scale (self-report balance efficacy scale) in 63 community dwelling people with stroke and yielded a Pearson correlation of 0.527. The construct validity of the postal version of the questionnaire was also examined by Daneski et al (2003) in a sample of 76 people with stroke. The RNLI was compared to the BI and a correlation of 0.42 on the total score was reported. The measure was also compared to the Frenchay Activities Index (Pearson correlation 0.69) and the Short Form 36 Health Survey (Pearson correlation 0.74).

Sensitivity to change

Wood-Dauphinee et al (1988) examined the sensitivity of the RNLI in 109 people with various illnesses, including 10 people with stroke. Individuals were assessed shortly after discharge from hospital and again three months later. Eighty-five percent of the cohort reported a two point change in at least one item of the RNLI. Of these participants, the average number of items to change was 3.7. The mean change in score between assessments was 6.75 points, which was statistically significant. While the authors did not report individual scores for people with stroke, the findings suggest that the RNLI is sensitive to change over a period of three months.

Nottingham Extended Activities of Daily Living Index

The N-EADL index was developed by Nouri and Lincoln (1987) to measure instrumental activities of daily living (activities that are not essential to basic functional independence but are needed to achieve independence in the community). The N-EADL is a self-report questionnaire that comprises 21 items grouped into 4 categories including mobility, kitchen tasks, domestic activities and leisure activities. Scoring for each item is hierarchical in order with 4 possible responses (rated from 0 to 3 points). The maximum score attainable on the scale is 63 indicating the highest level of independence. The N-EADL can be interview administered (face to face or over the telephone) or self-completed.

Test-retest reliability and SEM

The test-retest reliability of the N-EADL was examined by Green et al (2001) in 22 people with chronic stroke. Individuals were assessed by one assessor on two occasions at an interval of one week. Agreement between the individual items on the scale was investigated using percentage agreement and the kappa statistic. The percentage agreement was greater than 65% for all items in the scale (range 65%-95%). Kappa coefficients ranged from 0.30 (outdoor mobility) to 0.89 (climbing stairs). Gompertz et al (1993) also examined the test-retest reliability of the N-EADL and reported a Spearman correlation of 0.92 between the scores which were obtained in 121 people with stroke two weeks apart.

The error threshold reported by Green et al (2001) in their study of 22 people with chronic stroke was 5.6 points, indicating that a change of 6 points or more is necessary in the N-EADL to determine that the changes are real rather than due to a measurement error.

Construct validity

The N-EADL was compared to the Barthel Index by Hsueh et al (2000) in a telephone interview of 153 people with chronic stroke. A Spearman correlation of 0.69 was reported for the total scores of both scales.

Sensitivity to change

Hsueh et al (2000) compared the distribution of scores on the N-EADL to the BI and findings indicated that the N-EADL was more sensitive in capturing changes in recovery than the BI. The BI demonstrated a ceiling effect when compared to the N-EADL.

4.10.3 Measurement of the impact of FAME programme on the nominated 'family member/friend'

It was clear from the output of the focus groups with the expert physiotherapists that caregiver strain was a factor that needed to be considered in the implementation of the RCT. Furthermore, an initial FAME proposal was peer-reviewed when external funding was sought for the project in 2004. One of the recommendations from the peer

reviewers (Appendix 20) was that the impact (in terms of strain/burden) of the FAME programme on the nominated 'family member/friend' should be considered. Therefore a number of measures were considered to assess burden among the 'family members/friends' of the person with stroke. In a review of the literature conducted by Visser-Meily et al (2004) to evaluate the burden of care giving experienced by caregivers of people with stroke, the authors concluded that of the sixteen different measures of caregiver burden, no measure had proven superiority above others. However, the Caregiver Strain Index (Robinson 1983) was the most commonly used scale and had been used many times in randomised controlled trials (Visser-Meily et al 2004). This outcome measure was also recommended by one of the external peer-reviewers in the grant application.

Caregiver Strain Index

The Caregiver Strain Index (CSI) is a 13-item self-report measure designed to measure strain relating to care provision. Scoring on the CSI includes dichotomous response categories consisting of 'yes' if the strain item applies to the caregiver's situation and 'no' if it does not. A score of 7 or more indicates a high level of caregiver strain (Robinson 1983).

Test-retest reliability and SEM

Post et al (2007) examined the test-retest reliability of the CSI among 26 carers of people with chronic stroke. The measures were completed one week apart and an ICC of 0.93 was reported for the total score on the scale. Agreement on the individual items of the scale was computed using kappa coefficients. The percentage agreement was greater than 80% for 11 of the 13 items on the scale. The kappa scores were greater than 0.60 for 10 of the 13 items, moderate for two items (0.42 and 0.43) and fair for one item on the scale (0.24).

The SEM of the CSI, administered to caregivers of people with stroke, was reported as one point by Post et al (2007) and the smallest real difference was calculated at 2.8 points indicating that a change of more than 3 points is necessary in the CSI to infer that the are real rather than due to a measurement error.

Construct Validity

Van Exel et al (2004) compared the output of the CSI to the Caregiver Reaction Assessment (CRA) and Sense of Competence Questionnaire (SCQ) in 148 primary informal caregivers of people with stroke. A Spearman correlation was computed and a correlation of 0.71 was reported between the CSI and the SCQ. The CSI was then compared to the individual subscales of the CRA and correlations ranging from 0.15 (self-esteem subscale of CRA) to 0.8 (financial problems subscale of the CRA) were reported. The low correlation with the self-esteem subscale may have been due to the lack of a comparable subscale on the CSI.

Sensitivity to change

Van Exel et al (2004) reported than the CSI was more sensitive than the CRA in detecting carer burden due to the significant associations between higher caregiver burden scores in the CSI and patients disability and patient and carers health related quality of life ($p<0.05$).

4.11 Analysis of the quantitative data

All data was collected on paper and the records were stored by registration number in a secure cabinet in the Department of Physiotherapy at Trinity College. Anonymised data was transferred to a computer database and secured using a password. An independent researcher cross checked all entries. Appropriate statistical tests were carried out on the data using MINITAB Release 13.1 and Microsoft Office Excel 2003.

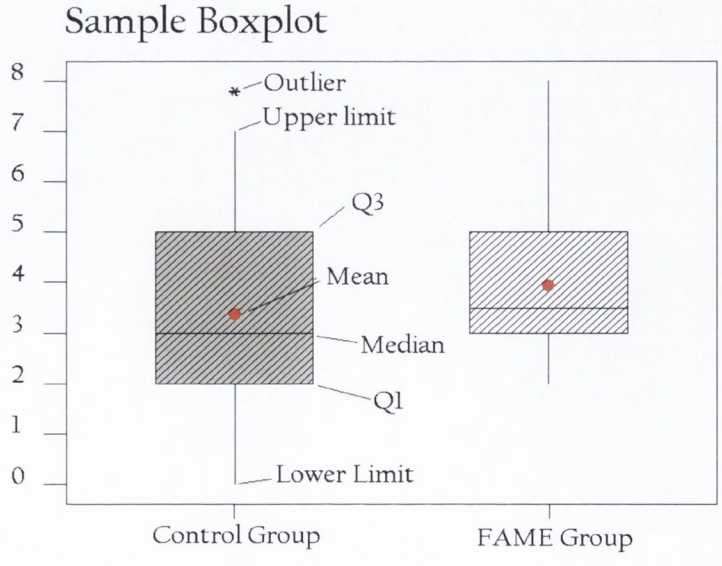
4.11.1 Baseline variables

While the participants were randomly assigned to either the control or the FAME group, the baseline demographic and outcome variables were compared to ensure homogeneity between the groups. A two-tailed Pearson chi-square test (with Yeats' continuity correction) was computed to determine if there was a statistically significant difference in the gender distribution or side of paresis in the two groups. A two-sample t-test (two-tailed) was computed to ascertain if there was a statistically significant difference in the mean age of the two groups and a Mann Whitney test was computed to determine if there was a difference in OPS scores of the participants in

each group. For ordinal data such as the LL-LMA, MAS, BBS and BI, a Mann Whitney test was computed to determine of there was a significant difference in the baseline scores of the control and the FAME group. For continuous data such as is the case with the SMWT, a two sample t-test (two-tailed) was computed to determine if there was a significant difference in the baseline scores of the groups. Each test was completed with a 0.05 level of significance.

Box and whisker plots were used to graphically display data - a sample is illustrated in Figure 4.3. For each boxplot, the mean scores of the two groups are indicated by the red circles. The median score of participants in each group is indicated by a line drawn across each grey/white box. The bottom of the box lies at the first quartile (Q1), and the top of the grey box indicates the third quartile (Q3) value. The whiskers extend from the top and bottom of the box to the adjacent values, which represent the lowest and highest scores observed in each group within the limits of the boxplot. Outliers are plotted with asterisks (*) and indicate points outside of the lower limit of the boxplot, as defined by the following formula [Q1 - 1.5(Q3 - Q1)] and the upper limit of the boxplot, as defined by the result of [Q3 + 1.5 (Q3 - Q1)].

Figure 4.3: Sample Box and Whisker Plot



4.11.2 Post-intervention and follow-up data

The change in scores from baseline (T1) to post-intervention (T2) in the various outcome measures was calculated for each group. The purpose of the statistical analysis was to test the hypothesis that there was a clinically significant difference in recovery on the various outcome measures between participants in the control group and the experimental group fromT1 to T2. Therefore the null hypothesis or H_0 was that there no difference between the groups in the change in scores from T1 to T2. The alternative hypothesis (H_A) was that the FAME group improved significantly more from T1 toT2 than the control group. A Mann Whitney test was computed to determine of there was a significant difference in the change in scores between the control and the FAME group for the LL-LMA, the MAS, the BBS and the BI. A two sample t-test (2 tailed) was computed to determine if the change in the distance travelled during the SMWT was significantly different between the two groups from T1 to T2. This method was also used to compare the change in results from T2 to the three month follow-up assessment (T3). Each hypothesis was tested with a 0.05 level of significance.

One participant was allocated to the FAME group but was unable to complete the allocated additional exercise therapy as his nominated family member sustained an injury and no longer the inclusion criteria. This participant allowed data to be collected at T2 and T3 and these assessments were analysed according to the 'intention to treat' principle. 'Intention to treat' is a strategy for the analysis of randomised controlled trials that compares patients in the groups to which they were originally randomly assigned (Hollis and Campbell 1999). The authors suggest that patients who do not start the allocated intervention should be included in the intention to treat analysis where possible (Hollis and Campbell 1999).

Two participants in the FAME group and one participant in the control group were unable to complete the assessment at T2 or T3 as they became medically unwell prior to the T2 assessment (confusion, myocardial infarction and second stroke). The participant allocated to the control group died three weeks after the T2 assessment point. These three participants' data was analysed according to the 'last observation carried forward' method for the assessment at T2 and T3.

Two further participants in the control group, who completed the T2 assessment died prior to the assessment at T3 (second strokes) and another participant in the control group was unable to complete the SMWT on the day of the T3 assessment due to back pain. A 'last observation carried forward' analysis technique was also adopted for these participants. With longitudinal studies, the 'last observation carried forward' approach preserves the sample size in the event of attrition from the study. In cases where a participant drops out of the study, their last observation is 'carried forward' and presumed to be the score at follow-up assessment points (Streiner 2002).

4.12 Qualitative assessment

Qualitative methodology has gained increasing acknowledgement and acceptance as a valuable outcome tool in health science research (Öhman 2005). The primary outcome measures used by physiotherapists to evaluate recovery following stroke are quantitative in nature, which has led to a methodological debate about the ability of quantitative measures to recognise patients' and therapists' expectations and experiences of the recovery process (Galvin et al 2009b). As rehabilitation outcomes are dependent on factors such as people's attitudes, thoughts and motivation regarding the rehabilitation process, studies with a qualitative design can inform the development and improvement of rehabilitation services. Furthermore, obtaining the perspective of patients is an important and valuable way of evaluating healthcare services. Therefore, a qualitative assessment in the form of a semi-structured interview was completed with the person with stroke on completion of the eight-week trial to acquire a sense of their experience in relation to their additional exercise therapy programme. Interviews were also conducted with the nominated 'family member/friend'. All interviews were conducted separately. These interviews were completed to gain a deeper insight into the impact of the programme on the individuals involved in the programme than was possible with the quantitative measures. A person[2] unknown to the participant completed the semi-structured interviews. The interview questions used in this study were in part based on previous work examining family and carer involvement in physiotherapy (Galvin et al 2009a,b) together with elements that were suggested by peer-reviewers and elements that the author considered relevant in terms of examining

[2] Dr. Tara Cusack, Lecturer, School of Physiotherapy and Performance Science, University College Dublin.

patient and families perception of treatment outcome. A copy of the questions that were used to guide the interview with the person with stroke and his/her family member are contained in Appendices 31 and 32 respectively. All interviews were audio recorded by means of a digital voice recorder for later transcription.

The conduct and analysis of this element of the RCT was based on the principles of 'phenomenology' as described by Husserl (1931). In order to protect the objectivity of interpretation against the 'natural attitude', Husserl believed that any preconceptions or beliefs held by the researcher should be examined, acknowledged and then put to one side or 'bracketed' in order to allow the 'true' phenomenon to be revealed (Lowes and Prowse 2001). In essence, the researcher is required to bracket any previously held presuppositions or preconceptions and allow the emphasis to be focused on the individual and their family member's subjective experience or 'lived in' experience and interpretation of the topic under investigation. In this case, the purpose of the interview was to enhance the authors understanding of the individuals 'lived in' experience of the FAME programme and also to examine whether the programme had influenced their perceptions of exercise and family involvement in exercise delivery after stroke.

4.13 Analysis of the qualitative data

Similar to the methodology used for the analysis of the user surveys detailed in Chapter 3, all of the semi-structured interviews conducted after the RCT were audio recorded and transcribed verbatim. Individual answers to each question were then grouped together in separate excel spreadsheets with a numerical identification of the individuals to which the responses were attributed. Following an examination of the responses to each question, a coding system was developed in order to facilitate the identification of recurrent themes. Codes were defined independently for each question by the author and were based upon the responses given to each question. The codes were designed to be understandable definitions, which could be easily interpreted and used by other independent coders.

4.13.1 Inter and intra-rater reliability of qualitative data analysis

Inter-rater and intra-rater reliability were determined according to the methods described by Miles and Huberman (1994). Ensuring intra and inter-rater reliability is an important feature of qualitative research and ensures that the methods used by a researcher are dependable, trustworthy and credible - the qualitative parallels of validity and reliability (Gibson and Martin 2003).

In terms of assessing the inter-rater reliability in order to ensure definitional clarity and reliability, it was necessary to check the coding. Miles and Huberman (1994) suggest that this may be achieved by asking a number of different individuals to code the transcriptions independently. Two independent researchers were provided with the responses to each question in an unencoded format and they independently coded the responses sequentially using the predefined codes. Following this process, the coded transcript from the two independent coders was examined and compared to the questions that had been previously coded by the author. The formula contained in Table 4.2 was used to calculate inter-rater reliability (Miles and Huberman 1994).

Table 4.2: Analysis of inter-rater reliability

INTER-RATER RELIABILITY
$\frac{\text{Number of agreements x 100}}{\text{Total number of agreements and disagreements}}$
or $\frac{\text{457 agreements between 3 raters (responses from individuals with stroke) x 100}}{\text{540 (total number of agreements and disagreements)}}$
and $\frac{\text{373 agreements between 3 raters (responses from family members) x 100}}{\text{450 (total number of agreements and disagreements)}}$

Initial inter-rater reliability is usually found to be in the region of 70% (Miles and Huberman 1994). Inter-rater reliability in this case was found to be 85% for the codes used to define the responses from individuals with stroke and 83% for their nominated family member.

In terms of intra-rater reliability, the same formula was used. However, in this instance the author re-checked her coding again on an unencoded copy of the responses several days after the initial coding. It was anticipated that the internal consistency here would be higher, in the region of 80% (Miles and Huberman 1994). Intra-rater reliability was found to be 95% for the responses (172 agreements from 180 agreements and disagreements) from the individuals with stroke and 93% (139 agreements from 150 agreements and disagreements) for the responses from their family members.

Following the examination of initial inter-rater reliability, a 'conflict resolution' meeting was held to resolve all coding disagreements between coders. Two new codes were identified and agreed upon by the three coders, in an attempt to more accurately reflect the data presented. Thereafter, a fourth coder independently verified all the codes. The output of the semi-structured interviews is contained in Chapter 6.

4.13.2 Triangulation of qualitative and quantitative data

As the merit for methodological pluralism has become more widely accepted in physiotherapy research, the appreciation of the value of using different or mixed methods needs to be accompanied by recognition of the pragmatic implications of how those methods are to be brought into relationship with each other in a particular study (Moran-Ellis et al 2006). The potential for 'knowing more' about a phenomenon through the use of different research methods in a study is often discussed under the umbrella of 'triangulation'. Triangulation or the examination of the same concept through two different approaches involves the support of one set of findings with another in anticipation that the two sets of evidence with triangulate or converge on a single outcome (Moran-Ellis et al 2006). This enables the researcher to conclude whether an aspect of a phenomenon has been accurately measured. In essence, once a finding has been confirmed by two independent processes, the uncertainty of its interpretation is reduced, thus providing a more accurate description of the phenomenon.

The impact of the FAME programme on the recovery of the individual with stroke was examined using two different approaches - firstly by means of the standardised outcome measures of impairment, activity and participation and secondly by means of

the semi-structured interviews. These approaches facilitated the triangulation of a number of common themes that arose in each method of evaluation. Furthermore, the examination of caregiver burden using the CSI questionnaire and the qualitative interviews with family members facilitated the comprehensive evaluation of caregiver burden, thus enabling the author to look beyond the quantitative measure and build a more complete picture of the family members' experience of the FAME programme. The triangulation approach was chosen in order to add depth and breadth in terms of evaluating the impact of the FAME programme on the individuals with stroke and their family members.

4.14 Conclusion

The aim of this chapter was to outline the methodology devised for the implementation of the RCT. The methodology described in this chapter was designed using information obtained from the user surveys of potential participants in such an intervention, the relevant literature and from peer-reviewers. The output from these sources of information allowed for the creation of an evidence-based, user-informed and centred exercise intervention. The quantitative output of the RCT is presented in Chapter 5.

CHAPTER 5

RESULTS OF RANDOMISED CONTROLLED TRIAL

The aim of this chapter is to present the quantitative findings of a RCT that examined the impact of family mediated exercise (FAME) therapy in addition to routine physiotherapy on outcome of the lower limb (LL) following acute stroke at the level of impairment, activity and participation. Chapter 4 described the methodology employed to conduct the trial. The methodology was informed by the output from the systematic review and meta-analysis which are described in Chapter 2, the findings from the three user surveys detailed in Chapter 3 and feedback from peer-reviewers (Appendix 20).

5.1 Results in context

- The single blind RCT commenced in August 2007 and was completed in June 2009.
- A power calculation was computed based on the primary outcome measure, the lower limb section of the Lindmark Motor Assessment (LL-LMA). A sample size of 40 participants was determined necessary for the trial.
- Potential participants were recruited from six acute hospitals in the greater Dublin area at two weeks following stroke onset.
- The Orpington Prognostic Score (OPS) was used to ensure homogeneity in the sample. If participants scored from 3.2-5.2 on the OPS and met the all other inclusion criteria, they were deemed eligible for inclusion to the trial.
- Participants were randomly allocated into one of two groups: a control group or an experimental FAME group, using computer generated numbers, stored in pre-sealed envelopes in the Discipline of Physiotherapy, Trinity College.
- Following enrolment to the study, all participants were assessed by a blinded outcome assessor at baseline (T1) using a battery of standardised outcome measures. These included the LL-LMA, Motor Assessment Scale, Berg Balance Scale, Six Minute Walk Test and Barthel Index.
- The RCT continued for 8 weeks. The control group received routine physiotherapy for the duration of the trial. No additional formal input was provided by their family members. Routine physiotherapy was provided by the

physiotherapy staff in the hospital. Participants in the experimental FAME group received additional LL exercise therapy on a daily basis in the form of FAME therapy. Each participant received an individualised exercise programme that was completed with their nominated 'family member/friend'. An exercise diary was also completed on a daily basis to document completion of the exercises.

- All participants were reassessed using the same battery of assessments following completion of the RCT (T2) by the same blinded outcome assessor. In addition two measures of participation, the Re-Integration to Normal Living Index (RNLI) and the Nottingham Extended Activities of Daily Living Index (N-EADL) were completed with the individual with stroke.
- The Caregiver Strain Index was administered to the nominated 'family member/friend' in the control and the FAME groups following the RCT. In addition, a qualitative interview was completed with each participant in the FAME group and their nominated 'family member/friend' by a person unknown to them. The focus of this semi-structured interview was to examine the impact of the programme on their daily lives. These results are presented in Chapter 6.
- A follow-up assessment was completed three months after completion of the programme (T3) by the same independent assessor using the same battery of outcome measures administered at the post-intervention assessment.

5.2 Screening of potential participants

The study originally commenced in Saint Vincent's University Hospital (SVUH). However, due to the low numbers recruited to the study, it was decided to seek ethical approval in a number of other centres. Therefore, recruitment commenced in the various hospitals at different time points ranging from August 2007 to September 2008. However, recruitment stopped in all hospitals on the week beginning the 5th January 2009, when the fortieth participant was successfully recruited to the trial. In total, 622 participants were screened from the six hospitals. Of these individuals, 40 were deemed suitable for participation in the FAME trial. This represents 6.4% of all individuals with stroke admitted to the participating hospitals during the recruitment phase. The remaining 582 (93.6%) of individuals screened did not meet the inclusion criteria for a variety of reasons. The most common reason for exclusion from the trial was discharge

home from the participating hospital less than two weeks post stroke. This reason was documented in 125 (21.5%) of cases. Only 7 potential participants or 1.2% of those excluded refused to be involved in the study. The reasons for excluding these individuals are documented for the individual centres in Table 5.1.

Table 5.1: Reasons for excluding potential participants screened prior to the FAME RCT

REASON FOR EXCLUSION	SVUH	SCH	MMUH	BEAUMONT	SJH	OLH	TOTAL
Discharged home	77	7	13	19	7	2	125
Discharged from physiotherapy prior to 2 week assessment	26	7	16	20	8	1	78
Cognitive impairment (MMSE < 24/30)	32	9	9	8	8	0	66
Dysphasia (receptive/expressive)	32	5	10	4	7	2	60
Previous stroke	19	4	7	9	6	1	46
Other neurological condition	13	5	13	4	5	1	41
OPS >5.2	21	8	4	2	4	2	41
Medically unstable	12	6	8	8	3	1	38
OPS < 3.2	8	4	8	7	6	1	34
Died	16	2	2	5	2	0	27
Family member not physically able to participate in FAME	1	1	1	5	3	0	11
On vacation in Dublin/Ireland	2	0	3	2	1	0	8
Refused	2	0	2	1	1	1	7
TOTAL	261	58	96	94	61	12	582

SVUH - Saint Vincent's University Hospital, SCH - Saint Colmcilles Hospital, MMUH - Mater Misercordiae University Hospital, SJH - Saint James's Hospital, OLH - Our Lady's Hospital, OPS - Orpington Prognostic Score

5.3 Description of the baseline variables of participants

This section contains a description of the 40 participants included in the RCT. The participants are described according to group allocation. The following baseline variables are described: gender, age, type of stroke, side of paresis and OPS score.

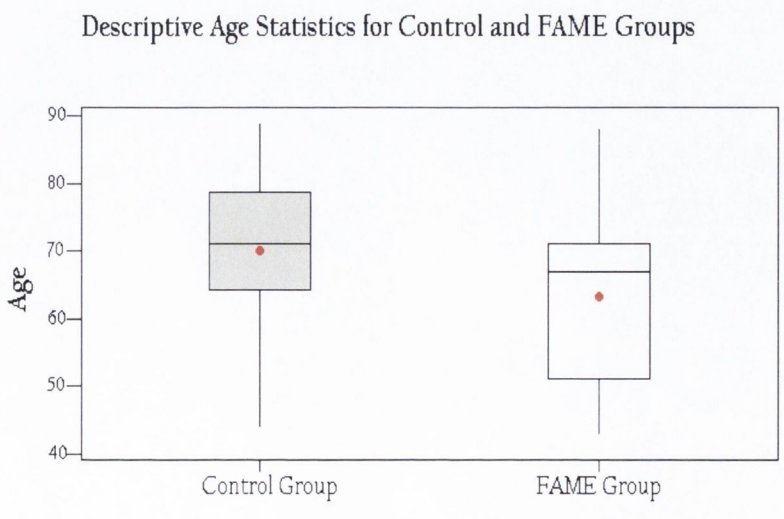
5.3.1 Gender

There were 7 males and 13 females in the control group and 13 males and 7 females in the FAME group. The proportion of males in the control group was 0.35 whereas the proportion of males in the FAME group was 0.65. The difference in proportions was not significant [χ^2 (1, n=40) = 2.5, p=0.11].

5.3.2 Age

The mean age of participants in the control group was 70 years with a standard deviation (SD) of 11.9 years (range 44 - 89 years). The mean age of participants in the FAME group was 63.2 years with a SD of 13.3 years (range 43 - 88 years). There was no significant difference in the mean ages of the control group and the FAME group (p=0.10). The descriptive age statistics are illustrated in Figure 5.1.

Figure 5.1: Age statistics for Control and FAME groups



5.3.3 Type of stroke and side of paresis

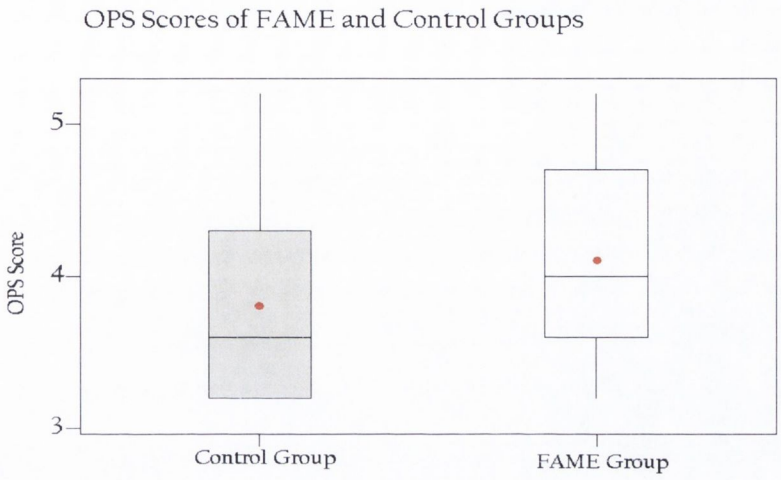
Two people in the control group had a haemorrhagic stroke and four people in the FAME group had a haemorrhagic stroke. The remaining participants in each group had an ischaemic stroke. Six participants in the control group presented with weakness on the left side and 14 participants presented with weakness on the right side. In the FAME group, 11 participants presented with weakness on the left side and 9 presented with weakness on the right side. Therefore, the proportion of individuals with left sided weakness in the control group was 0.30 whereas the proportion people presenting with left sided weakness in the FAME group was 0.55. The difference in proportions was not significant [χ^2 (1, n=40) = 1.637, p=0.201].

5.3.4 Baseline Orpington Prognostic Score

Individuals were eligible for inclusion to the study if they scored between 3.2 and 5.2 on the OPS at two weeks following stroke. The mean number of days from the time of stroke to the initial OPS screening for entry to the study was 14.6 days with a SD of 2 days (range 11 - 17 days) in all 20 participants in the control group. The mean number of days from the time of stroke to the initial OPS screening in the 20 participants the FAME group was 14.4 days with a SD of 2.4 days (range 10 - 18 days).

The mean OPS score documented in the control group at this time point was 3.8 with a SD of 0.8. The mean OPS score observed in participants in the FAME group was 4.1 with a SD of 0.7. The minimum score observed in both groups was 3.2 (which represented the lower limit of the inclusion criteria), and the maximum score was 5.2 (which represented the upper limit of the inclusion criteria). The mode or the most frequently observed OPS score in the control group was 3.6 and the mode score in the FAME group was 4.0. There was no significant differences in the OPS scores of the control and FAME groups (p=0.14). These statistics are illustrated in Figure 5.2.

Figure 5.2: Boxplots of Control and FAME OPS scores



5.3.5 Summary of baseline demographic variables

Table 5.2 contains a summary of the baseline demographic variables outlined in the previous sections. There were no significant differences noted between the groups of any of the variables described.

Table 5.2: Summary statistics for the baseline variables in the Control and FAME groups

VARIABLES	CONTROL GROUP	FAME GROUP
Number of participants	20	20
Mean age	69.95 years	63.15 years
Standard Deviation (age)	11.9 years	13.3 years
Gender	Male = 7 Female = 13	Male = 13 Female = 7
Type of stroke	Haemorrhagic = 2 Ischaemic = 18	Haemorrhagic = 4 Ischaemic = 16
Side of paresis	Left = 6 Right = 14	Left = 11 Right = 9
OPS score (SD)	3.8 (0.8)	4.1 (0.7)

SD - Standard Deviation

5.4 Baseline outcome measures

As described in Chapter 4, the baseline outcome measures were administered by the same physiotherapist who was blinded to group allocation. All outcome measures were administered in a gym setting using a standardised protocol and battery of assessments (Appendix 30). The self-report outcome measures were administered first followed by the measures of impairment and activity. Parametric and non-parametric statistical tests were employed to examine the difference between the scores of the groups at baseline concluded that there was no significant difference between the groups in any of the outcome variables. The RNLI and the N-EADL were not examined at this time point as they were considered to be measures of social participation and were not applicable to the population group at the baseline assessment post stroke. The baseline descriptive statistics of the different outcome variables are presented in Table 5.3.

Table 5.3: Summary statistics of the outcome measures at baseline

OUTCOME MEASURE	CONTROL GROUP (n=20)			FAME GROUP (n=20)			GROUP COMPARISON	
	MEAN	SD	RANGE	MEAN	SD	RANGE	DIFFERENCE	p=
LL-LMA (0-36 points)	25.7	11.9	0 - 36	21.1	11.3	0 - 36	5	0.11
MAS (0-48 points)	29.7	12.9	2 - 47	24.3	11.1	1 - 42	6	0.18
BBS (0-56 points)	26.8	18.1	0 - 49	22.3	17.6	0 - 52	3	0.46
SMWT (metres)	118.4	119.6	0 - 380	67.7	81.2	0 - 240	50.7	0.13
BI (0-100 points)	65.5	27.9	0 - 90	56.3	27	15 - 100	10	0.23

LL-LMA - Lower limb section of the Lindmark Motor Assessment, **MAS** - Motor Assessment Scale, **BBS** - Berg Balance Scale, **SMWT** - Six Minute Walk Test, **BI** - Barthel Index

5.5 Randomised controlled trial

5.5.1 Control group

All participants in the control group reported that they were independent in activities of daily living (ADLs) prior to the stroke. The mean number of days from the time of stroke to entry into the study was 19.7 days with a SD of 3 days (range 15 - 25 days). The mean number of days from the initial OPS screening to entry into the study was 5.2 days with a SD of 2.1 days (range 2 - 9 days). One participant was excluded from the post-intervention assessment as she became medically unwell during the eight week period. She subsequently died three weeks after the T2 assessment. The remaining nineteen participants in the control group remained in the acute hospital setting for a mean of 40.1 days with a SD of 15 days (range 23 - 83 days). Six participants were discharged home prior to the assessment at T2. Thirteen participants were discharged from the acute hospital to a 'rehabilitation unit'. The mean length of stay in the 'rehabilitation unit' for these participants was 52.3 days with a SD of 40 days (range 21 - 164 days). No participant in the control group remained in an acute hospital for the duration of the RCT, with the exception of the participant who became medically unwell.

5.5.2 FAME group

All participants in the FAME group also reported that they were independent in ADLs prior to the stroke. The mean number of days from the time of stroke to entry into the study was 18.9 days with a SD of 2.9 days (range 15 - 25 days). The mean number of days from the initial OPS screening to entry into the study was 4.5 days with a SD of 1.6 days (range 3 - 8 days). Three participants were unable to complete the FAME programme, however one participant allowed follow-up assessments to take place. Therefore eighteen participants completed the eight week assessment. The mean length of stay in the acute hospital for the participants in this group was 35.7 days with a SD of 10.5 days (range 23 - 61 days). During this time, participants received 'routine' physiotherapy for the duration of their hospital stay, similar to the control group. Eleven participants were discharged home prior to the eight week assessment. Seven participants were discharged from the acute hospital to a 'rehabilitation unit' where each participant received physiotherapy on a daily basis. The mean length of stay in the

'rehabilitation unit' for these participants was 40.3 days with a SD of 9.6 days (range 28 - 52 days). No participant in the FAME group remained in an acute hospital for the duration of the RCT, with the exception of two participants who became medically unwell during this time period.

5.5.3 Additional FAME therapy

Each participant in the FAME group received additional LL exercise therapy on a daily basis in the form of FAME therapy. At the beginning of the programme, each individual with stroke nominated a 'family member/friend' or a person(s) whom he/she would like to assist them with the exercise programme. Thirteen participants chose their spouse/partner (10-wife, 2-husband and 1-partner), four participants chose their daughter, one participant chose her son, one participant chose his mother and one participant chose a carer. Therefore from this point on in the thesis, the person assisting with the additional exercise will be referred to as a 'family member'. This person was responsible for assisting the person with stroke to complete their exercises on a daily basis. In cases where the family member was unable to complete the exercises for the week, a second family member attended the FAME session that particular week. This occurred on six occasions with three different participants.

Each exercise session lasted 35 minutes with an expectation that 1960 minutes of additional therapy would be delivered over the eight week period if participants completed their exercises on a daily basis, including weekends. Seventeen participants completed the FAME programme with their nominated family member. Each nominated family member was required to complete an exercise log on a daily basis in an exercise diary that was provided by the author. This exercise log was completed after each session and if the participant was unable to complete the session, a reason was documented. Each family member was required to sign this exercise diary following each entry and this was examined by the author on a weekly basis to document compliance to the programme. Ten family members documented that their family member with stroke was 100% compliant with the exercise programme and completed all of the prescribed exercises on a daily basis. Therefore these participants completed 1960 minutes of additional exercise therapy. The most common reason for not completing the prescribed exercises was fatigue. The mean number of additional

minutes of exercise therapy completed by the 17 participants and their family member was 1818 minutes with a SD of 271 minutes (range 1155 minutes - 1960 minutes). Table 5.4 illustrates the mean and SD number of minutes of additional exercise therapy completed by participants on a weekly basis.

Table 5.4: Summary statistics of additional FAME programme

WEEK*	MEAN (minutes)	SD (minutes)	RANGE (minutes)
1	228.8	41.3	105 – 245
2	226.5	41.3	105 – 245
3	234.7	29.7	140 – 245
4	222.4	40.9	105 – 245
5	220.3	49.1	70 – 245
6	232.6	24.6	175 – 245
7	224.4	37.2	140 – 245
8	228.5	41.3	105 – 245
TOTAL	**1818 minutes**	**270.7 minutes**	**1120 - 1960 minutes**

* The maximum number of minutes of additional exercise therapy that can be completed on a weekly basis is 245 minutes (35 minutes daily x 7 days), SD - Standard Deviation

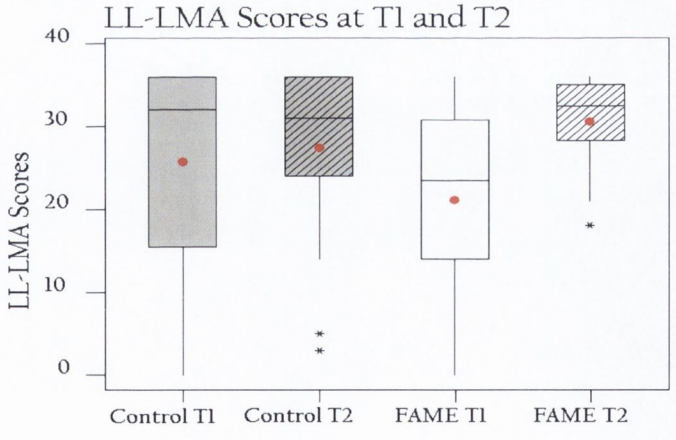
There was a significant difference in the actual versus the planned therapy that was delivered to participants in the FAME group each week ($p=0.046$). A mean of 227 minutes of additional exercise therapy was actually delivered each week with a standard deviation of 34 minutes whereas 245 minutes of additional exercise therapy was planned for each participant. The point estimate for the difference in the actual versus the planned duration of additional exercise therapy was computed using a paired t-test and yielded a difference of 18 minutes with a 95% CI (0.36 - 35.15 minutes).

5.6 Post-intervention outcome variables

5.6.1 Lower limb section of Lindmark Motor Assessment

The maximum score attainable on the LL-LMA is 36 points. The mean LL-LMA score at T2 in the control group was 27.5 points with a SD of 10.25 points (range 3 - 36 points). The mean LL-LMA score at T2 in the FAME group was 30.6 points with a SD of 5.5 points (range 18 - 36 points). The mean change in the LL-LMA score in the control group between T1 and T2 was 1.75 points with a SD of 6.28 points (range -10 - 18 points). The mean change in the LL-LMA score in the FAME group was 9.5 points with a SD of 9.94 points (range -3 - 32 points). Figure 5.3 displays the descriptive statistics for the LL-LMA scores at T1 and T2 in both groups. The two outliers, indicated by an asterisks (*), evident at T2 in the control group represent two participants who only made slight improvements (3 points) on the LL-LMA from T1 to T2. The outlier displayed in the FAME group at T2 represents a 'last observation carried forward' (baseline observation) for one participant who was unable to complete the T2 assessment.

Figure 5.3: LL-LMA scores at T1 to T2 in Control and FAME groups



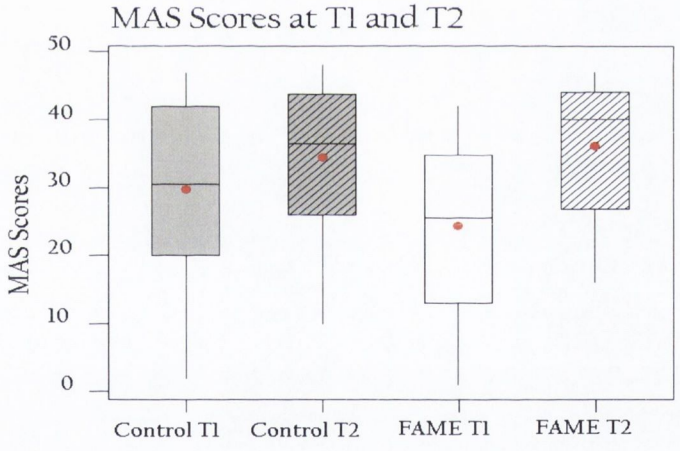
A Mann-Whitney test was computed to determine of there was a significant difference in the change in scores from T1 to T2 in the two groups. The point estimate for the difference in the change in scores from T1 to T2 in the two groups was 7 points with a 95% confidence interval (1 - 13 points) and a p-value of 0.01. Therefore H_0 can be

rejected and H_A can be inferred, indicating that the FAME group improved significantly more on the LL-LMA from T1 to T2 than the control group.

5.6.2 Motor Assessment Scale

The maximum score attainable on the MAS is 48 points. The mean MAS score at T2 in the control group was 34.5 points with a SD of 11.6 points (range 10 - 48 points). The mean MAS score at T2 in the FAME group was 36.1 points with a SD of 10.2 points (range 16 - 47 points). The mean change in the MAS score in the control group between T1 and T2 was 4.75 points with a SD of 6.2 points (range -2 - 22 points). The mean change in the MAS score in the FAME group was 11.9 points with a SD of 7.8 points (range 0 - 25 points). Figure 5.4 illustrates the outcomes on the MAS at T1 and T2.

Figure 5.4: MAS scores at T1 and T2 in Control and FAME groups

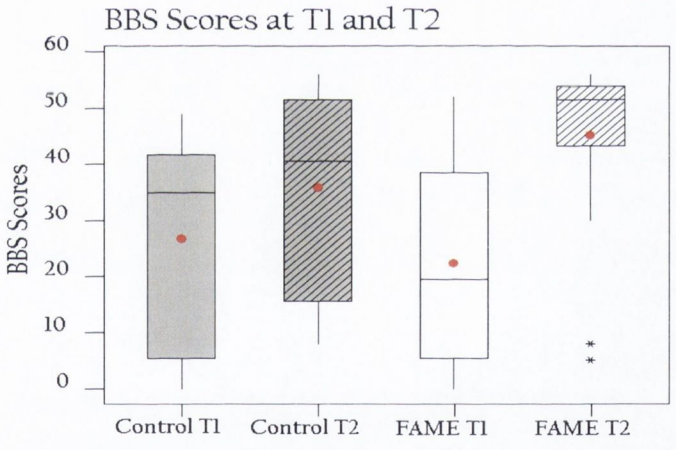


A Mann-Whitney test was computed and the point estimate for the difference in the change in scores from T1 to T2 in the two groups was 8 points with a 95% confidence interval (2 - 13 points and $p \leq 0.001$. Therefore H_0 was rejected and H_A was inferred i.e. the MAS scores of the FAME group improved significantly more from T1 to T2 than those of the control group.

