An Evaluation of Intensity of Community Based Multidisciplinary Therapy Following Stroke or Hip Fracture for People Aged 65 and Over.

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Summary of Thesis

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Background: Stroke and hip fracture remain the largest causes of disability in old age throughout the world. Hospital based rehabilitation programmes have been replaced or increasingly supplemented by community based rehabilitation provision over the last decade in both the developed and developing world. Research focused on the efficacy of community based programmes aimed at promoting recovery from stroke and hip fracture in old age has becomes increasingly important.

Objective: To compare intensive with non-intensive home based rehabilitation provision following stroke or hip fracture in old age (65 years +).

Design: Single blind randomised controlled trial

Setting: City wide Community Rehabilitation Team (CRT) comprising four local teams in Sheffield, UK.

Subjects: 89 Stroke patients, 71 hip fracture patients.

Interventions: Patients assigned to receive six or more face to face contacts or three or less face to face contacts from a member of a multi-disciplinary rehabilitation team.

Outcome Measures: Barthel, Therapy Outcome Measure (TOM), Euroqol, Hospital Anxiety and Depression Scale (HADS) and Frenchay Activities Index (FAI).

Results: No significant differences were detected amongst the hip fracture sub-group for any of the above outcome measures at three months or rate of change since baseline. Significant differences were detected amongst the stroke sub-group at three months for EQ-5D ($p=0.028$) and TOM Handicap ($p=0.028$) as well as change since baseline for EQ-5D ($p=0.023$) and Euroqol Health Status ($p=0.04$).

Conclusions: It is suggested that an increase in the number of face to face contacts with a member of a community based multidisciplinary team following stroke can benefit patients in their quality of life and levels of participation. The thesis also draws attention to the methodological challenges faced when undertaking rehabilitation research in primary care.

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Chapter One: Literature Review

The aim of this review is to locate the intensity study within existing evidence and policy context. There are four main themes. Firstly the epidemiological and policy context is examined. Secondly the literature regarding community rehabilitation, particularly evaluation of community rehabilitation and early supported discharge following stroke and hip fracture is reviewed. Thirdly, the rationale and the reality of intensive treatment is addressed. Included within this theme are clinical, professional and patient perspectives on why intensive treatment is viewed as desirable. Finally, the evidence relating to evaluation of intensity following stroke or hip fracture is scrutinised.

During the course of the review four databases were searched for literature being published between 1965 and 2003. They were: Medline, Cinhal, AHMED and PsychInfo. Within the review, particularly when addressing evidence relating to intensity of therapy, primacy has been given to evidence derived from randomised controlled trials, although other research strategies are referred to and noted where appropriate (see Appendix I for a list of keywords and free text alternatives used in the review).

1 Incidence, Prevalence and Policy Context

1.1 Incidence and Prevalence of Stroke

An international comparison concluded that the incidence of stroke is estimated to be between 300 and 500 per 100,000 (Sudlow & Warlow 1997). There are 100 000 first strokes every year in the U.K. Strokes effecting people aged 65 and over will account for three out of every four of these (Clark & Opit 1994). Stroke incidence rises from 1 per 1000 among those aged 45 and under to 15 per 1000 for those aged 85 or more (Wolfe et al 1995). Few studies have addressed the subject of morbidity following stroke in a U.K. context. Geddes et al conducted a survey of a population in North Yorkshire (Geddes et al. 1996). They report a prevalence rate of 14.7 per 1000 with 55 per cent needing help and assistance due to disability following stroke. O'Mahoney et al have

undertaken a cross-sectional survey of a population in Newcastle-upon-Tyne (O'Mahony et al. 1999). The survey indicated a high prevalence of disability following stroke, ranging from 61 per cent amongst the 65-74 age range, to 88 per cent amongst the oldest age group (85 and over). The authors conclude that there may be a prevalence of 1170 per 100 000 who are disabled following a stroke. The increased incidence of falls following stroke has also been noted (Forster & Young 1995). A review regarding depression following stroke undertaken by Turner Stokes and Hassan (Turner-Stokes & Hassan 2002) indicated that depression affects between one-third and one-half of all stroke patients at some time.

1.2 Incidence and Prevalence of Hip Fracture

Lifetime risk for femoral fracture is 17% for women and 6% for men (Meunier 1993). There is limited evidence regarding the incidence of hip fracture in the UK and associated mortality and morbidity, however, available information suggests that the incidence of hip fracture in the UK is increasing (McColl et al 1998). Above 65 years of age incidence of hip fracture doubles every five years (Schurch et al. 1996). Hip fracture has been shown to result in lower levels of participation and poor activities of daily living (particularly walking)(Keene et al 1993). The association between mortality and poor post injury activities of daily living has also been noted (Todd et al. 1995). Holmes and House (Holmes & House 2000) conducted a systematic review of the evidence relating to psychiatric illness following hip fracture. Reports revealed wide variation in the prediction of prevalence of between 9 and 47 per cent. The three UK studies cited ranged from 16 per cent to 33 per cent.

1.3 Predicting Outcome Following Stroke

Thommessen et al (Thommessen et al 1999) reported that age and urinary incontinence predicted place of living (home or nursing home) and first year mortality following stroke and that baseline Barthel was significantly associated with 12 month disability and poor participation. Ostir et al (Ostir et al. 2002) observed that baseline depression was associated with improvement

in ADL skills after one year following stroke. Kwakkel et al (Kwakkel et al. 1996) identified over 140 studies concerned with predicting outcome following stroke. Although the methodological quality of many of the studies was poor the authors cited age, previous stroke, urinary incontinence, consciousness at onset, admission activities of daily living (ADL) score and existence of social support as predictors of disability.

1.4 Predicting Outcome Following Hip Fracture

Several factors have been shown to be related to successful outcome following hip fracture. Higher mortality or institutionalisation amongst men has been highlighted (Cree et al. 2000;Fransen et al. 2002). Ostir et al (Ostir et al 2002), referred to above in relation to stroke outcome, also observed that baseline depression was associated with improvement in ADL skills after one year following hip fracture. Cognitive state, residence site and function at baseline were identified by one study as valid predictors of type of residence, walking and function at 12 months (Kaehrle et al. 2001). Fox et al (Fox et al. 1998) also showed that balance and gait at two months was predictive of hospitalisation and nursing home placement at 24 months. The need for assistance with ADL pre-fracture has also been associated with the need for more assistance with mobility post-fracture (Myers et al. 1996).

1.5 Cost Implications of Stroke and Hip Fracture

Putting to one side the enormous personal costs to individuals who suffer stroke or hip fracture, the cost to the public purse is also significant. The cost to the NHS, for stroke, has been estimated at around 4 per cent of its total budget (Ebrahim 1996). A much broader cost perspective has been undertaken by Kavanagh et al taking into account personal social services and primary care costs (Kavanagh et al 1999). Severity of disability, time since stroke and living alone were all associated with higher costs. Total costs to the public purse for osteoporotic fractures, for women alone, stand at £700m, 87 per cent is of which a result of hip fracture. When male hip fractures are included the cost rises to £940m (Cameron et al. 2000). Furthermore, these costs are set to

increase with an ageing population. Marini et al have shown that stroke incidence rises with an increase in the proportion of older people in the population (Marini et al. 2001) and by 2025 the number of hip fractures world wide will increase to 3.9 million and to 6.3 million by 2050 (Cooper 1990).

1.6 Community Based Rehabilitation: A shift in policy

The expansion of community based rehabilitation services has occurred at a dramatic rate over recent years (Enderby & Wade 2001) despite its struggle to emerge as an alternative method for the prevention of admission to long term care and facilitator of early hospital discharge for older people. This lack of progress occurred despite pressure on health authorities, from champions of community based services, to develop such provision. The Audit Commission in particular (Audit Commission 1997) focused attention on the 'vicious circle' for older people when faced with an abundance of residential and nursing home provision and contrasting dearth of services provided at the domiciliary level. It recommended that health authorities seek to reduce admissions and explore alternative methods for care and rehabilitation. Others noted at the time that community based rehabilitation services were not increasing at a rate comparable with hospital retraction (Nocon & Baldwin 1998). Others noted the lack of development despite it being recognised as a need by hospital consultants (Ebrahim & Redfern 1999). As an overt Government policy initiative, the determination to develop community based rehabilitation services can be identified in the latter half of the decade (Department of Health 1997;Department of Health 2001a;Department of Health 2001b). The differing approaches to what is meant by community rehabilitation have been noted alongside this growth (Enderby & Wade 2001). Enderby and Wade point to both the reduction in the capacity of acute based care and the increasing trend in health policy to emphasise the importance of community based delivery of care. But as they also point out, the increase in community based provision of rehabilitation is occurring in response to policy change rather than being evidence led. Other surveys have indicated that the application of the notion of community based rehabilitation varies (Geddes & Chamberlain 2001).

1.7 Defining Disability and Health: The International Classification of Function, Disability and Health (ICF)

The International Classification of Function, Disability and Health (ICF) (World Health Organisation 2002) was derived from its predecessor The International Classification of Impairment, Disability and Handicap (ICIDH) in the late 1990s. It provides an international framework and operational taxonomy for the anatomical, physiological and functional aspects of health and disability and comprehensive codes for the contextual attributes of the social, the economic and the personal. Its purpose is:

- To provide a scientific basis for understanding health
- To provide a common language for clinicians, researchers, policy makers and the public
- To permit comparisons over time and between nations
- To provide systematic coding scheme for information systems
- To enable a greater understanding of the focus of intervention and outcome

ICF is relevant here because it provides a framework for understanding health and ill health, as well as function and disability, in an integrated model, evolving over recent years in response to debates regarding the adequacy of the social and medical models. It also provides a model through which individual rehabilitation interventions and outcomes can be located. The framework is divided into two main parts (summarised in Table 1.1 below). It includes a broad range of components ranging from anatomical to contextual. The inclusion of contextual factors also means that it is an interactive model not merely linear in nature. In doing so it rejects the assumption that impairment results in reduced activity or participation or a lack of impairment results in an increase in performance or participation.

Parts	Part 1: Functioning and disability			Part 2: Contextual factors	
Components	Body Structure, function and impairment		Activity and participation	Environmental	Personal
Constructs and qualities	Change in body function	Change in body structure	Capacity and Performance	Facilitators or barriers	Facilitators or barriers

Table 1.1: World Health Organisations International Classification of Function, Disability and Health (summary)

The rationale for raising the ICF at this stage is to point out that it will be used throughout the thesis. The framework has only recently been finalised and was developed during the period that this research was being undertaken. For the time being it is useful to note that concepts central to the ICF can be identified throughout and hence the terminology associated with previous versions (disability and handicap) will not be used here (the exception being the use of the term handicap in relation to the Therapy Outcome Measure (TOM)). Instead more recent terminology, and changes in definitions (activity and participation) will be used. These concepts can be observed in terms of the basis of rehabilitation interventions, particularly in relation to body function and structure as well as outcomes (activity, participation (including well being)). The relative absence of reference to contextual factors in relation to rehabilitation research, and indeed the research undertaken for this thesis, should be noted, a point to which I shall return to later.

2 Community Based Rehabilitation Research

A major strand within rehabilitation evaluation over recent years has been the need to undertake an appraisal of the policy of early supported discharge (ESD). The studies cited below support ESD as a policy alternative, however, it is important to note that although in these cases home-based therapy provides the alternative to hospital care, such intervention is not a pre-requisite component of ESD policies. In addition to the burgeoning work focused upon

ESD there has also been some effort made to evaluate community based rehabilitation in its various forms.

2.1 ESD Evaluation: Stroke

Rudd et al carried out an RCT to evaluate early discharge to community rehabilitation of up to three months (Rudd et al. 1997). Three hundred patients were randomly allocated to community rehabilitation or routine/conventional treatment. Community rehabilitation included up to daily visits from each therapist involved. Conventional treatment consisted of routine care in an acute setting with discharge planned in the usual way. There were no significant differences in outcomes measured at 12 months. A stroke specific satisfaction questionnaire was administered and the community rehabilitation group tended to be happier with hospital treatment. The authors suggest that their shorter lengths of stay limits patient exposure to aspects of care that dissatisfies them. There were no differences in readmission or mortality rates. The study indicated that community rehabilitation was as effective as conventional acute therapy.

Mayo (Mayo et al. 2000) randomised 114 stroke patients to usual care or a programme of patient focused therapy and nursing care at home in order to evaluate the policy of ESD. The intervention group had shorter hospital stays and at three months the intervention group were significantly more satisfied with community re-integration and had better physical health scores (SF-36).

Gilbertson et al carried out a study evaluating the impact of domiciliary occupational therapy in comparison to routine rehabilitation (Gilbertson et al. 2000). Stroke patients (n=138), with no age criteria applied, were allocated to routine therapy or domiciliary based occupational therapy. Routine therapy encompassed inpatient multi-disciplinary rehabilitation, discharge and a multi-disciplinary review with possible referral to day hospital. The intervention group received home-based occupational therapy, reported to be client focused. This group received ten visits from an occupational therapist over a six-week period. Statistically significant differences were detected at eight weeks in the

Nottingham Health Profile score and global outcome, in both cases results were higher for the intervention group. Although these differences persisted at 6 months, they were not significant. In terms of patient satisfaction the intervention group were more likely to report satisfaction across all twelve domains of the measure. Resource use was evenly distributed.

A Cochrane review, which evaluated trials with an early supported discharge for stroke patients as an intervention, was undertaken in 1999 (Early Supported Discharge Trialists 2001). Nine trials were included. It has already been noted that home-based therapy does not provide a pre-requisite part of ESD policy. Hence, the review included trials where the policy of ESD was being pursued, but a co-ordinated approach (in the form of discharge planning and home-based therapy) did not always form part of the intervention. The results reflected the significance of a co-ordinated approach in reducing mortality, the numbers requiring institutional care, dependency and promoting competence in activities of daily living. All significant differences in favour of ESD as a policy were reversed where a co-ordinated approach did not exist. ESD patients were also found to be more anxious.

Richards et al (Richards et al. 1998) completed an RCT comparing early supported discharge with hospital based rehabilitation. As with the study described in this thesis study participants were drawn from those recovering from stroke and fractured neck of femur (as well as patients recovering from joint replacements). A small but significant benefit was found in the mean Barthel change for those receiving community-based rehabilitation. A cost comparison, relating to the same study, indicated lower costs for community-based care and rehabilitation (Coast et al. 1998).

A study indicating that the treatment of aphasia in the community is feasible was reported by Aftonomous et al (Aftonomos et al 1999). Sixty patients received treatment using computer assisted techniques, with treatment programmes defined by algorithms using on-line information and assessment and response to treatment. The authors noted that the intervention was

favourable, resulting in significant improvement in both impairment and communication.

2.2 ESD Evaluation: Hip Fracture

An RCT was conducted with 66 older people evaluating ESD for those recovering from hip fracture in Australia. Subjects were allocated to accelerated discharge or conventional rehabilitation. Those allocated to the home based rehabilitation group were discharged within 48 hours of randomisation. Outcomes were centred upon physical and social independence, balance confidence and carer strain. The results showed that the home based group indicated greater improvement in ADL skills as well as greater confidence in avoiding falls. Although this group had significantly shorter stay in hospital they used rehabilitation services for a longer period (Crotty 2002). Two cohort studies were identified as well as a study using pre-ESD policy control group. An historical study in Sweden examined mortality rates between the two treatment settings over a seven-year period in the 1970s (Ceder et al 1987). Findings indicated a slightly higher mortality rate for those who received hospital-based treatment. O'Cathain observed 76 patients recovering from fractured neck or femur being treated at home following early supported discharge and compared outcomes with a control group of 34 who remained in hospital for longer (O'Cathain 1994). Differences were not significant across mortality after three months and a range of Nottingham Health Profile dimensions. Farnworth et al (Farnworth et al 1994) conducted a 'before and after' study of an ESD policy, augmented by a small multi-disciplinary team providing planned discharge and therapy at home. The intervention group had shorter hospital stays, but the study reported little in the way of other outcomes.

2.3 Comparing Community Interventions

In addition to evaluation concerning ESD, some studies have focused on domiciliary-based rehabilitation as a specific intervention. In the main these evaluations have compared domiciliary based therapy with day hospital therapy. Widen-Holmqvist et al (Widen-Holmqvist et al. 1998) conducted a

similar trial in Sweden. Eighty-one stroke patients were randomly allocated to domiciliary rehabilitation or routine rehabilitation. A multi-disciplinary team provided domiciliary rehabilitation for a period of around three to fours months. Rehabilitation was tailored to meet with individual patient needs. Routine rehabilitation consisted of multi-disciplinary therapy in acute, day hospital and outpatient care. The study team concluded that domiciliary rehabilitation produced minor patient benefit and reduced mean hospital stay by 15 days for the domiciliary group.

Gladman et al undertook a similar study in Nottingham (Gladman & Lincoln 1994;Gladman et al 1993). The DOMINO study also compared domiciliary therapy with that of a service offered in a geriatric day hospital. A total of 327 patients were stratified according to type of hospital ward (Health Care for the Elderly, General Medical Ward or Stroke Unit) and randomly allocated to day hospital rehabilitation or home based physiotherapy and occupational therapy. To summarise, there was a slight but significant difference in EADL in favour of the day hospital group of those who had originated from the Stroke Unit. More consequential findings were reported regarding the other outcomes with 38 per cent of the home based group reported as being dead or institutionalised at 12 months compared to only 24 per cent of the day hospital group.

The tentative conclusion to be drawn here is that domiciliary-based therapy services are at least on a par with more traditional day hospital in terms of patient outcome, providing policy makers with evidence to support its development.

2.4 Community Based Rehabilitation Research: Conclusion

Evaluation thus far has indicated that although ESD policies do not appear detrimental to patient outcome, the benefits (when compared to hospital rehabilitation) are slight and limited to patient integration, satisfaction and length of hospital stay. Nevertheless it is an increasingly favourable option to policy makers. The question of how such outcomes are achieved, despite the absence of considerable and expensive hospital care, remains. Again

characteristics such as nursing care, home-life, family-life, nature of therapy intervention as well as the degree of inter-professional organisation are raised as possible enabling or inhibiting factors in this success.

3 Intensity of Therapy: Rhetoric, reality and rationale

Concern for the issue of intensity of community based rehabilitation services can be traced to a variety of sources. The remainder of this literature review will focus on this question and seek to ascertain why the issue is significant. In particular the pertinence of question of intensity of community based services will be scrutinised.

3.1 Policy Roots

The notion of intensity of treatment can be detected in the language of policy makers. Two significant policy initiatives over recent years have contributed to the underpinning of the development of community rehabilitation services. In Better Services for Older People (Department of Health 1997) community rehabilitation was held up as one of four areas for potential local development. The letter recognises that community based services had not had attention comparable with acute services but urges that, *'we have to see flexible and responsive community based intensive health and social care'*. More recently intermediate care has emerged as a theme. The guidance around this to contained terminology hinting at an underlying understanding that 'more is better' (Department of Health 2001b). Although it was unclear at the time which services were encapsulated under this banner, community based rehabilitation was evident in the Governments own notions of intermediate care and included *'hospital at home'*. This was defined as *'intensive support in the patients own home, including investigations and treatment which are above the level that would normally be provided in primary care'*.

3.2 Variation in Provision

The rhetoric of policy statements contrasts markedly with the variation that occurs in clinical practice. In considering how rehabilitation professionals go

about making choices about interventions a perspective which goes beyond the use of available evidence is required. Unsworth (Unsworth 1996) reviews the factors effecting decision making within rehabilitation teams, citing three: organisational and political (policy etc.), clinician attributes (views, attitudes and opinions) and team dynamics (team cohesion etc.) Given the many influences of decision outcomes t is understandable that inequity of provision is to occur. Of interest here is the literature regarding utilisation, intensity and duration of service provision within rehabilitation.

3.3 Inequity in Provision: resource and organisational influences

The literature indicates that variation in both use, practice and intensity of treatment occurs between nations, within nations and within and between similar providers. Berg et al highlighted variation between countries in the developed world, in a study of the provision of rehabilitation services in nursing homes in the U.S, Japan, Iceland, Italy and Denmark (Berg et al. 1997). The findings revealed wide variation with the U.S providing the least therapy to the nursing home residents in the sample. Inequality as a result of resource and organisational factors has also been highlighted within the U.S.. Lee et al undertook a random sample of Medicare recipients. (Lee et al 1997). Data were subjected to weighted least square regression analysis. Variation in utilisation between metropolitan districts was reported. The authors concluded that patient characteristic did not explain this variation both in terms of utilisation and intensity of treatment. Swan et al also analysed utilisation of Medicare patients in relation to physiotherapy and occupational therapy (Swan et al. 1995). Using data on 295 patients they observed that need did reflect the service provided, but other non-clinical factors were also important determinants of rehabilitation services provided. Notably provider structure and size of case-load were significant factors in determining service provision. Hoenig et al developed a taxonomy of stroke services and used this to observe patterns in the use of services in the U.S (Hoenig et al. 2000). The authors noted considerable variation in the services provided. Hoenig et al (Hoenig et al 1996) also discovered that size of hospital impacted upon the levels of physiotherapy and occupational therapy provided.

Variation in stroke and hip fracture care and rehabilitation services has been noted in the U.K (Audit Commission 1995;Ebrahim & Redfern 1999). These national surveys highlighted organisational factors as being influential on the experience of patients in terms of type of treatment and rehabilitation practice. However, these audits were almost entirely related to acute or in-patient provision.

3.4 Variation in Community Based Rehabilitation Services

Some evaluation work within community therapy services has reported on variation of treatment, despite the focus of these studies being between home and day hospital rehabilitation. Baskett et al (Baskett et al. 1999) evaluated domiciliary based rehabilitation and compared this with day hospital treatment in New Zealand. One-hundred stroke patients were randomly allocated to home-based therapy of routine day hospital and out-patient therapy. There were no significant differences between the two groups at follow up. However, contact time with therapists for the home-based group was higher, although the number of visits was equal.

Two British studies in the early 1990s reported conflicting outcomes from studies regarding domiciliary and day hospital rehabilitation. The contrasting findings led to further analysis by both groups of researchers resulting in implications for the issue of intensity. Young and Forster (Young & Forster 1992) compared day hospital rehabilitation with home based physiotherapy following stroke for a group of patients aged over 60 in Bradford. At six months both groups had improved significantly, however, there was a significant difference between Barthel and MAS scores between the groups. In particular analysis of individual items on the Barthel Index highlighted a significantly better capacity for those receiving home based physiotherapy to climb stairs. The home based rehabilitation group also scored significantly higher on the Frenchay Activities Index, although there was no perceived difference on the NHP or GHQ-28 for carers. One significant difference in terms of delivery emerged from analysis of contact with physiotherapy

services. The home based group received median of 15 visits from a physiotherapist whereas the day hospital group visited a physiotherapist on a median of 31 times.

Lincoln et al (Lincoln et al. 1998) assessed 93 community dwelling stroke patients who had not been admitted to hospital, whilst examining the rehabilitation services the sample accessed. They noted that amount of therapy provided was not consistently related to impairment, particularly in relation to speech and language services. Although the authors of this study were unable to point to any single patient characteristic as a barrier to service utilisation, they do suggest that the low referral rates to rehabilitation services for the sample were to blame. Of relevance here is the author's suggestion that there appeared to be little rationality in the provision of rehabilitation services.

Geddes and Chamberlain (Geddes & Chamberlain 2001) have noted variation in the provision of community based rehabilitation services. They surveyed six community based rehabilitation teams concluding that the composition of teams varied and that the amount of face to face contact and total number of interventions also varied widely. The authors suggest that intensity of treatment is one of the factors that may influence the number of patients teams are likely to treat over a given period.

The literature regarding utilisation of rehabilitation services supports Unsworth's model of decision making within rehabilitation teams (Unsworth 1996). The key elements of the theme of utilisation, intensity and duration, are important as they have resource implications and may impact upon clinical outcome. Yet utilisation of rehabilitation services is not influenced entirely by patient need. This section has highlighted that organisational and resource contexts of treatment play a significant role in determining provision. Furthermore, non-clinical patient characteristics can also be seen to influence access to services. The idea therefore that service provision is determined in a context that is void of external influence, be that organisational or attitudinal, is highly questionable. It can be assumed that the current notion of what constitutes an intensive service is inconsistent between providers and

individuals. Against such a backdrop the issue of intensity of treatment in relation to efficacy and optimal patient outcome remain unanswered.

3.5 A Clinical Rationale for Intensive Treatment

'Essential to the regaining of effective motor performance is the provision of an expert coach or trainer (the therapist) and the opportunity for intensive practice and exercise.' (Carr & Shepherd 2000)

The above quote, taken from an influential text in physiotherapy, summarises the essential features of the intensive hypothesis in rehabilitation. The justification for the 'more is better' argument relies upon an emerging body of evidence located within a physiological framework centred on rehabilitation from neurological and orthopaedic insult and recovery of function. It is from this physiological base that we can begin to understand why it is that intensive therapy following a stroke and fracture is viewed as important and why the intensive therapy-positive outcome approach may become invoked as a hypothesis ripe for evaluation.

The focus for the intensive hypothesis is threefold, plasticity of the Central Nervous System (CNS), physical conditioning and motor re-learning. This part of the thesis reviews those fundamental principles for effective rehabilitation and views, from a professional perspective, the justification for the intensive supposition.

3.5.1 The 'New' Neurology

For a long time the established understanding that the CNS is a fixed entity, put forward by Broca impeded an understanding that the CNS could adapt (Broca 1861). In recent decades, however, the potential for the CNS to adapt following brain lesion has been accepted. Perhaps the most significant contribution in the area has been that proposed by Bach-y-Rita (Bach-y-Rita 1990) citing structural, organisational and neuro-chemical change as examples of brain plasticity. More specifically he cites a deal of 'sharing and taking over of

function' between different sites of the brain following damage. However, examples of research highlighting the establishment of new connections from cortical areas of the CNS and of a notion of homeostasis within some neurones whereby they will adapt following a reduction in input are dependent upon observations from animal studies. Changes have been noted in the intact tissue surrounding the lesion, as well as in other areas remote from the site of injury (Nudo & Friel 1999). Physiological and structural changes have also been observed in aphasic stroke patients (Thulborn et al 1999). Also the functional change related to swallowing in the early post-stroke period is deemed to be highly indicative of the reorganisation of CNS (Hamdy et al. 2000).

3.5.2 The CNS and Stroke Rehabilitation

Although this evidence, regarding Neuroimaging studies in stroke patients, indicate altered poststroke activation patterns, suggesting some functional reorganisation, questions regarding how this relates to outcome remain. Promoting change in the CNS following lesion is also regarded as one of the great challenges facing stroke rehabilitative intervention (Tallis & Pomeroy 2002). Furthermore questions relating to the limits of such change and to what extent can rehabilitation services intervene in the process of re-organisation are pertinent (Johansson 2000).

It is within the context of such challenges, questions and debates that the intensive hypothesis is often invoked, although until recently such arguments were largely theoretical. It was argued, for instance, that intense physiological stressing could promote restructuring (Laidler 1994). Furthermore, intensive task specific practice was viewed as central to re-organisation (Nudo & Friel 1999).

Evidence regarding CNS re-organisation as an outcome of rehabilitative intervention, however, is beginning to emerge. Stephenson points to the change in neuron cell structure following deprivation and stimulation in other mammals, adding that repetition and intensity of experience enhances the process (Stephenson 1993). He goes on to make the link between such

stimulation and 'sprouting' (the growth of collateral dendrites within cells) in monkeys and cats, the 'unmasking of latent synapses' (or re-organisation of CNS) in chickens and rats and 'regeneration' (re-growth of axions and dendrites) in humans. This evidence, he suggests, offers a model for physiotherapeutic neuro-rehabilitation. The core of this model is *'...intensive, repeated stimulation ...to place demands upon the system.'*

Constraint-induced movement therapy has been shown to result in significant functional improvement and resulted in plasticity as demonstrated by functional MRI (Levy et al. 2001). In addition, the combination of forced-use therapy and conventional physiotherapy was shown to enhance motor cortex excitability and improved motor performance compared to a conventional physiotherapy on its own, in one group of stroke patients (Liepert et al. 2001). Robot aided sensorimotor training has also been shown to be associated with a reduction in impairment and an increase in adaptation within the CNS for stroke patients (Krebs et al. 2000).

It is evident that there is potential for specific rehabilitation interventions to result in reorganisation and adaptation within the CNS following stroke or other brain lesion. The question regarding intensity of intervention, CNS changes and subsequent improvement in function does however remain.

3.4.3 Physical Conditioning

Prior to the re-learning of function it is the role of rehabilitation to enable movement through combating weakness of muscles following CNS or musculoskeletal lesion. It is argued that weakness can cause disability directly, such as the prevention of performance of motor tasks, or indirectly, through the creation of abnormal stress on other parts of the musculoskeletal system (Herbert 1995). Muscle weakness is also a predictor of poor outcome following stroke (Olsen 1990). Weakness and stiffness in muscle and changes in the recruitment of motor-units have also been identified as factors in loss of function following a stroke (Gardiner 1996). As such rehabilitative strategies aimed at counteracting muscle weakness can be viewed as a pre-requisite to

motor re-learning and therefore a pivotal component of the rehabilitative phase (Carr & Shepherd 2000).

Evidence regarding efforts to promote physical conditioning amongst older adults, for the purposes of prevention and recovery from muscular-skeletal and brain lesion supports the intensity hypothesis. Intensive training that induces fatigue may induce muscle strength (Rooney et al 1994). Similarly weight-bearing exercise has been shown to result in improved outcome in walking following stroke (Nugent et al 1994). Frail elderly patients recuperating from acute illnesses have been shown to benefit from intensive physical therapy, improving muscle strength, sit-to-stand manoeuvre times and maximum gait speeds (Sullivan et al. 2001). A self-managed exercise programme for older patients with osteoarthritis resulted in reduction in pain and improvements in strength and quality of life (Hopman-Rock & Westhoff 2000). A 10-week (3 days/week) program consisting of a warm-up, aerobic exercises, lower extremity muscle strengthening, and a cool-down for stroke patients resulted in greater muscle strength, gait speed, rate of stair climbing, and higher scores on the Human Activity Profile (HAP), and the Nottingham Health Profile (NHP) (Teixeira-Salmela et al. 1999). Also a high-intensity leg-strengthening programme was also shown to be of benefit to elderly patients with a variety of medical problems in terms of walking times and sit-to-stand time (McCool & Schneider 1999). Furthermore, significant association between strength gain and function has also been found (Chandler et al. 1998).

3.5.4 Motor Re-learning and Task

Adaptive motor behaviour following a stroke or femoral fracture may persist long after spontaneous physiological change associated with plasticity of the CNS or repair (Carr & Shepard 1995). Re-establishing motor control (the ability to regulate movement essential to tasks) following lesion, to either CNS or musculoskeletal system, requires a degree of motor re-learning (Shumway-Cook & Woollacott 2001). Furthermore, this re-learning may co-exist alongside interventions aimed at physical conditioning and the apparent

improvement in the performance of tasks aimed at physical strengthening may be as a result of learning.

Practice forms a central component of the process of re-learning. Successful outcome is dependent on repetitive practise that can enable greater co-ordination of muscular synergies (Carr & Shepard 1995). These authors argue that re-learning is a similar process to the learning of new tasks. As such the process moves from excessive motor recruitment (clumsy, slow) to the cultivation and refinement of more specific motor recruitment (specific, increased speed and accuracy). The role of the therapist in providing feedback and direction is essential in such an intervention. However, Laidler (Laidler 1994) argues that by repeating tasks when therapists are not available patients will add to the library of motor control. A theory similar to that of Schmidt's regarding generalizable motor programs and recall/recognition schema. Again the emphasis is on intensity of repetition.

Within the realm of occupational therapy task focused re-learning is perhaps more prominent with the promotion of negotiation with the client to identify relevant tasks, practice and feedback in a variety of different environments and circumstances as being central (Christiansen & Baum 1997). The focus within such an approach remains the individual goal and task and the manipulation of musculoskeletal demands in order to promote efficiency (Flinn 1995). Blocked practice, where tasks are repeated prior to the acquisition of a new task is promoted by some (Jarus 1994)where others maintain that a variety of tasks should be undertaken at the same time and practised at random within sessions (Poole 1991;Sabari 1991). Furthermore, the role of the therapist in occupational therapy is viewed as pivotal to the issue of practice. Sabari (Sabari 1991) points to the importance of the therapist as a regulatory condition during the repetition of tasks, providing physical support, guidance and mild cueing.

Speech and language therapy is also influenced by the motor re-learning model, in particular the area of dysarthria. Dworkin recognises that frequency of treatment is one of the more significant decisions to be made following initial evaluation (Dworkin 1991). It is also argued that given the correct resources

(tools and time) dysarthric non-talkers can respond to treatment (Netssell & Rosenbek 1985). Again the emphasis on practice and carry over remains an important component of treatment plans.

3.6 The Patient Perspective

A growing body of literature has also enabled us to view the intensity debate from the patient's perspective, utilising satisfaction as an outcome. Global satisfaction has been associated with firm social networks following stroke (Wyller et al. 1998), functional progress (Clark & Smith 1998) and return to independent living (Keith 1998). Patient satisfaction has been shown to exist with the implementation of clinical care pathways (Baker et al. 1998), community reintegration following ESD (Mayo et al 2000) and patient and carer education(Rodgers et al. 1999). In addition Hart has noted (Hart 1999) dissatisfaction with 'system induced setbacks', a term used to describe a lack of continuity between health and social care providers of community stroke services. However, the goal of assessing satisfaction with service interventions, and in particular intensity of treatment, has also been addressed. It has been noted, for instance, that differences in levels of provision are related to satisfaction in post-stroke care (Dijkerman et al 1996;Gilbertson, Langhorne, et al 2000;Pound et al. 1999).

Intensity of treatment, or rehabilitation intervention, has also been highlighted as a specific domain in the satisfaction literature following stroke. Kramer describes intensity of therapy services (as well as nursing and physician care) as the most tangible dimension of services and argues that intensity of treatment should be determined through consultation between patient and clinical staff (Kramer 1997). The provision of exercise programmes by physiotherapists was also a source of satisfaction with community based services (Pound et al 1999). Furthermore, these authors noted that the provision of such exercise related closely to prevention of what patients termed 'seizing up'. In contrast a lower than expected intensity of treatment following discharge has also been identified as a major source of dissatisfaction amongst patients (Carr & Shepherd 2000).

ESD from hospital to home has been shown to be important in terms of patient satisfaction following hip fracture (O'Cathain 1994). The Communication between nursing and other care staff during transition from hospital to home has also been cited as an important factor in patient satisfaction following hip fracture (Slauenwhite & Simpson 1998). Improved pain relief and nutrition strategies following hip fracture has been noted in relation to increased satisfaction (Hallstrom et al 2000). No literature relating to patient satisfaction, intensity and duration of therapy following hip fracture could be identified.

4 Organised Rehabilitation Services: Intensity of treatment

Intensity of treatment is a cornerstone of clinical practice and as such it might be compared to the issue of dosage within pharmaceutical trials. However, the issue, as a component of outcome following stroke and muscular skeletal lesion, remains relatively under-researched. Instead the question of place of treatment has provided the central theme in recent evaluation of therapy in older age following stroke or hip fracture.

4.1 Organised Rehabilitation: Is intensity of treatment a factor?

The focus for the attention on this issue has been as a result of policy change, clinical guidance and questions prompted by cost-effectiveness. In the case of stroke rehabilitation this includes research undertaken to compare specialist stroke units with general medical wards and the domiciliary setting. Evaluative research concerning hip fracture is more centrally focused on the comparison of geriatric-orthopaedic rehabilitation units (GORUs) with orthodox care. However, despite this emphasis, the focus on site and setting does provide those with an interest in the intensity debate with valuable insight. Such organised rehabilitation settings boast a more intensive approach both in terms of nursing care and physical, occupational and speech therapy. It will be shown that the question of intensity, although addressed directly in some studies, is a feature of the place and setting research agenda. As such those evaluations are relevant here.

4.2 Organised Stroke Rehabilitation

Several studies comparing the shift from general medical wards to specialist stroke units can be identified. Indredavik et al (Indredavik et al. 1998) carried out a trial allocating 110 patients to general medical wards and 110 to a specialist stroke unit with combined acute and rehabilitation function in Norway. At five years the stroke unit patients were more likely to be living at home and a significant difference existed in terms of death, again favouring the stroke unit group. Ronning (Ronning & Guldvog 1998a) (Ronning & Guldvog 1998b) (Ronning & Guldvog 1998c) undertook a similar study in, set in Norway, also confirming the effectiveness of the stroke unit to enhance survival rate.

Evidence suggests that long term survival rate is a benefit attributed to stroke units (The Stroke Unit Trialists Collaboration 2002). Case fatality at final assessment was lower amongst stroke unit patients in 15 of the 20 trials reviewed. Stroke units also performed well in terms of institutional care and level of dependency. An American cost-effectiveness review also concluded that organised stroke care, in the form of stroke units, was economically favourable (Cardenas et al. 2001).

4.3 Organised Hip Fracture Rehabilitation

A systematic review of studies concerning comparison of more organised rehabilitation and general orthopaedic care for geriatric patients who had suffered femoral fractures (Cameron, et al 2000) highlighted three RCTs (Kennie et al. 1988) (Reid & Kennie 1989) (Gilchrist et al. 1988) and one cohort study (Hempsall et al. 1990) relevant here. The review reported that length of hospital stay was greatly reduced for patients whose treatment was carried out on rehabilitation wards but that there were no significant differences identified in terms of mortality or ADL outcomes.

A Cochrane review evaluating evidence that compared Geriatric Orthopaedic Rehabilitation Units (GORUs) with general orthopaedic rehabilitation has also been undertaken (Cameron et al. 2001). The three studies listed above were all included in the review which also embraced five other studies totalling 1609 subjects. The review concluded that there were no significant differences in regard to survival, length of stay and readmission and functional status.

4.4 Organised Stroke and Hip Fracture Rehabilitation: Why the success?

Clear explanation of the success of more organised in-patient rehabilitation is difficult. Selection of patients prior to randomisation offers a rationale on methodological grounds. It is also argued that it is difficult to identify which components of care or rehabilitation result in a favourable outcome. Unpacking the characteristics of care becomes an essential exercise in response to this question and in doing so descriptive evidence of the nature of service settings becomes important. Wagenaar and Meijer (Wagenaar 1991) noted that it remained unclear for some time which component of care was significant in terms of patient outcome for much rehabilitation research and the success of stroke units may be attributable to the synergy between teams of professionals. As such, limited work has been done to describe the process of rehabilitation on stroke units in order to help explain this success and in doing so the issue of intensity has been addressed. Pound et al (Pound et al 1999) observed a high degree of interaction with therapists and nurses on a stroke unit when compared with a general medical ward, but less when compared to an elderly care unit. Whereas Lincoln et al (Lincoln et al. 1996) indicated that patients on a stroke unit were observed to have more interaction with therapists and nurses than patients on a general medical ward. They were also more often in the recommended position.

Given the relationship between organised rehabilitation and improved patient outcome as well as evidence suggesting increased face to face contact between therapists and patients in such settings, the possibility that intensity of treatment may be a factor in improved patient outcome begins to arise. As a consequence of this, and in addition to the arguments already noted, a

compelling argument that is suggestive of a dose response effect is feasible. This now brings us on to a review of evaluation of intensity of therapy as undertaken thus far.

5 Intensity of Treatment: Existing Evidence

The use of physical therapy services was observed to have a direct relationship with early discharge from hospital (Freburger 1999). But in order to evaluate intensity of treatment a more subtle distinction than use or non-use is required. This section of the review will take each available study identified. Each study will be described in detail and any conclusions regarding outcome will be noted.

5.1 Existing Intensity Evidence: Stroke

A retrospective analysis of amounts of therapy in an acute setting in the UK was undertaken by Wade et al (Wade et al. 1984). The study examined firstly how much physiotherapy and occupational therapy was given and secondly what factors could be said to provide reliable predictors of such intensity to a group of 162 patients recovering from stroke. The amount of therapy had a significant relationship with initial and eventual measures of ADL and arm function. From this the authors concluded that severity of stroke played a significant role in determining the amount of therapy provided. Intensity of therapy was also related to improved ADL outcome. Differences between the effectiveness and intensity of treatment between community based rehabilitation in Bradford and Nottingham are offered by Gladman et al (Gladman et al 1995) as an explanation for this apparent anomaly between these two similar studies.

Sivenius et al randomised all consenting eligible patients identified through a register maintained between 1978 and 1980 on an acute setting in Finland, 95 in total to intensive or normal treatment (Sivenius et al. 1985). Intensive treatment (IT) was provided twice a day by a physiotherapist for as long as required in order to achieve independent movement or functional recovery was

taking place. Normal treatment (NT) was provided on the general medical ward and was prescribed in the normal ways. At three months the IT group received significantly more rehabilitation days (45.7 compared with 37.1). This difference, in amount of therapy provision, did not exist at 6 and 12 months. At three months there was a significant difference on ADL scores in favour of the IT group and although this differences persisted at 6 and 12 months this was not significant. No difference was detected between the two groups in terms of death or institutionalisation. The authors conclude that intensive therapy on an acute setting is effective in the first three months although they do add that the effect of the study on 'normal' treatment might account for more effective treatment for this group.

Richards et al (Richards et al. 1993) reported a pilot trial involving 27 patients selected from a total of 215 stroke patients in an acute setting in Canada. Participants were stratified according to severity of stroke and then randomly allocated to one of three treatment regimes. The experimental group consisted of an early intensive, 'focused' approach to therapy, including techniques promoting gait relearning through loco-motor activities. A second group received intensive therapy described as more traditional. A third group received conventional therapy that had been provided previously, this started later and was not intense. The experimental group and control group one received early intervention (mean 8.3 days following stroke) and was intensive (mean 1.74 hours per day). The first control group also received early intervention (mean 8.8 days following stroke) and was intensive (mean 1.79 hours per day), although the nature of the therapy was different. The final group began its treatment later (mean 13 days following stroke) and was less intense (mean 0.72 hours per day). The three regimes enabled the authors to examine outcome against type, timing and frequency of intervention. Examination of the gait velocity revealed that the experimental group fared far better than the other groups, including the group receiving early, intensive therapy. Although the sample size was small the authors argued that the size of the effect was reasonable for rehabilitation studies and that if the effect were to be repeated in an RCT this would be a clinically important finding.

Two meta-analyses have been undertaken evaluating data from several intensity studies. The first, reviewed interventions of physiotherapy after stroke where intervention was provided at a greater intensity than the routine practice (Langhorne et al 1996). All interventions were equal in terms of technique. The review included seven RCTs, with a combined total of 597 patients. The review concluded small yet significant benefit relating to intensity in terms of impairment and disability, but these differences were not significant at twelve months. The authors concluded that there was insufficient information to allow informed decisions regarding intensity of treatment following stroke and that larger controlled trials were required. Kwakkel et al undertook a further meta-analysis of nine studies published between 1970 and 1996 (Kwakkel et al. 1997). The inclusion criteria were that the research evaluated the effect of intensity of physiotherapy and/or occupational therapy for stroke patients, that the design was experimental or quasi-experimental, that outcome was measured in terms of ADL and that the study was published in a book or journal. Kwakkel concluded that small but significant improvements could be detected in ADL as well as functional outcome variables. Furthermore, it was noted that such differences could be attributed to more intensive therapy.

Some studies have been undertaken in order to evaluate intensive treatment on specific impairments following stroke. Sunderland et al (Sunderland et al 1992) increased the amount of treatment from 'orthodox' to 'enhanced' and introduced behavioural methods to aid motor re-learning. At six months the intervention group showed small yet significant benefits in strength, range of movement and speed of movement. At one year, however, the significant difference had disappeared. (Sunderland et al 1994). This was attributed to a delayed improvement of the control group.

Two studies not included in the above meta-analyses looked specifically at intensity of treatment to the leg and arm following stroke. One study carried out in Nottingham (Lincoln et al 1999;Parry et al 1999) evaluated the impact of ten extra hours of physiotherapy provided over a five-week period. Patients were randomly allocated one of three treatments: routine therapy; intensive treatment provided by a qualified physiotherapist; intensive treatment provided

by an assistant physiotherapist. The study concluded that there was no significant benefit detected at three and six months. However, a post hoc analysis was performed and patients were divided into two subgroups dependent upon baseline assessment. Parry et al (Parry et al 1999) reported that for those recovering from more severe strokes, there was no significant difference detected, whilst for those recovering from less severe strokes a significant difference was found. Kwakkel et al (Kwakkel et al. 1999) evaluated both intensive leg and arm treatment in one study involving 101 middle cerebral-artery stroke patients. Patients were allocated to one of three groups: routine care with arm/leg pressure splint support; routine care with intensive arm treatment; routine care with intensive leg treatment. The principal differences existed between the leg training and control group. At week 20 the leg training group had higher Barthel, walking ability and more dexterity than the control group, although with the exception of dexterity these differences did not exist at 26 weeks. The arm training group only showed differences in terms of dexterity with the control group.

The hypothesis that only some patients benefit from more intensive treatment was amplified by an evaluation of intensity of physiotherapy on a stroke unit (Partridge et al. 2000). The study randomised patients to receive either 30 or 60 minutes of physiotherapy per day. There were no significant differences at either six weeks or six months although a subgroup analysis did reveal that those with less severe strokes achieved more favourable outcomes relating to the extra physiotherapy, these not were not statistically significant.

Changes in Medicare rules in the U.S. precipitated intensity research for stroke patients. Ruff et al (Ruff et al 1999) conducted a quasi-randomised study of the effect of one extra day of physical therapy following stroke. Patients in the unit traditionally received six days per week therapy. However, a change in insurance company meant that some patients were now provided with seven day per week therapy. The authors analysed patient outcome on the basis of this quasi-random split. No significant differences were detected in patient outcome (walking, ADL and continence).

Work has also been undertaken looking at the more limited outcome of length of stay in rehabilitation settings. Slade et al (Slade et al 2002) randomised patients (all aged under 65) to receive routine levels of treatment or 67 per cent more multi-disciplinary treatment. The experimental group had significantly shorter lengths of stay (14 days).

More recently a systematic review of the literature concerning different types of arm therapy following stroke (van der Lee et al. 2001) was suggestive of a dose response effect. The authors were unable to draw a conclusion regarding types of intervention. They did, however, report that differences in results might be attributed to intensity of treatment, with more intensive exercise therapy being beneficial to patients. They end by stating that stroke patients should be offered extensive opportunities to exercise the affected arm.