5.6.3 Berg Balance Scale

The maximum score attainable on the BBS is 56 points. The mean BBS score at T2 in the control group was 35.8 points with a SD of 17.2 points (range 8 - 56 points). The mean BBS score at T2 in the FAME group was 45.1 points with a SD of 14.9 points (range 5 - 56 points). The mean change in the BBS score between T1 and T2 in the control group was 9 points with a SD of 9 points (range -1 - 37 points). The mean change in the BBS score in the FAME group was 22.8 points with a SD of 18.1 points (range 0 - 50 points). The BBS scores at T1 and T2 are displayed in Figure 5.5. The two outliers (*) illustrated at T2 in the FAME group represent the two participants who were excluded from the trial, whose 'last observation' or baseline observation was carried forward to T2.

Figure 5.5: BBS scores at T1 and T2 in Control and FAME groups

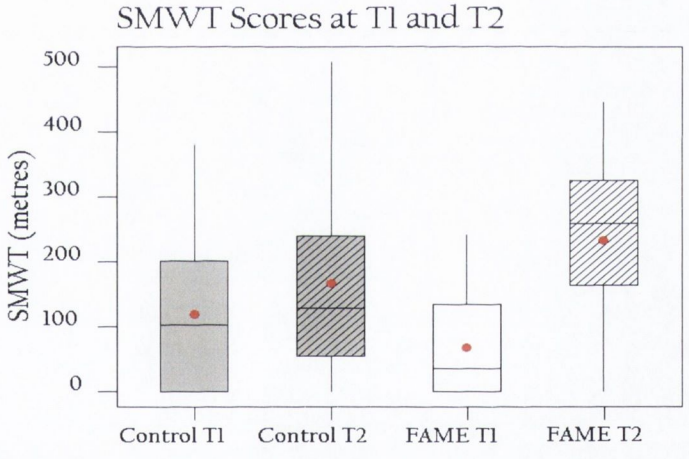


The point estimate for the difference in the change in scores from T1 to T2 in the two groups was 9 points with a 95% confidence interval (1 - 28 points) and a p-value of 0.02. Again H_0 was rejected and H_A was inferred. Therefore the FAME group improved significantly more from T1 to T2 than the control group, when assessed with the BBS.

5.6.4 Six Minute Walk Test

The SMWT calculates distance walked, in metres, in six minutes. The mean distance covered by participants in the control group at T2 was 165.6 metres with a SD of 146.1 metres (range 0 - 506 metres). The mean distance covered by participants in the FAME group at T2 was 231.8 metres with a SD of 131.3 metres (range 0 - 445 metres). The mean change in distance walked on the SMWT in the control group between T1 and T2 was 47.2 metres with a SD of 50.6 metres (range -27 - 147.5 metres). The mean change in distance walked on the SMWT in the FAME group was 164.1 metres with a SD of 128.7 metres (range 0 - 378 metres). Figure 5.6 illustrates the descriptive statistics for both groups at T1 and T2.

Figure 5.6: SMWT distances at T1 and T2 in Control and FAME groups

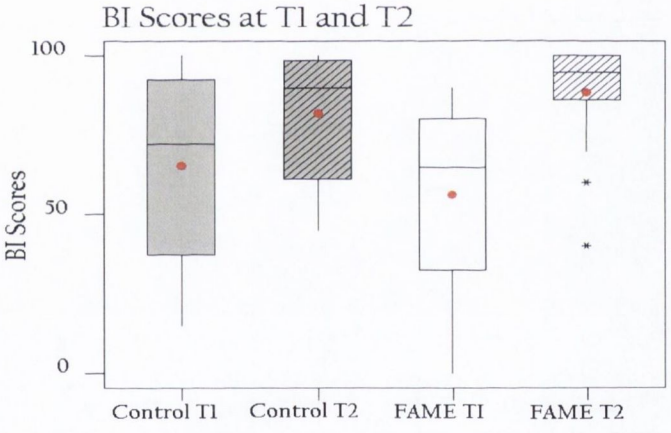


A 2 sample t-test (2-tailed) was computed to determine of there was a significant difference in the change in distance travelled during the SMWT from T1 to T2 in the two groups. The point estimate for the difference in the change in metres walked from T1 to T2 in the two groups was 117 metres with a 95% confidence interval (53.1 - 180.8 metres) and $p \leq 0.001$. Again, H_0 was rejected and H_A was inferred i.e. the increase in distance walked from T1 to T2 was significantly greater in the FAME group than the control group when assessed on the SMWT.

5.6.5 Barthel Index

The maximum score attainable on the BI is 100 points. The mean BI score at T2 in the control group was 81.8 points with a SD of 18.7 points (range 45 - 100 points). The mean BI score at T2 in the FAME group was 88.5 points with a SD of 15.6 points (range 40 - 100 points). The mean change in the BI score in the control group between T1 and T2 was 16.3 points with a SD of 14.2 points (range -5 - 40 points). The mean change in the BI score in the FAME group was 32.3 points with a SD of 24 points (range 0 - 70 points). Figure 5.7 illustrates the output for both groups at T1 and T2. The two outliers present at T2 in the FAME group represent two participants whose baseline observation was carried forward at T2.

Figure 5.7: BI scores at T1 and T2 in the Control and FAME groups

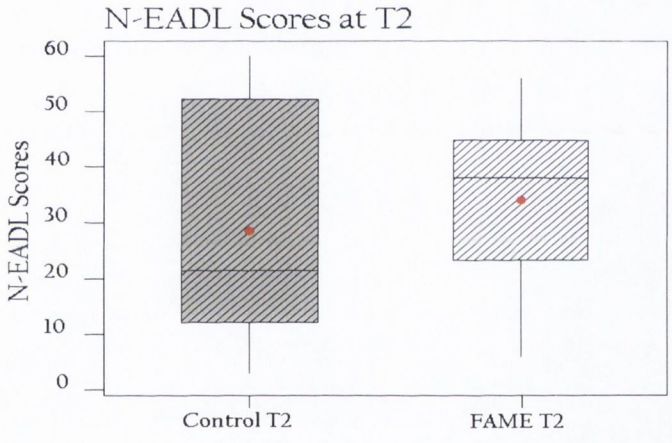


A Mann-Whitney test was computed to determine if there was a significant difference in the change in scores from baseline to post-intervention in the two groups. The point estimate for the difference in the change in scores from T1 to T2 in the two groups was 15 points with a 95% confidence interval (0 - 30 points) and a p-value of 0.04. This result suggested that H_0 could be rejected and it was inferred that the FAME group improved significantly more from T1 to T2 than the control group, when assessed with the BI.

5.6.6 Nottingham Extended Activities of Daily Living Index

Each participant was assessed at T2 with the self-report N-EADL. The maximum score attainable on this measure is 63 points. The mean N-EADL score post intervention in the control group was 28.4 points with a SD of 20 points (range 3 - 60 points). The mean N-EADL score at this assessment point in the FAME group was 33.9 points with a SD of 15.1 points (range 6 - 56 points). There was no significant difference in the scores of the two groups at this time point (p=0.45). The N-EADL scores of the two groups at T2 are presented in Figure 5.8.

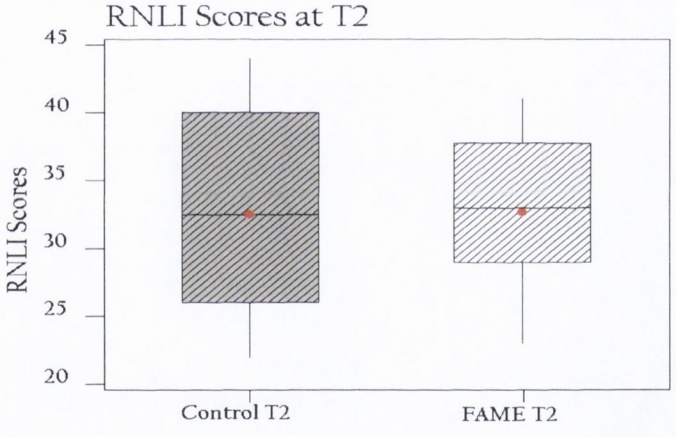
Figure 5.8: N-EADL scores in the Control and FAME groups at T2



5.6.7 Re-Integration to Normal Living Index

Each participant was also assessed at T2 with the self-report RNLI. The maximum score attainable on this measure is 44 points. The mean RNLI score post intervention in the control group was 32.5 points with a SD of 7.1 points (range 22 - 44 points). The mean RNLI score at this assessment point in the FAME group was 32.7 points with a SD of 5.2 points (range 23 - 41 points). These descriptive statistics are illustrated in Figure 5.9. There was no difference in the RNLI scores of participants in each group at T2 ($p=0.96$).

Figure 5.9: RNLI scores of the Control and FAME Groups at T2

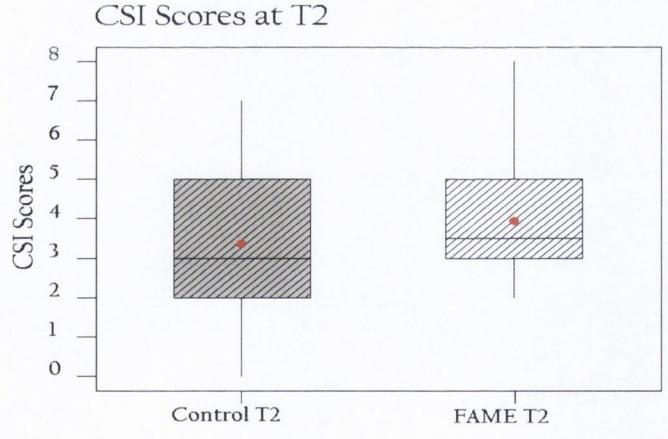


5.6.8 Caregiver Strain Index

The CSI was administered to the nominated family member of each participant with stroke after the trial. The CSI is a 13-item self-report measure designed to measure strain relating to care provision. A score of greater than 7 points indicates a high level of carer strain. One data set was missing from the control group and two data sets were missing from the FAME group at this time point. Therefore these data are excluded from the analysis as the 'last observation carried forward' cannot be applied to this data.

The mean CSI score post intervention in the nominated family member of participants in the control group (n=19) was 3.4 points with a SD of 2.2 points (range 0 - 7 points). The mean CSI score at this assessment point reported by the nominated 'family member/friend' of participants in the FAME group was 3.9 points with a SD of 1.7 points (range 2 - 8 points). There was no significant difference (p=0.29) in the levels of carer strain reported by the family members of individuals with stroke in either group. This information is visually displayed in Figure 5.10.

Figure 5.10: CSI scores of family members in the Control and FAME groups at T2



5.7 Summary of post-intervention (T2) outcome measures

- There was a statistically significant difference in the change in scores observed in the control and the FAME group between T1 and T2 in the following outcome measures, LL-LMA, MAS, BBS, SMWT and the BI. The participants in the FAME group improved significantly more than participants in the control group from T1 to T2 on these outcome measures.
- There was no significant difference between the groups in the N-EADL and RNLI scores documented at T2.
- There was no significant difference in the levels of carer strain reported by the family members in both groups at T2.
- Table 5.5 contains the summary statistics of the post-intervention (T2) outcome measures and the changes in scores observed in each group from T1 to T2.

Table 5.5: Summary statistics of the Control and FAME groups at T2 and changes in scores from T1 to T2

OUTCOME MEASURE	CONTROL GROUP				FAME GROUP			
	Mean Score T2	SD T2	Mean Change (T1 to T2)	SD (T1 to T2)	Mean T2	SD T2	Mean Change (T1 to T2)	SD (T1 to T2)
LL-LMA	27.5	10.25	1.75	6.28	30.6	5.5	9.5	9.9
MAS	34.5	11.6	4.75	6.2	36.1	10.2	11.9	7.8
BBS	35.8	17.2	9	9	45.1	14.9	22.8	18.1
SMWT	165.6	146.1	47.2	50.6	231.8	131.3	164.1	128.7
BI	81.8	18.7	16.3	14.2	88.5	15.6	32.3	24
N-EADL	28.4	20	N/A	N/A	33.9	15.1	N/A	N/A
RNLI	32.5	7.1	N/A	N/A	32.7	5.2	N/A	N/A
CSI	3.4	2.2	N/A	N/A	3.9	1.7	N/A	N/A

BBS - Berg Balance Scale, **BI** - Barthel Index, **CSI** - Caregiver Strain Index, **LL-LMA** - Lower limb section of the Lindmark Motor Assessment, **MAS** - Motor Assessment Scale, **N/A** - not applicable, **N-EADL** - Nottingham Extended Activities of Daily Living Index, **RNLI** - Re-integration to Normal Living Index, **SD** - standard deviation, **SMWT** - Six Minute Walk Test, **T1** - baseline measurement, **T2** - post-intervention measurement

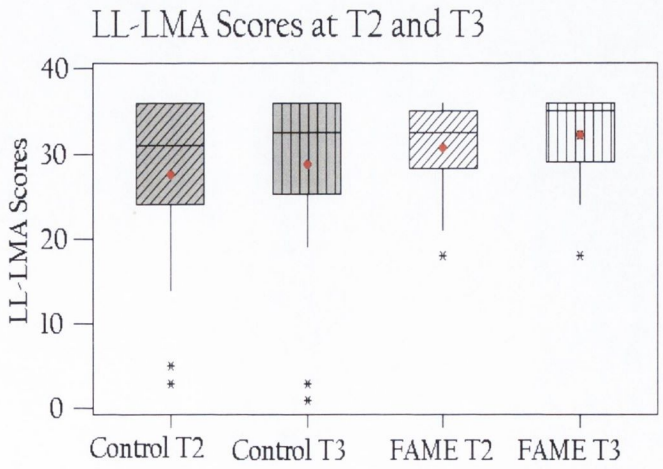
5.8 Three month follow-up

All outcome measures were administered by the blinded outcome assessor at three months. The self-report outcome measures were administered first followed by the measures of impairment and activity. The method used to analyse the data is contained in Chapter 4 (Section 4.11.2).

5.8.1 Lower limb section of Lindmark Motor Assessment

The mean LL-LMA score at T3 in the control group was 28.8 points with a SD of 10.4 points (range 1 - 36 points). The mean LL-LMA score at T3 in the FAME group was 32.2 points with a SD of 5.4 points (range 18 - 36 points). The mean change in the LL-LMA score in the control group between T2 and T3 was 1.3 points with a SD of 5.2 points (range -5 - 20 points). The mean change in the LL-LMA score in the FAME group was 1.6 points with a SD of 2.4 points (range -1 - 7 points). There was no significant difference in the change in scores from T2 to T3 in the control and FAME groups (p=0.12). Figure 5.11 illustrates the results of the groups at T2 and T3. One of the outliers evident at T2 and T3 in the control group and the outlier evident in the FAME group at T2 and T3 represent two participants whose 'last observation' was brought forward from T2. The second outlier in the control group represented a participant who regressed from T2 to T3.

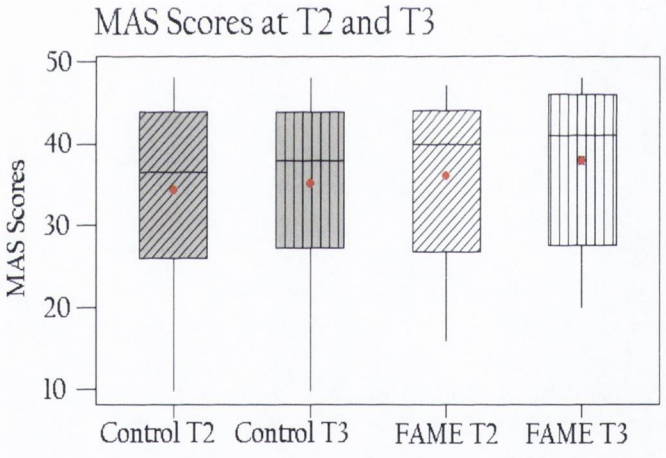
Figure 5.11: LL-LMA scores at T2 and T3 in the Control and FAME groups



5.8.2 Motor Assessment Scale

The mean MAS score at T3 in the control group was 35.2 points with a SD of 10.8 points (range 10 - 48 points). The mean MAS score at T3 in the FAME group was 37.9 points with a SD of 9.7 points (range 20 - 48 points). The mean change in the MAS score in the control group between T2 and T3 was 0.7 points with a SD of 2.6 points (range -4 - 6 points). The mean change in the MAS score in the FAME group was 1.8 points with a SD of 3.8 points (range -6 - 10 points). The boxplots illustrated in Figure 5.12 indicate that the MAS score at T3 is higher in the FAME group than the control group, However, there was no significant difference in the change in scores from T2 to T3 in the control and FAME groups when assessed using the MAS (p=0.59).

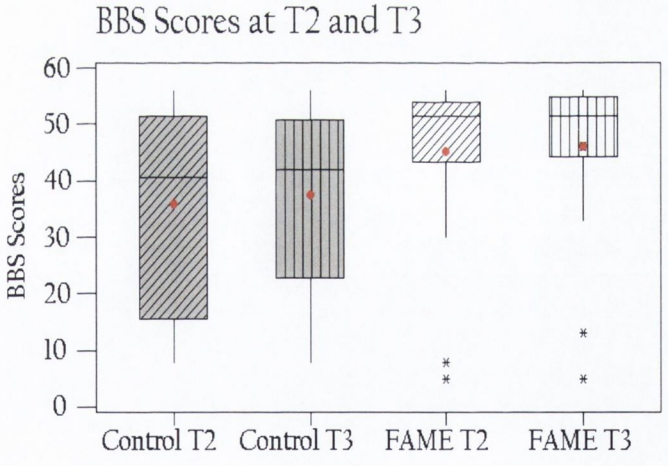
Figure 5.12: MAS scores at T2 and T3 in the Control and FAME groups



5.8.3 Berg Balance Scale

The mean BBS score at T3 in the control group was 37.6 points with a SD of 16.21 points (range 8 - 56 points). The mean BBS score at T3 in the FAME group was 46 points with a SD of 14.2 points (range 5 - 56 points). The mean change in the BBS score in the control group between T2 and T3 was 1.8 points with a SD of 8.5 points (range -8 - 34 points). The mean change in the BBS score in the FAME group was 0.9 points with a SD of 2.5 points (range -4 - 5 points). While the T3 BBS scores of the FAME group are significantly higher than the control group (p=0.04), the change in scores from T2 to T3 was not statistically significant (p=0.7). The descriptive statistics for both groups at T2 and T3 are illustrated in Figure 5.13. One of the outliers represented in the FAME group at T3 represents a 'last observation carried forward' from T2. The second outlier represents a participant who improved 5 points on the BBS from T2 to T3. However the BBS score documented at T2 was 8 points.

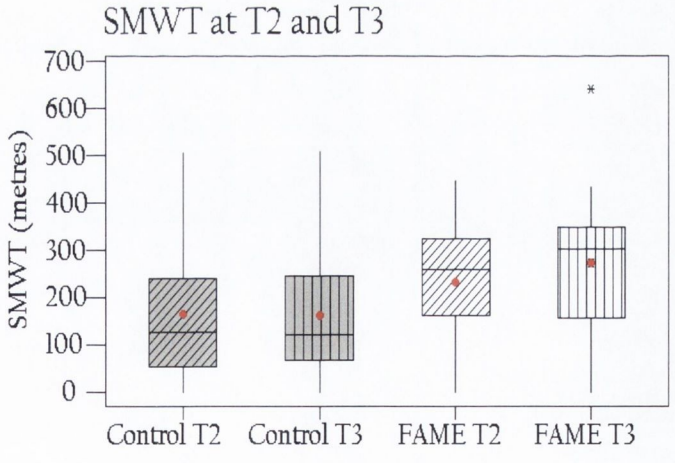
Figure 5.13: BBS Scores at T2 and T3 in the Control and FAME Groups



5.8.4 Six Minute Walk Test

The mean distance covered by participants in the control group at T3 was 162.1 metres with a SD of 143.4 metres (range 0 - 507 metres). The mean distance covered by participants in the FAME group at T3 was 271.6 metres with a SD of 154.5 metres (range 0 - 640 metres). The mean change in distance walked on the SMWT in the control group between T2 and T3 was -3.5 metres with a SD of 32.7 metres (range -106 to 52 metres). The mean change in distance walked on the SMWT in the FAME group was 39.8 metres with a SD of 55.4 metres (range -35 to 195 metres). The point estimate for the difference between the groups in the change in distance travelled from T2 to T3 was 43.3 metres with a 95% CI (13.9 - 72.6 metres) and a p-value of 0.01. This result indicates that the improvement in distance walked from T2 to T3 was significantly greater in the FAME group than the control group when assessed using the SMWT. Figure 5.14 presents the results for both groups at T2 and T3. The outlier presented at T3 in the FAME group represents a participant who walked a distance of 640 metres at the T3 assessment.

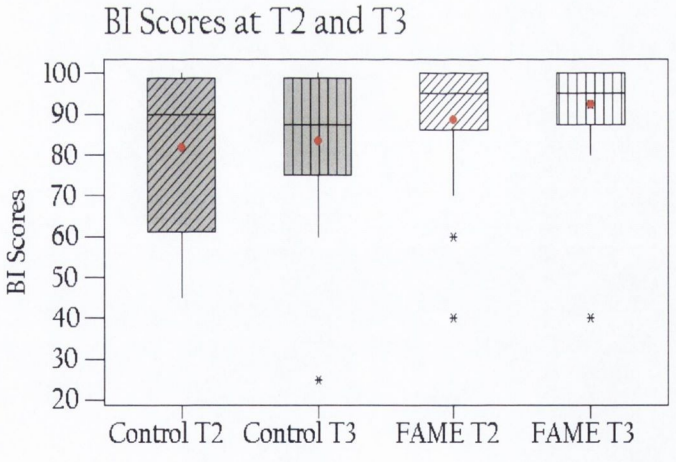
Figure 5.14: SMWT distances at T2 and T3 in the Control and FAME groups



5.8.5 Barthel Index

The mean BI score at T3 in the control group was 83.3 points with a SD of 19 points (range 25 - 100 points). The mean BI score at T3 in the FAME group was 92.3 points with a SD of 13.8 points (range 40 - 100 points). The mean change in the BI score in the control group between T2 and T3 was 1.5 points with a SD of 11.6 points (range -25 - 40 points). The mean change in the BI score in the FAME group was 3.8 points with a SD of 8.3 points (range -5 - 25 points). While the BI scores of the FAME group appear higher than the control group at T3, the change in scores from T2 to T3 was not significantly different in the control and FAME groups (p=0.36). The summary statistics for both groups at T2 and T3 are illustrated in Figure 5.15. The outlier displayed at T3 in the control group represents a participant who regressed from T2 to T3 when measured with the BI. The outlier presented at T3 in the FAME group represents a 'last observation' brought forward from T2.

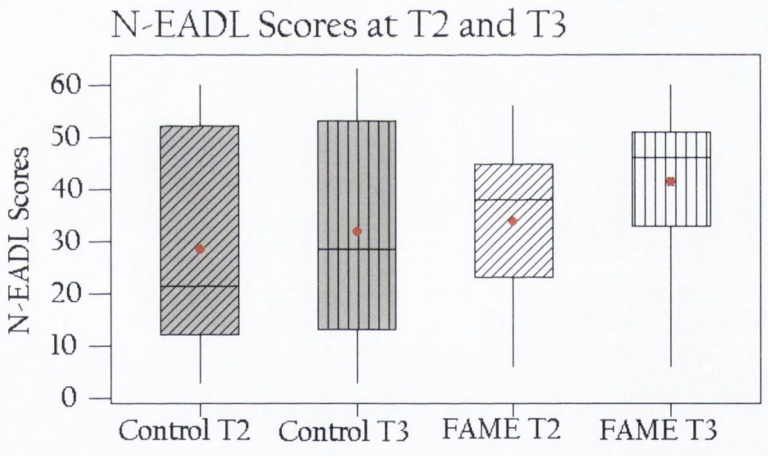
Figure 5.15: BI scores at T2 and T3 in the Control and FAME groups



5.8.6 Nottingham Extended Activities of Daily Living Index

The mean N-EADL score at T3 in the control group was 32 points with a SD of 20.7 points (range 3 - 63 points). The mean N-EADL score at T3 in the FAME group was 41.5 points with a SD of 15.5 points (range 6 - 60 points). The mean change in the N-EADL score in the control group between T2 and T3 was 3.6 points with a SD of 7.8 points (range -4 - 32 points). The mean change in the N-EADL score in the FAME group was 7.6 points with a SD of 8.3 points (range -1 to 21 points). The point estimate for the difference in the change in scores from T2 to T3 in the two groups was 4 points with a 95% CI (1 - 9 points) and a p-value of 0.02. Therefore it can be concluded that N-EADL scores of the FAME group improved significantly more from T2 to T3 than the control group. Figure 5.16 displays these results.

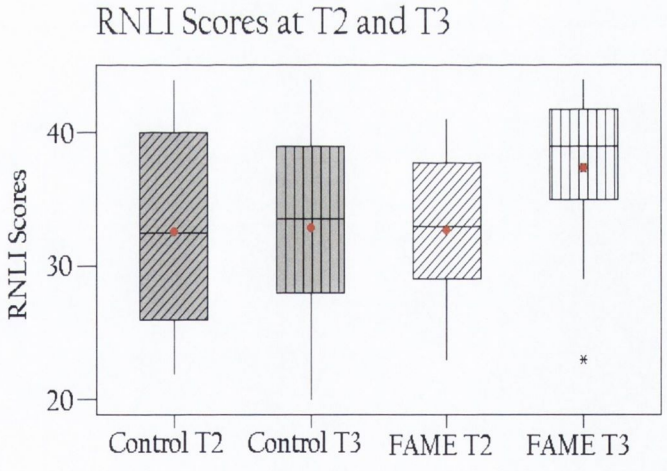
Figure 5.16: N-EADL scores at T2 and T3 in the Control and FAME groups



5.8.7 Re-Integration to Normal Living Index

The mean RNLI score at T3 in the control group was 32.9 points with a SD of 7.1 points (range 20 - 44 points). The mean RNLI score at T3 in the FAME group was 37.4 points with a SD of 5.6 points (range 23 - 44 points). The mean change in the RNLI score in the control group between T2 and T3 was 0.4 points with a SD of 2.9 points (range -9 - 5 points). The mean change in the RNLI score in the FAME group was 4.7 points with a SD of 4.3 points (range -3 - 14 points). The point estimate for the difference in the change in scores from T2 to T3 between the two groups was 4 points with a 95% CI (2 - 6 points), in favour of the FAME group ($p \leq 0.001$). Therefore it can be concluded that the RNLI scores of the FAME group improved significantly more from T2 to T3 than the control group. Figure 5.17 presents the summary statistics for both groups at T2 and T3. The outlier displayed at T3 in the FAME group represents a 'last observation carried forward' from the assessment at T2.

Figure 5.17: RNLI scores at T2 and T3 in the Control and FAME groups

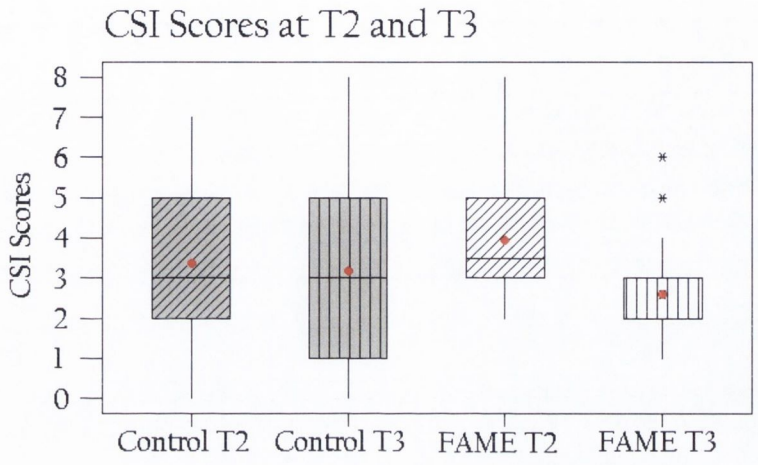


5.8.8 Caregiver Strain Index

The CSI was administered to the family member of each participant with stroke at T3. One data set was missing from the control group at the post-intervention time point. Therefore this data set was excluded from the T3 analysis as the 'last observation carried forward' could not be applied. However, two further data sets were lost from the nominated 'family member/friend' of participants in the control group at the 3 month follow-up assessment as two participants in the control group died prior to this assessment point. A 'last observation carried forward' method of analysis is applied to these two sets of data. Therefore the mean CSI score at the T3 in the nominated 'family member/friend' (n=19) of participants in the control group was 3.2 points with a standard deviation of 2.7 points (range 0 - 8 points).

Two data sets were lost from the FAME group before the T2 assessment and are subsequently excluded from the T3 assessment also (See Section 4.11.2). The mean CSI score at this assessment point reported by the nominated 'family member/friend' (n=18) of participants in the FAME group was 2.6 points with a standard deviation of 1.3 points (range 1 - 6 points). The mean change in the CSI scores of the nominated 'family member/friend' in the control group between post-intervention and the three month follow-up assessment was -0.2 points with a standard deviation of 1.1 points (range -3 - 1 point). The mean change in the CSI score in the FAME group was -1.3 points with a standard deviation of 1 point (range -3 - 1 point). The point estimate for the difference in the change in scores from T2 to T3 between the two groups was 1 point with a 95% confidence interval (1 - 2 points), in favour of the FAME group ($p \leq 0.001$). Therefore it can be concluded that there was a significant difference in the change in levels of carer strain reported by 'family members/friends' of the person with stroke from T2 to T3, when assessed using the CSI at T3. Family members of the individuals with stroke in the FAME group reported significantly less levels of carer strain than those in the control group. The summary statistics for both groups are presented in Figure 5.18. The outliers illustrated at T3 in the FAME groups represent two family members whose levels of carer strain has reduced from T2 to T3 but were still higher than the other family members in the group at this assessment point.

Figure 5.18: CSI scores of 'family members' in the Control and FAME groups at T2 and T3



5.9 Summary of three month follow-up outcome measures

- There was a statistically significant difference in the change in scores observed in the control and the FAME group between T2 and T3 in the following outcome measures: SMWT, RNLI and the N-EADL. The participants in the FAME group improved significantly more than participants in the control group from T2 to T3 on these outcome measures.
- There was no significant difference between the groups in the change in scores between T2 and T3 on the following outcome measures: LL-LMA, MAS, BBS and BI.
- There was a significant difference between the groups from T2 to T3 in the change in levels of carer strain reported by the family members. Family members of participants in the FAME group reported a significant decrease in their levels of carer strain from T2 to T3 when compared to family members in the control group.
- Table 5.6 contains the summary statistics of the three month follow-up (T3) outcome measures and the change in scores observed in these measures from T2 to T3.

Table 5.6: Summary statistics of the Control and FAME groups at T3 and changes in scores from T2 to T3

OUTCOME MEASURE	CONTROL GROUP				FAME GROUP			
	Mean Score T3	SD T3	Mean Change (T2 to T3)	SD (T2 to T3)	Mean Score T3	SD T3	Mean Change (T2 to T3)	SD (T2to T3)
LL-LMA	28.8	10.4	1.3	5.2	32.2	5.4	1.6	2.4
MAS	35.2	10.8	0.7	2.6	37.9	9.7	1.8	3.8
BBS	37.6	16.21	1.8	8.5	46	14.2	0.9	2.5
SMWT	162.1	143.4	-3.5	32.7	271.6	154.5	39.8	55.4
BI	83.3	19	1.5	11.6	92.3	13.8	3.8	8.3
N-EADL	32	20.7	3.6	7.8	41.5	15.5	7.6	8.3
RNLI	32.9	7.1	0.4	2.9	37.4	5.6	4.7	4.3
CSI	3.2	2.7	-0.2	1.1	2.6	1.3	-1.3	1

BBS - Berg Balance Scale, **BI** - Barthel Index, **CSI** - Caregiver Strain Index, **LL-LMA** - Lower limb section of the Lindmark Motor Assessment, **MAS** - Motor Assessment Scale, **N-EADL** - Nottingham Extended Activities of Daily Living Index, **RNLI** - Re-integration to Normal Living Index, **SD** - standard deviation, **SMWT** - Six Metre Walk Test, **T2** - post-intervention measurement, **T3** - three month follow-up measurement

5.10 Conclusion

The results of the quantitative measures presented in this chapter suggest that additional family mediated exercise had a significantly positive impact on outcome following stroke. The changes in scores from T1 to T2 in all outcome measures administered were significantly greater in the FAME group than the control group. There was no difference in the quality of life measures at T2. However, the three month follow-up scores indicated that participants in the FAME group were significantly more integrated into their community than their counterparts in the control group. Furthermore, the change in levels of carer strain reported by the family members in the FAME group from T2 to T3 was significantly better than the change in carer strain reported by those in the control group. The output of this chapter will be comprehensively discussed in Chapter 7.

CHAPTER 6

RESULTS OF SEMI STRUCTURED INTERVIEWS FOLLOWING THE FAME INTERVENTION

The aim of this chapter is to present the results of the semi structured interviews that were completed with participants with stroke and their family members following the FAME intervention. This qualitative assessment examined the impact of the additional family mediated exercise programme from the perspective of the person with stroke and his/her nominated family member. The content and analysis of this component of the study was based upon the principals of 'phenomenology' as described by Husserl (1931) and detailed in Chapter 4, Section 4.12.

'Phenomenology' is often considered a philosophical perspective as well as an approach to qualitative methodology. It has a long history in several social research disciplines including psychology, sociology and social work. Phenomenology is a school of thought that emphasises a focus on people's subjective experiences and interpretations of the world. Phenomenologists believe that the 'truth' of the event is subjective and knowable only through embodied perception (Starks and Brown-Trinidad 2007). The essence of 'phenomenology' is the requirement for the researcher to reduce or bracket any previously held preconceptions and assumptions in order to allow the 'true' phenomenon to be revealed (Lowes and Prowse 2001). Through close examination of individual experiences, phenomenological analysts seek to capture the meaning or essences of an experience or event. The purpose of the interview was to enhance the authors understanding of the participants 'lived in' experience of the FAME programme and also to examine whether the programme had influenced their perceptions of exercise and exercise delivery after stroke.

6.1 Semi-structured interview with the individual with stroke

Fifteen individuals with stroke completed the semi-structured interview following the eight week FAME intervention. The remaining five individuals, who were allocated to the FAME group initially, were unable to complete the interview due to attrition from the programme (n=3) and refusal to complete the interview (n=2). Interviews were

completed either in the hospital, at the person's home or at the Discipline of Physiotherapy in Trinity College - the location of the interview was determined by the location and preference of the individual with stroke and his/her family member at that time point. The interview with the participant consisted of a series of twelve questions (Appendix 31) that encouraged the individual to explore their experiences in relation to the involvement of their family member in the delivery of exercises to them and to identify any perceived benefits or otherwise resulting from their own participation in the study. Each interview was completed by a person unknown to the individual. All interviews were completed by the same person, who is experienced in qualitative data gathering methods.

6.1.1 Question 1

Did you think that the additional programme helped you in any way?

All participants (n=15) reported that the additional exercise programme had helped them with their recovery following stroke. The specific ways in which the programme helped them were further explored in question 2.

> *'Ah yes, a hundred percent'* [TCD 07]

> *I think it did, 'cause if I didn't have the additional exercises, there's no way I would've got back to my..., back to the way I am at the moment.'* [TCD 08]

> *I can, I..., my honest belief is that I wouldn't be where I am now without it...'* [TCD 09]

> *'Tremendously, absolutely'* [TCD 015]

6.1.2 Question 2

In what ways do you think that the additional exercise programme has helped you, for example, has it improved your ability to move around, your balance or your confidence?

Participants indentified a number of different ways that the programme had helped them, including improvements in their balance, confidence, mobility and physical impairments. Table 6.1 presents the number of participants that reported an improvement in the various aspects of their impairments and activities following stroke.

Table 6.1: Improvements identified by individuals with stroke following FAME intervention

IMPROVEMENT IN IMPAIRMENT/ACTIVITY	NUMBER OF INDIVIDUALS WITH STROKE* (n=15)
Physical impairment	7
Balance	11
Mobility	14
Confidence	10

* Individuals with stroke could indicate more than one area of improvement

The following quotations illustrate the responses noted in relation to an improvement in physical impairments:

'...the leg was getting stronger with the exercises, even in the bed you know.' [TCD 02]

'... all of those things (additional exercises) helped me develop a lot more strength in my legs, calves and thighs.' [TCD 09]

'... it kept the muscles worked up and all you know, all loosened up like.' [TCD 14]

Participants also noted an improvement in balance following the additional exercise programme.

> *'Well eh, it helped me with my balance, because I couldn't, you know the one, the amm..., the exercise where you put one foot in front of the other. You know the one. I couldn't, I eh wobbled all over the place. I can, I get it almost now and I'm improving all the time at it, but in the beginning I just wobbled, I couldn't close my eyes and do them which you're supposed to do, but that definitely helped me with my balance, yes...'* [TCD 03]

> *'The exercises that X (FAME physiotherapist) gave me everyday, I done them, and improved me balance and everything else...'* [TCD 07]

> *'... the various exercises that X (FAME physiotherapist) got me doing... all of those things helped my develop... my balance'* [TCD 09]

Ability to walk was also identified as an activity that improved following the programme.

> *'I can walk perfectly now I reckon, and I can walk for quite a long time and she (FAME physiotherapist) gave me these movements and I practised them every day and amm..., so I'm coming on every day.'* [TCD 01]

> *'I suppose the exercise then in the bed helped when I started to walk, I started to walk very quick after that...'* [TCD 02]

> *'It helped me to walk you know...'* [TCD 12]

Finally, participants also highlighted the impact that the additional exercise programme had on their confidence.

> *'My confidence grew all the time, every time I made progress, my confidence improved'* [TCD 03]

> *'I was getting more confident with it (the additional exercise), you know that type of way as I went on, you know so ammm... definitely helped with that an awful lot'* [TCD 07]

> *'I've got my confidence back now'* [TCD 08]

6.1.3 Question 3

What part of the programme was most beneficial?

In response to this question, participants were asked to identify the component of their FAME programme which they considered to be the most beneficial. The responses to this question are contained in Table 6.2.

Table 6.2: Element of the FAME programme that was most beneficial according to individuals with stroke

MOST BENEFICIAL ELEMENT OF FAME PROGRAMME	NUMBER OF INDIVIDUALS WITH STROKE* (n=15)
Additional exercise therapy	11
Family involvement	4
Balance exercises	5
Visit from physiotherapist	4

* Individuals with stroke could indicate more than one element of the programme

Seven respondents noted that a single element of the programme, such as the additional exercises, or the family involvement in their programme or the visit from the physiotherapist, was the most beneficial part of the FAME programme for them.

> *'The exercises, well all the exercises with my leg, that was the best.'* [TCD 08]

'Well I think all the exercises, you know, all of those were extremely important to me'
[TCD 09]

'Me wife attended all of these sessions and all and even though she wouldn't speak as much as I do, and the whole lot but she was taking things in...' [TCD14]

Seven others noted that a combination of two or more elements of the FAME programme were the most helpful for their recovery.

'Well I suppose it was the exercises and being helped by the family to do them you know.'
[TCD 02]

'I suppose X (FAME physiotherapist) visits were super but I think the exercises was the key to it all and the fact that they were explained so well and what the benefit was for me, where it was going to benefit me, was all explained so well, I had no doubts, no worries in doing them.'
[TCD 10]

'Well apart from the exercises, I suppose the encouragement from X (FAME physiotherapist)... She was so interested in my progress and the way she explained them to my family...' [TCD 15]

One person suggested that the programme in its entirety was very beneficial for him and was unable to single out an individual element that was most beneficial for him.

'I really can't say... I think the overall thing taken together as one, the overall thing was good.'
[TCD 05]

6.1.4 Question 4

What motivated you to continue and complete the programme? For example, was it the involvement of your family in the programme, filling out the daily exercise diary, weekly visits from the physiotherapist or an improvement in your balance, mobility or confidence that motivated you?

Table 6.3 contains the range of different responses to this particular question. Family involvement in the additional exercise programme was identified by ten participants as a motivator to complete the programme.

Table 6.3: Motivators that assisted individuals with stroke to complete the FAME programme

MOTIVATORS TO COMPLETE THE PROGRAMME	NUMBER OF INDIVIDUALS WITH STROKE* (n=15)
Family involvement	10
Visit from the physiotherapist	8
Physical improvements noted	7
Encouragement from physiotherapist	7
Self-motivation	4
Responsibility to physiotherapist	4
Filling in exercise diary	3

* Individuals with stroke could identify more than one motivator

A number of comments made by participants in this regard included the following:

> *'Just having my mom and my sister and my brother there to motivate me'* [TCD 08]

> *'The fact that I had XX (wife) pushing me as well with some of the exercises and making sure I did them, that was very important yeah'* [TCD 11]

> *'Having my family involved was great too'* [TCD 12]

Several other factors were identified by participants as having assisted in the completion of the FAME programme such as the weekly visits from the physiotherapist:

> *'And X (FAME physiotherapist's) visit every Monday, it was definitely helpful'* [TCD 02]

> *'Yeah definitely the visit from X (FAME physiotherapist) every week...'* [TCD 06]

The physical improvements noted by participants also motivated their continuation with the programme:

> *'Well the way I could see myself improving each week...'* [TCD 06]

> *'And what really motivated me... I think it was the improvement. I think it was when I was accomplishing the exercise.'* [TCD 10]

Encouragement from the FAME physiotherapist was also mentioned by seven participants.

> *I used to look forward to X (FAME physiotherapist) coming out...yeah and her encouragement when she'd come out and say, "Now that's great", that encouraged me to keep going better.'* [TCD 01]

> *'She encouraged me an awful lot you know'* [TCD 07]

The self drive and self motivation to improve and recover was also an important factor that motivated some participants to complete the additional exercise programme.

> *'Oh, because I'm motivated to get better and back to where I was, you know.'* [TCD 01]

> *'Amm, I would be motivated, I was born motivated. It's self motivation.'* [TCD 11]

Four participants commented that they felt a responsibility to the physiotherapist to complete the programme.

> *'Yes, I wouldn't let X (FAME physiotherapist) down, since she had invited me to be in it, there was no way I was going to let her down because apart from the physical development, it was also the encouragement that she gave every time she came out, it was immense, and there was no way I was going to let her down so I did it every single day...'* [TCD 09]

> *'To be as good and better as you can possibly be for X (FAME physiotherapist) the next day, for her to assess you..., to look at you, to see how well you did it and she'll always tell you could've done it a bit better...'* [TCD 10]

Finally three participants reported that filling out the exercise diary helped them to complete the programme.

> *'The exercise diary also helped... it made you do it.'* [TCD 03]

6.1.5 Question 5

Do you think that you will continue with your exercises now that you have completed the programme?

Thirteen participants maintained that they would continue with the exercise programme and two participants were unsure as to whether they would continue with the exercises. One of these participants indicated that he would continue with the programme if it maintained his current level of fitness and mobility.

> *'I don't really know. It's just to think that if it will keep me sort of.... fit and help me to do walking.'* [TCD 02]

6.1.6 Question 6

What do you think would help you to continue with your exercises? For example, would you like to keep an exercise diary and have it checked? Would you like it to be checked by post or in person? Would you like to meet with the physiotherapist at home or in the hospital?

Participants noted that a range of different facilities and services would assist them to continue with their exercises. Many of the responses were similar to those documented in question 4 (Section 6.1.4). Eight participants noted that their own self-motivation and self-drive would assist them to continue with their exercises following completion of the programme.

> *'Well, the motivation is really to get myself fit, to get back to work. You know, to be independent, to be able to drive my car again.'* [TCD 01]

> *'It's up to myself you see, to, to, to... continue you know, nobody can do it but myself so...'* [TCD 04]

> *'Amm, well some people might need a structured exercise programme going forward but I've no problem, I will do the exercises one way or the other...'* [TCD 11]

A visit to/from the physiotherapist on a regular basis was also identified by five participants as a service that would assist them with their continued involvement in exercise.

> *'Yeah, if somebody checked in with me at a regular basis that I knew they were going to be coming and asking questions again about how I was doing that would motivate me then to do it.'* [TCD06]

> *'If you had somebody independent testing you each week or each fortnight or even someone sending you out a set of exercises to do, you know while you have an independent assessment of what you're doing, yes would certainly help.'* [TCD 11]

'Somebody to visit my home, preferably every six weeks or so...' [TCD 12]

Four participants indicated that an exercise list including an exercise diary, similar to the one provided during the exercise programme (See Appendix 29), would motivate and assist them to continue exercising.

'Yes I think a diary, or someway of keeping, eh, a record.'[TCD 03]

'If I had a list, just a clear, one, I have them all on several pages, but if I had them all on page that could do a little tick of them each day when I'm, I'm doing them...(Interviewer: "Like a diary almost?") Yeah, yeah...' [TCD 09]

'I think having it down there, written down, ticking it off that you did it, signing it off.'
[TCD 10]

Continued family involvement in their exercise programme was also noted by two participants.

'No, well, just if, once my family around me and they could motivate, that would get me back.'
[TCD 08]

'If I had a clear list of the exercises that are good for me, for balance and things, if I had one of those, and eh, I know XXX (wife) is very good at this, she's, she wants me to improve as well...'
[TCD 09]

6.1.7 Question 7

Do you think that the programme added pressure to your daily life?

In response to this question, participants were asked if they perceived that participation in the FAME programme added pressure to their daily lives. None of the 15 participants reported that the programme added pressure to their daily lives. On the contrary, the majority of participants (n=10) indicated that participation in the programme was a positive experience and twelve participants reported that it added a sense of structure to their daily life.

> *'I don't think it added any pressure. I thought it was a thing to do and ammm..., it got me right and I'd get more confident doing it (exercise).'* [TCD 01]

> *'Oh no, no, not at all, in fact I looked forward to it...'* [TCD 03]

> *'Absolutely not, because the one thing that, you, drive you mad in, in a place like this, is you spend so much time sitting around in a chair... so it was an encouragement for me to get up and do something worthwhile...'* [TCD 09]

> *'No, no. It gave me a structure where I would have done my physio, I would've done my exercises again but then that would've been it really, whereas I had this exercise programme, it was structured, it was well thought out and it was you know, it motivated me again at 6 o' clock in the evening - I had something else to do.'* [TCD 10]

> *'No it added a small bit of structure to it actually, 'cause when you're sitting around doing nothing, you have to drive yourself, motivate yourself to do these exercises and you might not do them if you hadn't got the structure.'* [TCD 11]

6.1.8 Question 8

Do you think that your family member/friend [NAME] was happy to assist you with the programme?

All participants reported that their nominated family member/carer was happy to assist them with the additional exercise programme.

> *'Ah they were very happy yeah. Yes, very happy. There was no problem there. From the beginning, they said yes.'* [TCD 02]

> *'Very happy, she was absolutely brilliant, like one of my own you know, my own mightn't take as many pains as XXX (carer) but she got me there and got me to do them and made sure I did.'* [TCD 04]

> *'Yeah, cause all my wife wants is for me to get better.'* [TCD 14]

6.1.9 Question 9

Do you think that the programme added additional pressure to their daily lives?

Twelve participants reported that the additional programme did not add pressure to their family member/carers daily life. Six of these participants added that their family member thought that participation in the programme was a positive experience.

> *'No I think the programme was pretty good to her because ah, she could see me doing the exercises and see me getting better...'* [TCD 01]

> *'No, it definitely didn't put any pressure on them. They were happy enough to do it.'* [TCD 02]

> *'No, no, no. it actually took pressure off him. Because he knew what I was doing was right and he knew what I was doing was doing to benefit me...'* [TCD 10]

> *'No, he enjoyed doing it with me....'* [TCD 12]

Two participants indicated that the FAME programme added additional pressure to his/her family member's daily life.

> *'I think it probably did, because she'd to look after me and home and do the shopping and all.'* [TCD 05]

> *'Yes, absolutely, it took up their time... but they didn't mind...'* [TCD 15]

One participant was unsure as to whether the programme added pressure to his family's daily life.

> *'Well, that I don't know, if it did they didn't say...'* [TCD 08]

6.1.10 Question 10

Can you rate your satisfaction with the programme on a scale of 1 to 5? (1=very dissatisfied, 2=dissatisfied, 3=neither satisfied nor dissatisfied, 4=satisfied, 5=very satisfied)

Twelve participants indicated that they were 'very satisfied' with the FAME programme. One participant rated the programme as four out of five or 'satisfied' and two participants scored the programme as 4.5. Although this question was predominantly quantitative, a number of participants made illustrative comments. The following are a sample of these comments:

> *'Five yeah, I'd say five because it definitely did help me get up and walk. They (my family) couldn't believe I walked so quick.'* [TCD 02]

> *'Five, five, five out of five, you know. I was very happy.'* [TCD 07]

> *'Oh I was very satisfied with it. It was... from the first day the... X (FAME physiotherapist) came to me; I couldn't see how it was all going to pan out or how I was ever going to walk again. And when she was explaining what it was going to do, I couldn't foresee all of this happening and it has happened in leaps and bounds.'* [TCD 10]

6.1.11 Question 11

Would you encourage someone else in your position to undertake this programme?

All participants indicated that they would encourage other individuals with stroke in their position to undertake such a programme.

> *'Definitely yeah... Yes if they had... if they were the way I was, yes, definitely. It has to be... have to do them good you know.'* [TCD 02]

> *'Absolutely, absolutely, I mean I keep telling all the others here that I'm, about X (FAME physiotherapist) and what she did for me and how she helped me, mentally as well as physically, you know it was the encouragement was as much as, was a great help, with the physical exercises also strengthened my body to be able to deal with all the other things that came along.'* [TCD 09]

> *'Oh yeah, without a shadow of a doubt, oh not a hesitation, yeah.'* [TCD 10]

> *'Absolutely, I would really and truly 'cause I look at me and that's that. I would encourage everybody who could possibly do it to do it.'* [TCD 15]

6.1.12 Question 12

Finally, is there anything further you wish to say or add to what you have already said?

The majority of participants (n=11) stated that participation in the FAME exercise programme was a positive experience for them and that the programme itself was worthwhile. They also reported that the encouragement they received from the physiotherapist was helpful.

> *'No, I don't think so. I think we've been through it all. I think the encouragement I got throughout the programme was excellent and it was well worth doing. You know, so I don't find... I find it's been a great help really.'* [TCD 01]

> *'I mean, you only gain from it, you lose nothing, you gain. I must say that X (FAME physiotherapist) was an exceptionally nice tutor. And was very patient, listened to you and go on from there, she was very good.'* [TCD 03]

> *'No, I'm happy with everything now, it was great, absolutely brilliant doing it with her.'* [TCD 06]

> *'There isn't really. I think X (FAME physiotherapist) is a very dedicated girl. I think she was enthusiastic and her enthusiasm just fuelled all of ours. Apart from whatever it was doing to her PhD but I think her programme was wonderful... absolutely wonderful....'* [TCD 15]

6.2 Summary of the interviews with the individuals with stroke

The phenomenological basis for this piece of work allowed the author to gain a deeper understanding of the 'lived in' experience of being involved in the FAME programme, as experienced and expressed by the individual with stroke. Overall, it has been established that the participants in this RCT thought the FAME programme was worthwhile and identified several benefits to them as a result of their participation. Some participants (n=7) identified individual elements of the programme that they perceived to be the most beneficial in helping them with their recovery and their

continued participation in exercise. Others (n=7) noted that a combination of different elements of the programme assisted them with their recovery. These responses highlight the importance of an individual approach to patient care following stroke, which was an integral facet of the FAME programme. No participant remarked that the additional exercise programme was an additional pressure to their daily life. All participants indicated a high level of satisfaction with the programme and would encourage somebody else in their position to take part in such a programme. In terms of the pressure it added to their 'nominated' family members' daily life, the majority of participants did not perceive it as an additional pressure or strain and felt that their family members were happy to assist them with the exercises. The final remarks by participants suggested that the encouragement from the physiotherapist was helpful. This has also been mentioned by people with acute stroke as an important trait in physiotherapists treating this patient group (Galvin et al 2009b). On the whole, this qualitative data provides a rich insight into the experience of individuals with stroke in the FAME programme. The output from the interviews suggests that the participants in the FAME programme were happy with the programme and viewed their participation in the programme as a positive experience.

6.3 Semi-structured interview with the nominated family member

The semi-structured interview with the nominated family member (n=15) was also undertaken at eight weeks, when the person with stroke had completed the exercise programme. Five family members did not complete the interviews as a result of attrition from the study (n=3) and refusal to participate in the interview (n=2). Each interview was conducted immediately after the interview with the individual with stroke at the same location. The interview with the nominated family member consisted of a series of ten questions that encouraged the individual to explore their experiences in relation to their involvement in the delivery of exercises to their family member with stroke and to identify any perceived benefits or otherwise resulting from their participation in the study. All interviews were completed by the same person who completed the interviews with the individual with stroke.

6.3.1 Question 1

Do you think that the additional exercise programme helped [NAME] in any way?

Fourteen family members indicated that the additional exercise programme helped their family member with stroke in some way. The specific ways in which the programme helped their family member with stroke were explored in question 2.

> *'Oh yeah, big time, it helped right from the beginning...'* [TCD FM 02]

> *'Oh yes, without a doubt... When X (FAME physiotherapist) came and put him into the programme, the extra support and exercise was just great. Like, she continuously encouraged him and it definitely helped him... it was a massive help.'* [TCD FM 11]

> *'I do. I definitely do. I think it helped him in a very big way. Like I thought, like X (FAME physiotherapist) gave him great enthusiasm to help him to move. Like I remember the first night that he was able to lift up his foot, it was only a tiny little bit, but he was so thrilled about that but it's just, like there, and having the extra help, it just did, it meant an awful lot to have to be honest like, I think it really helped XX (husband).'* [TCD FM 14]

One family member reported that she found it difficult to get her husband to complete the required exercises on a daily basis due to fatigue. This was also noted in the participants exercise diary.

> *'He wasn't terribly co-operative in doing the exercises.... he was very, very, very tired at the start. He really hadn't the energy to be doing extra exercises for a good few weeks...'* [TCD 05]

6.3.2 Question 2

In what ways do you think the programme has helped them, for example has it improved their ability to move around or their balance or confidence?

This question was designed to allow family members to elaborate on their response to the first question. Table 6.4 displays the responses to this question.

Table 6.4: Improvements in the individual with stroke following the FAME programme as noted by their family members

IMPROVEMENT IN IMPAIRMENT/ACTIVITY	NUMBER OF FAMILY MEMBERS* (n=15)
Physical impairment	5
Balance	9
Mobility	6
Confidence	7

* Family members could indicate more than one area of improvement

Family members outlined a variety of ways in which the FAME programme helped their family member with stroke to recover. These included improvements in their physical impairments (n=5):

> *'...his stomach muscles, were strengthening like, so much quicker that what, because they weren't the exercises he was doing within the physiotherapy that week, but because X (FAME physiotherapist) had already started him on that, so literally within a week he was starting to stand again.'* [TCD FM 02]

> *'It did help her like and when she was doing the exercises, she was complaining, well not complaining, that the muscles were sore so they were obviously working then, you know...'* [TCD FM 12]

> *'She was actually getting a physical improvement in her exercises and I could see that.'* [TCD FM 15]

Family members (n=6) also noted an improvement in mobility following the additional intervention.

> *'Well it helped him get, he, his leg was, it wasn't completely paralysed on the left but it was, eh, he was dragging it, but now he is able to walk and he's, and he got the exercises so he was able to do the exercises at home and he did them everyday, so I think he's walking quite well, you know, whereas before if he'd gone they don't concentrate on one part, they'd be doing, they'd be giving him physio all over but at least that was just particularly for his leg. So I think it helped him greatly.'* [TCD FM 01]

> *'Oh I did see with the amm..., with the walking that he had got much better... you could see a gradual increase all the time, from week to week you could see a gradual increase.'*
> [TCD FM 08]

> *'She can get around with the stick now without any help... because, she..., she practised all her exercises every evening...'* [TCD FM 10]

The following quotations illustrate the improvement in balance noted by nine family members:

> *'...in the beginning her balance now was, it wasn't great... and it definitely did help her yeah, it did.'* [TCD FM 04]

> *'Like at the start his balance was all over the place and since he's been working on that programme I think his balance is a lot better you know.'* [TCD FM 07]

> *'Like her balance has improved every week with the exercises'* [TCD FM 10]

Family members (n=7) also commented on the impact that the programme had on their family member's confidence. The following selection of quotations demonstrates the improvement in confidence noted by the family members of the individual with stroke.

> *'I think it helped her confidence as well as, you know, the actual exercises, definitely did...'* [TCD FM 04]

> *'Well I think it, it, I think it improved his, I do think it improved his confidence because X (FAME physiotherapist) believed in him, you know...'* [TCD FM 09]

> *'He got more and more confident as the weeks went on and the encouragement and support from X (FAME physiotherapist) was just fantastic.'* [TCD FM 11]

> *'Oh yeah, I mean all of them because every little bit of exercise extra, anything extra, definitely to me. It was obvious that it was helping him and it gave him more confidence, it definitely gave him more confidence in what he could do.'* [TCD FM 13]

Three family members reported that the additional exercise programme gave their family member a sense of structure to their day.

> *'I would say, emm..., it gave her extra focus, it gave her something to do herself apart from what she did with the physio's at the time, because I don't think she would've been that good at doing stuff herself yeah, it kind of gave her, gave her something to do, that she had to do.'* [TCD FM 03]

> *'It gave him something very definite to work on, you know and to do himself, emm, because he likes to be, to take control over things himself, so it gave him some control over what was happening to him.'* [TCD FM 09]

> *'I think even though he is very motivated, it kind of got him into a new kind of, this was a routine that had to be done and you know when you went up in the evening time, no matter who was doing the work with him, it was "Ok, let's do the exercises"'.* [TCD FM 13]

6.3.3 Question 3

What part of the programme did you think was most beneficial?

Family members were asked to identify a component of the FAME programme that they perceived to be most beneficial to their family members recovery. Table 6.5 contains the responses of family members to this question.

Table 6.5: Element of the FAME programme that was most beneficial according to the family members

MOST BENEFICIAL ELEMENT OF FAME PROGRAMME	NUMBER OF FAMILY MEMBERS* (n=15)
Additional exercise therapy	13
Family involvement	7
Balance exercises	8
Visit from physiotherapist	10

* Family members could indicate more than one element of the programme

Seven family members detailed that a combination of different elements of the programme was most beneficial, while others (n=4) indicated that the entire programme was beneficial in terms of helping their family member to recover.

> *'I think the whole programme was really good, the exercises, X (FAME physiotherapist) calling and the filling out the... writing the exercises down. I think it all helped.'* [TCD FM 10]

> *'Well, the whole lot! The whole lot I think, because..., because it was different ones (exercises) every week, one of a week with the leg, pushing the bum up and that so I think the whole lot...'* [TCD FM 12]

> *'I think the whole thing, all together...'* [TCD FM 13]

> *'The whole programme... There was no one part of the programme. I think that the whole programme worked for her.'* [TCD FM 15]

Other elements of the programme that family members perceived to be helpful included the additional exercise therapy, the balance and mobility exercises, and the weekly visits from the physiotherapist.

'The extra therapy he was having...' [TCD FM 01]

'Well I think the fact that she saw X (FAME physiotherapist) every week and she was given something to do and I think the focus and the attention, yeah I think probably would have been, yeah, yeah...' [TCD FM 03]

'Emm, at the moment I'd say the balance like, you know what I mean, that, that part was brilliant, because he was all over the place when he came out of the hospital, so I'd that'll be yeh, the balance yeah.' [TCD FM 07]

'I..., I suppose the walking really was the most beneficial.' [TCD FM 08]

'Amm, I thought the weekly visits from X (FAME physiotherapist) were really good 'cause in a way..., they motivated XX (husband) to do the exercises everyday... 'cause he knew that they would be checked the following week by X (FAME physiotherapist). I think too, the fact that he could see the benefit of the exercise and how it was making him walk better and balance better....' [TCD FM 11]

'...I never expected him to walk again so like that really to me was brilliant. That he actually walked again.' [TCD FM 14]

6.3.4 Question 4

Do you think that the programme added additional pressure to [NAME] daily life?

Twelve family members reported that the FAME programme was not an added pressure to their family members' daily life. On the contrary, while the response was dichotomous in nature, several family members elaborated and suggested that the programme was a positive experience for the individual with stroke.

> *'Eh, no, no, he was quite, in fact he was very keen, and very, very eager, to do, get this done and get himself back together, he's been very positive about the whole thing, so it certainly was no effort to him at all...'* [TCD FM 01]

> *'Pressure, oh God no he loved it, oh he loved it.'* [TCD FM 02]

> *'No, not at all... In fact I think he was delighted to have the programme because it gave him a sense of control over his... getting better.'* [TCD FM 11]

> *'No because the only thing extra was he was doing was extra physio but he wanted to do the physio to get back to normal, to get back to some normality you know...'* [TCD FM 13]

Three family members noted that the additional programme was an added pressure for their family member, for various reasons such as fatigue and lack of time.

> *'I think it could have in that he was so tired it was just an extra thing for him to do and extra pressure for me to try and get him to do it.'* [TCD FM 05]

> *'...like you've got to find the time every night eh, at half eight or eight o'clock or whenever she gets rid of the visitors, to do the stairs, you've got to find the time to do it.'* [TCD FM 06]

> *'Yes, I do and I think she made it out to be a pressure when it shouldn't have been but I think that was Mammy's state of being at the time and I don't think that was a problem.'*
> [TCD FM 15]

6.3.5 Question 5

Do you think that you will continue to assist or encourage [NAME] to exercise now that the study has been completed?

Fourteen family members indicated that they would continue to encourage and assist their family member with stroke to exercise following completion of the study.

> *'Oh, yeah, yeah, I mean I've been, I've been at her to walk everyday and that, to go out for a little walk and stuff, yeah, yeah, definitely.'* [TCD FM 03]

> *'Oh definitely yeah, definitely, emm, definitely think he's going to continue on where he left off like you know, emm, because if he doesn't he's just going to back into the old rut again like, you know, and I know I..., if he doesn't I know I'll be there in any ways to, just give him that extra bit of push as well, you know.'* [TCD FM 07]

> *'Yes, without a doubt... But XX (husband) is very motivated to keep doing the exercise himself anyway.'* [TCD FM 11]

One family member noted that her husband had achieved his baseline mobility status and therefore suggested that she wouldn't encourage or assist him to continue with his exercises because:

> *'Well, physically he's quite good so probably not... no.'* [TCD FM 05]

6.3.6 Question 6

What do you think would help you to continue to assist or encourage [NAME] to exercise now that the study has been completed? For example keeping the exercise diary and having it checked regularly by the physiotherapist? Would you like to meet with the physiotherapist at home or in the hospital?

The majority (n=11) of family members noted that a visit with a physiotherapist either in the hospital or the home setting would assist them to encourage their family member to continue with their exercises.

> *'I think some contact definitely, because I think if there's no follow up she will kind of, and I think as she gets better she will be less likely, you know, which I suppose is normal.'*
> [TCD FM 03]

> *'Yeah, I think maybe some sort of a check, you know, now and again, just to kind of confirm I suppose were still continuing, you know when you continue something you might slip into sort of ways of not doing maybe correctly so yeah maybe, well whichever, maybe somebody would call occasionally or whatever would, I mean, I wouldn't mind coming...'* [TCD FM 04]

> *'I think if he could check in with a physiotherapist on a regular... like even we'll say once a month or even every six weeks. 'Cause he has come on so much since he first had the stroke... and I suppose to maintain that. I think a regular check up with a physiotherapist would be great for him... and again as I said, it would give him the added motivation to keep up with it.'*
> [TCD FM 11]

> *'I think if he met a physiotherapist regularly, like and amm, even if it was to come to the hospital or to go to the home but I think he could do with meeting somebody...'* [TCD FM 14]

Furthermore, five family members noted that the provision of an exercise diary would help them to encourage their family member to exercise.

> *'I definitely think an exercise diary would be important...'* [TCD FM 06]

> *'...but I think filling out her exercise sheet would help her too... she can see it in front of her then like...'* [TCD FM 10]

> *'I think yeah like that, a diary would be good as well.'* [TCD FM 13]

Self-motivation on the part of the individual with stroke was also mentioned as an important contributor to continued involvement in exercise by two family members.

> *'Yeah well he will, he does them himself even when he comes out at the weekend anyway, like, and he's, that's just the type of man he is, he's determined, so he will carry them on like...That's the type of man he is.'* [TCD FM 02]

> *'Mammy is certainly very determined and if some people weren't as determined as Mammy, I think a routine may be important for people to maintain the status quo of their physical ability.'* [TCD FM 15]

6.3.7 Question 7

Do you think that assisting with the exercise programme added pressure to your daily life?

Thirteen family members reported that the additional exercise programme did not add pressure to their daily lives. While the response to this question was again dichotomous, more than half of the family members detailed how the exercise programme gave them a sense of involvement in the rehabilitation process and allowed them to contribute towards the individual's recovery. The following are a selection of quotes that convey these sentiments:

> *'Pressure? No, no, no pressure, emm, because we were coming to see him anyway and for us it was more of a worry if we just seen him lying there doing nothing. If he was...emm, if he was just lying there doing nothing that would have been more of a worry than... no it was never a pressure on us, not at all.'* [TCD FM 02]

> *'No, no it didn't really, because, I mean I was in with XXX (individual with stroke) anyway so it was just really something else to do in the course, it didn't no, I didn't find it ... what I found personally in the hospital particularly you know, when I had to go into XXX (individual with stroke) each day, and it sort of gave me, like I felt I was doing something for her and with her, you know, it sort of gave a focus to the day as well, rather than just kind of sitting there and you know...'* [TCD FM 04]

> *'Eh no again it, I think it gave me a sense that I could do something, because, you know one of the worst things for me, was the feeling of helplessness, that I couldn't, I couldn't change this, I couldn't actually do much about it, and at least it gave me something positive that I could do when I was visiting... it did give me a sense that at least I could contribute something towards recovery, emm rather than just sitting and encouraging him, you know...'* [TCD FM 09]

> *'Ammm, no it didn't. The whole experience of the stroke and everything was a pressure and it was very hard to manage everything at the beginning... but no, not the exercises, because I could see how they were making such a difference and how happy XXX (individual with stroke) was when he saw that improvement, so no, no they weren't an added pressure.'* [TCD FM 11]

'No, not at all, I actually found it good to be involved. You know, that was a major help to me.' [TCD FM 13]

Two family members reported that their involvement in the FAME programme added pressure to their daily lives. One family member detailed that her husband was uncooperative with the programme and that this was the primary cause of the additional pressure.

'I think it did because he wasn't being cooperative enough.' [TCD FM 05]

The other family member reported that while their involvement in the exercise programme added pressure to their daily lives in terms of a time commitment, they viewed their participation as a positive experience.

'I clearly stated that I was here to do exercises - if they (visitors) wanted to stay they could stay... so did it put pressure on me? Yes, but did I mind, absolutely no. I would do it twice over.' [TCD FM 15]

6.3.8 Question 8

Can you rate your satisfaction with the programme on a scale of 1 to 5? (1=very dissatisfied, 2=dissatisfied, 3=neither satisfied nor dissatisfied, 4=satisfied, 5=very satisfied)

Thirteen family members indicated that they were 'very satisfied' with the programme and rated the programme as five out of five. One family member indicated that their satisfaction with the programme was:

'between four and five, definitely like, yeah.' [TCD FM 07]

Another family member, who outlined that her husband was uncooperative with the exercises, rated the programme as follows:

> *'Well from our point of view, I suppose maybe 2 or 3 in that... it doesn't say it's a bad programme because of that.'* [TCD FM 05]

6.3.9 Question 9

Would you encourage someone else in your position to undertake this programme with their 'family member/friend' with a stroke?

Fourteen family members reported that they would encourage someone else in their position to undertake the FAME programme with their family member with stroke and thought that the additional exercise therapy was very helpful in terms of its contribution towards their own family member's recovery. One family member reported that she would recommend the FAME programme to others if the person with stroke was more co-operative.

> *'only if the family member was co-operative. It's too much pressure otherwise.'* [TCD FM 05]

The following quotations serve to highlight the impact of the FAME programme on the recovery of the person with stroke, according to the family members involved.

> *'Oh yeah, definitely, yeah, definitely, I think the whole programme has been terrific, the hospital and X (FAME physiotherapist), and combined together it gave him that extra, like, he wouldn't have got the specialised treatment like he's got from X (FAME physiotherapist) if he hadn't been out on this particular thing, you know, which he has had, which I think was great benefit.'* [TCD FM 01]

> *'Oh yeah, yeah, from the point of view that any, any additional help, you know, any additional thing you can get that'll help, certainly, you know, go for it.'* [TCD FM 03]

> *'I think the programme was very beneficial and I would be... I would have no problem recommending it to anyone else. Absolutely no problem whatsoever...'* [TCD FM 11]

'I couldn't but recommend it. That's been honest with you 'cause you actually see the benefit as the person is getting better...' [TCD FM 15]

6.3.10 Question 10

Finally, is there anything further you wish to say or add to what you have already said?

The majority of family members (n=11) re-iterated that participation in the FAME exercise programme was a positive experience for them because it gave them a sense of involvement in the recovery process. Furthermore, they highlighted the positive impact of the additional therapy on their family member's physical recovery. They also reported that the encouragement their family member received from the physiotherapist was helpful and highlighted the need for follow-up visits with a physiotherapist following completion of the programme. The following quotations represent a selection of the final comments of the family members in relation to the FAME programme.

'Emm, well I definitely, definitely would encourage any other like, any other families or anyone that's going through it to go with the programme because it gives you that bit of hope... its just amazing, its amazing to watch like, your going one week he's slumped down in the chair the following week because of physiotherapy, he's not, he's sitting up, his whole life has changed, he's decided yes he wants to carry on, yes he's going to do this. So yeah definitely, definitely I would encourage anybody to do it.' [TCD FM 01]

'Just I think some ongoing kind of contact would help though, or encouragement from some source...' [TCD FM 03]

'Emm just the, just one thing I would say is I think X (FAME physiotherapist) approach is fabulous in terms of motivation, emm, you know, she is, she is so bubbly, I suppose, but it's just she has this ability to, to make them believe that they can do it, you know she made XXX (individual with stroke) believe he could do it, and because of that he did it, you know she, and he, he liked her from the, day one...' [TCD FM 09]

'Not really, only to thank X (FAME physiotherapist) so much for getting us involved in the study. I can honestly say it made such a difference to XXX (individual with stroke) recovery. She was so dedicated to the project and her enthusiasm was a big motivator for XXX (individual with stroke). I have to say that he wouldn't be at this point in his recovery only for the programme.' [TCD FM 11]

'Am, basically am, I think the whole exercise programme is very good like, like I think its very good, plus the fact that it was a week of different things so one week you'd have one set, another week you'd have another set and it's just its great it makes you feel that you're doing something rather than just sitting beside the bed and not being, helpless to do anything.' [TCD FM 12]

6.4 Summary of the interviews with nominated family members

The output from this study gave the author a greater insight into the impact of the FAME programme on the family member of the person with stroke and their perceptions on how the programme impacted on the daily life of their family member with stroke and indeed their daily lives. Having regard for the phenomenological basis for this work, the 'lived in' experience expressed by the family members appeared to be that the FAME programme was a positive experience in terms of the physical improvements that they noticed in their family member. Furthermore, family members expressed the sentiment that the FAME programme allowed them to be more involved in the recovery process and negated the feelings of helplessness that they felt. These sentiments have also been reported in other studies (Carr and Shepherd 1987, Kalra et al 2004). While one family member indicated that the FAME programme added pressure to her daily life, the majority of family members were happy to assist in the delivery of exercises and are willing to assist and encourage their family member with

stroke to exercise following completion of the programme. Family members also highlighted the need for some type of follow-up with the physiotherapist to encourage and motivate the individual with stroke to continue to exercise. Finally, all but one family member would encourage families in a similar situation to participate in a similar programme and identified several benefits to the person with stroke and themselves as a result of involvement in the FAME programme.

6.5 Conclusion

This qualitative study concurs with the findings of the quantitative study. The triangulation of the different themes will be discussed in Chapter 7. It is clear from the cohort of individuals with stroke and their family members who participated in the interviews that the FAME programme was beneficial to them in a number of different ways. These included improvements in physical impairments and activities, balance and mobility, confidence building, family involvement in exercise delivery and continued involvement and participation in exercise following stroke. The phenomenological approach to the analysis allowed the author to gain a sense of the 'lived in' experience of the FAME programme from two different perspectives, that of the individual with stroke and his/her family member. The conduct and analysis of the interviews focused on the participant's subjective experiences and interpretations of their involvement in the FAME study. Through close examination of these individual experiences, the author captured the meaning or the essence of the individual's experience of the additional exercise programme. The qualitative results will be discussed more comprehensively in Chapter 7.

CHAPTER 7

DISCUSSION

The aim of the FAME programme was to examine the impact of additional family mediated exercise on outcome after stroke through the implementation of a randomised controlled trial (RCT). The literature review, presented in Chapter 2 describes the previous RCTs that have examined the impact of additional exercise therapy on outcome following stroke. However, this is the first RCT that has investigated the provision of additional exercise therapy to people with acute stroke by their nominated family members. The trial also included a qualitative element that examined, on an individual basis, the impact of the programme on the person with stroke and their family member. The following sections discuss the findings of the RCT.

7.1 Description of study groups

7.1.1 Inclusion and exclusion criteria

The criteria set out for inclusion and exclusion of potential participants in the FAME RCT ensured that the control group and the FAME group were homogenous and comparable when recruited to the study at two weeks following stroke onset. The criteria were chosen based on evidence from the supporting literature, comments from peer-reviewers (Appendix 20) and the results of the user surveys detailed in Chapter 3. Forty people with stroke fulfilled these inclusion criteria, representing 6.4% of admissions with a clinical diagnosis of stroke. While there was a requirement for stringent inclusion criteria in the FAME study to ensure comparability of 'like with like', the selection of the admission criteria points the way for future research and clinical practice to examine the impact of such a programme on individuals who were not included in this study. Almost 10% of the sample in this study was excluded as they presented with either receptive or expressive dysphasia at this time point and would not have been able to complete the post-intervention semi-structured interview. A further 14% of those screened presented with a history of a previous stroke (7.4%) or another neurological condition (6.6%) such as Multiple Sclerosis or Parkinsons Disease. The impact of such a programme on individuals with communication difficulties and co-morbidities requires further multi-disciplinary research and such individuals may be

considered suitable for a FAME programme in routine clinical practice, should the individual wish for their family to be involved in their rehabilitation.

Eleven percent of individuals with stroke presented with an MMSE less than 24 points and were also excluded from the RCT due to the issue of informed consent. While the physiotherapists that participated in the focus groups reported that cognitive impairment can impede recovery due to limited carry-over by the patient, other studies have reported that involvement of the family in physiotherapy improves carry-over by allowing the patient to practice activities with the family member or carer outside of the routine treatment hours (Carr and Shepherd 1987, Forster and Young 1992, Evans et al 1994). The involvement of family members in exercise delivery to individuals with cognitive impairment needs to be considered from the perspective of the individual with stroke and the family member in future studies of this nature.

Seven family members refused to participate in the RCT, even though they were physically able and their family member with stroke was eligible for inclusion. This figure represents just over 1% of those screened for participation in the FAME trial. In a previous study by Galvin et al (2009a), 9% of family members (n=100) reported that they would not be available to help their family member with stroke with their exercises. Commitment to work and unsuitable physiotherapy treatment hours (9am - 5pm) were documented as the primary reasons that limited participation in physiotherapy. These two issues were addressed in the FAME trial and family members were asked to attend at a time convenient for them outside of 'routine' physiotherapy hours. This may have contributed to the increase in the number of family members that were willing to participate in the FAME trial.

A total of 38% of the individuals screened had a documented Orpington Prognostic Score (OPS) score of less than 3.2 indicating a mild stroke, had been discharged from physiotherapy or discharged home. These results suggest that these individuals presented with mild impairments following stroke. This finding is similar to a previous study of motor recovery in people with stroke in Ireland (Horgan and Finn 1997). In that study a group of 42 people with stroke were studied over a 14 week period using a functional mobility assessment. Forty-one percent (n=17) of the cohort presented with mild deficits, achieving independence in the first two to three weeks following stroke.

On the contrary, almost 13% of individuals screened for inclusion to the FAME study had an OPS score greater than 5.2 indicating a severe stroke, or were not well enough to participate in the study. These figures are lower than the 26% reported in the study by Horgan and Finn (1997) suggesting that the proportion of individuals with severe stroke screened as part of the FAME study was less than the study by Horgan and Finn (1997). However, the validity of comparisons made needs to be interpreted with caution due to the differences in measures of stroke severity. Further longitudinal, multi-centre studies are required in different populations before valid comparisons can be made in terms of the proportions of stroke severity groups.

7.1.2 Age

In all studies of stroke, there is a clear increase in the incidence and prevalence with age (De Freitas et al 2005). However, there are differing views with respect to the influence of age on outcome following stroke (Ashburn 1997). Although there are several studies on the subject, differences in patients groups, outcome used and duration of study periods make their comparison difficult (Kugler et al 2003). While the mean age (63.2 years) of participants in the FAME group at baseline appeared to be less than those in the control group (70 years), this difference was not statistically significant and age was not examined as an independent predictor of outcome. A similar difference in the mean ages of the control and intervention group was noted in a RCT by Kwakkel et al (1999) examining the impact of additional exercise therapy on outcome of the upper limb (UL) and lower limb (LL) following stroke. Some researchers have identified age as an important indicator of recovery following stroke (Lindmark 1988b, Lincoln et al 1999) and other studies have demonstrated the benefits of intensive stroke rehabilitation programmes in maximising functional recovery regardless of age (Friedman 1990, Kalra 1994b). Many authors suggest that the predictive value of age depends on evaluation of the outcome (Bagg et al 2002). It appears that the negative impact of age on functional outcome is most apparent when functional status at discharge is being assessed. Conversely, when change of function is assessed, age tends not to influence outcome negatively (Bagg et al 2002).

In a previous study (Galvin et al 2009a) examining the extent of the involvement of families in physiotherapy, physiotherapists (n=10) indicated that younger patients

tended to benefit more from additional therapy. This finding was also re-iterated in the findings of the systematic review presented in Chapter 2. In the current study, the age range in both groups was similar (43 - 89 years). However, participants in the FAME group, 11 of whom were over the age of 65 years, improved significantly more that those in the control group. Considering the expected increase in the population over the age of 65 in the future, the incidence of stroke is also expected to increase (Braun et al 2007). Hence, there is an urgent need to determine how rehabilitation professionals will provide timely access to effective stroke rehabilitation programmes for all stroke survivors, regardless of age, and also to determine what resources are necessary to ensure maintenance of functional gains after rehabilitation. Family involvement or the involvement of caregivers may be a feasible option to optimise recovery in this population group.

7.1.3 Severity of impairment

With respect to early prognosis of motor recovery, a systematic review by Hendricks et al (2002) concluded that the initial grade of paresis (as measured on admission to the hospital) was the most important predictor of outcome, although the authors suggest that the accuracy of prediction rapidly improves during the first few days after stroke. In the FAME study, individuals were assessed two weeks following stroke onset. The OPS was chosen as a measure of initial impairment as it incorporates elements of motor function, cognition balance and perception. This measure was used to achieve homogeneity in the sample and has been used in a similar RCT (Kwakkel et al 1999). A score of 3.2 - 5.2 points was chosen as the inclusion score as this represents the 'middle group' of individuals, presenting with moderate to severe deficits after stroke. It has been suggested that outcome in this cohort of individuals depends on extrinsic factors such as the intensity and quality of rehabilitation, family support, the motivation of the patient and the availability of community support systems (Kalra et al 2004). Furthermore, the majority of studies included in the systematic review favoured the suggestion that people with a milder initial impairment following stroke tend to benefit more from additional therapy (Galvin et al 2008b). Therefore it was decided to include participants presenting with a 'moderate to severe' initial impairment, as measured by the OPS in the FAME trial.

While the benefits of additional exercise therapy were evident in the intervention group (median OPS score was 4 points at two weeks) following the FAME programme, further consideration needs to be given to those presenting with a more severe initial impairment, or those presenting with an OPS of greater than 5.2 points at two weeks following stroke onset. In a study examining the impact of additional exercise therapy on 100 people with acute stroke, Feys et al (1998) reported that participants who demonstrated a more severe initial impairment, as measured by the Fugl-Meyer Assessment (FMA), benefitted most from the additional exercise therapy provided. However, because the FMA does not incorporate an element of cognition, valid comparisons cannot be made between the results of that study and the FAME study. However, the contradictory findings between the results of the study by Feys et al (1998) and the results of the FAME study suggest that there is a need to examine the impact of such a programme on people with severe impairments following stroke and their family members.

7.1.4 Family involvement in the additional FAME programme

'Physiotherapists need to develop strategies whereby patients and caregivers take full responsibility for the bulk of therapy - for instance, training of balance, strength and endurance, repetition of simple tasks, group therapy, fitness-related training and family involvement.' De Weert and Feys (2002) report this recommendation in the context of a discussion in the Lancet about the required level of input for cortical re-organisation following stroke. However, the translation from science into clinical practice is relatively non-existent and there has only been one other study that has considered the impact of the family assisted exercises following stroke (Maeshima et al 2003). The role of the family and friends in the rehabilitation process of a person with stroke is significant but members of family and friends are not routinely involved in the rehabilitation process as mediators of exercise (Bailey and Rennie 1997, Galvin et al 2009a).