Here in the UK Wellwood et al (Wellwood et al 2002) conducted an RCT in order to evaluate an augmented treatment regime in three acute settings in Scotland. Seventy patients were involved in the study. The study set out to achieve a treatment ratio of 2:1, (augmented/control) but achieved only 1.6:1. The results were not significant, but indicated improved outcomes for the augmented group. For instance the likelihood of achieving independent walking over ten metres with the augmented treatment regime was 1.48 (-0.9, 2.43). The authors concluded that that the difficulties with establishing a significant finding were related to power and lack of clinically relevant separate treatment regimes. Chen et al have also undertaken a retrospective analysis of patient data in an attempt to examine for the determinants of intensity of therapy and to evaluate its contribution to patient outcome (Chen et al 2002). The authors did identify significant predictors of intensity of therapy (impairment and facility type) as well as a relationship between functional gain and intensity although in both cases the variance explained by the predictors was small and gains were weakly related.

In the domain of speech and language therapy the intensity hypothesis has also been investigated. Basso and Caporali (Basso & Caporali 2001) conducted a non-randomised pilot study with aphasic patients. Three patients were

subjected to one hour sessions five days per week with a speech and language therapist, whilst three others received two to three hours of therapy seven days a week. The authors concluded that the experimental patients achieved higher test scores and showed longer term progress.

All of the above studies identified were undertaken in in-patient settings. However, two other studies carried out in the primary care setting were also identified. These studies, although described by authors as intensity studies, were, strictly speaking, evaluating treatment versus no treatment. Weis et al (Weis et al 2000) looked at a small group of patients (seven) using a time series clinical trial of intensive exercise at home. Patients were assessed for muscle strength, walking speed, sit-to-stand, stair climbing, motor performance, balance, activity and depression. Significant change was detected in the areas of muscle strength, sit-to stand, motor performance and balance. Werner (Werner 1996) randomised post-acute stroke patients to receive an intensive multi-disciplinary rehabilitation service or no intervention. The authors did not make clear where the intervention was provided (home, day centre or rehabilitation centre). The treated patients benefited significantly in terms of functional independence, social activity and self-esteem.

5.1 Existing Intensity Evidence: Hip Fracture

Studies concerning intensity of treatment for those patients recovering from fractured neck of femur have also been identified. Karumo (Karumo 1977) compared outcomes of patients randomly allocated to physiotherapy twice daily or once daily. Unfortunately reported outcomes were limited to length of stay in the hospital setting. The study found a significant difference in mean length of hospital stay with those receiving physiotherapy twice daily having a mean length of stay of 32.2 days compared with 35 days for those allocated to once daily physiotherapy. In addition Hoenig et al (Hoenig et al. 1997) did report on a cohort of patients who had received more than and less than five sessions of physiotherapy per week in the 1980s. Hoenig et al found that for those receiving more intensive therapy there was an association with earlier independent ambulation. A similar study was undertaken by Mitchell et al who

randomised 80 patients to receive either standard physiotherapy alone or standard physiotherapy with additional quadriceps training (Mitchell et al. 2001). The group receiving the additional exercise (n=40) fared significantly better in terms of muscle strength, increased mobility and ADL skills. Ruchlin et al (Ruchlin et al 2001) compared conventional post-operative care (not described in the paper) with an intensive strength inducing programme with patient education. A cost-benefit analysis was carried out as well as an assessment of quality of life (SF36). However, the proportion of the experimental group receiving additional therapy and training were low (59 per cent and 72 per cent respectively). Notwithstanding this statistically different levels of change occurred between the two groups for physical limitation, physical functioning and social functioning.

Tinetti et al (Tinetti et al. 1999) reports on a single blinded randomised trial evaluating usual care at home following a hip fracture (including low level physical therapy) with systematic multi-component rehabilitation (an ongoing assessment linked to specific interventions provided by physical and occupational therapists). There were no differences in the proportion of each group attaining pre-fracture ADL, social activity levels, mobility or lower body strength. The intervention group did, however, compare favourably in terms of upper body strength and gait. Means et al (Means et al. 1996) noted clinically important, yet statistically non-significant, improvement in functional outcome following the use of an obstacle course to improve balance and mobility and to prevent falls.

Intensity of treatment following hip fracture in older people has also been addressed as a single component of an early intervention approach. Swanson et al (Swanson et al. 1998) randomly allocated 38 patients to receive early surgery, minimal analgesia, close multi-disciplinary monitoring and twice daily therapy and compared patient outcome with standard care (daily therapy, routine surgery, weekly patient review meetings). Mean Barthel scores were higher at discharge for the intervention group. Although no other significant differences, in terms of patient outcome, were reported the standard care group used more community services after six months. Given the nature of the

intervention in this case it is difficult to assume that any one component could be responsible for these patient benefits.

6 Existing Evidence: An overview.

In attempting to provide an overview of the evidence presented here (particularly the evidence relating to intensity of treatment) several issues should be raised.

6.1 Adherence

Half of the studies presented little information regarding adherence to the intervention. The remainder, although raising the issue of adherence, indicated that patient/clinician adherence was poor. In these cases the difference between intervention and control groups was shown to be statistically significant, but doubt concerning clinical or practical differences remained. For instance, one major intensity study (Sivenius et al 1985) claimed statistical difference yet the mean difference between therapy sessions over a three-month period was seven. Others indicated that only half of the target intervention had been achieved (Mitchell et al 2001;Parry et al 1999;Ruchlin et al 2001;Ruff et al 1999;Wellwood et al. 2003).

6.2 Compensatory Services

The recognition that the evidence, relating to intensity of treatment and ESD evidence, is that evaluation is often provided in the context of a routine clinical setting, raising disquiet about the issue of compensatory provision for control group patients. ESD evaluation research is prone to the effect of control group patients receiving at least some effort on behalf of therapists or nursing staff to attempt to ensure discharge. Intensity evaluation is also open to such protocol deviation in the form of compensatory provision. Two of the studies describe at least the possibility of this occurring. One of these studies (Parry et al 1999) indicated that a proportion of the control group (non-intensive) actually received more physiotherapy than the intervention group.

6.3 Power

The sample sizes reported in the intensity literature appear small. The sample sizes reported here ranged from seven to 282. Although it is difficult to claim what proportion of these studies were under-powered, since most made explicit the calculations used to decide upon a desired target sample, the failure to indicate statistical difference in many of the studies might be illustrative of a common problem. Recruitment in rehabilitation research has been noted by others (Wade 2003) and continues to provide a major obstacle in the nurturing of an evidence base. It seems here that the failure to recruit large numbers to controlled trials is more a feature of eligibility criteria than failure to consent. This may also be indicative of a wider problem in rehabilitation research, that of the heterogeneous nature of recovery within seemingly homogeneous groups (i.e. Stroke or hip fracture) and the need for rehabilitation research to isolate specific groups (i.e. left stroke/right stroke) within the broader patient population. It is also indicative of the apparent desire to exclude some patient groups (those with a diagnosis of dementia or aphasia) from participation in research.

6.4 The Outcome Focus

The striking feature of much of the intensity evidence is the primacy given to the measurement of outcomes seemingly bound within the dimension of impairment or at most impairment and activity. A critique of the evidence presented in the review would not also be complete without shifting attention, away from the purely technical matter of 'doing experimental research', towards an appraisal of the broader epistemological issues. All of the evidence presented was by definition limited to RCTs and other quasi-experimental designs. The outcomes prescribed in all of the studies were of a clinical nature (muscle/limb function) activity based (ADL) or economic (resource use). This focus on outcomes that exist within the professional/clinical/researcher premise hides the potential to view the intensity debate from a different perspective: that of the patient. Whilst it might be argued that patients may indeed share

some common ground with outcomes bound within the clinical or economic dimensions, reliance on these preclude assessment and evaluation based upon patient centred outcomes. Little work has been done to find out what these might be let alone in developing the tools to measure such outcomes. Increasingly it is becoming clear that acknowledgement of other forms of evidence will enhance our understanding of these issues (Evans 1999). Different research designs, principally qualitative in nature (although mixed method approaches might also be proposed), might provide the means to address other 'socially valid' patient centred concerns.

7 Conclusion

The number of older people, as a proportion of the UK population, is increasing. Furthermore, the stability over time in the proportions of older people experiencing disability enable the sound prediction that there exist implications for the use of community based services (Jarvis & Tinker 1999). More specifically this review has indicated that the incidence and prevalence of morbidity due to stroke and hip fracture is greater in older populations. Under such circumstances the efficacy of health services, and in particular rehabilitation services aimed at reducing the prevalence of morbidity following stroke and hip fracture, is therefore significant. Evidence concerning the efficacy of ESD following stroke or hip fracture is growing. Thus far, the indications are that ESD is a feasible policy alternative. Furthermore, early evidence suggests that domiciliary-based therapy, as a specific form of community rehabilitation, is also effective. Policy initiatives have also contributed to the burgeoning number of services provided in the homes of older people recovering from a stroke or a hip fracture.

Utilisation of therapy services is central to the issues of efficacy. The 'more is better' hypothesis is dependent largely upon clinical reasons, especially those concerning plastic change following lesion and physical conditioning. A patient perspective also suggests a requirement for more intensive services. The evidence suggesting that more intensive rehabilitation service provision results in patient benefit is favourable yet underdeveloped. Evaluation of organised

rehabilitation suggests that intensity of care and treatment may, in part, be an explanation of its success. However, the focus of all existing intensity evaluation thus far has been in in-patient settings. Given that the rise in intermediate and community based rehabilitation is inevitable, efficacy of intervention in these domains will be pivotal to the future of services. More specifically, intensity of domiciliary-based rehabilitation services is an area ripe for evaluation.

Chapter Two: Methodology

This chapter outlines the methods used in this study. It is divided into three distinct sections. The first section deals with major issues relating to design. The second section outlines the trial implementation, describing development, piloting, implementation and dissemination of results. A final section describes decisions made concerning outcome measurement.

1 Design Considerations

Reduction of bias and subsequent risk of exaggerated effect (Schulz et al. 1995) was a primary concern for this study. As such a Randomised Controlled Trial (RCT) was initially proposed as the most appropriate way of addressing the question. There also existed a relative absence of such experimental evaluation of the intensity of treatment within primary care in the rehabilitation literature (Keith 1997), yet growing utilisation of the design in rehabilitation research on the whole (Tate et al. 1999). However, prior to the start of the study a process of consultation with clinical staff and managers was undertaken in order to assess feasibility and appropriateness of this approach. This process is outlined throughout this chapter.

A reluctance amongst clinical and managerial staff to accept randomisation, without first considering alternatives, was the subject of early discussions. In particular two competing strategies were suggested by clinicians. These were: historical comparison and a patient preference model. A broad assessment of these methods will be followed by their feasibility in relation to this study.

1.1 Historical Comparison

The use of historical comparisons has been proposed as a design that may, potentially, moderate the need for randomised contemporary samples. However, Pocock dismisses historical trials as inadequate on the grounds that patient selection may be less clearly defined and that selection for the contemporary experimental group may be more selective that historical group selection

(Pocock 1994). He also cites changes in quality of recorded data, changes in ancillary support and the difficulty of excluding retrospectively as other concerns around the historical design. He also cites several examples where historical designs have exaggerated the effect of intervention. Altman (Altman 1991) maintains that the use of historical comparisons should be restricted to tightly controlled circumstances. An historical design was considered and discussed but this was not feasible in this study for reasons of assignment, lack of comparable data and the changing nature of the teams (CRTs only served the North of the City of Sheffield as recent as January 1999).

1.2 Patient Preference Model

A patient preference model of randomisation (Silverman & Altman 1996) was considered for this study. This model proposes that patients are given the opportunity to be treated with their preferred option, in this case intensive or non-intensive therapy, with those patients who do not have a preference being randomly allocated. Again this strategy was discussed with clinicians at an early stage but rejected on the following grounds on the grounds that it might introduce bias. Although this model may have the advantage of increasing recruitment by giving patients more control over the treatment process, its use in the context of this study was viewed as problematic. It was felt that such a model may generate a difference between the two arms of the study. Health locus of control was one area where patients may differ, the rationale being that patients preferring less intensive therapy may not be as accepting of therapeutic interventions as those preferring a more intensive regime. The main concern was however, that patients recovering from more severe impairments might naturally wish to receive more therapy. The use of a patient preference model may well have led to an imbalance between the two groups in the degree of impairment and disability. Indeed this fear appears to have been born out. During consent meetings the implications of the study was discussed with patients. Those patients recovering from more severe strokes generally held the view that involvement in the study might jeopardise their receipt of a five-day service. Patients recovering from hip fractures were more concerned with what can be termed the possibility of unnecessary intervention.

Following a rejection of these methods, other non-randomised strategies were considered with clinical staff. Again a general assessment of these is presented alongside the feasibility to this study.

1.3 Judgement Assignment

Although the need to ensure 'balance' in terms of demography, age and so on is important, attention on the need to safeguard for assignment bias is paramount. It is argued that such assignment may also lead to bias (for instance allocation by investigator or clinician) (Roberts & Torgerson 1998). Altman and Bland argue that assignment that interferes with randomisation may lead to patients being referred to studies for the wrong reasons (Altman & Bland 1999). For instance a clinician may refer only those patients who he or she feels will succeed. Pocock (Pocock 1994) calls this 'judgement assignment' and would account for the exaggerated effects concerning RCTs that fail to report randomisation adequately (Schulz et al 1995). Judgement assignment was considered to be a significant issue in the development of a robust research design and was discussed with clinicians at an early stage. It was suggested that clinicians make the decision to place patients in the 'experimental' group. This was rejected on the grounds of bias due to judgement assignment.

1.4 Systematic Assignment

Pocock also adds that systematic assignment, the allocation of treatment based on some unrelated basis (such as birthdays falling on even dates) may lead to potential bias. Such systematic assignment has a clearly identifiable method for assignment where investigators can predict the potential intervention of a patient referred to a trial. The following non-randomised and quasi-randomised designs were considered for use in the study but rejected, mainly on the grounds that there would be a risk of group related threat.

1.5 Cluster Randomisation

One further option was to utilise a cluster randomisation model whereby patients within a particular team would be provided with an enhanced service. However, the use of such a design would have implications for resources in that particular cluster (CRT base) chosen to provide the enhanced service. Cluster randomisation is often used in trials where contamination is a risk (e.g. health promotion interventions), given that no risk existed there did not appear to be the need to take action to prevent this.

1.6 Zelen's design

Zelen's design (Zelen 1979) was also considered. In such a design all patients are randomised to receive standard or experimental treatment, only those allocated to the experimental treatment are approached for consent. This design does not require a positive consent for all participating patients and was viewed as unfavourable on ethical grounds.

Following such consideration it was decided that the study be conducted through the utilisation of a parallel RCT. This approach would protect the study from the problems associated with non-randomised alternatives described above. Such an approach would also increase the potential to achieve balance in both groups. I shall now turn my attention to specific strategies aimed at achieving a satisfactory randomisation procedure, stratification, blinding, consent and the provision of a sound basis from which to undertake data analysis.

2 Quality Assurance in RCTs

The significance of adequate planning and management of an RCT in terms of evidence bias has been underlined in the development of reporting guidelines (Begg et al. 1996). The guidance, motivated by the knowledge that poor reporting and trial administration is associated with bias and exaggerated findings, describes adequate description of the hypotheses to be tested, the sample studied, allocation, accounting for all randomly assigned patients and

the provision of information on outcomes as being essential components (Freemantle et al. 1997). The detailed design of this study endeavoured to meet with such standards outlined by Knatterud et al (Knatterud et al. 1998).

2.1 Ethical Approval

An application to obtain ethical approval was made to North Sheffield Ethics Committee in February 1999. The committee raised questions regarding the exact wording of the patient information leaflet. An amended version was submitted some time later (see Appendix II). The final changes were made and ethical approval granted in June 2000 (see Appendix III).

Each component of the study will now be addressed. This description of decisions taken during the design phase will reflect upon advice obtained from the literature and the specific implementation of systems for the study.

2.2 Randomisation Procedure

Schulz (Schulz 1995) maintains that the 'human spirit' leads to subversion of randomisation but this can prevented with: *assiduous attention to design and implementation.* In particular attention should be focused on attempts to safeguard the authenticity of the randomisation procedure (such as the prediction of allocation by looking in sealed envelopes). Attempts to undermine randomisation have been described by others (Martyn 1996). However, for reasons of self-reliance and blinding a decision was taken to give CRT staff the responsibility for allocating patients. This was done to avoid unnecessary delays in allocating patient intervention, due to absence of members of the research team. At this stage it was also assumed that members of the research team (TR) would be undertaking at least some of the follow up assessments and blinding was therefore also an issue. However, there were concerns that the allocation may be corrupted if the CRTs themselves were given the allocation task. It was decided that necessary safeguards needed to be put in place. Administrative staff were given the responsibility of the procedure in each of the four teams- removing this responsibility from the therapists themselves. Pocock (Pocock

1994) suggests the use of a table of random numbers to allocate treatment or the use of computer generated sequences of numbers. He too advises that researchers use robust systems to prevent subversion. For reasons of stratification administrative staff were given two boxes (one with allocation envelopes for trial participants recovering from hip fracture and one for patients recovering from stroke) containing allocation envelopes. Each envelope contained a slip of paper determining intervention. The order of these allocations was decided using a random numbered table made up of permutations in blocks of ten. Each envelope was numbered and its contents and the envelope number were recorded and kept by TR. Whilst carrying out the allocation procedure, administrative staff were requested to record both the allocation and envelope number. The research team (TR) monitored allocation and envelope numbers at regular intervals to ensure that the procedure was being adhered to.

2.3 Stratified Randomisation

In some circumstances there may well be a case for stratifying the randomisation procedure. Stratification helps ensure that both experimental and control groups are balanced in terms of demography, gender, severity of disability etc. However, the use of stratified randomisation is not advisable in some circumstances . Firstly, very large trials involving hundreds of patients should arrive at equilibrium because of chance. Secondly, if a smaller trial lacks the capacity to monitor stratified randomisation accurately errors may result, hence it is perhaps more appropriate that other methods are used. Finally, stratification need only be used in circumstances where concomitant patient characteristics are well known. Pocock argues that stratification can occur when a trial is not sufficiently large enough, when randomisation is well monitored and where extraneous patient characteristics are well defined (Pocock 1994). In particular Pocock points to stratification on the basis of location or participating institution and advises against stratification unless necessary. He maintains that large trials will themselves generate the necessary balance required. Furthermore, Pocock regards the use of over stratification in circumstances where the monitoring of the procedure is difficult as well as hazardous (p81).

2.4 Stratified Randomisation Procedure

Stratified randomisation was used in this study. However, its use was limited to aetiology. Given that the research question sought to evaluate outcomes from two distinct groups of patients, it was felt that it would be necessary to ensure that these two groups were sufficiently well represented in both intensive and less intensive arms of the trial. Further stratification for severity of impairment was considered but not employed, due to the administrative work this would have created. Administrative staff within the CRTs were given the task of allocation. There were four such CRTs involved in the study, one in each sector of the City. Each CRT administrative worker was given two allocation boxes, one containing allocation envelopes for patients recovering from a stroke, the other containing allocation envelopes for patients recovering from a hip fracture.

2.5 Blinding

Blinding represents one of the most important methodological components for the reduction of bias (Schulz et al. 1996). In the context of rehabilitation trials the significance of blinding has been emphasised (Siemonsma & Walker 1997). These authors indicate several potential sources whereby the treatment allocation of the subject may be unveiled. This article is significant in that it offers sound advice with regards to the practical implementation for RCTs in community settings. They argue that the disclosure of information in an office environment, un-blinding by patients and by fellow therapists may result in un-blinding and ultimately risk bias. Siemonsma and Walker also stress the significance of monitoring potential sources of un-blinding and the importance of the reporting of such instances is important.

2.6 Procedures to Aid Assessor Blinding

An agreement with Community Health Sheffield Therapy Services was reached whereby all follow up assessments would be undertaken by therapy staff.

Resources were made available to do this. However, in order to maximise the potential of blinding all follow up assessments were completed by assessors working outside the team treating the patient, the result being that assessors should have been unaware which arm of the trial the patient had been allocated to. Assessors were also requested to report instances of un-blinding, in particular by patients and carers, prior to and during follow up assessments.

2.7 Procedures to Aid Patient Blinding

The issue of patient blinding is somewhat less clear. The subject of randomisation was discussed during each consent meeting and patient information explicitly described the issue. Although, patients were not informed which arm of the trial they had been allocated to, the frequency of contact with CRT staff may have led them to guess the allocation. It must therefore be assumed that they were knowledgeable of their allocation and hence were not blinded during the trial. The issue of patient blinding in rehabilitation evaluation will be discussed later in this thesis.

2.8 Informed Consent

The need to establish informed consent prior to patient involvement in RCTs has been widely acknowledged (Ellenberg 1997;Tognoni & Geraci 1997). Despite this widely held acceptance, adherence to its implementation is not universal. Edwards et al (1998) cite examples where consent in medical research has been side-stepped or given minor attention. In an attempt to improve methods of informed consent Lavori et al (Lavori et al. 1999) argue that the methodology concerned with establishing informed consent should itself be the subject of experimental research. However, in establishing the cornerstones of informed consent they cite assessment of capacity to consent, disclosure of relevant information, ensuring the patient understands the information, voluntary choice and written records as the key elements.

2.9 Consent Procedure

It was the original intention to conduct consent meetings within the hospital setting prior to discharge. However, following meetings with nursing staff responsible for liaison with patients and their carers prior to discharge this intention was reviewed. The primary reason for reviewing this strategy was that it was felt that staff often 'sold' the notion of Early Supported Discharge (ESD) as an intensive programme of therapy and after care. Although they acknowledged that this was not the case, they were uneasy that discussions regarding intensity of treatment would take place with patients prior to discharge as it might result in anxiety and reluctance for patients to be discharged. A secondary reason was that it was felt that patients might make a more informed choice if they were provided with information and time in their own homes when considering whether to participate in the study. Hence it was decided to contact patients within seven days of their return home (or first contact with CRT) in order to discuss their possible participation.

2.9.1 Referral

Senior therapists were requested to refer patients to the study in line with detailed protocol. Broadly speaking these criteria were: aged 65 and over; recovering from a hip fracture or CVA; living at home (not in residential or nursing home care); not suffering from secondary complicating aetiology (specifically: Parkinson's Disease; Dementia); consenting to receive treatment from CRT. Referrals were passed to Team administrative staff, using a referral sheet. Administrative staff telephoned TR, who took details and entered data into an MS Access database.

2.9.2 Contacting Patients

TR made initial contacts by telephone. If patients were happy to meet in order to discuss involvement in the study, a date and time were arranged. Initially first contacts were made within two days of referral. However, the frequency by

which patients refused initial discussion because of other visiting professionals and occupation of time following ESD was high. Following discussions with CRT staff it was agreed that the first contacts be delayed until around about five to six working days following initial CRT contact.

2.9.3 Consent Meetings

During consent meetings patients were provided with a verbal description of the study, followed by written information (see Appendix II). Patients and carers were then given a chance to ask questions and discuss. They were then asked if they would consider participation in the study. Following positive consent, patients were requested to sign a written form (see Appendix IV). Difficulties in recruitment were experienced through the recruitment phase of the study. Details concerning these difficulties will be explored in the results section of this thesis. However, following early difficulties TR and PE met with the Chair of North Sheffield Local Ethics Committee to discuss modification to the wording of the patient information sheet. These changes were accepted and a slight improvement to recruitment rate was noted.

2.9.4 Informing CRT of the Outcome of Consent Meetings

Following consent meetings, CRT administrators were informed of the outcome. The consent forms of those patients who consented to participate were then faxed to the relevant CRT office.

2.9.5 Trial Register

A Micro Soft (MS) Access database was used to record information regarding all referrals to the study. This database was retained under protected conditions, only accessible to TR and a University administrator. The database recorded basic details such as date of birth, aetiology, date of admission to hospital, NHS number, and address, including postal code.

Following consent the details of patients were entered onto a separate MS Access database file. Added to the original MS Access file were the dates for

follow up assessment. This file was then searched on a monthly basis for forthcoming assessments, which were shared with the appropriate assessor.

2.10 Sample Size

The sample size calculation was based on a clinically relevant change of two points on the Barthel Index. This was also the change used by Young and Forster(Young & Forster 1992). Altman's nomogram was used to determine the sample size on this basis (Altman 1991). The standardised difference (0.4) was calculated assuming a standard deviation of five, which was estimated using data generated previously by CRTs. With a 5 per cent significance level (two tailed) and power of 80 per cent a sample size of 100 per arm was estimated (200 patients in total). No allowance was made for patient drop-out.

3.0 Phase One: Engaging CRTs

Good communication and robust systems are essential for a successful RCT (Farrell 1998). Phase one of the study had the aim of establishing these essential characteristics. Phase one had three distinct objectives: promoting the aims and methods of the study, establishing communication (with each of the four teams and senior colleagues) and detailed protocol development

3.1 Promoting the study

It was essential that CRT staff understood both the aims of the study and the methods of implementation. Verbal presentations were given to senior staff and to each of the four teams, comprising also therapy assistants and administrative colleagues. The importance of the study in terms of efficacy, lack of available evidence and future practice development was underlined. Broad design issues were also addressed at these meetings.

3.2 Establishing Communication

Efforts in this first phase of the study also emphasised negotiation regarding access to patients and attempts at problem identification and solution. It was anticipated that there was to be a degree of unease amongst the teams about the study. Time was devoted to ensuring that discussions aimed at addressing this unease were able to take place.

3.3 Meeting Senior Managers

Two months prior to the beginning of the study meetings were held with the senior personnel responsible for managing the services. These meetings were designed to allow managers to become acquainted with the aims of the study and possible implications for the teams. At the very first of these meetings a degree of anxiety was expressed about the study. Two of those managers directly responsible for the service expressed the need for a great deal of discussion about the study before it could begin and concerns about patient safety were also articulated. Assurances about these were provided. It was also noted that the research question itself was not a priority to the community rehabilitation teams in Sheffield at the time. The significance of the study in relation to the evidence gap and efficacy were underlined during this meeting.

3.4 Meetings with Teams

At the earliest opportunity TR met with Senior Therapists and Team Leaders. The purpose of this meeting was not to begin detailed discussions about how the trial might work, but rather to begin to identify issues of concern. Nine senior staff (including one Psychologist) and one administration co-ordinator attended the meeting. The aims of the study were introduced and a brief description of the methods was provided. The subject of the discussion that followed ranged from practical and logistical points through to technical and ethical issues.

3.4.1 Concerns Expressed During Phase One and Procedures Aimed at Reducing Concern

It is important here to describe these issues as they form part of the discussion which occurred during the months of the development phase, prior to the beginning of the trial. They also highlight the methodological difficulties associated with evaluation of community-based rehabilitation and throw up important theoretical points of interest regarding the perception of therapists about their role in the lives of patients.

3.4.2 Concerns Regarding Randomisation

Randomisation is not a procedure that is 'intuitively appealing' (Pocock 1994). Reducing decisions about care to such a random procedure seemingly undermines the role of the clinician and if taken at face value its use contradicts the clinical aim of providing the best possible care and treatment to patients. The rationale for its use rests upon the research design and methodological requirements that may at first appear alien to some clinicians or practitioners. Indeed early anxieties expressed by therapists can be attributed to concerns about randomisation. At this stage the function and implementation of randomisation was not clear to therapists. Senior therapists were initially reluctant to surrender their role in the decision regarding the frequency of contact with a patient. To defer to the opening of an envelope in this respect was uncomfortable. But exactly why randomisation was viewed in this light is unclear. The absence in the study of any attempt to explore this issue systematically with therapists means that the answer to this is speculative.

Professional control became a feature of these discussions. Therapists, without a full understanding of the purpose of randomisation, requested a role in selecting who should take part in the trial and which arm of the trial they be allocated to. This indicates that, for whatever reason, therapists wished to retain control over what they saw as a purely arbitrary method of allocating their own time and resources. This issue will be explored in further detail in the discussion section of this thesis.

3.4.3 Concerns Regarding Treatment Allocation

The nature of the research question and decision to control for intensity also caused concern for therapists. The study set out to allocate patients to receive either six or more or three or less visits per week from a therapist. This reflects current provision by CRTs in Sheffield. Analysis of contact sheets for the months of November and December 1999 indicated that the mean number of visits was 3.04. Assurances by Team managers that this reflected established practice were also given. Despite this concern on the grounds of treatment denial and patient safety were expressed.

3.4.4 Treatment Levels

Although the mean number of visits for patients was approximately three per week, there were some patients, particularly those recovering from a stroke, who received five visits per week for at least the first week of treatment by the CRT. However, it was viewed as a necessary response to the needs of some patients. The issue therefore of providing less treatment to some patients was troublesome in the minds of therapists at this stage. One senior therapist noted that she would find it hard to 'stay away'.

3.4.5 Patient Safety

Patient safety was of particular concern for those patients recovering from a stroke who were discharged earlier than others and who were treated by the CRTs. Therapists felt that these patients do require daily visits. However, it was acknowledged that the nature of these visits was not necessarily to aid rehabilitation, but to establish that the patient's medical status was not deteriorating. Such visits allowed therapists to monitor chest condition for instance.

3.4.6 Procedures Aimed at Addressing Concerns

The detailed protocol for this study can be viewed in Appendix V. It should be noted here that the two areas of concern regarding 'reduction of treatment' and patient safety were addressed in this protocol. First, a degree of flexibility was built in to the protocol. Therapists who had concerns about a patient on the non-intensive arm of the trial could:

1. Count the number of visits over a two-week period, leaving flexibility to increase the number of visits in a given week.
2. Approach their team leader with concerns. Following this expression of concern approaches could be made to TR to discuss crossover.

3.5 Meetings with Administration Staff

During phase one TR engaged with administration staff (four in all) in order to consult and begin to establish procedures and documentation. The outcomes of these discussions led to the development of the referral and consent process described above and all the necessary documentation.

4.0 Phase Two: Piloting

A distinct pilot study did not form part of this study. However, an internal pilot, similar to that described by Wittes and Brittain (Wittes & Brittain 1990), was used. This is essentially based on the designation of a small part of the main trial in order to finalise the detailed protocol and trial administration.

4.1 Internal Piloting

This phase of the study took place between July and September of 2000. Meetings were held with each of the teams during this phase. TR also met with team Leaders during this phase.

4.2 Changes Following Pilot Phase

Two major changes to the detailed protocol were implemented following this phase. The first change concerned those on the intensive arm of the trial. The source of this change came from therapist concern that patients allocated to the intensive arm of the trial were being provided with an intensive service almost up to the point of discharge. It was felt that it would be more helpful if this intensive provision could be 'phased out' if the therapist determined that the patient did not clinically need the intervention. It was agreed that those patients allocated to the intensive arm of the trial could have the visits decreased in the three weeks prior to discharge. The second change concerned baseline assessments. Initially Senior Therapists were requested to carry out baseline assessments following randomisation. There were concerns, however, regarding the quality of the data collection. Missing data and delayed assessments gave cause for concern. It was decided that TR would conduct all baseline assessment from September 2000 onwards.

5.0 Phase Three: Trial Monitoring and Management

Recruitment and treatment began in July 2000 and ended in August 2002. However, recruitment and treatment of patients recovering from a CVA did not begin until mid-August of 2000. This was due to delays in the completion of another study concerning community stroke rehabilitation. The table below (Table 2.1) summarises ongoing monitoring and operational tasks, with appropriate action and frequency

5.1 Rate of Referrals and Trial Allocation

It was necessary to monitor the levels of study referrals in relation to actual workload of the team. This would not only aim to sustain a satisfactory referral rate but also avoid judgement assignment. This was done by holding face to face meetings and telephone contact with CRT administration staff in each of the four sites. Each Team Administrator was also requested to complete and return recording sheets listing allocations (patient ID, name, date, allocation and

allocation envelope number). These were collected during site visits and checked against an existing record.

5.2 Treatment Compliance

Each face to face contact between therapist (or therapy assistant) and study patient were recorded on a contact sheet. These were collected as CRT discharged each patient. Data were entered periodically and analysed in order to monitor treatment compliance. The results of this analysis were presented to each of the four teams at six-monthly intervals.

5.3 Ongoing Communication

Aside from regular requests for advice and information regarding trial implementation, time was also set aside to ongoing communication with the teams and staff. These activities are summarised in Table 2.1 below.

Task	Action	Frequency
Rate of referrals	1. Site visits	6-weekly
	2. Contact with administration staff	Weekly
Allocation	1. Site visits	6-weekly
	2. Contact with Administration staff	Weekly
Treatment compliance	Data collection and analysis	6-monthly
Ongoing communication with teams	Attending team meetings	Quarterly
Ongoing communication with Senior therapists	Attending team meetings	Quarterly

Table 2.1: Summary project management tasks

The purpose of these discussions was to update staff on recruitment progress, inform them of monitoring, remind staff about completion of necessary documentation and to thank them for their continued support and help.

6 Outcome Measurement

Outcome measures were selected using those available to TR during the period February to June 2000. Copies of tools used to gather the data can be found in Appendix VI. Alongside the obvious requirement for measures to be well tested for reliability and validity the selection criteria for outcome measures contained five elements (classification of impairment, function, activity and participation, aetiology, compatibility with participating clinicians, patient attrition and meta-analysis). The process of deciding on a range of measures to meet with these criteria will be discussed shortly. Tables (2.2 and 2.3) summarising the outcome measures that were considered against this criteria, including those rejected, are presented at the end of this section. However, it is useful at this stage to outline the criteria in order to provide a context within which final decisions were taken.

6.1 WHO ICF: Criteria for selection of outcome measures

The ICF provides a theoretical and operational tool for understanding the experience of ill health and disability. As such it provides researchers and clinicians with a method for evaluating outcomes for patients on a number of levels. During the study the ICF was being developed and changes made included the development of context as a factor. However, the three principle cornerstones of ICIDH (impairment, disability and handicap) remained, albeit re-labelled impairment, activity and participation. As such measures seeking to assess the areas of impairment, functional performance, social integration provided the first criteria for selection for outcome measures. It should also be noted that psychological well-being is considered within WHO ICF as forming one element of impairment. However, given the distinction between physical impairment and mental impairment it was felt that a separate measure was required in order to address this divide. Furthermore, the inclusion of a separate

measure is reflective of the significance of psychological aspects of impairment when considering patient outcome(Astrom, Asplund, & Astrom 1992) .

Whilst making final decisions regarding measures, assurance that each of these four domains were addressed was essential.

6.2 Aetiology

Patient eligibility for inclusion in the trial rested upon age and two specific impairments, hip fracture and stroke. The justification for this decision is discussed elsewhere. The decision to broaden the focus of the study to include two impairments did impact upon the criteria for outcome measurement selection. The discussion below will highlight that there were some very sensitive measures that could be used to evaluate changes in functional performance, however these also remained specific to only one of the impairments. It was therefore essential that measures chosen were generic to both stroke and hip fracture.

6.3 CRT Compatibility

Thirdly, was the question of acceptable degree of compatibility with current tools utilised by the CRTs in Sheffield. It was felt that requesting that both patients and therapists undertake a separate batch of measures, in addition to the measures already being completed, might prove onerous for both parties and possibly unethical. It was therefore felt that part of the criteria for selection should be compatibility with current practice.

6.4 Patient Attrition

Alongside the logistical issue of CRT compatibility there was also a necessity to limit the time patients would be expected to invest in being assessed. First, it was felt that time was relevant to the level of patient attrition. Second, length of time is also relevant to patient tiredness and was an expressed concern of

therapists. A balance between desirability of a given outcome measure and length of time taken to administer was required.

6.5 Meta-analysis

Finally, compatibility with other studies formed part of the decision-making process. It was felt that the findings from the study might be utilised as part of any future meta-analysis. Hence outcome measure selection would need to be partially consistent with earlier studies carried out under the banner of community based rehabilitation evaluation. Although this was not a central consideration, it was felt that core measures previously used should be examined in a favourable light.

In order to examine in more detail the process of decision making regarding outcome measurement it is necessary to offer a description of the decision making exercise. This will be dealt with by dealing in turn with the four domains at the centre of the evaluation, impairment, activity, participation and well being.

6.6 Impairment Measurement

There exist very few generic measures of impairment available to the researcher. Those considered here, were specific to stroke as the cause of impairment. In particular the Action Research Arm Test (ARAT) (Lyle 1981), the Motor Club Assessment (MAC) and the Rivermead Motor Assessment Test (RMA) (Lincoln 1979) are all well validated and reliable measures of dysfunction, but are limited to patients recovering from CVA. For the purposes of measuring outcome for patients recovering from hip fracture, these measures would prove inappropriate. Therapy Outcome Measures (TOMS) (Enderby et al 1998) proved advantageous on three counts. Firstly, TOMS can be used to assess outcome for both patients recovering from CVA as well as orthopaedic patients. Secondly, the measures are quick and easy to utilise. Finally, TOMS was already in use amongst the teams and hence posed few problems in terms of patient attrition and assessor training. The Euroqol (The Euroqol Group 1990)

contains a specific item concerning pain and is extremely short. Hence TOMS and the Euroqol were chosen as measures to address the dimension of impairment.

6.7 Disability Measurement

The measurement of functional performance provides greater scope for the researcher, with a range of tools available. The outcome measures considered here were the Barthel Index (Mahoney & Barthel 1965), TOMS, the Rivermead ADL Index and the Katz ADL Index (Katz et al 1963). In addition it was felt that some items of the Euroqol also measure some aspects of functional performance such as mobility and self care.

The Barthel Index had four distinct advantages over other measures of disability. First, it has been widely used and although developed over twenty years ago, it continues to provide a reliable and valid measure of functional performance (Wade 1997). Second because of this its ease of use in meta-analysis is apparent. Thirdly, it was already in use by the Sheffield CRTs. Finally, it is used for both patients recovering from CVA as well as femural trauma. The Barthel has been criticised for its apparent lack of sensitivity (Wellwood et al 1995), this was a cause of concern. However adaptation in the form of weighting has led to greater sensitivity (Philp et al. 1998) and hence provided the study with this option at the analysis phase.

The Rivermead rated well in terms of its capacity to measure disability or participation in activities of daily living. However, the Rivermead had been established as a measure for patients recovering from CVA and not orthopaedic patients. Some of the items on the Rivermead appear to replicate those on the Barthel. For these reasons it was decided not to use this measure.

The Katz ADL Index was also identified as an appropriate method for the measurement of disability. However, its length proved prohibitive (McDowell and Newell 1996).

6.8 Participation Measurement

Of all four dimensions (impairment, activity, participation and well-being), measures to assess participation (handicap) were more difficult to identify. This has been documented elsewhere (de Hann 1995). Four measures were considered, the Frenchay Activities Index (FAI) (Wade 1999) , the Rankin Index (Van Swieten et al 1988) ,the Nottingham Extended Activities of Daily Living Index (NEADL) (Nouri & Lincoln 1987) and the Impact on Participation and Autonomy questionnaire (IPA) (Cardol et al 1999). Each of these will be considered in turn.

The FAI was developed by a Social Worker, working in the field of stroke rehabilitation, although it was developed as a tool initially utilised with patients recovering from a CVA. The index does contain some items closely associated with instrumental performance, but the bulk of the index addresses aspects of social integration and participation. The index is not one that was currently being used by Sheffield CRTs.

The Rankin Index is widely promoted as a measure of social integration or participation. However, it has been noted that the Rankin ADL Index is actually a closer measure of instrumental ADL (de Hann 1995). This point was upheld and the Rankin Index was not considered suitable. This was also a criticism that could be levelled at the NEADL. Compared to the FAI the NEADL appears to also provide a good measure of disability but its emphasis on this is to the detriment of its capacity to measure participation (handicap).

One other available measure of participation at this time was the IPA. This measure was undiminished in its emphasis on social integration. Its reliance on the opportunity to participate in social relationships, family roles as well as social activities and mobility made it an appealing alternative. However, the measure was at an early stage in establishing reliability and validity and hence it was not appropriate that the questionnaire be used in this study.

The FAI was selected as a measure of participation (handicap). Despite the concern that it had not been used with orthopaedic patients prior to the study, the index was well established, suitable for meta-analysis and short. In addition the handicap dimension of TOMS was also deemed a suitable method of measurement.

6.9 Psychological Well Being Measurement

Tools for the measurement of patient well-being are numerous (Bowling 1990). Four measures (in addition to TOMS Well-being) were seriously considered for this purpose, the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith 1983), the General Health Questionnaire-28 (GHQ-28)(Goldberg & Williams 1990), The Sickness Impact Profile (SIP) (Bergner et al 1976) and the Nottingham Health Profile (NHP) (Hunt et al 1980).

The SIP and the NHP are not entirely devoted to well being, but are defined as being measures of general health status, including aspects of pain and mobility. The length of these measures was also viewed as being problematic in the context of the administration of a battery of measures.

The GHQ, a tool used to identify psychiatric disturbance, has been well used to aid both clinicians and researchers. The longer versions GHQ-60 and GHQ-28 have been shown to be reliable and well validated. They have the advantages of being able to distinguish between somatic aspects of well being, anxiety, depression and social functioning. These are however very long. The shorter version (GHQ-12) has been shown to be just as reliable in identifying 'cases', but cannot distinguish between the causes of morbidity.

The HADS has the advantage of being short and can also distinguish between the causes of psychiatric morbidity. The HADS was also being used by Sheffield CRTs for clinical purposes for some of its patients and gave the HADS an advantage for use in this study. In addition the HADS had also been utilised in recent RCTs evaluating community rehabilitation for stroke patients and was therefore more amenable to meta-analysis. On these grounds the HADS

was chosen as a measure of psychological well being for the study. In addition the well being dimension of TOMS would aid in the evaluation.

6.10 Health Related Quality of Life Measurement

In addition to the measures used to address the dimensions of impairment, activity, participation and well being, an assessment of self-perceived health status was also used to assess the impact of medical and rehabilitative interventions. Two such measures were seriously considered, others, such as SIP and NHP, were excluded because of their length. The SF-36 and the Euroqol (The EuroQol Group 1990) were considered.

The SF-36 (McHorney et al 1993) generates a profile of scores, is short and has been shown to be reliable, valid and sensitive to a range of health problems. The measure has also been used with elderly populations (Brazier et al 1996). The Euroqol is also a short, reliable and valid tool used to evaluate self-perceived health status. It consists of five items and it too has been used with an elderly population (Brazier et al 1996, Coast et al 1998).

In choosing between the two, the administration of a generic tool with geriatric patients became the most serious consideration. Significant in this decision was the comparative study undertaken by Brazier et al (1996). This study suggested that in comparison the Euroqol performed better than the SF-36 with a geriatric population in terms of test-retest reliability and completion rate. It should be noted that the self-administration status of the Euroqol, particularly regarding the thermometer–like scale, is questionable (Coast et al 1998). However, given that the measure was to be use in a face-face context this did not present a problem. The Euroqol has also been shown to be highly correlated with the Barthel Index (Coast et al 1998). Following these considerations it was decided to use the Euroqol in favour of the SF-36. Appendix VII summarises each of the measures considered against the selection criteria.

6.11 Baseline Assessment

All baseline assessments from September 2000 onwards were conducted following consent and prior to randomisation. Prior to this baseline assessments were conducted by Senior Therapists, following consent and randomisation.

6.12 Timing of Assessments

It was decided to follow patients up at one month and three months following consent. Three-month follow up was appropriate as CRT provision would have ceased for all patients, providing the author with an opportunity to assess patients soon after discharge from the teams. One-month follow up gave an opportunity to undertake an evaluation of recovery at an earlier stage when, according to other studies cited in the Chapter 1, the difference between treatment regimes was predicted to be at a premium. These two assessment points also concurred with other studies for the purpose of meta-analysis. All follow up assessments were administered through face-to-face interview.

6.13 Inter-rater Reliability

The simplest method of establishing the degree of inter-rater reliability is to conduct multiple measures on the same subject in order to establish the level of agreement (Altman 1991). Given that all of the subjects in this study were living in their own home, recovering from either a stroke or hip fracture it was decided that multiple assessment of this kind would be inappropriate. However, training, quarterly assessment meetings, use of well-established reliable measures and the provision of further written guidance for each measure were provided. Two of the assessors had also been involved in a previous study utilising a similar set of measures where moderate to good inter-rater reliability had been established kappa value of 0.41-0.8). Appendix VIII shows a table summarising the number of assessors, the number of assessments undertaken by each and the median score for each of the measures for each assessor. The purpose of this table is to provide information regarding the number of assessors involved and the overall contribution of each. In addition the median score for each assessor for each

measure provides us with data from which we assess the quality of assessments undertaken.

Chapter Three: Baseline Results

There are two main aims to this chapter. The first is to discover if the study patients differed significantly from those patients who did not consent to taking part in the study (sample). The second aim is to discover if the two arms of the trial were balanced in terms of key variables, both as a whole and within aetiologies. The chapter uses the data gathered during the recruitment phase of the study. It is based on data concerning those patients referred to the study (sample) and those patients who did consent to take part (study patients). Following presentation of the data a short discussion will draw attention to the salient points here, particularly those which have implications for further analysis and interpretation of follow up data.

1.1 Methods of Analysis

Three methods form the core of the analysis. For the most part the chapter relies on non-parametric methods (Mann Whitney test for difference). This has been done in circumstances where data are ordinal or non-normal in distribution. In such circumstances the median (range) has been used to describe groups and their differences. Under normal circumstances Chi Square would be used in order to test for trend for ordinal data. However, in the majority of the cases here, some of the cells have very few cases making the calculation of x^2 difficult. Hence, differences between proportions with confidence intervals are quoted in order to establish the significance of differences between categorical data. In addition Odds Ratios (OR) with confidence intervals are quoted for 2x2 tables in order to test for significant differences for non-ordered data. For ratio data (such as age, time variables) parametric methods are used, most notably the independent t-test for unrelated samples. An arbitrary level of 5% significance was assumed. Much of the statistical testing, as well as the generation of histograms, box-plots and graphs, has been done using SPSS v10. However, where the difference between two proportions with 95% CI and OR with 95 % CI are quoted, these have been calculated manually using the formulae in Appendix IIX.

2 Sample and Study Data

2.1 Patient Referral and Consent

Patients were referred to the trial during the period July 2000 and July 2002. There were three sources from which patients were referred to each of the Community Rehabilitation Teams (CRTs). The to primary sources were the Northern General Hospital (NGH) and the Royal Hallamshire Hospital (RHH). Patients were also referred to CRTs via GPs and other community based therapy services. These were labelled Community referrals by each of the CRTs and it will be shown that they accounted for a small proportion of eligible referrals.

2.2 Referrals made by CRT

The referral process has already been described in a previous chapter. During this period the four teams made 420 referrals. Table 3.1 summarises referrals made by the teams by aetiology. The table indicates that there were considerably more referrals for stroke patients (n=259, 61.7 per cent) than there were for patients recovering from a hip fracture (n=161, 38.3 per cent). Teams differed in the number referred to the study with CRT North East referring the least number of patients (n=87, 20.7 per cent) and CRT South East referring the greatest number (n=116, 27.6 per cent).

Diagnosis		Team				Total
		NE	SE	SW	W	
Stroke	Count	54	80	60	65	259
	% within stroke	20.8	30.9	23.2	25.1	100.0
	% within Team	62.1	69.0	57.1	58.0	61.7
Hip fracture	Count	33	36	45	47	161
	% within NoF	20.5	22.4	28.0	29.2	100.0
	% within team	37.9	31.0	42.9	42.0	38.3
Total	Count	87	116	105	112	420
	% of total	20.7	27.6	25.0	26.7	100.0

Table 3.1: Number of patients referred by each CRT and patient aetiology.

The teams also differed in the number of stroke patients referred with CRT South East referring almost one-third of the overall stroke referrals (n=80, 30.9 per cent) and CRT North East referring one-fifth (n=54, 20.8 per cent). CRT South West and CRT West was each responsible for one-quarter of all of the stroke patients referred (n=60, 23.2 per cent and n=65, 25.1 per cent respectively). There was also disparity between teams in the number of patients recovering from hip fracture. CRT South west and CRT West referred more patients recovering from hip fracture (n=45, 28 per cent and n=47, 29.2 per cent respectively).

It should be noted that the author is confident that the differences in referral rates were not as a result of differing referral practices between teams. The activity of all four teams were monitored at regular intervals and at no time was there cause to believe that CRT NE was failing to refer eligible study patients. The differences were as a result of the differing patient profiles of each of the four teams in terms of age and diagnosis.

2.3 Exclusions

Of the 420 patients referred to the study patients 45 patients were considered not eligible for inclusion or not included in the study (see Table 3.2 below). This includes patients originally referred and subsequently identified as ineligible on the basis of age and the wrong diagnosis. It also includes those patients who were identified as ineligible on the basis of co-morbidity (Parkinson's Disease and Dementia). A large group of patients were considered not to have capacity to give informed consent. Six of these patients were not contacted on these grounds on the advice of a clinician, all were reported to indicate expressive and receptive dysphasia. The remainder were considered unable to give informed consent following an assessment by TR. Five patients referred to the study were subsequently considered medically unstable and not contacted on the advice of a clinician. A further two patients were not consenting to CRT treatment and not contacted.

Reason for non-eligibility	n
Unable to give consent	22
Wrong diagnosis	8
Co-morbidity	6
Medically unstable	5
Not consenting to treatment	2
Under 65	2

Table 3.2: Reason for non inclusion in study

2.4 Reason for Non-contact

In addition a further 41 patients were classified as unable to contact (see Table 3.3 below). This includes patients who were not contacted within the five working days of being assessed by CRT. This occurred for a variety of reasons. On occasion prospective patients did not answer the telephone, patients were referred to TR too late. In addition patients were referred to the study and subsequently admitted to hospital or short or long term care. Patients were also discharged by CRT following referral and prior to consent. A further two patients died following referral and prior to consent.

Reason for non-contact	n
Unable to contact within 5 working days	23
Re-admitted to hospital	6
Discharged by CRT prior to consent	6
Admitted to care	4
Died	2

Table 3.3: Reason for non-contact of referred patients

2.5 Consent rate

The remaining 334 patients were assessed as being eligible for consent. Of these 160 patients consented to participation in the study. This represents a positive consent rate of 47.9 per cent. Positive consent rates were broadly similar between the two patient groups with 46 per cent of stroke patients

(n=89) and 49.6 per cent of hip fracture patients (n=71) agreeing to participate in the trial.

2.5.1 Reason for Non-consent

Although patients were not formally required to give a reason for non-participation, their explanations for doing so were recorded after each consent meeting. Explanations were divided into three types. Patients who were non-specific included those who described themselves as being too old or not well enough. It also includes those who were not enthusiastic about being involved in research (no specific reason: n=100, 57.5 per cent). Other patients did not wish to have a therapist visiting with the regularity that would have resulted if allocated to the intensive arm of the trial (patient wants less intensive: n=42, 24.1 per cent). Some patients felt that they were already receiving an intensive service from CRT and would not wish to place this in jeopardy (patient wants intensive: n=32, 18.4 per cent).

2.5.2 Reason for No-consent by Aetiology

Explanations for not taking part were different on the basis of aetiology. Table 3.4 (below) indicates these differences.

Diagnosis		Reason for non-consent			Total
		None specific	No, want low intensity	No, Want more intensive	
Stroke	Count	49	27	26	102
	% within stroke	48.0	26.5	25.5	100.0
Neck of femur	Count	51	15	6	72
	% within NoF	70.8	20.8	8.3	100.0
Total	Count	100	42	32	174
	% of total	57.5	24.1	18.4	100.0

Table 3.4: Reason for non-participation by aetiology

Under one third of hip fracture patients (n=21, 29.1 per cent) felt that the amount of treatment was a factor, whilst this was the case for over half of the

stroke patients who refused (n=53, 52 per cent). Furthermore, half of stroke patients who refused on the grounds of intensity of treatment viewed the risk of missing out on an intensive service as a reason for non-participation in the study (n=26, 52.2 per cent). The difference between these two proportions was significant (22.9 (8.7, 37.1)).

2.6 Differences Between Non-Consenting and Consenting Patients

Analysis of the data concerning non-consenting and consenting patients was undertaken. The results of this analysis will now be presented. The data concerning non-consenting patients was restricted to demographic factors.

2.6.1 Time Since Stroke or Hip Fracture and Age

Two continuous variables, time since event (TSE) (number of days between event and referral to the study) and age are considered first. Tables 6 and 7 (below) indicate that there were no significant differences between consenting and non-consenting patients for these variables.

	Mean	Sig. (2-tailed)	Mean difference	SE	95% CI	
					Lower	Upper
Positive	46.7	.634	2.8159	5.975	-8.9097	14.6136
Reject	43.9					

Table 3.5: Results of independent t-test for comparison of length of time since stroke/hip fracture by consent outcome (n= 286).

	Mean	Sig. (2-tailed)	Mean difference	SE	95% CI	
					Lower	Upper
Positive	78.9	.398	-.6851	.8095	-2.2779	.90777
Reject	79.4					

Table 3.6: Results of independent t-test for comparison of mean age by consent outcome (n= 311).

2.6.2 Gender

Other factors were also considered. Table 3.7 indicates a difference between consenting and non-consenting patients on the basis of gender. The table shows that men who were eligible were one and a half times more likely to consent compared with eligible women, moreover the confidence intervals around the Odds Ratio indicates that this difference was significant (OR= 1.56. (1.01, 2.45)). The result is an increase in the number of men in the study sample (39.4 per cent) over the proportion of men in the main sample (34.1 per cent).

Consent outcome		Gender		Total
		Positive	Reject	
Female	Count	97	123	220
	% within gender	44.1	55.9	100.0
	% within positive	60.6	70.7	65.9
	% within total	29.0	36.8	65.9
Male	Count	63	51	114
	% within gender	55.3	44.7	100.0
	% within reject	39.4	29.3	34.1
	% within total	18.9	15.3	34.1
Total	Count	160	174	334
	% of total	47.9	52.1	100.0

Table 3.7: Consent outcome by gender

2.6.3 Co-residing Carer

Similarly those who lived with a carer were also more likely to positively consent to participate in the study. Table 3.8 indicates the proportions (the status of three of the patients was unknown). Table 3.8 indicates that those patients who co-resided with a family member (or other informal carer) were more likely to consent to participate, although this was not a significant difference (1.34 (.86, 2.06)).

Consent outcome		Does patient live alone?			Total
		Don't know	Yes	No	
Positive	Count		78	82	160
	% within positive		48.7	51.3	100.0
Reject	Count	3	96	75	174
	% within reject	1.7	55.2	43.1	100.0
Total	Count	3	174	157	334
	% of total	1.7	52.5	45.8	100.0

Table 3.8: Consent outcome by co-residing status

Consequently the proportion of those who lived alone and who participated in the study was slightly smaller than the proportion of those who lived alone in the main sample.

2.6.4 Source of Referral

Source of referral to CRT was also considered. Table 3.9 indicates that the proportion of RHH not consenting was higher than for Community or NGH patients. The overall proportion of RHH patients referred to the study was higher than the proportion of RHH patients who consented to participate in the study. When compared with either NGH (10.3 (-9.7, 30.3)) or community (17.9 (-7.1, 42.9)) the difference was not significant.

Consent outcome		Source of original referral			Total
		Community	NGH	RHH	
Positive	Count	30	101	29	160
	% within positive	18.8	63.1	18.1	100.0
	% within source	56.6	49.0	38.7	47.9
Reject	Count	23	105	46	174
	% within reject	13.2	60.3	26.4	100.0
	% within source	43.4	51.0	61.3	52.1
Total	Count	53	206	75	334
	% of total	15.9	61.7	22.5	100.0

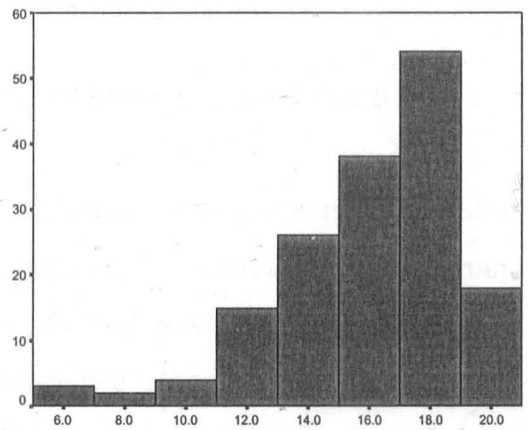
Table 3.9: Consent outcome by source of referral

3 Baseline Data for Study Patients

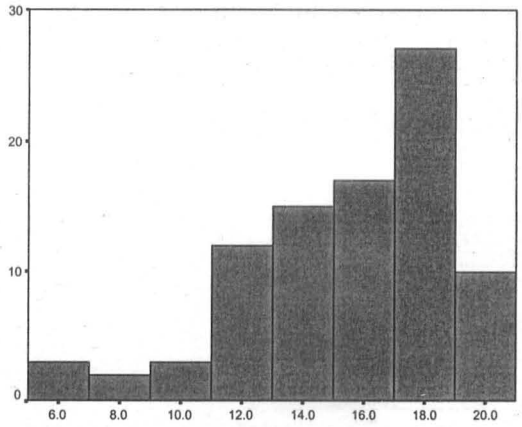
The following section describes the baseline data for all outcome measures. The purpose of this section is twofold. Firstly, I shall describe the distribution of the scores for each of the measures for all study patients as well as on the basis of aetiology subgroup. This is done to underpin the argument in favour of the use of non-parametric statistical testing later on in this chapter and subsequent chapters. Secondly, differences between patients on the basis of aetiology will be explored.

3.1 Barthel Scores at Baseline

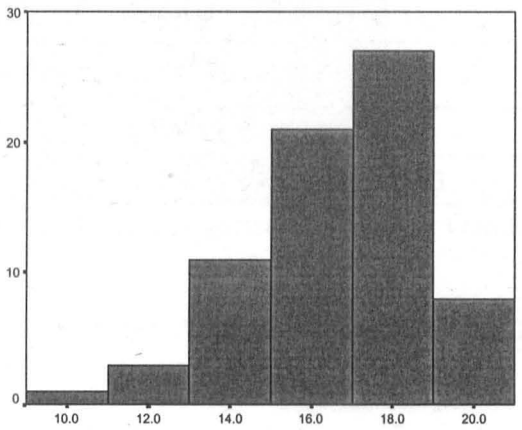
Barthel data was gathered following consent, prior to randomisation. Histogram 3.1 shows the distribution of the Barthel baseline data for all patients in the study. Histogram 3.2 shows the distribution of the Barthel scores for stroke patients and Histogram 3.3 for hip fracture patients. All three histograms indicate that the data is negatively skewed. Given that the distributions are non-normal, the medians and range for each are presented.



Histogram 3.1: Barthel scores at baseline for all patients.
Median = 16.00 (6, 20)



Histogram 3.2: Barthel scores at baseline for stroke patients.
Median = 16.00 (6, 20)



Histogram 3.3: Barthel scores at baseline for hip fracture patients.
Median = 16.00 (10, 19)

Using non-parametric testing there was no significant difference between the two aetiologies at baseline for Barthel (p=.248 (z=-1.156)).

3.2.1 Categorised Barthel at Baseline

One other method commonly used in the analysis of Barthel data is to categorise the scores into three groups. Scores between 0 and 14 labelled dependent, scores between 15 and 19 semi-independent and scores of 20 dependent. An identical approach has been used before with Barthel data (Young & Forster 1992).

Table 3.10 (below) shows categorised Barthel score by aetiology. Over two thirds (66.9 per cent (n=107) of study patients were assessed as semi-independent at baseline and three assessed as independent at this stage. By considering the proportions of each subgroup being assessed as dependent, a significant difference emerges. Just over one-fifth of hip fracture patients were

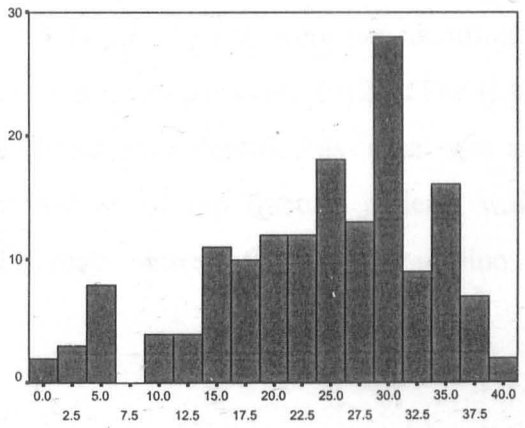
assessed as dependent at baseline (21.1 per cent (n=15), whilst this was the case for almost two fifths of stroke patients (39.3 per cent (n=35)). The difference between these two proportions was significant (18.2 (4.4, 32)).

Aetiology		Categorised Barthel data			Total
		Dependent	Semi-independent	Independent	
Stroke	Count	35	51	3	89
	% within	39.3%	57.3%	3.4%	100
Hip Fracture	Count	15	56	0	71
	% within	21.1%	78.9%	0	100
Total	Count	50	107	3	160
	% of total	31.3	66.9	1.9	100

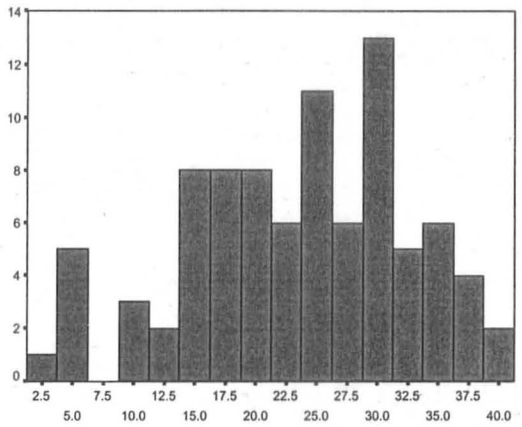
Table 3.10: Categorised Barthel by Gender of the patient.

3.2 Frenchay Activities Index (FAI) at Baseline

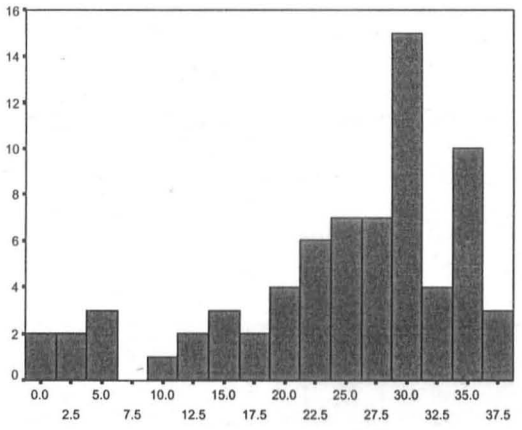
Patients were asked to report on their activities in the three months prior to stroke or hip fracture. As such a pre-morbid FAI score was attained following consent, prior to randomisation. Histograms 3.4, 3.5 and 3.6 show the distribution of the scores for all patients, stroke patients and hip fracture patients respectively. As with baseline Barthel data for all patients, Histograms 3.4, 3.5 and 3.6 show that the pre-morbid FAI scores for all patients, stroke patients and hip fracture patients were negatively skewed.



Histogram 3.4: Pre-morbid FAI scores for all patients at baseline
Median = 26.00 (1, 41)



Histogram 3.5: Pre-morbid FAI scores for stroke patients at baseline
Median = 24.00 (3, 41)



Histogram 3.6: Pre-morbid FAI scores for hip fracture patients at baseline
Median = 28.00 (1, 38)

A Mann-Whitney test for difference was conducted on the FAI baseline data in order to detect any difference between the two subgroups, stroke and hip fracture. There was no significant difference (p= .162 (z= -1.399)).

3.3 Hospital Anxiety and Depression Scale at Baseline

Tables 3.11 and 3.12 summarise the HADS Anxiety and Depression sub-scores on the basis of 'case' identification (Zigmond & Snaith 1983). The majority of patients in the study were not identified as anxious (65.6 per cent n=105) or depressed (75 per cent, n=120). For HADS Anxiety overall the proportion of study patients identified as 'case' was small (16.9 per cent (n= 26). A larger proportion of hip fracture patients was identified as 'case'. However, the difference between these two proportions was not significant (6.6 (-5.4, 18.6)).

Aetiology		HADS Anxiety			Total
		Non-Case	Doubtful	Case	
Stroke	Count	58	16	12	86
	% within	67.4%	18.6%	14.0%	100.0%
Hip fracture	Count	47	7	14	68
	% within	69.1%	10.3%	20.6%	100.0%
Total	Count	105	23	26	154
	% of total	68.2%	14.9%	16.9%	100.0%

Table 3.11: HADS Anxiety at baseline by aetiology.

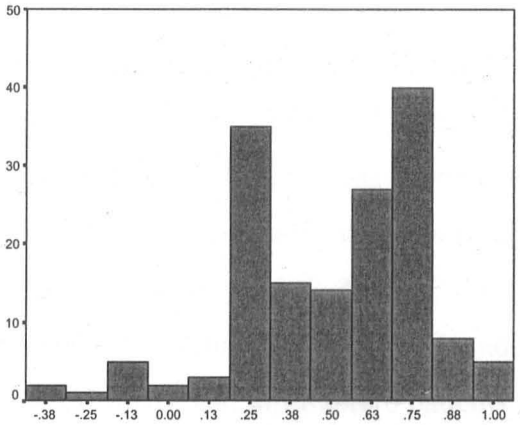
For HADS Depression again only a small proportion of study patients were identified as 'case' at baseline (8.4 per cent (n=13)). A larger proportion of stroke patients were identified as 'case' and the difference between these two proportions was significant (12.5 (4.8, 20.2)).

Aetiology		HADS Depression			Total
		Non-Case	Doubtful	Case	
Stroke	Count	63	11	12	86
	% within	73.3%	12.8%	14.0%	100.0%
Hip fracture	Count	57	10	1	68
	% within	83.8%	14.7%	1.5%	100.0%
Total	Count	120	21	13	154
	% of total	77.9%	13.6%	8.4%	100.0%

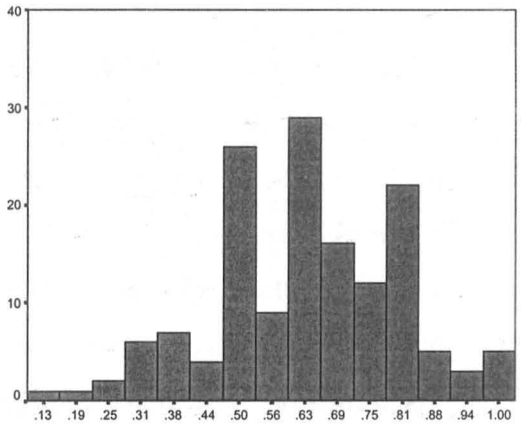
Table 3.12: HADS Depression at baseline by aetiology.

3.4 Euroqol Scores at Baseline

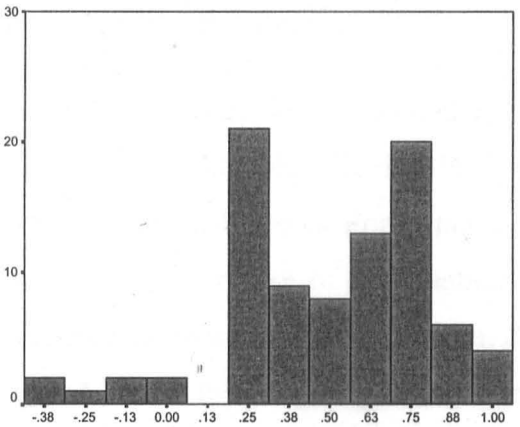
Histograms 3.7 and 3.8 show the data collected for the EQ-5D and Health Status Assessment for all patients at baseline. The Histograms indicate a non-normal distribution. Given the non-normal distribution a non-parametric approach will be used with Euroqol data for the remainder of the thesis.



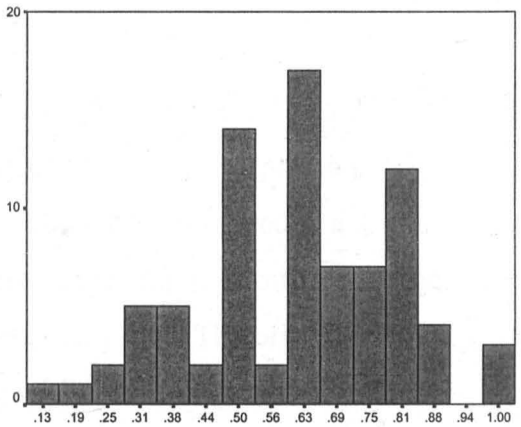
Histogram 3.7: Baseline EQ5D scores for all patients.



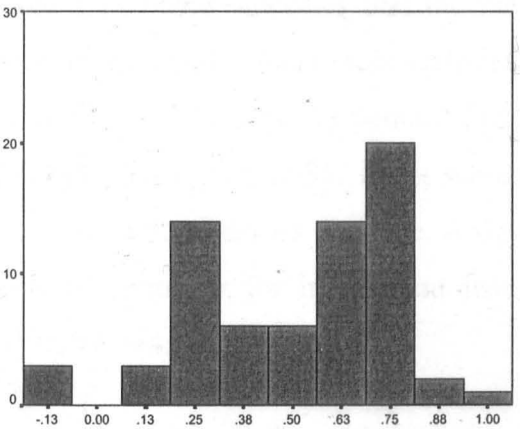
Histogram 3.8: Baseline self perceived health status scores for all patients



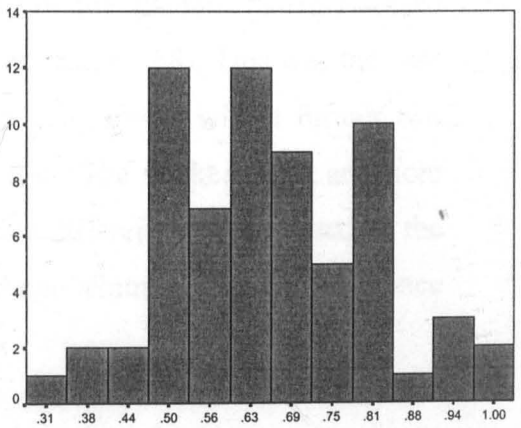
Histogram 3.9: Baseline EQ-5D scores for stroke patients.



Histogram 3.10: Baseline self perceived health status scores for stroke patients



Histogram 3.11: Baseline EQ-5D scores for hip fracture patients.



Histogram 3.12: Baseline self perceived health status scores for hip fracture patients.

The median EQ-5D score for all patients was .59 (min. -.4 , max. 1). For stroke patients the median EQ-5D score at baseline was .5750 (min. -4, max. 1), and for hip fracture patients it was .6 (min. -1, max, 1). The median self perceived health status score for all patients was .60 (min. .1, max. 1) and was .6 (min. .1, max. 1) and .61 (min. .3, max. 1) for stroke and hip fracture patients respectively. Statistical testing was undertaken in order to test for difference between stroke and hip fracture patients at baseline. There were no significant differences for EQ-5D (p= .866 (z=-.168)) or self perceived health status (p=.245 (z=-1.164)).

3.5 TOMS baseline data

The TOMS baseline data by allocation is presented in Tables 3.13 to 3.16. It should be noted here that the data have been collapsed from its previous form which included half scores. For instance 3.5 has now been re-coded to a 3. This has been done for ease of presentation at this stage and is permitted by the authors of the measure (Enderby, John, & Petheram 1998). The original scores are used later in the analysis when conducting statistical testing.

3.5.1 Impairment at Baseline

Table 3.13 below indicates that the majority of hip fracture patients scored three on the TOMS impairment scale (84.1 per cent, n= 58). This was the case for only half of the stroke patients (48.3 per cent, n=42) with a further two fifths (40.2 per cent, n=35) being scored at four. The stroke scores are more evenly distributed across the scale. A significant difference was detected on the basis of aetiology for impairment using Mann-Whitney test for difference (p=.000 (z=-4.009)).

Aetiology		TOM score: Impairment					Total
		1	2	3	4	5	
Stroke	Count	2	6	42	35	2	87
	% within stroke	2.3	6.9	48.3	40.2	2.3	100.0
Hip Fracture	Count	0	1	58	10	0	69
	% within hip	0	1.4	84.1	14.5	0	100.0
Total	Count	2	7	100	45	2	156
	% of total	1.3	4.5	64.1	28.8	1.3	100.0

Table 3.13: TOMS impairment scores at baseline by aetiology.

3.5.2 Disability Scores at Baseline

A similar pattern emerges when addressing TOMS Disability at baseline. Overall over one half of all patients (51 per cent (n=79)) scored a three and one fifth (19.4 per cent (n=30)) were assessed as a two.

Aetiology		TOM score: Disability					Total
		1	2	3	4	5	
Stroke	Count	1	28	40	17	0	86
	% within stroke	1.2	32.6	46.5	19.8	0	100.0
Hip Fracture	Count	0	2	39	28	0	69
	% within hip	0	2.9	56.5	40.6	0	100.0
Total	Count	1	30	79	45	0	155
	% of total	.6	19.4	51.0	29.0	0	100.0

Table 3.14: TOMS disability scores at baseline by aetiology.

The two aetiologies also differed on TOMS disability scores. Table 3.14 (above) indicates that hip fracture patients were assessed as being having greater ADL skills than the stroke patients. The majority of hip fracture patients scored a three or four (97.1 per cent, n=67), whilst this was case for two thirds of stroke patients (66.3 per cent, n= 57) with the remainder being assessed as

two or one. The difference between the two aetiologies was significant using Mann-Whitney test for difference (p=.000 (z=-3.874)).

3.5.3 Handicap Scores at Baseline

Unlike the baseline FAI, the TOMS Handicap score was not a pre-morbid assessment, but a reflection of each patient's current levels of participation. It can be observed in Table 3.15 (below) that at this stage a large numbers of patients were restricted in terms of participation. Over half (50.6 per cent (n=79)) were assessed as a two and only 12 patients (7.7 per cent) were seen to be actively engaged in normal activities and generally autonomous. There were no observable differences between stroke and hip fracture patients and no significant difference (p=.952 (z=-.06)).

Aetiology		TOM score: Handicap					Total
		1	2	3	4	5	
Stroke	Count	12	40	28	7	0	87
	% within stroke	13.8	46.0	32.2	8.0	0	100.0
Hip Fracture	Count	4	39	21	4	1	69
	% within hip	5.8	56.5	30.4	5.8	1.4	100.0
Total	Count	16	79	49	11	1	156
	% of total	10.3	50.6	31.4	7.1	.6	100.

Table 3.15: TOMS handicap scores at baseline by aetiology.

3.5.4 Well-being Scores at Baseline

Patient well-being was assessed more favourably (Table 3.16 Below) with almost two thirds (62.1 per cent (n=97)) being assessed as a four or five. Although a larger proportion of hip fracture patients was assessed as a five (20.3 per cent (n=14)) there were no significant differences between hip fracture and stroke patients (p=.386 (z=-.867)).

Aetiology		TOM score: Well being					Total
		1	2	3	4	5	
Stroke	Count	3	7	23	45	9	87
	% within stroke	3.4	8.0	26.4	51.7	10.3	100.0
Hip Fracture	Count	2	3	21	29	14	69
	% within hip	2.9	4.3	30.4	42.0	20.3	100.0
Total	Count	5	10	44	74	23	156
	% of total	3.2	6.4	28.2	47.4	14.7	100.0

Table 3.16: TOMS well-being scores at baseline by aetiology.

4 Baseline Data by Allocation

All 160 patients were randomly allocated to either intensive or non-intensive treatment regimes. This section will describe the results at baseline for each of the two groups The allocation procedure has been described in an earlier Chapter.

4.1 Allocation by Aetiology

Just over half (51.25 per cent, n=82) were allocated to receive an intensive treatment regime. Table 3.17 below summarises allocation by aetiology.

Allocation		Aetiology		Total
		CVA	NOF	
Non-intensive (NI)	Count	44	34	78
	% within NI	56.4	43.6	100.0
	% within Aetiology	49.4	47.9	48.8
Intensive (I)	Count	45	37	82
	% within I	54.9	45.1	100.0
	% within Aetiology	50.6	52.1	51.3
Total	Count	89	71	160
	% of total	55.6	44.4	100.0

Table 3.17: Allocation by aetiology

A larger proportion of hip fracture patients were allocated to the more intensive programme of therapy with just over half (52.1 per cent (n=37)) being allocated to the intensive group. Similarly just over half of stroke patients (50.6 per cent (n=45)) were allocated to the intensive group (OR=1.06 (.56, 1.97)).

4.2 Allocation by CRT Team

One important factor contributing to the capacity of therapists to provide an intensive programme of therapy was how the allocations compared within teams, the rationale being that an imbalance within teams might have resulted in therapists not having sufficient time to provide a more intensive treatment programme. Table 3.18 below indicates that, broadly speaking, the allocation to both arms of the trial was equal within teams, justifying the decision to stratify randomisation by team.

Allocation		Team				Total
		NE	SE	SW	W	
Non-intensive (NI)	Count	19	25	16	18	78
	% within NI	24.4	32.1	20.5	23.1	100.0
	% within Team	51.4	49.0	48.5	46.2	48.8
Intensive (I)	Count	18	26	17	21	82
	% within I	22.0	31.7	20.7	25.6	100.0
	% within team	48.6	51.0	51.5	53.8	51.3
Total	Count	37	51	33	39	160
	% of total	23.1	31.9	20.6	24.4	100.0

Table 3.18: Allocation by CRT Team

4.3 Allocation by Length of Time Since Stroke or Hip Fracture and Age

Two factors often viewed as co-variates in rehabilitation from stroke and hip fracture are age and length of time since the event itself. Tables 18 and 19 summarise independent t-tests undertaken in order to establish if a difference existed in these two variables between the two arms of the trial. Both indicate that the two arms of the study were well balanced for these factors.

	Mean	Sig. (2-tailed)	Mean difference	SE	95% CI	
					Lower	Upper
Non-int.	41.0	.794	-1.9480	6.0671	-13.9335	10.0374
Int.	42.9					

Table 3.19: Results of an independent t-test for comparison of time since stroke or hip fracture by allocation (n= 156).

	Mean	Sig. (2-tailed)	Mean difference	SE	95% CI	
					Lower	Upper
Non-int.	78.9	.626	.5281	1.0820	-1.6090	2.6653
Int.	78.3					

Table 3.20: Results of an independent t-test for comparison of an independent t-test for comparison of age by allocation (n= 160)

4.4 Allocation by Gender

Gender has also been viewed as a factor in success in relation to Barthel scores (Wyller et al. 1997). Given that the Barthel was used as the primary outcome measure in this study it was important to establish balance in terms of gender.

Allocation		Gender		Total
		Female	Male	
Non-intensive (NI)	Count	51	27	78
	% within NI	65.3	34.7	100.0
	% within female	52	43.5	48.8
Intensive (I)	Count	47	35	82
	% within I	57.3	42.7	100.0
	% within male	48.0	56.5	51.2
Total	Count	98	62	160
	% of total	61.3	38.8	100.0

Table 3.21: Gender by allocation.

Table 3.21 above indicates that a greater proportion of males received intensive treatment. Over half of the men participating in the study were allocated to the intensive arm (56.5 per cent, n=35) whereas this was true for less than half of women (48 per cent, n=47). In relative terms men were more often placed in

the intensive group, the difference, however, was not significant (OR=1.4 (.73, 2.65)).

4.5 Barthel at Baseline

4.5.1 Barthel Scores at Baseline by Group

The median total Barthel score was the same for the two groups (16.00). However whilst both arms shared a minimum score of 6, the maximum in the intensive groups was 20 compared with 19 in the non-intensive arm. The median Barthel score for stroke patients was equal for each group (16.00) However, there existed a slight imbalance between the arms of the trial for patients recovering from hip fracture. For these participants the median Barthel score for the non-intensive arm was 16.00 (min.12, max.19) and was 17.00 for the intensive group (min.10, max.19). The difference was, however, non-significant as indicated in Table 21 .Table 21 (below) also indicates the results of the Mann Whitney test for difference between the groups for all patients and stroke sub-group.

Group	n	Mann-Whitney U	Z Score	Significance (2-tailed)
All	160	2883.5	-1.082	p>0.05
Stroke	89	851.5	-1.145	p>0.05
Hip fracture	71	604.0	-.293	p>0.05

Table 3.22: Results of Mann-Whitney U Test for difference between the two groups in Barthel at baseline for all and aetiology sub-groups.

4.5.2 Categorised Barthel at Baseline by Group

Table 22 shows the categorised Barthel by allocation for all patients. It can be seen that a larger proportion of the non-intensive arm fell into the more disabled category, although this difference is not significant (6.6 (-7.7, 20.9).

Allocation		Categorised Barthel			Total
		Dependent	Semi-independent	Independent	
Non-Int.	Count	27	51	0	78
	% within NI	34.6	65.4	0.0	100.0
Intensive	Count	23	56	3	82
	% within I	28.0	63.3	3.7	100.0
Total	Count	50	107	3	160
	% of total	31.3	66.9	1.9	100.0

Table 3.23: Categorised Barthel by allocation.

Table 3.24 (below) shows the categorised Barthel by allocation for stroke patients in the study at baseline. The Table indicates a similar distribution for the two groups. A larger proportion of the non-intensive patients were assessed as being dependent, this difference in proportions was, however, not significant (7.6 (-12.6, 27.8)).

Allocation		Categorised Barthel			Total
		Dependent	Semi-independent	Independent	
Non-Int. (NI)	Count	19	25	0	44
	% within NI	43.2	56.8	0	100.0
Intensive (I)	Count	16	26	3	45
	% within I	35.6	57.8	6.	100.0
Total	Count	35	51	3	89
	% of total	39.3	57.3	3.4	100.0

Table 3.24: Categorised Barthel by allocation (stroke)

Table 3.25 (below) shows the categorised Barthel for the hip fracture patients. Again a similar distribution can be noted. Again a larger proportion of the non-intensive patients were assessed as dependent, although this difference was not significant (4.6 (-14.2, 23.40)).

Allocation		Categorised Barthel			Total
		Dependent	Semi-independent	Independent	
Non-Int.	Count	8	26	0	34
	% within NI	23.5	76.5	0	100.0
Intensive	Count	7	30	0	37
	% within I	18.9	81.1	0	100.0
Total	Count	15	56	0	71
	% of total	21.1	78.9	0	100.0

Table 3.25: Categorised Barthel by allocation (hip fracture)

4.6 Hospital Anxiety and Depression Scale (HADS) Baseline Data by Allocation

4.6.1 HADS by Allocation (all patients)

Table 3.26 below displays the proportion of patients who are anxious according to the HADS anxiety sub-scale for each allocation. The intensive group had a higher proportion who were anxious according to the HADS. Almost one-quarter of the non-intensive group were identified as 'case', whereas just over one tenth of the intensive patients were identified as 'case'. The difference between these two proportions was not significant (8.3 (-3.3, 19.9)).

Allocation		HADS Anxiety			Total
		Non-case	Doubtful	Case	
Non-intensive (NI)	Count	46	14	16	76
	% within NI	60.5	18.4	21.1	100.0
	% within anxiety	29.9	9.1	10.4	49.4
Intensive (I)	Count	59	9	10	78
	% within I	75.6	11.5	12.8	100.0
	% within anxiety	38.3	5.8	6.5	50.6
Total	Count	105	23	26	154
	% of total	68.2	14.9	16.9	100.0

Table 3.26: HADS Anxiety by allocation at baseline

Table 3.27 (below) does the same for the depression sub-scale. The difference between the two groups is not however significant on the depression sub-scale with 77.6 per cent (n=59) and 78.2 per cent (n=61) being assessed as 'non-case' by the HADS for non-intensive and intensive arms of the trial respectively. A larger proportion of the intensive group was identified as 'case' for HADS depression, although the difference was not significant (3.7 (-4.8, 12.2)).

Allocation		HADS Depression			Total
		Non-case	Doubtful	Case	
Non-intensive (NI)	Count	59	12	5	76
	% within NI	77.6	15.8	6.6	100.0
	% within depress	38.3	7.8	3.2	49.4
Intensive (I)	Count	61	9	8	78
	% within I	78.2	11.5	10.3	100.0
	% within depress	39.6	5.8	5.2	50.6
Total	Count	120	21	13	154
	% of total	77.9	13.6	8.4	100.0

Table 3.27: HADS depression by allocation at baseline

4.6.2 ***HADS by Allocation (stroke patients)***

The following two tables (3.28 and 3.29) show the proportions of stroke patients within each arm of the trial assessed as anxious or depressed according to the HADS. Table 3.28 shows that there was an increased proportion of stroke patients assessed as non-anxious in the intensive arm (76.7 per cent, n=33). The difference between these two proportions was significant (18.6 (4.7, 32.5)).

Allocation		HADS Anxiety			Total
		Non-case	Doubtful	Case	
Non-intensive (NI)	Count	25	10	8	43
	% within NI	58.1	23.3	18.6	100.0
	% of total	29.1	11.6	9.3	50.0
Intensive (I)	Count	33	6	4	43
	% within I	76.7	14.0	9.3	100.0
	% of total	38.4	7.0	4.7	50.0
Total	Count	58	16	12	86
	% of total	67.4	18.6	14.0	100.0

Table 3.28: HADS anxiety by allocation for stroke patients at baseline

In terms of HADS depression for stroke patients, the two arms of the study were well balanced (Table 3.29 below). Just over three quarters of the non-intensive group (76.7 per cent, n=33) being assessed as 'non-case' and 69.8 per cent (n=30) of the intensive group also being assessed as 'non-case'. However, a larger proportion of the intensive group was assessed as case, although the difference between these two proportions was not significant (9.3 (-5, 23.6)).

Allocation		HADS Depression			Total
		Non-case	Doubtful	Case	
Non-intensive (NI)	Count	33	6	4	43
	% within NI	76.7	14.0	9.3	100.0
	% of total	38.4	7.0	4.7	50.0
Intensive (I)	Count	30	5	8	43
	% within I	69.8	11.6	18.6	100.0
	% total	34.9	5.8	9.3	50.0
Total	Count	63	11	12	86
	% of total	73.3	12.8	14.0	100.0

Table 3.29: HADS depression by allocation for stroke patients at baseline

4.6.3 HADS by Allocation (hip fracture patients)

For hip fracture patients, the differences between the two arms of the trial in terms of baseline HADS was less apparent. The results of the HADS anxiety sub-scale are presented in Table 3.30. It shows that the proportions assessed as

non-case between the two arms were broadly similar (76.7 per cent and 69.8 per cent). The proportion of the non-intensive group identified as 'case' was larger than it was for the intensive group, although the difference between these two proportions was not significant (7.1 (-12, 26.2)). The results of the HADS depression sub-scale for hip fracture patients are presented in Table 3.31. Again it shows that the proportion of intensive patients assessed as 'non-case' was larger than for the non-intensive arm (78.8 per cent and 88.6 per cent). Only one hip fracture patient was identified as 'case' for HADS depression.

Allocation		HADS Anxiety			Total
		Non-case	Doubtful	Case	
Non-intensive (NI)	Count	21	4	8	33
	% within NI	63.6	12.1	24.2	100.0
	% of total	30.9	5.9	11.8	48.5
Intensive (I)	Count	26	3	6	35
	% within I	74.3	8.6	17.1	100.0
	% of total	38.2	4.4	8.8	51.5
Total	Count	47	7	14	68
	% of total	69.1	10.3	20.6	100.0

Table 3.30: HADS anxiety by allocation for hip fracture patients at baseline

Allocation		HADS Depression			Total
		Non-case	Doubtful	Case	
Non-intensive (NI)	Count	26	6	1	33
	% within NI	78.8	18.2	3.0	100.0
	% of total	38.2	8.8	1.5	48.5
Intensive (I)	Count	31	4	0	35
	% within I	88.6	11.4	0.0	100.0
	% total	45.6	5.9	0.0	51.5
Total	Count	57	10	1	68
	% of total	83.8	14.7	1.5	100.0

Table 3.31: HADS depression by allocation for hip fracture patients at baseline

4.7 Pre-Morbid Frenchay Activities Index by Allocation

A difference between the two arms in terms of pre-morbid FAI did exist. The median score for the intensive group was 25.5, the score for the non-intensive group being 27. However Table 3.32 (below) indicates that this difference was not significant. For both stroke and hip fracture patients the pre-morbid FAI scores were broadly equal for both arms of the trial. The median scores for stroke patients was 28 for both groups, whilst for the hip fracture patients the medians were 25 and 24 for non-intensive and intensive arms respectively. Again Table 3.32 indicates that no significant differences existed at baseline.

Group	n	Mann-Whitney U	Z Score	Significance (2-tailed)
All	159	2964.5	-.664	p>0.05
Stroke	88	856.0	-.932	p>0.05
Hip fracture	71	623.0	-.069	p>0.05

Table 3.32: Results of Mann-Whitney U Test for difference between the two groups for pre-morbid Frenchay Activities Index at baseline for all and aetiology sub-group.

4.8 Euroqol at Baseline by Allocation

4.8.1 EQ-5D by Allocation

There was a marginal non-significant difference between the two arms of the trial on the Euroqol EQ-5D. For EQ-5D the median score for the non-intensive group was .59, whilst it was .54 for the intensive group. For stroke patients at baseline it was the intensive group that had the higher median (.56, compared with .52). For hip fracture patients the difference was reversed with the median score for non-intensive group being .62 and .52 for the intensive group. Table 29 summarises the results of all three Mann Whitney tests for difference. The table shows that there were no significant differences at baseline for EQ-5D.

Group	n	Mann-Whitney U	Z Score	Significance (2-tailed)
All	157	2872.0	-.731	p>0.05
Stroke	88	955.0	-.104	p>0.05
Hip fracture	69	505.0	-1.083	p>0.05

Table 3.33: Results of Mann-Whitney U Test for difference between the two groups for EQ-5D at baseline for all and aetiology sub-group.

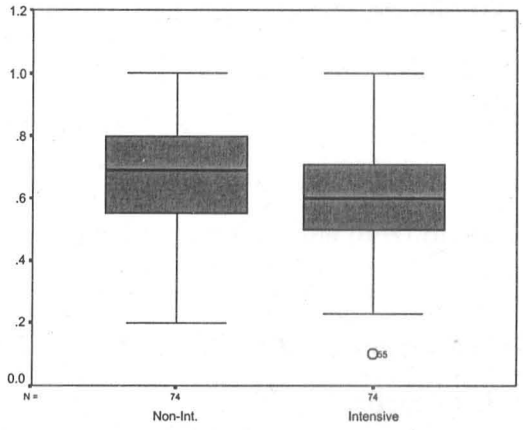
4.8.2 Self Perceived Health Status at Baseline by Allocation

Significant differences existed between the two groups at baseline when examining the self perceived health status scores for all patients as well as when stroke patient data was examined. No significant difference was detected at baseline for hip fracture patients. For all patients the median score favoured the intensive group (.69 compared with .60). This difference was similar for stroke patients, .60 for the intensive group, .70 for the non-intensive. The self perceived health status scores for hip fracture patients were broadly similar (.63 for the non-intensive and .60 for intensive). Table 30 summarises the Mann Whitney tests for difference for all patients and for separate aetiologies. It is shown that the differences on the basis of all patients and stroke patients were significant.

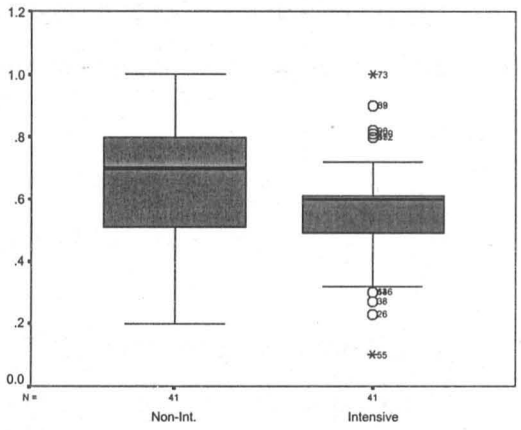
Group	n	Mann-Whitney U	Z Score	Significance (2-tailed)
All	148	2087.5	-2.500	p<0.05
Stroke	82	630.0	-1.956	p<0.05
Hip fracture	66	423.0	-1.562	p>0.05

Table 3.34: Results of Mann-Whitney U Test for difference between the two groups for self perceived health status at baseline for all and aetiology sub-group .

The box plots shown below indicate that in both cases, where significant differences existed, the non-intensive group scored significantly higher.



Box Plot 3.1: Self perceived health status scores by allocation at baseline for all patients.



Box Plot 3.2: Self perceived health status scores by allocation at baseline for stroke patients.

4.9 Baseline TOMS data by Allocation (all)

Both arms of the trial are similar in terms of the impairment, disability, handicap and well-being assessments made at baseline. No significant differences existed between the two arms of the trial.

4.9.1 Impairment at Baseline by Allocation (all patients)

Allocation		TOM score: Impairment					Total
		1	2	3	4	5	
Non-int.	Count	1	2	52	19	1	75
	% within stroke	1.3	2.7	69.3	25.3	1.3	100.0
Int.	Count	1	5	48	26	1	81
	% within hip	1.2	6.2	59.3	32.1	1.2	100.0
Total	Count	2	7	100	45	2	156
	% of total	1.3	4.5	64.1	28.8	1.3	100.0

Table 3.35: TOMS impairment baseline scores by allocation.

Patients allocated to both arms of the trial scored broadly similar in terms of TOMS impairment (Table 3.35). The majority were assessed at a score of three

(64.1 per cent overall) with both intensive and less intensive arms being balanced (59.3 per cent, n= 48 and 69.3 per cent, n=52, respectively). There was no significant difference using Mann-Whitney test for difference (p=.807 (z=-.245)).