The involvement of family members in the FAME programme was central to the success of this intervention. At the beginning of the programme, each individual with stroke was required to nominate a family member/friend, whom they would like to assist them with their exercises, thus providing each individual with a sense of control

over the proposed intervention. Blennerhassett and Dite (2004) also report that individuals with stroke are more likely to practice motor activities when they are supervised. The additional exercise therapy was delivered primarily in the evening time between 6 and 8pm, outside of routine physiotherapy hours. This pre-arranged time of exercise delivery was of benefit to the person with stroke and his/her family member for a number of reasons. Firstly, it allowed the individual with stroke to participate in his/her routine rehabilitation programme during the day and also allowed the nominated family member to continue with their daily working schedule. Secondly, the provision of additional exercise therapy in the evenings allowed the participants the opportunity to practice tasks and activities outside routine hours.

Finally, both the individuals with stroke and their family members indentified physical and psychological benefits as a result of their participation in the FAME programme. It is important to recognise that family members and carers play an important supporting role in the rehabilitation process, a role which may increase with a growing trend of providing stroke rehabilitation in the individuals own home following discharge from hospital (Low et al 1999). Informal stroke carers represent an important resource in the promotion of successful health outcomes in people with stroke and they also provide a more cost-effective use of health and social service resources (Low et al 1999). Therefore it is imperative that family members are involved in all aspects of the multi-disciplinary rehabilitation of people with stroke from the outset.

7.2 Quantitative results

7.2.1 Post-intervention standardised outcome measures

The focus of the additional exercise programme was to improve balance and mobility in the FAME group when compared to the control group, through the involvement of their family in the delivery of an exercise programme to them. The output of the standardised outcome measures at eight weeks indicate that participants in the FAME group had improved significantly more than their counterparts in the control group. This finding is in keeping with previous studies where a significant improvement was noted in participants following an additional focused exercise therapy programme that was delivered by healthcare workers (Feys et al 1998, Kwakkel et al 1999, Blennerhassett and Dite 2004). However, this was the first RCT that examined the

involvement of family members in structured, quantifiable exercise delivery. Maeshima et al (2003) compared the improvements in LL muscle strength and mobility in a convenience sample of 60 people with acute stroke. Of these, 42 participants had family members involved in the delivery of additional exercise therapy. Each participant received 40 minutes of additional family mediated therapy daily for a period of two weeks, which was supervised by a therapist or a medical intern. The remaining 18 participants received conventional exercise therapy. Lower limb strength was measured on the unaffected leg using an isokinetic machine. Mobility status was assessed using the Rivermead Mobility Index. All participants were assessed at baseline and again after two weeks. Participants in the additional intervention group improved significantly more that those in the control group. However these results need to be interpreted with caution due to the nature of recruitment and the large inequality in numbers in the each group.

The primary outcome measure utilised in the FAME study was the lower limb section of the Lindmark Motor Assessment (LL-LMA), which is a modification of the original Fugl-Meyer Assessment (FMA). The LL-LMA is a measure of impairment that examines selective and combined movements in the LL. This measure has been used previously in a number of research trials (Widén Holmqvist et al 1998, Lincoln et al 1999, Sommerfeld et al 2004). In many of the studies reviewed in Chapter 2, the initial short-term impact of focused additional exercise therapy appeared to be evident on measures of impairment. Winstein et al (2004) compared standard care with functional task performance and strength training. The intervention groups each received an additional 1200 minutes of therapy over a four to six week period, with excellent compliance. Compared to those participants who received standard care, the intervention groups had significantly greater increases in the FMA motor scores. Feys et al (1998) report a study with focused UL augmented intervention. An additional 900 minutes of therapy was provided to the intervention group with excellent compliance. Outcome measures employed included measures of both impairment and disability (See Table 2.2). Both groups improved in different ways and there was a significantly greater and clinically relevant improvement in scores on the FMA between the groups at 6 and 12 months, in favour of the experimental group. Both Feys et al (1998) and Winstein et al (2004) suggest that the nature of the interventions provided to participants in their

study groups may have resulted in an initial improvement in impairment, on which later improvements in function could occur.

On the contrary, two other studies provided generalised additional exercise therapy to a combined total of 251 participants and noted a difference between groups at the level of function rather than impairment following the additional intervention. Fang et al (2003) provided participants with an additional 900 minutes of general therapy over a four-week period. The outcome measures utilised are listed in Table 2.4. Significant differences were only evident at the level of function, as measured by the Modified Barthel Index at the four-week assessment. This difference in functional gain was not evident on re-evaluation at six months. However, the compliance rate in the additional early therapy (AEP) group was poor with 36% of participants failing to tolerate the augmented therapy. A further 102 participants were lost at the six month follow-up, limiting the interpretation of these results. An earlier study by Sivenius et al (1985) also examined the significance of increased duration of general therapy in terms of assessment of ADL function and ambulation. An additional 651 minutes of therapy was provided in total. However, only 78% of participants completed the three month assessment. In the analysis of covariance, there was a difference of 28% in ADL scores in favour of the intervention group at this assessment point. This difference also remained at the six and twelve month follow-up. However, it did not reach statistical significance. While these two studies demonstrated an impact on function following additional general exercise therapy, there are methodological and compliance issues with the studies that limit the wider application of the results.

In the FAME study, significant improvements were evident in the FAME group when compared to the control group on all outcome measures of function, including the Berg Balance Scale (BBS), the Motor Assessment Scale (MAS), the Six Minute Walk Test (SMWT) and the Barthel Index (BI) at the post-intervention assessment. The additional intervention focused on exercises that promoted improvements in LL impairment and activity including balance and walking. These findings are in keeping with the findings of other studies with focused LL interventions (Kwakkel et al 1999, Blennerhassett and Dite 2004).

No difference was noted between the groups on the two measures of participation, the RNLI and the N-EADL, at the post-intervention (T2) assessment point. In studies that have examined the impact of additional exercise therapy on outcome following acute stroke, this is one of the first RCTs to examine re-integration to normal living within the first three months of stroke. However at the post-intervention assessment, many of the participants in both groups were adjusting to community living following discharge from hospital and it may have been too soon to administer the measure. Two other studies (Logan et al 1997, Gilbertson et al 2000) administered the N-EADL to individuals with sub-acute stroke following 6 to 12 weeks of additional exercise in the community setting. Results demonstrated significantly better N-EADL scores in the intervention group following the additional therapy.

7.2.2 Three month follow-up standardised outcome measures

At the end of the additional FAME intervention, the author encouraged all participants and their family members in the intervention group to continue with their family mediated exercise therapy. All participants in the control group were advised to continue on with their prescribed care package that may or may not have included physiotherapy input. The three month follow-up outcome measures are interesting for a number of reasons. Firstly, in relation to outcome on the LL-LMA, both groups only improved by a mean of 1 to 2 points from the post intervention assessment (T2) to the three month follow-up assessment (T3). Therefore there was no significant difference in the change in scores in either group from T2 to T3. However, the LL-LMA scores at T3 in the intervention group (mean score 32.2 points) and the control group (mean score 28.8 points) were high, indicating a low level of impairment at this time point. The lack of significant findings is consistent with other studies (Richards et al 1993, Kwakkel et al 1999). Some authors have postulated that the lack of significant findings at follow-up assessments may be in part due to the later ongoing recovery in the control group - in essence, control group eventually 'catch up' with the intervention group in terms of advances in recovery (Kwakkel et al 1999). However, this is not the case in this study as both groups were comparable in their rate of recovery on the LL-LMA from T2 to T3. The lack of significant changes in both groups from T2 to T3 suggests that the optimal time for recovery is in the early stages following stroke, particularly in the first three months. These findings support the early initiation of intensive stroke

rehabilitation as an important feature of specialised stroke care. Similar non-significant results between the groups were found for the MAS, BBS and the BI.

The SMWT was the only measure of activity that improved significantly more in the FAME group than the control group from T2 to T3. This finding could be due to a number of reasons. Firstly, given the continuous nature of the measure, the possibility of a ceiling effect was negated. Participants in both groups scored quite highly on the other measures of impairment and activity at T3 and the range of scores noted at this time point included the maximum score attainable on all of the other measures including the MAS, BBS and BI. Secondly, the exercises were task orientated, functional exercises aimed at improving LL impairment, balance and mobility. The initial significant improvement in impairments, as noted by the LL-LMA may have led to a later improvement in a functional activity such as walking. This hypothesis is in keeping with that of other authors also (Feys et al 1998, Winstein et al 2004).

Many people with stroke have a low level of satisfaction with community reintegration after they are discharged from the hospital and return to the community (Clarke and Smith 1998). As many as 39% to 65% of community-dwelling people with stroke report limitations in daily activities and restrictions in re-integration into community activities following discharge from hospital (Mayo et al 2002). Several studies have examined the effect of stroke-related factors, for example, physical impairments and mental status on satisfaction with community reintegration and a link between physical function and satisfaction with community reintegration has been reported (Pang et al 2007). The measures of participation (RNLI and N-EADL) administered at T3 indicated that the intervention group had reintegrated significantly more into their home environment and community than participants in the control group. This finding may be in part attributed to the significant improvements in mobility observed in this group at T3 when compared to the control group, as many of the topics explored on the two measures of participation examine the extent to which people can perform mobility related tasks in their home environment and community- see Appendix 30. These findings are also in keeping with those documented in two other studies (Logan et al 1997, Gilbertson et al 2000) that examined the impact of additional exercise therapy in the community setting.

7.3 Caregiver strain

The difficulties that carers face in managing people with stroke in the community have been cited as a contributory factor to carer strain, social exclusion and isolation (Low et al 1999). In clinical practice, early recognition of informal caregivers at risk of adverse effects may prevent or alleviate caregivers' problems (Van Exel et al 2004). Post et al (2007) suggest that the levels of strain experienced by families and carers of people with stroke should be monitored as part of routine post-stroke care. In the past, several studies have focussed on interventions to support stroke caregivers by providing additional information and education, counselling, emotional support, or help with accessing services by using information packages, social workers, specialist nurses, or family support workers (Forster et al 2001). However, these interventions have shown little impact on individuals with stroke and only modest improvements in psychological and social measures in care givers (Kalra et al 2004). This lack of effect may be in part due to the inability of some of the measures chosen to capture change as a result of the interventions and furthermore because few interventions took into account the physical demands of caring for individuals with physical deficits following stroke (Van den Heuvel et al 2001). The FAME programme provided carers with skills essential for the day to day care of their family member with stroke, including demonstrations of the proposed exercises included in the programme and supervised practice of a variety of activities including manual handling, transfers and walking.

Caregiver strain was measured using both quantitative and qualitative data gathering techniques. Rauscher and Greenfield (2009) note that the application of a mixed methods approach can enhance physiotherapy research by creating a more holistic understanding of the rehabilitation process. The combination of qualitative and quantitative data facilitated the in-depth analysis of the concept of carer strain in this cohort and allowed for the triangulation of common themes. The Caregiver Strain Index (CSI) was used to capture levels of carer strain experienced by family members in the control group and the FAME group at T2 and at T3. No significant differences in the levels of carer strain experienced by family/carers in the FAME and control groups were noted at T2. However, the reduction in the levels of carer strain reported by family members between T2 and T3 strain was significantly greater in the FAME group than the control group. The self-reported low levels of carer strain reported by family members who took part in the intervention was consistent with the output of the semi-

structured interviews where the majority of family members reported that the FAME programme did not add additional pressure to their daily lives. While the response to this question was dichotomous, several family members detailed that the additional exercise programme allowed them to become more involved in the rehabilitation process and make a 'real' contribution towards the individual's recovery. These sentiments have also been reported by other authors. Carr and Shepherd (1987) and Kalra et al (2004) noted that the involvement of family members and carers in rehabilitation from the outset can lessen fears that carers may have about their ability to cope at home. Kalra et al (2004) also suggest that the use of a structured programme of activities under professional supervision during inpatient rehabilitation may serve to empower consenting informal caregivers in their future role by teaching them appropriate skills. Two family members reported that involvement in the FAME programme added pressure to their daily lives in terms of a time commitment. However, they viewed their participation in the additional exercise programme as a positive experience. This finding is not surprising since work and family commitments had been cited as a limitation in the participation in physiotherapy by other family members in the initial FAME surveys (See Table 3.3). These findings illustrate the need for the careful consideration of family members that are appropriate for participation in such as intervention after stroke.

7.4 Amount of additional exercise therapy

There is still uncertainty regarding the most appropriate amount of additional therapy input required to demonstrate a significant impact on outcome following stroke. However, most researchers (Kwakkel et al 2004, Galvin et al 2008b) agree that at least 900-1200 minutes of additional exercise therapy in excess of 'routine' levels of therapy, delivered over a period of 4-6 weeks is required to demonstrate a significant improvement in function. Poor compliance has been reported as an issue by several authors who have delivered additional exercise interventions to people with stroke in the past (Sivenius et al 1985, Fang et al 2003). The issue of compliance was also discussed in the systematic review presented in Chapter 2 and methods to improve compliance were explored in the user surveys described in Chapter 2. The output from the quantitative surveys indicated that the provision of daily exercise diaries combined with supervised practice time for the family members and regular meetings with the

therapist would assist family members with exercise delivery. Furthermore, the output of the user surveys highlighted that walking was an important aspect of recovery from the perspective of the person with stroke and 'family members/friends'. These elements were incorporated into the FAME programme in an effort to increase motivation and compliance among participants.

The amount of additional exercise therapy provided to participants in the intervention group ranged from 1120 minutes to 1960 minutes over the eight week period. Compliance with the FAME programme was good and ten participants documented 100% compliance with the programme. However, there was a significant difference between the amount of additional therapy that was proposed (245 minutes per week for 8 weeks) and the actual therapy delivered each week (mean 227 minutes per week for 8 week). Two participants completed an average of 140 and 144 minutes of additional exercise therapy per week, completing a total of 1120 and 1152 minutes of additional exercise therapy in total. These results may have skewed the data. Therefore, a post-hoc analysis of the actual versus planned therapy delivered to participants on a weekly basis was completed excluding the two participants who failed to complete at least 1200 minutes of additional exercise over the study period. The results indicated that the difference between planned and actual therapy delivered was not significant. However, the overall results suggest that on average, participants in the FAME group did not complete the additional FAME programme on one day of each week. The most common reason for non completion of exercises was fatigue. While there is no universally accepted definition of fatigue in relation to stroke in the literature, the available literature suggests that it is a common complaint and a significant cause of concern to those attempting to recover following the physical impact of a stroke (O'Connell and Stokes 2007). The evaluation of post-stroke fatigue is hindered by the lack of systematic use of a standardised definition, heterogeneous populations of people with stroke, and the lack of a stroke specific, standardised outcome measure to evaluate fatigue. The effects of fatigue were not directly examined in the FAME study. However, participants were advised by the author not to complete their exercises if they experienced fatigue and family members were required to document this reason in their exercise diary. This finding needs to be considered on the development of future trials. Perhaps an exercise intervention that incorporates the delivery of additional exercises on six days of each week or the prescription of exercises that are delivered for a shorter

duration everyday (7 days/week) may be more amenable to individuals with stroke and their family members.

7.5 Type of additional exercise therapy

The type of additional exercise therapy has also been highlighted as an important contributory factor to the success of an additional exercise intervention (Galvin et al 2008b). The FAME intervention was based on the output of a systematic review of interventions that demonstrated a significant impact on recovery of the LL following acute stroke (Van Peppen et al 2004). In addition, the systematic review of RCTs that delivered additional interventions to people with stroke suggested that increasing the time spent on general, traditional or conventional therapy was not beneficial and that more focused, task orientated interventions at the level of impairment or function were more effective. Furthermore, it is evident from research that two neurons or groups of neurons that have been disconnected by a lesion (as occurs with a stroke) may be reconnected if they are activated simultaneously and repeatedly (Robertson and Murre 1999). This is known as the 'Hebbian principle'. In order to stimulate these neurons, there is a requirement for high levels of repetition of tasks and exercises that are both challenging and engaging (Pomeroy and Tallis 2000, Plautz et al 2000, Nudo et al 1996). Activities such as these appear to 'condition' the brain so that it is temporarily more responsive to afferent input. With several repetitions of this process, the two damaged neurons may become reconnected, supporting the Hebbian theory. The FAME programme comprised exercises that were progressive, repetitive, functional and task orientated in nature, including exercises such as repetitive sit to stands, weight bearing exercises during standing, stair climbing, balance activities and walking. The combination of these elements contributed to the significant improvements noted in the intervention group at the eight week assessment. These results are also inkeeping with other studies that delivered a focused task orientated LL intervention (Richards et al 1993, Kwakkel et al 1999, Yang et al 2005). These findings suggest that rehabilitation programmes should be based on evidence based physiotherapy irrespective of specific neurological treatment approaches. This sentiment is also reiterated by Quinn et al (2009) in a document published by the European Stroke Organisation outlining guidelines for the management of individuals with ischaemic stroke. This document

highlights the need for future research to examine the efficacy of exercise interventions in individuals with chronic stroke.

7.6 Length of hospital stay

There was no significant difference in the length of hospital stay or the length of stay in a rehabilitation unit between the intervention and the control group. Participants in the FAME group remained in the acute hospital an average of 4 days less than their counterparts in the control group. In addition, 11 people in the intervention group were discharged home prior to the assessment at T2 whereas only six participants in the control group were discharged home. Furthermore, participants in the FAME group remained in a 'rehabilitation unit' an average of 12 days less than those in the control group. While it must be acknowledged that the small numbers of participants analysed in each group limit the wider application of the results, the findings are supportive of the suggestion that additional exercise therapy in the acute stage following stroke may have a positive impact on length of stay in hospital or a rehabilitation unit. This suggestion is also supported by Horn et al (2005) in a study examining the impact of increased duration of therapy on functional outcome and discharge destination following acute stroke. The authors report that rates of discharge home were positively correlated with a greater duration of therapy that focused on the repetition of gait related activities. The impact of additional therapy on discharge location or length of hospital stay has not been widely examined to date, therefore the results of this study need to be interpreted with caution and the topic warrants further investigation.

7.7 Qualitative data

The conduct and analysis of this element of the RCT was based on the principles of 'phenomenology' as described by Husserl (1931). The interviews examined the 'lived in' experience of the programme from the perspective of the individual with stroke and his/her nominated family member, allowing the author to focus on the participant's subjective experiences and interpretations of the FAME programme. Firstly, in relation to the individuals with stroke, several quotations indicated that these individuals benefitted physically from the additional programme, in terms of improvements in physical impairments, balance, confidence and mobility. These findings triangulated

with the findings of the quantitative impairment and activity based outcome measures administered at this time point, including the LL-LMA, BBS, MAS, SMWT and BI. These convergent findings enabled a more confident interpretation of the phenomenon that evolved, which was that the FAME programme contributed to improvements in the individual's level of impairment and activity following stroke. This phenomenon was also supported by several quotations from the family members. Family members outlined a variety of ways in which the FAME programme helped their family member with stroke to recover including improvements in physical impairments, balance, confidence and mobility. Both family members and the individuals with stroke stressed the importance of the recovery of mobility following the stroke. This finding is also highlighted in previous research in a similar population (Galvin et al 2009a).
In terms of identifying a component of the programme that was most beneficial such as the additional exercises, the weekly visits from the physiotherapist, the provision of an exercise diary, or family involvement in exercise delivery, both the individuals with stroke and their family members indicated that different individual elements, or indeed a combination of these elements were most beneficial for them. The response to this question was subjective and individual and highlights the importance of an individual approach to the prescription of exercises following stroke.

All of the individuals with stroke reported that the FAME programme did not add pressure to their daily lives. While the answer to this question was in a sense, dichotomous, several participants reported that the programme added a sense of structure to their daily life. The concept that perhaps people with stroke want to have a sense of structure and control when working towards recovery is important and should be considered in both short and long term goal setting with the patient. In recent years, research on stroke has focused attention on psychological outcomes such as quality of life and subjective well-being in addition to survival and functional outcomes. Depression has been most intensively studied and other psychological problems that have been explored include fear of loss of control, fears about death and residual impairment, social isolation, helplessness and worry about loss of social roles (Donnellan et al 2006). Developing successful strategies to cope with the emotional, cognitive and physical changes after stroke is an important element of the rehabilitation process. The impact of locus of control and the willingness to adopt effective coping strategies to avoid psychological distress that may occur following

stroke may be likened to a quotation from Conrad's *Heart of Darkness*, 'To him the meaning of an episode was not inside like a kernel but outside, enveloping the tale which brought it out only as a glow brings out a haze, in the likeness of one of these misty halos that sometimes are made visible by the spectral illumination of moonshine'. Essentially, the contribution of positive coping strategies and self-belief need to be considered and evaluated in the context of post-stroke recovery. The FAME study did not measure coping strategies employed by individuals with stroke or their family members during the study and was not designed to target improved coping strategies. However, the programme served to empower the individual with stroke and their 'nominated' family member to take 'ownership' of their exercise delivery and indeed their physical recovery following stroke. Furthermore, evidence indicates that a combination of both patient and therapist centred goals facilitates individuals with stroke to regain a sense of control over their situation, which is imperative in the rehabilitation process (Rochette et al 2006).

Twelve people with stroke and their nominated family members reported that the FAME programme did not add pressure to the family member's daily life. The triangulation of these findings allowed the author to propose with increased confidence that the FAME programme did not add additional pressure to the family member's daily life. Two family members reported that the FAME programme was an additional pressure in terms of a time commitment but viewed the programme as a positive experience. This finding was also corroborated by the one of the individuals with stroke who reported that, '*Yes, absolutely, it took up their time... but they didn't mind...*' [TCD 15].

Satisfaction with the FAME programme was also explored during the interviews using a Likert type scale where the anchors were 'strongly agree' to 'strongly disagree'. Overall, both individuals with stroke and their family members reported that they were 'very satisfied' with the FAME programme and were happy to encourage someone else in their position to participate in such a programme. While, there is a possibility that satisfaction with the programme was linked to the patient/physiotherapist encounter, the findings clearly illustrate that both people with stroke and their family members were happy with the support and information they received. This finding also serves to highlight the multidimensional nature of the relationship between patients, their

families and physiotherapists following stroke and is consistent with previous findings where people with stroke and their carers view physiotherapy positively and that participating in physiotherapy provides them with a sense of well-being, self-worth and control (Pound et al 1994, Wiles et al 2002).

Finally, both the individuals with stroke and their family members indicated that follow-up with a physiotherapist either in the hospital or the home setting would assist them in the long-term to continue with their exercises. This finding has been re-iterated in other studies where individuals with stroke have reported a lack of follow-up services in the community. One of the primary themes emerging from a qualitative study of individuals with stroke and their carers by Hare et al (2006) was the lack of services available to them to meet their continuing needs in the community. Furthermore, participants reported that the 'primary care' team, including physiotherapists, needed to be more cognisant of the issues that were important to them and involve them more in the recovery process. This finding is also highlighted in the Irish Heart Foundation National Audit of Stroke Care (2008), where 44% of a cohort of 139 individuals with stroke surveyed, reported that they were not consulted about their needs or wishes for rehabilitation on discharge from hospital. This report also highlighted the difficulties that individuals with stroke face in terms of accessing services in the community. The provision of adequate follow-up services to both people with stroke and their informal carers is an aspect of healthcare that needs to be addressed immediately.

7.8 Implications for clinical practice

The FAME programme comprises several elements that that can be applied in everyday clinical practice. Firstly, the kernel of the programme was the involvement of the family in exercise delivery. While the author used strict inclusion criteria to comprehensively evaluate the impact of the programme from a qualitative and quantitative perspective, the stringent methods used in this study may not need to be applied as rigorously in the clinical setting and point the way for evaluation of the FAME programme on participants with co-morbidities. This would facilitate the inclusion of a larger pool of individuals that may be suitable for a similar intervention. Secondly, the findings indicate that the involvement of families in such an intervention in the acute stage post

stroke does not add an additional pressure to family members' daily lives. On the contrary, the FAME programme provided family members with a sense of involvement in the recovery process. Thirdly, there is a requirement that the provision of physiotherapy during the traditional hours of 9am-5pm be broadened to facilitate the involvement of family members in exercise delivery in the evening time. In the physiotherapy setting, staff limitations or established practices such as 'half an hour of treatment' regimes may prevent therapists from embracing novel treatment ideas to increase the duration of therapy (De Weerdt and Feys 2002). Fourthly, the FAME programme serves to identify a type, duration and frequency of exercise therapy that has demonstrated a positive impact on recovery at the level of impairment, activity and participation following acute stroke. The significant findings following the eight week intervention programme highlights the importance of the early implementation of intensive physiotherapy to promote the recovery of impairment and function in a similar population. In addition, the implementation of this RCT in the clinical setting and the detailed description of the methods used to conduct the study facilitate the implementation of a similar programme in clinical practice. Furthermore, a mixed methods approach was used to examine the impact of the FAME intervention. This is important clinically because while the results of the quantitative data demonstrated a significant impact on recovery as a result of participation in the programme, it was also important that the individuals with stroke and their family members also indentified benefits to participation in the programme. Therefore, it may be useful for physiotherapists to consider the inclusion of a qualitative aspect to their evaluation of an individual's status also. Finally, both family members and individuals with stroke commented that encouragement from the treating physiotherapist was an important part of the intervention. This has also been reported in previous research in a similar population (Galvin et al 2009b). Although physiotherapists need to encourage patients to participate in physiotherapy, they also need to be realistic in terms of goal setting and discourage over optimistic expectations that may develop from the perspective of the individual with stroke or their family member through the process. However, there is considerable evidence that patients and their carers want to have a clear and honest appraisal of their level of impairment and information about likely recovery as well as information on a range of other issues in relation to stroke (Wiles et al 2002).

7.9 Implications for future research

The results of this study pave the way for a number of clinically based RCTs aimed at optimising recovery following stroke through the implementation of additional exercise therapy. The homogenous sample of people with stroke included in this study represented those presenting with a moderate/severe impairment following stroke, as defined by the Orpington Prognostic Score. However, while the results of the study support the hypothesis that additional exercise therapy improves LL outcome in individuals presenting with a moderate/severe impairment following stroke, the question remains to be answered in relation to the impact of additional exercise therapy on those presenting with a more severe deficit. Studies to date favour the provision of additional exercise therapy to individuals presenting with a less severe deficit following stroke but authors have noted that the involvement of families may enhance carry-over in individuals with a more severe deficit (Carr and Shepherd 1987, Forster and Young 1992, Evans et al 1994). Therefore the impact of additional exercise therapy on this population warrants further investigation.

The concept of evidence based practice is continuing to evolve in healthcare research. The expansion of the 'traditional' physiotherapy service to include the provision of evidence based intensive physiotherapy interventions in the evenings and at weekends in acute stroke facilities needs to be examined in terms of patient outcome, staff satisfaction and economic impact. The economic impact of the involvement of family members in exercise delivery needs to be explored, in terms of length of hospital stay and provision of various supports to families in the community setting.

The lack of significant findings on the measures of impairment and activity at T3, with the exception of the SMWT, suggests that while the effects of the additional therapy on recovery were maintained at 6 months, significant improvements did not take place from T2 to T3. In the semi-structured interviews conducted at T2, both individuals with stroke and their families indicated that a visit to/from a physiotherapist would motivate and encourage them to continue with the exercise programme. Future research should focus on novel and conventional methods to motivate ongoing family and patient participation in exercise interventions, including an evaluation of the impact of regular follow-up physiotherapy visits on adherence to exercise regimens in people with stroke in the community.

Finally, the use of a qualitative method of enquiry enhanced the study by permitting the inspection of aspects of the FAME programme that were not accessible through quantitative measurement alone. This qualitative approach allowed the triangulation of concepts and outcomes gained through the use of objective, self-report and qualitative measures. Since the success of any rehabilitation intervention is dependent on many variables including people's attitudes, thoughts and motivation regarding the rehabilitation process, studies with a mixed methods design should be implemented in future research trials to inform the development and improvement of rehabilitation services.

7.10 Limitations of the study

The limitations of the work completed prior to the implementation of the RCT are contained in Chapter 3-Section 3.8. In relation to the RCT, a number of limitations exist. The RCT was multi-centre in nature and there is a possibility that participants may not have received comparable amounts of 'routine' therapy in each centre as the frequency and duration of 'routine' therapy (minutes of treatment) received by the control group and the FAME group was not recorded in any centre. However, as part of the preliminary user survey the physiotherapists estimated that usual treatment ranged from 30-60 minutes. In addition, the amount of multi-disciplinary therapy input before enrollment to the study i.e. first 3 weeks after stroke (potential participants were screened with OPS at 2 weeks and allowed an additional week to decide whether or not they would participate in the study) and the amount of therapy that may have been received from the post-intervention assessment point to the three month follow-up period was not recorded. The logistics of arranging the treating physiotherapist and/or occupational therapist to document the frequency and duration of each session in each centre was not possible due to the number of centres involved, changing staff grade rotations and annual leave. Furthermore, some participants were transferred to different areas of the hospital and were treated by different physiotherapists during the course of the RCT. However, a number of different acute clinical sites were chosen to improve recruitment. There is also a possibility that satisfaction with the programme was linked with the participant/physiotherapy encounter and questions posed during the semi-structured interviews may have prompted responses that were acceptable

rather than accurate. However, all interviews were conducted by a person unknown to the participant, thus reducing the risk of bias. Furthermore, the author delivered the additional exercise intervention and while the same protocol, in terms of family training and supervision, was followed for each participant, the possible influence of therapist motivation, due to the nature of the study, may have affected the overall results. Finally, while the duration of each session was the same for all participants, the content of each exercise programme varied according the individual, making the content difficult to quantify. However, all exercises delivered were evidence based, regardless of the specific neurological treatment approach.

7.11 Conclusion

- An eight week programme of family assisted/mediated exercise (FAME) therapy after acute stroke, in addition to routine therapy, had a significant impact on LL impairment, balance and mobility in people presenting with a moderate/severe deficit following stroke.
- The improvement in impairment and activity was maintained at a three month follow-up assessment in the intervention group but it was not statistically significant when compared with the control group at the same time point, with the exception of the SMWT.
- Individuals with stroke who were allocated to the additional FAME intervention were significantly more re-integrated into their community at the three month follow-up assessment point, when compared to the control group.
- The additional FAME programme did not appear to add additional pressure to the daily lives of the individual with stroke or his/her family member.
- Both people with stroke and their family members reported that participation in the FAME programme was a positive experience both physically and psychologically.

This RCT clearly demonstrated that additional exercise therapy in the form of FAME had a significant impact on recovery following acute stroke. While the quantitative element of the study gave an insight in relation to the value of additional exercise therapy, the qualitative component of the study gave a clear picture of the 'lived in' experience of the FAME programme from two different perspectives: that of the person

with stroke and his/her family member. A number of salient aspects relating to different elements of the FAME programme became apparent from the implementation of the mixed methodology approach. These areas would not have been exposed through quantitative examination alone. The triangulation of results from these different research methods facilitated a more comprehensive insight into the impact of the programme on the participants involved.

In his introduction to the first Irish National Audit of Stroke Care (2008) commissioned by the Irish Heart Foundation, Dr. Brian Maurer stated that 'stroke is the third most common cause of death and the most common cause of acquired major physical disability in Ireland. A failure to recognise effective therapies has led to a fatalistic approach to treatment and an often nihilistic approach to coping with the survivors.' In the current economic climate, it is imperative that healthcare professionals identify interventions such as FAME that can serve to optimise patient recovery and family involvement following stroke, while being mindful of available resources. The FAME study responds to the clear need for the provision of an evidence based intervention that can be delivered in the hospital or the community setting and that is acceptable to people with stroke and their family members.

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APPENDIX 1

Publication of study protocol

Galvin, R., Cusack, T., Stokes, E. (2008a). A randomised controlled trial evaluating family mediated exercise (FAME) therapy following stroke. *BioMed Central Neurology* [online]. Available at: ‹URL: http://www.biomedcentral.com/1471-2377/8/22›, 8(22).

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Study protocol

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A randomised controlled trial evaluating family mediated exercise (FAME) therapy following stroke

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Abstract

Background: Stroke is a leading cause of disability among adults worldwide. Evidence suggests that increased duration of exercise therapy following stroke has a positive impact on functional outcome following stroke. The main objective of this randomised controlled trial is to evaluate the impact of additional family assisted exercise therapy in people with acute stroke.

Methods/Design: A prospective multi-centre single blind randomised controlled trial will be conducted. Forty patients with acute stroke will be randomised into either an experimental or control group. The experimental group will receive routine therapy and additional lower limb exercise therapy in the form of family assisted exercises. The control group will receive routine therapy with no additional formal input from their family members. Participants will be assessed at baseline, post intervention and followed up at three months using a series of standardised outcome measures. A secondary aim of the project is to evaluate the impact of the family mediated exercise programme on the person with stroke and the individual(s) assisting in the delivery of exercises using a qualitative methodology. The study has gained ethical approval from the Research Ethics Committees of each of the clinical sites involved in the study.

Discussion: This study will evaluate a structured programme of exercises that can be delivered to people with stroke by their 'family members/friends'. Given that the progressive increase in the population of older people is likely to lead to an increased prevalence of stroke in the future, it is important to reduce the burden of this illness on the individual, the family and society. Family mediated exercises can maximise the carry over outside formal physiotherapy sessions, giving patients the opportunity for informal practice.

Trial Registration: The protocol for this study is registered with the US NIH Clinical trials registry (NCT00666744)

Background

Stroke is a leading cause of disability among adults in developed countries [1]. The progressive increase in the population of older people is likely to lead to an increased prevalence of stroke in the future [2]. In contrast to coronary heart disease and cancer, the burden of stroke lies with long-term disability as opposed to death. Any rehabilitation intervention that can speed recovery and reduce

long-term disability would have a major impact on both the individual and the social burden of this illness. One major component of rehabilitation after a stroke is exercise therapy which serves to minimise the effects of the brain cell damage and optimise re-learning [3-5]. In this manuscript, we describe a novel protocol to increase exercise therapy time following stroke by involving the family members in the delivery of additional exercises to people with stroke.

Physiotherapists have traditionally been the mediators of exercise therapy post-stroke. Over the years different physiotherapy approaches have been advocated to promote motor recovery, including the methods of Bobath, Brunnstrom, Rood and the Proprioceptive Neuromuscular Facilitation (PNF) technique [6,7]. All of these therapy approaches are exercise based and there is evidence that physiotherapy and occupational therapy, using a mix of components from these different approaches, is significantly more effective than no treatment or placebo control in the recovery of functional independence following stroke [6]. Nonetheless, it has been suggested that the duration of exercise therapy that is delivered post stroke is, at best, 'homeopathic' [8].

Evidence from two systematic reviews [9,10] has suggested that a more intensive exercise therapy input is associated with enhanced improvement of the performance of functional activities after stroke, although the exact dose of practice required for significant functional improvements to take place is lacking. A later meta-analysis [11] also demonstrated that additional exercise therapy has a positive outcome on gait speed and activities of daily living. However this meta-analysis included studies where no formal exercise therapy was documented in the 'control' group [12-15]. The authors completed a systematic review and meta-analysis [17] that examined the effects of additional exercise therapy time by comparing randomised controlled trials that provided 'routine' therapy to the control group versus studies that provided 'routine' therapy together with 'additional' exercise therapy to the intervention group. The findings demonstrated that increased duration of exercise therapy time had a small but positive effect on activities of daily living as measured by the Barthel Index. Although the meta-analysis of the lower extremity outcome measures lacked significant findings, very few studies were included in the analysis and the results were supportive of the hypothesis that more exercise therapy improved gait speed and lower limb impairment in people with stroke. The review also highlighted the need for further randomised controlled trials with large sample sizes to evaluate the effectiveness of increased duration of exercise therapy on lower extremity outcome [17].

While the available evidence suggests that more physiotherapy is better, additional therapy is expensive and not routinely funded routinely by the National Health Service in the UK or by health insurance companies [18]. Therefore, research is now focusing on novel ways of increasing the duration of exercise therapy that occurs following stroke with minimal use of resources [8]. One suggestion has been that 'physiotherapists need to develop strategies whereby patients and caregivers take full responsibility for the bulk of therapy – for instance, training of balance, strength and endurance, repetition of simple tasks, group therapy, fitness-related training and family involvement' [19]. To date no randomised controlled trial (RCT) has evaluated the delivery of exercise by people who are not health care workers, although in a RCT by Lincoln, Parry and Vass [20], both qualified physiotherapists and physiotherapy assistants delivered two different forms of additional exercise therapy and no differences were noted between the groups. The following paper reports on the design of an evidence-based, user informed and centred RCT to evaluate the impact of increased duration of family mediated exercise (FAME) therapy in people with stroke.

Background Work

A full systematic review and meta-analysis of previous work in this area was completed and has been accepted for publication [17]. The meta-analysis supported the theory that additional exercise therapy has a positive impact on outcome following stroke. However, the systematic review highlighted issues with patient compliance, particular patient subgroups, type of therapy, number of additional minutes of exercise therapy delivered to patients and long terms benefits of additional exercise therapy. These issues were considered in the development of the FAME RCT.

In addition, three user surveys were conducted to explore the views of potential participants in the FAME programme i.e. the individual with stroke, 'family members/friends' of people with stroke and the physiotherapists. A self-report questionnaire was administered to 100 'family members/friends' and 75 people with stroke. Two focus groups were conducted with ten expert physiotherapists working in the area of stroke rehabilitation. The results of the three user surveys supported and informed the development of the FAME trial. Family members of people with stroke indicated that they were willing to participate in the delivery of unsupervised exercises in the hospital and the home setting (n = 91). Furthermore, this method was also acceptable to people with stroke (n = 65) as an adjunct to routine physiotherapy. Physiotherapists highlighted a number of factors that influenced participation in physical therapy such level of interest and motivation of the family (n = 5), availability (n = 3) and importance of education (n = 2). 'Family members/friends' also identified

reasons that would also limit participation such as work commitments (n = 24), lack of confidence (n = 20) and unsuitable treatment times (n = 13). The results of these user surveys are described elsewhere [21-24].

Aims and Objectives of the Study

The aim of the study is to evaluate the functional recovery in two groups of primary stroke patients presenting with moderate/severe disability over a six month period through the implementation of a randomised controlled trial. The first group or the experimental group will receive routine therapy and additional lower limb exercise therapy in the form of family assisted exercises. The second group or the control group will receive routine therapy with no additional formal input from their family members. A secondary aim of the project is to evaluate the impact of the FAME programme on the person with stroke and the individual(s) assisting in the delivery of exercises.

Ethical Considerations

The study has obtained ethical approval from four clinical sites: Saint Vincent's University Hospital Ethics and Medical Research Committee (Ref 9/5/07), Saint Colmcilles Hospital (Ref 9/5/07), the Mater Misercordiae University Hospital Research Ethics Committee (Ref 1/378/1138) and Beaumont Hospital Ethics (Medical Research) Committee (Ref 08/19).

Methods

Study Design

A prospective single-blind randomised controlled trial will be conducted. Forty subjects will be randomised into either an experimental group or a control group using sealed, computer generated random numbers. The progression from screening and enrollment to randomisation is illustrated in Figure legend 1.

Intervention

Members of the control group and the experimental group will receive 'routine' physiotherapy for the duration of the trial, which will be delivered by the physiotherapy staff in the hospital. In addition, participants in the experimental group will be given individualised FAME programmes to be conducted at the bedside with his/her nominated 'family member/friend'. Each programme will consist of training the 'family member/friend' with the skills necessary to carry out the exercise-training programme with the person with stroke on a weekly basis. This specialised intervention will be designed and delivered by the research physiotherapist (RG). Exercises will be designed appropriate to the participants' ability. The emphasis of the lower limb exercise intervention will be on achieving stability and improving gait velocity and lower limb strength, based on patterns derived from findings reported in a systematic review of 151 intervention studies on stroke rehabilitation [25].

Based on the output from the systematic reviews and meta-analyses [11,17], it was determined that the trial would continue for eight weeks with an expectation that at least 1200 additional minutes of family mediated exercise therapy will be delivered over this time period. Each FAME session is expected to last 35 minutes and will be conducted on a daily basis. The nominated 'family member/friend' will be requested to fill out a daily exercise diary following completion of the prescribed exercises to document compliance.

Blinding

An independent physiotherapist blinded to group allocation will assess all participants using the battery of outcome assessments on entry to the study, on completion of the eight-week trial and finally at the three month follow-up stage.

Outcome

The primary outcome measure used in this trial will be the lower extremity section of Fugl Meyer (FM) Assessment [26]. The FM is considered by many in the area of stroke rehabilitation to be one of the most inclusive quantitative measures of sensorimotor impairment following stroke and its use has gained international acceptance as a feasible and appropriate clinical and research tool for evaluating changes in motor impairment following stroke [27]. Excellent intra-rater and inter-rater reliability and construct validity have been demonstrated [28,29].

A series of secondary outcome measures will also be used to evaluate participants' recovery including the Motor Assessment Scale [30], the Berg Balance Scale [31], the Six Minute Walk Test [32] the Barthel Index [33], the Reintegration to Normal Living Index [34] and the Nottingham Extended Activities of Daily Living Index [35].

The Caregiver Strain Index [36], a 13-item self-report measure designed to measure strain relating to care provision, will be administered to the nominated 'family member/friend' of the person with stroke. In addition, a semi-structured interview will take place with each participant and their nominated 'family member/friend' individually, in relation to their experience of the exercise therapy programme. A physiotherapist unknown to the participant will conduct interviews. All interviews will be audio recorded.

Participant Selection

Potential participants will be recruited from four acute hospitals. A register of all stroke patients admitted to these hospitals will be sent to the research physiotherapist on a

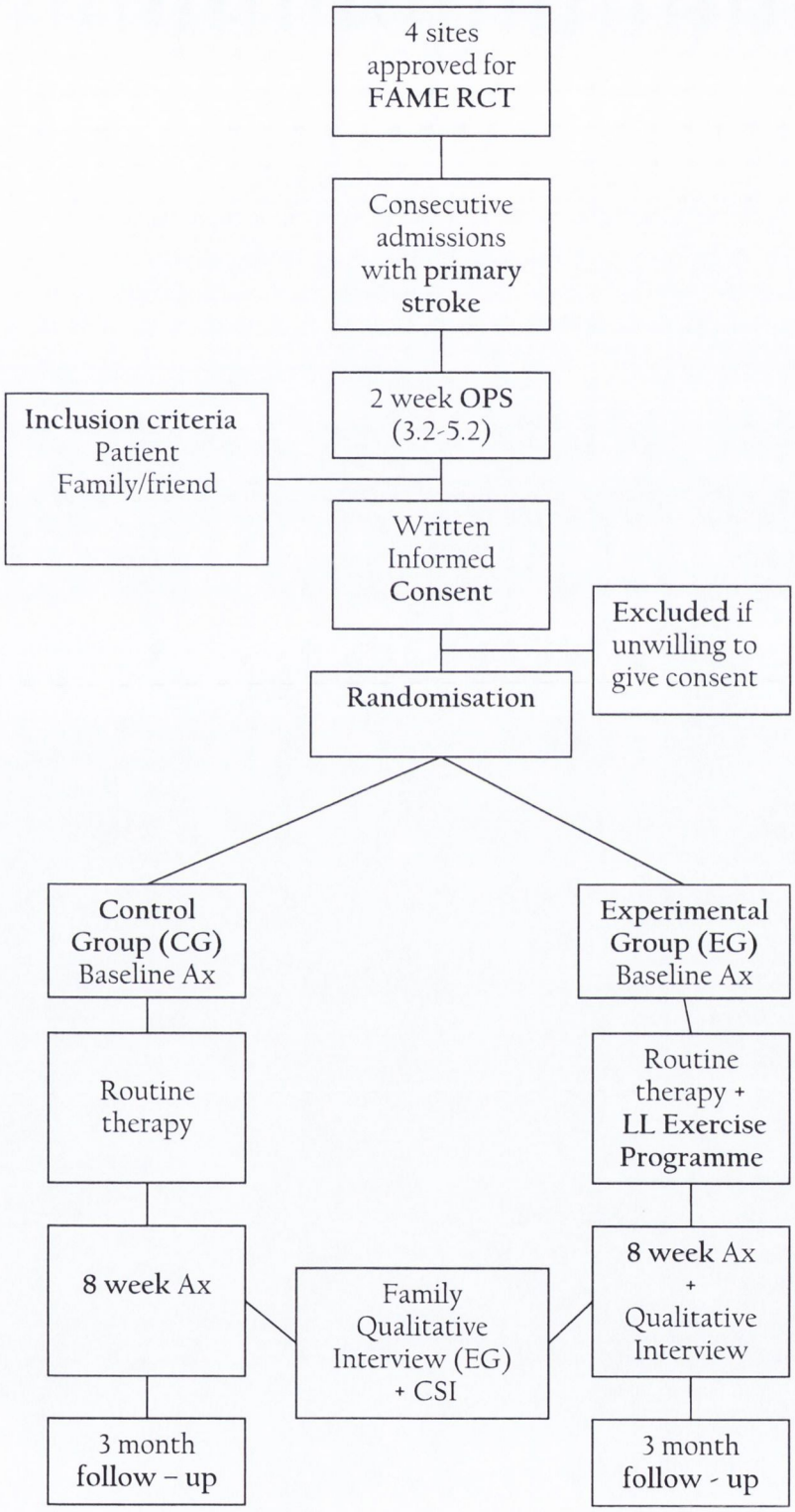

Figure 1
Outline of FAME study design.

weekly basis. Those patients who are survivors at two weeks following the onset of stroke will be assessed using the Orpington Prognostic Scale. The Orpington Prognostic Scale was developed by Kalra and Crome [37] in order to stratify stroke patients according to severity of stroke. The Orpington Prognostic Score (OPS) is a clinically derived score that incorporates measures of cognitive impairment, motor deficit, balance and proprioception. The score ranges from 1.6 (best prognosis/lowest level of disability) to 6.8 (worst prognosis/highest level of disability). It has its highest predictive power of levels of dependence when assessed at two weeks following the onset of stroke [37-39]. Only patients who achieve a score from 3.2 – 5.2 on the OPS at two weeks post stroke will be recruited to this study. This cohort of patients has been described as the '*middle group*' of stroke patients and consists of people presenting with a moderate/severe deficit following stroke [38]. It has been suggested that outcome in this band of patients depends on extrinsic factors such as the intensity and quality of rehabilitation, family support, the personality and motivation of the patient and the availability of statutory and voluntary support systems in the community [38]. The scale has been validated for both an elderly and an Irish stroke population [37,40]. The test-retest and inter-rater reliability of the OPS has also been established [40].

Inclusion/Exclusion Criteria

Patients will be admitted to the study if they present with a formal diagnosis of first unilateral stroke, are over 18 years, are willing to give informed consent and have 'family members/friends' willing to participate in their assigned physiotherapy intervention programme. Patients will be excluded if they present with hemiplegia of a non-vascular origin, are discharged from hospital at baseline less than two weeks following stroke, have an OPS score of less than 3.2 or greater than 5.2 at two weeks following stroke onset, have a pre-existing neurological disorder resulting in a motor deficit in addition to that resulting from the stroke, present with any lower extremity orthopaedic condition such as recent fractured femur or amputation or have receptive/expressive dysphasia.

'Family members/friends' will be included if they have been nominated by the person with stroke to assist him/her in the performance of their prescribed exercises and are medically stable and physically able to assist in the delivery of exercises to the person with stroke. Suitability will be determined in liaison with the physiotherapist in charge on the patients' routine care. Family members/friends' will also be required to give informed written consent agreeing to help their 'family member/friend' with stroke in the performance of his/her prescribed exercises.

Recruitment

The research physiotherapist (RG) will be responsible for assessing eligibility for inclusion into the study and also for obtaining informed consent from the patient and his/her 'family member/friend'. Following identification of suitable participants i.e. people with stroke and their nominated family member/friend, the aims of the project, including the role of the participant and his/her "family member/friend" in the FAME programme, will be outlined and any questions answered by RG. The person with the stroke and his/her 'family member/friend' will each receive a separate information brochure in advance of being asked to give written informed consent agreeing to participate. Participants will have seven days between receipt of the information brochure and being requested to give written permission. Following the 7-day interval, RG will answer or clarify any further questions that arise and both the person with stroke and his/her 'family member/friend' will be requested to sign a consent form in the presence of each other. If either the patient or his/her 'family member/friend' are unwilling to give written consent, they will be excluded from the study. If they decide to partake in the study, participants will be advised that they can withdraw from the study at any time and that the study will not interfere with their routine rehabilitation programme. Participants will be allocated a reference code. Names and other details that may identify the participants will be removed.

Randomisation

To minimise the possibility of recruitment bias, a person independent of the recruitment process will complete random group allocation. Computer generated random numbers will be kept in pre-sealed envelopes in a locked drawer. Allocation will be revealed after recruitment by a telephone call from RG to an independent person, who will open the next envelope in the sequence and give the randomisation information to RG. Each envelope will only be opened on enrollment of an eligible participant. After allocation has been revealed, the appropriate intervention will be organised by RG.

Power

Sample size is based on a power analysis. A sample size calculation was performed for the primary outcome variable, which is the lower extremity section of the Fugl-Meyer (FM). For the FM lower extremity, a change of greater than five points reflects a change greater than measurement error [42]. Power calculations indicate that a total of 40 participants are needed in order to detect with 80% power a difference of 20% between the groups at a significance level of 5%. It is anticipated that it will take 18–24 months to recruit the required number of participants.

Analysis

All data will be collected on paper and the records will be stored by registration number in a secure cabinet. Anonymised data will be transferred to a computer database and secured using a password. An independent researcher will cross check all entries. Appropriate statistical tests will be carried out on the data using MINITAB Release 13.1.

The statistical analyses will be performed according to the 'intention to treat' principle and participants will be analysed in the group to which they were randomly assigned. Participants who withdraw from the experimental group but allow further data collection will have data collected. A 'last measurement carried forward' method is used to predict outcome in dropouts [43].

The purpose of the statistical analysis is to test the hypothesis that there will be a clinically significant difference in functional recovery between participants in the control group and the experimental group from baseline to post-intervention assessment. Firstly, the baseline scores of the participants' demographic, primary and secondary outcomes will be compared in the two groups. If necessary, adjustments for baseline variables will be made using analysis of covariance. Analyses will be carried out to examine the difference between the groups with respect to the change in the lower extremity FM test score from baseline to post-intervention assessment. Secondary outcomes will be compared between the two groups using Student's t-test or the Wilcoxon rank sum test for ordinal data. Descriptive statistics will also be used to represent demographic data.

All interviews will be tape recorded, transcribed and examined in terms of themes according to the method devised by Miles and Hubberman [44]. The responses from all participants to each question will be transferred to Microsoft Excel for examination. Following an examination of the responses to each question, a coding system will be developed in order to facilitate the identification of recurrent responses. Three researchers will be provided with the responses to all of the questions in an unencoded format; thereafter they will independently code the responses sequentially using the predefined codes. All coding disagreements will be resolved through discussion.

Discussion

The concept of family mediated exercise therapy is not a new phenomenon. It is common practice in rehabilitation of children with neurological impairments [45]. While it cannot be denied that the sudden and profound effects of stroke on family roles and functioning create stress for the stroke survivor and their families, the available evidence suggests that carers and families want information and want to be more fully involved in their rehabilitation [46,47]. It is also evident that more therapy is of benefit to people with stroke and the aim of this RCT is to maximise motor recovery by allowing the patient to practice activities with his/her family outside of the routine treatment hours. The qualitative data will allow the researchers a deeper insight into the impact of the programme of the patient and his/her family. Only by establishing evidence-based interventions, such as the one outlined in this protocol, can we strive to reduce the impact of this illness on the individual, the family and society.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors contributed to the development and writing of the protocol. All authors have been involved in the drafting and revision of this manuscript and have given approval of the final manuscript.

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APPENDIX 2

Publication of systematic review and meta-analysis

Galvin, R., Murphy, B., Cusack, T., Stokes, E. (2008b). The impact of increased duration of exercise therapy on functional recovery following stroke - what is the evidence? *Topics in Stroke Rehabilitation*, 15(4), 365-377.

The Impact of Increased Duration of Exercise Therapy on Functional Recovery Following Stroke – What Is the Evidence?

Rose Galvin, Brendan Murphy, Tara Cusack, and Emma Stokes

This article focuses on the impact of increased duration of exercise therapy on functional recovery after stroke. A comprehensive literature search using multiple databases was used to identify all relevant randomized controlled trials. Their quality was reviewed by two independent assessors, and a narrative systematic review and meta-analysis was completed. Methodological quality of all the 20 randomized controlled trials (RCTs) identified had a median of 6 points (range 5–8) on the 10-point PEDro scale. A meta-analysis was completed for studies that had a common outcome measure. For each outcome measure, the estimated effect size (ES) and the summary effect size (SES) were expressed as standardized mean differences (SMD). The results of the meta-analysis demonstrated that increased duration of exercise therapy time has a small but positive effect on activities of daily living as measured by the Barthel Index (SES 0.13; CI 0.01–0.25; Z = 2.15; p = .03) and that these improvements are maintained over a 6-month period (SES 0.15; CI 0.05–0.26; Z = 2.8; p = .00). Pooling reported differences in the various upper and lower extremity outcome measures demonstrated no significant SESs. However, the meta-analysis is supportive of the hypothesis that additional, focused exercise on the lower extremity has a favourable effect on lower extremity impairment and walking speed. The narrative review raises a number of issues that need to be considered in the development of future RCTs. **Key words:** *exercise therapy, functional outcome, increased duration, rehabilitation, stroke*

Stroke is a major social and health care issue. In the United States, it is estimated that every 45 seconds someone has a stroke.[1] Advances in neuroscience and clinical research are beginning to merge and demonstrate that the human brain is capable of significant recovery after stroke, provided that the correct treatment and stimuli are applied in adequate amounts and at the right time.[2] One major component of stroke rehabilitation is exercise therapy to minimize the effects of the brain cell damage and optimize re-learning. It is well recognized that for cortical re-organisation to occur post stroke, there is a requirement for high levels of repetition of tasks and exercises that are both challenging and engaging.[3–6]

Physical therapists have traditionally been the mediators of exercise therapy post stroke. Over the years, different physical therapy approaches have been advocated to promote recovery, including the methods of Bobath, Brunnstrom, Rood, and the Proprioceptive Neuromuscular Facilitation (PNF) technique.[7,8] All of these therapy approaches are exercise based, and there is evidence that physical and occupational therapy, using a mix of components from these different approaches, is significantly more effective than no treatment or placebo control in the recovery of functional independence following stroke.[7] Nonetheless, it has been suggested that the duration of exercise therapy that is delivered post stroke is, at best, "homeopathic," and uncertainties still remain about the most appropriate level of therapy input.[9] Findings from two systematic reviews have suggested that an increased exercise therapy input is associated with enhanced improvement of the performance of activities of daily living (ADLs)

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after stroke, although the exact dose of practice required for functional effects to take place is not reported.[10,11] A later meta-analysis also supported the hypothesis that additional exercise therapy has a small but favorable effect on ADLs, particularly if the additional input is at least 16 hours more than the control group in the first 6 months.[12] However, this meta-analysis included studies where no formal exercise therapy was documented in the control group.[13–17] Although other recent literature reviews have included studies that examined the impact of novel technology and robotics on functional outcome following stroke, such interventions were provided as an alternative to the traditional physical therapy approaches to the delivery exercise therapy,[18–20] and no additional intervention was provided. Therefore, the purpose of this systematic review and meta-analysis is to examine the effects of additional exercise therapy time by reviewing studies that assess the effects of additional exercise therapy, using different physical therapy approaches, when compared to routine formal exercise therapy on a variety of outcomes at the level of impairment and function.

Method

Literature search

A computerized literature search was conducted and included AMED, CINAHL, Science Direct, the Cochrane Library (all), MEDLINE, DARE, PEDro, EMBASE, and PubMed. The databases were searched using a combination of the following key words: "stroke," "cerebrovascular accident," "physical therapy," "physiotherapy," "occupational therapy," "exercise therapy," "dose of therapy," "additional," "augmented," "intensity," "frequency," "arm," "leg," "upper limb," "lower limb," "rehabilitation," "effectiveness," "impact," "randomized controlled trial," and "functional outcome." The search was supplemented by obtaining additional articles cited in articles in the original list.

Definitions and inclusion criteria

The authors used methods based on the Cochrane Handbook for Systematic Reviews of Interventions 4.2.6.[21] *Participants* in the studies to be included were people who presented with stroke as defined by the World Health Organization.[22] *Interventions* of interest were those where "additional," "augmented," or "increased duration" of exercise therapy was compared to "normal," "routine," or "traditional" levels of exercise therapy. *Exercise therapy* was defined as motion of the body or its parts to relieve symptoms or to improve function, leading to physical fitness, but not physical education and training.[23] Exercise therapy included both occupational and physical therapy for the purposes of this review. There is a general lack of consensus on what constitutes traditional or routine exercise therapy, and the exact definition can only be considered in relation to each individual study; in many cases this definition is not provided. *Additional, augmented*, or *increased duration* of exercise therapy refers to the amount, in minutes, of exercise therapy that people with stroke received that was in excess of their routine exercise intervention. If no exercise therapy was delivered to the control group, then such studies were not included in the analysis. *Frequency* refers to the number of days of exercise per week. *Outcome measures* to be included were those that focused on impairment of structures, limitations of ADLs, and quality of life. Types of study design to be included were randomized controlled trials (RCTs).

Study identification and selection

One reviewer read the titles of the identified references and eliminated irrelevant studies. Articles that did not meet the inclusion criteria, were not published in English, were not relevant to the nature of the topic, or that included participants with diagnoses other than stroke were excluded from further analysis. This review focused only on different physical therapy treatment approaches that delivered additional or augmented time in exercise therapy as opposed to the use of specific interventions for recovery. Therefore, studies that considered a massed practice approach such as the effectiveness of constraint-induced movement therapy or application of special equipment to augment therapy such as balance platforms, robotic devices, or biofeedback equipment were excluded from analysis. The remaining articles

were obtained and based on the inclusion criteria; one reviewer marked them as relevant, irrelevant, or unsure. A second reviewer independently ranked these trials using the same method. Any disagreements were resolved through discussion between the reviewers.

Methodological quality

Two reviewers independently documented the methodological quality of the studies and extracted the relevant data. Studies were evaluated using criteria to eliminate selection bias, performance bias, attrition bias, and detection bias.[21] If all of the criteria are met, the study is considered to have a low risk of bias. If one or more criteria are partly met, the study is deemed to have a moderate risk of bias. If one or more of the criteria are not met, then the study is considered to have a high risk of bias. In addition, the Physiotherapy Evidence Database (PEDro) was also used to document the quality of the studies.[24] Each clinical trial on the PEDro database is rated on the basis of its methodological quality, allowing access to the best available evidence of the effects of physical therapy interventions. Any disagreements in the quality of the studies were resolved through discussion between the reviewers.

Data extraction

Data extraction was undertaken separately for each intervention. The following data were documented for each study: authors, size of intervention and control groups, study design, duration (in minutes) and frequency of intervention, results of study, and the battery of outcome measures used. For the purposes of analysis, scores (mean and standard deviation) on the relevant outcome measures were recorded at baseline, first assessment post intervention, and again at 6 months. Authors were contacted for clarification or to provide missing data where necessary.

Quantitative analysis

The extracted data were inputted into Microsoft Office Excel 2003. For studies where the mean values were not available, the median was recorded instead. When the standard deviations were not available for the particular outcome measure, the interquartile ranges were recorded; if these were not available, the ranges were recorded when available. The median was used as a proxy for the mean. Multiples of 0.75 times the interquartile range or 0.25 times the range were used as proxies for the standard deviation values.[25] The meta-analysis was completed using the metacont function in the meta package version 0.8-2[26] for the statistical package R.[27] The meta-analysis method outlined in Cooper and Hedges[28] was implemented in the analysis, and standard mean difference (SMD) was used as the mode of analysis. The impact of sample size was addressed by estimating a weighting factor for each study and assigning larger effect weights in studies with bigger samples. The fixed effect and random effect models were completed; if significant between-study variation (statistical heterogeneity) existed, a random effects model was applied.[29] Based on the classification of Cohen, effect sizes below 0.2 were classified as small, from 0.2 to 0.5 as medium, and above 0.5 as large.[30]

Results

The search strategy resulted in a list of 4,773 citations. Following the exclusion of irrelevant articles, 48 studies were deemed potentially relevant. Application of the inclusion criteria resulted in 29 remaining articles. Two studies had a PEDro score less than 5 and were also excluded from final analysis based on their methodological quality.[31,32] A further study that included participants with traumatic brain injury was also excluded from the analysis.[33] Five studies compared routine treatment to no treatment and were thus excluded.[13,17] Two articles reported data on the same cohort of patients[34,35] – only one study was included in the meta-analysis.[34] Therefore 20 articles were included in the final analysis. Three of these studies followed up participants for 1 year or more.[36–38] **Table 1** illustrates the results of the methodological quality of the studies included.

Table 1. Review of randomized controlled trials

	Sivenius et al., 1985	Sunderland et al., 1992	Richards et al., 1993	Logan et al., 1997	Feys et al., 1998	Lincoln et al., 1999
Selection bias	Adequate	Adequate	Adequate	Adequate	Unclear; method not described	Adequate
Performance bias	Unmet	Met	Met	Met	Unmet	Met
Attrition bias	Unmet	Unmet	Unmet	Met	Met	Met
Detection bias	Met	Met	Met	Met	Met	Met
Risk of bias	High	High	High	Low	High	Low
PEDro score (/10)	5/10	6/10	6/10	7/10	6/10	6/10

	Kwakkel et al., 1999	Gilbertson et al., 2000	Partridge et al., 2000	Anderson et al., 2002	Di Lauro et al., 2003	Fang et al., 2003	Martinsson et al., 2003
Selection bias	Adequate	Adequate	Adequate	Adequate	Unclear; method not described	Adequate	Adequate
Performance bias	Met	Met	Met	Met	Met	Met	Unmet
Attrition bias	Met	Met	Unmet	Met	Unmet	Unmet	Met
Detection bias	Met	Met	Met	Met	Met	Met	Met
Risk of bias	Low	Low	High	Low	High	High	High
PEDro score (/10)	7/10	8/10	7/10	8/10	6/10	6/10	7/10

	Rodgers et al., 2003	Winstein et al., 2004	GAPS, 2004	Blennerhassett & Dite, 2004	Yang et al., 2005	Platz et al., 2005	Askim et al., 2006
Selection bias	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
Performance bias	Unmet	Met	Met	Met	Met	Met	Unmet
Attrition bias	Unmet	Met	Met	Met	Met	Met	Met
Detection bias	Met	Unmet	Unmet	Met	Unmet	Met	Met
Risk of bias	High	High	High	Low	High	Low	High
PEDro score (/10)	8/10	6/10	7/10	8/10	6/10	8/10	7/10

Effects of increased duration of arm exercise therapy on arm function

Eight RCTs were analyzed to ascertain whether increased duration of exercise therapy had an impact on outcome of the affected arm following acute stroke.[34,39–45] Two of these studies published 1 year follow-up studies,[36,37] and one study published a 5-year follow-up paper.[38] Numbers of participants, characteristics of the interventions, measures of outcome, and reported results are shown in **Table 2**. Additional exercise therapy time (in minutes) prescribed to experimental groups ranged from 24 minutes[42] to 60 minutes per weekday.[40,41] Six studies prescribed this additional therapy at a frequency of five times per week for a period of 4–6 weeks.[34,39–42,44] One study applied the additional therapy for a period of 20 weeks.[43] An earlier study by Sunderland et al.[45] documents that participants in the experimental group received a median of 180 minutes additional arm exercise therapy per week for a median period of 18 weeks in comparison to a 10-week control intervention. Methodological quality ranged from 5 to 8 on the PEDro scale.

Effects of increased duration of lower extremity exercise therapy on lower extremity function

Four RCTs that consider the effects of increased duration of exercise therapy on outcome of the affected leg are included in this analysis.[41,43,46,47] One study published a 1-year follow-up of participants.[37] Numbers of participants, characteristics of the interventions, measures of outcome, and reported results are shown in **Table 3**. Additional exercise therapy sessions ranged from 30 minutes[43,46] to 120 minutes per day[47] and were applied at a frequency of 3–5 times per week for a period of 3–20 weeks. Methodological quality ranged from 6 to 8 on the PEDro scale.

Table 2. Increased duration (in minutes) of arm exercise therapy on arm outcome following stroke

Authors	Intervention group (IG)	Control group (CG)	Study design/participants	Intervention	Results	Outcome measures
Platz et al., 2005	IG 1: RT + conventional arm therapy (*n*=21) IG 2: RT + arm impairment training (*n*=21)	RT (*n*=20)	Multicentre RCT/ mean 4.6–6.5 weeks post CVA	225 minutes per week/4 weeks	IG 2 improved significantly on FM score when compared to IG1 and CG.	FM–UL, ARAT, Ashworth Scale
Winstein et al., 2004	IG 1: RT + functional task practice (*n*=22) IG 2: RT + strength training (*n*=21)	RT (*n*=21)	Single-centre RCT/ mean 15–17 days post CVA	300 minutes per week/4–6 weeks	IG 1 & IG 2 improved significantly on FM score & isometric torque post treatment.	FM, Dynamometer, FTHUE
Blennerhassett & Dite, 2004	RT + task related therapy (*n*=15)	RT + lower extremity therapy (*n*=15)	Single-centre RCT/ mean 36–50.1 days post CVA	300 minutes per week/4 weeks	Significant changes in JTHFT & MAS at 4 weeks	JTHFT, MAS
Rodgers et al., 2003	RT + conventional arm therapy (*n*=62)	RT (*n*= 61)	Single-centre RCT/ median 5 days post CVA	150 minutes per week/up to 6 weeks	No significant differences between the two groups at 3 and 6 months	ARAT, MI, FAT, BI, ADL Index
Kwakkel et al., 1999	RT + functional exercises (*n*=33)	RT + immobilization of arm & leg (*n*=37)	Single-centre RCT/ mean 7–7.5 days post CVA	150 minutes per week/20 weeks	IG 1 - significant difference in ARAT	ARAT, BI
Lincoln et al., 1999	IG 1 (*n*=94): RT + qualified PT IG 2 (*n*=93): = RT + assistant PT	RT (*n*=95)	Single-centre RCT/ median 12 days post CVA	120 minutes per week/5 weeks	No significant changes in groups overall postintervention or at 3 or 6 months.	RMA, ARAT, BI, THPT, MCA
Feys et al., 1998	RT + sensorimotor stimulation (*n*=50)	R T (*n*=50)	Multicentre RCT/ mean 21–24 days post CVA	150 minutes per week/6weeks	Significant improvement in impairment at 6 & 12 months	FM, ARAT, BI
Sunderland et al., 1992	RT + conventional arm therapy (*n*=65)	RT (*n*=67)	Single-centre RCT/ median 8–10 days post CVA	Double therapy/18 weeks	Significant improvement in impairment at 6 months	Extended MI, MCA, FAT, NHPT

Note: RT = "routine" therapy; PT = physical therapy; FM-UL = upper extremity section of Fugl-Meyer; ARAT = Action Research Arm Test; FM = Fugl-Meyer; FTHUE = Functional Test of Hemiplegic Upper Extremity; JTHFT = Jebsen Taylor Hand Function Test; MAS = Motor Assessment Scale; MI = Motricity Index; FAT = Frenchay Arm Test; BI = Barthel Index; RMA = Rivermead Motor Assessment; NHPT/THPT = Nine/Ten Hole Peg Test; MCA = Motor Club Assessment.

Effects of general/less specific additional therapy on functional outcome

Six studies adopted a more general, less specific approach to the delivery of additional arm and leg exercise therapy.[48–53] Participants received between 10 minutes[53] and 75 minutes[49] of additional exercise therapy daily over a period of 1–24 weeks. Methodological quality ranged from 5 to 7 on the PEDro scale. Numbers of participants, characteristics of the interventions, measures of outcome, and reported results are shown in **Table 4**.

Effects of increased duration of community-based exercise therapy on functional outcome

Four RCTs examined the effects of augmented community-based exercise therapy on functional outcome in people with stroke living in the community.[54–57] Participants received between 167 minutes[57] and 450 minutes[56] of additional exercise therapy over a period of 4–12 weeks. Methodological quality ranged from 7 to 8 on the PEDro scale. Numbers of participants, characteristics of the interventions, measures of outcome, and reported results are shown in **Table 5**.

Meta-analysis

Upper extremity outcome measures

Five studies[34,39,42–44] (N = 669) measured the effects of additional exercise therapy on the arm using the Action Research Arm Test (ARAT). No significant SES was demonstrated post treatment (SES –0.06; CI –0.21 to 0.09; Z = –0.80; p = .43) or at 6 months (SES –0.07; CI –0.35 to 0.21; Z = –0.51; p = .6561). Pooling posttreatment effect sizes for the two studies (n = 193) that used the Motricity Index (MI)[42,48] (SES 0.01; CI –0.27 to 0.29; Z = 0.08; p = .94) and the two studies (N = 126) that used the upper extremity section of the Fugl-Meyer (FM-UL)[39,40] (SES –0.2; CI –0.51 to 0.11; Z = –1.25; p = .21) also yielded nonsignificant SESs.

Lower extremity outcome measures

A meta-analysis was possible for the lower extremity section of the Fugl-Meyer (FM-LL) and walking speed. Pooling the five studies[43,46,47,52,54] (N = 296) that used walking speed as a common outcome measure showed no significant posttreatment (SES 0.13; CI –0.1 to 0.36; Z = 1.12; p = .26) or 6-month effect (SES 0.24; CI –0.02 to 0.51; Z = 1.81; p = .07) supporting the use of additional exercise therapy. In addition, there was no evidence that additional exercise therapy demonstrated a favorable postintervention effect in the two studies (n = 183) that measured outcome using the lower extremity section of the FM-LL[47,50] (SES 0.23; CI –0.06 to 0.51; Z = 1.56; p = .12).

Activities of daily living

A meta-analysis was possible for the Nottingham Extended Activities of Daily Living Index (N-EADL) and the Barthel Index (BI). Ten studies[34,42–45,48–50,55,56] (N = 1,349) used the Barthel Index to measure ADLs following additional exercise therapy. Significant posttreatment (SES 0.13; CI 0.01 to 0.25; Z = 2.15; p = .03) and 6-month outcomes (SES 0.15; CI 0.05 to 0.26; Z = 2.8; p = .00) favored the use of additional exercise therapy. Four studies[34,42,48,56] (N = 613) used the Nottingham Extended Activities of Daily Living Index to measure performance following additional exercise therapy input. No significant 6-month outcome was demonstrated following augmented therapy (SES 0.13; CI –0.02 to 0.28; Z = 1.72; p = .85).

Discussion

From the present meta-analysis, it can be concluded that additional exercise therapy has a small but positive effect on ADLs as measured by the Barthel Index post intervention and that these improvements are maintained over a 6-month period. These findings are similar to those of a previous meta-analysis by Kwakkel et al.[12] who also demonstrated that increased time spent in exercise training in the first 6 months after stroke results in small but favorable improvements in ADLs.

However, pooling reported differences in the various upper and lower extremity outcome measures showed no significant SESs. In contrast, Kwakkel et al.[12] demonstrated a significant effect on walking speed, but the analysis included two

Table 3. Increased duration (in minutes) of lower extremity exercise therapy on lower extremity outcome following stroke

Authors	Intervention group (IG)	Control group (CG)	Study design/ population	Intervention	Results	Outcome measures
Yang et al., 2005	RT + gait training (*n*=13)	RT (*n*=12)	Single-centre RCT/ mean 5.45–7.33 months post CVA	90 minutes per week/3 weeks	Significant improvement in IG	Stride analyser
Blennerhassett & Dite, 2004	RT + task related therapy (*n*=15)	RT + upper extremity therapy (*n*=15)	Single-centre RCT/ mean 36–50.1 days post CVA	300 minutes per week/4 weeks	Significant improvement in IG on TUG & 6MWT at 4 weeks	MAS, TUG, Walking speed
Kwakkel et al., 1999	RT + functional exercises + gait training (*n*=31)	RT + immobilization of arm & leg (*n*=37)	Single-centre RCT/ mean 7–7.5 days post CVA	150 minutes therapy per week/20 weeks	Significant improvement in ADL & walking.	BI, Functional Ambulation Categories
Richards et al., 1993	IG 1: RT+ conventional therapy (*n*=8). IG 2: RT + focused leg therapy (*n*=10)	RT (n=9)	Single-centre RCT/ mean 8.3–13 days post CVA	600 minutes therapy weekly/5 weeks	Walking speed was significantly higher in IG 2 at 6 weeks. No difference at 3 and 6 months.	BI, Walking speed, BBS, FM

Note: RT = routine therapy; MAS = Motor Assessment Scale; TUG = Timed Up and Go; BI = Barthel Index; BBS = Berg Balance Scale.

Table 4. Increased duration (in minutes) of general exercise therapy on outcome following stroke

Authors	Intervention group (IG)	Control group (CG)	Study design/ participants	Intervention	Results	Outcome measures
GAPS, 2004	Double conventional therapy (*n*=35)	RT (*n*=35)	Multi-centre RCT/ mean 22–25 days post CVA	125 minutes per week/~10 weeks	No statistically significant differences in groups at 4, 12, 26 weeks	RMI, Walking speed, BI, MI
Di Lauro et al., 2003	Intensive therapy (*n*=29)	RT (*n*=31)	Single-centre RCT/ <24 hours post CVA	525 minutes per week/2 weeks	No statistically significant differences in groups at 2 or 26 weeks	Modified NIH Stroke Scale, BI
Fang et al., 2003	RT + additional early physical therapy (*n*=78)	RT (*n*=78)	Single-centre RCT/ <1 week post CVA	225 minutes per week/4 weeks	Significant difference in BI at 4 weeks; no difference at 6 months	FM, Modified BI, Clinical Neurological Deficit Scale
Martinsson et al., 2003	Intensive treatment (*n*=15)	RT (*n*=15)	Single-centre RCT/ median 2 days post CVA	325 minutes /5 days	No statistically significant differences in groups at 5 days or 3 or 6 months	LMAC, NIH Stroke Scale, Activity Index
Partridge et al., 2000	Double conventional PT (*n*=54)	RT (*n*=60)	Single-centre RCT/ participants post acute CVA	150 minutes per week/6 weeks	No significant differences at 6 or 26 weeks	Profiles of Recovery Scale, Functional reach, 5-m walk test
Sivenius et al., 1985	RT + additional therapy (*n*=50)	RT (*n*=45)	Single-centre RCT/ <1 week post CVA	54 minutes per week/12 weeks	No significant differences at 3, 6, or 12 month follow-up	ADL, strength & range of movement 4-point scale

Note: RT = routine therapy; RMI = Rivermead Mobility Index; BI = Barthel Index; MI = Motricity Index; Modified NIH Stroke Scale = Modified National Institute of Health Stroke Scale; FM = Fugl-Meyer scale; LMAC = Lindmark Motor Assessment Chart.

Table 5. Increased duration (in minutes) of community exercise therapy

Authors	Intervention group (IG)	Control group (CG)	Study design / participants	Intervention	Results	Outcome measures
Askim et al., (2006)	Intensive task specific therapy (*n*=31)	RT (*n*=31)	Multi-centre RTC/ post discharge from hospital following CVA	Intensive therapy/4 weeks	No statistically significant differences in groups at 1, 6, 26, and 52 weeks	BBS, Walking speed, Scandinavian Stroke Scale
Anderson et al., (2002)	Follow-up with PT (*n*=53)	CG 1: Routine community care (*n*=48) CG 2: Follow-up with physician (*n*=54)	Multi-centre RTC/ post discharge from hospital following CVA	174 minutes in total/6–12 weeks	No statistically significant differences in groups at 6 months	Functional Quality of Movement, BI, FAI, Extended ADL
Gilbertson et al., (2000)	Intensive service (*n*=67)	RT (*n*=71)	Single-centre RCT/post discharge from hospital following CVA	300–450 minutes total/6 weeks	Significant difference in N-EADL score at 8 weeks; no difference at 6 months	N-EADL, BI
Logan et al., (1997)	Enhanced service (*n*=53)	RT (*n*=58)	Multi-centre RTC/ post discharge from hospital following CVA	167 minutes total/6 weeks	Significant difference in N-EADL score at 3 months; evident only in mobility section only at 6 months	N-EADL, BI, General Health Questionnaire

Note: RT = routine therapy; BI = Barthel Index; BBS = Berg Balance Scale; FAI = Frenchay Activities Index; N-EADL = Nottingham Extended Activities of Daily Living Index.

studies that provided no formal exercise therapy to the control group.[13,17] The focus of this meta-analysis was to compare studies that provided routine therapy to the control group versus studies that provided routine therapy as well as additional exercise therapy to the intervention group. Although the lower extremity meta-analyses lack significant findings, the results are supportive of the hypothesis that more exercise therapy is indeed better. The posttreatment and 6-month outcomes are nearing significance, and the lack of significant findings may be a result of the limited number of studies included in the analysis. The individual effect sizes of the studies included in the analysis also indicate that studies with a focused lower extremity intervention demonstrate larger SMDs between the intervention and the control groups than studies that compare general augmented intervention to a control group. However, the number of minutes of additional exercise therapy that is required to demonstrate a significant effect is not clear from these studies and ranges from 270 to 2500; this requires further research. These results also highlight the need for more RCTs with large sample sizes to evaluate the efficacy of focused additional therapy on lower extremity outcome.

In contrast, the benefits of additional exercise therapy on arm function are not evident from this meta-analysis. There are a number of possible reasons for the lack in significant findings. Two studies[39,44] with a combined total of 162 participants provided an additional 900 minutes of impairment-orientated arm training and demonstrated significant posttreatment effects at the level of impairment as measured by the FM-UL. Compliance was excellent and the quality of the studies ranged from 6 to 8 on the PEDro scale, respectively. Similarly, three studies[40,41,43] delivered in excess of 1200 minutes of focused additional exercise intervention with a focus on arm disability and also noted significant differences between the groups at the level of impairment and disability. In contrast to the more focused intervention, three studies[34,39,42] that delivered an additional 600–900 minutes of traditional or conventional arm exercise therapy failed to demonstrate a significant effect following treatment. With the exception of one study[38] with a focused exercise therapy intervention, none of the participants who had received the additional exercise therapy demonstrated long-term follow-up benefits.

The particular subgroups of patients that appear to benefit more from the additional exercise therapy are also of interest in these studies. Feys et al.[44] reported that participants who demonstrated more severe motor deficits had a more marked improvement following additional therapy. This finding is contrary to findings of a post hoc analysis[35] of participants in the study by Lincoln et al.[34] and two other studies[40,45] that report a more favourable improvement in impairment and function in the intervention group who presented with a milder initial impairment.

Evidence from these studies suggests that further research work is required to establish what particular type of patient gains optimum benefit from additional exercise therapy post stroke. This review would also suggest that perhaps a more focused approach should be adopted when administering arm therapy and that additional therapy needs to be delivered on a longer term basis to demonstrate significant longer term benefits. It also emerges from these studies that at least 900–1200 minutes of additional therapy delivered over a 4- to 6-week period following acute stroke is required to have a significant impact on level of impairment and/or function.

Conclusion

Following the meta-analysis of the studies described above, the evidence is supportive of the hypothesis that additional, augmented, or increased duration of exercise therapy results in improved functional outcome as measured by the Barthel Index. The lack of evidence in the various upper and lower extremity outcome measures may be a result of a number of reasons. There may be an insufficient number of studies included in the meta-analysis. In addition, the systematic review raises a number of issues that may point the way for further research studies. First, in the inpatient studies where no effect of additional exercise therapy is demonstrated, compliance within the experimental group has not been optimal.[34,50] For this reason, a review of interventions that would be acceptable to people with stroke should be performed prior

to the design of such an intervention. Second, there is contradictory evidence in the studies reviewed as to which subgroups of people with stroke may benefit most from augmented intervention. The majority of the studies favor the suggestion that people with a milder initial impairment following stroke tend to benefit more from additional exercise therapy.[35,36,40,52,54] Hence, careful consideration should be given to the level of impairment of a person following stroke prior to the implementation of an additional exercise therapy program. Third, the nature of intervention that is delivered is of interest. Evidence from this review suggests that increasing the time spent on traditional or conventional therapy approaches is not beneficial[34,39,42,47–49,51,52,54,55] and that more focused exercise therapy interventions either at the level of impairment or function are more effective.[39,41–43,44,46,47] There is a paucity of evidence examining the clinical effectiveness and cost effectiveness of novel technology as a method of delivering additional exercises following stroke, and further work using the results of neuroscientific research should inform the design of such exercise interventions. Fourth, in the majority of studies included in this review, therapists delivered the intervention. To date, no RCT has evaluated the delivery of exercise by people who are not health care workers; although interestingly in an RCT by Lincoln et al.,[34] both qualified physical therapists and physical therapy assistants delivered two different forms of additional exercise therapy and no differences were noted between the groups. These findings would give credence to the suggestion in the *Lancet* by de Weerdt and Feys[58] that "physiotherapists need to develop strategies whereby patients and caregivers take full responsibility for the bulk of therapy—for instance, training of balance, strength and endurance, repetition of simple tasks, group therapy, fitness-related training and family involvement."(p182) Furthermore, the intensity of the additional intervention is also a key factor that requires careful consideration; the inpatient groups that demonstrated successful augmented intervention delivered at least an additional 900–1200 minutes of exercise during a period of 4–6 weeks, although this varied between studies. Insufficient intensity of augmented intervention may have predisposed some studies to the inability to show statistically significant changes in outcome.[34,55] Finally, even though the meta-analysis indicates that improvements in ADLs are still evident at 6 months, two studies that published 1 year follow-up assessments[36,37] reported no significant findings at this timepoint. These findings suggest that the benefits of additional exercise therapy are not maintained if the additional therapy is not sustained. It is therefore important for therapists to devise programs of delivering additional therapy on a longer term basis. Future research should focus on novel ways of delivering this increased intervention, perhaps in the form of family-mediated exercise therapy, in addition to methods to motivate ongoing participation in these programs.

Limitations

This review used a comprehensive and systematic search strategy to identify all relevant trials, but it does have some limitations. First, studies not published in scientific journals or papers written in languages other than English were not included in the review. Second, due to lack of comparability of some outcomes, a qualitative analysis was primarily used in the discussion section. Although this method may be open to criticism for its use of random criteria, it has been used elsewhere.[20,59] Finally, several studies exhibited methodological flaws such as unclear randomization processes, inadequate sample sizes, lack of use of intention-to-treat analyses, contamination of the intervention to the control group, and the use of unblinded outcome assessors. Future studies should ensure that a clearly defined, sound methodology is implemented to prevent the occurrence of the aforementioned biases.