4.9.2 Disability at Baseline by Allocation (all patients)

Almost half of all patients were assessed as '3' in terms of their disability at this stage. This was also divided equally amongst the intensive (51.9 per cent, n= 42) and non-intensive (50 per cent, n=37) arms of the trial. Other categories also remained equal. There was no significant difference using Mann-Whitney test for difference (p=.495 (z=-.682)).

Allocation		TOM score: Disability				
		1	2	3	4	Total
Non-int.	Count	0	14	37	23	74
	% within stroke	0	18.9	50.0	31.1	100.0
Int.	Count	1	16	42	22	81
	% within hip	1.2	19.8	51.9	27.2	100.0
Total	Count	1	30	79	45	155
	% of total	.6	19.4	51.0	29.0	100.0

Table 3.36: TOMS disability baseline scores by allocation.

4.9.3 Handicap at Baseline by Allocation (all patients)

In contrast to other domains patients were assessed as performing less well in terms of handicap (Table 3.37 above). Therapists assessed a higher proportion of patients as experiencing less participation in social activities, with half of all patients (50.6 per cent, n= 79) scoring a two on the TOMS handicap scale. Again, however, the scores were well balanced between the two arms of the trial. There was no significant difference using Mann-Whitney test for difference (p=.647 (z=-.457)).

Allocation		TOM score: Handicap					Total
		1	2	3	4	5	
Non-int.	Count	6	39	25	4	1	75
	% within stroke	8.0	52.0	33.3	5.3	1.3	100.0
Int.	Count	10	40	24	7	0	81
	% within hip	12.3	49.4	29.6	8.6	0	100.0
Total	Count	16	79	49	11	1	156
	% of total	10.3	50.6	31.4	7.1	.6	100.0

Table 3.37: TOMS handicap baseline scores by allocation

4.9.4 Well-being at Baseline by Allocation (all patients)

Relatively few patients were assessed by therapists as displaying poor psychological health (Table 3.38 below), with almost two thirds scoring four or above on the TOMS well being scale (62.1 per cent, n=97). Again the proportions are well balanced between the two arms of the trial. There was no significant difference using Mann-Whitney test for difference (p=.83 (z=-.215)).

Allocation		TOM score: Well-being					Total
		1	2	3	4	5	
Non-int.	Count	4	5	19	37	10	75
	% within stroke	5.3	6.7	25.3	49.3	13.3	100.0%
Int.	Count	1	5	25	37	13	81
	% within hip	1.2	6.2	30.9	45.7	16.0	100.0%
Total	Count	5	10	44	74	23	156
	% of total	3.2	6.4	28.2	47.4	14.7	100.0%

Table 3.38:TOMS well-being scores at baseline by allocation.

4.10 Baseline TOMS data by Allocation (stroke)

4.10.1 Impairment at Baseline by Allocation (stroke patients)

TOMS impairment for stroke was not as well balanced at baseline (Table 3.39 below). Over half (51.1 per cent n=23) of the intensive group was assessed at a four or five at this stage, compared with one third of non-intensive patients. The difference was not, however, significant (-5.5, 41.1). There was no significant difference using Mann-Whitney test for difference (p=.257 (z=-1.134)).

Allocation		TOM score: Impairment					Total
		1	2	3	4	5	
Non-int.	Count	1	2	25	13	1	42
	% within stroke	2.4	4.8	59.5	31.0	2.4	100.0
Int.	Count	1	4	17	22	1	45
	% within hip	2.2	8.9	37.8	48.9	2.2	100.0
Total	Count	2	6	42	35	2	87
	% of total	2.3	6.9	48.3	40.2	2.3	100.0

Table 3.39: TOMS Impairment scores for stroke patients by allocation

4.10.2 Disability at Baseline by Allocation (stroke patients)

The same could also be said for TOMS Disability at baseline for stroke patients (Table 3.40 below). Again there was no significant difference using Mann-Whitney test for difference (p=.958 (z=-.052)).

Allocation		TOM score: Disability					Total
		1	2	3	4	5	
Non-int.	Count	0	14	19	8	0	41
	% within stroke	0	34.1	46.3	19.5	0	100.0
Int.	Count	1	14	21	9	0	45
	% within hip	2.2	31.1	46.7	20.0	0	100.0
Total	Count	1	28	40	17	0	86
	% of total	1.2	32.6	46.5	19.8	0	100.0

Table 3.40: TOMS Disability scores for stroke patients by allocation

4.10.3 Handicap at Baseline by Allocation (stroke patients)

Table 3.41 (below) shows that a small proportion of the stroke study patients scored a four for TOMS handicap dimension (8 per cent, n=7). None were assessed at five. The difference between the two group proportions was small and non-significant. Table 3.42 (below) shows that a larger proportion of the intensive arm were assessed at four or five for TOMS well being (66.7 per cent, n=30, compared with 57.1 per cent, n=24). There was no significant difference using Mann-Whitney test for difference (p=.461 (z=-.307)).

Allocation		TOM score: Handicap					Total
		1	2	3	4	5	
Non-int.	Count	5	22	13	2	0	42
	% within stroke	11.9	52.4	31.0	4.8	0	100.0
Int.	Count	7	18	15	5	0	45
	% within hip	15.6	40.0	33.3	11.1	0	100.0
Total	Count	12	40	28	7	0	87
	% of total	13.8	46.0	32.2	8.0	0	100.0

Table 3.41: TOMS Handicap scores for stroke patients by allocation

4.10.4 Well-being at Baseline by Allocation (stroke patients)

The scores for TOMS Well-being at baseline were also well balanced between the two groups. There was no significant difference using Mann-Whitney test for difference (p=.307 (z=-1.022)).

Allocation		TOM score: Well-being					Total
		1	2	3	4	5	
Non-int.	Count	3	4	11	20	4	42
	% within stroke	7.1	9.5	26.2	47.6	9.5	100.0
Int.	Count	0	3	12	25	5	45
	% within hip	0	6.7	26.7	55.6	11.1	100.0
Total	Count	3	7	23	45	9	87
	% of total	3.4	8.0	26.4	51.7	10.3	100.0

Table 3.42: TOMS Well-being scores for stroke patients by allocation

4.11.1 Impairment at Baseline by Allocation (hip fracture patients)

None of the hip fracture patients scored a five in the impairment dimension and a larger proportion of the non-intensive group was assessed at a four (Table 3.43). There was no significant difference using Mann-Whitney test for difference (p=.332 (z=-.970)).

Allocation		TOM score: Impairment					Total
		1	2	3	4	5	
Non-int.	Count	0	0	27	6	0	33
	% within stroke	0	0	81.8	18.2	0	100.0
Int.	Count	0	1	31	4	0	36
	% within hip	0	2.8	86.1	11.1	0	100.0
Total	Count	0	1	58	10	0	69
	% of total	0	1.4	84.1	14.5	0	100.0

Table 3.43: TOMS Impairment scores for hip fracture patients by allocation

4.11.2 Disability at Baseline by Allocation (hip fracture patients)

Table 3.44 (below) shows that as with TOMS impairment for hip fracture, none of the patients were assessed as a five for TOMS Disability. A larger proportion of the hip fracture patients was assessed at four. There was no significant difference using Mann-Whitney test for difference (p=.224 (z=-1.216)).

Allocation		TOM score: Disability					Total
		1	2	3	4	5	
Non-int.	Count	0	0	18	15	0	33
	% within stroke	0	0	54.5	45.5	0	100.0
Int.	Count	0	2	21	13	0	36
	% within hip	0	5.6	58.3	36.1	0	100.0
Total	Count	0	2	39	28	0	69
	% of total	0	2.9	56.5	40.6	0	100.0

Table 3.44: TOMS Disability scores for hip fracture patients by allocation

4.11.3 Handicap at Baseline by Allocation (hip fracture patients)

For TOMS handicap also, there was little difference between the two hip fracture groups (Table 3.45 below). Just two of the intensive group were assessed as a four or five and just three of the non-intensive group. There was no significant difference using Mann-Whitney test for difference (p=.103 (z=-1.633)).

Allocation		TOM score: Handicap					Total
		1	2	3	4	5	
Non-int.	Count	1	17	12	2	1	33
	% within stroke	3.0	51.5	36.4	6.1	3.0	100.0
Int.	Count	3	22	9	2	0	36
	% within hip	8.3	61.1	25.0	5.6	0	100.0
Total	Count	4	39	21	4	1	69
	% of total	5.8	56.5	30.4	5.8	1.4	100.0

Table 3.45: TOMS Handicap scores for hip fracture patients by allocation

4.11.4 Well-being at Baseline by Allocation (hip fracture patients)

Over two-thirds (69.7 per cent, n=23) of the non-intensive group were assessed as a four or five for TOMS well being compared with just over half of the intensive group (55.5 per cent, n=20). There was no significant difference using Mann-Whitney test for difference (p=.458 (z=-.742)).

Allocation		TOM score: Well-being					Total
		1	2	3	4	5	
Non-int.	Count	1	1	8	17	6	33
	% within stroke	3.0	3.0	24.2	51.5	18.2	100.0
Int.	Count	1	2	13	12	8	36
	% within hip	2.8	5.6	36.1	33.3	22.2	100.0
Total	Count	2	3	21	29	14	69
	% of total	2.9	4.3	30.4	42.0	20.3	100.0

Table 3.46: TOMS Well-being scores for hip fracture patients by allocation

5 Discussion

5.1 Recruitment, Referral and Consent

The recruitment phase for the study was a lengthy and protracted exercise. The proportion of non-responses was significantly higher than was anticipated, resulting in a delay of six months in the completion of recruitment. Even given this delay the sample size for the study fell short of the original power calculation of 200 patients (see methods Chapter). This small sample size is not uncommon in rehabilitation research, a point to which I shall return in the final discussion Chapter. The explanation for such a high non-response is an issue worth addressing. For the time being it should be noted that the primary care setting may be a factor in the problems encountered during this phase, although again this will be addressed more fully later on. It is worth commenting, however, upon the significant difference detected around the reasons given for non-consent on the basis of aetiology. Intensity of treatment was much more an issue for concern amongst stroke patients than it was for hip fracture patients, whose reasons tended to be related to a lack of enthusiasm for research and the use of old age as an explanation for non-consent. It might be ventured that the role of community rehabilitation was perceived as more consequential in the process of stroke recovery and therefore discussions about intensity of treatment more pertinent. On the other hand some of the stroke study patients were less impaired than the hip fracture patients. If this were to be reflected in the main sample it might be postulated that lack of impairment is an explanation for wanting a less intensive service. Without the data on the non-responders this is difficult to say with any certainty.

5.2 Consenting and Non-consenting Patients

One important result from the baseline data is that the study patients were broadly similar to the non- responders on some key variables. Age and time since stroke or hip fracture (TSE) were two important factors in the recovery process and these were similar in both consenting and non-consenting patients.

Other variables however demonstrated important differences. A larger proportion of men was represented in the study sample than existed in the main sample. Given the evidence that men perform less favourably on the Barthel and FAI, this is something to consider. Also those living alone were less likely to agree to participation in the study resulting in a smaller proportion taking part. Given the significance of the existence of a family carer to the recovery phase this is also a difference worthy of closer and more in depth consideration. For ethical reasons other data, such as Barthel at CRT admission, has not been accessed. Comparisons therefore between the activity and impairment profile of the non-responders are not available.

5.3 Randomisation and Balance Between Two Groups

One of the primary objectives of the chapter was to illustrate that the two arms of the trial were well balanced in terms of the key variables, therefore rendering the randomisation procedure a successful exercise. The results presented in this chapter indicate this to be the case. On all outcome measures, with the exception of one of the Euroqol scores, balance between the arms has been achieved. This is also the case for other variables such as age and TSE. The issue of gender is problematic in that more men were allocated to receive the intensive programme of therapy, although this difference was non-significant. Again, the issue that men also scored lower on the Barthel at baseline does, however, compound this problem. Gender may therefore be a confounding variable and thought needs to be given to how this handled in subsequent strategies for analysis (see Chapter 8: Logistic Regression).

Within aetiology there also remains few problems regarding balance between the two arms of the trial. The exception to this is for stroke HADS anxiety where the non-intensive patients were significantly less anxious. Despite this the broad conclusion that can be drawn from this Chapter is that the randomisation procedure was successful.

Chapter Four: Treatment Compliance

This short chapter describes the treatment regimes provided to the patients participating in the trial. It will outline the methods for data collection, the face to face contact data for each arm of the trial and a commentary of the results.

Therapists and therapy assistants were requested that they record each visit paid to a patient on a recording sheet. There were two reasons for this. Firstly, this helped each team monitor for itself the number of visits paid in any one week to a study patient. Secondly, it provided the author with data regarding contacts again for monitoring purposes and ultimately for analysis.

1 Comparing Treatment Regimes

1.1 Statistical significance of the difference between treatment regimes: Number of visits.

The number of visits provided for each group were also calculated for each patient. The differences between the total number of contacts at week four, week eight and week 12 for both arms of the trial are presented in tables 4.1, 4.2 and 4.3.

	Mean	Sig. (2-tailed)	Mean difference	SE	95% CI	
					Lower	Upper
Non-Int.	9.4138	0.000	-6.6063	.6153	-7.8223	-5.3903
Intensive	16.2000					

Table 4.1: Results of independent t-test comparing the number of visits after four weeks of CRT treatment by allocation

	Mean	Sig. (2-tailed)	Mean difference	SE	95% CI	
					Lower	Upper
Non-Int.	14.9865	0.000	-8.4135	1.3242	-11.0304	-5.7966
Intensive	23.4000					

Table 4.2: Results of independent t-test comparing the number of visits after eight weeks of CRT treatment by allocation.

	Mean	Sig. (2-tailed)	Mean difference	SE	95% CI	
					Lower	Upper
Non-Int.	16.7162	.000	-8.1105	1.6857	-11.4419	-4.7790
Intensive	24.8267					

Table 4.3: Results of independent t-test comparing the number of visits after 12 weeks of CRT treatment by allocation.

The tables indicate that there existed a significant difference between the number of face to face contacts provided by CRT to the two arms of the trial at weeks four, eight and twelve.

1.2 Week to week contact data by allocation

Line graph 4.1 (below) shows the treatment activity for each group for all patients over the twelve-week treatment period. The lines represent mean number of visits in each week.

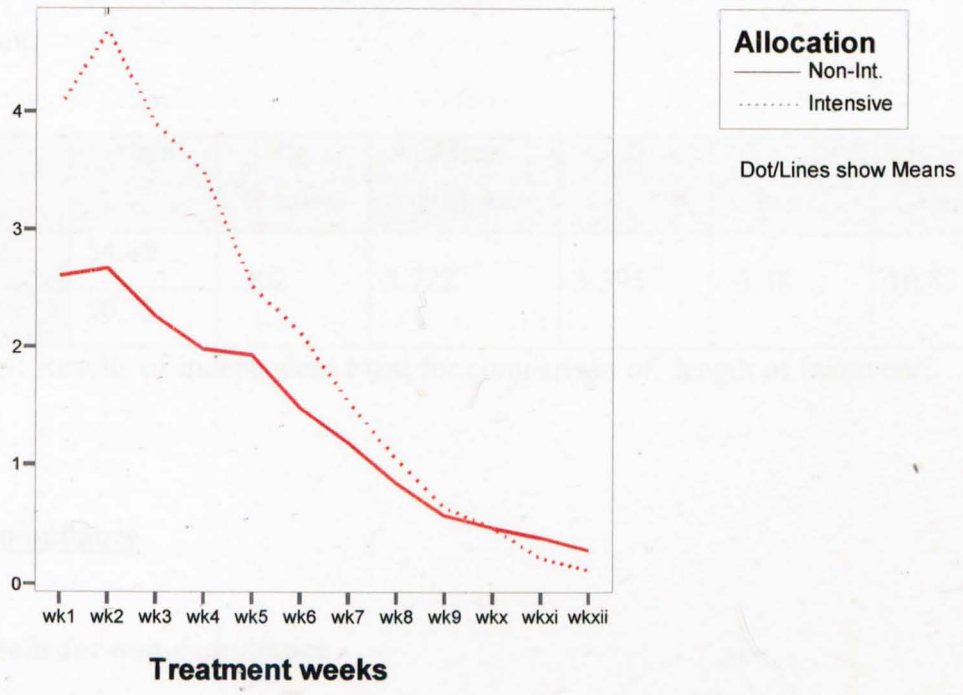


Chart 4.1: Mean number of visits per week by allocation

The line graph indicates that there was a difference between the two treatment groups, however this difference only exists in the early part of the treatment.

1.3 Statistical significance of the difference between treatment regimes: week to week

The week by week contact data was examined using independent t-tests. The tests indicate that the treatment regimes were statistically significant, up until the sixth week of treatment ($p<.05$). From week seven through to week 12 the difference between the groups was non-significant.

1.4 Length of Treatment

Although there was a significant difference in the treatment regimes of the two groups, no such significant difference was detected on the length of treatment. Table 4.4 shows the results of an independent t-test of the number of days between admission to CRT and discharge. The results indicate a longer stay for non-intensive patients (by just over 4 days). However, the difference is not significant.

	Mean	Sig. (2-tailed)	Mean difference	SE	95% CI	
					Lower	Upper
Non-Int.	54.48	.302	3.722	3.595	-3.38	10.83
Intensive	50.75					

Table 4.4: Results of independent t-test for comparison of length of treatment by CRT.

2 Non-compliance

2.1 Reasons for non-compliance

The graph indicates that at no point does the mean number of visits for the non-intensive group exceed 3 visits per week. However, the line graph also indicates that the mean number of visits for the intensive group does at no point extend to the intended six face to face contacts per week. Staff were requested

to include on the contact sheet the details of any visits cancelled by patients or explanation for not visiting patients. There were a number of examples of therapists recording reasons for failure to complete a face to face contact with patients. Firstly, the lack of staff time was the most frequently cited explanation for not achieving the target number of visits, this was particularly true during bank holiday periods. Patient compliance was also cited. These included patient rejection of treatment and participation in leisure activities or attendance of other appointments (such as hospital) preventing visits. In addition to this it should be noted that issues such as patient motivation, tolerance and preference may have had a baring upon the level of contact that actually occurred, regardless of treatment allocation within the study.

2.2 Crossover

During the internal pilot phase of the study therapists requested the authority to switch patients between the two arms of the study. A discussion regarding this was held with staff. The eventual protocol suggested that this could only occur in circumstances where patient safety was an issue or where it was clear that intensive treatment was not possible (see protocol in Appendix V). There were five instances where changes such as this were brought to the attention of the author. In two cases patients were switched to the less intensive arm. One therapist felt that he was able to do very little for a woman and he felt that she was growing suspicious of him. In a second case the therapists were working with the patient on driving a car and felt it was inappropriate to request that the patient drive every day. In three instances patients with balance and swallowing difficulties were switched to the intensive arm for reasons of safety.

2.3 Discharge Protocol

Therapists were requested that they treat until they felt that patients could be discharged. However, they were also given licence to 'tail off' the number of visits within three weeks of a discharge date. Line graph one shows that both treatment arms both have steep slopes, the intensive more so than the less intensive. These steep slopes appear to be the result of such protocol in that

therapists were 'tailing off' a greater number of visits over a shorter period of time.

3 Conclusion

This study set out to compare the effect of two different treatment regimes on patient outcome. Initially the treatment regimes were defined as six or more visits per week and three or less. In very few cases did the therapy teams manage to provide the number of visits per week required for the intensive treatment regime. In a small number of cases (mainly due to patient safety issues) the number of visits for some patients in the non-intensive arm exceeded three visits per week. The failure to achieve 2:1 treatment regimes is disappointing. Appendix IX shows the number of contacts at four, eight and 12 weeks in the form of scattergrams by age with cases identified by allocation. These scatergrams help illustrate how compliance was moderated over time. However, given the circumstances of available therapist time, patient preference and safety, is also understandable. It should also be noted that despite these breaches in protocol, data were analysed on an intention to treat basis. Furthermore, I did find it encouraging that despite this failure to achieve a 2:1 treatment ratio, there was a significant difference ($p<0.05$) in the mean number of face to face contacts at week four, week eight and week 12. In addition the mean number of face to face contacts on a week to week basis were also significant for the first six weeks of treatment ($p<0.05$). This significant difference gives confidence that the study is examining two different treatment regimes, the issue of whether or not the difference was clinically significant is a point I shall address in the discussion chapter.

Chapter Five: One-Month Assessment Data

1.1 Patients lost to follow up

Fifteen patients were not assessed at one month. The reasons for this were patient withdrawal (8), patients in hospital (4) and unable to contact a further three within reasonable time (3). Of the withdrawals six of the eight were all within the non-intensive group. This indicates that patients allocated to the non-intensive arm were more likely to withdraw from the study, although the difference was not significant. There was also no significant difference between the two groups in the OR for hospital admission at one month. Table 5.1 (below) shows the odds ratio for hospital admission and withdrawal at one month using the non-intensive group as the reference. The 95% CI for each shows that here were no significant differences between the two groups.

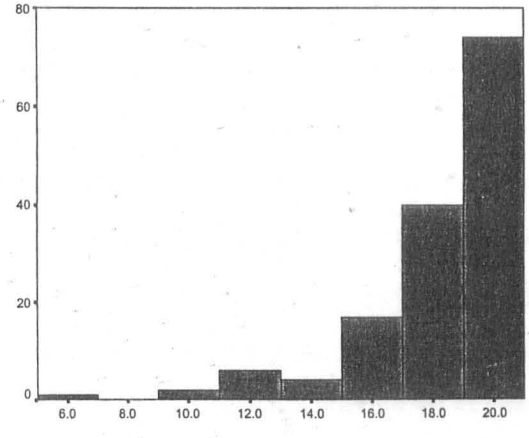
Outcome	OR	95 % CI
Hospital at three months	1.07	.05, 20.8
Withdrawn at three months	3.2	.62, 16.33

Table 5.1: Odds ratio for loss to follow up outcome at three months

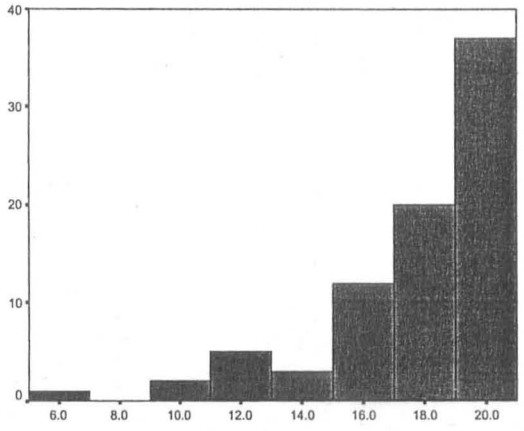
2 Barthel Scores at one-month

2.1 Distribution of Barthel at One-month

The distribution of Barthel scores for all patients is represented in Histograms 5.1, 5.2 and 5.3.

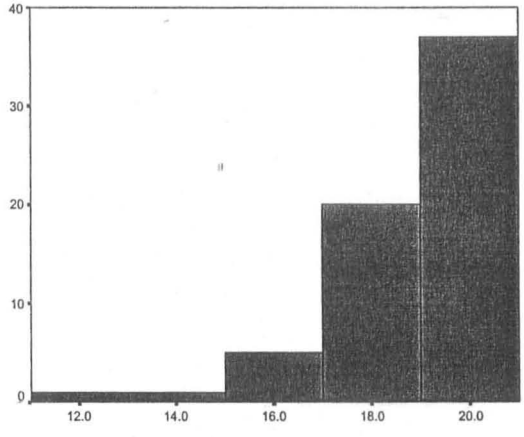


Histogram 5.1: Barthel scores for all patients at one month.
Median = 19.00 (6, 20)



Histogram 5.2: Barthel scores for stroke patients at one month.
Median = 18.00 (6, 20)

Histogram 5.1 indicates that the Barthel scores at one month are negatively skewed. The majority of patients (61.3 per cent, n=98) scored between 18 and 20. Almost one-third (29.4 per cent, n= 47) scored a maximum 20 by the one month follow up. The histograms showing the data for stroke patients and hip fracture patients are also negatively skewed.



Histogram 5.3: Barthel scores for hip fracture patients at one month.
Median = 19.00 (11, 20)

2.2 Barthel: Change since baseline

A degree of favourable change was detected in the one-month Barthel scores when compared with baseline data. The median Barthel score at for all patients was 16.00 at baseline and, as noted above, was 19.00 at one month. This represents a significant change between the two time points. The median Barthel score at baseline for stroke patients was 16.00 and, as noted above, was 18.00 at one month. This represents a significant change between the two time points for stroke patients regardless of allocation. The median Barthel score at for hip fracture patients was 16.00 at baseline and, as noted above, was 19.00 at

one month. Table 5.2 (below) shows the results of the Wilcoxon signed ranks tests for change at one month for all patients as well as subgroup analysis for the two aetiologies. It can be noted that the results indicate significant change from baseline to one month for all patients as well as within each of the aetiology sub-group.

Wilcoxon Signed Ranks Test	Z Score	Significance (2-tailed)
All patients	-8.895	$p<0.05$
Stroke	-6.233	$p<0.05$
Hip fracture	-6.6362	$p<0.05$

Table 5.2: Results of Wilcoxon Signed Ranks test for change in from baseline to one month.

2.3 Barthel at One-month by Allocation

2.3.1 Barthel at One-month by Allocation (all)

The distribution of the Barthel data by allocation is indicated in Chart 5.1 (below).

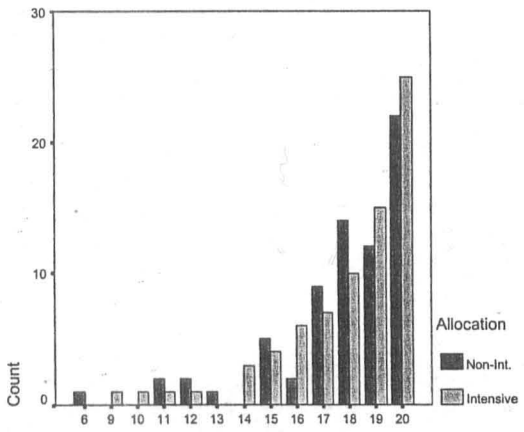


Chart 5.1: Distribution of Barthel score for patients by allocation

The chart indicates that the distribution of the data for both arms of the trial is broadly similar. This is reflected in the median scores for the two arms of the trial. The median for the intensive arm of the trial was 19 (min. 9, max. 20),

whilst the median score for the less-intensive arm of the trial was 18 (min. 6, max. 20).

2.3.2 Barthel Scores at One-month by Allocation (stroke)

The median score for all stroke patients at one month was 18.00 (min.6, max.20). There did exist a difference in the median Barthel scores between two arms of the trial at one month for stroke patients. The median score for the non-intensive group was 18.00 (min.6, max.20) whilst the median score for the intensive group was 18.50 (min. 9, max.20).

2.3.3 Barthel Scores at One-month by Allocation (hip fracture)

The median score for all hip fracture patients at one month was 19.00 (min, 11, max. 20). There was no difference in the median Barthel scores between two arms of the trial at one month. The median for the non-intensive group was 19.00 (min. 16, max. 20) and for the intensive group 19.00 (min. 11, max.20).

2.4 Mann-Whitney U Test for Significance for Difference in Barthel Score by Allocation

The Mann-Whitney U Test was used in order to compare the Barthel scores for the allocated groups. The results are shown in Table 5.3 (below). The table indicates that there was no significant difference between the two groups when conducting the test for all patients as well as when analysing by subgroup.

Group	Mann-Whitney U	Z Score	Significance (2-tailed)
All	2530.5	-.244	p>0.05
Stroke	765.500	-.337	p>0.05
Hip fracture	509.000	-.014	p>0.05

Table 5.3: Results of Mann-Whitney U Test for difference between the two groups in Barthel at one month.

2.5 Categorised Barthel at One-month

2.5.1 Categorised Barthel at One Month by Allocation (all)

Table 5.4 (below) indicates the categorised Barthel data by allocation. Almost one-third (32.6 per cent, n= 47) had realised independent status by one month. The Table shows that the distribution for both intensive and less intensive treatment regimes is almost identical. The difference in the proportion of each group achieving independent status (scoring 20) at this stage was not significant (2.4 (-12.8, 17.6)).

Allocation		Categorised Barthel			Total
		Dependent	Semi-independent	Independent	
Non-Intensive (NI)	Count	6	42	22	70
	% within NI	8.6	60.0	31.4	100.0
Intensive (I)	Count	7	42	25	74
	% within I	9.5	56.8	33.8	100.0
Total	Count	13	84	47	144
	% of total	9.0	58.3	32.6	100.0

Table 5.4: Categorised Barthel at one month by Allocation.

2.5.2 Categorised Barthel at One Month by Allocation (stroke)

Table 5.5 shows categorised Barthel for stroke patients at one month by allocation. One quarter (26 per cent, n=21) were assessed as independent at this stage, whilst almost two-thirds (60 per cent, n= 48) remained semi-independent according to the Barthel. The table indicates a similar distribution between the two arms of the trial. The difference between the proportions of each group achieving independent status was not significant (2.5 (-16.7, 21.7)).

Allocation		Categorised Barthel			Total
		Dependent	Semi-independent	Independent	
Non-Intensive (NI)	Count	6	23	11	40
	% within NI	15.0	57.5	27.5	100.0
Intensive (I)	Count	5	25	10	40
	% within I	12.5	62.5	25.0	100.0
Total	Count	11	48	21	80
	% of total	13.8	60.0	26.	100.0

Table 5.5: Categorised Barthel at one month by allocation for stroke patients.

2.5.3 Categorised Barthel at One Month by Allocation (hip fracture)

Table 5.6 (below) shows categorised Barthel for hip fracture patients at one month by allocation.

Allocation		Categorised Barthel			Total
		Dependent	Semi-independent	Independent	
Non-Intensive (NI)	Count	0	19	11	30
	% within NI	0	63.3	36.7	100.0
Intensive (I)	Count	2	17	15	34
	% within I	5.9	50.0	44.1	100.0
Total	Count	2	36	26	64
	% of total	3.1	56.3	40.6	100.0

Table 5.6: Categorised Barthel at one month by allocation for hip fracture patients.

The table indicates a difference in the distribution between the two arms of the trial. It shows that 44.1 per cent of the intensive arm had achieved a maximum Barthel score of 20 (Independent) at one month, whereas this was the case for only 36.7 per cent of the non-intensive patients. The difference between the proportions of each group achieving independent status was not significant (7.4 (-16.5, 31.3)).

3 HADS at One-month

3.1 Categorised HADS at One-Month

Tables 5.7 and 5.8 present the HADS data for all study patients at one-month. The tables indicate modest levels of anxiety and depression amongst the study sample at one-month. In both sub-scales nearly two thirds of the sample were not identified as 'case'.

HADS Anxiety		Frequency	Percent
Valid	Non-case	97	60.6
	Doubtful	30	18.8
	Case	18	11.3
	Total	145	90.6
Missing		15	9.4
Total		160	100.0

Table 5.7: Categorised HADS Anxiety score for all patients at one-month

HADS Depression		Frequency	Percent
Valid	Non-case	99	61.9
	Doubtful	30	18.8
	Case	16	10.0
	Total	145	90.6
Missing		15	9.4
Total		160	100.0

Table 5.8: Categorised HADS Depression score for all patients at one-month

3.2 Comparison with Baseline HADS Data

It is not appropriate to consider the difference between the two proportions identified as 'case' at baseline and at one month as I have already done in several circumstances when comparing two independent groups. This is because some consideration of the matched nature of the sample that occurs when making two observations of the same sample, as is the case when comparing baseline and one month proportions here needs to be made (Altman 1991) (page236). Using this approach a test statistic Z can be calculated to test the null hypothesis that there is a no difference between the two (see appendix for method of calculation).

3.2.1 Comparison with Baseline HADS (all)

At baseline 26 patients were identified as 'case', by one month this had reduced to 18. The difference is not significant (z=1.6 (p=.109)). The same can be done with proportions identified as HADS Depression 'case'. Thirteen study participants were identified as HADS Depression 'case' at baseline compared with 16 at one month. The difference was not significant (z=-1 (p=.317)).

3.2.2 Comparison with Baseline HADS (stroke)

The time between baseline and one month saw the proportion of stroke patients in the study identified as 'case' HADS Anxiety reduce. At baseline twelve stroke patients were identified as 'case', at one month this was nine. The difference was not significant (z=.377 (p=.711)). For HADS Depression at baseline 12 (86) stroke patients were identified as 'case' this was the case for 13 (80) at one month (z=-.447 (p=.659)).

3.2.3 Comparison with Baseline HADS (hip fracture)

The number of hip fracture patients identified as HADS Anxiety 'case' decreased from 14 at baseline to 9 at one month. The difference was not significant (z=1.73 (p=.083)). The number of hip fracture patients identified as

HADS Depression 'case' increased from 1 at baseline to 5 at one month. The difference was not significant (z=-1 (p=.317)).

3.3 Categorised HADS at One-month by Allocation

3.3.1 Categorised HADS at One-month by Allocation (all)

Tables 5.9 and 5.10 summarise the HADS anxiety and depression sub-scales by allocation. Some differences can be seen in Table 7, with the non-intensive group indicating higher levels of anxiety. Twelve (17.1 per cent) of those in the non-intensive group were identified as 'case' and 17 (24.3 per cent) as 'doubtful'. Only six (8.0 per cent) of the intensive group were identified as cases and 13 (17.3 per cent) as doubtful. Although there was a higher proportion of patients from the non-intensive arm of the study identified as 'case', the difference in proportions was not significant (9.1 (-1.6, 19.8)).

Allocation		Categorised HADS Anxiety data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	41	17	12	70
	% within NI	58.6	24.3	17.1	100.0
Intensive	Count	56	13	6	75
	% within Int.	74.7	17.3	8.0	100.0
Total	Count	97	30	18	145
	% of total	66.9	20.7	12.4	100.0

Table 5.9: Categorised HADS Anxiety by allocation at one-month.

The findings from the depression sub-scale (Table 5.10 below) show that no differences existed between the two groups in terms of HADS depression with broadly similar distributions. The difference between the proportions of each group identified as case was not significant (3.6 (-5.4, 12.6)).

Allocation		Categorised HADS Depression data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	48	13	9	70
	% within NI	68.6	18.6	12.9	100.0
Intensive	Count	51	17	7	75
	% within Int.	68.0	22.7	9.3	100.0
Total	Count	99	30	16	145
	% of total	68.3	20.7	11.0	100.0

Table 5.10: Categorised HADS Depression by allocation at one-month

3.3.2 Categorised HADS at One-month by Allocation (stroke)

Tables 5.11 and 5.12 show the categorised HADS data for stroke patients by allocation. HADS anxiety sub-scales do indicate a difference between the two groups with two fifths (40 per cent, n= 16) of the non-intensive group showing case or ambiguous status. This is the case for less than one quarter (22.5 per cent, n=9) of the intensive group. The difference between the proportions of each group identified as case was not significant (12.5 (-.09, 25.9)).

Allocation		Categorised HADS Anxiety data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	24	9	7	40
	% within NI	60.0	22.5	17.5	100.0
Intensive	Count	31	7	2	40
	% within Int.	77.5	17.5	5.0	100.0
Total	Count	55	16	9	80
	% of total	68.8	20.0	11.3	100.0

Table 5.11: Categorised HADS anxiety at one-month for stroke patients by allocation.

Table 5.12 would suggest that here existed virtually no difference between the two groups for stroke patients on the HADS anxiety depression sub-scale, Table 10 indicates this below.

Allocation		Categorised HADS Depression data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	26	7	7	40
	% within NI	65.0	17.5	17.5	100.0
Intensive	Count	26	8	6	40
	% within Int.	65.0	20.0	15.0	100.0
Total	Count	52	15	13	80
	% of total	65.0	18.8	16.3	100.0

Table 5.12: Categorised HADS depression at one-month for stroke patients by allocation.

The difference between the proportions of each group identified as case was not significant (2.5 (-13.5, 18.5)).

3.3.3 Categorised HADS at One-month by Allocation (hip fracture)

Table 5.13 (below) shows the categorised HADS anxiety scores for hip fracture at one month. A difference between the two arms of the trial can be observed. Twenty-five (71.4 per cent) of the patients allocated to the intensive arm were assessed as non-cases, where as this was the case for only 17 (56.7 per cent) of the non-intensive arm. However, the difference between the proportions of each group identified as case was not significant (5.3 (-11.4, 22)).

Allocation		Categorised HADS Anxiety data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	17	8	5	30
	% within NI	56.7	26.7	16.7	100.0
Intensive	Count	25	6	4	35
	% within Int.	71.4	17.1	11.4	100.0
Total	Count	42	14	9	65
	% of total	64.6	21.5	13.8	100.0

Table 5.13: Categorised HADS anxiety for hip fracture patients by allocation.

Allocation		Categorised HADS Depression data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	22	6	2	30
	% within NI	73.3	20.0	6.7	100.0
Intensive	Count	25	9	1	35
	% within Int.	71.4	25.7	2.9	100.0
Total	Count	47	15	3	65
	% of total	72.3	23.1	4.6	100.0

Table 5.14: Categorised HADS depression for hip fracture patients by allocation.

No difference existed for the categorised HADS depression scores for hip fracture at this stage. Table 5.14 (above) shows that the distribution between the two arms of the trial was broadly similar. The difference between the proportions of each group identified as case was not significant (3.8 (-5.8, 13.4)).

4 Euroqol Data at One-Month

4.1 EQ-5D and Self-perceived Health Status at One-month

The median EQ-5D score for all patients at one month was 62.00 (min. -.35, max. 1.00). The median self perceived health status score for all patients at one-month was also 62.00 (min.19, max. 1.00).

4.2 Comparison with Baseline Euroqol Data

4.2.1 Comparison with Baseline Euroqol (all)

No significant difference was detected between baseline and one-month EQ-5D scores for all patients. Also no change was made in terms of self-perceived health status for all patients between baseline and one month.

Wilcoxon Signed Ranks Test	Z Score	Significance (2-tailed)
EQ-5D	-.850	p>0.05
Health Status	- .413	p>0.05

Table 5.15: Results of Wilcoxon Signed Ranks test for change in from baseline to one month for all patients.

4.2.2 Comparison with Baseline Euroqol (stroke)

No significant difference was detected between baseline and one-month EQ-5D scores for all patients and no change was made in terms of self-perceived health status for all patients between baseline and one month (see Table 5.16 below).

Wilcoxon Signed Ranks Test	Z Score	Significance (2-tailed)
EQ5D	-.920	p>0.05
Health Status	- .444	p>0.05

Table 5.16: Results of Wilcoxon Signed Ranks test for change in from baseline to one month for stroke patients.

4.2.3 Comparison with Baseline Euroqol (hip fracture)

Wilcoxon Signed Ranks Test	Z Score	Significance (2-tailed)
EQ-5D	-1.584	p>0.05
Health Status	- .306	p>0.05

Table 5.17: Results of Wilcoxon Signed Ranks test for change in from baseline to one month for hip fracture patients.

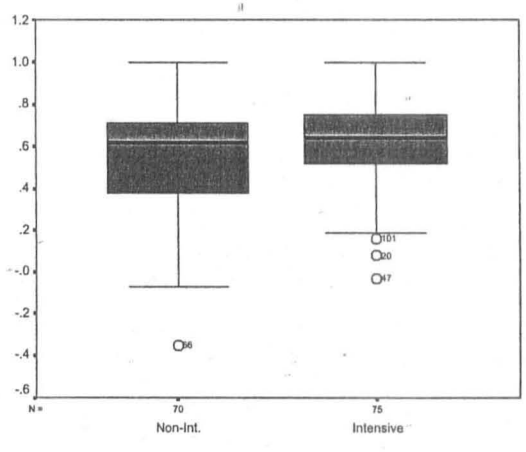
No significant difference was detected between baseline and one-month EQ-5D scores for hip fracture patients (Table 5.17). Also no change was made in terms

of self-perceived health status for hip fracture patients between baseline and one month.

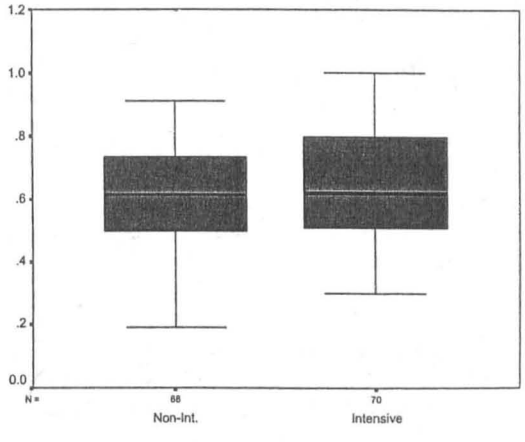
4.3 Euroqol Data by allocation at One-Month

4.3.1 Euroqol by Allocation at One-month (all)

The EQ-5D and self perceived health status scores at one-month by allocation are presented in Box Plots 5.1 and 5.2 (below). Both box plots show differences in favour of the intensive arm of the trial. Box Plot one shows a more favourable median for the intensive group (.64 compared with .62). The 95% range is smaller for the intensive group with its lower values being plotted above those of the non-intensive group. Box Plot 2 indicates that the median for the intensive group is above that of the non-intensive group (.61 compared with .63). The 95% range for the intensive group is also distributed over a range of values greater than that of the non-intensive group.



Box Plot 5.1: EQ5D by Allocation at one month

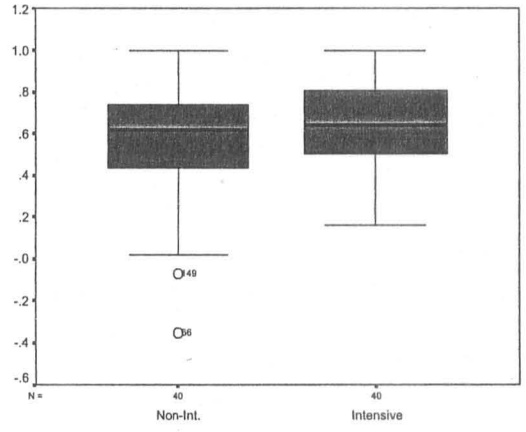


Box Plot 5.2: Self- perceived health status by allocation at one month

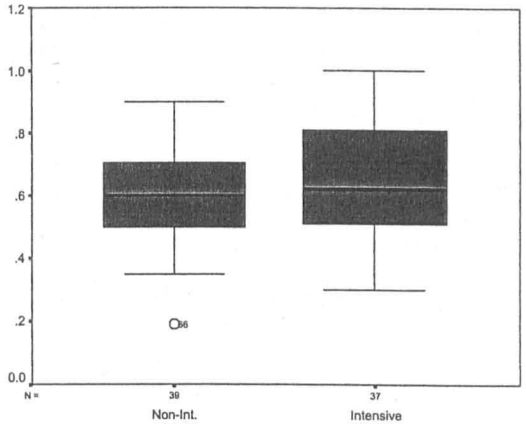
4.3.2 Euroqol by Allocation at One-month (stroke)

Box Plots 5.3 and 5.4 (below) show the EQ-5D and self-perceived health status data for stroke patients by allocation. For both outcome measures there exists a

difference in favour of the intensive arm of the trial. As with the analysis for all patients the median EQ-5D score for the intensive stroke group was marginally above that of the non-intensive group (.64 compared with .62). The 95% range also shows that the non-intensive group includes values below that of the intensive group. The median score for the intensive stroke group for the self-perceived health status at one month was also above that of the non-intensive group (.62 compared with .60), however the 95% range is wider, including both higher and lower values.



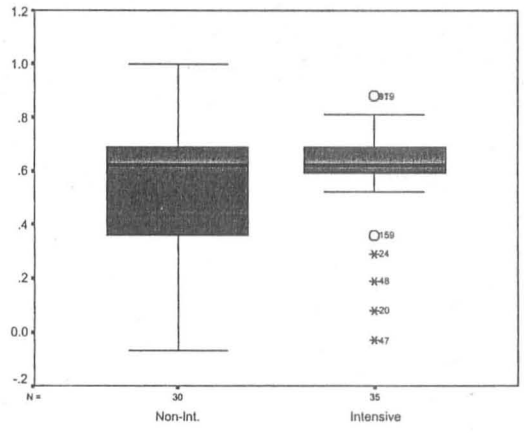
Box Plot 5.3: EQ5D by Allocation at one month for stroke.



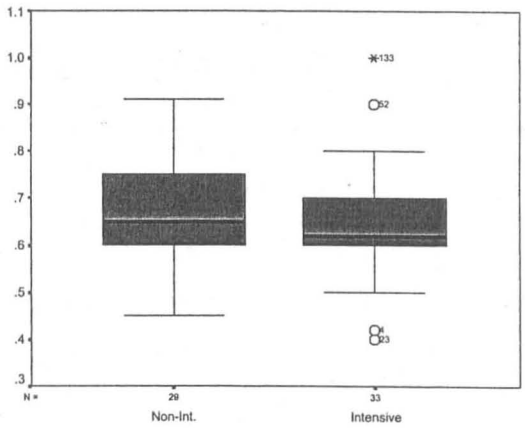
Box Plot 5.4: Self- perceived health status by allocation at one month for stroke.

4.3.3 Euroqol by Allocation at One-month (hip fracture)

Box Plots 5.5 and 5.6 show the Euroqol data at one month for hip fracture patients by group allocation. For EQ-5D the medians were equal (.62), however the 95% range is much shorter for the intensive group. For self-perceived health status the non-intensive hip fracture group scored a median above that of the intensive group (.64 compared with .62). The 95% range for the non-intensive group includes values, which are both above and below that of the intensive group.



Box Plot 5.5: EQ5D by Allocation at one month for hip fracture



Box Plot 5.6: Self- perceived health status by allocation at one month for fracture neck of femur

4.4 Mann Whitney test for difference for Euroqol Data at one month

With the exception of the hip fracture data, the above box plots point favourably to the intensive group. Table 5.18 and Table 5.19 (below) summarise the results of Mann Whitney tests for difference undertaken on this data. The table shows that despite the apparent differences indicated by the distribution of the scores (above) no significant differences emerge for either EQ-5D or Self-perceived health status.

Group	Mann-Whitney U	Z Score	Significance (2-tailed)
All	2261.500	-1.442	p>0.05
Stroke	691.500	-1.046	p>0.05
Hip fracture	449.000	-1.009	p>0.05

Table 5.18: Results of Mann-Whitney U Test for difference between the two groups for EQ-5D at one month.

Group	Mann-Whitney U	Z Score	Significance (2-tailed)
All	2210.500	-.725	p>0.05
Stroke	587.000	-1.402	p>0.05
Hip fracture	417.500	-.866	p>0.05

Table 5.19: Results of Mann-Whitney U Test for difference between the two groups for self-perceived health status at one month.