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APPENDIX 3

Physiotherapy Evidence Database (PEDro) Scale

PEDro scale

1.	eligibility criteria were specified	no ❑ yes ❑ where:
2.	subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no ❑ yes ❑ where:
3.	allocation was concealed	no ❑ yes ❑ where:
4.	the groups were similar at baseline regarding the most important prognostic indicators	no ❑ yes ❑ where:
5.	there was blinding of all subjects	no ❑ yes ❑ where:
6.	there was blinding of all therapists who administered the therapy	no ❑ yes ❑ where:
7.	there was blinding of all assessors who measured at least one key outcome	no ❑ yes ❑ where:
8.	measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no ❑ yes ❑ where:
9.	all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no ❑ yes ❑ where:
10.	the results of between-group statistical comparisons are reported for at least one key outcome	no ❑ yes ❑ where:
11.	the study provides both point measures and measures of variability for at least one key outcome	no ❑ yes ❑ where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999

Notes on administration of the PEDro scale:

All criteria	**Points are only awarded when a criterion is clearly satisfied**. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	*Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
Criteria 4, 7-11	*Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-7	*Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group × time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

APPENDIX 4

Publication of the results of User Survey 1, User Survey 2A and User Survey 3

Galvin, R., Cusack, T., Stokes, E. (2009a). To what extent are family members and friends involved in physiotherapy and the delivery of exercises to people with stroke? *Disability and Rehabilitation*, 31(11), 898-905.

Disability and Rehabilitation, 2009; 31(11): 898–905

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RESEARCH PAPER

To what extent are family members and friends involved in physiotherapy and the delivery of exercises to people with stroke?

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Abstract

Purpose. To examine the views of people with stroke, their 'family members/friends' and physiotherapists on the role of the family in physiotherapy and the delivery of exercises following stroke.

Methods. A self-report questionnaire was administered to 100 'family members/friends' and 75 people with stroke. Two focus groups were conducted with 10 expert physiotherapists working in the area of stroke rehabilitation.

Results. Family members of people with stroke are willing to participate in the delivery of unsupervised exercises in the hospital and the home setting ($n = 91$). Furthermore, this is also acceptable to people with stroke ($n = 65$) as an adjunct to routine physiotherapy. Physiotherapists highlighted a number of factors that influenced participation in physiotherapy such as; level of interest and motivation of the family ($n = 5$), availability ($n = 3$) and importance of education ($n = 2$). 'Family members/friends' identified reasons that would also limit participation such as work commitments ($n = 24$), lack of confidence ($n = 20$) and unsuitable treatment times ($n = 13$). The expert practitioners outlined a number of areas that family involvement can have an impact, such as treatment carry-over, assisting the family unit to cope on discharge and improving handling skills.

Conclusions. Our study identifies an under-utilised role for 'family members/friends' in the rehabilitation of people with stroke. Family mediated exercises can maximise the carry-over outside formal physiotherapy giving patients the opportunity for informal practice. This study highlights the need to examine the value of a structured programme of exercises that can be delivered to people with stroke by their 'family members/friends'.

Keywords: *Stroke, family, involvement, additional excercise therapy*

Introduction

Stroke is a major social and health care issue. In contrast to coronary heart disease and cancer, the burden of stroke lies with long-term disability as opposed to death. In the UK, it is estimated that ~6% of the annual total health care budget and social services expenditure is attributable to the management of stroke [1]. Any rehabilitation intervention that can speed recovery and reduce long-term disability would have a major impact on both the individual and the social burden of this illness.

One major component of stroke rehabilitation is exercise intervention, to minimise the effects of the brain cell damage and optimise re-learning. Findings from two systematic reviews [2,3] have suggested that a more intensive exercise therapy input is associated with enhanced improvement of the performance of functional activities after stroke and a later meta-analysis [4] also supported the hypothesis that additional exercise therapy has a small but favourable effect on activities of daily living. However, additional physiotherapy is expensive and not routinely funded by the National Health Service in the UK or by health insurance companies [5] and research is now focusing on novel ways of increasing the 'dose' of physiotherapy following stroke. One suggestion has been that 'physiotherapists need to develop strategies whereby patients and caregivers take full responsibility for the bulk of therapy – for instance, training of balance, strength and endurance, repetition of simple tasks, group therapy, fitness-related training and family involvement' [6]. Although the contribution of caregivers to healthcare

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is recognised worldwide [7], there is little known about carers' perspectives of rehabilitation following stroke.

In this article, we consider the views of family members on their role in physiotherapy and in the delivery of additional exercises to people following stroke. We also consider the views of people with acute stroke and physiotherapists on the delivery of family assisted exercise therapy. Data collected from these studies informed the development of an ongoing randomised controlled trial designed to evaluate the effectiveness of family mediated exercises (FAME) on functional outcome of the lower limb following stroke.

Method

Quantitative and qualitative data gathering methods were utilised. The combined use of qualitative and quantitative techniques is increasingly used in clinical research to expand the scope of the research question and to improve the analytical power of studies [8–10]. We used mixed-method techniques to deepen our insight into the involvement of 'family members/friends' in physiotherapy following stroke from three different perspectives i.e. people with stroke, 'family members/friends' and physiotherapists. 'Family members/friends' of people with stroke were defined as family, friends, carers, or significant others. 'Exercise' was defined as any type of physical activity aimed at improving a particular skill or ability, delivered to the person with a stroke, in the inpatient, outpatient or home environment.

Quantitative method – survey instruments

Two self-report questionnaires were administered. The questionnaires were designed by the authors and reviewed by five senior therapists working in neurology and age related healthcare and a hospital based survey review board to ensure suitability for use with people with stroke and their 'family members/friends'. Some changes to the content of the questionnaires were suggested and all recommendations made were implemented.

The aim of the first questionnaire (FAME Survey One) [11] was to investigate the views of 'family members/friends' of people with stroke on their perceived role in physiotherapy. The self-report questionnaire contained four sections that documented the demographic details of the respondent, frequency of their involvement in their 'family member/friends' physiotherapy following stroke, the views of respondents on the delivery of exercises by them with and without the supervision of a physiotherapist in the hospital and in the home environment, reasons that may limit or potentially enhance their participation in physiotherapy and opinions of respondents on different aspects of their 'family member/friends' physiotherapy.

The aim of the second questionnaire (FAME Survey Two) [12] was to ascertain the views of people with stroke on the involvement of their 'family members/friends' in their physiotherapy rehabilitation. The survey instrument used consisted of 'mirror' questions that were recorded in the first user survey. It was decided to use a quantitative methodology to explore the opinions of people with stroke and their 'family members/friends' as the questionnaire was brief and easy to administer, facilitating the recruitment of a large sample.

Qualitative method – focus groups

Two focus groups were conducted to explore the opinions of physiotherapists working in the area of stroke rehabilitation in relation to the involvement of 'family members' in the delivery of exercises to people with stroke. This methodology allowed the authors to gain in-depth information in relation to each physiotherapist's previous experience of family involvement in physiotherapy. Three topics were identified for discussion; questions were prepared in advance by the authors and are contained in Table I.

Ethical approval

The project had ethical approval from the relevant hospitals and from the Research Ethics Committee, Trinity College Dublin.

Setting

The questionnaires were distributed in four hospitals in the greater Dublin area. Samples of convenience were recruited for both questionnaires. FAME Survey One commenced in June 2005 and was completed in May 2006. 'Family members/friends' of people with stroke who were receiving inpatient physiotherapy following first unilateral stroke, and who were willing to give informed consent were invited to participate in the study. Only one response was permitted per family. FAME Survey Two commenced in September 2006 and was completed in August 2007. People with stroke receiving inpatient physiotherapy following first unilateral stroke and who were willing to give informed consent were invited to participate in the study. Suitable participants were identified in liaison with the senior physiotherapists in the hospital. Each potential participant was provided with a participant information brochure prior to obtaining written consent. All questionnaires were administered by the same researcher.

Table I. Content of focus groups.

Definitions – 'exercise', 'family member/friend', 'physiotherapy'
Theme 1 – Frequency/intensity/benefits of physiotherapy
How many days per week do people with a stroke receive physiotherapy in your service? How long does a physiotherapy session last?
Probe
Do you think that patients would benefit from more physiotherapy? What particular patient subgroups, if any, would benefit from this additional therapy?
Theme 2 – Role of family members in physiotherapy
Do you think that 'family members/friends' have a role in the delivery of exercise to the person with a stroke?
Probe
Do you think that their involvement in the delivery of exercises might be a cause of additional strain? Do you think that they would like to be involved in the delivery of exercises? Do you think that this is routine practice?
Theme 3 – Involvement of family members in physiotherapy
Have you ever involved a 'family member/friend' of a patient in the delivery of an exercise programme in the inpatient, outpatient or home environment?
Probe
What were the characteristics of this person that you thought made them suitable? Did you provide additional information in writing to the 'family member/friend' on how to perform the exercises unsupervised? Did you provide an 'exercise log' that enabled 'family members/friends' of the person with the stroke to record whether or not the exercise programme had been completed?
Closing Question
Finally, did you find this a positive experience?
Probe
Can you tell me a little more about it?

Two focus groups were conducted in September 2006. The focus groups were conducted in the same venue and all participants provided written consent prior to the session. Group A and Group B were held 2 weeks apart. All participants were requested not to discuss the sessions with their colleagues in order to avoid contamination of the data. A moderator facilitated the meeting and a second researcher took notes during each session. Each focus group was audio-visually recorded by an independent person.

Data analysis

Each questionnaire was inputted into Microsoft Office Excel 2003. Descriptive statistics were primarily used to represent the data. An independent researcher cross checked all entries. Appropriate statistical tests were carried out on the data where necessary using MINITAB Release 13.1.

The approach described by Miles and Hubberman [13] was adopted for analysis of the focus groups. All recorded data was transcribed verbatim by the moderator. All participants were assigned a code to ensure anonymity in the transcript. The transcripts were explored by a process of reading and re-reading. On the first reading, transcripts were read in their entirety to acquire a sense of the whole. On the second reading, using line by line analysis, patterns and themes were identified and listed. A coding system was developed in order to facilitate the identification of recurrent patterns and themes. Prior to the third reading, the responses from all participants to each question were transferred to Microsoft Excel for further examination. The third reading involved checking the suitability of the coding system and pursuing patterns both consistent and inconsistent with the codes defined.

Three researchers were provided with the responses to all of the questions in an unencoded format; thereafter they independently coded the responses sequentially using the predefined codes. The researchers disagreed on the coding system outlined for two responses. The first coding disagreement related to the characteristics of patients that benefit most from additional physiotherapy and the second disagreement arose when coding the characteristics of family members that are involved in physiotherapy. All coding disagreements were resolved through discussion. The original coding system was modified and further sub-divided to more clearly represent the emergent responses in the data. A fourth coder independently verified the coding system following the conflict resolution meeting. This coder was in full agreement with the revised coding system that was developed for the two responses in question.

Results

FAME survey one

A convenience sample of 100 'family members/friends' who met the inclusion criteria was recruited during the study period. Twenty-nine respondents were male and seventy-one were female. Ninety-seven respondents surveyed were related to the person with the stroke, e.g. wife, husband, daughter, son. Three respondents described themselves as a 'friend' of the person with stroke and interacted with the person with the stroke on a daily basis in the home environment. Respondents were stratified according to their age category. There was no statistically significant difference in the proportion of male and female respondents across all age categories [χ^2 (5, $n = 100$) = 5.19, $p = 0.39$].

Ninety-one respondents (91%) reported that they would be available to help their 'family member/friend' with a stroke with his/her exercises in the hospital setting. Commitment to work was documented as the primary reason that limited respondents'

participation in physiotherapy (24%). However, 22 of these respondents documented that a pre-arranged time of attendance would facilitate their participation in physiotherapy. The various reasons that limited respondents' participation in physiotherapy are highlighted in Table II.

Thirty-six respondents (36%) reported that they had been invited to attend physiotherapy sessions an average of two times since their 'family member/friend' commenced physiotherapy. Thirty respondents (30%) took part in the physiotherapy sessions. The most common activities demonstrated by the physiotherapist to the respondent during these sessions were positioning of the affected arm/leg and helping their 'family member/friend' to walk. Seventeen respondents were asked to deliver these exercises unsupervised.

Respondents were also asked if they would be willing to assist in the delivery of different exercises after their 'family member/friend' was discharged from hospital, following suitable training and follow-up with the physiotherapist. With the exception of one respondent, all were willing to help with general exercises. However, only 85 respondents (85%) were willing to help practice more complex activities such as transfers and walking.

In the final section of the questionnaire, respondents were asked to rate their satisfaction on different aspects of physiotherapy using a Likert type scale where the anchors were strongly agree to strongly disagree. The results of these findings are contained in Table III. Finally, 34% of respondents reported that regaining the ability to walk was the most important part of their 'family member/friend's' recovery.

Table II. Reasons that limit family members/friends participation in physiotherapy according to people with stroke and their 'family members/friends'.

'Person with stroke'	'Family member/friend'
'It is not the role of my family/friends' ($n=7$)	'I have work commitments' ($n=24$)
'I would not feel confident' ($n=5$)	'I have no confidence' ($n=20$)
'My family/friends would put too much pressure on me' ($n=5$)	'I am not physically able' ($n=18$)
'I have no interest in allowing them to participate' ($n=4$)	'The physiotherapy treatment times unsuitable' ($n=13$)
'I would not benefit from their additional therapy' ($n=4$)	'I have family commitments' ($n=12$)

FAME survey two

A sample of convenience of 75 people with acute stroke who met the inclusion criteria was recruited during the study period. Forty respondents were male and thirty-five were female. Again, respondents were stratified according to age category and there was no significant difference in the proportion of male and female respondents across all age categories [χ^2 (3, $n=75$) = 4.12, $p=0.25$].

Forty-seven respondents (63%) reported receiving physiotherapy on a daily basis. There was no relationship between frequency of physiotherapy and duration of treatment ($r=0.142$). Fifty-nine respondents (79%) reported that their 'family members/friends' had not been invited to attend any of their physiotherapy sessions since they commenced physiotherapy following their stroke. No respondent reported that their 'family member/friend' had been asked by the physiotherapist to help them with their exercises at times when the physiotherapist was not present.

Sixty-six respondents (88%) reported that they thought they could benefit from more physiotherapy. Eighty-seven percent of respondents ($n=65$) reported that family mediated exercise therapy would be acceptable to them in the hospital and home environment following training by a physiotherapist. Sixty-three respondents (84%) reported that they would be willing to keep a record of exercises performed using an exercise diary. The reasons documented by respondents who did not wish to have their 'family members/friends' involved in their physiotherapy are contained in Table II.

Sixty-eight respondents (91%) either agreed or strongly agreed that their 'family member/friend' had

Table III. 'Family members/friends' ($n=100$) opinions on their role in physiotherapy.

'Family members/friends' of people with stroke	Strongly agree (%)	Agree (%)	Neither agree/disagree (%)	Disagree (%)	Strongly disagree (%)
Should be actively encouraged to participate in PT*	66	24	7	3	0
Would like to be more involved in PT*	60	26	12	2	0
Wish to discuss treatment goals with physiotherapist	72	27	0	1	0
Should get more information about the stroke	71	25	3	1	0
Feel PT* is of benefit	86	13	0	0	1

*PT, physiotherapy.

a role in their physiotherapy following stroke. The range of responses is displayed in Table IV. Fifty-seven respondents (76%) reported that they felt that regaining the ability to walk was the most important part of their recovery.

Focus groups

An invitation to participate in the study was sent to 12 physiotherapists working in the area of stroke rehabilitation. All therapists from Group A agreed to participate ($n = 6$). All of the therapists in group B agreed to participate ($n = 6$); however only four were able to attend on the arranged day. The duration of each focus group was ~40 min.

All participants agreed that inpatients with stroke receive physiotherapy on a daily basis, 5 days per week and that outpatients receive physiotherapy once or twice a week. The average length of treatment ranged from 30 to 60 min. The two groups identified particular subcategories of patients that tend to benefit from physiotherapy following stroke, for example patients that are motivated and also younger patients ($n = 4$). In contrast, physiotherapists reported that physical and cognitive impairments as well as medical complications impede recovery ($n = 7$).

> 'The kind of patients who are well motivated and if they don't have any cognitive impairment and things like that, they're obviously going to improve.' (Physio B1)

> 'Cognitive impairment would be a huge factor in the carry-over and instructions' (Physio A4)

> 'Or, if they have a lot of other medical complications ... ' (Physio A3)

The groups also agreed that patients could benefit from more physiotherapy than is routinely provided in the inpatient and outpatient setting ($n = 7$). One physiotherapist noted that fatigue was an issue for some of her patients in the acute setting and that this was a factor that needed to be considered in the rehabilitation programme. Participants highlighted a number of different roles that the family member plays in the rehabilitation process especially in terms of treatment ($n = 8$), and helping the family unit to cope ($n = 4$).

> ' ... just to maintain what you're doing, to carry over, to improve carry over and that.' (Physio B4)

> 'I think if you involve them earlier, you might have a better chance of lessening the shock when they go home' (Physio A5)

> 'I think it makes a huge difference because they're, they're not frightened' (Physio AI)

> ' ... if they were used to handling a bit earlier on, that it would be a lot easier to, to sort of cope with that as well.' (Physio A4)

No physiotherapist perceived that involvement of family members in physiotherapy would be a cause of additional strain to the family and reported that families are often motivated and eager to participate in physiotherapy ($n = 8$). The groups reported routinely involving family members in the rehabilitation process. Furthermore, a number of issues were identified that influenced participation in physiotherapy, such as level of interest and motivation of the family members ($n = 5$), availability ($n = 3$) and importance of education ($n = 2$).

> 'Like some families would approach, would approach me and ask what they can do' (Physio A4)

> 'Families are quite glad to be involved' (Physio A1)

> 'Like their families are asking what I can do in the evening time ... ' (Physio B4)

Participants were also asked if they provided written information for these family members on how to perform particular exercises. The primary answer that emerged from the groups was that the physiotherapists provided individual written programmes to the families if they deemed that it was necessary to provide the same. One physiotherapist reported occasionally using an exercise log to document completion of exercises. However, all

Table IV. The opinions of people with stroke ($n = 75$) on 'family members/friends' involvement in physiotherapy.

'Family members/friends' of people with stroke	Strongly agree (%)	Agree (%)	Neither agree/disagree (%)	Disagree (%)	Strongly disagree (%)
Should be actively encouraged to participate in PT*	47	34	7	12	0
Should be more involved in the delivery of exercises	45	32	3	16	4
Should be more involved in short/long term goal setting	47	36	7	9	1
Have a role in PT* following stroke	41	49	3	7	0

*PT, physiotherapy.

other participants followed up with the patient verbally.

The group reported some negative experiences when involving family members and highlighted incidences where the family were over enthusiastic ($n = 5$), very emotional ($n = 1$) or overly critical of the patient's performance ($n = 1$) and therefore would always ask the patient prior to the involvement of the family. Again, motivation of the family was mentioned as a contributory factor to success.

> '... the family member wants to do so much and they're so intense ... ' (Physio A1)

> 'Or it can be a bit emotional sometimes ... ' (Physio A2)

> '... their spouse or son or daughter trying to say, "no you're not doing that properly" or "do that again", it can create frustration ... ' (Physio A3)

Discussion

This study examined the role of 'family members/friends' in physiotherapy and the delivery of exercises to people with stroke from three different perspectives: people with stroke, 'family members/friends and physiotherapists. Current findings highlight that 'family members/friends' have a valuable role to play in the rehabilitation process. The expert practitioners highlighted a number of areas that family involvement can have an impact, such as treatment, assisting the family unit to cope and improving handling skills. Our findings also indicate that the 'family members/friends' who participated in the study were willing to assist in the delivery of exercises in the hospital and home setting. Carr and Shepherd [14], report that carer involvement in the rehabilitation of a person with stroke maximises the effects of rehabilitation by allowing the patient to practice activities with the carer outside of the routine treatment hours. However, results of the two self-report questionnaires indicate that family involvement in physiotherapy is not practised routinely following stroke. The level of involvement of 'family members/friends' in physiotherapy reported in the two groups of respondents ranged from 21 to 36%, the latter figure being reported by 'family members/friends' of the person with stroke. Evans et al. [15] found that gains made in initial rehabilitation are more effectively maintained if the family are involved and also suggest that family members can be helped to adjust to stroke in several practical ways, including involvement in the rehabilitation process to maximise learning and to provide a means for generalising new behaviours to the home. This theory is also supported by the physiotherapists in the focus groups and by Forster and Young [16] who emphasise that if carers are not aware of a patients' progress, then the 'carry over' from therapy may be limited. Although the physiotherapists reported that they routinely involved family members in the rehabilitation process, they identified a number of issues that limited participation such as lack of interest, motivation and availability of family members. 'Family members/friends' of people with stroke in this study reported that commitment to work was the primary reason that would limit their participation in physiotherapy. Visser-Meily et al. [17] hypothesised that the rehabilitation of people with stroke could be maximised by taking into account the position of the family during the different rehabilitation phases and this was also highlighted by respondents. In this study, 13 respondents reported that the physiotherapy treatment times i.e. 9 am to 5 pm were not suitable for them and 72 respondents reported that a prearranged time of attendance would facilitate their participation in physiotherapy. This finding would support the use of an 'out of hours' physiotherapy service to capitalise on family involvement in the acute setting.

There was a discrepancy between people with stroke and family members in reported participation in unsupervised exercises. This may have arisen due to retrospective self-report nature of the question, where the accuracy of the response was dependent on people's perspective, memory and interpretation of the particular question. In addition, this question may have prompted a response from families that was 'socially desirable' and acceptable rather than accurate. Furthermore, the majority of physiotherapists reported that they did not request that patients and their families keep a written record of unsupervised exercises completed. Therefore it may prove useful in future to formally document the completion of exercises in an 'exercise diary' to avoid such inconsistencies.

In a study of patients expectations of recovery following stroke, Wiles et al. [18] report that patients ($n = 16$) felt that more physiotherapy would be beneficial and raised concerns that they were not receiving the amount of physiotherapy that they needed to maximise their recovery. In our study, 66 (88%) people with stoke reported that they thought they could benefit from more physiotherapy. Furthermore, they reported that family mediated exercise intervention would be acceptable to them Physiotherapists also identified the benefits of increased physiotherapy following stroke, in keeping with the findings of a recent systematic review and meta-analysis [4]. In addition, 91% of 'family members/friends' reported that they would be available to assist with these exercises following suitable

training by the physiotherapist. These results are similar to those of Bailey and Rennie [19], who found that 86% of carers wished to assist in physiotherapy following stroke. The findings from this study suggest that family mediated exercise therapy could be used to maximise the carry over outside of formal physiotherapy and give patients the opportunity for informal practice. Although some studies have found that caregivers of people with stroke often experience high levels of burden [20,21], Carr and Shepherd [14] and Kalra et al. [22] suggest that carer involvement in the rehabilitation process may help to reduce fears that carers may have about their ability to cope at home. This theme also emerged clearly from the two focus groups and physiotherapists strongly agreed that family involvement from the outset can help families to cope and indeed 'lessen the shock' and 'fright' on discharge.

Finally, it is clear from Table II that 'family members/friends' of people with stroke would like to receive more information about the stroke. Lack of information about the nature, causes and consequences of stroke and available services is frequently reported [23]. Garrett and Cowdell [24] conducted a study to explore patients and carers perceived needs for information following stroke. The study found that there was a marked desire from both patients and carers to revisit information in order to build on it or to make sense of it at different time points in their stroke journey. This finding is similar to the results of our study and those of Bailey and Rennie [19] where respondents reported that they would like the opportunity to discuss treatment goals with the physiotherapist. Similarly, physiotherapists also reported that adequate education was an important factor in the involvement of families in rehabilitation.

Limitations

There are methodological limitations to this study. Samples of convenience were used which may have introduced a systematic bias. Furthermore, due to the qualitative nature of the focus groups, the findings are specific to the participants who took part in this research. Nonetheless, transferability of the findings is enhanced by using extensive quotes from which conclusions were drawn. Finally, because of the complex nature of the topic being explored, a mixed methodology approach was chosen to provide a more robust consideration of the research question. However, the use of two different data gathering methods to collect the data from therapists and patients as well as their family members could have limited the study's ability to make the data of the three groups of persons comparable in all aspects.

Conclusion

The concept of family mediated care is not a new phenomenon. It is common practice in child rehabilitation and care of older people with dementia [17]. However, 'family members/friends' are not routinely involved in a systematic way to enhance stroke rehabilitation. While the sudden and profound effects of stroke on family roles and functioning create stress for the stroke survivor and their families, the available evidence suggests that carers and families want information and want to be more fully involved in their rehabilitation. Indeed the primary theme emerging from the two focus groups was that process may help to reduce fears that family may have about their ability to cope at home. While the findings from this study has been supportive of the idea of FAME following stroke, to date no randomised controlled trial has evaluated the delivery of exercises to people with stroke who are not healthcare workers. Research is needed to gather data from larger, more representative samples and to evaluate the effectiveness of structured family mediated exercise interventions. The output from this mixed methods approach has provided the researchers with vital qualitative and quantitative data on the impact and limitations of a family mediated exercise programme from the perspectives of potential participants in such a programme i.e. the individual with stroke, 'family members/friends' and prescribers of exercise intervention. This information has allowed for the creation of an evidence-based, user informed and centred ongoing family mediated exercise intervention. Outcomes are focused on the family members' quality of life and satisfaction as well as the physical, emotional and social functioning of the person with stroke.

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APPENDIX 5

Publication of the results of User Survey 2B and User Survey 3

Galvin, R., Cusack, T., Stokes, E. (2009b). Physiotherapy after stroke in Ireland: a qualitative insight into the patient's and physiotherapist's experience. *International Journal of Rehabilitation Research*, 32(3), 238-244.

Physiotherapy after stroke in Ireland: a qualitative insight into the patients' and physiotherapists' experience

Rose Galvin[a], Tara Cusack[b] and Emma Stokes[a]

The study aimed to examine the experience of inpatient physiotherapy intervention delivered after stroke in Ireland from two different perspectives: that of the person with stroke and that of the physiotherapist. A qualitative study was conducted involving semi-structured interviews with 10 people with stroke and two focus groups with 10 senior physiotherapists working in the area of neurology. All transcriptions were analysed using the grounded theory approach. People with stroke and physiotherapists agreed that people with stroke could benefit from more physiotherapy than is routinely provided in the rehabilitation setting. However, the timing of the intervention was disputed. Family-mediated exercise therapy was identified as an acceptable adjunct to routine physiotherapy after stroke. People with stroke identified walking and lower-extremity exercises as the most important components of their programme. Furthermore, they identified honesty and encouragement as two important traits in a physiotherapist working with people with stroke. Obtaining the perspective of patients is an important and valuable way of evaluating healthcare services. Physiotherapists need to be cognizant of the elements of rehabilitation that are important to people with stroke. Methods of delivery of stroke care need to evolve and incorporate families not only for practical purposes but also from a psychological aspect. Family-assisted exercise therapy after stroke may enhance the carry-over outside formal physiotherapy, giving patients and their families the opportunity to maximize recovery.

Die vorliegende Studie untersucht die in Irland gewonnene Erfahrung mit der physiotherapeutischen Stationärbehandlung nach einem Schlaganfall aus zwei verschiedenen Perspektiven: aus der Perspektive des Schlaganfallpatienten und aus der des Physiotherapeuten. Im Rahmen einer qualitativen Studie wurden semi-strukturierte Interviews mit zehn Patienten nach Schlaganfall und mit zwei Fokusgruppen mit zehn leitenden Physiotherapeuten (Spezialgebiet: Neurologie) durchgeführt. Alle Abschriften wurden unter Zuhilfenahme der gegenstandsverankerten Theoriebildung analysiert. Schlaganfallpatienten und Physiotherapeuten waren sich einig, dass Menschen nach einem Schlaganfall von einer stärkeren physiotherapeutischen Betreuung profitieren würden, die routinemäßig in der Rehabilitation eingesetzt wird. Strittig war jedoch der Zeitpunkt der Intervention. Eine Bewegungstherapie unter Einbeziehung der Familie galt als akzeptable zusätzliche Maßnahme zur Routine-Physiotherapie nach Schlaganfall. Schlaganfallpatienten gaben das Gehen und Übungen für die unteren Extremitäten als wichtigste Komponenten ihrer Bewegungstherapie an. Außerdem nannten sie Aufrichtigkeit und Aufmunterung als zwei wichtige Charakterzüge bei einem Physiotherapeuten, der Schlaganfallpatienten betreut. Die Sammlung von Informationen über die Sichtweise von Patienten ist eine wichtige und nützliche Methode der Beurteilung der Gesundheitsversorgung. Physiotherapeuten müssen sich der einzelnen Elemente der Rehabilitation bewusst sein, die Schlaganfallpatienten wichtig sind. An ihrer Pflege und Behandlung müssen die Familienmitglieder nicht nur aus praktischen, sondern auch aus psychologischen Gründen beteiligt sein. Eine Bewegungstherapie für Schlaganfallpatienten unter Einbeziehung der Familie kann der Fortdauer über eine formale Physiotherapie hinweg förderlich sein und Patienten und ihren Familien die Chance auf eine möglichst rasche und vollständige Genesung geben.

El objetivo de este estudio fue valorar la experiencia del tratamiento fisioterapéutico hospitalizado realizado tras un accidente cerebrovascular, en Irlanda, a partir de dos perspectivas diferentes: la de la persona afecta de un accidente cerebrovascular y la del fisioterapeuta. Se realizó un estudio cualitativo en el que se utilizaron entrevistas semiestructuradas realizadas a 10 personas afectadas de un accidente cerebrovascular y dos grupos focales de 10 fisioterapeutas experimentados que trabajan en los servicios de neurología. Todas las transcripciones de las entrevistas se analizaron utilizando la teoría fundamentada. Tanto las personas afectadas de un accidente cerebrovascular como los fisioterapeutas coincidieron en que las personas afectadas de accidentes cerebrovasculares podrían derivar mayores beneficios si reciben más fisioterapia que la habitualmente brindada en los servicios de rehabilitación. Sin embargo, se cuestionó el momento de aplicación del tratamiento. La fisioterapia consistente en ejercicios realizados con ayuda de familiares se identificó como un complemento aceptable de la fisioterapia habitual en personas afectas de un accidente cerebrovascular. Las personas afectadas de accidentes cerebrovasculares identificaron el andar y los ejercicios de las extremidades inferiores como los componentes más importantes del programa de rehabilitación que recibían. Además, señalaron la honestidad y el fomento del ánimo como dos características importantes de un fisioterapeuta que trabaje con personas afectas de accidentes cerebrovasculares. Conocer la opinión de los pacientes es una forma importante y valiosa de evaluar los servicios de

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salud. Los fisioterapeutas deben dominar los elementos de la rehabilitación que resultan importantes en personas con accidentes cerebrovasculares. Los métodos de brindar asistencia y atención a las personas con accidentes cerebrovasculares han de evolucionar e incorporar a los familiares, no sólo por razones prácticas sino también por razones psicológicas. Los ejercicios de fisioterapia realizados por pacientes con accidentes cerebrovasculares con la ayuda de sus familiares podrían complementar la fisioterapia profesional, con lo que los pacientes y sus familiares tienen mayores oportunidades de maximizar la recuperación.

Cette étude visait à examiner l'expérience de l'intervention de physiothérapie délivrée en Irlande aux patients hospitalisés après un AVC selon deux perspectives différentes: celle du patient et celle du physiothérapeute. Une étude qualitative a été réalisée en menant des entretiens semi-structurés avec 10 personnes victimes d'AVC et deux groupes de discussion comportant 10 physiothérapeutes experts dans le domaine de la neurologie. Toutes les transcriptions ont été analysées à l'aide d'une approche ancrée dans la théorie. Les victimes d'AVC et les physiothérapeutes ont convenu que les personnes victimes d'un AVC pourraient bénéficier d'une physiothérapie plus intensive que ce qui est habituellement prévu dans le cadre de la rééducation. Toutefois, le calendrier de l'intervention a été contesté. L'exercice dans le cadre familial a été identifié comme un complément acceptable à la physiothérapie routinière après un AVC. Les victimes d'AVC ont identifié la marche et les exercices des membres inférieurs comme les composants les plus importants de leur programme. En outre, ils ont identifié l'honnêteté et l'encouragement comme deux caractéristiques importantes dans le travail du kinésithérapeute avec les victimes d'AVC. Le fait de recueillir la perspective des patients constitue un précieux élément pour évaluer les services de santé. Les physiothérapeutes doivent être conscients des éléments de la rééducation qui sont considérés comme importants par les victimes d'AVC. Les méthodes de prestation des soins aux victimes d'ACV ont besoin d'évoluer et d'intégrer les familles, non seulement pour des raisons pratiques, mais également d'un point de vue psychologique. La thérapie par l'exercice dans le cadre familial après un AVC peut consolider les effets bénéfiques de la physiothérapie formelle, et donner aux patients et à leurs familles la possibilité de maximiser la rééducation. *International Journal of Rehabilitation Research* 32:238–244 © 2009 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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Keywords: additional exercise therapy, experience, physiotherapist, rehabilitation, stroke

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Introduction

Stroke is the third most common cause of death in the developed world and the most common form of acquired disability in Europe. The European Brain Council estimates that in the European Union and European Free Trade Association, 6 million people have survived stroke and that the total cost of stroke in Europe is €21 895 000 000 (Andlin-Sobocki *et al.*, 2005). The question of what constitutes a successful rehabilitation outcome is of ongoing concern to rehabilitation professionals. For the management and evaluation of any rehabilitation intervention, outcome measures have become more and more essential. This is partly because of the increasing need for evidence-based practice and also service accreditation (Grimby *et al.*, 2005). Qualitative methodology has gained increasing acknowledgement and acceptance as a valuable outcome tool in health science research (Ohman, 2005). As rehabilitation outcomes are dependent on people's attitudes, thoughts and motivation regarding the rehabilitation process, studies with a qualitative design can inform the development and improvement of rehabilitation services.

The progressive increase in the population of older people in developed countries is likely to lead to an increased prevalence of stroke in the future. In contrast to coronary heart disease and cancer, the burden of stroke lies with long-term disability as opposed to death. The most common deficit after stroke is motor impairment (Wohlin-Wottrich *et al.*, 2004) and research suggests that in order for motor recovery to occur after stroke, there is a requirement for a significant level of repetition of tasks and exercises that are challenging and engaging (Nudo *et al.*, 1996; Plautz *et al.*, 2000; Pomeroy and Tallis, 2000). Physiotherapists have traditionally been the mediators of exercise therapy after stroke. However, one of the areas of greatest dissatisfaction with stroke services identified by people with stroke and their carers relates to the amount of rehabilitation, particularly physiotherapy that they receive after stroke (Wiles *et al.*, 2002). The primary outcome measures used by physiotherapists to evaluate recovery after stroke are quantitative in nature, which has led to a methodological debate regarding the ability of quantitative measures to recognise patients' and therapists' expectations and experiences of the recovery

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process. The aim of this study was to examine the nature of inpatient physiotherapy delivered after stroke and the involvement of the family in physiotherapy from two different perspectives: that of the person with stroke and that of the physiotherapist. This piece of work also informs the development on an intervention trial focussing on the involvement of families in the delivery of exercises to people after stroke.

Methods

Study design and participating patients

Ten semi-structured interviews were conducted with a sample of convenience of people with stroke in two acute stroke inpatient hospitals in the greater Dublin area. The aim of the semi-structured interviews was to explore the views of people with stroke in relation to their physiotherapy intervention and the involvement of their family in their rehabilitation programme. Questions were prepared in advance by the authors after a review of the literature. Three areas were highlighted for exploration including the duration and content of the persons' physiotherapy programme, the role of their family in their physiotherapy programme and their views on the concept of family-assisted exercises as an adjunct to their routine physiotherapy.

Patients were eligible for interview if they presented with a diagnosis of first stroke, were attending physiotherapy at the time of selection and were willing to give informed consent to take part in the study. Patients were not considered for interview if they presented with a diagnosis of another neurological condition such as Parkinson's disease or multiple sclerosis, had a cognitive impairment or a diagnosis of expressive or receptive dysphasia. Suitable participants were identified in each hospital in consultation with the senior neurological physiotherapist. Each potential participant was provided with a participant information brochure before obtaining written consent. All interviews were conducted by the same researcher (T.C.), who was unknown to the individual with stroke, in a prebooked meeting room in each hospital. All interviews were audio-recorded for later transcription and analysis.

Study design and participating physiotherapists

Focus groups were conducted with 10 senior physiotherapists, all currently employed in the area of stroke rehabilitation. The aim of the focus groups was to examine the views of experienced physiotherapists actively involved in the rehabilitation of people with stroke. In advance of the conduct of the focus groups, through literature reviews, three topics were identified as relevant for discussion. Questions were prepared in advance by the authors to guide and develop the discussion in these thematic areas. The first theme focussed on the frequency, duration and benefits of physiotherapy. The second and third themes covered the role of the family in the rehabilitation process and the level of involvement of families in physiotherapy.

Two focus groups were conducted in September 2006. The focus groups were conducted in the same venue and all participants provided written consent before starting the session. Group A and group B were held 2 weeks apart. All participants were requested not to discuss the sessions with their colleagues in order to avoid contamination of the data. A moderator facilitated the meeting and a second researcher took notes during each session. Each focus group was audio-visually recorded by an independent person for later transcription and analysis.

Ethical approval

Informed consent was obtained from all participants. The project had ethical approval from the relevant hospitals and from the Medical Research Ethics Committee, Trinity College Dublin.

Data analysis

All recorded data from the semi-structured interviews and focus groups were transcribed verbatim by an independent person. All participants were assigned a code to ensure anonymity in the transcript. The approach described by Miles and Huberman (1994) was adopted for the analysis of all transcriptions. This involved examining the transcripts line by line and coding responses that emerged from the data into themes. Initially, the transcripts were read in their entirety to acquire a sense of the whole. On the second reading, using line-by-line analysis, patterns and themes were identified and listed. A coding system was developed to facilitate the identification of recurrent patterns and themes. Before the third reading, the responses from all participants to each question were transferred to Microsoft Excel for further examination. The third reading involved checking the suitability of the coding system and pursuing patterns both consistent and inconsistent with the codes defined.

Three independent researchers (R.G., T.C., E.O.G.) were given the semi-structured interview transcripts and the focus group transcripts in an unencoded format and were requested to independently code the responses in succession using the predefined codes. Analysis of intra-rater reliability of the researchers coding the interviews of people with stroke revealed three areas of disagreement. The first disagreement related to the components of their physiotherapy programme that the people with stroke liked the most. The second related to the acceptability of family involvement in their rehabilitation programme and the third disagreement arose while describing desirable attributes in a physiotherapist involved in the rehabilitation of people with stroke.

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In relation to analysis of the data from the focus groups conducted with the physiotherapists involved in stroke rehabilitation, two disagreements arose. The first coding disagreement related to the characteristics of patients who benefit most from physiotherapy and the second disagreement arose when coding the characteristics of family members that are involved in physiotherapy. All coding disagreements were resolved through discussion. The original coding systems were modified and further subdivided to more clearly represent the emergent themes in the data. A fourth coder (D.L.) independently verified the coding systems after the conflict-resolution meeting. This coder was in full agreement with the revised coding systems developed for the responses in question.

Results

Semi-structured interviews

Four male and six female participants were interviewed. Participants were at a mean of 58 days poststroke (range 31–89 days) and ranged in age from 56 to 88 years (mean 73 years). All participants were independent in their daily activities before the stroke.

The majority of participants ($n = 8$) reported that they received physiotherapy on a daily basis for 30–45 min. However, nine of the 10 participants reported that they could benefit from more physiotherapy, particularly walking ($n = 7$) and leg exercises ($n = 5$). Participants were asked whether their families were invited to assist them with their physiotherapy programme. Seven participants reported that their family members were not invited to attend physiotherapy but would be happy to do so.

'They would like to know what help they could give me' [TCD 02].

'...he would be interested in finding out what I do and doing it with me...' [TCD 03].

Three participants reported that their families had attended a physiotherapy session and were 'very interested' [TCD 01] in the programme. Another participant reported that her husband's involvement in her physiotherapy was a very positive experience.

'The first time he seen me walking and he... he... it was a major boost to him' [TCD 06].

Participants were then asked whether additional family-assisted exercise therapy would be acceptable to them. Eight participants reported that family-mediated exercises would be acceptable to them for a variety of reasons. Some participants identified potential benefits of this type of additional exercise therapy for their families ($n = 5$) in terms of building confidence in relation to 'handling' their relative both in the hospital and in the home environment, being able to provide assistance with walking and also being able to contribute towards a more speedy physical recovery.

Participants were asked whether they perceived any drawbacks to this type of therapy. Six participants reported no drawbacks to this type of additional therapy. One participant reported that family-assisted exercises would 'irritate' him [TCD 01]. Two others reported that this type of therapy might add pressure to their families' daily lives.