5 TOMS Data at One month

5.1 TOMS at One-month by Allocation (all)

5.1.1 Impairment by Allocation

Tables 5.20 to 5.23 show the TOMS data at one month for all patients by allocation. All four tables indicate little difference between the two groups under the domains of impairment, activity, participation and well being. In terms of impairment (Table 5.20) the majority of all patients (90.3 per cent, n=131) were assessed as either a three or a four. A larger proportion of the intensive group were assessed as a four or five (54 per cent, n= 40 for intensive, 48.5 per cent, n= 34 for non-intensive). The difference between these proportions was non-significant (5.5 (-10.8, 21.8)).

Allocation		TOM score: Impairment					Total
		1	2	3	4	5	
Non-int.	Count	3	2	31	33	1	70
	% within NI	4.3	2.9	44.3	47.1	1.4	100.0
Int.	Count	0	4	30	36	4	74
	% within Int.	0	5.4	40.5	48.6	5.4	100.0
Total	Count	3	6	61	69	5	144
	% of total	2.1	4.2	42.4	47.9	3.5	100.0

Table 5.20: TOMS Impairment scores at one month by allocation.

5.1.2 Disability by Allocation

A similar observation can be made regarding TOMS disability scores (Table 5.21) with the majority (84.3 per cent, n=122) being assessed as either a three or four. The distributions for both non-intensive and intensive arms of the trial were similar. A minor non-significant difference between the two groups existed in the proportion of each being assessed as a four or five (60.9per cent, n=45 for intensive, 62.9 per cent, n=44 for non-intensive).

Allocation		TOM score: Disability					Total
		1	2	3	4	5	
Non-int.	Count	1	7	18	41	3	70
	% within NI	1.4	10.0	25.7	58.6	4.3	100.0
Int.	Count	0	9	20	42	3	74
	% within Int.	0	12.2	27.0	56.8	4.1	100.0
Total	Count	1	16	38	83	6	144
	% of total	.7	11.1	26.4	57.6	4.2	100.0

Table 5.21: TOMS Disability scores at one month by allocation.

5.1.3 Handicap by Allocation

For handicap TOMS scores were more evenly distributed across the scales (Table 5.22). In terms of handicap it appears that the more intensive arm of the trial prospered in comparison with the non-intensive patients.

Allocation		TOM score: Handicap					Total
		1	2	3	4	5	
Non-int.	Count	2	19	24	22	2	69
	% within NI	2.9	27.5	34.8	31.9	2.9	100.0
Int.	Count	1	14	28	25	6	74
	% within Int.	1.4	18.9	37.8	33.8	8.1	100.0
Total	Count	3	33	52	47	8	143
	% of total	2.1	23.1	36.4	32.9	5.6	100.0

Table 5.22: TOMS Handicap scores at one month by allocation.

Over two fifths (41.9 per cent, n=31) were assessed at either a four or five whereas this was the case for just over one third of non-intensive patients (34.8 per cent n=24). The difference between these two proportions was non-significant (7.1 (-8.7, 22.9)).

5.1.4 Well-being by Allocation

The table below (Table 5.23) shows to TOMS well being data by allocation. More of the patients in the intensive arm of the trial were assessed at four or five (78.2 per cent, n=58 for intensive, as compared with 77.2 per cent , n= 54).

Allocation		TOM score: Well-being					Total
		1	2	3	4	5	
Non-int.	Count	3	5	8	37	17	70
	% within NI	4.3	7.1	11.4	52.	24.3	100.0
Int.	Count	1	2	13	32	26	74
	% within Int.	1.4	2.7	17.6	43.2	35.1	100.0
Total	Count	4	7	21	69	43	144
	% of total	2.8	4.9	14.6	47.9	29.9	100.0

Table 5.23: TOMS Well-being scores at one month by allocation.

5.2 TOMS at One-month by Allocation (stroke)

The following four tables show the TOMS scores for stroke patients participating in the trial at one month by allocation.

5.2.1 Impairment by Allocation

Table 5.24 (below) shows the impairment scores for stroke patients. It can be observed that the distribution between the two arms of the trial is even, with the emphasis for both groups being a TOMS score of four (61.25 per cent, n=49). However, a minor non-significant difference in favour of the intensive group existed in the proportion of each group being assessed at four or five (67.5 per

cent, n=27 for intensive, 60 per cent, n= 24 for non intensive)(7.5 (-13.5, 28.5)).

Allocation		TOM score: Impairment					Total
		1	2	3	4	5	
Non-int.	Count	2	2	12	24	0	40
	% within NI	5.0	5.0	30.0	60.0	0	100
Int.	Count	0	3	10	25	2	40
	% within Int.	0	7.5	25.0	62.5	5.0	100.0
Total	Count	2	5	22	49	2	80
	% of total	2.5	6.3	27.5	61.3	2.5	100.0

Table 5.24: TOMS impairment scores at one month for stroke patients by allocation

5.2.2 Disability by Allocation

In Table 5.25 (below) the distribution of TOMS disability scores is also evenly distributed between the two groups. The majority of patients were assessed as a three or four on the TOMS scale (80.0 per cent, n=64), with over half of both groups recorded as four (52.5 per cent, n= 21 for both groups). Again a non-significant difference, in favour of the intensive group, in the proportions being assessed as four or five was observed (5 (-16.6, 26.6)).

Allocation		TOM score: Disability					Total
		1	2	3	4	5	
Non-int.	Count	1	6	11	21	1	40
	% within NI	2.5	15.0	27.5	52.5	2.5	100.0
Int.	Count	0	5	11	21	3	40
	% within Int.	0	12.5	27.5	52.5	7.5	100.0
Total	Count	1	11	22	42	4	80
	% of total	1.3	13.8	27.5	52.5	5.0	100.0

Table 5.25: TOMS disability scores at one month for stroke patients by allocation

5.2.3 Handicap by Allocation

Table 5.26 (below) shows the TOMS Handicap scores for stroke patients at one month..

Allocation		TOM score: Handicap					Total
		1	2	3	4	5	
Non-int.	Count	1	11	15	12	0	40
	% within NI	2.6	28.2	38.5	30.8	0	100
Int.	Count	0	9	16	12	3	40
	% within Int.	0	22.5	40.0	30.0	7.5	100.0
Total	Count	1	20	31	24	3	79
	% of total	1.3	25.3	39.2	30.4	3.8	100.0

Table 5.26: TOMS handicap scores at one month for stroke patients by allocation

Stroke patients from both groups fared less favourably in terms of participation. One quarter (25.3 per cent, n=20) were assessed as a two, with only three patients (3.8 per cent) being assessed as a five. Again a greater proportion of intensive patients were assessed as a four or five. Almost two-fifths (37.5 per cent, n= 15) were assessed as such, compared with under one-third (30.8 per cent, n= 12) of the non-intensive group. The difference between these two proportions was not significant (6.7 (-14, 27.4))

5.2.4 Well-being by Allocation

Table 5.27 (below) shows that stroke patients in the study were indicating relatively high levels of well-being over three quarters (77.6 per cent, n= 62) being assessed at either four or five. The proportion of patients being assessed as four or five in each group was the same (77.5 per cent).

Allocation		TOM score: Well-being					Total
		1	2	3	4	5	
Non-int.	Count	2	3	4	22	9	40
	% within NI	5.0	7.5	10.0	55.0	22.5	100.0
Int.	Count	0	1	8	19	12	40
	% within Int.	0	2.5	20.0	47.5	30.0	100.0
Total	Count	2	4	12	41	21	80
	% of total	2.5	5.0	15.0	51.3	26.3	100.0

Table 5.27: TOMS well-being scores at one month for stroke patients by allocation

5.3 TOMS at One-month by Allocation (hip fracture)

5.3.1 Impairment by Allocation

Table 5.27 shows that in the majority of cases TOMS impairment scores for fracture neck of femur patients at one month were assessed as either three or four (92.2 per cent, n=59). A larger proportion of the intensive group scored a four or five on the TOMS impairment. Almost two fifths of the intensive group scored four or five (38.3 per cent, n= 13) compared with one-third of the non-intensive group (33.3 per cent, n=10). The difference was not significant (5 (-18.4, 28.4)).

Allocation		TOM score: Impairment					Total
		1	2	3	4	5	
Non-int.	Count	1	0	19	9	1	30
	% within NI	3.3	0	63.3	30.0	3.3	100.0
Int.	Count	0	1	20	11	2	34
	% within Int.	0	2.9	58.8	32.4	5.9	100.0
Total	Count	1	1	39	20	3	64
	% of total	1.6	1.6	60.9	31.3	4.	100.0

Table 5.28: TOMS Impairment scores at one month for hip fracture patients by allocation

5.3.2 Disability by Allocation

As with impairment (Table 5.28 below), fracture neck of femur patients were also more likely to be assessed as either three or four (89.1 per cent, n=57). However, there was also a greater proportion of non-intensive hip fracture patients scoring a four or five. Almost three-quarters of the group were assessed at these scores (73.4 per cent, n=22) compared with almost two thirds of the intensive group (61.8 per cent, n= 21). The difference was not significant (11.6 (-11.2, 34.4)).

Allocation		TOM score: Disability					Total
		1	2	3	4	5	
Non-int.	Count	0	1	7	20	2	30
	% within NI	0	3.3	23.3	66.7	6.7	100.0
Int.	Count	0	4	9	21	0	34
	% within Int.	0	11.8	26.5	61.8	0	100
Total	Count	0	5	16	41	2	64
	% of total	0	7.8	25.0	64.1	3.1	100.0

Table 5.29: TOMS Disability scores at one month for hip fracture patients by allocation

5.3.3 Handicap by Allocation

Table 5.29 (below) indicates that the TOMS handicap scores were more evenly distributed across the five points of the scale in comparison with the other three domains. It is also apparent that the intensive arm of the trial fared more favourably (41 per cent (n=16) compared with 40 per cent (n=12)). The difference between the two proportions was not significant (1 (-23.1, 25.1)).

Allocation		TOM score: Handicap					Total
		1	2	3	4	5	
Non-int.	Count	1	8	9	10	2	30
	% within NI	3.3	26.7	30.0	33.3	6.7	100.0
Int.	Count	1	5	12	13	3	34
	% within Int.	2.9	14.7	35.3	38.2	8.8	100.0
Total	Count	2	13	21	23	5	64
	% of total	3.1	20.3	32.8	35.9	7.8	100.0

Table 5.30: TOMS Handicap scores at one month for hip fracture patients by allocation

5.3.4 Well-being by Allocation

Table 5.31 (below) shows that, as with stroke patients, hip fracture patients also indicated relative favourable well-being with the majority being assessed as four or five (78.2 per cent, n=50). A larger proportion of the intensive group were assessed at the uppermost end of the scale, scoring a four or five (79.4 per cent, n= 27) when compared with the non-intensive group (76.7 per cent, n=23). The difference being non-significant (2.7 (-17.8, 23.2)).

Allocation		TOM score: Well-being					Total
		1	2	3	4	5	
Non-int.	Count	1	2	4	15	8	30
	% within NI	3.3	6.7	13.3	50.0	26.7	100.0
Int.	Count	1	1	5	13	14	34
	% within Int.	2.9	2.9	14.7	38.2	41.2	100.0
Total	Count	2	3	9	28	22	64
	% of total	3.1	4.7	14.	43.8	34.4	100.0

Table 5.31: TOMS Well-being scores at one month for hip fracture patients by allocation

5.4 Change in TOMS Scores Since Baseline

5.4.1 Comparison with Baseline TOMS (all)

Table 5.32 (below) summarises the Wilcoxon signed ranks tests conducted in order to detect change between baseline and one month TOMS scores for all patients in respect of impairment, disability, handicap and well-being. The table indicates that there was a significant positive change in impairment, disability and handicap, although no significant improvement in terms of well being.

TOMS Domain	Wilcoxon Z score	2- tailed significance
Impairment	-2.578	P<0.05
Disability	-2.129	P<0.05
Handicap	-4.176	P<0.05
Well-being	-1.774	P>0.05

Table 5.32: Results of Wilcoxon signed ranks test for significance for all patient TOMS data at one-month.

5.4.2 Comparison with Baseline TOMS (stroke)

Table 5.33 (below) summarises the Wilcoxon signed ranks tests conducted in order to detect change between baseline and one month TOMS scores for stroke patients in respect of impairment, disability, handicap and well-being.

TOMS Domain	Wilcoxon Z score	2- tailed significance
Impairment	-1.397	P>0.05
Disability	-3.146	P<0.05
Handicap	-4.045	P<0.05
Well-being	-1.464	P>0.05

Table 5.33: Results of Wilcoxon signed ranks test for significance for stroke patient TOMS data at one-month.

The table indicates that there was a significant positive change in disability and handicap, although no significant improvement in terms of impairment and well being.

5.4.3 Comparison with Baseline TOMS (hip fracture)

Table 5.34 (below) summarises the Wilcoxon signed ranks tests conducted in order to detect change between baseline and one month TOMS scores for hip fracture patients in respect of impairment, disability, handicap and well-being. The table indicates that there was a significant positive change in all but one of the four TOMS domains (impairment, disability and handicap).

TOMS Domain	Wilcoxon Z score	2- tailed significance
Impairment	-2.898	$p<0.05$
Disability	-3.732	$p<0.05$
Handicap	-5.396	$p<0.05$
Well-being	-1.774	$p>0.05$

Table 5.34: Results of Wilcoxon signed ranks test for significance for hip fracture patient TOMS data at one-month.

5.7 Mann-Whitney Test for Difference between the two groups

Table 5.36 (below) shows the results of the Mann-Whitney test for difference for all four TOMS dimensions by allocation at one month.

	All		Stroke		Hip fracture	
	Z-score	Sig.	Z-score	Sig.	Z-score	Sig.
Impairment	-1.025	p>0.05	-1.204	p>0.05	-.382	p>0.05
Disability	-.250	p>0.05	-1.262	p>0.05	-1.236	p>0.05
Handicap	-1.222	p>0.05	-.749	p>0.05	-.892	p>0.05
Well-being	-1.299	p>0.05	-1.225	p>0.05	-.626	p>0.05

Table 5.35: Mann Whitney test for difference for TOMS data by allocation at one month

The tests were based on all patients and by subgroup by aetiology. The table confirms that there were no significant differences between the two groups.

6 Discussion

Although a fuller discussion of the results presented in this chapter will be presented in the final chapters of this thesis I would at this point wish to volunteer some comment on the principal findings.

6.1 Comparison with Baseline Data

The findings from the Wilcoxon signed ranks test for all outcome measures suggest that there was significant improvement for patients in terms of Barthel and TOMS scores. Table 5.36 (below) summarises these changes, highlighting where significant change has occurred and in which direction (+). These changes are noted regardless of allocation.

Outcome Measure	All patients	Stroke Patients	Hip Fracture
Barthel	Sig. (+)	Sig. (+)	Sig. (+)
HADS Anxiety	No change	No change	No change
HADS Depression	No change	No change	No change
EQ5D	No change	No change	No change
Self Perceived HS	No change	No change	No change
TOMS Impairment	Sig. (+)	No change	Sig. (+)
TOMS Disability	Sig. (+)	Sig. (+)	Sig. (+)
TOMS Handicap	Sig. (+)	Sig. (+)	Sig. (+)
TOMS Well-being	No change	No change	No change

Table 5.36: Change since baseline (summary).

6.2 Outcome at One-month by Allocation

Although some differences did exist in favour of the intensive arm of the trial the most striking aspect of the results presented here is the lack of any statistically significant differences between the intensive and non-intensive arms of the trial.

It should be noted that the two arms of the study received very different treatment regimes in terms of intensity. The difference was significant on a week to week basis up until week six of treatment. The total number of visits after four weeks, eight weeks and 12 weeks was also significantly different (see Chapter Four). It appears, however, that intensive treatment, as measured by face to face contacts, has not, at this stage, resulted in any statistically significant benefit for patients.

Outcome Measure	All patients	Stroke Patients	Hip Fracture
Barthel	No difference	No difference	No difference
HADS Anxiety	No difference	No difference	No difference
HADS Depression	No difference	No difference	No difference
EQ5D	No difference	No difference	No difference
Self Perceived HS	No difference	No difference	No difference
TOMS Impairment	No difference	No difference	No difference
TOMS Disability	No difference	No difference	No difference
TOMS Handicap	No difference	No difference	No difference
TOMS Well-being	No difference	No difference	No difference

Table 5.38: Summary of results of statistical testing for the difference between two groups

This issue will be addressed more fully in the discussion Chapters of this thesis. For the moment I might note that sample size, the existence of confounding variables, the nature of the intervention are potential explanations for the lack of any difference.

Chapter Six: Three Month Data

The previous chapter examined the data gathered during the one-month follow up assessments. Whilst the data established significant changes, in some but not all of the outcomes, from baseline for all patients in the study, it was notable that there existed no significant differences between the two arms of the trial. This Chapter will examine the data gathered during the three-month assessments. I shall present outcome data for all patients in order to establish still further any change since one-month before going on to examine the data on the basis of trial allocation and aetiology.

1.1 Loss to follow up

Between baseline and one month 15 patients were lost to follow up. Between one month and three months a further 23 patients were lost (three admitted to care, four in hospital, three were deceased, assessors were not able to contact five and there were eight further withdrawals). Two patients who it was not possible to contact at one month and one who was in hospital at the time of her one-month assessment were subsequently assessed at three months. The net number of observations at three months was therefore 125. The further eight withdrawals brought the total to 16. Table 6.1 (below) shows the odds ratio for outcomes and 95% CI using the intensive group as reference. It is shown that although the intensive group was almost 4 times more likely to be admitted to care and almost twice as likely to be deceased at three months, none of the differences are significant. The intensive group was less likely to be in hospital and to have withdrawn at three months, although again this was not significant.

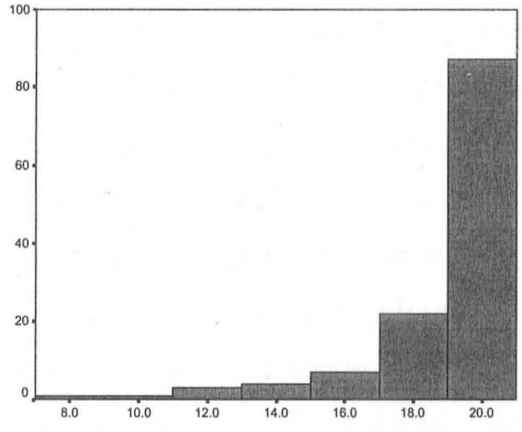
Outcome	OR	95 % CI
Admitted to care at three months	3.67	.4, 33.45
Death at three months	1.84	.16, 20.69
Hospital at three months	.69	.15, 3.18
Withdrawn at three months	.71	.24, 2.02

Table 6.1: Odds ratio for loss to follow up outcome at three months

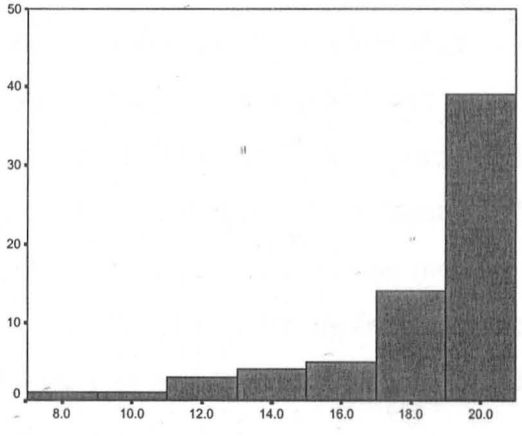
2 Barthel Scores at Three-Months

2.1 Distribution of Barthel at Three Months

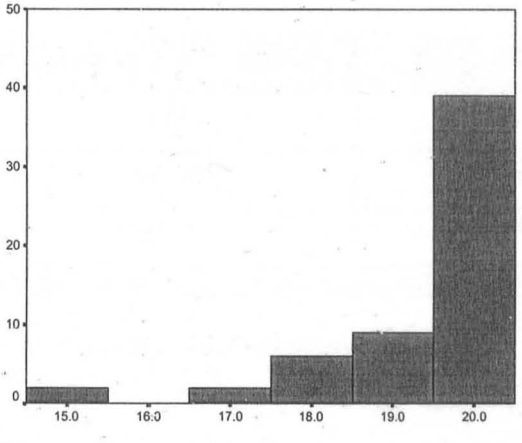
The distribution of the Barthel scores is represented in Histograms 6.1, 6.2 and 6.3 below.



Histogram 6.1: Barthel scores at three months for all patients.
Median = 20 (min.7, max.20)



Histogram 6.2: Barthel scores at three months for stroke patients.
Median = 19 (min.7, max.20)



Histogram 6.3: Barthel scores at three months for hip fracture patients.
Median = 20 (min.15, max.20)

The three histograms indicate that the scores at three months are highly negatively skewed, with over half of all patients (55.1 per cent, n= 69) being assessed as being independent (maximum score 20).

2.2 Barthel Change Since One-month

The above histograms illustrate graphically the change that has occurred in the Barthel scores for the study patients since baseline. Chapter Three and Chapter Five also showed negatively skewed distributions. However, by three months the skewness has increased from -.931 to –2.333. This not only reflects the change made in the disability of the patient group but also the ceiling effect of the Barthel itself. The median Barthel score for all patients was 19.00 at one-month and, as noted above, was 20.00 at three months. This represents a significant change between the two time points (see Table 6.2). Significant differences between the two time points also existed when analysing on the basis of aetiology. The median Barthel score at for stroke patients was 18.00 (min.6, max.20) at one month and was 19.00 (min.7, max.20) at three months. The change between the two time points for all stroke patients is significant (see Table 69 below). The median Barthel score for hip fracture patients was 19.00 (min 11, max.20) at one month and 20.00 (min. 15, max. 20) at three months. The change for hip fracture patients was tested using Wilcoxon Signed Ranks Test and the results are also indicated in Table 69. The change was significant.

Wilcoxon Signed Ranks Test	Z-Score	Significance (2-tailed)
All	-.4337	$p<0.05$
Stroke	-2.284	$P<0.05$
NOF	-4.010	$P<0.05$

Table 6.2: Results of Wilcoxon Signed Ranks Test for change from one-month to three-month Barthel scores.

2.3 Barthel at Three-months by Allocation

2.3.1 Barthel at Three Months by Allocation (all)

The distribution of the Barthel data by allocation at three months is indicated in Chart 6.1 (below). The chart indicates that the distribution of the data for both arms of the trial is similar. This is reflected in the median scores for the two arms of the trial. The median for the intensive arm of the trial was 20.00 (min. 13, max.20), whilst the median score for the less-intensive arm of the trial was also 20 (min.7, max.20).

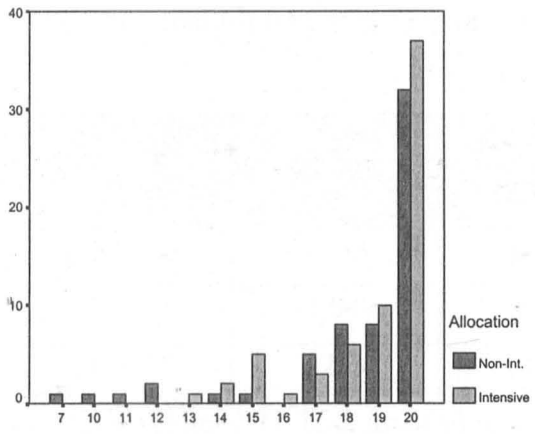


Chart 6.1: Distribution of Barthel scores by allocation

2.3.2 Barthel at Three Months by Allocation (stroke)

There existed a difference in the median Barthel scores between two arms of the trial at three months for stroke patients. The median score for the non-intensive group was 18.50 (min.7, max.20), whilst the median score for the intensive group was 19.00 (min.13, max.20).

2.3.3 Barthel at Three Months by Allocation (hip fracture)

There was no difference in the median Barthel scores between the two arms of the trial at Three month for these patients (20.00) (min.17, max 20 for non-intensive)(min. 15, max.20 for intensive).

2.4 Mann-Whitney U Test for Significance for Difference in Barthel Score by Allocation

The Mann-Whitney U Test was used in order to compare the Barthel scores for the allocated groups. The results are shown in Table 6.3. The table indicates that there was no significant difference between the two groups when analysing for all patients as well as when analysing by subgroup on the basis of aetiology.

Group	Mann-Whitney U	Z Score	Significance (2-tailed)
All	1852.000	-.533	p>0.05
Stroke	480.500	-1.049	p>0.05
Hip fracture	404.000	-.299	p>0.05

Table 6.3: Results of Mann-Whitney U Test for difference between the two groups in Barthel at three-months (all patients).

2.5 Categorised Barthel at Three Months

2.5.1 Categorised Barthel at Three Months by Allocation (all)

Table 6.4 (below) indicates the categorised Barthel data by allocation. The Table shows that the distribution for both intensive and less intensive treatment regimes is similar. Almost two fifths were assessed as being semi-independent (37.6 per cent, n= 47) whilst only a small number (7.2 per cent, n= 9) remained dependent. Over half were now assessed as independent (55 per cent, n=69).

Allocation		Categorised Barthel			Total
		Dependent	Semi-independent	Independent	
Non-Intensive (NI)	Count	6	22	32	60
	% within NI	10.0	36.7	53.3	100.0
Intensive (I)	Count	3	25	37	65
	% within I	4.6	38.5	56.9	100.0
Total	Count	9	47	69	125
	% of total	7.2	37.6	55.2	100.0

Table 6.4: Categorised Barthel at three months by allocation for all patients

A larger proportion of the intensive group was assessed as being independent at this stage, although the difference between the two proportions was not significant (3.6 (-13.8, 20)).

2.5.2 Categorised Barthel at Three Month by Allocation (stroke)

Table 6.5 shows categorised Barthel for stroke patients at three months by allocation.

Allocation		Categorised Barthel			Total
		Dependent	Semi-independent	Independent	
Non-Intensive (NI)	Count	6	13	13	32
	% within NI	18.8	40.6	40.6	100.0
Intensive (I)	Count	3	15	17	35
	% within I	8.6	42.9	48.6	100.0
Total	Count	9	28	30	67
	% of total	13.4	41.8	44.8	100.0

Table 6.5: Categorised Barthel at three month by allocation for stroke patients.

Just over two fifths (44.8 per cent, n=30) were assessed as independent at this stage, whilst a similar proportion (41.8 per cent, n=28) remained semi-independent according to the Barthel. A higher proportion of non-intensive patients were assessed as dependent (18.8 per cent). The table indicates a

slightly higher proportion of the intensive patients being assessed as independent (48.6 per cent), although this difference was not significant (8 (-15.7, 31.7)).

2.5.3 Categorised Barthel at Three Months by Allocation (hip fracture)

Table 6.6 (below) shows categorised Barthel for hip fracture patients at Three months by allocation.

Allocation		Categorised Barthel			Total
		Dependent	Semi-independent	Independent	
Non-Intensive (NI)	Count	0	9	19	28
	% within NI	0.0	32.1	67.9	100.0
Intensive (I)	Count	0	10	20	30
	% within I	0.0	33.3	66.7	100.0
Total	Count	0	19	39	58
	% of total	0.0	32.8	67.2	100.0

Table 6.6: Categorised Barthel at three months by allocation for hip fracture patients.

The table indicates that none of the hip fracture patients were assessed as dependent (Barthel score of <14). Over two-thirds were assessed as being independent (67.2 per cent, n=39). There existed little non-significant difference in the proportions of each group being assessed as independent (1.2 (-23.1, 25.5)).

3 HADS Scores at Three Months

3.1 Categorised HADS at Three Months

Tables 6.7 and 6.8 present the HADS data for all study patients at three-months.

HADS Anxiety		Frequency	Percent
Valid	Non-case	98	78.4
	Doubtful	13	10.4
	Case	14	11.2
	Total	125	100
Missing		35	
Total		160	

Table 6.7: Categorised HADS Anxiety scores at three-months for all patients

The tables indicate modest levels of anxiety and depression amongst the study sample at this time point. In both sub-scales over three quarters (78.4 per cent, n=98) of the sample were identified as non-cases.

HADS Depression		Frequency	Percent
Valid	Non-case	99	79.8
	Doubtful	18	14.5
	Case	7	5.6
	Total	124	100
Missing		36	
Total		160	

Table 6.8: Categorised HADS Depression score at three-months for all patients

3.2 Comparison with One-month HADS Data

3.2.1 Comparison with One-month HADS Data (all)

Fourteen per cent of study patients identified as 'case' at three months for HADS anxiety was. This compared favourably with one month data. At one month 18 patients were identified as case. Using the same approach as that outlined in Chapter Five a test statistic was calculated in order to test for

difference between these two related samples. The difference was not significant (z=-.258 (p=0.802)).

The number identified as 'case' for HADS depression at three months was seven again this compares favourable to the situation at one month. The number identified as 'case' for HADS depression at one month was 16. The difference was not significant (z=.632 (p=0.528)).

3.2.2 Comparison with One-month HADS Data (stroke)

The number of stroke patients identified as 'case' at three months for HADS Anxiety was seven. This compared equally with the one month data. At one month 9 patients were identified as 'case'. The difference was not significant (z=0 (p=1)). The number of stroke patients identified as 'case' for HADS depression at three months four. This compares favourable to the situation at one month. The proportion identified as 'case' for HADS depression at one month was 13. The difference was not significant (z=1 (p=0.317)).

3.2.3 Comparison with One-month HADS Data (hip fracture)

A smaller proportion of hip fracture patients was classed as 'case' for HADS anxiety at three months compared to one month. Nine hip fracture patients were classed as such at one month, compared with seven patients at three months. The difference was not significant (z=.333 (p=.741)). The same can not be said of HADS depression. Just three patients were classed as 'case' at one month, by the three month assessment this remained at three patients (one patient was identified as 'case' at both time points).

3.3 Categorised HADS by Allocation

3.3.1 Categorised HADS by Allocation (all)

Tables 6.9 and 6.10 summarise the HADS anxiety and depression sub-scales by allocation.

Allocation		Categorised HADS Anxiety data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	46	4	10	60
	% within NI	76.7	6.7	16.7	100.0
Intensive	Count	52	9	4	65
	% within Int.	80	13.8	6.2	100
Total	Count	98	13	14	125
	% of total	78.4	10.4	11.2	100.0

Table 6.9: Categorised HADS Anxiety at three-months by allocation.

Table 6.9 (above) indicates a difference in favour of the intensive arm of the trial with more non-intensive patients being assessed as case for HADS anxiety. A larger proportion of the non-intensive group was assessed as 'case' for HADS anxiety. The difference between these two proportions was not significant (10.5(-.4, 21.4)).

The findings from the depression sub-scale (Table 6.10 below) also show that minor differences existed between the two groups in terms of HADS depression. A larger proportion of the intensive arm (87.5 per cent, n=56) were classed as non-case when compared with the non-intensive patients (71.7 per cent, n=43). The results are shown in Table 78. The difference between the proportion of each group being identified as case was, however, not significant (5.2 (-2.8, 13.2)).

Allocation		Categorised HADS Depression data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	43	12	5	60
	% within NI	71.7%	20.0%	8.3%	100.0%
Intensive	Count	56	6	2	64
	% within Int.	87.5%	9.4%	3.1%	100.0%
Total	Count	99	18	7	124
	% of total	79.8%	14.5%	5.6%	100.0%

Table 6.10: Categorised HADS Depression at three-month by allocation.

3.3.2 Categorised HADS by Allocation (stroke)

Table 6.11 shows the categorised HADS Anxiety data for stroke patients by allocation.

Allocation		Categorised HADS Anxiety data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	25	2	5	32
	% within NI	78.1	6.3	15.6	100.0
Intensive	Count	30	3	2	35
	% within Int.	85.7	8.6	5.7	100.0
Total	Count	55	5	7	67
	% of total	82.1	7.5	10.4	100.0

Table 6.11: Categorised HADS anxiety at three-months by allocation for stroke patients.

The majority of stroke patients were assessed as non-case at three months (82.1 per cent, n=55) (see Table 6.12 above). A larger proportion of the intensive group was assessed as non-case and a larger proportion of non-intensive assessed as case. The difference between the proportion of those from each group being identified as case was not significant (9.9 (-4.4, 24.2)).

Allocation		Categorised HADS Depression data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	24	5	3	32
	% within NI	75.0	16.6	9.4	100
Intensive	Count	30	3	1	34
	% within Int.	88.2	8.8	2.9	100.0
Total	Count	54	8	4	66
	% of total	81.8	12.1	6.1	100.0

Table 6.12: Categorised HADS depression at three-months by allocation for stroke patients.

As with the anxiety sub-scale, the HADS depression scale reveals that the majority of stroke patients were assessed as non-case at three months (see Table 6.12) (81.1 per cent, n= 54). There were minor differences between the two arms of the trial with the higher proportion of the non-intensive group being assessed as doubtful or depressed (25.0 per cent, n=8) when compared with the intensive arm of the trial (11.8 per cent, n=4). A larger proportion of the non-intensive group was assessed as case. The difference in the proportion of each group assessed as case was not significant (6.5 (-4.4, 17.4)).

3.3.3 Categorised HADS by Allocation (hip fracture)

No difference existed for the categorised HADS anxiety scores for hip fracture at this stage. Table 6.13 (below) shows that three quarters of hip fracture patients were assessed as non-case (74.1 per cent, n=43). Table 24 also indicates that the distribution between the two arms of the trial were marginally different, with a higher proportion of non-intensive patients were identified as case. This difference was not significant (11.2 (-5.1, 27.5)).

Allocation		Categorised HADS Anxiety data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	21	2	5	28
	% within NI	75.0	7.1	17.9	100.0
Intensive	Count	22	6	2	30
	% within Int.	73.3	20.0	6.7	100.0
Total	Count	43	8	7	58
	% of total	74.1	13.8	12.1	100.0

Table 6.13: Categorised HADS anxiety by allocation for hip fracture patients.

Table 6.14 (below) shows the categorised HADS depression scores for hip fracture at three months.

Allocation		Categorised HADS Depression data			Total
		Non-case	Doubtful	Case	
Non-intensive	Count	19	7	2	28
	% within NI	67.9	25.0	7.1	100.0
Intensive	Count	26	3	1	30
	% within Int.	86.7	10.0	3.3	100.0
Total	Count	45	10	3	58
	% of total	77.6	17.2	5.2	100.0

Table 6.14: Categorised HADS depression by allocation for hip fracture patients.

A difference between the two arms of the trial can be observed. Over four fifths (86.7 per cent, n=26) of the patients allocated to the intensive arm were assessed as non-cases, where as this was the case for 67.9 per cent (n=19) of the non-intensive arm. However, the difference between the two proportions identified as 'case' was not significant (3.8 (-7.4, 15)).

4 Frenchay Activities Index at Three Months

4.1 Frenchay Activities Index Scores at Three Months

No FAI data were collected at one month, therefore the three-month assessment provided the first opportunity to compare current participation with pre-morbid participation status. The median pre-morbid FAI score was 26.00 (min. 1, max. 41, (all patients). The median FAI score at three months for all patients was 18.00 (min. 0, max.38). Wilcoxon Signed Ranks Test was undertaken. The results, which were significant, are shown in Table 28. The median pre-morbid FAI score for stroke patients in the study was 24.00. At three months the median FAI score for stroke patients was 15.00 (min. 0, max.37). Wilcoxon Signed Ranks test was used in order to examine change between one-month and three-month FAI scores for stroke patients. The results are summarised in Table 6.16. The results show a significant difference. An examination of the negative ranks over the positive ranks reveal that this change was based on a

decrease in scores. The median pre-morbid FAI score for hip fracture patients in the study was 28.00. The median score for all hip fracture patients remaining in the study at three months was 19.00 (min.4, max.38).

4.2 Change Since Baseline in Frenchay Activities Index

Wilcoxon Signed Ranks test was used in order to examine change between one-month and three-month FAI scores for hip fracture patients. The results show a significant difference (below). An examination of the negative ranks over the positive ranks revealed that this change was based on a decrease in scores.

FAI	Z Score	Significance (2-tailed)
All	-8.359	$p<0.05$
Stroke	-6.170	$p<0.05$
Hip fracture	-5.616	$p<0.05$

Table 6.15: Results of Wilcoxon Signed Ranks Test to assess change between pre-morbid and three months FAI scores.

4.3 Mann-Whitney U Test for Significance for Difference in Frenchay Activities Index Score by Allocation

The Mann-Whitney U Test was used in order to compare the FAI scores for each of the allocated groups (Table 6.16 below).

Group	Mann-Whitney U	Z Score	Significance (2-tailed)
All	1845.000	-.519	$p>0.05$
Stroke	529.000	-.389	$p>0.05$
Hip fracture	408.500	-.179	$p>0.05$

Table 6.16: Results of Mann-Whitney U Test for difference between the two groups for FAI at three-months (all patients).

There was no significant difference between the groups, for all patients or when examining patient sub-groups on the basis of aetiology

5 Euroqol at Three Months

5.1 Euroqol Scores at Three-Months

The median EQ-5D score for all patients at three months was .64. The median self perceived health status score for all patients at three months was .70. Both of these three month scores compare favourable with one-month data where the median EQ-5D score for all patients at one month was 62.00. The median EQ-5D for all stroke patients at one month was and at three months was .64 (min.-.09, max. 1.00). The median EQ-5D for all hip fracture patients at one month was .62 (min.-.07, max.1.00) and at three months it remained at .62 (min..09, max.1.00). The median self perceived health status score for all patients at one-month was 62.00. The median self perceived health status for all stroke patients at one month was .60 (min. .19, max.1.00) and at three months was .70 (min. .2, max.1.00. Wilcoxon Signed Ranks test was used in order to examine change between one-month and three-month self-perceived health status data. The results are summarised in Table 6.18. The table indicates that there was a significant difference between one-month and three months for stroke patients in terms of self perceived health status. The median self perceived health status for all hip fracture patients at one month was .65 (min..4, max.1.00) and at three months was .70 (min..3, max..95).

5.2 Comparison with One-month EQ-5D

A significant difference was detected between one-month and three month EQ-5D scores for hip fracture patients (see Table 6.17). Wilcoxon Signed Ranks test was used in order to examine change between one-month and three-month EQ-5D data. The table indicates that there was no significant difference between one-month and three months for stroke patients on the EQ-5D.

EQ5D	Z Score	Significance (2-tailed)
All	-1.413	p>0.05
Stroke	-.628	p>0.05
Hip fracture	-2.574	p<0.05

Table 6.17: Results of Wilcoxon Signed Ranks test to examine change between one-month and three-month EQ-5D data.

5.3 Comparison with One-month Self Perceived Health Status

Again this represented a significant change between the two time points for the hip fracture patients.

Health Status	Z Score	Significance (2-tailed)
All	-3.639	P<0.05
Stroke	-2.972	p<0.05
Hip fracture	-2.142	p<0.05

Table 6.18: Results of Wilcoxon Signed Ranks Test to examine change between one month and three months self perceived health status scores for stroke patients.

5.4 EQ-5D Data by allocation at Three-Months

The median EQ-5D scores for the non-intensive arm of the study was .62 (min.-.09, max.1.00) at three months, this was compared to .69 (min. .09, max.1.00) for patients in the intensive arm of the trial. However, the confidence intervals around the medians indicate that these differences are non-significant. The Mann-Whitney U Test was used in order to compare the EQ-5D scores for patients for each of the allocated groups. The results are shown in Table 6.19. There was no difference between the groups. The median EQ-5D score for stroke patients in the non-intensive arm of the study was .54 (min. -.09, max.1.00) whilst it was .71 (min..09, max.1.00) for the intensive group. The Mann-Whitney U Test was used in order to compare the EQ-5D scores for stroke patients for each of the allocated groups. The results of the test (Table

6.19 below) show that there was a significant difference between the two arms of the trial for the EQ-5D for stroke patients at three-months. The median EQ-5D scores suggests a difference in favour of the non- intensive group. The median for the non-intensive group was .68 (min..16, max.1.00) and .62 (min..09, max.1.00) for the intensive group. Nevertheless the confidence intervals indicate that the difference is non-significant. The Mann-Whitney U Test was used in order to compare the scores for hip fracture patients for each of the allocated groups. The results of the tests (Table 6.19 below) show that there was indeed no significant difference.

Group	Mann-Whitney U	Z Score	Significance (2-tailed)
All	1814.500	-.075	$p>0.05$
Stroke	382.000	-2.238	$p<0.05$
Hip fracture	359.500	-.947	$p>0.05$

Table 6.19: Results of Mann-Whitney U Test for difference between the two groups for EQ5D at three-months.

5.5 Self Perceived Health Status Scores at Three Months by Allocation

The medians for the self perceived health status scores for groups by allocation were similar. The median for the non-intensive patients was 7.0 (min. .25, max..95) whilst the median score for the intensive patients was .71 (min. .2, max. 1.00). The Mann-Whitney U Test was used in order to compare the self perceived health status scores for patients for each of the allocated groups. The results are shown in Table 6.21. There was no difference between the groups. In terms of self perceived health status the results were similar for both arms of the trial for stroke patients. The median for the non-intensive group were .70 (min..25, max..9) and .71 (min..2, max.1.00) for the intensive group. The Mann-Whitney U Test was used in order to compare the scores for stroke patients for each of the allocated groups. The results of the test (Table 6.20 below) show that there was no significant difference. There was a minor difference in favour of the intensive hip fracture patients on the self perceived

health status scale, .72 (min..3, max..88) compared with .70 (min..39, max..95). Table 6.20 (below) confirms the non-significance of this difference.

Group	Mann-Whitney U	Z Score	Significance (2-tailed)
All	1814.500	-.075	p>0.05
Stroke	538.000	-.077	p>0.05
Hip fracture	376.500	-.025	p>0.05

Table 6.20: Results of Mann Whitney test for difference at three months for self perceived health status

6 TOMS Data at Three-months

6.1 TOMS at Three Months by Allocation (all)

Tables 6.21 to 6.24 show the TOMS data at three month for all patients by allocation. Three tables (6.21, 6.22 and 6.24) appear to indicate little difference between the two groups.

6.1.1 Impairment

Allocation		TOM score: Impairment					Total
		1	2	3	4	5	
Non-int.	Count	1	0	22	35	2	60
	% within NI	1.7	0	36.7	58.3	3.3	100.0
Int.	Count	1	2	20	38	4	65
	% within Int.	1.5	3.1	30.8	58.5	6.2	100.0
Total	Count	2	2	42	73	6	125
	% of total	1.6	1.6	33.6	58.4	4.8	100.0

Table 6.21: TOMS Impairment scores at three months by allocation for all patients

In terms of impairment (Table 6.21 above) over half of all patients were assessed as being a four (58.4 per cent, n=73) with the majority of all patients (92 per cent, n=115) being assessed as either a three or a four.

The distributions for both non-intensive and intensive arms of the trial were almost identical. Nearly two thirds of each group were assessed as either a four or five for impairment (61.6, n=37 for non-intensive and 64.7 per cent, n=42 for intensive). The difference between these two proportions was not significant (3.1 (-13.8, 20)).

6.1.2 Disability

A similar observation can be made regarding TOMS disability scores (Table 6.22) with almost one third (62.4 per cent, n=78) being assessed as four. For TOMS disability the proportion of the non-intensive group scoring four or five was 70 per cent (n=42) where as this was the case for 70.9 (n=43) per cent of the intensive group.

Allocation		TOM score: Disability					Total
		1	2	3	4	5	
Non-int.	Count	0	8	10	38	4	60
	% within NI	0	13.3	16.7	63.3	6.7	100.0
Int.	Count	0	2	14	40	9	65
	% within Int.	0	3.1	21.5	61.5	13.8	100.0
Total	Count	0	10	24	78	13	125
	% of total	0	8.0	19.2	62.4	10.4	100.0

Table 6.22: TOMS Disability scores at three months by allocation for all patients

6.1.3 Handicap

TOMS Handicap scores (Table 6.23 below) are also skewed towards the top end of the scale. Over three quarters (76.8 per cent, n=96) were assessed as either a four or five with one third (36 per cent, n=45) being assessed as age

appropriate participation. TOMS handicap scores favoured the intensive arm of the study. The majority of the intensive group (86.2 per cent, n=56) were assessed as a four or five, whilst this was the case for less than two-thirds of the non-intensive patients (66.7 per cent, n=40). The difference between these two proportions was significant (19.5 (5.1, 33.9)).

Allocation		TOM score: Handicap					Total
		1	2	3	4	5	
Non-int.	Count	3	4	13	21	19	60
	% within NI	5.0	6.7	21.7	35.0	31.7	100.0
Int.	Count	0	4	5	30	26	65
	% within Int.	0	6.2	7.7	46.2	40.	100.0
Total	Count	3	8	18	51	45	125
	% of total	2.4	6.4	14.4	40.8	36.0	100.0

Table 6.23: TOMS Handicap scores at three months by allocation for all patients

6.1.4 Well Being

Table 6.24 (below) shows the TOMS well-being data for all patients at three months by allocation. As with TOMS impairment and disability scores, the majority (70.4 per cent, n=88) were assessed as either a three or four. The distribution was similar for both arms of the trial.

Allocation		TOM score: Well-being					Total
		1	2	3	4	5	
Non-int.	Count	2	9	16	26	7	60
	% within NI	3.3	15.0	26.7	43.3	11.7	100.0
Int.	Count	0	8	17	29	11	65
	% within Int.	0	12.3	26.2	44.6	16.9	100.0
Total	Count	2	17	33	55	18	125
	% of total	1.6	13.6	26.4	44.0	14.4	100.0

Table 6.24: TOMS Well-being scores at three months by allocation for all patients.

A larger proportion of the intensive group, however, was assessed as either a four or five (61.5 per cent, n=40) when compared with the non-intensive group (55 per cent, n=33). The difference was not significant (6.5 (-11.6, 23.8)).

6.2 TOMS Change Since One-Month (all)

Table 6.25 (below) summarises the Wilcoxon signed ranks tests conducted in order to detect change between one month and three months TOMS scores for all patients in respect of impairment, disability, handicap and well-being. The table indicates that there was a significant positive change in impairment, disability and handicap. Although there was a significant change in well-being scores this change was in a negative direction.

TOMS Domain	Wilcoxon Z score	2- tailed significance
Impairment	-3.139	P<0.05
Disability	-4.106	P<0.05
Handicap	-6.711	P<0.05
Well-being	3.806	P<0.05

Table 6.25: Results of Wilcoxon Signed Ranks Test to examine change between one month and three months TOMS scores for all patients.

6.3 TOMS at Three Months by Allocation (stroke)

The following four tables show the TOMS scores for stroke patients participating in the trial at three months by allocation.

6.2.1 Impairment

Table 6.26 (below) shows the impairment scores for stroke patients. The distribution between the two arms of the trial is even, with the emphasis for both groups being a TOMS score of three or four (92.6 per cent, n=62). The proportion of non-intensive patients scoring a four or five was larger than that of the intensive group (71.9 per cent (n=23) compared with 68.6 per cent

(n=24)). The difference was not significant (3.3 (-18.74, 25.34)). It should be noted that none of the non-intensive group were assessed at five whereas three of the intensive group were assessed at five.

Allocation		TOM score: Impairment					Total
		1	2	3	4	5	
Non-int.	Count	1	0	8	23	0	32
	% within NI	3.1	0	25.0	71.9	0	100
Int.	Count	0	1	10	21	3	35
	% within Int.	0	2.9	28.6	60.0	8.6	100.0
Total	Count	1	1	18	44	3	67
	% of total	1.5	1.5	26.9	65.7	4.5	100.0

Table 6.26: TOMS impairment scores at three months by allocation for stroke patients.

6.3.2 Disability

In Table 6.27 (below) the distribution of TOMS disability scores is also evenly distributed between the two groups. The majority of patients were assessed as a three or four on the TOMS scale (79.1 per cent, n=53), with over half of both groups recorded as four (55.2 per cent, n= 37). The proportion of the intensive group assessed at four or five (68.4 per cent, n=24) was larger than for the non-intensive group (59.4 per cent, n=19). The difference between the two proportions was not significant (9 (-13.9, 31.9)).

Allocation		TOM score: Disability					Total
		1	2	3	4	5	
Non-int.	Count	0	6	7	18	1	32
	% within NI	0	18.8	21.9	56.3	3.1	100.0
Int.	Count	0	2	9	19	5	35
	% within Int.	0	5.7	25.7	54.3	14.3	100.0
Total	Count	0	8	16	37	6	67
	% of total	0	11.9	23.9	55.2	9.0	100.0

Table 6.27: TOMS disability scores at three months by allocation for stroke patients.

6.3.3 Handicap

Table 6.28 (below) shows the TOMS participation data for stroke patients by allocation. A larger proportion of those patients in the intensive arm of the trial scored a four or five on the scale. Thirty one (88.6 per cent) intensive patients scored a four or five compared to 20 (62.6 per cent) of non-intensive patients. The difference between these two proportions is significant (26 (6.4, 45.6)). The difference is compounded with a larger proportion of non-intensive patients scoring three or less (37.6 per cent, n= 12) compared with patients in the intensive arm (11.4 per cent, n= 4).

Allocation		TOM score: Handicap					Total
		1	2	3	4	5	
Non-int.	Count	2	2	8	14	6	32
	% within NI	6.3	6.3	25.0	43.8	18.8	100.0
Int.	Count	0	2	2	17	14	35
	% within Int.	0	5.7	5.7	48.6	40.0	100.0
Total	Count	2	4	10	31	20	67
	% of total	3	6.0	14.9	46.3	29.9	100.0

Table 6.28: TOMS handicap scores at three months by allocation for stroke patients.

6.3.4 Well-being

The scores for TOMS well-being at three months for stroke patients are shown in Table 6.29 (below). The table indicates a similar distribution between the two arms of the trial. A relatively small proportion of stroke patients from both arms of the trial (13.4 per cent, n=9) were assessed as a five.

Allocation		TOM score: Well-being					Total
		1	2	3	4	5	
Non-int.	Count	2	5	7	15	3	32
	% within NI	6.3	15.6	21.9	46.9	9.4	100.0
Int.	Count	0	5	10	14	6	35
	% within Int.	0	14.3	28.6	40.0	17.1	100.0
Total	Count	2	10	17	29	9	67
	% of total	3	14.9	25.4	43.3	13.4	100.0

Table 6.29: TOMS well-being scores at three months by allocation for stroke patients.

6.4 TOMS Change Since On-month (stroke)

Table 6.30 (below) summarises the Wilcoxon signed ranks tests conducted in order to detect change between one month and three-months TOMS scores for stroke patients in respect of impairment, disability, handicap and well-being. The table indicates that for all stroke patients there was a significant positive change in disability and handicap and a negative change in well being. There was no significant improvement in terms of impairment.

TOMS Domain	Wilcoxon Z score	2- tailed significance
Impairment	-1.670	P>0.05
Disability	-2.421	P<0.05
Handicap	-5.093	P<0.05
Well-being	-2.969	P<0.05

Table 6.30: Results of Wilcoxon signed ranks test for significance for stroke patient TOMS data at three-months.

6.5 TOMS at Three Months by Allocation (hip fracture)

6.5.1 Impairment

Table 6.31 shows that in the majority of cases TOMS impairment scores for fracture neck of femur patients at three-months were assessed as either three or

four (91.4 per cent, n= 53). There does not appear to be any difference in the distributions of the two arms of the study.

Allocation		TOM score: Impairment					Total
		1	2	3	4	5	
Non-int.	Count	0	0	14	12	2	28
	% within NI	0	0	50.0	42.9	7.1	100.0
Int.	Count	1	1	10	17	1	30
	% within Int.	3.3	3.3	33.3	56.7	3.3	100.0
Total	Count	1	1	24	29	3	58
	% of total	1.7	1.7	41.4	50.0	5.2	100.0

Table 6.31: TOMS Impairment scores at three months by allocation for hip fracture patients.

The proportion of the intensive group scoring a four or five for TOMS impairment was 60 per cent (n=18) and 50 per cent (n=14) for the non-intensive group (Table 28). The difference between the two proportions was not significant (10 (-15.5, 35.5)). It should also be noted that two intensive patients were assessed as a one or two compared with none of the non-intensive patients.

6.5.2 Disability

Table 6.32 (below) shows that fracture neck of femur patients were more likely to be assessed as a four (70.7 per cent, n=41) in terms of disability. The distribution of the data was similar for the two groups. The proportion of each group being assessed as four or five was almost identical (83.3 per cent (n=25) for intensive, 82.1 per cent (n=23) for non-intensive)

Allocation		TOM score: Disability					Total
		1	2	3	4	5	
Non-int.	Count	0	2	3	20	3	28
	% within NI	0	7.1	10.7	71.4	10.7	100.0
Int.	Count	0	0	5	21	4	30
	% within Int.	0	0	16.7	70.0	13.3	100.0
Total	Count	0	2	8	41	7	58
	% of total	0	3.4	13.8	70.7	12.1	100.0

Table 6.32: TOMS disability scores at three months by allocation for hip fracture patients.

6.5.3 Handicap

Table 6.33 (below) indicates that the TOMS handicap scores for hip fracture were favourable. Over two fifths (43.1 per cent, n=25) were assessed as participating at an age appropriate level. The distributions for the two arms of the trial appear similar. However, a larger proportion of the intensive group were assessed as a four or five (82.2 per cent (n=23)) compared with the non-intensive group (71.4 per cent (n=20)). The difference between these two proportions was not significant (10.8 (-11.2, 32.8)).

Allocation		TOM score: Handicap					Total
		1	2	3	4	5	
Non-int.	Count	1	2	5	7	13	28
	% within NI	3.6	7.1	17.9	25.0	46.4	100.0
Int.	Count	0	2	3	13	12	30
	% within Int.	0	6.7	10.0	43.3	40.0	100.0
Total	Count	1	4	8	20	25	58
	% of total	1.7	6.9	13.8	34.5	43.1	100.0

Table 6.33: TOMS handicap scores at three months for hip fracture patients by allocation

6.5.4 Well-being

Table 6.34 (below) shows that, as with stroke patients, hip fracture patients also indicated less favourable well-being scores when compared with the one-month assessments. The majority were assessed as three or four (72.4 per cent, n= 42). The proportion of the intensive group achieving a score of four or five was larger than for the non-intensive group (66.7 per cent (n=20) compared with 53.6 per cent (n=15)). The difference between the two proportions was, however, not significant (13.1 (-11.1, 39.7)).

Allocation		TOM score: Well-being					Total
		1	2	3	4	5	
Non-int.	Count	0	4	9	11	4	28
	% within NI	0	14.3	32.1	39.3	14.3	100.0
Int.	Count	0	3	7	15	5	30
	% within Int.	0	10.0	23.3	50.0	16.7	100.0
Total	Count	0	7	16	26	9	58
	% of total	0	12.1	27.6	44.8	15.5	100.0

Table 6.34: TOMS well-being scores at three months by allocation for hip fracture patients.

6.6 TOMS Change Since On-month (hip fracture)

Table 6.35 (below) summarises the Wilcoxon signed ranks tests conducted in order to detect change between one month and three-month TOMS scores for hip fracture patients in respect of impairment, disability, handicap and well-being. The table indicates that there was a significant positive change in all but one of the four TOMS domains (impairment, disability and handicap). As with stroke patients in the study, there was a significant negative change in terms of well-being.

TOMS Domain	Wilcoxon Z score	2- tailed significance
Impairment	-2.657	p<0.05
Disability	-3.437	p<0.05
Handicap	-4.457	p<0.05
Well-being	-2.302	P<0.05

Table 6.35: Results of Wilcoxon signed ranks test for significance for hip fracture patient TOMS data at Three-month.

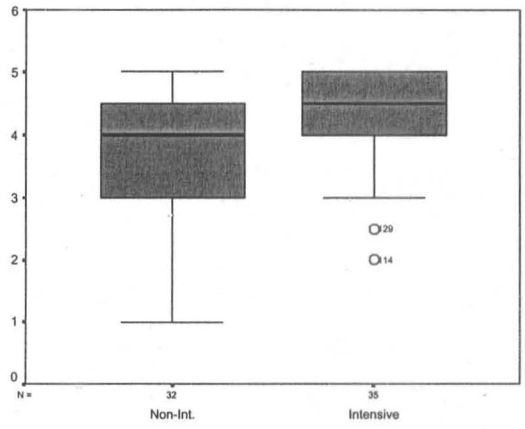
6.7 Mann-Whitney U Test for Significance for Difference for TOMS by Allocation

In order to test for any significant difference between intensive and non-intensive groups the Mann-Whitney test was used. Table 6.36 shows the results of the Mann-Whitney test for all patients each of the TOMS dimensions at three months. The table shows that when analysing all patients, no significant differences between the two groups existed

	All		Stroke		Hip fracture	
	Z-score	Sig.	Z-score	Sig.	Z-score	Sig.
Impairment	-.095	p>0.05	-.137	p>0.05	-.243	p>0.05
Disability	-.149	p>0.05	-.586	p>0.05	-.439	p>0.05
Handicap	-1.579	p>0.05	-2.203	p<0.05	.000	p>0.05
Well-being	-.801	p>0.05	-.731	p>0.05	-.483	p>0.05

Table 6.36: Results of Mann-Whitney test for all patients each of the TOMS dimensions at three months.

Table 6.36 (above) also shows the results of the Mann-Whitney test for each of the TOMS dimensions by allocation for hip fracture patients. The tests confirm that no significant differences existed on any of the TOMS dimensions for hip fracture patients at three months. For stroke patients Table 6.26 indicates that for three of the four TOMS dimensions there is no difference between the two arms of the trial. There does exist a significant difference between the two arms of the study for stroke patients for TOMS handicap. Box Plot 6.(below) confirms that the difference favours the intensive arm of the study.



Box Plot 6.1 TOMS Handicap at three months by allocation for stroke

7 Discussion

This chapter has presented the initial results from the data gathered from patients at three months. It is appropriate now to highlight briefly the primary substantive issues that emerged in the Chapter. I will of course return to these issues more specifically in later sections of this thesis.

7.1 Change Since One-Month

As with the previous chapter there were notable changes made for study patients between the one month and three month assessment. Table 6.37 below summarises the significant changes for patients by aetiology. The table indicates that there were significant favourable changes in Barthel, Self Perceived Health Status, TOMS Impairment, Disability and Handicap. Stroke patients made significant favourable change in all of these with the exception of impairment. Hip fracture patients also made similar positive change in these outcomes but also made significant progress in the EQ-5D. There was also significant negative change in FAI and TOMS well-being. In terms of the FAI this is not surprising. The FAI data gathered at baseline was a pre-morbid representation of participation and as such it is predictable that for many of the patients in the study the impact of the stroke or fracture would continue to

effect participation even months after the event. The significant decline in TOMS well-being is less easily explained.

Outcome Measure	All patients	Stroke Patients	Hip fracture
Barthel	Sig. (+)	Sig. (+)	Sig. (+)
HADS Anxiety	No change	No change	No change
HADS Depression	No change	No change	No change
FAI*	Sig. (-)	Sig. (-)	Sig. (-)
EQ-5D	No change	No change	Sig. (+)
Self Perceived HS	Sig. (+)	Sig. (+)	Sig. (+)
TOMS Impairment	Sig. (+)	No change	Sig. (+)
TOMS Disability	Sig. (+)	Sig. (+)	Sig. (+)
TOMS Handicap	Sig. (+)	Sig. (+)	Sig. (+)
TOMS Well-being	Sig. (-)	Sig. (-)	Sig. (-)

Table 6.37: Change since one month (* baseline) assessment (summary).

7.2 Differences Between Allocated Groups

As with the Chapter concerning one-month data the principal point to be made concerning differences based upon trial allocation is that there remained few significant examples (see summary Table 6.38 below). In all but two of the tests the difference between the intensive and non-intensive arms of the trial were not significant.

The exceptions to this were EQ-5D and TOMS handicap for stroke patients. In addition the difference between the proportions identified as HADS Depression 'case' (all) were close to being significantly different. The intensive group were the beneficiaries of these three differences. Further discussion relating to potential explanations for these differences will take place later in the thesis. There were no significant differences for hip fracture patients by allocation.

Outcome Measure	All patients	Stroke Patients	Hip Fracture
Barthel	No difference	No difference	No difference
HADS Anxiety	No difference	No difference	No difference
HADS Depression	No difference	No difference	No difference
FAI	No difference	No difference	No difference
EQ-5D	No difference	Sig. difference	No difference
Self Perceived HS	No difference	No difference	No difference
TOMS Impairment	No difference	No difference	No difference
TOMS Disability	No difference	No difference	No difference
TOMS Handicap	No difference	Sig. difference	No difference
TOMS Well-being	No difference	No difference	No difference

Table 6.38: Summary of results of statistical testing for the difference between two groups at three months.

Chapter Seven: Exploring Patient Change as an Outcome

This chapter seeks to look at patient change as a variable. Patient change is often cited as being important when attempting to evaluate difference within randomised controlled trials (Altman 1991). This allows us to analyse each individual's change in function, participation or well-being rather than the final outcome. In order to do so, new variables were created for each outcome measure, with the amount of change for each patient being calculated at one month from baseline and at three months from baseline. Single scores for each patient, for each outcome measures were then used as the basis for further comparison between groups. These comparisons were executed in three ways. Firstly, the median change for each group is presented. Secondly, the scores were used as the basis for Mann-Whitney tests for difference. Finally, in order to examine the data more fully, proportions of change for each group were compared. Where a clinically relevant change was available (Barthel, TOMS) this has been used. Where no clinically relevant value was available proportions of each group making positive change has been used as the benchmark. When doing so a confidence interval derived from the standard error of the difference between proportions is shown.

1 Patient change at one month for all patients

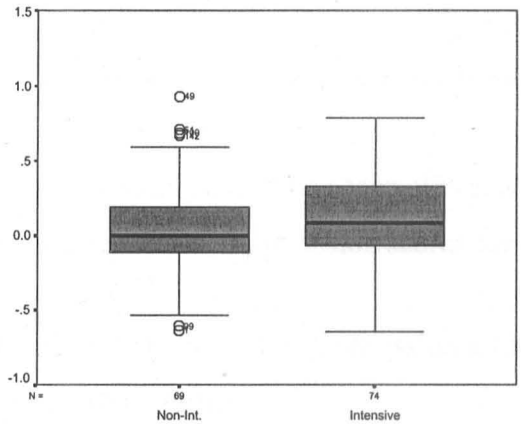
1.1 Barthel and Euroqol Change at One Month: Mann-Whitney test for difference.

Table 7.1 (below) shows the results of the Mann-Whitney test for difference for change for all patients at one month from baseline for the Barthel and Euroqol scores. The table shows no significant difference for patient change on the Barthel, the median change was the same for both groups. Change in one of the Euroqol dimensions was, however, different between the groups and although not significant, the z-score for the EQ5D comes close to being so. Box Plot one (below) indicates that the change is favourable to the intensive arm of the trial.

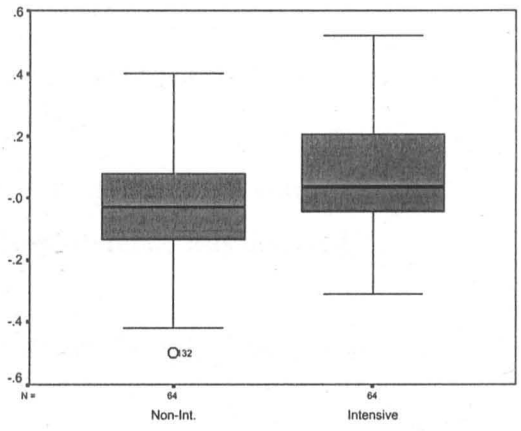
Outcome Measure		All		Stroke		Hip Fracture	
		Non-Int.	Int.	Non-Int.	Int.	Non-Int.	Int.
Barthel Change	Median	2.00	2.00	2.00	2.00	2.50	2.50
	Min.	-2.00	-3.00	-2.00	-3.00	-1.00	-3.00
	Max.	11.0	8.00	11.0	8.00	7.00	7.00
	Z (Sig.)	-.693 (p>.05)		-.375 (p>.05)		-.720 (p>.05)	
EQ-5D Change	Median	.00	.085	.00	.07	-.01	.01
	Min.	-.64	-.65	-.53	-.65	-.64	-.65
	Max.	.93	.79	.93	.79	.71	.69
	Z (sig.)	-1.747 (p>.05)		-.864 (p>.05)		-1.711 (p>.05)	
Self perceived H.S. Change	Median	.03	.035	-.035	.04	-.025	.00
	Min.	-.50	-.31	-.42	-.31	-.50	-.30
	Max.	.40	.52	.30	.52	.40	.30
	Z (sig.)	**-2.882 (p<.05)**		**-2.875 (p<.05)**		-1.113 (p>.05)	
HADS Anx. Change	Median	.00	.00	.00	.00	1.00	.00
	Min.	-8.00	-8.00	-8.00	-8.00	-5.00	-7.00
	Max.	12.0	10.0	9.00	10.0	12.0	10.0
	Z (sig.)	-1.174 (p>.05)		-1.103 (p>.05)		-.486 (p>.05)	
HADS Depress. Change	Median	1.00	.00	1.00	-1.00	.00	1.00
	Min.	-5.00	-9.00	-5.00	-9.00	-4.00	-5.00
	Max.	10.0	8.00	9.00	4.00	10.0	8.00
	Z (sig.)	-1.285 (p>.05)		**-2.081 (p<.05)**		-.284 (p>.05)	
TOMS Impair. Change	Median	.00	.00	.00	.00	.00	.00
	Min.	-2.50	-2.00	-2.50	-2.00	-2.00	-1.00
	Max.	2.50	3.00	2.50	3.00	2.00	2.00
	Z (sig.)	-.827 (p>.05)		-.088 (p>.05)		-1.12 (p>.05)	
TOMS Disability Change	Median	.50	.50	.50	.50	.50	.00
	Min.	-3.50	-1.50	-3.50	-1.00	-1.00	-1.50
	Max.	2.00	2.00	2.00	2.00	1.50	2.00
	Z (sig.)	-.765 (p>.05)		-1.506 (p>.05)		-.536 (p>.05)	
TOMS Handicap Change	Median	.50	1.00	.50	.75	.50	1.00
	Min.	-2.50	-2.00	-1.00	-1.50	-2.50	-2.00
	Max.	3.50	3.00	3.50	2.50	3.00	3.00
	Z (sig.)	-1.440 (p>.05)		-.274 (p>.05)		-1.599 (p>.05)	
TOMS Well-being Change	Median	.00	.00	.00	.00	.00	.25
	Min.	-3.50	-2.50	-2.50	-2.00	-3.50	-2.50
	Max.	5.00	3.00	4.00	3.00	5.00	2.50
	Z (sig.)	-.886 (p>.05)		-.213 (p>.05)		-1.117 (p>.05)	

Table 7.1: Results of Mann-Whitney tests for difference (with medians (range)) for patient change in all outcomes at one month (significant differences in bold).

Box Plot 7.1 (below) also points favourably to the intensive patients in terms of self perceived health status. Indeed Table 7.1 shows that the difference between the groups for self-perceived health status change was significant.



Box Plot 7.1: Change in - scores for all patients by allocation at one month.



Box Plot 7.2: Change in self perceived health status scores for all patients by allocation at one month

1.2 Barthel and Euroqol Change: Comparison of proportions (all).

The proportion of patients making a clinically significant change of two or more for the Barthel was different with 65.7 per cent of the non-intensive patients making this change and 59.4 per cent of the intensive patients making such a change. The intervals around the difference between proportions indicate a non-significant difference (10.0 (-5.1, 25.1)).

The difference between the groups is highlighted when looking at the proportion of each group making positive change at one month in both EQ-5D and self perceived health status scores. Nearly three fifths (58.1 per cent (n=43)) of the intensive patients made positive change and just over two fifths (43.5 per cent (n=30)) of the non-intensive made such a change. The confidence interval around the difference between these two proportions does not, however, indicate significance (14.6 (-1.6, 30.8)). Furthermore, the

difference between the proportions of self perceived health status positive change for each group was significantly different. Over half (56.3 per cent (n=36)) of the intensive patients made positive change compared with under two fifths (39.1 per cent (n= 25)). This difference between the two proportions was significant and favoured the intensive arm of the study (17.2 (0.2, 34.2)).

1.3 HADS change at one month: Mann Whitney test for difference (all).

Table 7.1 summarises the Mann Whitney tests for difference for change in both HADS anxiety and depression scores for all. No difference was detected.

1.4 HADS Anxiety and Depression Change at One Month: Comparison of proportions (all).

An examination of the proportion of change in each group also reveals little difference. For positive change in HADS anxiety score a larger proportion of patients was observed to experience positive change in the non-intensive group (41.1 per cent (n=28) compared with 38.3 per cent (n=28)). The difference was not significant (2.8 (-13.3, 18.9)). For HADS depression a similar result was observed, although for this outcome the intensive group emerged more favourably (39.7 per cent (n=29) compared with 36.7 per cent (n=25). The difference between the two proportions being non-significant (3 (-12.9, 18.9)).

1.5 TOMS change at one month: Mann Whitney test for difference (all)

Change in TOMS scores for all patients by allocation is presented in Table 7.1. It can be seen that no significant differences exist between the two arms of the study. It should also be noted that the median change in each of the four dimensions (with the exception of TOMS Handicap) is the same.

1.6 TOMS Change at One Month: Comparison of proportions (all)

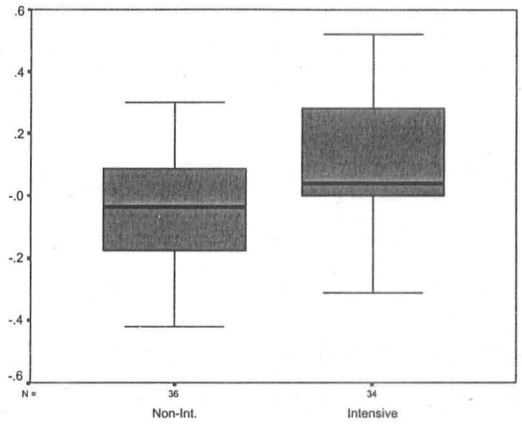
A closer examination of the data in terms of proportions of patients making clinically significant change of one or more was undertaken. Just over one fifth (21.6 per cent (n=16)) of the intensive patients made a positive change of one

or more in TOMS Impairment. Just under one fifth (19.4 per cent (n= 13)) of the non-intensive patients made a similar change. The difference between these proportions was not significant (2.0 (-11.2, 15.2)). Change in TOMS disability for all patients shows more of a marked difference. One third (33.7 per cent (n=25)) of the intensive patients made a change of one or more, whereas just over one-fifth (23.8 per cent (n=16)) of the non-intensive patients made this change. The intervals for the difference between these proportions indicate that the difference was not significant (10.0 (-4.7, 24.7)). The pattern continues when looking at clinically significant change in TOMS handicap. Over half (56.7 per cent (n=42) of the intensive patients made a change of one or more in TOMS handicap and 43.2 per cent (n=29) of the non-intensive patients made a similar gain. The intervals suggest that the difference in these proportions is not significant 13.5 (-2.8, 29.8)). A larger proportion of intensive patients (39.8 per cent (n=29)) made a change of one or more in TOMS well-being than did non-intensive patients (32.8 per cent (n=21)), although the difference between these proportions was not significant (7.0 (-9.3, 22.1)).

2.0 Patient change at one month for stroke patients

2.1 Barthel and Euroqol change at one month: Mann-Whitney test for difference (stroke)

Table 7.1 shows no difference between the two arms of the trial in terms of Barthel change for stroke patients at one month. There was also no difference between the two groups at one month for stroke patients in terms of EQ-5D change. However, a significant difference between the two arms for change in self perceived health status for stroke patients existed. For self-perceived health status the median change in scores for the intensive patients is above that of the non-intensive patients and the range suggests also that the distribution favoured the intensive patients. Box Plot 6, below, confirms that the difference is in favour of the intensive arm of the trial.



Box Plot 7.3: Change in self perceived health status scores for stroke patients by allocation at one month

2.2 Barthel and Euroqol Change at One Month: Comparison of proportions (stroke).

The proportion of stroke patients from both arms of the trial making clinically significant change is also similar (57.5 per cent (n=23) for intensive patients, 62.5 (n=25) for non-intensive stroke patients). The intervals around the difference confirm its non-significance (5.0 (-16.4, 26.4)). The Proportion of each group making positive change for EQ-5D and self-perceived health status was examined at one month for stroke patients. For EQ-5D the proportion of intensive patients making a positive change was 55.0 per cent (n=22) and 46.2 per cent for the non-intensive patients. The difference was not significant (8.8 (-13.1, 30.7)). Similarly a larger proportion of intensive stroke patients experienced positive change in terms of self-perceived health status (64.7 per cent (n=22)) compared with non-intensive stroke patients (38.9 per cent (n=14)). Furthermore the confidence intervals for the difference indicate a significant difference between the proportions (25.8 (3.2, 48.4)).

2.3 HADS Change at One Month: Mann-Whitney test for difference (stroke).

A significant difference was detected in HADS depression score change at one month for stroke patients (see Table 7.1). The median change and range suggest that this favours the intensive arm of the study. The median change for non-intensive patients suggests an increase in depression scores, with the intensive patients moving in the opposite direction. The range for each group supports this.

2.4 HADS Change at One Month: Comparison of proportions (stroke).

An examination of proportions of each group experiencing positive change for HADS anxiety shows similarity between the two (46.1 per cent (n=18)) for non-intensive and 38.4 per cent (n=15) for intensive. The difference was not significant (7.7 (-14.1, 29.5)). A larger difference existed in terms of HADS depression. Over half of the intensive patients (51.2 per cent (n=20)) had reduced depression scores at one month compared with just under two fifths of the non-intensive patients (38.4 per cent, n=15). The difference between the two proportions was not significant (12.8 (-9, 34.6)).

2.5 TOMS Change at One Month: Mann Whitney test for difference (stroke).

Table 7.1 shows the results of the Mann-Whitney test for change in TOMS by group. No significant differences existed between the two arms. The median change in each group is also similar.

2.6 TOMS Change at One Month: Comparison of proportions (stroke).

Using the proportion of each group achieving a clinically significant change of one, there remains no difference in terms of TOMS impairment. The proportion of intensive patients making such change was 15.0 per cent (n=6) the

proportion for the non-intensive patients was almost identical (15.7 per cent (n=6). The difference was not significant (0.7 (-15.1, 16.5)). A difference in proportions in terms of patients making a change of one or more existed for TOMS disability. Two fifths (40.0 per cent (n=16) of the intensive patients made this clinically significant change and this was the case for under one-quarter of non-intensive patients (23.6 per cent (n=9)). The intervals indicate that the difference between the two proportions was not significant (16.4 (-3.8, 36.6)). Whilst there was a minor difference in favour of the intensive group in terms of the proportion achieving a change of one or more for TOMS handicap, the intervals indicate that this difference was not significant (50.0 per cent (n=20) for intensive, 42.1 per cent (n=16) for non-intensive) (7.9 (-14.2 , 30)). Stroke patients did not differ on the basis of allocation in terms of the proportions of patients making significant change for TOMS well-being, the proportions in each arm being almost identical (36.8 per cent (n= 14) for non-intensive and 35 per cent (n=14) for the intensive). The confidence interval around the difference confirms non-significance (1.8 (-19.4, 23)).

3 Patient Change at One-month for Hip Fracture patients

3.1 Barthel and Euroqol Change at One Month: Mann-Whitney test for difference (hip fracture).

Table 7.1 shows Mann-Whitney tests for difference as well as median scores for patient change for Barthel and Euroqol for hip fracture patients. It can be noted that there were no significant differences between the two arms of the trial.

3.2 Barthel and Euroqol Change at One Month: Comparison of Proportions (hip fracture).

The proportion of patients making a clinically significant change on the Barthel was marginally higher in the non-intensive arm of the trial. The proportion of non-intensive patients making a change of two or more was 70 per cent (n=21)

compared with 61.7 per cent (n=21) of the intensive arm. The difference in these proportions was not significant (9.0 (-14.1, 32.1)). The proportion of intensive patients making positive EQ-5D change was larger than that of the non-intensive patients. Almost two-thirds of the intensive patients (61.8 per cent (n=21)) made such change compared with two fifths of the non-intensive patients (40 per cent (n=12)). The confidence intervals for the difference between the proportions indicate non-significance (21.8 (-2.2, 45.8)). A smaller non-significant difference between proportions existed for self perceived health status, favouring the intensive group (7.4 (-17.9, 32.7)).

3.3 HADS Change at One Month : Mann-Whitney test for difference (hip fracture).

The results of the Mann-Whitney test for difference between the groups for change in HADS anxiety and depression are shown in Table 7.1, which indicates no difference between the groups.

3.4 HADS Change at One Month: Comparison of proportions (hip fracture).

A closer look at the proportion of each group experience positive change in HADS anxiety shows little difference between the two groups (38.2 per cent (n=13) for intensive patients compared with 34.4 per cent (n=10) for non-intensive, the difference being non-significant (14.4 (-11.5 40.3)). A larger proportion of non-intensive hip fracture patients experienced a reduction in HADS depression score at one month, over half (51.7 per cent (n=15) compared with just over one third (35.2 per cent (n=12)) of intensive patients. The difference was not significant (16.5 (-7.7, 40.7)).

3.5 TOMS Change at One Month: Mann-Whitney test for difference (hip fracture)

Table 7.1 shows the results of the Mann-Whitney test for difference for TOMS change at one month. No significant differences existed between the groups. The median change for both groups is also similar.

3.6 TOMS Change at One Month: Comparison of proportions (fracture neck of femur).

The proportions of hip fracture patients making a change of one or more in TOMS impairment were similar (24.1 per cent (n=7) for non-intensive and 29.4 per cent (n=10) for intensive) the difference between these proportions was not-significant (5.3 (-16.4, 27)). Similarly, the proportions of each arm making clinically significant change in TOMS disability were also alike (24.1 per cent (n=7) for non intensive, 26.4 per cent (n=9) for intensive. The difference around the confidence interval shows a non-significant difference (2.3 (-19.1, 23.7)). Almost two-thirds of the intensive arm made such a change in TOMS handicap (64,7 per cent (n=22)) and this was the case for under half of the non-intensive arm (44.8 per cent (n=13)). The difference and confidence interval indicate that the difference not significant (19.9 (-4.3, 44.1)). For TOMS well-being just over two fifths (41.1 per cent (n=14)) made a clinically significant change and one –quarter of the non-intensive patients did the same (24.1 per cent (n=7)). Again the difference and confidence interval indicate that the difference was not significant (17.0 (-5.6, 39.6)).

4 Patient Change at Three Months for All Patients

4.1 Barthel, Euroqol and FAI Change at Three Months: Mann-Whitney test for difference (all).

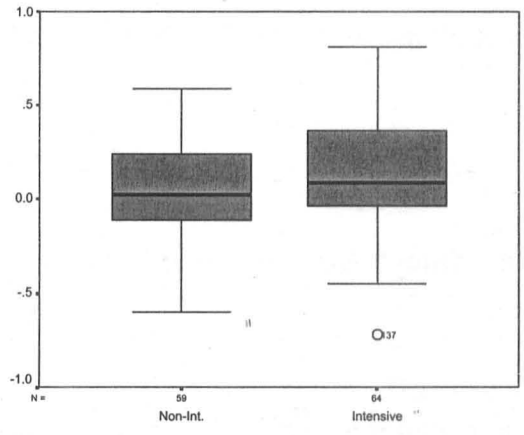
Table 7.2 (below) shows patient change at three months in four of the outcome measures (Barthel, FAI, EQ5D and self-perceived health status). I shall deal with each in turn. The Median change for both intensive and non-intensive arms of the study were equal (3.00) and the range would also suggest a similar distribution of scores. The Mann-Whitney test confirms that there was no difference between the two arms of the study.

The change on the FAI also indicates little difference between the two groups with the median change being minus 6.00 and minus 9.00 for the non-intensive and intensive arms of the study respectively. This change was in a negative direction because the FAI score at baseline was a pre-morbid assessment and it would be expected for participation as measured by the FAI would fall. The range for the intensive arm is smaller. The Mann-Whitney test result confirms a non-significant difference.

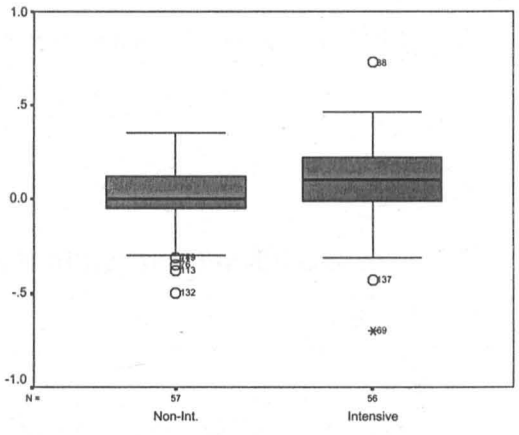
Outcome Measure		All		Stroke		Hip Fracture	
		Non-Int.	Int.	Non-Int.	Int.	Non-Int.	Int.
Barthel Change	Median	3.00	3.00	2.00	3.00	3.00	3.00
	Min.	-2.00	-3.00	-2.00	-3.00	.00	.00
	Max.	12.0	8.00	12.0	8.00	7.00	8.00
	Z (Sig.)	-.135 (p>.05)		-.546 (p>.05)		-.449 (p>.05)	
EQ-5D Change	Median	0.02	0.08	-.07	.13	.13	0.07
	Min.	-.60	-.72	-.60	-.45	-.57	-.72
	Max.	.59	.81	.59	.81	.59	.69
	Z (sig.)	-1.595 (p>.05)		**-2.276 (p<.05)**		-.096 (p>.05)	
Self perceived H.S. Change	Median	.00	.10	0.02	.13	-0.01	0.05
	Min.	-.50	-.70	-.38	-.70	-.50	-.43
	Max.	.35	.73	.35	.73	.25	.37
	Z (sig.)	**-2.294 (p<.05)**		**-2.051 (p<.05)**		-1.284 (p>.05)	
FAI Change	Median	-6.00	-9.00	-6.00	-10.0	-6.00	-8.00
	Min.	6.00	8.00	6.0	3.00	6.00	8.00
	Max.	-29.0	-20.0	-29.0	-20.0	-16.0	-17.0
	Z (sig.)	-.957 (p>.05)		-.675 (p>.05)		-.545 (p>.05)	
HADS Anx. Change	Median	1.00	-1.00	1.00	-1.50	.00	-1.00
	Min.	-10.0	-9.00	-10.0	-9.00	-6.00	-7.00
	Max.	13.0	8.00	8.00	8.00	13.0	4.00
	Z (sig.)	-1.846 (p>.05)		-1.896 (p>.05)		-.676 (p>.05)	
HADS Depress. Change	Median	.50	.00	.00	-1.00	2.00	.00
	Min.	-6.00	-6.00	-6.00	-6.00	-5.00	-5.00
	Max.	9.00	9.00	7.00	6.00	9.00	9.00
	Z (sig.)	**-2.091 (p<.05)**		-1.590 (p>.05)		-1.377 (p>.05)	
TOMS Impair. Change	Median	.50	.50	.00	.00	.50	1.00
	Min.	-2.00	-2.00	-2.00	-1.00	-1.00	-2.00
	Max.	2.50	2.00	2.50	2.00	2.00	2.00
	Z (sig.)	-.378 (p>.05)		-.257 (p>.05)		-.526 (p>.05)	
TOMS Disability Change	Median	.50	.75	.50	1.00	.50	.50
	Min.	-2.00	-1.00	-1.70	-1.00	-2.00	-.50
	Max.	2.50	2.00	2.50	2.00	1.50	2.00
	Z (sig.)	-1.857 (p>.05)		-1.536 (p>.05)		-.880 (p>.05)	
TOMS Handicap Change	Median	1.50	2.00	1.00	1.50	1.50	2.00
	Min.	-2.50	.00	-2.00	.00	-2.50	.00
	Max.	3.00	4.00	3.00	4.00	3.00	4.00
	Z (sig.)	**-2.246 (p<.05)**		-1.789 (p>.05)		-1.420 (p>.05)	
TOMS Well-being Change	Median	.00	.00	.00	.00	-.25	.00
	Min.	-2.00	-3.00	-2.00	-2.00	-2.00	-3.00
	Max.	4.50	3.00	3.00	3.00	4.50	2.00
	Z (sig.)	-.909 (p>.05)		-.240 (p>.05)		-1.546 (p>.05)	

Table 7.2: Results of Mann-Whitney tests for difference (with medians (range)) for patient change in all outcomes at three month (significant differences in bold).

The medians for the two groups are similar but the range for the non-intensive arm was smaller. The data are illustrated in Box Plot 7.4 (below). One significant change is detected in change in self-perceived health status. Although the medians are similar the z-score for the Mann-Whitney tests exceeds 1.96 indicating significant difference. Box Plot 7.5 below indicates that the difference favours the intensive arm of the study.



Box Plot 7.4: Change in EQ-5D score by allocation



Box Plot 7.5: Change in Health status by allocation.

4.2 Barthel, Euroqol and FAI: Comparison of proportions (all).

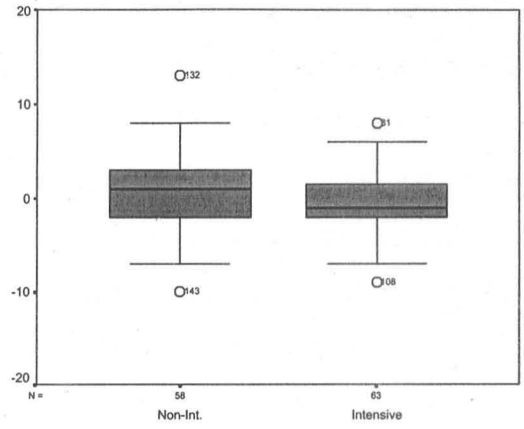
The proportion within each arm making a clinically significant change for Barthel score of two was also almost identical (75.3 per cent (n=49) for intensive patients, 75 per cent (n=45) for non-intensive patients. The difference and confidence interval showing non-significance (0.3 (-14.9, 15.5)). Difference between the groups exists when looking at the proportion of each group making positive change at one month in both EQ-5D and self perceived health status scores. Nearly two thirds (62.5 per cent (n=40) of the intensive patients made positive change and just over half (52.5 per cent (n=31) of the

non-intensive made such a change. The difference between these two proportions is not, however, significant (10.0 (-7.4, 27.4)). Just under half (49.1 per cent (n=28) of the intensive patients made positive change in self perceived health status. This compared favourable with the non-intensive group for whom under two thirds (64.3 per cent (n= 36) made a similar change. This difference between the two proportions was not significant (15.2 (-2.9, 33.3)).

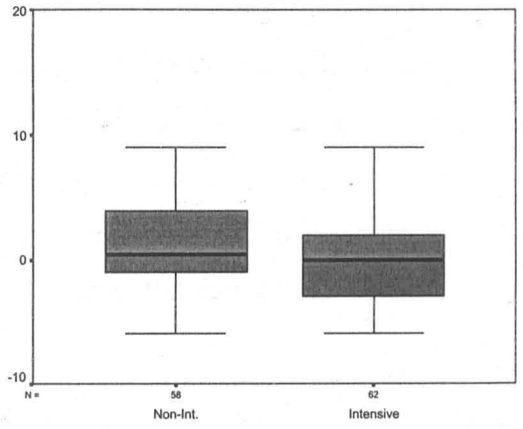
In the absence of a clinically significant equivalent for the change in Frenchay Activities Index, proportions above and below the median change were compared for each group. This comparison favoured the non-intensive group with 61 per cent (n=36) scoring the median or below (this equates to a more favourable outcome) and 47.7 Per cent (n=31) of the intensive patients do likewise. The difference between these proportions was not significant (18.5 (-5.2, 42.2)).

4.3 HADS Change at Three Months: Mann Whitney test for difference (all).

Table 7.2 (above) shows the results of a test for difference in change in HADS anxiety and depression scores at three months since baseline. The table indicates that there was no significant difference between change in HADS anxiety and group. The table also indicates that there was a significant difference in change in HADS depression score since baseline. The median change for both groups does not indicate which group this change favours. Box Plots 7.6 and 7.7 show that in both instances change in the intensive group is negative. Negative change is favourable for the HADS denoting that in both instances change favoured the intensive group.



Box Plot 7.6 : HADS Anxiety change for both groups (all patients).



Box Plot 7.7 : HADS Depression change for both groups (all patients).

4.4 HADS Change at Three Months: Comparison of proportions (all).

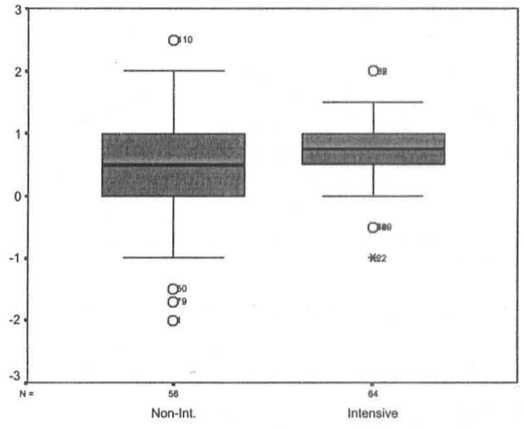
An examination of the proportion of patients from each group experiencing positive change may help to shed light on this. Over half (55.5 per cent (n=35) of the intensive patients showed a reduction in their HADS anxiety scores, whereas this was the case for just over one third of the non-intensive patients (36.2 per cent, n=21). Furthermore, the difference between these two proportions is shown to be significant (19.3 (36.7, 1.9)). Almost half of the intensive group (48.3 per cent, n=30) showed a reduction in their HADS depression score, this was the case for one third of the non-intensive patients (34.5 per cent, n=20). The difference was not significant (13.9 (-3.5, 31.3)).

4.5 TOMS Change at Three Months: Mann Whitney test for difference (all).

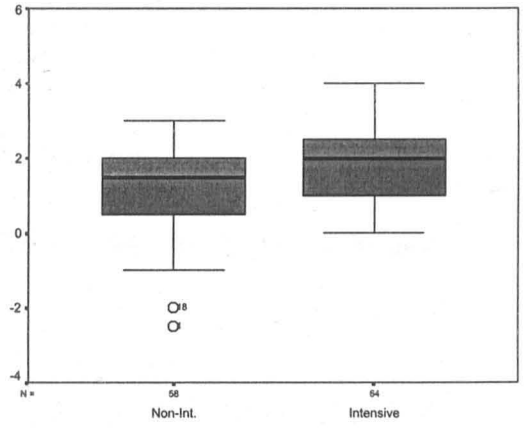
Table 7.2 (above) gives the median changes and results of Mann-Whitney test for difference in change for the TOMS data for all patients.

Change in impairment within the two arms of the study was almost identical. The median change for both arms was 0.5 and the range for each arm also similar. The z- score for the Mann-Whitney test shows no difference. No difference was detected for TOMS well being. Change in TOMS disability

scores do however indicate a difference. The median change for the intensive arm is slightly above that of the non-intensive arm whilst the range is similar. A significant difference between the two arms was detected in TOMS handicap change using Mann-Whitney. The median change for the intensive arm was above that of the non-intensive arm as was the maximum score. In order to illustrate these differences Box Plots 7.8 and 7.9 show the data for each of the outcomes for the two groups.



Box Plot 7.8: TOMS Disability change at three months for each group (all patients)



Box Plot 7.9: TOMS Handicap change at three months for each group (all patients)

4.6 TOMS Change at Three Months: Comparison of proportions (all).

The difference in the proportion of patients making clinically significant change was in favour of intensive patients. Almost two fifths (37.5 per cent (n=24) of the intensive patients made a change of one or more, this was the case for nearly one-third of non-intensive patients (29.3 per cent (n=17). However, the confidence intervals indicate that this difference in proportions is not significant (8.2 (-8.4, 24.8)). Also a great proportion of intensive patients (50.0 per cent (n=32) made clinically significant change than did non-intensive patients (37.9 per cent (n= 22) for TOMS disability change. The confidence interval indicates the difference between the two proportions is non-significant (12.1 (-5.3, 29.5)).

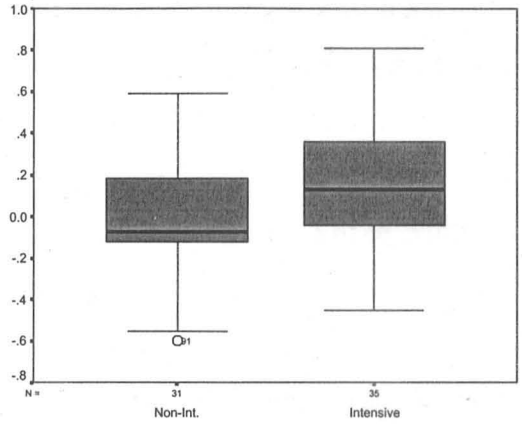
The difference in TOMS handicap detected using Mann Whitney test for difference is compounded when we examine the data for proportions of clinically significant change. A greater proportion of intensive patients (90.6 per cent (n=57) made clinically significant gains when compared with the non-intensive patients (41.1 per cent (n=24)). The confidence intervals around the difference confirm that the difference between the proportions was significant (18.2 (32, 4.4)). A larger proportion of the intensive group made clinically significant change in TOMS well being (37.5 per cent (n=24) compared with 29.3 per cent (n=17)). The difference was not significant (8.2 (-8.4, 24.8)).