'... after all they have their lives to live as well...' [TCD 08].

Participants were asked what component of their physiotherapy programme they liked the most. Walking was the most frequent response ($n = 6$) followed by lower-extremity exercises ($n = 4$).

Participants were asked to identify what attributes they thought were important in a physiotherapist treating people with stroke. Characteristics identified included physiotherapists who are encouraging ($n = 6$), caring ($n = 3$) and honest ($n = 2$).

Focus groups

Focus group A comprised six physiotherapists and focus group B comprised four physiotherapists. It was intended that focus group B would also comprise six physiotherapists; however, two were unable to attend on the day. Nine of the therapists were female. Seven participants were senior therapists in the area of stroke rehabilitation for more than 5 years. One therapist was a senior physiotherapist in stroke rehabilitation for 3 years. The two staff-grade therapists had completed rotations in the area of stroke rehabilitation and at the time of the focus group, more than half of their caseload consisted of people with stroke.

Seven therapists reported that inpatients with stroke receive physiotherapy on a daily basis, 5 days per week. The average length of treatment ranged from 30 to 60 min. The two groups identified particular subcategories of patients that benefited from physiotherapy after stroke, for example, patients who are motivated and younger patients ($n = 4$).

'If they're well motivated' [A1].

'The kind of patients who are well motivated and if they don't have any cognitive impairment and things like that, they're obviously going to improve' [B1].

'The younger patient groups ... as well as being more motivated' [B2].

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Seven physiotherapists reported that patients could benefit from more physiotherapy than is routinely provided after stroke, four of these therapists felt that the additional therapy would be most beneficial when patients were discharged from hospital. All participants agreed that family members of people with stroke had a role in the rehabilitation process, especially in terms of treatment ($n = 8$) and helping the family unit to cope ($n = 4$).

'If you have a family member who is involved from the start and it's just carrying over rather that giving out a prescriptive exercise sheet, I think that can make the transition [home] a lot easier' [A5].

'If they're a bit more used of doing a little bit of hands on, the family members find it a lot easier.... A lot of the caring stuff that they'll have to do when they go home' [A4].

Therapists also reported that families were eager and motivated to participate in physiotherapy sessions.

'Often that they will ask, 'What input can I have while they [the patient] are not getting physio' and they would take that on board' [B1].

'They're [families] enthusiastic about trying to be part [of physiotherapy] and trying to help' [B2].

'They'd be keen to do whatever they can' [B3].

'Like some families would approach..., would approach me and ask what they can do' [A4].

'Families are quite glad to be involved' [A1].

'Like their families are asking what I can do in the evening time...' [B4].

No physiotherapist suggested that involvement of family members in physiotherapy would be a cause of additional strain to the family and all therapists reported routine involvement of family members in the rehabilitation process.

'Yeah we routinely would yeah' [A3].

'Yeah you would try because I suppose just so much of our physio treatment is repetition' [A4].

The group reported some negative experiences when involving family members and recalled examples where the family were overenthusiastic ($n = 5$), very emotional ($n = 1$) or overly critical of the patient's performance ($n = 1$) and therefore would always ask the patient before the involvement of the family in their rehabilitation programme.

'...the family member wants to do so much and they're so intense...' [A1].

'...their spouse or son or daughter trying to say, 'no you're not doing that properly' or 'do that again', it can create frustration...' [A3].

Discussion

Qualitative method

The aim of this study was to gain an insight into both patients' and physiotherapists' experiences and expectations of physiotherapy after stroke in an Irish setting. The methodology was appropriate to the topic, as it allowed issues to be pursued in a greater depth than would have been possible using a more quantitative approach.

Duration of physiotherapy

There are several concordant opinions and similarities between the perspectives of people with stroke and physiotherapists. Both groups agreed that people with stroke could benefit from more physiotherapy than they routinely receive, which according to the therapists varied from 30 to 60 min a day five times per week. However, physiotherapists suggested that additional therapy would be most beneficial on discharge from hospital, whereas nine of the 10 participants with stroke reported that they could benefit from more additional physiotherapy during their inpatient stay. There is still considerable uncertainty in the physiotherapy profession regarding the process and timescale of recovery poststroke because of a lack of evidence; however, most researchers agree that the majority of recovery occurs in the first 3 months after stroke (Wiles *et al.*, 2004), typically when the person with stroke is an inpatient. It has also been suggested that the amount of input professionals can give to inpatients is very little compared with normal daily activities. In the physiotherapy setting, staff limitations or established practices such as 'half an hour of treatment' and 'three times a week' regimens may prevent therapists from embracing novel treatment ideas to increase the duration of therapy (De Weerdt and Feys, 2002). One suggestion has been that 'physiotherapists need to develop strategies whereby patients and caregivers take full responsibility for the bulk of therapy – for instance, training of balance, strength and endurance, repetition of simple tasks, group therapy, fitness-related training and family involvement' (De Weerdt and Feys, 2002). This sentiment has been re-iterated by several other authors (Morimoto *et al.*, 2001; Jullamate *et al.*, 2006, 2007).

Involvement of family members in physiotherapy

All physiotherapists reported that they 'routinely' involved families in the inpatient treatment programme.

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Contrary to this, seven participants with stroke reported that their family members had not been invited to attend physiotherapy sessions even though this was acceptable to the person with stroke and the family were happy to do so. This inconsistency may have arisen for a number of reasons, the most likely being the lack of availability of family members at the time of treatment. However, where possible, family involvement should be a primary goal in the rehabilitation of people with stroke and prearranged times of attendance should be organized with families to maximize involvement.

Role of families in rehabilitation

People with stroke identified several potential benefits to themselves and their families, should their families become involved in their rehabilitation process. Therapists reported that younger and more motivated patients benefit most from physiotherapy after stroke. This finding is consistent with previous findings where physiotherapists view patient motivation as central to outcome in stroke rehabilitation (Maclean and Pound, 2000). However, in order to develop patient motivation, physiotherapists need to encourage patients and their families to believe that physiotherapy is effective and families can assist in motivating the patient to participate fully in their rehabilitation programme. Physiotherapists also reported that cognitive impairment could impede recovery because of limited carryover by the patient. Several studies have shown that family involvement in the rehabilitation of a person with stroke maximizes the effects of rehabilitation by allowing the patient to practice activities with the carer outside the routine treatment hours and therefore enhance carryover (Forster and Young, 1992; Evans *et al.*, 1994; Carr and Shepherd, 1997).

Characteristics of physiotherapists

People with stroke also identified encouragement and honesty as two important characteristics in a physiotherapist involved in the rehabilitation of a person with stroke. Although physiotherapists need to encourage patients to participate in physiotherapy, they also need to be pragmatic and discourage overoptimistic expectations that may develop through the process. However, there is considerable evidence that patients and their carers want to have a clear and honest appraisal of their condition and information about likely recovery as well as information on a range of other issues in relation to stroke (Wiles *et al.*, 2002).

Finally, both therapists and people with stroke reported that families are eager and motivated to participate in the physiotherapy and that their involvement can be advantageous both physically and emotionally. This is in keeping with previous findings where people with stroke and their carers view physiotherapy positively and that participating in physiotherapy provides them with a sense of well-being, self-worth and control (Pound *et al.*, 1994; Wiles *et al.*, 2002), thereby allowing them to regain a sense of control over their condition which is imperative for the rehabilitation process of a person with stroke (Rochette *et al.*, 2006).

Limitations of the study

There are methodological limitations to this study. Samples of convenience were used which may have introduced a systematic bias. In addition, the number of patients selected for the study was small. However, this piece of work was designed to inform the development of an intervention trial focussing on the involvement of families in the delivery of exercises to people after stroke. Furthermore, different qualitative methodologies were used for the patient and the physiotherapist. However, focus groups were considered to be difficult for patients as confidentiality and anonymity cannot be assured. This approach was chosen for physiotherapists to enhance discussion and development of ideas. Finally, owing to its qualitative nature, the findings of this study are specific to the participants who took part in this research. However, transferability of the findings is enhanced by using extensive quotes from which conclusions were drawn.

Conclusion

Obtaining the perspective of patients is an important and valuable way of evaluating healthcare services and assessing progress and implementation of standards set out in each department's framework. This is the first survey to interview individuals with acute stroke and physiotherapists working in the area of stroke rehabilitation with a view to gain an insight into their expectations and experiences of physiotherapy and the involvement of their family in their rehabilitation after stroke. The results show that both patients' and physiotherapists' experiences of physiotherapy are generally quite positive. Physiotherapists need to be cognizant of the elements of rehabilitation that are important to people with stroke. The challenge to physiotherapists is to find out ways of encouraging realistic goals and expectations of physiotherapy without affecting the process of active rehabilitation and skill acquisition. All participants identified areas where the quality of physiotherapy care could be improved such as more involvement of families in the delivery of exercises and the need for additional physiotherapy in the inpatient and outpatient setting. Many of the people who survive a stroke will suffer long-term effects and will require continuing care and support from their family; therefore, it is essential that families play a key role in their rehabilitation programme from the outset. Further qualitative and quantitative studies are warranted to explore the value of structured family-mediated exercise programmes on the individuals with stroke and their families.

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APPENDIX 6

User Survey 1

Department of Physiotherapy,
Trinity College Dublin.

'Family-mediated exercises' following stroke
- A survey of the views of family and friends.

Thank you for agreeing to fill out this survey. For the purposes of clarity, your friend or family member with a stroke is referred to as

'Family member/friend'

Section A- Tell us who you are ...

1. Male [1] ❒ Female [2] ❒

2. Which of the following age categories best describes you?

18 – 29 [1]	❒	30 – 39 [2]	❒
40 – 49 [3]	❒	50 – 59 [4]	❒
60 – 69 [5]	❒	70 + [6]	❒

3. Which of the following categories best describes your relationship to your 'family member / friend' with a stroke? (Please tick one)

Wife [1]	❒	Husband [2]	❒
Partner [3]	❒	Parent [4]	❒
Daughter [5]	❒	Son [6]	❒
Neighbour [7]	❒	Friend [8]	❒

Other, please specify [9] _____

4. Prior to the stroke, was your 'family member/friend' independent in activities of daily living (e.g. washing, toileting, and dressing) at home?

Yes [1] ❒ No [2] ❒

If no, what activities did they require help with?

Washing [1] ❒ Toileting [2] ❒

Dressing [3] ❒ Feeding [4] ❒

Other [5] ❒

Please specify _____

Section B- You, your 'family member/friend' and their physiotherapy intervention.

5. On average, how often do you think your 'family member/friend' receives physiotherapy?

Once weekly [1] ❒ Twice a week [2] ❒

Three times a week [3] ❒ Four times a week [4] ❒

Five times a week [5] ❒ Not at all [6] ❒

Don't know [7] ❒

6. Have you been invited to any physiotherapy sessions since your 'family member/friend' has commenced physiotherapy?

Yes [1] ❒ No [2] ❒

If yes, please state how many? ____

7. Have you taken part in any physiotherapy sessions?

Yes [1] ❒ No [2] ❒

If yes, please state how many? ____

If no, please go to **Section C**

8. Do you attend physiotherapy sessions by pre-arranged appointment with the physiotherapist or do you use a more casual 'drop-in' basis for participating in physiotherapy sessions?

   Pre arranged appointment [1] ❒ Casual 'drop in' basis [2] ❒

9. Please read list of activities below and tick which activities the physiotherapist showed you to do to help your family member / friend?

Position the affected arm/leg	Yes [1]	❒	No	❒
Stand up from a chair	Yes [2]	❒	No	❒
Get into/out of bed	Yes [3]	❒	No	❒
Transfer in/out of car	Yes [4]	❒	No	❒
Transfer on/off toilet	Yes [5]	❒	No	❒
Help him/her to walk	Yes [6]	❒	No	❒
Get up from the floor	Yes [7]	❒	No	❒

   Other, please explain [8] _____

10. Have you been asked to help with exercises, at other times when the physiotherapist is not there?

    Yes [1] ❒ No [2] ❒

    If no, please go to **Section C.**

    If yes, please tell us what exercises and how often you do them with your 'family member/friend'?

What exercise (e.g. hip exercises, arm exercises, stretching exercises, stepping exercise)?
How often do you do this exercise?

11. Did you get any information (e.g. video, information booklet, written guidelines, one to one treatment session) from the physiotherapist on how to perform these activities?

Yes [1] ❒ No [2] ❒

If yes, please specify what type of information was received?

Video [1] ❒ Information booklet [2] ❒

Written guidelines [3] ❒ One to one treatment session [4] ❒

Other, please specify [5] _____

Section C- Helping with exercises

12. If you were invited to help your family member / friend with physiotherapy exercises would you be available?

Yes [1] ❒ No [2] ❒

(If no, please go to question 16.)

13. If yes, which of the following would you be prepared to do (tick as many boxes as you wish)

While your '*family member/friend*' is still in hospital and after suitable training...

Help with exercises, in the physiotherapy gym,

with the physiotherapist nearby [1] ❒

Help with exercises at the ward/bed without supervision

of the physiotherapist [2] ❒

14. **When your '*family member/friend*' is discharged from hospital and after suitable training and follow-up...**

Help with exercises [1] ❒

Help to practice transfers (e.g. from bed to chair etc.) [2] ❒

Help to practice walking [3] ❒

15. Please read the list below and tick which reasons you feel would limit you or prevent you from participating in physiotherapy or helping with exercises? *(Please tick as many as appropriate)*

I would have no interest in participating/helping [1] ❒

I would not have enough time [2] ❒

The physiotherapy treatment times i.e. 9-5 are not suitable for me [3] ❒

I have other family commitments [4] ❒

I have work commitments [5] ❒

I would not feel confident enough [6] ❒

My 'family member/friend' would not feel comfortable if I was helping with his/her exercises [7] ❒

I am not physically able to help with physiotherapy [8] ❒

Others, please specify [9] _____

16. What are the reasons, if any, that would make it easier for you to participate in physiotherapy and/or help with exercise? *(Please tick as many as appropriate)*

Pre-Arranged time of attendance [1] ❒

Provision of educational material (e.g. video, exercise booklet etc) [2] ❒

'Hands on' training with physiotherapist [3] ❒

Supervised practice time following physiotherapy training [4] ❒

Provision of an 'exercise diary' [5] ❒

Other, please specify [6] _____

17. Would you feel confident helping your 'family member/ friend' with their physiotherapy exercises?

Yes [1] ❒ No [2] ❒

Section D

18. The following are a list of statements. Please indicate your opinion on each of them by circling the most appropriate phrase (e.g. strongly agree [1], agree [2], neither agree nor disagree [3], disagree [4], strongly disagree [5]).

    Family members / friends of persons with stroke:

    a) should be actively encouraged to participate in physiotherapy.
    strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

    b) should get more information regarding the nature of the stroke and its prognosis
    strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

    c) would like to be more involved in physiotherapy treatments
    strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

    d) wish to discuss treatment goals and outcomes with the physiotherapist
    strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

    e) feel that physiotherapy is of benefit to this person
    strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

19. In your opinion, is the most important part of physiotherapy treatment?
    (Please rank in order of your preference, where 1 is the highest rank and six is the lowest rank.)

    a) Getting in/out of bed ❒

    b) Transferring from the bed to the chair ❒

    c) Sitting/standing without support ❒

    d) Walking ❒

    e) Regaining strength in the arm/hand ❒

    f) Halt muscle wasting ❒

Thank you for taking the time to fill out this questionnaire

APPENDIX 7

User Survey 2A

Department of Physiotherapy,
Trinity College Dublin.

'Family-mediated exercises' following stroke
- A survey of the views of people with stroke.

Thank you for agreeing to fill out this survey. For the purposes of clarity, your friend or family member who may wish to be involved in the delivery of exercises to you is referred to as

'family member/friend'

Section A- Tell us who you are ...

1. Male [1] ❒ Female [2] ❒

2. Which of the following age categories best describes you?

   18 – 29 [1] ❒ 30 – 39 [2] ❒

   40 – 49 [3] ❒ 50 – 59 [4] ❒

   60 – 69 [5] ❒ 70 + [6] ❒

3. Prior to the stroke, were you independent in activities of daily living (e.g. washing, toileting, dressing) at home?

   Yes [1] ❒ No [2] ❒

   If **YES**, please skip to Section B, if **NO** please continue.

4. What activities did you require help with?

   Washing [1] ❒ Toileting [2] ❒

   Dressing [3] ❒ Feeding [4] ❒

   Other [5] ❒

   Please specify _____

5. Who assisted you in the performance of these activities?

Wife [1]	❒	Husband [2]	❒
Partner [3]	❒	Parent [4]	❒
Daughter [5]	❒	Son [6]	❒
Neighbour [7]	❒	Friend [8]	❒

Other, please specify [9] _____

Section B- Your physiotherapy intervention.

6. On average, how often do you currently receive physiotherapy?

Once weekly [1]	❒	Twice a week [2]	❒
Three times a week [3]	❒	Four times a week [4]	❒
Five times a week [5]	❒	Not at all [6]	❒
Don't know [7]	❒		

7. How is this physiotherapy delivered to you? (*Please tick as many as appropriate)*

One-to-one treatment with a physiotherapist [1]	❒
One-to-one treatment with a physiotherapy assistant [2]	❒
Group exercise setting in the physiotherapy gym [3]	❒
Exercises performed with a 'family member/friend' [4]	❒
Other, please specify [4] _____	❒

8. On average, how long does each physiotherapy session last?

1 - 15 minutes [1]	❒	16 – 30 minutes [2]	❒
31-45 minutes [3]	❒	46 – 60 minutes [4]	❒
More than an hour [5]	❒	Don't know [6]	❒

9. Do you think that you could benefit from more physiotherapy that you currently receive?

Yes [1] ❒ No [2] ❒

Section C - Your 'family member/friends' involvement in your physiotherapy

10. Have any of your 'family members/friends' been invited to any of your physiotherapy sessions since you commenced physiotherapy after your stroke?

Yes [1] ❒ No [2] ❒

If **YES**, please continue.

If **NO**, please skip to Section D.

11. Who was invited to attend your physiotherapy sessions?

Wife [1] ❒ Husband [2] ❒

Partner [3] ❒ Parent [4] ❒

Daughter [5] ❒ Son [6] ❒

Neighbour [7] ❒ Friend [8] ❒

Other, please specify [9] _____

12. Who nominated this particular 'family member/friend' to attend your physiotherapy session?

Physiotherapist [1] ❒ You [2] ❒

'Family/member friend' volunteered [3] ❒

Other [4], please specify _____

13. Please state how many times your 'family member/friend' has been invited to attend your physiotherapy sessions?

_____ times.

14. Has your 'family member/friend' taken part in any physiotherapy sessions?

Yes [1] ❒ No [2] ❒

If YES, please state how many? ____

If NO, please skip to Section D.

15. Does your 'family member/friend' attend your physiotherapy sessions by pre-arranged appointment with the physiotherapist or does he/she use a more casual 'drop-in' basis?

Pre arranged appointment [1] ❒ Casual 'drop in' basis [2] ❒

16. Please read list of activities below and tick which activities the physiotherapist showed you and your 'family member / friend' to do during these sessions?

Position the affected arm/leg	Yes [1]	❒	No	❒
Stand up from a chair	Yes [2]	❒	No	❒
Get into/out of bed	Yes [3]	❒	No	❒
Transfer in/out of car	Yes [4]	❒	No	❒
Transfer on/off toilet	Yes [5]	❒	No	❒
Help you to walk	Yes [6]	❒	No	❒
Get up from the floor	Yes [7]	❒	No	❒

Other, please explain [8] _____

17. Has your 'family member/friend' been asked to help you with your exercises, at other times when the physiotherapist is not there?

Yes [1] ❒ No [2] ❒

If NO, please go to Section D.

If **YES**, please tell us what exercises they were asked to help you with and how often they were asked to complete these exercises with you?

What exercise (e.g. hip exercises, arm exercises, stretching exercises, stepping exercise)?
How often do you do this exercise?

18. Did your 'family member/friend' get any information (e.g. video, information booklet, written guidelines, one to one treatment session) from the physiotherapist on how to perform these activities?

Yes [1] ❒ No [2] ❒

Don't know [3] ❒

If **YES**, please specify what type of information was received?

Video [1] ❒ Information booklet [2] ❒

Written guidelines [3] ❒ One to one treatment session [4] ❒

Other, please specify [5] _____

Section D- Helping with exercises

19. In the future, if your /family member/friend' was invited to deliver exercises to you, in addition to your 'routine' physiotherapy, would that be acceptable to you?

Yes [1] ❒ No [2] ❒

If **NO**, please go to Question 22.

20. In addition to your 'routine' physiotherapy while you are in hospital and following suitable training by the physiotherapist, would you be willing to allow your 'family member/friend' to....

Help you with exercises, in the physiotherapy gym,

with the physiotherapist nearby [1] ❒

Help you with exercises at the ward/bed without supervision

of the physiotherapist [2] ❒

Keep a record of the completion of these exercises using an exercise 'diary' [3] ❒

21. When you are discharged from hospital and after suitable training and follow-up, would you be willing to allow your 'family member/friend' to....

Help with your exercises [1] ❒

Help to practice transfers (e.g. from bed to chair etc.) [2] ❒

Help to practice walking [3] ❒

Keep a record of the completion of these exercises using an exercise 'diary' [3] ❒

22. Please read the list below and tick the reasons why you would not like your 'family member/friend' to participate in physiotherapy or helping with exercises? *(Please tick as many as appropriate)*

I do not feel that I would benefit from additional physiotherapy provided by my 'family member/friend' [1] ❒

I would have no interest in allowing my 'family member/friend' to participate my physiotherapy [2] ❒

I would not feel confident if my 'family member/friend' was helping me with my exercises [3] ❒

My 'family member/friend' would put too much pressure on me to complete my additional exercises [4] ❒

I do not think that it is the role of my 'family member/friend' to help me with my exercises [5] ❒

Other, please specify [6] _____

Section E...Opinions on Physiotherapy

23. The following are a list of statements. Please indicate your opinion on each of them by circling the most appropriate phrase (e.g. strongly agree [1], agree [2], neither agree nor disagree [3], disagree [4], strongly disagree [5]).

People with stroke feel that their 'family member/friend':

a) has a role in their physiotherapy following stroke.

strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

b) should be actively encouraged to participate in physiotherapy sessions.

strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

c) should be involved in the delivery of exercises to the person with the stroke without the supervision of the physiotherapist

strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

b) should be more involved in the setting of short and long term physiotherapy goals

strongly agree / agree / neither agree nor disagree / disagree / strongly disagree

24. In your opinion, is the most important part of your physiotherapy?

(Please rank in order of your preference, where 1 is the highest rank and six is the lowest rank.)

a) Getting in/out of bed ❒

b) Transferring from the bed to the chair ❒

c) Sitting/standing without support ❒

d) Walking ❒

e) Regaining strength in the arm/hand ❒

f) Halt muscle wasting ❒

Thank you for taking the time to fill out this questionnaire.

APPENDIX 8

User Survey 2B

Questions for semi-structured interviews

The purpose of this interview is to explore your views in relation to your physiotherapy intervention since your stroke.

1. Firstly, can you tell me how many days per week you receive physiotherapy and how long does each physiotherapy session last?

2. Do you think that you could benefit from more physiotherapy than you currently receive?

3. Have any of your 'family members/friends' been invited to any of your physiotherapy sessions since you commenced physiotherapy after your stroke?
    - Probe – who was invited?
    - Probe – who invited this person?
    - Probe – how many times have they attended?

4. What activities did the physiotherapist show you and your 'family member /friend' to do during these sessions?

5. Has your 'family member/friend' been asked to help you with your exercises, at times when the physiotherapist is not there?
    - Probe – did your 'family member/friend' receive any information from the physiotherapist on how to perform these activities?

6. In addition to your 'routine' physiotherapy while you are in hospital and following suitable training by the physiotherapist, would you be willing to allow your 'family member/friend' to help you to complete a series of exercises?
    - If not, why not?

7. Would you be happy to allow your 'family member/friend' to assist you with exercises when you are discharged from hospital?

8. Would you be happy to allow your 'family member/friend' to keep a record of these exercises using an 'exercise diary'?

Thank you for your time.

APPENDIX 9

User Survey 3

Protocol for Focus Group

Venue: Department of Physiotherapy, Trinity College Dublin
Date: XXX
Time: XXX

Preamble

Focus group research involves an organised discussion with a selected group of individuals to gain information about their views and experiences of a topic i.e. the involvement of 'family members/friends' in the rehabilitation process following stroke. This method is particularly useful for exploring people's knowledge and experiences and can be used to examine not only what people think but how they think and why they think that way (Kitzinger 1995). The idea behind the focus group methodology is that the group processes can help people explore and clarify their views in ways that would be less easily accessible otherwise.

Aim

The primary aim of each focus group is to explore the views of physiotherapists working in the area of stroke rehabilitation on the involvement of 'family members' in the delivery of exercises to the person with stroke.

Objectives

The objectives are threefold namely:

1. To identify the intensity and frequency of physiotherapy that is delivered to people in the acute stages following stroke
2. To ascertain the views of physiotherapists on the role of the family member in the rehabilitation process
3. To explore the outcome, based on the individuals personal experience, of family involvement in physiotherapy

PROTOCOL

Preparing for Session - In preparation for each session, potential participants will be emailed to invite them to the meeting a week before the scheduled meeting. A follow-up invitation with a proposed agenda, session time and list of questions for discussion will be sent three days before the proposed meeting.

Planning the Session - The sessions will be held in a lecture room with adequate airflow and lighting. Chairs will be configured so that all members can see each other. Refreshments will also be provided prior to the session commencing. Sessions will be recorded with an audio video recorder provided by a person not associated with the project.

Facilitating the Session - Following introduction of the facilitator and co-facilitator, a brief outline of the project will be explained. The means to record the session will be explained. Written consent will be obtained from each participant. Each question will be presented to the group and a discussion will be facilitated around the answers to each question, one individual at a time. **Three themes** have been identified for discussion. The following section presents an outline of the format that will be followed at each meeting.

1. Introduction

Today we are going to explore your views on the involvement of 'family members/friends' in the delivery of exercises to people following a stroke. Firstly, I think that it is important that I define some terms that will be used throughout the discussion.

2. Definitions

When I say, **'family member/friend'**, I am referring to the person's family member, friend, carer, neighbour or anyone willing to provide assistance in the delivery of exercise to the person following their stroke.

When I refer to **'physiotherapy'**, I mean any form of one-to-one treatment provided by the physiotherapist (with/without the assistance of another physiotherapist/physiotherapy assistant), any type of group exercises or any form of therapy provided by an assistant physiotherapist with the physiotherapist nearby.

Finally, when I mention **'exercise'**, I am referring to any type of physical activity aimed at improving a particular skill or ability, delivered to the person with a stroke, in the in-patient, outpatient or home environment e.g. passive stretching, movements of a limb. Transfer practice is not considered exercise in this context

Key Questions

1. How many days per week do people with a stroke receive physiotherapy in your service? How long does a physiotherapy session last?

PROBE: Do you think that patients would benefit from more physiotherapy? What particular patient subgroups, if any, would benefit from this additional therapy?

2. Do you think that 'family members/friends' have a role in the delivery of exercise to the person with a stroke?

PROBE: Do you think that their involvement in the delivery of exercises might be a cause of additional strain? Do you think that they would like to be involved in the delivery of exercises? Do you think that this is routine practice?

3. Have you ever involved a 'family member/friend' of a patient in the delivery of an exercise programme in the inpatient, outpatient or home environment?

PROBE: What were the characteristics of this person that you thought made them suitable? Did you provide additional information in writing to the 'family member/friend' on how to perform the exercises unsupervised? Did you provide an 'exercise log' that enabled 'family members/friends' of the person with the stroke to record whether or not the exercise programme had been completed?

[If you have never involved a 'family member/friend' of a patient in the delivery of an exercise programme, would you ever consider involving them in such a programme if it was shown to be of benefit?]

Closing Question

Finally, did you find this a positive experience?

PROBE: Can you tell me a little more about it?

Thank you for your time

APPENDIX 10

Ethical approval for User Survey 1 and User Survey 2A

Joint Research Ethics Committee of the Adelaide and Meath Hospital incorporating the National Children's Hospital and Saint James's Hospital.

THIS NOTEPAPER MUST NOT BE USED FOR PRESCRIPTIONS OR INVOICING PURPOSES

THE ADELAIDE & MEATH HOSPITAL, DUBLIN
INCORPORATING
THE NATIONAL CHILDREN'S HOSPITAL

TALLAGHT, DUBLIN 24, IRELAND
TELEPHONE +353 1 4142000

Dan Lynch, Secretary, SJH / AMNCH Research Ethics Committee
Telephone : 4142860. Fax : 4142371. Email: dan.lynch@amnch.ie

Ms. Emma Stokes
Lecturer
School of Physiotherapy
Trinity Centre for Health Sciences
James's Street
Dublin 8

May 18th 2005

Re: To investigate the views of family/ friends of persons with stroke on their perceived role in physiotherapy.

Please quote this reference in all communications regarding this study 05/05/02 Chairman's Action.

Dear Ms. Stokes,

The proposal to conduct the study under the above title has been reviewed by the Vice-Chairman of the SJH / AMNCH Research Ethics Committee.
On behalf of the Committee, the Vice-Chairman has given ethical approval to this proposed study.

Yours sincerely,

Daniel R. Lynch

Daniel R. Lynch,
Secretary,
SJH / AMNCH Research Ethics Committee.

APPENDIX 11

Ethical approval for User Survey 1 and User Survey 2A, User Survey 2B

Ethical and Medical Research Committee Saint Vincent's University Hospital.

St. Vincent's Healthcare GROUP

UCD DUBLIN

Ethics and Medical Research Committee

ELM PARK, DUBLIN 4

Tel. (01) 2774117 Fax (01) 2838123 email: joan.mcdonnell@ucd.ie

27/04/06

Dr. Diarmuid O'Shea
Consultant Geriatrician
St. Vincent's University Hospital,
Elm Park,
D. 4

Re: Family mediated exercises following stroke - A survey of the views of family members and friends

Dear Dr. O'Shea

Thank you revisions and clarifications which were requested prior to approval at the Ethics and Medical Research committee meeting on 5th April 2006 at which the above study was reviewed.

This study is now approved.

Yours sincerely,

Dr. D. Veale,
Chairman,
Ethics and Medical Research Committee

cc to ~~Freddie~~ Emma Stoler.

APPENDIX 12

Ethical approval for User Survey 1 and User Survey 2A, User Survey 2B and User Survey 3

Physiotherapy Manager at the Royal Hospital Donnybrook (in the absence of a formal Ethics Board).

The Royal Hospital Donnybrook

Morehampton Road, Dublin 4. Telephone 668 0600 Fax 668 0605 Founded 1743

Royal Hospital Donnybrook,
Morehampton Road,
Dublin 4.

03.03.2006

Re: FAME – A randomised controlled trial of family mediated exercise intervention following stroke

To whom it may concern,

Please accept this letter as confirmation that the Royal Hospital Donnybrook has granted ethical approval for the following:

- User surveys to explore the views of potential participants in the FAME project.
- A randomised controlled trial (RTC) to determine whether 'family mediated exercise intervention' (FAME) in addition to routine physiotherapy improves muscle strength and function in the lower limb in persons with stroke.

The RTC is due to commence in the hospital in October 2006.

Kind Regards,

Barbara Sheerin

Barbara Sheerin. BSc Physio, MA, MISCP.
Physiotherapy Manager.

APPENDIX 13

Participant information leaflet – User Survey 1

VOLUNTARY PARTICIPATION

If you volunteer to take part in this questionnaire, you may stop completing the survey at any time.

If you decide not to participate neither you nor your family member/friend with stroke will be penalised in any way.

PERMISSION

This study has been approved by the Joint Research Ethics Committee, St. James' Hospital and the Adelaide & Meath Hospital incorporating the National Childtrens Hospital, Dublin..

FURTHER INFORMATION

You can get more information or answers to your questions about the study, or your participation in the project from:

Ms Rose Galvin 086-8463842

Email: rgalvin@tcd.ie

Ms Emma Stokes 01 -608 3119

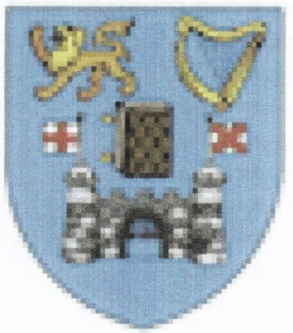
087-2905062

Email: estokes@tcd.ie

V2 MAY 2005

PARTICIPANT INFORMATION LEAFLET

Family mediated exercises following stroke – we're interested in your views



Research project carried out by Rose Galvin.

Supervised by Emma K. Stokes

School of Physiotherapy, Trinity College Dublin.

THE AIM OF THIS QUESTIONNAIRE IS TO INVESTIGATE YOUR VIEWS ON THE PROVISION OF EXERCISES TO YOUR 'FAMILY MEMBER/FRIEND' FOLLOWING STROKE.

Physiotherapy is considrerd an established component of stroke rehabilitation. However, uncertainties remain about the most appropriate level of therapy input. It is widely reported that more physiotherapy is better. Research tells us that to learn or re-learn we probably need more exercise time than that provided on a rehabilitation unit or stroke unit.

The role of the family/friends in the *rehabilitation process* of a person with stroke is significant but members of family and friends are rarely asked to participate in the rehabilitation process as mediators of exercise.

The aim of this study is to investigate **YOUR** views on your perceived role in physiotherapy and to identify methods that would facilitate your participation in the rehabilitation process.

WHAT THIS PROJECT INVOLVES .....

Family members/friends of people with stroke, who are currently inpatients, or have previously received physiotherapy in this hospital, and who are willing to give informed consent will be invited to participate in the study.

You will be asked to complete a questionnaire relating to your views on the involvement of 'family member/friend' in physiotherapy following stroke.

RISKS

There are no risks associated with filling out this questionnaire.

BENEFITS

The information from these questionnaires will be used to identify methods that will facilitate participation of 'family members/friends' of persons with stroke in the rehabilitation process in the future

EXCLUSION FROM PARTICIPATION

If your family member/friend received no physiotherapy following stroke as an inpatient or outpatient, you will not be eligible to participate.

CONFIDENTIALITY

Your identity will remain confidential. You will be allocated an identification number, which will be used by the project team.

COMPENSATION

The investigator carrying out this questionnaire is a qualified physiotherapist, working under the supervision of Ms. Emma Stokes, Lecturer in Trinity College, School of Physiotherapy. All are insured to carry out this work.

APPENDIX 14

INFORMED CONSENT FORM

PROJECT: FAMILY MEDIATED EXERCISES FOLLOWING STROKE - A SURVEY OF THE VIEWS OF FAMILY AND FRIENDS.

PRINCIPAL INVESTIGATOR: EMMA STOKES.

RESEARCH ASSISTANT (S): ROSE GALVIN.

BACKGROUND: The aim of this self-report questionnaire is to identify the views of 'family members/friends' of persons with stroke on their perceived role in physiotherapy.

PROCEDURES: WITH PERMISSION, THE PARTICIPANT IS REQUESTED TO FILL OUT A QUESTIONNAIRE THAT RELATES TO FAMILY INVOLVEMENT IN PHYSIOTHERAPY FOLLOWING STROKE.

DECLARATION:
This study and this consent form have been explained to me. The investigator(s) has/have answered all my questions to my satisfaction. I believe I understand what will happen if I agree to participate in this study.

I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement and I understand that, if there is a sponsoring company, a signed copy will be sent to that sponsor.

PARTICIPANT'S NAME:.....

PARTICIPANT'S SIGNATURE:.....

Date:.....

Statement of investigator's responsibility: I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S SIGNATURE:.....

Date:.....

APPENDIX 15

Participant information leaflet – User Survey 2A

Voluntary Participation

If you volunteer to take part in this questionnaire, you may stop completing the survey at any time.

If you decide not to participate in this study, your routine physiotherapy intervention will not be affected in any way.

Permission

The Joint Research Ethics Committee, St. James' Hospital and the Adelaide & Meath Hospital incorporating the National Childtrens Hospital, Dublin have approved this study. The study has also received ethical approval from the Ethics and Medical Research Committee, St. Vincent's University Hospital.

Further Information

You can get more information or answers to your questions about the study, or your participation in the project from:

Ms Rose Galvin 086-8463842

Email: rgalvin@tcd.ie

Ms Emma Stokes 01-608 3119

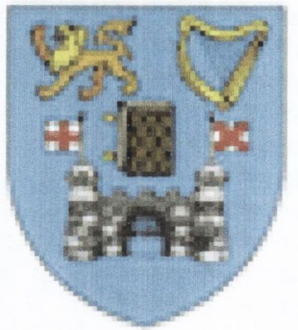
087-2905062

Email: estokes@tcd.ie

VI – OCT 2006

PARTICIPANT INFORMATION LEAFLET

Family mediated exercises following stroke – we're interested in your views



Research project carried out by Rose Galvin.

Supervised by Dr. Emma K. Stokes & Dr. Tara. Cusack.

School of Medicine, Trinity College Dublin.

THE AIM OF THIS QUESTIONNAIRE IS TO INVESTIGATE YOUR VIEWS ON THE PROVISION OF EXERCISES TO YOU FOLLOWING YOUR STROKE BY A NOMINATED 'FAMILY MEMBER/FRIEND'

Physiotherapy is considered an established component of stroke rehabilitation. It is widely reported that more physiotherapy is better. Research tells us that to learn or re-learn we probably need more exercise time than that provided on a rehabilitation unit or stroke unit.

The role of the family/friends in the *rehabilitation process* of a person with stroke is significant but members of family and friends are rarely asked to participate in the rehabilitation process as mediators of exercise.

The aim of this study is to investigate **YOUR** views on the delivery of exercises to you by a 'nominated' family member or friend following suitable training by a physiotherapist.

WHAT THIS PROJECT INVOLVES...

You will be asked to complete a questionnaire relating to your views on the involvement of your 'family member/friend' in your physiotherapy following stroke.

RISKS

There are no risks associated with filling out this questionnaire.

BENEFITS

The information from these questionnaires will be used to identify methods that will facilitate participation of 'family members/friends' of persons with stroke in the rehabilitation process in the future.

EXCLUSION FROM PARTICIPATION

You will not be eligible to participate if you are not currently receiving physiotherapy input in the hospital following a stroke or if you are not willing to give informed consent.

CONFIDENTIALITY

Your identity will remain confidential. You will be allocated an identification number, which will be used by the project team.

COMPENSATION

The investigator carrying out this questionnaire is a qualified physiotherapist, working under the supervision of Ms. Emma Stokes, Lecturer in Trinity College, School of Physiotherapy. All are insured to carry out this work.

APPENDIX 16

INFORMED CONSENT FORM

PROJECT: FAMILY MEDIATED EXERCISES FOLLOWING STROKE – A SURVEY OF THE VIEWS OF PEOPLE WITH STROKE.

PRINCIPAL INVESTIGATOR (S): DR. EMMA K. STOKES, DR. TARA CUSACK.
RESEARCH ASSISTANT (S): ROSE GALVIN.

BACKGROUND: The aim of this self-report questionnaire is to identify the views of people with stroke on the involvement of a nominated 'family member/friend' in their physiotherapy.

PROCEDURES: WITH PERMISSION, THE PARTICIPANT IS REQUESTED TO FILL OUT A QUESTIONNAIRE THAT RELATES TO FAMILY INVOLVEMENT IN PHYSIOTHERAPY FOLLOWING STROKE.

DECLARATION:
This study and this consent form have been explained to me. The investigator(s) has/have answered all my questions to my satisfaction. I believe I understand what will happen if I agree to participate in this study.

I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement and I understand that, if there is a sponsoring company, a signed copy will be sent to that sponsor.

PARTICIPANT'S NAME:.....

PARTICIPANT'S SIGNATURE:.....

Date:.....

Statement of investigator's responsibility: I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S SIGNATURE:.....

Date:.....

APPENDIX 17

Participant information leaflet – User Survey 2B

Voluntary Participation

If you volunteer to take part in this study, you may terminate the interview at any time.

If you decide not to participate in this study, your routine physiotherapy intervention will not be affected in any way.

Permission

The Joint Research Ethics Committee, St. James' Hospital and the Adelaide & Meath Hospital incorporating the National Childtrens Hospital, Dublin have approved this study. The study has also received ethical approval from the Ethics and Medical Research Committee, St. Vincent's University Hospital.

Further Information

You can get more information or answers to your questions about the study, or your participation in the project from:

Ms Rose Galvin 086-8463842

Email: rgalvin@tcd.ie

Ms Emma Stokes 01 -608 3119

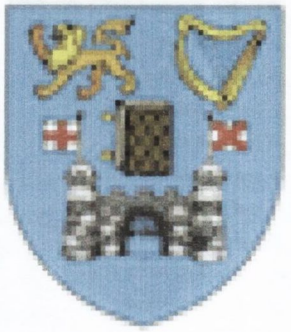
087-2905062

Email: estokes@tcd.ie

VI – OCT 2006

PARTICIPANT INFORMATION LEAFLET

Family mediated exercises following stroke – we're interested in your views



Research project carried out by Rose Galvin.