5 Patient Change at Three Months for Stroke Patients

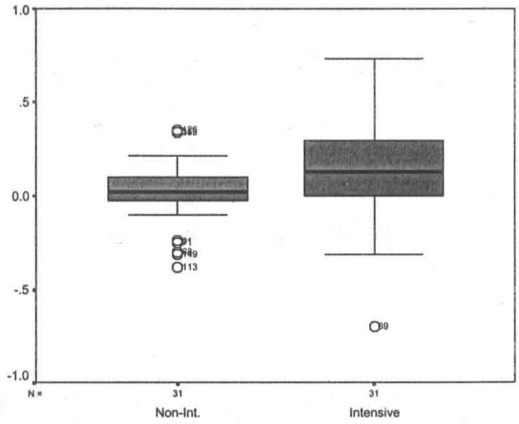
5.1 Barthel, Euroqol and FAI Change at Three Months: Mann Whitney test for difference (stroke).

Table 7.2 (above) shows change for stroke patients for Barthel, FAI and Euroqol data. Change in Barthel was not significantly different between the two arms of the study despite the median change for intensive patients being three and two for the less intensive arm. FAI change was also non-significant, again despite disparity in the median change (-6 and –9) for non-intensive and intensive patients respectively.

Change in the two Euroqol dimensions was, however, significantly different for stroke patients. The median EQ-5D change for intensive patients was 0.13 and 0.07 for non-intensive patients, the range also indicates a different distribution between the two arms. Box plots 7.10 and 7.11 (below) illustrate clearly that this difference in change favours the intensive patients.



Box Plot 7.10: Change in EQ5D scores for stroke patients by allocation at three months



Box Plot 7.11: Change in self perceived health status scores for stroke patients by allocation at three months

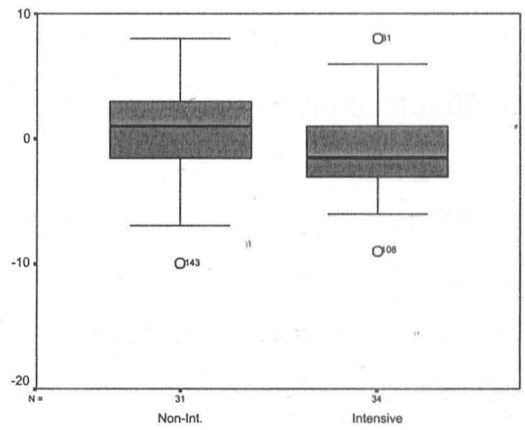
5.2 Barthel, Euroqol and FAI Change at Three Months: Comparison of proportions (stroke).

Examination of the data in terms of clinically significant change also reveals little difference between the two arms of the study. Almost three-quarters (71.4 per cent (n=25) of the intensive patients and 68.75 per cent (n=22) of the non intensive patients changed up to and above this clinically relevant level. The difference between these two proportions was not significant (2.6 (-19.4, 24.7)). The proportion of each group scoring equal to or above the median also favoured the non-intensive group. Almost two-thirds (61.3 per cent (n=19) of the non-intensive patients scored equal to or above the median and this was the case for just over two fifths of the intensive patients (42.8 per cent (n=15)). The difference between these two proportions was not significant (18.5 (42.2, -5.2)). The proportion of each group making positive change for EQ-5D and self-perceived health status was examined. A larger proportion of intensive patients was assessed as making positive change. Almost two thirds (60 per cent (n=21)) of intensive patients made positive change, whereas just under two-fifths (38.7 per cent (n=12) of the non-intensive patients made such a change. The difference between the two proportions was not significant (21.3 (-2.2, 44.8)). Similarly, a larger proportion of intensive patients made positive

change in self-perceived health status (71 per cent (n=22) compared with 58.1 per cent (n=18)). The difference between these proportions was also not significant (12.9 (-10.7, 36.5)).

5.3 HADS Change at Three Months: Mann-Whitney test for difference (stroke).

No significant difference was detected between intensive and non-intensive patients in terms of change in the HADS anxiety and depression scores (Table 7.2 above). The median changes did however, favour the intensive patients. Box Plot 7.12 (below) shows again that the difference favoured the intensive group.



Box Plot7.12 : HADS Anxiety change at one month for both groups (stroke patients)

5.4 HADS Change at Three Months: Comparison of proportions (stroke).

A closer look at the data shows that again this difference favours the intensive patients with over half (55.8 per cent, n=19) reducing their HADS anxiety scores compared with one third (32.2 per cent, n=10) of the non-intensive patients. The difference between these proportions indicates significance (23.6 (0.2, 47)). A smaller difference, again in favour of the intensive group, existed in proportion of each group reducing HADS depression scores. Over half (51.5 per cent (n=17) of the intensive group had reduced scores compared with one

third (35.4 per cent (n=11). The difference was not significant (16.1 (-7.8, 40)).

5.5 TOMS Change at Three Months: Mann-Whitney test for difference (stroke).

Table 7.2 above shows the results of the Mann-Whitney tests for difference in change in TOMS scores for stroke patients.. In terms of impairment and well being there appears to be no difference between the arms with the medians and ranges being similar. This is reflected in the z-scores. There are no significant differences either on the disability and handicap dimensions of the TOMS. The median change is larger for intensive patients in both dimensions.

5.6 TOMS Change at Three Months: Comparison of proportions (stroke).

For impairment the changes were 25.7 per cent (n=9) and 23.3 per cent (n=7) for intensive and non-intensive respectively (2.4 (-18.3, 22.1)). For TOMS well being the difference was inconsequential (0.5 (-19.8, 20.8)). The difference in proportions making a clinically significant change in these two dimensions is also negligible. In terms of disability, a higher proportion of intensive patients experienced clinically significant change (57.1 per cent (n=20)) compared with 36.6 per cent (n=11). The confidence interval for the difference between the two proportions indicates significance (20.5 (0.1, 40.9)). In handicap also, a larger proportion of intensive patients changed to a clinically significant level (97.1 per cent (n=34)) as compared with 70 per cent (n=21). Again the difference between the two proportions is significant (27.0 (9.7, 44.3)). Therefore in both TOMS disability and TOMS handicap there was a significant difference in the proportion of patients making clinically significant change. In both cases intensive patients were the beneficiaries of the difference.

6 Patient Change at Three Months for Hip Fracture Patients

6.1 Barthel, Euroqol and FAI Change at Three Months: Mann-Whitney test for difference (hip fracture).

Table 7.2 includes the results of Mann-Whitney tests on patient change from baseline data for the Barthel, FAI and Euroqol for hip fracture patients. All four indicate that there were no significant differences between the two arms of the study for these patients. There are also no differences between the median change for each with the exception of EQ-5D where the median change for non-intensive patients is higher than that of the intensive patients.

6.2 Barthel, Euroqol and FAI Change at Three Months: Comparison of proportions (hip fracture).

Looking closer at the proportions of clinically significant change for the Barthel also shows no difference. The proportion from the non-intensive arm achieving a change of two or more was 82.1 per cent (n=23) compared with 80 per cent of the intensive patients (n=24). The difference was not significant (2.1 (-18.1, 22.3)). The proportion of each group scoring equal to or above the median change for FAI also favoured the non-intensive group. Over half (53.5 per cent (n=15) of the non-intensive patients scored equal to or above the median and this was the case for just over two fifths of the intensive patients (46.6 per cent (n=14)). The difference between these two proportions was not significant (6.9 (-18.7, 32.5)).

There was little difference between the groups in terms of positive change in EQ5D (67.9 (n=19) for non-intensive and 65.5 (n=19) for intensive. The difference was, predictably, not significant (2.4 (2-22.1, 6.9)). The difference in proportions of the groups making positive self-perceived health status change was larger. Over half (56 per cent (n=14)) of the intensive patients made such change, whereas under two-fifths (38.5 per cent (n=10)) of the non-intensive

group made similar change. The difference between the two proportions was not significant (17.5 (-9.4, 44.4)).

6.3 HADS Change at Three Months: Mann-Whitney test for difference (hip fracture).

No significant difference existed in terms of change in HADS anxiety or depression from baseline for the hip fracture patients (Table 7.2). It should be noted, however, that the median change for the intensive arm of the trial was favourable to that of the non-intensive patients.

6.4 HADS Change at Three Months: Comparison of Proportions (hip fracture).

The proportion of each group reducing both HADS anxiety and depression scores by three months showed some differences, although neither difference was significant. Over half (55.2 per cent (n=16)) of the intensive group had a reduced anxiety score compared with two fifths of the non-intensive group (40.7 per cent (n=11)). The confidence intervals confirm the non-significance of the difference (14.4 (-11.5, 40.3)). One third of non-intensive patients experienced favourable change in HADS depression (33.3 per cent (n=9)) compared with over two fifths of the intensive group (44.8 per cent (n=13)). As noted above the difference was not significant (11.5 (-13.8, 36.8)).

6.5 TOMS Change at Three Months: Mann-Whitney test for difference (hip fracture).

Table 7.2 shows the results of Mann-Whitney test for difference in change for the TOMS scores from baseline to three months for hip fracture patients in the study. None of the differences are significant. However, it is worth noting that in all but disability, the median change for intensive patients was favourable to that of the non-intensive patients.

6.6 TOMS Change at Three Months: Comparison of proportions (hip fracture).

I also examined these data for proportions of change. In terms of TOMS impairment change for hip fracture patients just over half of the intensive patients (51.7 per cent (n=15) changed by one or more whilst just over one-third (35.7 per cent (n=10) of the non-intensive patients experienced a similar change. The intervals indicate that this difference in proportions was not significant (16 (-9.3, 41.3)). For clinically significant change in TOMS disability there was little difference between the proportions (39.2 per cent (n=11) for non-intensive patients and 41.3 per cent (n=12). The difference was non-significant (2.1 (-23.3, 27.5)). For TOMS handicap the proportions achieving clinically significant change were 75 per cent (n=21) and 89.6 (n=26) for non-intensive and intensive respectively although the difference between the two proportions was not significant (14.6 (-5, 34.2)). For TOMS well-being the proportions making clinically significant change were 25 per cent (n=7) for non-intensive and 31 per cent (n=9) for intensive, although again this difference was not significant (6.0 (-17.2, 29.2)).

7 Discussion

Table 7.3 below summarises the findings described in this chapter. As with previous results chapters significant differences and non-significant differences are clearly labelled.

It can be observed that (as with previous results) some outcome measures show no difference in change at both one month and three months. In particular the Barthel, the primary outcome measure for this study, Frenchay Activities Index, TOMS Impairment and TOMS Well-being show no differences in change for patients across both aetiologies. There are two instances where a difference comes close to being significant for HADS anxiety, both of these occur at three months and one instance where difference in change in TOMS disability comes close to being significant, again at three months. Significant

differences in change at one month is restricted to TOMS HADS depression for stroke patients and self perceived health status for all patients and stroke patients. Significant difference in change at three months is restricted to HADS depression, TOMS Handicap and self perceived health status for all patients and both dimensions of Euroqol for stroke patients. There are no significant differences in change for hip fracture patients on their own at any assessment point in any of the measures. One important note to make is that where significant differences do exist, or indeed where there exists a difference that comes close to being significant, such differences, an all cases, favour intensive patients.

Outcome Measure	Change from baseline at one month			Change from baseline at three months		
	All patients	Stroke Patients	Hip fracture patients	All patients	Stroke Patients	Hip fracture patients
Barthel	NS	NS	NS	NS	NS	NS
HADS Anxiety	NS	NS	NS	NS	NS	NS
HADS Depression	NS	Significant difference	NS	Significant difference	NS	NS
FAI	NS	NS	NS	NS	NS	NS
TOMS Impairment	NS	NS	NS	NS	NS	NS
TOMS Disability	NS	NS	NS	NS	NS	NS
TOMS Handicap	NS	NS	NS	Significant difference	NS	NS
TOMS Well Being	NS	NS	NS	NS	NS	NS
EQ-5D	NS	NS	NS	NS	Significant difference	NS
Health Status	Significant difference	Significant difference	NS	Significant difference	Significant difference	NS

Table 7.3: Summary of Results of Mann-Whitney tests for Difference in Change

Tables 7.4, 7.5 and 7.6 summarise the comparison made on the basis of the proportion of each group making beneficial change. They show which group benefited in terms of the proportion making greater change at one month and three months.

Outcome Measure	Change at One month		Change at Three months	
	Proportions favour non-intensive group	Proportions favour intensive group	Proportions favour non-intensive group	Proportions favour intensive group
Barthel	✓(NS)			✓(NS)
HADS Anxiety	✓(NS)			✓(Significant)
HADS Depression		✓(NS)		✓(NS)
FAI			✓(NS)	
TOMS Impairment		✓(NS)		✓(NS)
TOMS Disability		✓(NS)		✓(NS)
TOMS Handicap		✓(NS)		✓(Significant)
TOMS Well Being		✓(NS)		✓(NS)
EQ5D		✓(NS)		✓(NS)
Health Status		✓(Significant)	✓(NS)	

Table 7.4: Summary of comparisons of proportions of each group making clinically significant change (all patients).

In most cases the difference between the proportions was not significant (NS), however, where differences between proportions were significant this is indicated. Table 7.4 summarises the results of all patients, Table 7.5 summarises for stroke patients only and Table 7.6 summarises the comparisons for hip fracture patients. All three tables indicates the tendency for those patients from the intensive group to benefit from change in comparison to the less intensive group. Obvious exceptions include Barthel change where the non-intensive group benefits in all but some comparisons. This will be discussed in more detail in the following Chapter dealing with co-variance. The less-intensive group also benefit in proportions experiencing favourable change in FAI.

This tendency to the intensive group should not be ignored and will be reflected upon in the discussion. It is worth noting at this point that the lack of significance in the difference in proportions is mainly due to wide confidence intervals resulting from a small sample size.

It is also worth noting that change may be associated with those patients whose initial baseline scores were low. Appendix X shows the results from tests for

correlation between baseline score (for each measure) and change. All indicate a significant correlation. Although none show good or very good positive correlation, some achieve moderate to good.

Outcome Measure	Change at One month		Change at Three months	
	Proportions favour non-intensive group	Proportions favour intensive group	Proportions favour non-intensive group	Proportions favour intensive group
Barthel	✓(NS)			✓(NS)
HADS Anxiety	✓(NS)			✓(Significant)
HADS Depression		✓(NS)		✓(NS)
FAI			✓(NS)	
TOMS Impairment		✓(NS)		✓(NS)
TOMS Disability		✓(NS)		✓(NS)
TOMS Handicap		✓(NS)		✓(NS)
TOMS Well Being	✓(NS)			✓(NS)
EQ5D		✓(NS)		✓(NS)
Health Status		✓(Significant)		✓(NS)

Table 7.5: Summary of comparisons of proportions of each group making clinically significant change (stroke patients).

Outcome Measure	Change at One month		Change at Three months	
	Proportions favour non-intensive group	Proportions favour intensive group	Proportions favour non-intensive group	Proportions favour intensive group
Barthel	✓(NS)			✓(NS)
HADS Anxiety		✓(NS)		✓(NS)
HADS Depression	✓(NS)			✓(NS)
FAI			✓(NS)	
TOMS Impairment		✓(NS)		✓(NS)
TOMS Disability		✓(NS)		✓(NS)
TOMS Handicap		✓(NS)		✓(NS)
TOMS Well Being		✓(NS)		✓(NS)
EQ5D		✓(NS)		✓(NS)
Health Status		✓(NS)	✓(NS)	

Table 7.6: Summary of comparisons of proportions of each group making clinically significant change (hip fracture patients).

Chapter 8: Logistic Regression

1.1 Rationale and Strategy

This short chapter represents the final part of the result section of this thesis. It sets out to determine the existence of confounding variables on the other results presented. I have identified three factors and two covariates as potential confounding variables. The factors were co-resident carer, gender and aetiology, with the covariates being, age and time since event. The binary outcomes selected were, for the most part, based on achievement of change (either clinically significant change or change above the median). In order to do this change data was transformed into binary outcomes (0=no, 1= yes). Identification as 'case' at three months has been used as the binary outcome for the HADS anxiety and depression data (0=no, 1= yes).

1.2 Results

The results of the logistic regression analysis for each binary outcome are presented below (Table 8.1).

The table shows the results of logistic regression analysis of patient change data. The table shows OR^1 represents the odds unadjusted and OR^2 represents the odds when adjusting for the identified factors and co-variates using a logistical regression model. The table also shows the 95% confidence interval around the OR^2 (adjusted) as well as precise significance level.

The first point to note is that with the exception of Barthel and FAI change the Ors favour the intensive group, in some cases the 95% CI for the OR these show significant differences. These differences are reflective of other significant findings noted earlier. The adjusted odds ratios also remain largely unchanged when compared to the unadjusted calculations. The adjusted OR for significant change in Barthel, EQ5D, Self perceived Health Status, TOMS Impairment, disability, handicap and well being are all similar to the

unadjusted values. The odds ratio for above FAI change does increase, favouring the non-intensive group, however this remains non-significant.

Outcome	Allocation	n	OR^1	OR^2	95% CI		Sig.
Clinically significant change in Barthel	Non-Intensive	58	0.98	1.03	.435	2.446	0.94
	Intensive	64	1.00	1.00			
>Median FAI change score	Non-Intensive	57	1.7	2.00	.907	4.443	0.085
	Intensive	64	1.00	1.00			
>Median EQ5D change score	Non-Intensive	55	0.83	0.77	.360	1.679	0.52
	Intensive	59	1.00	1.00			
>Median Health Status change score	Non-Intensive	53	0.46	0.4	.174	.919	0.31
	Intensive	53	1.00	1.00			
Identified as HADS anxiety 'case'	Non-Intensive	58	3.05	5.23	1.253	21.845	0.023
	Intensive	64	1.00	1.00			
Identified as HADS depression 'case'	Non-Intensive	58	2.81	7.46	.764	72.762	0.084
	Intensive	63	1.00	1.00			
change in TOMS Impairment	Non-Intensive	56	0.69	0.6	.261	1.362	0.22
	Intensive	63	1.00	1.00			
change in TOMS Disability	Non-Intensive	56	0.61	0.66	.261	1.362	0.23
	Intensive	63	1.00	1.00			
change in TOMS Handicap	Non-Intensive	56	0.27	0.26	.008	.742	0.012
	Intensive	63	1.00	1.00			
change in TOMS Well-being	Non-Intensive	56	0.82	0.74	.310	1.772	0.5
	Intensive	63	1.00	1.00			

Table 8.1: Results of Logistic Regression Analysis

OR^1 = unadjusted

OR^2 = adjusted for co-residing carer, gender, aetiology, age and times since event.

The most notable difference can be observed with HADS change. Under unadjusted conditions the odds ratio for non-intensive patients being identified as 'case' is 3.05. When adjusting for the above factors and co-variates the odds ratio rises to 5.23, with both the significance value and 95% CI indicating a significant finding, although the 95% CI is wide. Similarly the odds ratio for non-intensive patients being identified as 'case' under non-adjusted conditions

was 2.81 and 7.25 when adjusting for co-residing carer, gender, aetiology, age and TSE. The odds ratio continues to favour the intensive group under such conditions, but the 95% CI and significance value suggest that this is not a significant finding. The 95% CI is also very wide.

Chapter Nine: Discussion

1.1 Literature

The literature review at the beginning of this thesis set out to do two things. Firstly, it provided the context for the research in terms of the development of the primary research question. Secondly, it provided existing evidence relating to the topic of intensity and setting in order to give justification for the selection of the research environment.

The review placed emphasis on the growing importance of the intensity question in rehabilitation following stroke and hip fracture. The ageing population points to an increase in the incidence of both stroke and hip fracture as well as the prevalence of related impairment and disability. The need for efficient, appropriate rehabilitation services because of this was made. The review also made the case for the inclusion of these two groups because of this.

The literature went on to describe why it is that intensity in rehabilitation services is considered to be important. The most tangible constituent of health service provision is the face to face contact with professionals and care staff and in the review it was suggested that intensive treatment was increasingly viewed as an important factor in relation to patient satisfaction within rehabilitation provision.

Attention was drawn to an emerging theoretical possibility that intensive treatment (increased stimulation, practice and physiological stressing) could lead to improved patient outcome. This, it was argued, may occur through exploitation of plasticity of the CNS (particularly in the weeks and months immediately following stroke); more efficient re-learning of skills through improved motor re-learning and improved strength. The focus of these arguments is centred upon impairment and the physiological and anatomical dimensions of rehabilitation. The assumption that these changes could lead to better outcomes in activity and participation domains for patients is of course arguable, a point I shall return to later in this Chapter.

Variation in practice was also touched upon as a theme of the review, concluding that it is not always patient need that determines intensity of treatment and that resource and organisation of services contributed to levels of treatment provided.

However, the remainder of the review was left to attend to the evidence relating to two areas, both of which provided the most significant justification for undertaking this research. These were the evidence relating to intensity of treatment following stroke or hip fracture and the issue of setting in the rehabilitation of older people.

The review highlighted a small, yet emerging, evidence base concerning itself with the question of intensity in rehabilitation research. This evidence had suggested that there was a small, albeit short lived, significant effect associated with a more intensive form of rehabilitation provision. However, the review indicated that the focus of much research had been on impairment and impairment related outcomes for patients. Setting was also a feature of the literature relating to the intensity evidence base. The literature concerned with the evaluation of specialist stroke units and dedicated orthopaedic units was also examined. The notion that such services were often associated with more intensive multi-disciplinary services was given as the rationale for doing this. It was shown that the evidence relating to such provision suggested that these units did indeed promote better outcomes for patients and it was proposed that the intensive component of specialist units may provide a partial explanation of this success. However, the most pertinent message to be taken from the literature is that without exception all research had been undertaken in secondary care settings.

Thus far, however, the review did not spell out sufficiently the justification for undertaking research concerning intensity of treatment in the primary or community care setting. To this end the evidence and policy relating to the shift towards rehabilitation services provided in primary care were presented. The suggestion that these services were now a permanent, but still developing, part

of the landscape of rehabilitation provision was made alongside the reality that there existed know known research addressing the very important issue of intensity of treatment in the primary care setting. It was these things together which provided the rational basis for undertaking this study.

Having now provided a remainder of the rationale and context for this research, this discussion chapter will principally explore three areas. Firstly, I feel it important to address some of the strengths and weaknesses of the study. Secondly, I would like to take the opportunity to discuss and offer possible explanations for the findings presented in Chapters Five, Six and Seven. Finally, it will be necessary to draw attention to some of the challenges faced by researchers conducting rehabilitation research in primary care before looking at some of the short and medium term questions arising out of the study.

2 Strengths and Weakness of the study

2.1 Strengths of the Study

The Table below compares the essential components of the study design against the CONSORT framework (Freemantle et al. 1997) checklist used to evaluate RCTs in health research.

Randomis-ation procedure ✓	**Patient Blinding** ✖	**Assessor Blinding** ✓	**Informed consent** ✓	**Intention to treat analysis** ✓
Randomisation completed using sealed opaque envelopes and random number tables.	Not possible due to the nature of the intervention	Achieved through the use of assessors unknown to patient. Assessors not made aware of allocation.	Procedure openly reported. Ethically approved.	All patient data analysed on the basis of original allocation and not eventual treatment

Table 9.1: Comparison of the study design against CONSORT framework.

Table 9.1 indicates that in all but one of the key areas for RCT design, the study was robust. The randomisation procedure, strategies to promote assessor

blinding, the consent procedure and an ITT approach to the data analysis all conformed to the CONSORT framework. Patient blinding was difficult to achieve because of the nature of rehabilitation as an intervention, a problem faced by the majority of rehabilitation research (Siemonsma & Walker 1997).

2.2 Threats to Internal and External Validity

Study weaknesses will be divided into errors in design before moving on to look at operational errors.

2.2.1 Length of sessions

Although therapists were requested to record each contact with a research participant, no plans were made to aid therapists in recording the length of time each session took. The detailed protocol finalised at the end of the internal pilot phase specified a maximum length for each session (1.5 hours), no plans were included to monitor this or gather data relating to the length of time spent in each session. However, studies aimed at evaluating intensity in rehabilitation should ideally record data relating to the time patients and therapists spend together. The limited data available at the end of the fieldwork can therefore act only as a crude indicator of intensity. In hindsight strategies aimed at gathering accurate data regarding the length of face to face contacts between patient and therapists would have been desirable. The difficulties associated with this type of problem in primary care rehabilitation research will be addressed later in the discussion.

2.2.2 Nature of the intervention

A clear deficiency, in both the study design and the thesis, concerns the nature of the therapist and therapy assistant activities when providing the two interventions (intensive/non-intensive). Therapists were requested to provide a more intensive treatment regime to those allocated to the intensive arm of the trial. However, what occurred within those additional face to face contacts was not prescribed at the outset. Individual therapists and the patients whom they

were treating were left to negotiate the nature of the programme themselves, through the goal setting process, as is standard in multi-disciplinary rehabilitation provision. This was done in order to address the issue of intensity and not the nature of the intervention itself. A further problem concerning the nature of the intervention was that the activity within treatment sessions was not recorded.

This lack of prescription, and perhaps more importantly, the lack of recorded data concerning the nature of the intervention, may have resulted in there being not only a quantitative difference between the two arms of the trial, but also a qualitative difference. No method was employed in order to help reduce our reliance on supposition or assumption on this matter. Patient notes were considered as a source of data, however, patient consent to access this was not obtained at the point of recruitment. Furthermore, discussions with team leaders concluded that the information provided in patient notes would not provide a reliable or adequate source of data. In hindsight some method of gathering this data, such as a tool aimed at coding interventions or a sample of patient/therapists activities described by therapist, might have been employed in order to partially address this problem.

Qualitative research undertaken with the Sheffield CRTs may assist us in reducing speculation about the nature of the intervention. Research aimed at developing a taxonomy of therapy and using Sheffield CRT as a data collection site, suggests that interventions within the community were aimed at activity and participation dimensions of the ICF rather than impairment (body structure) (Marshall 2003). However, the observations made for this taxonomy development are inconsistent with the context within which the intensity study was undertaken. Firstly, the taxonomy was developed under 'routine', less intensive conditions. Secondly, no observations involving hip fracture patients were made. Its utility for this study is therefore limited.

2.2.3 The Inclusion of Multiple Aetiologies

This study set out to evaluate the effect of a more intensive programme of multi-disciplinary therapy in the community for older people recovering from a hip fracture or a stroke. The rationale behind the inclusion of two aetiologies is rooted within an increasing incidence, largely due to an ageing population, and its associated prevalence of disability. Because of these changes the necessity for studies concerned with efficacy in rehabilitation has become apparent. In addition, from a policy point of view, it was also noted, that the workload of CRTs is dominated by the two aetiologies. Hence, again, the interest in evaluating both stroke and hip fracture. It was therefore decided that the two aetiologies be included within the same study in order to address the issue of epidemiology and policy within community based practice. The inclusion of both of these groups in a single study is not unique (Chen et al. 1999;Kane et al. 1998;Kramer et al. 1997;Ostir et al. 2002).

This decision does, however, give rise to potential problems. Firstly, the inclusion of different aetiologies potentially undermined the study because the two have very different recovery patterns. Recovery from hip fracture is often a less protracted one. In terms of intervention hip fracture intervention has an emphasis on early mobilisation, conditioning, re-learning and confidence building. The nature of stroke intervention relies on re-learning as well as the repair or re-routing of the central nervous system through techniques aimed at stimulating CNS. Secondly, further compounding this problem is that stroke itself has a highly individualised recovery pattern requiring different approaches. Much can depend upon the side the stroke affects and the region of the brain the lesion has occurred. A third problem, which was highlighted in Chapter Two concerned the selection of outcome measures. Chapter Two noted that one of the selection criteria was that measures needed to be generic to both groups of patients and acted as a constraint on the measures that could usefully be considered.

However, the criticism levelled at studies utilising multiple aetiologies in order to evaluate novel or alternative treatments is that the nature of the experimental

treatment may not be appropriate to one of the groups. The decision to conduct this study with patients recovering from two different aetiologies can be defended in two ways. Firstly, 'routine' methods of treatment for each group (stroke and hip fracture) continued to be employed by therapists. The difference with this study is that for some patients (allocated to the intensive arm) the 'routine' intervention was conducted on a more intensive footing.

Secondly, in order to assist with the issue of multiple aetiologies in this thesis separate analyses have been executed and segregated presentation of results has been provided. Although the analysis of subsets has its dangers, the examination of data by re-executing statistical tests using important sub-groups is feasible (Altman 1991). In addition the stratified randomisation also aided 'balance' within each of allocated groups for the two sets of aetiologies. The inclusion of two separate patient groups, and separate analysis, also therefore provides the opportunity for specificity when considering the findings of the research. Indeed, one of the interesting observations is that the two aetiologies may have responded differently to intensive therapy. One implication might be that stroke rehabilitation is placed on a more intensive footing in relation to hip fracture rehabilitation. This shall be discussed later in the chapter.

2.2.4 Piloting

Piloting is seen as an important component of experimental research (Pocock 1994). During this study I did not conduct a pilot independent of and prior to the initiation of the main body of the study. Instead, an approach using internal piloting was utilised (Wittes & Brittain 1990). Although this has obvious advantages, particularly relating to time, some limitations also exist.

In particular one major decision taken following the internal pilot was to relieve Senior Therapists of the task of undertaking baseline assessments. The task was not viewed favourably by some staff. In addition to this some important data were missing. These are problems which may have been resolved should a pilot, independent of the main study, have been conducted.

The second change concerned those patients being treated on the intensive arm of the study. The source of this change was therapist concern that patients allocated to the intensive arm of the trial were being provided with an intensive service almost up to the point of discharge. It was felt that it would be more helpful if this intensive provision could be 'phased out' if they did not clinically need the intervention. Changes to the protocol were made. Again a pilot study this may have identified this as an issue to be included in an earlier version of the protocol.

2.2.5 Inter-rater reliability

It was noted in Chapter Three that no inter-rater reliability was assessed. It was also noted that this was largely due to the problem of taking repeated measurements from a limited number of patients in their own homes, a problem compounded by the number of assessors involved (10 including TR). One proposed solution, discussed in detail with supervision staff, was for assessors to observe a series of short video vignettes and reliability to be determined by a kappa analysis of reported scores. This idea was rejected on the grounds that good assessment practice was based on patient/assessor interaction, not simply observation. In order to prevent difficulties associated with poor reliability between observers, training was provided and meetings with observers were held at regular intervals (once every three months as a team, although I did meet more regularly with individuals to discuss progress and problems). Issues relating to measurement remained a standing item at team meetings. Appendix 1 shows the median scores for assessments made by each assessor at one month. It was felt that this may help indicate which observers, if any, had routinely examined patient outcome in more favourable or less favourable terms. Appendix one suggests that this was not the case. In addition one other study (Hammerton 2003) utilised two of the observers used in this research. The reliability checks presented in Hammerton's thesis reveal high levels of agreement, providing another source of consolation on this matter.

However, it ought to be noted that the calibre of this study is somewhat undermined by an absence of inter-rater reliability tests. The number of

assessors also raises concern, although this was an issue that remained largely out of my control. Three assessors were away for a time on maternity leave, one on long-term sickness leave and another found that helping with the research placed too much pressure on her workload and asked to be released. Were the study to be repeated, emphasis would need to be placed on stringent plans ensuring that the number of observers was limited. This would not solve, but would go some way to assisting, the problem of undertaking multiple assessments, in order to ascertain reliability, in the homes of older people recovering from a significant health event.

2.2.6 Outcome Measurement

Wade (Wade 1999) argues that the problems associated with outcome measurement described within the rehabilitation literature are not as significant as poor research design and that the tools available within rehabilitation research are adequate. This does not overcome some of the anxieties felt about some of the measures used within this thesis and in particular the way that they have been used in other rehabilitation studies and replicated here. The most significant anxiety surrounds the use of the summary scores for the Barthel Index and FAI. Both were originally designed as diagnostic assessment tools not as research tools. The items within each of these measures appear to capture the constructs they were designed to, hence they have good face validity as well as good construct validity. However, by summarising each (of what is in both cases a series of ordinal scales) into summary scores the usefulness of the data collected is lost. For instance by examining the Barthel Index it could be postulated that stroke and hip fracture patients may score equally but may need assistance in different items/areas. Furthermore, some items may impact upon daily living more than others (take the contrast between needing assistance for eating and bathing). For the FAI also, important comparisons might be possible for key independent variables. This could also be said to be true of the EQ-5D. Again in this thesis, and of course elsewhere, it has been used to generate a single score from a series of ordinal scales, where important data is lost. By doing so an opportunity for specificity is forfeited.

2.2.7 Power Calculation

The power of this study will be discussed later in this chapter, however, a point regarding the way in which the power calculation was calculated should be made here. The original power calculation utilised a method based on the calculation of the standard difference. The standard difference was devised by using the anticipated standard deviation of the baseline Barthel Index score for the sample. It is appropriate to use this method only when calculating a sample size for a continuous outcome measure. Several authors have used this approach when calculating a sample size (Rudd et al. 1997;Young & Forster 1992). The Barthel Index is not a continuous outcome measure, but is ordinal in nature. Thus concerns about this approach arose. An alternative method, based on a prediction of the proportion of patients expected to 'improve' might have been a more appropriate method (Altman 1991). This approach involves calculating the standard difference from the expected difference between the two proportions and using this to calculate the sample size in the normal way. Although I do not believe that this technical error has had any serious consequences for the study, in future studies of this kind the latter method should be used.

2.2.8 Sample Size and Recruitment

The original power calculation for this study was 200 patients (100 per arm). However, just 160 patients were recruited to the study. This number of 160 patients was achieved after an extended recruitment phase. It can not be said that the problems in regard to recruitment were due to an underestimation of referrals. The project time-scale was developed on the basis of a referral rate of 12 patients per month and the eventual referral rate was around about 14 patients per month.

Two principal difficulties can explain why the original sample size was not achieved.

The primary difficulty throughout the study was the rate of non-consent which was far higher than anticipated. Original plans estimated around about one third of patients would not participate in the study. However, Chapter Three indicated that more than 50 per cent of those eligible patients, who were contacted to participate in the study, did not consent to do so. This disappointing consent rate can not easily be explained. Coding undertaken following refusals suggests a range of reasons for non-participation as discussed in Chapter Three. Almost two thirds were non-specific in their explanation, citing being unwell, age or a lack of enthusiasm for research. Hip fracture patients were more likely to be non-specific, with almost three quarters falling into this category. Stroke patients were more likely to consider the issue of intensity of treatment in their deliberations. Furthermore, the proportion of stroke patients rejecting because they felt that they might be denied an intensive service was also observed. Overall the proportion of patients rejecting because they felt that they might be denied an intensive service was small. It would seem, therefore, that the primary explanation for non-consent was more closely related to issues other than intensity of treatment.

A second operational error, which compounded the low consent rate, occurred in a failure to include patient drop out in the original power calculation. The primary sources of advice when calculating the sample size (Altmen 1991, Bland 2000) make no mention of how this problem might be included within a sample size calculation, although both recognise it as an issue when beginning data analysis. Both also point to a strategy of extensive piloting in order to better predict both recruitment rate and drop out. By three months almost 22 per cent (n=35) of those patients who consented to take part had either withdrawn, died, moved away or were unavailable for assessment. Although this rate of withdrawal and loss to follow up was not dramatically high, the power of the study was undermined still further. Chapters Five and Six examined the proportion of participants in both groups that were lost to follow up. No significant differences were detected between the two groups. However, at one month the OR for withdrawal from the non-intensive groups was large. One might suppose that this was due to patients 'gambling' on being allocated

to the intensive group, in order to receive more treatment, and having not done so withdrawing from the study. This, however, can not be said for certain.

The important outcome for this research is that the study was, potentially, under powered. This lack of power will emerge as a theme throughout this chapter.

2.2.9 Volunteer Bias

Consenting patients were compared to non-consenting patients using some key variables. These included age, time since stroke or hip fracture, co-residing status and gender. The methods section of this thesis also indicated that broadly speaking those participating in the study were geographically representative of the population. In two of these variables, however, differences between consenting and non-consenting patients existed. A larger proportion of patients living with carers consented to participate in the study. Similarly, a larger proportion of men agreed to take part. This inconsistency might raise questions about the external validity of the study. In the case of co-residing carer there is nothing to suggest that this is problematic as no evidence relating to the presence or absence of a co-residing carer and patient outcome currently exists. There might be more concern on the issue of gender. Women are more likely to suffer both stroke and hip fracture and hence the recruitment of a higher proportion of males relative to the proportion referred to the study may weaken its findings. However, despite the literature relating to the Barthel Index and gender (Diamond et al. 1997;Hachisuka et al. 1999), there is nothing to suggest that males are more likely to experience a less favourable or more favourable outcome to females.

It was not possible to gather data relating to key variables such as level of disability or well-being from non-consenting patients. Discussions with the Chair of North Sheffield LREC and with a representative from South Sheffield LREC concluded that data gathered by the teams for routine purposes could not be accessed without patient consent. In order to judge whether or not the consenting patients were representative of the population of older CRT patients

as a whole I was left to rely on Barthel figures published by the teams in their annual reports. These figures suggest that the study sample may indeed have been representative of the population. The median Barthel score for stroke patients at admission to CRT was 15.5. The median Barthel score for the stroke patients entering the study was 16. The median Barthel score for patients referred to the team for orthopaedic reasons was 16 and for hip fracture patients in this study it was 16. There are two problems with making direct comparisons however. Firstly, they represent an aggregation of all strokes, including those aged under 65. Secondly, the figure for orthopaedic patients includes those patients recovering from other fractures as well as younger people aged under 65.

2.2.10 Confounding Variables

Chapter Eight examined patient change scores in relation to several factors and co-variates using logistic regression techniques. In particular there were concerns about the effect of two factors for which the two groups were unequal at the point of randomisation, namely gender and co-residing carer. Other factors and covariates were included in the model (aetiology, age and time since event). The tests revealed that, in the main, the unadjusted odds ratios were unaltered following analyses under adjusted conditions. The two exceptions to this were HADS anxiety and HADS depression change. However, for both of these although the effect size did change considerably, the direction and significance did not.

2.2.11 Failure to Achieve Intensive Treatment Target

From the outset this study had an aim of comparing intensive (6 or more face to face contacts per week) with non-intensive (3 or less face to face contacts per week) rehabilitation treatment. The rationale for deciding upon these figures is set out in Chapter Two: Methodology. Essentially, however, it was the intention to compare a treatment ratio of 2:1 (intensive/non-intensive). Despite protocol arrangements to ensure that this ratio was provided, the data presented in Chapter Four reveals that this was not achieved. The ratio achieved using the

number of contacts at the end of week four was 1.7:1. The ratio achieved using the number of contacts at the end of week eight was 1.6:1 and at the end of treatment it was 1.5:1. The reasons for this failure were also described in Chapter Four. Although the contact data revealed a statistically significant difference between the two groups at four weeks, eight weeks and 12 weeks, the question regarding the clinical significance of this difference remains. The failure to achieve this ratio may have contributed to the lack of difference detected between the two groups in most outcomes- particularly impairment. Some of the implications for ensuring therapists compliance in primary care research will be discussed shortly.

3 Interpretation of Results

3.1 Impairment Overview

The results indicate that, on the whole, there were no differences between the groups in terms of impairment. At none of the assessment points for all patients, or either of the aetiologies, was there a statistically significant difference between the two groups for this dimension.

Even when examining the results beyond the use of p values to denote significance there appears to be little in the findings which might suggest any differences between the groups. For instance when examining the results around patient change the proportion of the intensive group experiencing positive impairment change (as assessed by TOMS impairment score) favoured the intensive group at one and three months for all patients. This was also the case when undertaking a sub-group analysis on the basis of aetiology. However, in most cases, with the exception of hip fracture patients at three months, the difference between the proportions was small.

3.2 Interpretation of Impairment Results

3.2.1 Null Hypothesis

One explanation for this could lie in the ineffectiveness of the intensive treatment as an intervention in the dimension of impairment. This explanation would seem to contradict our theoretical understanding concerning the impact of intensity on organic aspects of recovery. It has already been noted that the arguments concerning intensity centre upon plasticity of the central nervous system and physiological stressing. One would therefore assume that an increase in intervention for one group would translate into a significant difference in outcome. This has not been the case in this study.

3.2.2 Outcome Measurement

One concern regarding the capacity of the outcome measures selected to detect change in impairment must be expressed. One tool (TOMS Impairment) was used in the study to measure impairment. TOMS impairment has been shown to be a reliable instrument in measuring general levels of impairment (Enderby et al 1998), particularly in a benchmarking capacity (John 2002). However, TOMS impairment was not designed to centre upon specific changes in body structure such as spasticity in the arm (stroke example) or exercise tolerance (hip fracture example). Instead the tool was used to aggregate the experience of impairment. As a result assessors were requested to count the number of limbs where hemiplegia persisted or to refer to patient's accounts regarding exercise tolerance for example. One item on the EQ-5D was also related to impairment (pain and discomfort), although the tool was used here to obtain an overall score. Hence the specific items have not been presented. It may be the case, therefore, that some changes in impairment were taking place, but these changes remained undetected by the chosen instruments.

3.2.3 Impairment Not a Focus of CRT treatment

Another explanation might be found in the contrast between acute and community based approaches to therapy. Reflecting for a moment on the literature review at the beginning of this thesis, and in particular the evidence relating to intensity, it could be noted that these intensive interventions were focused very much on impairment as a dimension. In the case of stroke

evidence, intensity studies have described experimental interventions focusing purely on the arm or leg and outcomes measured in terms of function. For hip fracture studies the emphasis has been on physical conditioning and promotion of muscle strength. When considered against the WHO ICF the intensity hypothesis, as it relates to the reduction of impairment, is centred entirely upon body function and structure as a course for change.

Our knowledge, however limited, about the process of community based therapy suggests a contrasting approach. Although this knowledge is emerging it could be suggested that therapists working in the community tend not to focus their activity on issues of impairment but rather in the dimensions of activity and participation (particularly given the role of therapy assistants in the delivery of CRT treatment). Given this it might be feasible to assume that the potential for differences to be detected in the dimension of impairment would be limited.

3.2.4 Carers as Providers of Rehabilitation

The role of carers in the rehabilitation process has also not been examined in detail here. Hence the potential for the role of those carers living with patients in the non-intensive group to play a more significant role in the reduction of impairment can not be ruled out. It could be hypothesised that therapists relied more heavily upon those carers in the non-intensive group. Advice and training to carers has already been noted to improve patient outcome (Forster et al. 2001). Providing training to carers regarding exercises to be completed by patients may therefore have been one way of compensating for the non-intensive allocation. The result may have been that carers of those in the non-intensive group were more active in monitoring the carrying out of exercises as prescribed by therapists. Due to the inadequacy of data regarding the nature of the interventions provided to both groups, this notion remains speculative.

3.2.5 Therapist Decision Making Under Intensive Conditions

One final explanation could also lie in the nature of the intervention, but this time regarding decision making under intensive conditions. It could be supposed that therapists, given more opportunity to be with patients, found that impairment focused work was not appropriate under such conditions. For instance there may have been therapist concern that the repetition of specific exercise may result in patient dissension or boredom. The outcome is the same, an increase in face to face contact did not result in an increase in impairment focused work. The result being little difference between the two groups in terms of impairment outcome.

3.3 Activity (Disability) Results Overview

The results regarding activity for each of the groups were not as comprehensively comparable as was the case with impairment. In addition the study employed more than one tool in its assessment. The issue of gender and the imbalance that existed at the point of allocation also complicated the results relevant to activity, particularly the results of the Barthel assessments.

The TOMS activity scores indicate little difference when examined using statistical testing. Although at three months for all patients, as well as sub-group analysis, a larger proportion of intensive patients scored a five and a larger proportion of non-intensive patients were represented at the lower end of the scale. None of these differences were significant. In terms of the Barthel, it was also the case that no significant changes were detected throughout. Non-significant differences favoured the intensive arm of the study especially when comparing medians (all patients at one month, stroke patients at one and three months).

It is the examination of patient change, however, that differences begin to emerge. One Mann-Whitney test at three months for all patients comparing TOMS activity change comes close to being significant. This difference favoured the intensive patients. For TOMS activity, in all cases, the proportion of patients making a clinically significant change was larger in the intensive

group. In some cases these differences were large, especially when comparing all patients and conducting sub-group analysis for stroke. Indeed the difference between the two proportions at three months for stroke patients making clinically significant change for TOMS activity was statistically significant.

The data concerning Barthel change is more complex. In some cases the proportion of non-intensive patients making clinically significant change is larger than that of the intensive group, however these differences in proportions are small and all are non-significant.

There are two methodological points I wish to raise, the first concerns the potential for systematic error the second associated with power, prior to going on to consider substantive explanations for the differences occurring here.

The potential systematic error is related to the issue of gender imbalance noted earlier. The literature review noted that there was no reason to suspect that women recover more quickly or to a better extent than men. However, it has been noted that women perform much better on the Barthel index relative to men. It has been suggested that it is the specific items of the Barthel and not the underlying construct of activity that produces this apparent difference in performance. Stratified analysis presented earlier in this thesis would suggest that an inflated assessment of female activity or underestimation of male activity has occurred here and this has acted as a co-variate in all analysis when comparing intensive and non-intensive groups. This would also provide an explanation as to why the apparent comparability between the groups has not been replicated in the TOMS activity data.

This brings us to the second methodological point. Although the detection of a significant difference in TOMS activity assessments was rare, there existed an inclination for outcomes to favour the intensive arm of the study. This is particularly true when examining the proportions of each group making clinically significant change. Indeed it is here that a significant difference was detected for stroke at three months.

Total reliance on statistical significance in an appraisal of the results may mask inclinations and trends within the data that might be important. I feel that the evidence would therefore suggest that in terms of TOMS activity outcomes for the intensive regime were favourable when compared with patient outcome in the non-intensive group, particularly stroke, and that the explanation for the scarcity of significant findings was related to power. The use of confidence intervals assists us in drawing such a conclusion. The width of a confidence interval is directly related to the standard error, which in turn is a product of the sample size. As a rough guide, the smaller the sample size, the wider the interval. The intervals presented in Chapter Seven of this thesis are particularly wide, especially for the results of sub-group analysis. Hence it might reasonably be argued that these wide intervals paper over differences that might well exist.

3.4 Interpretation of Activity (Disability) Results

3.4.1 The Activity Dimension as a Focus for CRT Intervention

It is within our understanding about the nature of community based intervention that we must again rely in order to help assist in an interpretation for this. In contrast to impairment, the work of the therapist in the community is more closely related to interventions aimed at promoting patient change in ADL or as classified in the WHO ICF as activity. From this we could conclude that an increase in attention around these skills will result in better outcomes within this dimension. Theories of motor re-learning can help elucidate these processes. The literature review (Chapter One) suggests that practice is essential to the re-learning of tasks, in particular is the practice of tasks in their entirety as opposed to the practice of segments of tasks. It is therefore feasible to suggest that is the more intensive contact gave rise to enhanced patient outcome because of the increased opportunity for therapist and patient to work on and practice specific ADL tasks such as washing, dressing and eating. This is particularly true of stroke patients in this study. The areas of ADL most affected by stroke for patients in this study were those involving dexterity and complexity. It is these areas where intensive work between therapist and patient

appears to have borne most fruit. Although just one significant difference existed, I have noted that the inclination for the intensive group to show better patient outcome was consistent.

3.5 Participation (Handicap) Results Overview

I shall now turn my attention to the results concerning participation. I shall first review these results, point to some inconsistencies between outcome measures, offer some explanations for these apparent inconsistencies before raising some possible explanations for the results.

As with activity, two measures were used to assess levels of participation, the Frenchay Activities Index (FAI) and TOMS Handicap. At three months the FAI showed no significant differences between the two groups. However, the medians for each group differed slightly in favour of the non-intensive group. In contrast to this TOMS handicap at one month indicated that although no significant differences emerged, the proportion of patients from the intensive group achieving scores at the upper end of the scale was consistently larger than the non-intensive group. This pattern was repeated at three months. Indeed the Mann-Whitney test for stroke patients revealed a significant difference in favour of the intensive group.

This contrast between the two measures is also reflected in the data concerning patient change. No significant differences were identified at one month for the TOMS handicap change scores. However, for all patients at three months it emerged that TOMS handicap change was significantly different. The difference again favoured the intensive patient group. Also, the test comparing the groups for stroke patients also came close to being significant, again in favour of the intensive group. No such difference existed for FAI although again the medians favoured the non-intensive group slightly. In terms of achieving clinically significant change in the TOMS handicap at one month, the intensive groups showed consistently larger proportions. At three months a significant difference in proportion of the two groups achieving clinically significant change existed, this too favoured the intensive group, whilst the

proportions, when analysing these differences for each aetiology, also favoured the intensive group.

One plausible explanation for the apparent contrast in the results of these two measures, lies in the items being taken into consideration for each. It was noted within Chapter Two that the FAI remained the only available tool to measure participation at the point in time when decisions regarding outcome measures were being taken. It was also noted that there was some unease about this, despite taking advice (in the form of e-mail exchange) from Wade on the matter. The uncertainty about the FAI is that a large proportion of the items focus upon domestic participation and the frequency that respondents undertake such activity. As well as this it is prescriptive about what is considered (shopping, driving a car, gardening). TOMS on the other hand assesses a wider definition of participation including autonomy, age appropriate activity and what is considered to be the respondent's normal activity. It is feasible to conclude that what is being measured by the two tools are not only the performance of different activities but also different underlying constructs.

One further explanation for this apparent contradiction lies in the issue of Gender. It has been noted on several occasions that there existed an imbalance on the basis of gender and co-residing carer. A larger proportion of women was represented in the non-intensive group as was a larger proportion of those living at home without a co-residing carer. An analysis of FAI at three months indicated that there was a significant difference between males and females, with women achieving a higher median score (19 compared with 12). A significant difference was also detected on the basis of co-residing carer, with those living alone indicating higher levels of participation (20 compared with 15.5). It is suggested here that this imbalance at randomisation has contributed to the apparent inconsistency between the group comparisons for TOMS handicap and the comparisons based on FAI. It could be argued that these differences have occurred because large parts of the FAI are centred upon domestic tasks. It could therefore be argued that since older women would traditionally have undertaken these tasks this may have contributed to the difference between the two.

3.7 TOMS Participation differences: Explanations

3.7.1 Participation as a focus for CRT treatment

It is again to the process of the intervention that we can look for the apparent favourable outcome for the intensive patients, particularly stroke, in the dimension of participation.

It has already been noted that much of the emphasis within community rehabilitation occurs at the level of activity or disability. It is also emerging that an emphasis of the work of community based rehabilitation can be located within the dimension of participation. In particular much participation work is done following the initial hiatus around ensuring that patients have in place the proficiency and technology to assist themselves in ADL skills. Such work might include supporting patients to walk to local shops, use public transport or the car. This support and advice is aimed at enabling patients to achieve a level of participation that they feel appropriate and happy with. Such activities are also reflective of the nature of patient goals, often expressed as a return to 'normal life' (Parker et al 1997). As such they represent outcomes more favourable to patients than perhaps outcomes associated with body function and structure.

It was noted earlier in this chapter that decisions to use the time afforded through intensive treatment on non-impairment based interventions may have contributed to the lack of a difference being detected in impairment. The logical conclusion to such an argument is that the emphasis of therapist time shifted toward participation and activity interventions. Hence patients in the intensive group were provided with an intervention which comprised a greater proportion of time devoted to promoting participation, such as those described above.

3.7.2 Use of CRT Therapy Assistants for Additional Intervention

A second interpretation might lie in the way in which therapy assistants were used to provide the more intensive treatment. The data concerning contacts is presented in Chapter Four. It shows that whilst a significant difference existed between the two groups in the mean of the total number of face to face contacts at four weeks, eight weeks and 12 weeks. However, it also shows that a sample of the participants was used to indicate who provided the additional face to face contacts for the intensive group. Independent t-tests were undertaken using these data. The mean number of contacts provided by therapy assistants was significantly different, whereas this was not the case for the difference in contacts with senior therapists or the number of joint visits. The conclusion that was drawn was that the additional face to face contacts were more often provided by therapy assistants and not qualified Senior Therapists. This helps in our explanation for the tendency for there to be differences in the outcomes relating to activity and participation and not impairment. The work of therapy assistants is almost exclusively focused on supporting patients in the re-learning and practising of ADL skills and gaining confidence in re-engaging with the social world. From this one could surmise that it is the additional practise and experience of social participation which has resulted in the superior outcomes in participation for the intensive group, relative to the non-intensive group.

3.8 Well Being results Overview

Again an overview of results will be provided followed by potential explanation for the findings. The differences in proportions identified as HADS case at one and three months were non-significant at both one and three months for both anxiety and depression. For both anxiety and depression, however, it was the non-intensive group which contained the larger proportion of those identified as case for both anxiety and depression. Statistical testing of TOMS well-being scores also indicated no significant differences. Indeed the distributions of well being score were remarkably similar between the two groups at both one and three months. Change in TOMS well being at one

month and three-month also showed no differences, although when examining the proportions of each group making clinically significant change, more patients in the intensive group experienced such change. It is when looking at change, however, that two significant differences were detected in the HADS scores for depression and two significant differences were detected in the proportions of each group making significant change in HADS anxiety. Statistical testing indicated significant differences, in favour of the intensive group, for stroke patients at one month and all patients at three months. The proportion of intensive patients making significant change at three months was also larger when analysing all patients and stroke patients as a sub-group. The differences on these occasions were significant.

It is important to remind ourselves that no differences were detected when analysing the data, whether it be proportions (HADS) or raw scores (TOM Well-being) and that it is again change which has shown to reveal such differences.

3.9 Well-being differences: Interpretations

Two possible interpretations might be put forward in order to enable us to understand what is happening in relation to the patient change HADS and TOM well-being data.

3.9.1 Additional Face-to-Face Contact

The first is that the intensive group benefited from the extra attention afforded through the additional face to face contact with the therapy team. This is consistent with other findings (Kotila et al. 1998). This explanation is, however, undermined when we consider that just one of these significant differences was detected at one month, when, for intensive group patients, the additional face to face contact was at its peak. Furthermore, the other significant differences were detected when many of the patients had been discharged by CRTs and when additional face to face contacts had long since been significantly different.

3.9.2 Well-being as a Result of Increased Activity and Participation

A second explanation, therefore, relating to the correlation between activity, participation, quality of life and well-being, is perhaps more feasible. In particular it may be that there exists an association between positive change in activity, participation and quality of life and positive change in well-being. Given that significant differences favouring the intensive group in these areas, especially around change, it is conceivable that positive well-being and psychological health are related to these other dimensions. Bond et al for instance observed a cohort of over 1000 people recovering from stroke or hip fracture (Bond et al. 2000). Follow up assessments showed significant relationships between severe disability and anxiety and depression and also between lack of social participation and depression. Further analysis of the data gathered for this research is required in order to determine the nature and strength of these relationships.

4 Challenges Inherent in Undertaking primary care Rehabilitation Research

4.1 Community Based Rehabilitation Research: The significance of context

Earlier in the thesis the ICF was described and its pertinence to our understanding of function and activity was described. There are two points I wish to make regarding the ICF in relation to the research strategy used here and indeed in relation to much of the research undertaken in rehabilitation. The first relates to the scope of the ICF in relation to the relatively narrow focus adopted here. The ICF comprises two broad categories, function and activity and contextual factors. However, the approach adopted here focuses almost entirely upon the category concerning function and structure. The rationale for intensive therapy relies heavily upon attempts to change body structure. By this is meant that much of what is described in the literature review, concerning plasticity, physical condition and motor relearning, is associated with promoting changes to body structure in order to enhance and improve body

functions. Similarly, the approach to the measurement of outcomes is similarly located within the category of function and activity. However, the contextual factors accounted for remain limited. Personal contextual factors such as age, gender and existence of co-residing carer were accounted for within the study design and, as was indicated, evenly distributed through randomisation. However, other contextual features that, it has been argued, are pivotal to outcome were not sufficiently accounted for in this research or indeed in other rehabilitation research. These features go beyond those immediately identified and operationalised within rehabilitation research and include: wider community help, attitudes of patients and others, existence of accessible transport systems or the nature of the immediate built environment. The point being made here is not concerned simply with the adequacy of research design and methodology. It is also concerned with the continued focus upon function rather than adaptation and context. This is all the more ironic when we consider that much of the work of the therapist, particularly occupational therapist, is related to the environment as a facilitative or restrictive factor. An example being the role that the therapist now has in the provision of assistive technology (Stephenson 1996, Hall 1996).

The second point to be made in relation to rehabilitation research and the ICF is that implicit in the rationale for many interventions, including the intensity hypothesis, is a linear association between impairment change and subsequent change in activity, participation and well being. The ICF has shown that the reality for many people is not a linear progression but rather an interactive experience. Change in impairment does not necessarily relate to an increase in activity or participation. A lack of change in impairment does not necessarily result in a lack of change in activity or participation and so on. Furthermore, change in contextual factors may also lead to changes in impairment, even where there has been an absence of intervention.

This issue of context as a confounder in rehabilitation research is all the more crucial in the primary care setting. Secondary, and intermediate, care interventions within rehabilitation can be said, to some extent, to occur in relatively stable, standardised contexts. The attitudinal, cultural and physical

contexts of rehabilitation remain homogeneous for any cohort of patients involved in secondary care research. In an operational sense such research can be tightly controlled. Undertaking such research in the primary care setting presents the investigator with a problem when we begin to consider the varied, changing context of the cultural, attitudinal and physical environment. The factors that may affect outcome are therefore complex in the primary care setting. Assistive products, housing that has been adapted or the role of a facilitative or restrictive carer, might influence outcomes in the dimension of activity. Outcomes in the dimension of participation might be influenced by the location of accessible transport. The socio-economic and personal (such as coping style) aspects of recovery become accentuated in contrast to secondary care research. It could be argued that randomisation helps control for such factors. However, without being able to gather data relating to these complex factors we can not be sure that this is the case. It is when considering these aspects of rehabilitation and recovery that we might propose alternative research strategies for primary care.

Zhan and Ottenbacher (Zhan & Ottenbacher 2001) outline the case for single subject research designs within disability research. They recognise the utility of large group comparison, but comment upon its usefulness in therapeutic decision making around individual patients or service users. Backman et al (Backman C.L. et al 1997) identify 40 research papers based on this research strategy from the rehabilitation field. It has been argued that the use of such designs allows the clinical community to look beyond group mean or median comparisons towards individual change for patients possessing certain characteristics and circumstances (Ottenbacher & Hinderer 2001).

The use of such designs may go some way to enabling researchers to describe more fully the individual circumstances and change occurring following intervention, but not, of course necessarily, resolve the much wider matter of defining which outcomes are significant and whose concerns they might be addressing. It was noted for instance in Chapter One that questions relating to outcomes that have greater validity to patients and resonate more closely with their concerns in everyday life might more usefully be defined and evaluated

using a mixed method or entirely different approach. The concerns raised above, relating to carrying out an RCT within primary care, might also be addressed using such approaches. For instance a mixed method approach, choosing to conduct unstructured interviews for a small sample of RCT participants may have assisted in gaining insight into the patient perspective in relation to intensity of treatment. Such a design might also have highlighted other variables that might potentially have influenced outcome, such as environmental or contextual aspects of the rehabilitation process and perhaps more interestingly whether or not the chosen outcomes necessarily reflect that of the patients themselves.

4.2 Community Based Rehabilitation Research: The problem of recruitment

Chapter Three revealed that the proportion of patients consenting to participate in the study was under half of the total number referred. It would be useful at this stage to reflect upon this poor response rate. Earlier (Chapter two page 38) a rationale for undertaking the consent procedure in the patient's own home was provided. It was suggested that nursing staff were uncomfortable with a discussion about intensity of treatment prior to discharge as this might prejudice patient and family views about the level of services available in the community. It was felt that patients and families held the view that they would be treated daily, where as this was, in reality, not the case. The relative absence of unease about this issue, when meeting with patients and their families, and lack of association with a refusal to participate in the study was therefore surprising. Indeed it was more often the case, for non-consenting patients, that they did not wish to place themselves in the position of possibly receiving daily treatment and having a therapist visit at least once a day.

A more likely explanation for the high number of rejections for this study, I think, lies elsewhere, in the context and process of the consent procedure. Consent meetings were described in Chapter Two (page 38). Whilst it is recognised that the relationship between researcher and patient can be regarded as unequal, it was felt that this overall approach would have the impact of at

least bringing about some equity in these relations. These meetings were often lengthy, verbal and written information being provided and a position of neutrality presented by myself. Patients who considered participation for a long period and were still not confident about making a decision were advised not to take part. It was through such an approach that it was felt that a more enthusiastic and motivated group of consenting patients would result. It was also through such an approach that I could be confident that free choice was being achieved. My position as a non-clinical professional, having no role in making decisions about future health care underpinned this confidence.

As well as citing the issue of intensity of community treatment as a basis for not holding consent meetings in hospital, was the notion that patients would also be in a better position to make a free choice about participation (see page 39). Therefore another explanation for the high numbers of non-consenters lies in the setting for consent meetings. Patients were approached at home, often accompanied by family. It was made clear that their decision about participation would not affect future health care. Given that they had already been discharged there was no pressure to acquiesce in order to conform to perceived expectations or satisfy a covert agenda or requirement. The position of the patient during consent meetings was therefore more powerful than might otherwise have been the case.

It could be concluded that this combination of an enabling process and context contributed overwhelmingly to a large number of rejections seems feasible. However, impairment related explanations to non-consent should also be considered. Patients were approached early after discharge from hospital following a serious health event. For some this was the first time they had experienced such trauma. It is also likely therefore that these disturbances to normal family routine, along with the attention of therapists and home care assistants, was in itself enough to cope with. To complicate matters further with participation in a research study may not have been appropriate for many. Indeed this theory is borne out to some extent in the description of changes made to timing of consent meetings described in Chapter Two (page 40), where

the initial approach to patients was changed (from two days after discharge to five days after discharge) and consent rates improved.

When considering the problems and dilemmas discussed here in relation to the conduct of primary care rehabilitation research it is worthwhile reflecting upon the experience of researchers undertaking work in secondary care. Other, similar, rehabilitation studies undertaken in secondary care show a very different response to research participation. One study (Rudd et al 1997) recruited over 300 patients to a study about ESD. It reported just two non-consenting patients. This is not to say that researchers in secondary care are being fraudulent or underhand, but rather that the context is more likely to deliver a group of patients which is relatively dis-empowered.

4.3 Community Based Rehabilitation Research: Monitoring intervention

Chapter Four provided information concerning the level of face to face contact provided by therapists for each of the two groups. Further to this, an earlier part of the discussion highlighted the problem associated with non-adherence to the original stated aim of providing a ratio of 2:1 face to face contacts. This issue raises concern about how interventions such as this are monitored and managed in the primary care setting. To contrast secondary and primary care rehabilitation research again is useful in identifying the problem here. Secondary care intervention studies in rehabilitation, particularly those concerned with intensity, it might be argued, are more easily monitored to ensure adherence to treatment regimes. Settings are closed and few in number. The result is an environment where the researcher is able to observe much more easily the activities of the therapy team. In primary care rehabilitation research the settings (in this case the patient's home) are multiple and the environment is open and extensive (in this case the four teams providing services for the City of Sheffield). The problem is clear to see. The researcher is presented with an environment where observation of the activities of therapy teams is difficult. This study used two methods to try to ensure adherence (visit recording sheets for each patient participating in the study and paying the service to use

management time to monitor the activities of individual clinicians). It is difficult to assess how effective these strategies were.

5 Concluding Remarks

5.1 Does Intensity Matter?

I have now examined the results of the research in turn. I have also proposed possible explanations for the existence or non-existence of significant differences between the groups. It might now be prudent to reflect further on whether a type II error has occurred or second that the null hypothesis is true. For the first possibility I shall again turn to the results and judge these against a lack of power. For the second possibility I will also offer an explanation based upon the complex nature of the rehabilitation process in old age and the difficulties and uncertainties inherent in its evaluation.

5.2 Type II Error?

Chapter 3 outlined the methods used within this study. In this Chapter the basis upon which a sample size of 200 patients (100/arm) was concluded was described. It was also noted that it was based upon conditions not dissimilar to those used within other rehabilitation studies. Throughout the thesis, the difficulties associated with recruitment have been highlighted. Furthermore, loss of participating patients was experienced at follow up due to a number of reasons. The result was an insufficient amount of data available for analysis at one month, but particularly at three months.. This has meant that the original power of 80% was reduced to 70% at one month and 63% at three months (see Altman page 456). This has had a significant impact on the capacity of the study to detect differences between the intervention group and routine treatment group.

It is against this backdrop of reduced power that we should now consider the findings presented in this thesis. Firstly, we should consider the evidence presented in the results Chapters (Five and Six), in order to ascertain whether

an effect has taken place and that a lack of significance has resulted in a Type II error. From this we might then wish to deliberate over what proposals might be made concerning the issue of intensity of treatment in clinical practice in primary care rehabilitation for older people recovering from stroke and hip fracture.

There are two opportunities for specificity here. Firstly, we can be specific about with which patients a Type II error has occurred. If we consider patient change for instance, it might feasibly be concluded that although significance was reached on few occasions the proportion of the intensive group to make important clinical change, in nearly all outcomes, was larger than the non-intensive group. Other findings, when comparing the two groups using Mann Whitney test for difference also show results either significant or close to significance, in favour of the intensive regime.

This inclination is, however, more prominent amongst the stroke patients than it is for the hip fracture patients. For instance the difference in proportions on the basis of making clinically significant change tended to be larger for the intensive group when examining stroke data alone. The examples where differences between two proportions are large yet non-significant amongst the hip fracture patients are limited. This might lead us to justifiably conclude that, if anywhere, a Type II error has occurred within the stroke group only and that the null hypothesis is true amongst the hip fracture patients.

The second opportunity for specificity is within the outcomes addressed and in particular within each of the dimensions (most typically defined by WHO ICF). Again the dimensions of activity and participation appear more likely to yield greater discrimination between the two groups when examining patients change or results of Mann-Whitney tests for difference. Results concerned with impairment as a dimension indicated little difference (for both hip fracture and stroke patients in the study). Again this might lead us to justifiably conclude that, if anywhere, a Type II error has occurred within the dimensions of activity and participation and that the null hypothesis is true for impairment related outcomes.

5.3 The Null Hypothesis is True?

I shall now turn to the alternative explanation, that of the null hypothesis being true. There are of course many reasons for this. Cifu and Stewart (Cifu & Stewart 1999) maintain that intensity of treatment is not a significant factor in the recovery of stroke. Instead they argue that the evaluation of task specific interventions should remain the focus of our attention. However others go further and feel that experimental and quasi-experimental research is simply not practicable in rehabilitation research because we can not separate intensity out as a component of rehabilitation and that even if we did the nature of rehabilitation renders its evaluation impossible. Rice-Oxley and Turner-Stokes (Rice-Oxley & Turner-Stokes 1999) argue that there are four aspects of rehabilitation that make its evaluation difficult, diversity of condition, diversity of goals, spontaneous recovery and the impossibility of the uniform approach. It is this final point which is more pertinent here. Rice Oxley and Turner – Stokes maintain that just as there are good and bad tennis players, there are also good and bad therapists. This is central to the issue of intensity. It has already been noted that there are numerous variables at play in the case of primary care rehabilitation (particularly in terms of context), however, the inclusion of effective and ineffective individuals providing non-intensive and intensive therapy would render the whole question of intensity a non-starter. Wade describes the possibility of a Type III error in rehabilitation research (Wade 2001). He argues that the various components of multidisciplinary rehabilitation teams create outcomes from the synergy between them and not on their own. The important point is that it is the synergy of the whole system and not the frequency of the delivery.

This is all before we even begin to consider other variables associated with patients and carers, which might mitigate against the intensity hypothesis. Patient tolerance, patient motivation and the nature of the relationship between therapist and patient are three that spring to mind. All individuals receiving therapy interventions have different levels of tolerance to therapy. Individuals also have different levels of motivation for therapy. Finally, the nature of the

relationship between therapist, patient and carer may also render the frequency of contact irrelevant. All three remain un-researched in relation to home based rehabilitation.

5.4 A Future Research Agenda

In drawing this thesis to a conclusion it would be wise to consider a future research agenda arising out of the comments made above. The agenda surrounding the question of intensity within primary care rehabilitation is, however, more concerned with discovering things about the process of intervention than it is with refining our methodologies for further evaluation. At the heart of this suggested programme, therefore, sits a need to conduct a series of projects that might be concerned with the following questions:

- What is the process of rehabilitation at home (including the function of the domiciliary environment)?
- What is the role of family caregivers in the rehabilitation process?
- What is the nature of the role of the therapist in domiciliary rehabilitation provision?
- What is the nature of patient defined outcomes in primary care rehabilitation?

These questions (of which there will of course be more) are located around the need to understand much more fully what is 'going on' when older people return home from hospital to receive rehabilitative services and continue the process of recovery. Furthermore, these questions can only usefully be addressed by utilising methods from the qualitative paradigm. It is only when we can begin to assert with some confidence that we understand this process and its components, that evaluation of these components might begin.

Appendix I: Major key words and alternatives used for the literature review

Review	Major Key words	Alternatives
General	Cerebrovascular Accident	Stroke
	Hip Fractures	Femoral fracture
Intensity	Exercise Therapy	Intensity
Satisfaction	Patient satisfaction	
Clinical Rationale	Neuronal Plasticity	Brain Plasticity, motor learning
	Recovery	
	Training	Physical conditioning
Variation in provision	Service utilisation	Service use
Outcome	Prognosis	Predictor, outcome
Community Provision	Early supported discharge	

PATIENT INFORMATION SHEET

THIS STUDY AIMS TO COMPARE THE EFFECT NORMAL COMMUNITY REHABILITATION AND INTENSIFIED REHABILITATION FOLLOWING A STROKE OR FRACTURED NECK OF FEMUR.

Why have I been asked to take part in this study?

When you become incapacitated following a stroke or breaking a leg you may need quite a lot of therapy in order to help you improve your movements, abilities or speech.

Since 1995 in Sheffield some people have been able to leave hospital earlier and have their therapy at home.

We would like to find out how often people need therapy in order to recover from their difficulties and we would also like to find out more about how carers cope. To do this we would like to see people at regular intervals following their stroke or fracture and ask them some questions about how they are getting on and what things they are able to do.

How long will the study last?

About a year to 18 months.

What will it involve?

If you agree to participate in this study, you will be placed in a group that is having either the usual amount of community rehabilitation, or having it more intensively. Thus, some patients will be allocated up to three visits per week by the Community Rehabilitation Team and others will receive six visits or more per week. If you agree to take part, you will be placed in one of these two groups, which will be decided by a method similar to tossing a coin. Not taking part in the study will not affect your rehabilitation.

We will need to follow your progress through therapy and afterwards. This will be done by someone visiting you at regular stages, (within one week of discharge from hospital; one month after community rehabilitation commences; three months after your stroke/fracture and twelve months after your stroke/fracture), recording your thoughts, feelings and abilities. These will be measured by simple question and answer sessions or watching you do normal everyday activities. Only some of the measures will be done on each visit but some may be repeated on more than one occasion. If it is appropriate and you agree we would also like to ask your carer some questions. Each visit should only take up to an hour of your time and would be arranged at your convenience.

We would also need to gather information about the health and social services that you use. This would mean contacting Sheffield City Council Social Services and

asking them to tell us if you used Home Care, meals-on-wheels, day care or residential and nursing home care during the year following your agreement to take part in the study. We would also need to contact Community Health Sheffield and ask them if you use other services, such as community nursing over the same period.

What if I do not wish to take part?

Not taking part in the study will not affect your rehabilitation.

What if I change my mind during the study?

You can withdraw from the study at any time without affecting your treatment.

What will happen to the information from the study?

All the information will be entirely confidential. All information will be stored in a secure place and will be destroyed at the end of the project. We can inform you of the final results if you would like but they may not be fully analysed for a couple of years after the study is completed.

What if I have further questions?

If you have any questions please ring Tony Ryan on 271 4861 and he will call you back.

Appendix III: Ethical approval of study by North Sheffield Ethics Committee

NORTHERN GENERAL
HOSPITAL N.H.S. TRUST

Herries Road,
Sheffield S5 7AU

Telephone:
[illegible]

Fax:
[illegible]

NORTH SHEFFIELD
RESEARCH ETHICS COMMITTEE

Chairman: Dr S R Brennan
Tel: (0114) 271 4739

Honorary Secretary:
Dr C M H Newman

Admin Sec: Sue Rose
Tel: (0114) 271 4011
Fax: (0114) 2582469
email: Sue.Rose@northsheff-tr.trent.nhs.uk

CMHN/SR/172/99
Inderby/NS99 2 419
(Please quote reference on all correspondence)

5 July 2000

Mr I Ryan
Research Fellow
Centre for Ageing and Rehabilitation Studies
Community Sciences Centre
Northern General Hospital

Dear Mr Ryan

Re **A randomised, controlled trial to evaluate the cost effectiveness and patient and carer satisfaction associated with different levels of intensity of community rehabilitation**
Ref: NS99 2 419

Thank you for your letter of the 29 June 2000 and enclosed modifications.

I note that the two points have now been satisfactorily addressed and can confirm full approval on behalf of North Sheffield Research Ethics Committee.

Yours Sincerely

C M H Newman
HONORARY SECRETARY - RESEARCH ETHICS COMMITTEE
Senior Lecturer in Cardiology/Honorary Consultant Physician

Cc Professor Pam Enderby
Centre for Ageing and Rehabilitation Studies
Community Sciences Centre
Northern General Hospital

Dr Kevin Morgan
Centre for Ageing and Rehabilitation Studies
Community Sciences Centre
Northern General Hospital

PATIENT CONSENT FORM

THIS STUDY AIMS TO COMPARE THE EFFECT OF INTENSIVE AND LESS INTENSIVE COMMUNITY REHABILITATION FOLLOWING A STROKE OR FRACTURED NECK OF FEMUR

We would like you to agree to take part in this study but only when you have a good understanding of what it involves.

Have you read the information sheet about this study? **YES / NO**

Have you been able to ask questions about this study? **YES / NO**

Have you received answers to all your questions? **YES / NO/**

Have you received enough information about this study? **YES / NO**

Do you feel that you can make an informed decision about taking part in the study? **YES / NO**

Do you grant permission for Sheffield City Council Social Services, Community Health Sheffield and Sheffield Health Authority to provide us with information about the services that you use during the length of the study? **YES / NO**

Who have you spoken to about this study? **NAME** .....

Do you understand that you are free to withdraw from this study:

at any time **YES / NO**

without giving a reason for withdrawing **YES / NO**

without affecting your future medical care **YES / NO**

Do you agree to take part in this study? **YES / NO**

Signed: _____

Date: _____

Name *(Block Letters)*:_____

Witness:_____

Appendix V: Study Protocol

Sheffield Intensity of Rehabilitation in the Community Study *(SiRCS)*

SIRCS PROTOCOL

In order to ensure that the Sheffield Intensity of Rehabilitation in the Community Study (SIRCS) operates efficiently, it is important that each participant (including patients and therapists) is clear about procedures and the timing of events, a detailed outline of the study's protocol is needed. This short document sets out in detail the trial procedures.

Eligibility for the Trial

1. All patients recovering from stroke and fractured neck of femur, aged 65 and above who are referred to CRTs will be given information about the trial prior to discharge.

2. Eligibility for the trial is very simple. Those patients accepted for treatment by CRT recovering from fractured neck of femur or stroke, aged 65 or over and who live in their own homes are eligible. Those patients living in permanent care are **not** eligible.

Referral to the Trial

1. Responsibility for referring patients lies solely with CRT therapists. Following a first visit, the name of those considered eligible for the trial will be recorded on the SIRCS referral form. The date of the first visit and diagnosis will also be recorded. Forms can be found in the large black lever arch file in the team office.

2. You do not have to inform the patient that you are referring them at this stage and treatment continues as normal.

3. Administrative staff in each of the teams will then contact SIRCS staff by telephone. The following information will be given to SIRCS staff:

   - Patient's name
   - Patient's address
   - Patient's date of birth
   - Diagnosis
   - Carers name and address (if applicable)

   At this stage a SIRCS number will be provided for each patient. This will be recorded on the referral form. This number is unique to each patient and is to be used for any trial documentation.

Consent

1. Following referral to the SIRCS team contact will be made with the patient and an appointment made to discuss consent to taking part in the trial. At least two days notice will be given to patients. More detailed information about the trial will be given at this stage.

2. Directly following a meeting with a patient, a member of the SIRCS team will contact the team administrator to inform them of the outcome of the consent meeting.

3. If a patient does not consent to participation the team administrator records this on the referral form. The patient then continues to receive treatment as deemed appropriate by the CRT member responsible for the treatment plan.

4. If a patient does consent to taking part in the study then the patient or their carer will sign a form. For each patient who consents, the form confirming this will be faxed to the appropriate team for inclusion in the patient's notes.

Allocation

1. Two boxes will be held by each team administrator, one box for patients recovering from stroke and one box for those recovering from fracture. For each consenting patient the team administrator draws an envelope from the appropriate box (i.e. stroke or fracture). Each envelope has written on it a number.

2. The envelope is opened and the slip of paper inside taken out. The slip of paper will allocate the patient to either 'intensive' or 'non-intensive' therapy. The allocation (either 'intensive' or 'non-intensive') is recorded on the referral form. The allocation, envelope number is also recorded on the referral form.

3. Following allocation, the team administrator will transfer the patient's notes to a yellow folder and their name will be recorded in purple on the board.

First Set of Measures

1. Following allocation senior therapists will, at the earliest opportunity, carry out the following outcome measures: Barthel, TOMS, HADS, Frenchay Activities Index, EQ-5D and GHQ-28 with patient's carers. A set of measures will be found in the patient's notes.

2. Completed measures should be placed in the yellow box file.

Treatment

Having been allocated to one of the two treatment groups the patients treatment will then proceed on the following basis:

1. ***Intensive Group:*** Allocation to the intensive group of the study will mean that patients may receive **six or more** visits per week from a Therapist or Therapy Assistant.

2. ***Non-Intensive Group:*** Allocation to the non-intensive group of the study will mean that a patient will receive **three or less** visits per week from a Therapist or Therapy Assistant. However, in order to allow for some flexibility, Therapists can arrange visits over a two-week period. The total number of visits, however, should not exceed six over the two-week period and the number of visits should not be more than four visits per week. For example four visits in one week must be followed by no more than two the following week.

3. Each visit needs to be recorded on the recording sheet, which is to be found with the patient's notes. Therapists should enter their initials in the appropriate box. If a joint visit took place then the initials of those who visited should be entered. This will help the teams in monitoring the number of visits a patient has received on a week-to-week basis. It will also act as a data collection form for trial purposes. When a patient has been discharged please place this recording sheet in the yellow box file.

Patient withdrawal and Crossover

1. This study will be analyzed on what is known as an intention to treat basis. The aims of this are: to ensure that the trial has in place certain clinical safeguards which allow for patients to switch groups; to prevent these 'switches' happening unnecessarily. It is important that these changes are recorded.

2. There may be occasions when a patient's medical status and their continued participation in the non-intensive arm of the trial concerns a therapist. In such circumstances you should first speak to your Team Leader. Then a **SIRCS 1** (purple) form should be completed by the therapist responsible and faxed to the SIRCS office (242 0809). A meeting between the therapist, and a member of the SIRCS team will be convened (if a delay occurs in convening this meeting, the therapist should visit the patient as he or she sees appropriate). The outcome of any such discussion will be recorded and treatment continues as appropriate.

3. It may be the case that a patient on the trial, who has been allocated to the more intensive arm, reaches a stage in their recovery when it is agreed that the level of therapy (i.e. six or more visits per week) is of no benefit. This may be when all patient goals have been achieved or when it is felt that no more progress on clinical outcomes can be made. At this stage such patients can receive less than the original

six visits. The decision to go below this level should be recorded on a **SIRCS 2** form (green). This should be placed in the yellow box file.

Discharge

1. When a participating patient has been discharged by the CRT, either because their treatment has ended or they have been admitted into care, this should be recorded by completing a **SIRCS 3** (blue) form and placed in the yellow box file. A member of the SIRCS team will collect these approximately every fortnight. This form outlines the SIRCS number, patient details, admission to the CRT and discharge dates as well as reason for discharge.

Other

Tony Ryan can be contacted in the following ways:

Tel: 271 4861(voice-mail)
Mobile: 0797 983 6923
Fax: 242 0908
e-mail: t.ryan@shef.ac.uk

Appendix VI: Copies of Outcome Measures

SIRCS number:	Date:	Initials:

Barthel Index

Bowels

Continent	
Occasional Accident	
Incontinent	

Bladder

Continent/Catheterised	
Occasional Accident	
Incontinent	

Grooming

Independent (face/hair/teeth/shave)	
Needs Help	

Toilet Use

Independent	
Needs some help	
Dependent	

Feeding

Independent in all actions	
Needs help (cutting, spreading butter)	
Dependent	

Transfers

Independent	
Minor help (verbal/physical)	
Major help (can sit)	
Unable	

Walking

Independent	
Walks wit the help of one person	
Independent in wheelchair	
Unable	

Dressing

Independent (inc. buttons)	
Needs help, but does half	
Dependent	

Stairs

Independent	
Needs help (verbal/physical)	
Unable	

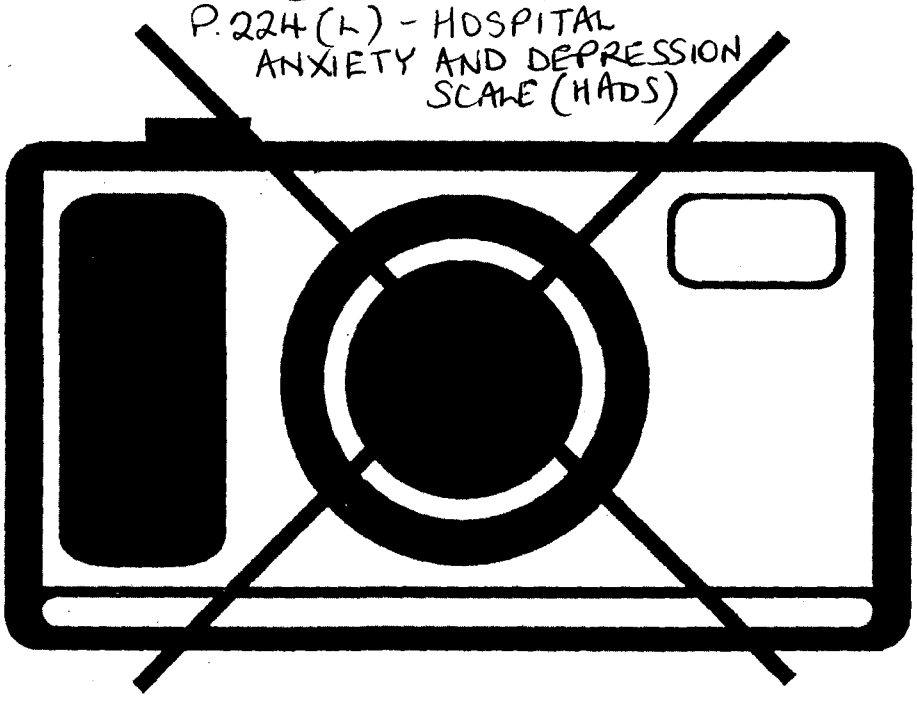
Bathing

Independent	
Unable	

(for office use)

Published Papers Not filmed for Copyright reasons

P. 224 (L) - HOSPITAL ANXIETY AND DEPRESSION SCALE (HADS)



Institute of General Practice & Primary Care

SiRCS

Frenchay Activities Index

Please ask the respondent how many times they have carried out the following activities in **the last three months**. Please ensure that actual activity is recorded from the recent past, not distant past performance or potential.

Preparing main meals	
Washing up	

0=Never
1=Under once a week
2=1-2 times/week
3=Most days

Washing clothes	
Light housework	
Heavy housework	
Local shopping	
Social occasions	
Walking outside for more than 15 mins.	
Actively pursuing a Hobby	
Driving a car or going on a bus	

0=Never
1=1-2 times in 3 months
2=3-12 times in 3 months
3=At least weekly

Please ask the respondent how many times they have carried out the following activities in **the last six months**.

Travel outings	

0=Never
1=1-2 times in 6 months
2=3-12 times in 6 months
3=At least twice weekly

Gardening	
Household/Car maintenance	

0=Never
1=Light
2=Moderate
3=All necessary

Reading books	

0=Never
1=One in 6 months
2=Less than 1 in a fortnight
3=More than 1 in a fortnight

Gainful work	

0=Never
1=Up to 10 hours/week
2=10-30 hours/week
3=Over 30 hours/week

SIRCS number:	Date:	Initials:

224(M)

SIRCS number:	Date:	Initials:

EQ-5D

By placing a tick in one box in each group below, please indicate which statement best describes you own health status today. Do not tick more than one box.

Mobility

I have no problems walking about. ☐

I have some problems in walking about. ☐

I am confined to bed. ☐

Self-care

I have no problems with self-care. ☐

I have some problems washing and dressing myself. ☐

I am unable to wash and dress myself. ☐

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

I have no problems with performing my usual activities ☐

I have some problems performing my usual activities. ☐

I am unable to perform my usual activities. ☐

Pain/discomfort

I have no pain or discomfort. ☐

I have moderate pain or discomfort. ☐

I have extreme pain or discomfort. ☐

Anxiety/depression

I am not anxious or depressed. ☐

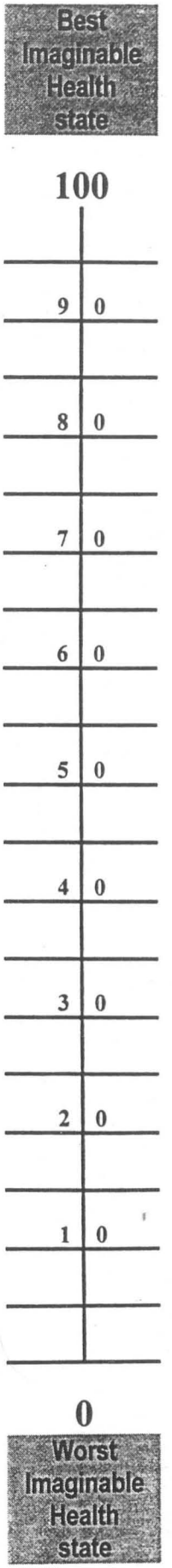
I am moderately anxious or depressed. ☐

I am extremely anxious or depressed. ☐

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

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

Your own health state today



Appendix VII: Outcome measures considered for use in the study against selection criteria.

	Barthel	HADS	TOMS	FAI	EQ-5D
Compatibility	✓	✓	✓		
Impairment			✓		✓
Disability	✓		✓	✓	
Participation			✓	✓	
Well-being		✓	✓		✓
Stroke	✓	✓	✓	✓	✓
NOF	✓	✓	✓	✓	✓
Time	✓	✓	✓	✓	✓
Meta-analysis	✓	✓		✓	✓

	SIP	ARAT	RMA	KATZ	IPA	RANKIN	MCA	NEADL	NHP
Compatibility									
Impairment		✓	✓				✓		
Disability		✓	✓			✓	✓		
Participation	✓			✓	✓			✓	
Well-being	✓			✓					✓
Stroke	✓	✓	✓	✓	✓	✓	✓	✓	✓
NOF	✓			✓	✓			✓	✓
Time		✓	✓		✓	✓	✓	✓	
Meta-analysis							✓	✓	

Appendix IX: Assessor by Median score

Barthel score 2:assessent two

		N	Minimum	Maximum	Median
Asessor Number	1	35	6	20	18.00
	2	37	11	20	19.00
	3	13	15	20	18.00
	4	7	18	20	20.00
	5	8	12	20	17.00
	6	11	11	20	19.00
	7	6	9	20	17.00
	8	4	18	20	19.00
	9	2	15	19	17.00
	10	16	10	20	18.50
	Total	139	6	20	19.00

Appendix IIX: Formula used

Equation used to calculate the SE of the difference between two proportions is as follows:

$$\sqrt{\frac{(p \times (1-p)}{n} + \frac{(p \times (1-p)}{n}}$$

$$95\%\ CI = \pm 1.96 \times SE\ (Difference)$$

Equation used to calculate an odds ratio is as follows:

$$OR = ad/bc$$

Equation used to calculate a 95 % confidence interval around an odds ratio is as follows:

$$95\%\ CI = Log\ (OR) \pm 1.96 \times SE\ (OR)$$

Equation used to calculate the standard error (SE) of an odds ratio is as follows:

$$SE\ (OR) = \sqrt{(1/a)+(1/b)+(1/c)+(1/d)}$$

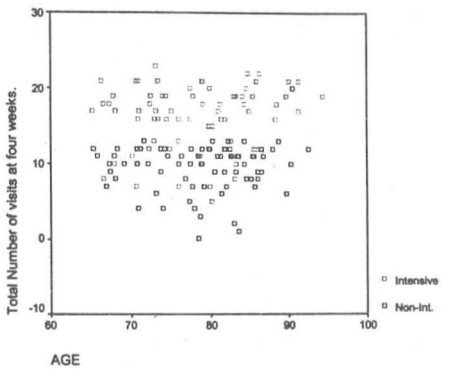
Equation used to test the null hypothesis that there is no difference between two paired proportions is as follows:

$$Z = \frac{p1-p2}{\sqrt{p1-p2}}$$

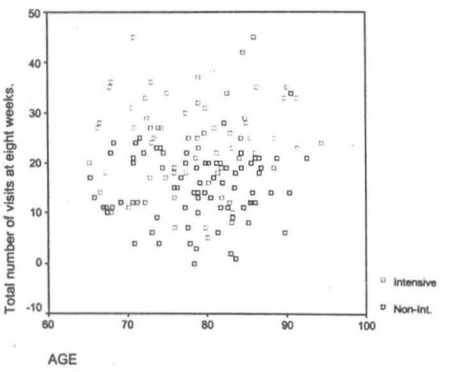
Appendix X: Results of Kendall's Taub test for correlation between baseline scores and change

Outcome Measure	Sig.	Kendall's
Barthel	<.05	-.551
TOMS Impairment	<.05	-.437
TOMS Disability	<.05	-.458
TOMS Handicap	<.05	-.471
TOMS Well-being	<.05	-.513
HADS Anxiety	<.05	-.348
HADS Depression	<.05	-.382
Frenchay Activities Index	<.05	-.202
EQ-5D	<.05	-.432
Self-Perceived Health Status	<.05	-..536

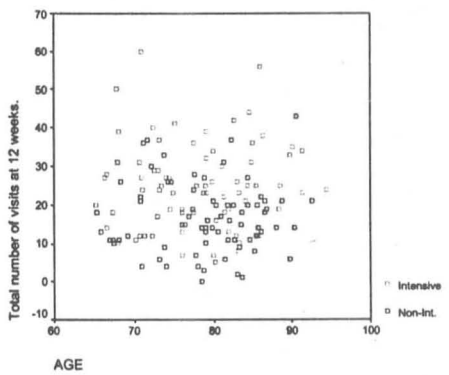
Appendix IX: Scatterplots indicating patient contact data



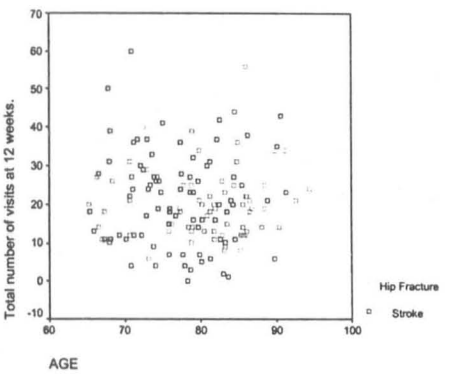
Scatterplot 1: Age by total number of visits at four weeks (cases identified by allocation).



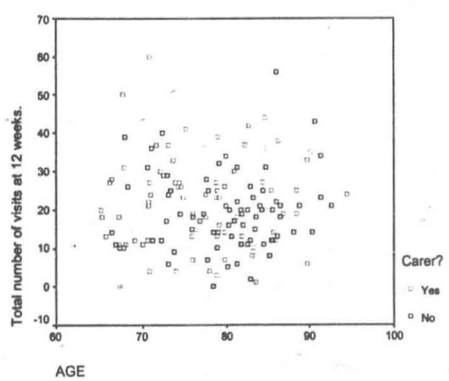
Scatterplot 2: Age by total number of visits at eight weeks (cases identified by allocation).



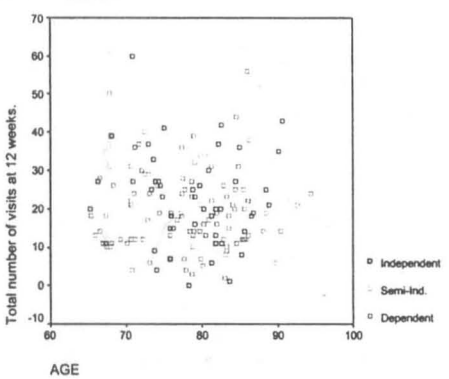
Scatterplot 3: Age by total number of visits at 12 weeks (cases identified by allocation).



Scatterplot 4: Age by total number of visits at 12 weeks (cases identified by aetiology).



Scatterplot 5: Age by total number of visits at 12 weeks (cases identified by co-residing carer).



Scatterplot 6: Age by total number of visits at 12 weeks (cases identified by baseline Barthel)

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