Supervised by Dr. Emma K. Stokes & Dr. Tara. Cusack.

School of Medicine, Trinity College Dublin.

THE AIM OF THIS INTERVIEW IS TO INVESTIGATE YOUR VIEWS ON THE PROVISION OF EXERCISES TO YOU FOLLOWING YOUR STROKE BY A NOMINATED 'FAMILY MEMBER/FRIEND'

Physiotherapy is considered an established component of stroke rehabilitation. It is widely reported that more physiotherapy is better. Research tells us that to learn or re-learn we probably need more exercise time than that provided on a rehabilitation unit or stroke unit.

The role of the family/friends in the *rehabilitation process* of a person with stroke is significant but members of family and friends are rarely asked to participate in the rehabilitation process as mediators of exercise.

The aim of this study is to investigate **YOUR** views on the delivery of exercises to you by a 'nominated' family member or friend following suitable training by a physiotherapist.

WHAT THIS PROJECT INVOLVES...

You will be asked a series of questions relating to your views on the involvement of your 'family member/friend' in physiotherapy following stroke. This interview will be recorded for the purposes of analysis at a later date. All information will remain confidential.

RISKS

There are no risks associated with this project.

BENEFITS

The information from these interviews will be used to identify methods that may prove useful in providing people with stroke with additional physiotherapy in the future.

EXCLUSION FROM PARTICIPATION

You will not be eligible to participate if you are not currently receiving physiotherapy input in the hospital following a stroke or if you are not willing to give informed consent.

CONFIDENTIALITY

Your identity will remain confidential. You will be allocated an identification number, which will be used by the project team.

COMPENSATION

The investigators conducting this research are qualified physiotherapists. All are insured to carry out this work.

APPENDIX 18

INFORMED CONSENT FORM

PROJECT: FAMILY MEDIATED EXERCISES FOLLOWING STROKE - A SURVEY OF THE VIEWS OF PEOPLE WITH STROKE.

PRINCIPAL INVESTIGATOR (S): DR. EMMA K. STOKES, DR. TARA CUSACK.
RESEARCH ASSISTANT (S): ROSE GALVIN.

BACKGROUND: The primary aim of this interview is to explore your views on the involvement of a nominated 'family members/friend' in the delivery of exercises to you.

PROCEDURES: With permission, you will be requested to discuss a series of questions relating to the involvement of 'family members/friends' in your physiotherapy following stroke.

MODEL RELEASE: I grant the project team the right to use my likeness, image, voice, appearance, and performance recorded on audio recorder for the purposes of this study only. This grant includes without limitation the right to edit, mix or duplicate and to use or re-use in whole or part as the project team may elect.

I acknowledge that I have no interest or ownership in the product or it's copyright. I have read the model release above and understand its terms and stipulations and agree to all of them.

DECLARATION:
This study has been fully explained to me. I have read, or had read to me, this consent form. The researcher, _____, has answered all my questions to my satisfaction. I believe I understand what will happen if I agree to participate in this study.

I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.

PARTICIPANT'S NAME:.....

PARTICIPANT'S SIGNATURE:..... Date:.....
Statement of researcher's responsibility: I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHER'S SIGNATURE:..... Date:.....

APPENDIX 19

INFORMED CONSENT & MODEL RELEASE FORM

PROJECT: FAMILY MEDIATED EXERCISES FOLLOWING STROKE (FAME) – EXPLORING THE VIEWS OF PHYSIOTHERAPISTS USING A FOCUS GROUP METHODOLOGY.

PHD SUPERVISOR (S): DR. EMMA K. STOKES, DR TARA CUSACK
FACILITATOR (S): ROSE GALVIN, DR TARA CUSACK.

BACKGROUND: The primary aim of this focus group is to explore the views of physiotherapists working in the area of stroke rehabilitation on the involvement of 'family members/friends' in the delivery of exercises to the person with stroke.

PROCEDURES: With permission, participants will be requested to discuss a series of questions relating to the involvement of 'family members/friends' in physiotherapy following stroke.

MODEL RELEASE: I grant the project team the right to use my likeness, image, voice, appearance, and performance recorded on audio-visual recorder for the purposes of this study only. This grant includes without limitation the right to edit, mix or duplicate and to use or re-use in whole or part as the project team may elect.

I acknowledge that I have no interest or ownership in the product or its copyright. I have read the model release above and understand its terms and stipulations and agree to all of them.

DECLARATION:
This study has been explained to me and I have received a copy of the proposed questions for discussion. I have read, or had read to me, this consent form. The facilitator, Rose Galvin, has answered all my questions to my satisfaction. I believe I understand what will happen if I agree to participate in this study.

I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.

PARTICIPANT'S NAME:.....

PARTICIPANT'S SIGNATURE:..... Date:.....

Statement of facilitator's responsibility: I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

FACILITATOR'S SIGNATURE:..... Date:.....

APPENDIX 20

Feedback from peer-reviewers following submission of Health Research Board Grant

Feedback from Reviewer 1

1. It would appear that the authors are planning to recruit all stroke patients despite the evidence for a certain subgroup that have shown to benefit from additional intervention.
2. How many people will be included in pilot trial of the main intervention – justification of numbers?
3. The power calculation for the main RCT seems strangely low - what SOMs (standardised outcome measures) was the power calculation based on?
4. The authors have not stated the primary SOM for the main RCT.
5. The authors should consider the Carer Strain Index, Barthel Index
6. It is unclear if there has been any consumer input into the research design at all.
7. Inclusion criteria should include that the patient should have a carer or friend.
8. Procedure - information brochure left for 7 days - this seems an unnecessarily long time interval.
9. Randomisation process of patients is not described anywhere at all.
10. Qualitative assessment appears confusing - is it to the patient or carer or both?

Feedback from Peer Reviewer 2

1. What evidence do the applicants have that family members will be willing to undergo the necessary training and then deliver the intervention over a six week period?
2. Frequency and duration of each session is not documented.
3. Although the user survey suggests that family members wish to be more involved in rehabilitation, the practicalities and reality of delivering the intervention have not been explored with family members.
4. No pilot work has been described to demonstrate the feasibility of the intervention and its acceptability to patients and their families.

5. It is not clear how the sample for the first user survey will be selected.
6. There is no assessment of effect on caregivers e.g. caregiver burden.
7. How soon after stroke onset will participants be included?
8. Will the family member also consent?
9. No account is taken of the attrition/drop-out rates? Will the results be analysed by intention to treat (ITT)?
10. How will the investigators ensure blinding of outcome assessors? Will the degree of blinding be assessed?

Feedback from Peer Reviewer 3

1. Evidence is required to demonstrate that family members are not only both willing and able to engage in training and intervention delivery but also do not suffer any negative consequences because of participation (especially post discharge).
2. How do we know that patients will be as compliant with family members as physiotherapists?
3. The proposal is lacking a clear description of qualitative techniques
4. How will attrition and homogeneity of the sample be dealt with?
5. It is not clear whether the intervention continues at home yet places an additional burden on the caregiver.

Feedback from Peer Reviewer 4

It is not entirely clear how the number of subjects for each strand of the trial is determined. There is nothing to indicate that such figures are based on a power calculation.

Feedback from Peer Reviewer 5

1. The definition of stroke is excessively broad.
2. The applicant makes no reference to the level of disability of the patient, other than to state that they should not be cognitively impaired – too broad, a baseline level of disability should be defined.
3. What is the window from onset of stroke to inclusion in the study?
4. Will patients with evidence of prior stroke on CT/MRI be included?
5. Although a series of clinical tests is planned for all participants in the clinical trial, no primary end-point had been monitored. The absence of a well-defined end-point will make data interpretation difficult and subject to errors associated with multiple testing.....

APPENDIX 21

Ethical approval for RCT

Ethical and Medical Research Committee Saint Vincent's University Hospital.

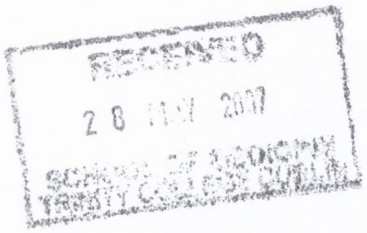
Louise

St. Vincent's Healthcare GROUP LIMITED

UCD DUBLIN

Ethics and Medical Research Committee
ELM PARK, DUBLIN 4
Tel. (01) 2774117 Fax (01) 2838123 email: joan.mcdonnell@ucd.ie

16/5/07



Dr. Emma Stokes
Lecturer
Dept. of Physiotherapy
School of Medicine
Trinity College
Dublin 2

Re: A randomised controlled trial of family mediated exercises following stroke. Protocol. Participant Letter. PIL/Consent Person with stroke. Vs 2 May 2007 PIL/Consent Family Member/Friend vs 2 May 2007

Dear Dr. Stokes,

Thank you for the clarifications and revisions to the Patient Information Leaflets, which were requested prior to approval at the Ethics and Medical Research committee meeting held on Wednesday 2nd May, 2007.

This study is now approved.

Yours sincerely,

Dr. D. Veale,
Chairman,
Ethics and Medical Research Committee.

c.c. Ms. Rose Galvin
c.c. Dr. Diarmuid O'Shea

APPENDIX 22

Ethical approval for RCT

Research Ethics Committee, Mater Misercordiae University Hospital.

Mater Misericordiae University Hospital
SISTERS OF MERCY
Eccles Street, Dublin 7, Ireland.

Ospidéal Ollscoille Mater Misericordiae
SIÚRACHA NA TRÓCAIRE
Sráid Eccles, Baile Átha Cliath 7, Éire.

Misericordia
Maintaining an Attitude of Tenderness
Empathy and Respect

UCD DUBLIN

Not for prescription purposes

Tel: +353 1 8032000
Fax: +353 1 8032404
Email: mmh@mater.ie
Web: www.mater.ie

Ms Anne Marie Keown
Physiotherapy Manager
Department of Physiotherapy
Mater Misericordiae University Hospital
Eccles Street
Dublin 7

23rd November 2007

Our Ref: 1/378/1138

RE: A randomised controlled trial of family mediated exercise (FAME) following stroke
Participant Information Leaflet (Participant) Version 2 - November 2007
Participant Information Leaflet (Family member/Friend) Version 2 - November 2007
Consent Form, Version 1 - September 2007

Dear Ms Keown

I acknowledge receipt of Ms Galvin's correspondence dated 13th November 2007 enclosing the revised Patient Information Leaflets and clarification with regard to Trinity College's indemnity arrangements as requested by the Mater Misericordiae University Hospital/Mater Private Hospital Research Ethics Committee for the above research study to be carried out at the Mater Misericordiae University Hospital.

This correspondence has been noted and the revised Patient Information Leaflets have been approved. Approval to proceed with this research study at the Mater Misericordiae University Hospital is granted; this approval is valid until 24th October 2009.

It is your responsibility to adhere to the study protocol without deviation (unless it has been agreed by the Research Ethics Committee), to submit annual reports setting out the progress of the research (giving details of the number of participants who have been recruited, the number who have completed the study and details of any adverse events etc.) and to notify the Research Ethics Committee when the research is concluded.

Yours sincerely

Dr Harry Frizelle
Chairman Research Ethics Committee

c.c. Ms Rose Galvin, Physiotherapy PhD Student, Depart of Physiotherapy, School of Medicine, TCD
Ms Ann Horgan, Deputy Physiotherapy Manager, Mater Misericordiae University Hospital
Ms Grace Cooke, Clinical Services Manager, Mater Misericordiae University Hospital
Dr Peter Kelly, Consultant Neurologist, Mater Misericordiae University Hospital

Directors: Mr. John Morgan (Chairman), Fr. Kevin Doran, Mr. Eamon Clarke, Mr. Don Mahony, Sr. Margherita Rock, Mr. Martin Cowley, Mr. Kevin O'Malley, Mrs. Anne Carrigy, Mr. Brian Conlan, Sr. Eugene Nolan, Dr. Anthony Clarke, Mr. Kevin Murphy, Dr. Nuala Healy.

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APPENDIX 23

Ethical approval for RCT

Ethics (Medical Research) Committee - Beaumont Hospital

Ethics (Medical Research) Committee - Beaumont Hospital
Notification of ERC/IRB Approval

Investigator: Ms. Rose Galvin

Protocol No.: 08/19

Protocol Title: A Randomised controlled trial of family mediated exercises (FAME) following stroke

Ethics Committee Meeting date: 22nd February 2008

Final Approval Date: 12th March 2008

From: Ethics (Medical Research) Committee - Beaumont Hospital, Beaumont, Dublin 9

Document and Date	Documents Reviewed Date Reviewed	Approved
Application Form, signed 28/01/08	12/3/08	Yes
Study Protocol, 03/08	12/3/08	Yes
Participant Information Leaflet, V2, March 2008	12/3/08	Yes
Family Member/Friend Information Leaflet, V2, March 2008	12/3/08	Yes
Consent Form, V1, 01/08	12/3/08	Yes
GP Letter, V1, 03/08	12/3/08	Yes
<u>Semi-Structured Interview Questions</u> (Family Member/Friend) V1, 03/08	12/3/08	Yes
Participant, V1, 03/08	12/3/08	Yes
<u>Certificates of Insurance:</u>		
E. O'Grady, valid to 30/6/08	12/3/08	Noted
R. Galvin, valid to 30/6/08	12/3/08	Noted
TCD, dated 17/10/07	12/3/08	Noted
Curriculum Vitae, R. Galvin, signed 31/1/08	12/3/08	Noted

Professor Kieran Murphy
ERC/IRB – Convenor's Signature
Approval # 1, dated 12th March 2008

APPENDIX 24

Ethical approval for RCT

Healthcare Research Advisory Committee, Our Lady's Hospital Navan

Údarás na Seirbhíse Sláinte
Health Service Executive

H.S.E. Area Office
Dublin North East
Dublin Road
Kells, Co. Meath

Tel: +353 (0) 46 9280500
Fax: +353 (0) 46 9241459

15th July 2008

Ms Rose Galvin
140 Allendale Square
Clonsilla
Dublin 15

Re/ **Research Study Proposal:**
"A randomised controlled trial of family mediated exercises (FAME) following stroke"
HRAC Meeting Date: 3rd July 2008

Dear Ms Galvin

I am in receipt of the changes from you as recommended by the Healthcare Research Advisory Committee (HRAC).

I can confirm that you have met all the conditions of the Committee and you may commence your study. This will be formally noted at the next HRAC meeting.

Yours sincerely,

Dr. Declan Bedford
Chairperson
Healthcare Research Advisory Committee

Copied to/ **Ms Aideen Carroll, Senior Physiotherapist, Our Lady's Hospital, Navan, Co Meath,**
Ms Margaret Sorohan, Hospital Administrator, Our Lady's Hospital, Navan, Co Meath
Ms Lara Bourton Cassidy, Physiotherapy Manager, Our Lady's Hospital, Navan, Co Meath
Dr Emma Stokes, Senior Lecturer, Department of Physiotherapy, School of Medicine, Trinity Centre for Health Sciences, James's Street, Dublin 8

APPENDIX 25

Ethical approval for RCT

Joint Research Ethics Committee of the Adelaide and Meath Hospital incorporating the National Children's Hospital and Saint James's Hospital.

THIS NOTEPAPER MUST NOT BE USED FOR PRESCRIPTIONS OR INVOICING PURPOSES

THE ADELAIDE & MEATH HOSPITAL, DUBLIN
INCORPORATING
THE NATIONAL CHILDREN'S HOSPITAL

TALLAGHT, DUBLIN 24, IRELAND
TELEPHONE +353 1 4142000

SJH/AMNCH Research Ethics Committee Secretariat
Dan Lynch Ph: 4142860 email: Dan.Lynch@amnch.ie
Ursula Ryan Ph: 4142342 email: Ursula.Ryan@amnch.ie
Secretariat Fax 4142371

Ms. Niamh Murphy
Physiotherapy Manager
St. James's Hospital
James Street
Dublin 8

May 30th 2008

Re: A Randomised Controlled Trial of Family Mediated Exercise (FAME) Therapy Following Stroke.

Please quote this reference in any follow up to this letter: 2008/05/02 Chairman's Action.

Dear Niamh,

Thank you for your recent submission of the above proposal to the SJH/AMNCH Research Ethics Committee.
The Vice-Chair, having reviewed the proposal, has given ethical approval on behalf of the Committee.

Yours sincerely,

Daniel R. Lynch,
Secretary,
SJH/AMNCH Research Ethics Committee

APPENDIX 26

PARTICIPANT INFORMATION LEAFLET
'Individual with stroke'

Principal Investigator: XXX
Physiotherapist: XXX

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The primary purpose of the study is to evaluate your physical recovery after your stroke over a period of 20 weeks with/without the provision of additional physiotherapy in the form of family assisted exercises. A secondary aim of the study is to assess the impact of the family assisted exercise programme on your 'family member/friend'.

WHY HAVE I BEEN CHOSEN?

You and your 'family member/friend' have been randomised for inclusion into this study and we are interested in evaluating whether this type of intervention has an impact on your physical recovery following stroke.

WHAT WILL HAPPEN IF I VOLUNTEER?

Your participation is entirely voluntary. If you initially decide to take part you can subsequently change your mind without difficulty. This will not affect your future treatment in any way.

If you agree to participate, you may/may not be required to complete a series of exercises on a daily basis for approximately 35-40 minutes with your 'family member/friend' in addition to your 'routine' physiotherapy. The exercise programme will continue for eight weeks. You will also have one follow-up assessment in the hospital three months after you complete the eight week exercise programme. Suitable transportation will be arranged and all assessments will be carried out by a trained physiotherapist.

Prior to commencing the programme, you and your 'family member/friend' will receive suitable training from a physiotherapist. This training will continue on a weekly basis. At the end of the programme, you progress will be measured using clinical tests that are commonly used in physiotherapy practice.

If you are not required to complete the exercise programme, you will continue to receive 'routine' physiotherapy in the hospital.

ARE THERE ANY BENEFITS FROM MY PARTICPATION?

You may benefit from the additional family mediated exercise therapy and that the training you and your 'family member/friend' receive will be useful for both of you on a long-term basis.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?
There are no risks associated with this study.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?
If you decide not to participate in this study your treatment will not be affected in any way.

CONFIDENTIALITY
Your identity will remain confidential. A study number will identify you. Your name will not be published or disclosed to anyone.

COMPENSATION
The investigators carrying out this research are qualified physiotherapists and members of the Irish Society of Chartered Physiotherapists, working under the supervision of Dr. Emma K. Stokes, Lecturer in Trinity College, Department of Physiotherapy. All are covered under the indemnity of Trinity College Dublin and in addition all have personal professional liability insurance.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?
This study is part of a research project carried out by Rose Galvin and Dr. Emma K. Stokes, Department of Physiotherapy, School of Medicine, Trinity College Dublin.

IS THIS STUDY SAFE AND BENEFICIAL?
The St. Vincent's Healthcare Group, Ethics and Medical Research Committee have reviewed and approved this study.

CONTACT DETAILS
You can get more information or answers to your questions about the study, or your participation in the study from:

Ms Rose Galvin Tel: 087-2540850
Email: rgalvin@tcd.ie

Ms Emma Stokes Tel: 01-8963613
Email: estokes@tcd.ie

APPENDIX 27

PARTICIPANT INFORMATION LEAFLET
'Individual with stroke'

Principal Investigator: XXX
Physiotherapist: XXX

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The primary purpose of the study is to evaluate the physical recovery of your 'family member/friend' with stroke over a period of 20 weeks with/without the provision of additional physiotherapy in the form of family assisted exercises. A secondary aim of the study is to assess the impact of this family assisted exercise programme on you.

WHY HAVE I BEEN CHOSEN?

You and your 'family member/friend' with stroke have been randomised for inclusion for inclusion into this study and we are interested in evaluating whether this type of intervention has an impact on physical recovery following stroke.

WHAT WILL HAPPEN IF I VOLUNTEER?

Your participation is entirely voluntary. If you initially decide to take part you can subsequently change your mind without difficulty. This will not affect your 'family member/friend's' future treatment in any way.

If you agree to participate, you may/may not be required to complete a series of exercises on a daily basis for approximately 35-40 minutes with your 'family member/friend' in addition to their 'routine' physiotherapy. The exercise programme will continue for eight weeks. You will also be required to complete an exercise diary documenting the series of exercises completed daily. Your 'family member/friend' will also have one follow-up assessment in the hospital three months after he/she completes the eight week exercise programme. Suitable transportation will be arranged and all assessments will be carried out by a trained physiotherapist.

Prior to commencing the programme, you and your 'family member/friend' will receive suitable training from a physiotherapist. This training will continue on a weekly basis. At the end of the programme, you will be asked to complete a questionnaire that evaluates impact of the exercise programme on you.

If you are not required to complete the exercise programme with your 'family member/friend', they will continue to receive 'routine' physiotherapy in the hospital.

ARE THERE ANY BENEFITS FROM MY PARTICPATION?

It is hoped that your 'family member/friend' will benefit from the additional family mediated exercise therapy and that the training you receive will be useful for you and your 'family member/friend' on a long-term basis.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?
There are no risks associated with this study.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?
If you decide not to participate in this study your 'family members /friends' treatment will not be affected in any way.

CONFIDENTIALITY
Your identity will remain confidential. A study number will identify you. Your name will not be published or disclosed to anyone.

COMPENSATION
The investigators carrying out this research are qualified physiotherapists and members of the Irish Society of Chartered Physiotherapists, working under the supervision of Dr. Emma K. Stokes, Lecturer in Trinity College, Department of Physiotherapy. All are covered under the indemnity of Trinity College Dublin and in addition all have personal professional liability insurance.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?
This study is part of a research project carried out by Rose Galvin and Dr. Emma K. Stokes, Department of Physiotherapy, School of Medicine, Trinity College Dublin.

IS THIS STUDY SAFE AND BENEFICIAL?
The St. Vincent's Healthcare Group, Ethics and Medical Research Committee have reviewed and approved this study.

CONTACT DETAILS
You can get more information or answers to your questions about the study, or your participation in the study from:

Ms Rose Galvin	Tel: 087-2540850 Email: rgalvin@tcd.ie
Ms Emma Stokes	Tel: 01-8963613 Email: estokes@tcd.ie

APPENDIX 28

A RANDOMISED CONTROLLED TRIAL OF FAMILY ASSISTED EXERCISES FOLLOWING STROKE

Principal Investigator: XXX

Physiotherapist: XXX

CONSENT FORM

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have read and understood the attached Participant Information Leaflet YES ☐ NO ☐
- I have had the opportunity to ask questions and discuss the study YES ☐ NO ☐
- I have received satisfactory answers to all my questions YES ☐ NO ☐
- I have received enough information about this study YES ☐ NO ☐
- I understand that I am free to withdraw from the study at any time without giving a reason and without this affecting my/my 'family member/friend's' future medical care YES ☐ NO ☐
- I agree to take part in the study YES ☐ NO ☐

Participant's Signature: _____ Date: _____

Participant's Name in print: _____

Family members Signature: _____ Date: _____

Family members Name in print: _____

Investigator's Signature: _____ Date: _____

Investigator's Name in print: _____

APPENDIX 29

Sample of Exercise Diary

Prescribed by:	FAME Physiotherapist
Telephone:	XXX
Week X:	Date

Exercise 1 (standing)

1. Stand up straight with feet shoulder width apart
2. Slowly lower the body, with the hips moving back as if sitting in a chair
3. Maintain the weight directly over the heels or mid-foot.
4. Lower until your knees are bent to approximately 80 degrees.
5. Pause, and then slowly return to the starting position.

Exercise 2 (standing)

1. Stand with right side beside the back of the chair.
2. Hold on to chair/family member's shoulder with right hand.
3. Place right heel directly in front of toes of left foot.
4. **CLOSE EYES**
5. Take right hand off the chair/ family member's shoulder.
6. Hold position for 20 seconds.
7. Repeat with left leg.
8. Repeat 10 times.

Exercise 3 (standing)

1. Stand up straight facing the back of the chair.
2. Close both eyes.
3. Using the chair/shoulder only for a little support, raise one leg a foot off the ground.
4. Maintain your balance while standing on one leg.
5. Hold for a count of ten seconds.
6. Repeat with other leg.
7. Perform five on each leg.

Exercise 4 (stair climbing)

1. Go up and down the stairs holding onto rail with right hand.

2. When stepping up - step up with right foot first, then place the left foot beside it on every step.

3. When stepping down - step with the left foot first, then place the right foot beside it on every step.

4. Repeat 2 times.

Exercise 5 (walking)

1. Walk length of corridor as per physiotherapist's recommendations for walking.

2. Repeat 3 times.

Please place a tick in the box beside the exercises as you complete them on a daily basis.

Exercise	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
1							
2							
3							
4							
5							
Initials:							

NOTES:

APPENDIX 30

BATTERY OF OUTCOME MEASURES

Lower Limb Section of the Lindmark Motor Assessment

		P	NP
PART A: Ability to perform active movements			
LOWER EXTREMITY	Score 0-3		
Supine with legs extended and resting on the bed			
1	Flexion of the hip and knee to more than 90 degrees flexion in both joints		
2	Extension of hip and knee from more than 90 degrees flexion in both joints		
3	Abduction of leg with the knees extended and the toes pointing towards the ceiling		
4	Adduction of leg with the knees extended and the toes pointing towards the ceiling		
	SUBTOTAL SCORE	/12	/12
Sitting on edge of bed			
5	Extension of knee from 90 degrees flexion		
6	Flexion of knee from full extension to more than 90 degrees flexion. The foot should brought under the bed or the chair		
7	Dorsiflexion of the ankle. For 1-2 p the knee is flexed 90 degrees, for 3 knee is extended		
8	Plantarflexion of ankle. For scoring see 7		
9	One leg is brought across other		
	SUBTOTAL SCORE	/15	/15
Standing with support			
10	Flexion of hip and knee to 90 degrees		
11	Extension of hip backwards with extended knee		
12	Standing on tiptoe		
	SUBTOTAL SCORE	/9	/9
	MAXIMUM SCORE LOWER EXTREMITY	/36	/36

The Barthel Index

FEEDING
0 = unable
5 = needs help cutting, spreading butter, etc., or requires modified diet
10 = independent _____

BATHING
0 = dependent
5 = independent (or in shower) _____

GROOMING
0 = needs to help with personal care
5 = independent face/hair/teeth/shaving (implements provided) _____

DRESSING
0 = dependent
5 = needs help but can do about half unaided
10 = independent (including buttons, zips, laces, etc.) _____

BOWELS
0 = incontinent (or needs to be given enemas)
5 = occasional accident
10 = continent _____

BLADDER
0 = incontinent, or catheterized and unable to manage alone
5 = occasional accident
10 = continent _____

TOILET USE
0 = dependent
5 = needs some help, but can do something alone
10 = independent (on and off, dressing, wiping) _____

TRANSFERS (BED TO CHAIR AND BACK)
0 = unable, no sitting balance
5 = major help (one or two people, physical), can sit
10 = minor help (verbal or physical)
15 = independent _____

MOBILITY (ON LEVEL SURFACES)
0 = immobile or < 50 yards
5 = wheelchair independent, including corners, > 50 yards
10 = walks with help of one person (verbal or physical) > 50 yards
15 = independent (but may use any aid; for example, stick) > 50 yards _____

STAIRS
0 = unable
5 = needs help (verbal, physical, carrying aid)
10 = independent _____

TOTAL (0–100): _____

The Berg Balance Scale

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

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on.
( ) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

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

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

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

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

STANDING UNSUPPORTED WITH FEET TOGETHER

INSTRUCTIONS: Place your feet together and stand without holding on.

( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING

INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION

INSTRUCTIONS: Pick up the shoe/slipper, which is place in front of your feet.

( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING

INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.

( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES

INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.

( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED

INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touch the step/stool four times.

( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in › 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete › 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)

( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG

INSTRUCTIONS: Stand on one leg as long as you can without holding on.

( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

The Caregiver Strain Index

I am going to read a list of things that other people have found to be difficult. **Would you tell me whether any of these apply to you?** (GIVE EXAMPLES)

YES = 1 POINT, NO = 0 POINTS

LIST	Response
Sleep is disturbed (e.g., because . . . is in and out of bed or wanders around at night)	
It is inconvenient (e.g., because helping takes so much time or it's a long drive over to help)	
It is a physical strain (e.g., because of lifting in and out of a chair; effort or concentration is required)	
It is confining (e.g., helping restricts free time or cannot go visiting)	
There have been family adjustments (e.g., because helping has disrupted routine; there has been no privacy)	
There have been changes in personal plans (e.g., had to turn down a job; could not go on vacation)	
There have been emotional adjustments (e.g., because of severe arguments)	
Some behavior is upsetting (e.g., because of incontinence; . . . has trouble remembering things; or . . . accuses people of taking things)	
It is upsetting to find . . . has changed so much from his/her former self (e.g., he/she is a different person than he/she used to be)	
There have been work adjustments (e.g., because of having to take time off)	
It is a financial strain	
Feeling completely overwhelmed (e.g., because of worry about . . . ; concerns about how you will manage)	

The Motor Assessment Scale

1) Supine to Side Lying onto Intact Side. Starting position must be supine lying, less extended leg.	SCORE

Pulls self into side lying.	1
Moves leg across actively and the lower half of the body follows. Arm is left behind.	2
Arm is lifted across body with other arm. Leg is moved actively and body follows in a block.	3
Moves arm across body actively and the rest of the body follows in a block.	4
Move arm and leg and rolls to side but overbalances. (Shoulder protracts and arm flexes forward.)	5
Rolls to side in 3 seconds. (Must not use hands).	6
PATIENT SCORE	

2) Supine to Sitting over side of bed.	SCORE

Side lying, lifts head sideways but cannot sit up. (Patient assisted to side lying.)	1
Side lying to sitting over side of bed. (Therapist assists patient with movement. Patient controls head position throughout.)	2
Side lying to sitting over side of bed. (Therapist gives stand-by help [see General rules item 5] by assisting legs over side of bed.	3
Side lying to sitting over side of bed. (With no stand-by help.)	4
Supine to sitting over side of bed. (With no stand-by help.)	5
Supine to sitting over side of bed within 10 seconds. (With no stand-by help.)	6
PATIENT SCORE	

3) Balanced Sitting.	SCORE

Sits only with support. (Therapist should assist patient into sitting.)	1
Sits unsupported for 10 seconds. (Without holding on, knees and feet together, feet can be supported on floor.)	2
Sits unsupported with weight well forward and evenly distributed. (Weight should be well forward with hips flexed, head and thoracic spine extended.)	3
Sits unsupported, turns head and trunk to look behind. (Feet supported and together on floor. Do not allow legs to abduct or feet to move. Have hands resting on thighs; do not allow hands to move onto plinth. Turn to each side.)	4
Sits unsupported, reaches forward to touch floor, and returns to starting position. Feet supported on floor. Do not allow patient to hold on. Do not allow legs and feet to move, touch floor at least 10 cm (4 in) in front of feet. Reach with each arm.	5
Sits on stool unsupported, reaches sideways to touch floor, and returns to starting position. (Feet supported on floor. Do not allow patient to hold on. Do not allow legs and feet to move, support affected arm if necessary. Patient must reach sideways not forward. Reach to both sides.)	6
PATIENT SCORE	

4) Sitting to Standing	SCORE

Gets to standing with help from the therapist. (Any method.)	1
Gets to standing with stand- by help. (Weight unevenly distributed, uses hands for support.)	2
Gets to standing. (Do not allow uneven weight distribution or help from hands.)	3
Gets to standing and stands for 5 seconds with hips and knees extended. (Do not allow uneven weight distribution.)	4
Sitting to standing to sitting with no stand-by help. (Do not allow uneven weight distribution.)	5
Sitting to standing to sitting with no stand-by help three times in 10 seconds. (Do not allow uneven weight distribution.)	6
PATIENT SCORE	/6

5) Walking	SCORE

Stands on affected leg and steps forward with other leg. (Weight-bearing hip must be extended. Therapist may give stand-by help.)	1
Walks with stand-by help from one person.	2
Walks 3 m (10 ft) alone or uses or uses any aid or stand-by help.	3
Walks 5 m (16 ft) with no aid in 15 seconds.	4
Walks 10 m (33m) with no aid, picks up a small sandbag from floor, turns around and walks back in 25 seconds. (May use either hand.)	5
Walks up and down four steps with or without an aid but without holding on to the rail three times in 35 seconds.	6
PATIENT SCORE	/6

6) Upper Arm Function	SCORE

Supine, protract shoulder girdle with arm in 90 degrees of shoulder flexion. (Therapist places arm in position and supports elbow in extension.)	1
Supine, hold arm in 90 degrees of shoulder flexion at 90 degrees to body for 2 seconds. (Therapist places arm in position and patient must maintain position with some [45 degrees] external rotation. Elbow must be held within at least 20 degrees of full extension.)	2
Supine, hold arm in 90 degrees of shoulder flexion, flex and extend elbow to take palm to forehead. (Therapist may assist supination of forearm.)	3
Sitting, hold extended arm in forward flexion at 90 degrees to body for 2 seconds. (Therapist should place arm in position and patient maintains position. Patient must hold arm in mid-rotation [thumb pointing up]. Do not allow excess shoulder elevation.)	4
Sitting, patient lifts arm to above position, holds it there for 10 seconds and then lowers it. (Patient must maintain position with some external rotation. Do not allow pronation.	5
Standing, handing against wall. Maintain hand position, while turning body toward wall. (Arm is abducted to 90 degrees with palm flat against the wall.)	6
PATIENT SCORE	/6

7) Hand Movements	SCORE
Sitting, extension of wrist. (Patient sits at a table with forearm resting on the table. Therapist places cylindrical object in palm of patient's hand. Patient is asked to lift object off the table by extending the wrist. Do not allow elbow flexion.)	1
Sitting, radial deviation of wrist. (Therapist places forearm in mid pronation, supination, i.e. resting on ulnar side, thumb in line with forearm and wrist in extension, fingers around a cylindrical object. Patient is asked to lift hand off table. Do not allow elbow flexion or pronation.)	1
Sitting, elbow into side, pronation and supination. (Elbow unsupported and at a right angle. Three-quarter range is acceptable.)	1
Sitting, reach forward, pick up large ball of 14 cm (5in) diameter with both hands and put it down. [Ball should be placed on table at a distance that requires elbow extension. Palms should be kept in contact with the ball.]	1
Sitting, pick up a polystyrene cup from table and put it on table across other side of body. (Do not allow alteration in shape of cup.)	1
Sitting, continuous opposition of thumb and each finger more than 14 times in 10 seconds. (Each finger in turn taps the thumb, starting with index finger. Do not allow thumb to slide from one finger to the other, or to go backwards.)	1
PATIENT SCORE	/6

8) Advanced Hand Activities	SCORE
Pick up the top of a pen and put it down again. (Patient reaches forward to arm's length, picks up pen top, and releases it on table close to body.)	1
Pick up one jellybean from a cup and place it in another cup. (Teacup contains 8 jellybeans. Both cups must be at arms' length. Left hand takes jellybean from cup on right and releases it in cup on left.)	1
Draw horizontal lines to stop at a vertical line 10 times in 20 seconds. (At least five lines must touch and stop at the vertical line. Lines should be approximately 10 cm in length.)	1
Hold a pen; make rapid consecutive dots on a sheet of paper. (Patient must do at least 2 dots a second for 5 seconds. Patient picks pen up and positions it without assistance. Pen must be held as for writing. Dots not dashes.)	1
Take a dessertspoon of liquid to the mouth. (Do not allow head to lower towards spoon. Liquid must not spill.)	1
Hold a comb and comb hair at back of head. (Shoulder must be externally rotated, abducted at least 90 degrees. Head erect.)	1
PATIENT SCORE	/6

The Nottingham Extended Activities of Daily Living Index

SCORE
0 = Not at all
1 = With Help
2 = Alone with Difficulty
3 = Alone easily

DO YOU	SCORE
MOBILITY	
walk around outside?	
climb stairs?	
get in and out of the car?	
walk over uneven ground?	
cross roads?	
travel on public transport?	
IN THE KITCHEN	
manage to feed yourself?	
make yourself a hot drink?	
take hot drinks from one room to another?	
do the washing up?	
make yourself a hot snack?	
DOMESTIC TASKS	
manage your own money when out?	
wash small items of clothing?	
do your own shopping?	
do a full clothes wash?	
LEISURE ACTIVITIES	
read newspapers and books?	
use the telephone?	
write letters?	
go out socially?	
manage your own garden?	
drive a car?	
GRAND TOTAL	

The Reintegration to Normal Living Index

Please RATE each item by the following scale

1 = does not describe my situation
2 = describes my situation a little
3 = describes my situation a lot
4 = fully describes my situation

ITEM	DESCRIPTION	RATING
1	I move around my living quarters as I feel is necessary. (Wheelchairs, other equipment or resources may be used)	
2	I move around my community as I feel necessary. (Wheelchairs, other equipment or resources may be used)	
3	I am able to take trips out of town as I feel are necessary. (Wheelchairs, other equipment or resources may be used)	
4	I am comfortable with how my self-care needs (dressing, feeding, toileting, bathing) are met. (Adaptive equipment, supervision and/or assistance may be used)	
5	I spend most of my days occupied in a work activity that appears to be necessary or important to me. (Work activity could be paid employment, housework, volunteer work, school, etc.) (Adaptive equipment, supervision and/or assistance may be used)	
6	I am able to participate in recreational activities (hobbies, crafts, sports, reading, television, games, computers etc.) as I want to. (Adaptive equipment, supervision and/or assistance may be used)	
7	I participate in social activities with family, friends, and/or business acquaintances as is necessary or desirable to me. (Adaptive equipment, supervision and/or assistance may be used)	
8	I assume a role in my family which meets my needs and those of other family members. (Family means people with whom you live and/or relatives with whom you don't live but see on a regular basis)	
9	In general, I am comfortable with my personal relationships.	
10	In general, I am comfortable with myself when I am in the company of others.	
11	I feel I can deal with life events as they happen.	

Participant ID: _____

Date: _____

The Six Minute Walk Test

(Each Lap = 10 metres)

Participant ID Number: _____
Date of Assessment: _____

Baseline Assessment ☐
(Tick as appropriate)

Post-intervention Assessment ☐
(Tick as appropriate)

Follow-up Assessment ☐
(Tick as appropriate)

Aid used: YES ☐ NO ☐

Type of aid used: _____

Number of Laps Completed: _____

Number of Rests Taken: _____

TOTAL DISTANCE (metres): _____

ADDITIONAL COMMENTS:

_____
_____
_____
_____
_____

Physiotherapist's Name: _____

Date: _____

APPENDIX 31

AN EVAULATION OF FAMILY ASSISTED EXERCISES FOLLOWING STROKE

Semi-structured interview questions

Individual with stroke

Question 1

Do you think that the additional exercise programme helped you in any way?

PROMPT: In what ways do you think the programme has helped you, for example has it improved your ability to move around or your balance or your confidence?

Question 2

What part of the programme did you think was most beneficial?

Question 3

What motivated you to continue and complete the programme?

PROMPT: For example, was it the involvement of your family in the programme, filling out the daily exercise diary, weekly visits from the physiotherapist or an improvement in your balance, mobility or confidence that motivated you?

Question 4

Do you think that you will continue with your exercises now that you have completed the programme?

PROMPT: What do you think would help you to continue with your exercises? For example, would you like to keep an exercise diary and have it checked?

Would you like it to be checked by post or in person?

Would you like to meet with the physiotherapist at home or in the hospital?

Question 5

Do you think that the programme added pressure to your daily life?

Question 6

Do you think that your family member/friend [NAME] was happy to assist you with the programme?

Question 7

Do you think that the programme added additional pressure to their daily lives?

Question 8

Can you rate your satisfaction with the programme on a scale of 1 to 5?
(1=very dissatisfied, 2=dissatisfied, 3=neither satisfied nor dissatisfied, 4=satisfied, 5=very satisfied)

Question 9

Would you encourage someone else in your position to undertake this programme?

Question 10

Finally, is there anything further you wish to say or add to what you have already said?

APPENDIX 32

AN EVAULATION OF FAMILY ASSISTED EXERCISES FOLLOWING STROKE

Semi-structured interview questions

Family member/friend

Question 1

Do you think that the additional exercise programme helped [NAME] in any way?

PROMPT: In what ways do you think the programme has helped them, for example has it improved their ability to move around or their balance or confidence?

Question 2

What part of the programme did you think was most beneficial?

Question 3

Do you think that the programme added additional pressure to [NAME] daily life?

Question 4

Do you think that you will continue to assist or encourage [NAME] to exercise now that the study has been completed?

PROPMT: What do you think would help you to do this, for example keeping the exercise diary and having it checked regularly by the physiotherapist?

Would you like to meet with the physiotherapist at home or in the hospital?

Question 5

Do you think that assisting with the exercise programme added pressure to your daily life?

Question 6

Can you rate your satisfaction with the programme on a scale of 1 to 5?

(1=very dissatisfied, 2=dissatisfied, 3=neither satisfied nor dissatisfied, 4=satisfied, 5=very satisfied)

Question 7

Would you encourage someone else in your position to undertake this programme with their 'family member/friend' with a stroke?

Question 8

Finally, is there anything further you wish to say or add to what you have already said?